Date:11/05/97ISR Number: 100000165Report Type:Expedited (15-DaCompany Report #ZANA0319970279
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Health	Zanaflex	PS		ORAL	PER ORAL	
	Hypoglycaemia	Professional	Valium	C				
	Hypokalaemia		Betaseron	C				
	Respiratory Depression		Darvocet	C				
			Tylenol	C				
			Synthroid	C				

Date:11/10/97ISR Number: 100000206Report Type:Expedited (15-DaCompany Report #ZANA0319970282
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysphagia	Health	Zanaflex	PS		ORAL		
	Muscle Spasms	Professional	Ritonavir	C				
	Urinary Retention							

Date:11/26/97ISR Number: 3002805-0Report Type:Expedited (15-DaCompany Report #ZANA0319970288
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Lower	Health	Zanaflex	PS		ORAL	24 MG DAILY, PER ORAL	
	Acute Respiratory Distress Syndrome	Professional	Prednisone	C				
	Anxiety		Ditropan	C				
	Constipation		Halcion	C				
	Dehydration		Zantac	C				
	Dyspnoea		Amitriptyline	C				
	Hypotension		Lasix	C				
	Pneumothorax		Multivitamins	C				
	Pulmonary Oedema		Ecotrin	C				
			Os-Cal	C				

			Advil	C		

Date:12/01/97ISR Number: 3003022-0Report Type:Expedited (15-DaCompany Report #ZANA0319970291
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Health	Zanaflex	PS		ORAL PER ORAL		
		Professional	Baclofen	C				
			Synthroid	C				
			Naproxen	C				
			Hytrin	C				
			Senokot	C				
			Depakote	C				

Date:12/01/97ISR Number: 3003025-6Report Type:Expedited (15-DaCompany Report #ZANA0319970292
Age:87 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Asthenia
	Bradycardia
	Depressed Level Of

	Consciousness						
	Dyspnoea						
	Hyperhidrosis						
	Hypersensitivity	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Hypotension	Health	Zanaflex	PS		ORAL	2MG DAILY,
	Pallor	Professional					PER ORAL
	Pulse Pressure Decreased		Lasix	C			
			Codamine	C			
			Ticlid	C			
			Zyloprim	C			
			Cordarone	C			
			Ativan	C			
			Paxil	C			
			Pepcid	C			
			Multivitamins	C			
			Metamucil	C			
			Darvocet-N	C			
			Ambien	C			

Date:12/15/97ISR Number: 3008767-4Report Type:Expedited (15-DaCompany Report #ZANA0319970291
Age:45 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Convulsion	Health	Zanaflex	PS		ORAL	12 MG DAILY
Initial or Prolonged	Grand Mal Convulsion	Professional	Baclofen	C			
			Synthroid	C			
			Naproxen	C			
			Hytrin	C			
			Senokot	C			
			Depakote	C			
			Dulcolax	C			

Date:12/16/97ISR Number: 3008280-4Report Type:Direct Company Report #
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Condition Aggravated		Zanaflex	PS		ORAL	4MG PO Q 8HR;

4MG-4MG-8MG ;

12-6-97 X 1

DOSE

	Calcium Carbonate	C
	Darvocet-N-100	C
	Vicodin	C

Date:12/24/97ISR Number: 3048844-5Report Type:Periodic Company Report #ZANA0319970257
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Jaundice Cholestatic	Health Professional	Zanaflex	PS		ORAL	PER ORAL	
			Synthroid	C				
			Prozac	C				
			Avonex	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/24/97ISR Number: 3048847-0Report Type:Periodic Company Report #ZANA0319970241
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coordination Abnormal	Consumer	Zanaflex	PS		ORAL	6 MG DAILY,	
	Sedation						PER ORAL	
	Speech Disorder		Ambien	C				
			Neurontin	C				
			Xanax	C				
			Axid	C				
			Trazodone	C				
			Zoloft	C				

Date:12/24/97ISR Number: 3048850-0Report Type:Periodic Company Report #ZANA0319970243
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasticity	Consumer	Zanaflex	PS		ORAL	6 MG DAILY,	
							PER ORAL	

Date:12/24/97ISR Number: 3048854-8Report Type:Periodic Company Report #ZANA0319910244
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination	Consumer	Zanaflex	PS		ORAL	24 MG DAILY,	
							PER ORAL	
			Diflucan	C				
			Tylenol	C				
			Aspirin	C				
			Imipramine	C				
			Glucophage	C				

Date:12/24/97ISR Number: 3048858-5Report Type:Periodic Company Report #ZANA0319970245
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasticity	Consumer	Zanaflex	PS		ORAL	PER ORAL	

Date:12/24/97ISR Number: 3048863-9Report Type:Periodic Company Report #ZANA0319970247
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscular Weakness	Consumer	Zanaflex	PS		ORAL	PER ORAL	
	Oliguria		Baclofen	C				
			Nifedipine	C				
			Clonidine	C				
			Atenolol	C				

Date:12/24/97ISR Number: 3048866-4Report Type:Periodic Company Report #ZANA0319970248
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Zanaflex	PS		ORAL	PER ORAL	
	Coordination Abnormal		Avonex	C				
	Urinary Incontinence							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/24/97ISR Number: 3048871-8Report Type:Periodic Company Report #ZANA0319970251
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error	Health	Zanaflex	PS		ORAL	2 MG DAILY,	
	Menometrorrhagia	Professional					PER ORAL	
			Lasix	C				
			Zestril	C				
			Vitamins	C				

Date:12/24/97ISR Number: 3048939-6Report Type:Periodic Company Report #ZANA0319970252
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia	Health	Zanaflex	PS		ORAL	PER ORAL	
	Liver Function Test Abnormal	Professional	Prednisone	C				
			Solu-Medrol	C				
	Photosensitivity Reaction		Copaxone	C				
	Urinary Tract Infection		Lo-Ovral	C				
	Vasodilatation		Cipro	C				
	Weight Decreased							

Date:12/24/97ISR Number: 3048946-3Report Type:Periodic Company Report #ZANA0319970254
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypertension	Health	Zanaflex	PS		ORAL	PER ORAL	
	Keratoconjunctivitis Sicca	Professional	Bromfed	C				
			Relafen	C				
	Lacrimation Increased							
	Liver Function Test Abnormal							

Date:12/24/97ISR Number: 3048951-7Report Type:Periodic Company Report #ZANA0319970255
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Mouth	Consumer	Zanaflex	PS		ORAL	4 MG DAILY,	
	Sedation						PER ORAL	
			Cardizem	C				
			Vasotec	C				
			Isosorbide	C				
			Insulin	C				

Date:12/24/97ISR Number: 3048955-4Report Type:Periodic Company Report #ZANA0319970258
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Consumer	Zanaflex	PS		ORAL	PER ORAL	
	Dry Mouth		Baclofen	C				
	Sedation		Ativan	C				

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Freedom Of Information (FOI) Report

Date:12/24/97ISR Number: 3048959-1Report Type:Periodic Company Report #ZANA0319970259
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test	Health	Zanaflex	PS		ORAL	8 MG DAILY,	
	Abnormal	Professional					PER ORAL	
			Lo-Estren	C				
			Paxil	C				

Date:12/24/97ISR Number: 3048962-1Report Type:Periodic Company Report #ZANA0319970260
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Erectile Dysfunction	Health	Zanaflex	PS		ORAL	20 MG DAILY,	
	Sedation	Professional					PER ORAL	
			Diazepam	C				

Date:12/24/97ISR Number: 3048967-0Report Type:Periodic Company Report #ZANA0319970261
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation	Consumer	Zanaflex	PS		ORAL	PER ORAL	
			Prednisone	C				
			Prilosec	C				
			Macrodantin	C				
			Relafen	C				

Date:12/24/97ISR Number: 3048970-0Report Type:Periodic Company Report #ZANA0319970262
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Fatigue	Consumer	Zanaflex	PS		ORAL	2 MG DAILY,	PER ORAL
			Dantrium	C				
			Zoloft	C				
			Verapamil	C				
			Aspirin	C				

Date:12/24/97ISR Number: 3048974-8Report Type:Periodic Company Report #ZANA0319970267
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Fall	Consumer	Zanaflex	PS		ORAL	PER ORAL	
	Sedation		Oxybutynin	C				
			Daypro	C				
			Prozac	C				
			Xanax	C				

Date:12/24/97ISR Number: 3048976-1Report Type:Periodic Company Report #ZANA0319970268
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyspepsia	Consumer	Zanaflex	PS		ORAL	12 MG DAILY,	
	Nausea						PER ORAL	
			Tegretol	C				
			Glucotrol	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/24/97ISR Number: 3048979-7Report Type:Periodic Company Report #ZANA0319970270
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Health	Zanaflex	PS		ORAL	12 MG DAILY,	
	Fatigue	Professional					PER ORAL	
	Insomnia		Docusate	C				
			Darvocet N-100	C				

Date:12/24/97ISR Number: 3048983-9Report Type:Periodic Company Report #ZANA0319970271
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Conjunctival Hyperaemia	Health	Zanaflex	PS		ORAL	12 MG DAILY,	
	Eye Irritation	Professional					PER ORAL	
	Flushing							

Date:12/24/97ISR Number: 3048987-6Report Type:Periodic Company Report #ZANA0319970275
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test	Health	Zanaflex	PS		ORAL	PER ORAL	
	Abnormal	Professional	Carbamazepine	C				
	Sedation		Baclofen	C				
			Valproic Acid	C				
			Amantadine	C				
			Bromocriptine	C				
			Cisapride	C				

Date:12/24/97ISR Number: 3048989-XReport Type:Periodic Company Report #ZANA0319970277
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Health	Zanaflex	PS		ORAL	10 MG DAILY,	
		Professional					PER ORAL	
			Cylert	C				
			Pamelor	C				
			Betaseron	C				
			Ambien	C				
			Baclofen	C				

Date:12/24/97ISR Number: 3048992-XReport Type:Periodic Company Report #ZANA0319970278
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Health	Zanaflex	PS		ORAL	24 MG DAILY,	
		Professional					PER ORAL	
			Zestril	C				
			Cardizem	C				
			Paxil	C				
			Prozac	C				
			Ibuprofen	C				
			Klonopin	C				

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Freedom Of Information (FOI) Report

Date:12/24/97ISR Number: 3049024-XReport Type:Periodic Company Report #ZANA0319970280
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Consumer	Zanaflex	PS		ORAL	4 MG DAILY,	
	Dry Mouth						PER ORAL	
			Ditropan	C				
			Baclofen	C				
			Klonopin	C				

Date:12/24/97ISR Number: 3049029-9Report Type:Periodic Company Report #ZANA0319970281
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nightmare	Health	Zanaflex	PS		ORAL	6 MG DAILY,	
		Professional					PER ORAL	

Date:12/24/97ISR Number: 3049036-6Report Type:Periodic Company Report #ZANA0319970283
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension	Health	Zanaflex	PS		ORAL	4 MG DAILY ,	
		Professional					PER ORAL	
			Diovan	C				
			Synthroid	C				
			Premarin	C				
			Progesterone	C				
			Baclofen	C				

Date:12/24/97ISR Number: 3049039-1Report Type:Periodic Company Report #ZANA0319970284
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test	Health	Zanaflex	PS		ORAL	26 MG DAILY,	
	Abnormal	Professional					PER ORAL	
			Amantadine	C				
			Avonex	C				
			Advil	C				
			Synthroid	C				

Date:12/24/97ISR Number: 3049044-5Report Type:Periodic Company Report #ZANA0319970285
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accident		Zanaflex	PS		ORAL	12 MG DAILY,	
	Influenza Like Illness						PER ORAL	
	Sedation		Depakote	C				
			Clonazepam	C				
			Phenobarbital	C				
			Lozol	C				
			Prilosec	C				
			Premarin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/24/97ISR Number: 3049058-5Report Type:Periodic Company Report #ZANA0319970286
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasms	Consumer	Zanaflex	PS		ORAL	16 MG DAILY,	
	Sedation		Demadex	C		PER ORAL		
			K-Dur	C				
			Lanoxin	C				
			Quinidex	C				
			Tegretol	C				
			Aspirin	C				

Date:12/24/97ISR Number: 3049062-7Report Type:Periodic Company Report #ZANA0319970287
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hiccups	Health Professional	Zanaflex	PS		ORAL	16 MG DAILY,	
						PER ORAL		
			Valium	C				
			Baclofen	C				
			Amantadine	C				
			Percocet	C				

Date:12/24/97ISR Number: 3049067-6Report Type:Periodic Company Report #ZANA0319970289
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Consumer	Zanaflex	PS		ORAL	4 MG DAILY,	
	Hypertonia					PER ORAL		
			Synthroid	C				

Date:12/24/97ISR Number: 3049070-6Report Type:Periodic Company Report #ZANA0319970290
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscular Weakness		Zanaflex	PS		ORAL	24 MG DAILY,	
	Sedation						PER ORAL	
			Baclofen	C				
			Klonopin	C				

Date:12/24/97ISR Number: 3049074-3Report Type:Periodic Company Report #ZANA0319970293
Age:93 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health	Zanaflex	PS		ORAL	4 MG DAILY,	
	Hypotension	Professional					PER ORAL	
			Pepcid	C				
			Ultram	C				
			Parlodel	C				

Date:12/24/97ISR Number: 3049077-9Report Type:Periodic Company Report #ZANA0319970294
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension		Zanaflex	PS		ORAL	12 MG DAILY,	
	Sedation						PER ORAL	
	Stupor		Norvasc	C				

			Zoloft	C		
			Coumadin	C		
			Pepcid	C		

Date:12/24/97ISR Number: 3049127-XReport Type:Periodic Company Report #ZANA0319970295
Age:81 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma	Health	Zanaflex	PS		ORAL	6 MG DAILY,	
	Drug Effect Decreased	Professional					PER ORAL	
	Hypotension		Digoxin	C				
	Lethargy		Verapamil	C				
			Haldol	C				
			Phenobarbital	C				

Date:12/24/97ISR Number: 3049132-3Report Type:Periodic Company Report #ZANA0319970296
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Health	Zanaflex	PS		ORAL	16 MG DAILY,	
		Professional					PER ORAL	
			Methadone	C				
			Diazepam	C				

Date:12/24/97ISR Number: 3049137-2Report Type:Periodic Company Report #ZANA0319970297
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Skin	Health	Zanaflex	PS		ORAL	12 MG DAILY,	
		Professional					PER ORAL	

Date:12/24/97ISR Number: 3049141-4Report Type:Periodic Company Report #ZANA0319970298
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Headache	Health	Zanaflex	PS		ORAL	16 MG DAILY,	
		Professional					PER ORAL	
			Baclofen	C				
			Tegretol	C				

Date:12/24/97ISR Number: 3049145-1Report Type:Periodic Company Report #ZANA0319970299
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Gamma-Glutamyltransferase	Health	Zanaflex	PS		ORAL	PER ORAL	
	Increased	Professional	Dilantin	C				

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

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

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/24/97ISR Number: 3049153-0Report Type:Periodic Company Report #ZANA0319970301
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Triglycerides	Health	Zanaflex	PS		ORAL	PER ORAL	
	Increased Hyperglycaemia	Professional						

Date:12/24/97ISR Number: 3049157-8Report Type:Periodic Company Report #ZANA0319970302
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Triglycerides	Health	Zanaflex	PS		ORAL	PER ORAL	
	Increased	Professional						

Date:12/24/97ISR Number: 3049161-XReport Type:Periodic Company Report #ZANA0319970303
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation	Health	Zanaflex	PS		ORAL	PER ORAL	
	Dysphagia Hypertonia	Professional						

Date:12/24/97ISR Number: 3049163-3Report Type:Periodic Company Report #ZANA0319970304
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Zanaflex	PS		ORAL	4 MG DAILY,	
	Sedation						PER ORAL	
			Prozac	C				
			Prosom	C				
			Baclofen	C				

Date:12/24/97ISR Number: 3049165-7Report Type:Periodic Company Report #ZANA0319970007
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Zanaflex	PS		ORAL	4 MG DAILY,	
	Coordination Abnormal						PER ORAL	
	Cyanosis		Baclofen	C				
	Sedation		Methotrexate	C				
			Tegretol	C				
			Betaseron	C				

Date:12/24/97ISR Number: 3049172-4Report Type:Periodic Company Report #ZANA0319970177
Age:78 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Pain	Health	Zanaflex	PS		ORAL	4 MG DAILY,	
	Hypotension	Professional					PER ORAL	
	Sedation		Norvasc	C				
	Stupor		Estrace	C				
			Fosamax	C				
			Prednisone	C				
			Promod	C				
			Reglan	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/24/97ISR Number: 3049175-XReport Type:Periodic Company Report #ZANA0319970203
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dysgeusia	Consumer	Zanaflex	PS		ORAL	PER ORAL	
	Hallucination		Levoxyl	C				
			Ventolin	C				
			Aerobid	C				
			Slo-Bid	C				
			Beconase	C				
			Hismanal	C				

Date:01/28/98ISR Number: 3021651-5Report Type:Direct Company Report #
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia		Zanaflex	PS	Athena Neuro Sciences	ORAL	4 MG PO	
	Bradycardia							
	Chest Pain							
	Hypotension							

Date:01/29/98ISR Number: 3021217-7Report Type:Direct Company Report #
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hallucination		Tizanidine	PS		ORAL	4MG X3D; 6MG X2	PO
			Fluoxetine	C				
			Oxybutynin	C				
			Nitrofurantoin	C				
			Cipro	C				
			Diazepam	C				
			Ibuprofen	C				

Date:02/05/98ISR Number: 3024405-9Report Type:Direct Company Report #
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased Heart Rate Decreased Syncope		Tizanidine Hcl	PS		ORAL	6 MG PO QD ;4 MG PO DID	;4

Date:02/18/98ISR Number: 3030594-2Report Type:Expedited (15-DaCompany Report #ZANA0319980328
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia	Health	Zanaflex	PS		ORAL	4 MG DAILY	
Hospitalization - Initial or Prolonged	Bradycardia Chest Pain Dizziness Hypotension	Professional					PER ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/02/98ISR Number: 3039669-5Report Type:Expedited (15-DaCompany Report #ZANA0319980334
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Shock	Foreign	Ternelin	PS		ORAL	3 MG DAILY,
		Distributor					PER ORAL
			Zaltoprofen	C			
			Soleton	C			

Date:03/02/98ISR Number: 3040502-6Report Type:Expedited (15-DaCompany Report #ZANA0319980333
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Dysarthria	Foreign	Ternelin	PS		ORAL	3.0 MG DAILY
Hospitalization -	Face Oedema	Distributor					PER ORAL
Initial or Prolonged	Malaise		Indomethacin	C			
	Oedema Peripheral		Benzbromarone	C			
	Pulmonary Oedema		Camostat	C			
	Weight Increased		Famotidine	C			
			Triazolam	C			
			Foy	C			

Date:03/02/98ISR Number: 3040505-1Report Type:Expedited (15-DaCompany Report #ZANA0319980332
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Antinuclear Antibody	Foreign	Sirdalud	PS		ORAL	2.0 MG DAILY,
	Positive	Distributor					PER ORAL
	Systemic Lupus Erythematosus		Myolastan	C			

Date:03/02/98ISR Number: 3040508-7Report Type:Expedited (15-DaCompany Report #ZANA0319980331
Age:5 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Convulsion	Foreign	Sirdalud	PS		ORAL	2.5 MG DAILY,	
Hospitalization - Initial or Prolonged	Drug Interaction	Distributor					PER ORAL	
	Shock							

Date:03/05/98ISR Number: 3050056-6Report Type:Direct Company Report #
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety		Zanaflex	PS	Athena/Sandoz		AS DIRECTED	
	Hallucination							
	Paranoia							

Date:03/10/98ISR Number: 3054307-3Report Type:Expedited (15-DaCompany Report #ZANA0319980341
Age:22 YR Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Accidental Overdose
Hospitalization - Initial or Prolonged	Arrhythmia
	Blood Bilirubin Increased
	Hepatic Function Abnormal
	Hypotonia
	Respiratory Disorder

	Sedation					
		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Foreign	Sirdalud	PS		ORAL
PER ORAL						
		Distributor				

Date:03/10/98ISR Number: 3054310-3Report Type:Expedited (15-DaCompany Report #ZANA0319980342
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Hypokalaemia	Foreign	Ternelin	PS		ORAL
3 MG DAILY,						
Initial or Prolonged	Loss Of Consciousness	Distributor				
PER ORAL						
	Sedation		Votraren	C		

Date:03/17/98ISR Number: 3055540-7Report Type:Expedited (15-DaCompany Report #ZANA0319980342
Age:74 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Dizziness	Foreign	Ternelin	PS		ORAL
3 MG						
Initial or Prolonged	Hypokalaemia	Distributor				
DAILY/PER						
	Hypovolaemia					
ORAL						
	Loss Of Consciousness		Voltaren	SS		
	Oral Intake Reduced		Myonal	SS		
	Sedation		Loxonin	SS		
			Vitamedine	C		
			Methycobal	C		

Date:03/20/98ISR Number: 3057057-2Report Type:Expedited (15-DaCompany Report #199600728HJL2
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Hospitalization - 300 MG PO 3 MON	Alanine Aminotransferase	Foreign	Trental	PS		ORAL
Initial or Prolonged 300 MG 3 MON	Increased	Study	Hextol	SS		ORAL
Other ORAL 1 MON	Anorexia	Health	Tegretol	SS		ORAL
	Aspartate	Professional	Ternelin	SS		ORAL
ORAL 1 MON	Aminotransferase		Basen	C		
	Increased		Kinedak	C		
	Gamma-Glutamyltransferase		Minipress	C		
	Increased					
	Haematocrit Decreased					
	Haemoglobin Decreased					
	Hepatic Function Abnormal					

Date:03/20/98ISR Number: 3057107-3Report Type:Expedited (15-DaCompany Report #ZANA0319980328
Age:70 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening 4 MG DAILY,	Asthenia	Health	Zanaflex	PS		ORAL
Hospitalization - PER ORAL	Bradycardia	Professional				
Initial or Prolonged	Chest Pain					
	Dizziness					
	Hypotension					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/30/98ISR Number: 3059380-4Report Type:Expedited (15-DaCompany Report #ZANA0319980341
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Accidental Overdose	Foreign	Sirdalud	PS		ORAL	PER ORAL	
Hospitalization - Initial or Prolonged	Arrhythmia	Distributor						
	Asphyxia							
	Bradycardia							
	Hepatic Function Abnormal							
	Hypotonia							
	Respiratory Disorder							
	Sedation							
	Tachycardia							

Date:03/30/98ISR Number: 3140701-9Report Type:Periodic Company Report #ZANA0319970306
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Health	Zanaflex	PS		ORAL	8 MG DAILY,	
		Professional					PER ORAL	
			Baclofen	C				
			Ativan	C				
			Tessalon	C				
			Cipro	C				

Date:03/30/98ISR Number: 3140712-3Report Type:Periodic Company Report #ZANA0319970307
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Insomnia	Consumer	Zanaflex	PS		ORAL	4 MG DAILY,	
	Sedation						PER ORAL	
			Tylenol	C				
			Insulin	C				
			Allegra	C				
			Resulin	C				

Date:03/30/98ISR Number: 3140714-7Report Type:Periodic Company Report #ZANA0319970308
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Consumer	Zanaflex	PS		ORAL	16 MG DAILY,	
	Dry Mouth						PER ORAL	
	Muscle Spasms		Valium	C				
	Oedema		Baclofen	C				
	Paraesthesia		Aspirin	C				
	Urinary Retention		Advil	C				
			Niacin	C				
			Vitamin B12	C				

Date:03/30/98ISR Number: 3140730-5Report Type:Periodic Company Report #ZANA0319970309
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Infection	Health	Zanaflex	PS		ORAL	PER ORAL	
	Sedation	Professional	Valium	C				
			Vitamin C	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/30/98ISR Number: 3140733-0Report Type:Periodic Company Report #ZANA0319970310
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Orthostatic Hypotension	Health	Zanaflex	PS		ORAL	PER ORAL	
	Sedation	Professional	Trazodone	C				
			Toprol-Xl	C				
			Cardias Mcd	C				

Date:03/30/98ISR Number: 3140735-4Report Type:Periodic Company Report #ZANA0319970311
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasms	Consumer	Zanaflex	PS		ORAL	8 MG DAILY,	
	Nausea						PER ORAL	
			4-Aminopyridine	C				

Date:03/30/98ISR Number: 3140739-1Report Type:Periodic Company Report #ZANA0319970312
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Consumer	Zanaflex	PS		ORAL	4 MG DAILY,	
							PER ORAL	

Date:03/30/98ISR Number: 3140741-XReport Type:Periodic Company Report #ZANA0319970313
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension	Consumer	Zanaflex	PS		ORAL	4 MG DAILY,	
	Visual Disturbance						PER ORAL	

			Prilosec	C		
			Lactulose	C		
			Vitamin C	C		

Date:03/30/98ISR Number: 3140743-3Report Type:Periodic Company Report #ZANA0319970314
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Consumer	Zanaflex	PS		ORAL	PER ORAL	
	Myasthenia Gravis		Wellbutrin	C				
			Ditropan	C				
			Colace	C				
			Axid	C				
			Hormone	C				
			Thyroid Medication	C				

Date:03/30/98ISR Number: 3140747-0Report Type:Periodic Company Report #ZANA0319970315
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Consumer	Zanaflex	PS		ORAL	PER ORAL	
	Dry Mouth							
	Sedation							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/30/98ISR Number: 3140773-1Report Type:Periodic Company Report #ZANA0319970316
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Consumer	Zanaflex	PS		ORAL	24 MG DAILY,	
	Diarrhoea						PER ORAL	
			Pepcid	C				
			Parnate	C				
			Meprobamate	C				
			Propantheline	C				
			Sulfonate	C				
			Tylenol	C				
			Vitamin B12	C				
			Hydrochlorothiazide	C				
			Diazepam	C				
			Avonex	C				
			Prazocin Hydrochloride	C				
			Potassium Chloride	C				
			Chlorpheniramine Maleate	C				

Date:03/30/98ISR Number: 3140776-7Report Type:Periodic Company Report #ZANA0319970317
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Consumer	Zanaflex	PS		ORAL	PER ORAL	
	Sedation		Progesterone	C				

Date:03/30/98ISR Number: 3140779-2Report Type:Periodic Company Report #ZANA0319970318
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Consumer	Zanafex)	PS		ORAL	PER ORAL	
	Vaginal Candidiasis		Ultram	C				
			Ibuprofen	C				

Date:03/30/98ISR Number: 3140782-2Report Type:Periodic Company Report #ZANA0319970319
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Consumer	Zanaflex	PS		ORAL	4 MG DAILY,	
	Hypertension						PER ORAL	
	Nausea		Desipramine	C				
			Zestril	C				
			Relafen	C				
			Neurontin	C				
			Lipitor	C				
			Clonazepam	C				

Date:03/30/98ISR Number: 3140788-3Report Type:Periodic Company Report #ZANA0319970320
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Flatulence	Health	Zanaflex	PS		ORAL	4 MG DAILY,	
		Professional					PER ORAL	
			Baclofen	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/30/98ISR Number: 3140790-1Report Type:Periodic Company Report #ZANA0319970321
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaemia	Company	Zanaflex	PS		ORAL	PER ORAL	
		Representative						

Date:03/30/98ISR Number: 3140794-9Report Type:Periodic Company Report #ZANA0319980322
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia	Consumer	Zanaflex	PS		ORAL	1 MG DAILY,	
	Constipation						PER ORAL	
	Influenza Like Illness							
	Nausea							

Date:03/30/98ISR Number: 3140798-6Report Type:Periodic Company Report #ZANA0319980323
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasms	Consumer	Zanaflex	PS		ORAL	2 MG DAILY,	
							PER ORAL	
			Oxycontin	C				
			Baclofen	C				
			Humibid	C				

Date:03/30/98ISR Number: 3140801-3Report Type:Periodic Company Report #ZANA0319980324
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aphasia	Health	Zanaflex	PS		ORAL	4 MG DAILY,	

	Chills	Professional				
PER ORAL						
	Coordination Abnormal		Baclofen	C		
	Diarrhoea		Klonopin	C		
	Dizziness		Trimpex	C		
	Dry Mouth					
	Hyperhidrosis					
	Muscle Spasms					
	Sedation					

Date:03/30/98ISR Number: 3140803-7Report Type:Periodic Company Report #ZANA0319980325
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Muscle Twitching	Consumer	Zanaflex	PS		ORAL
4 MG DAILY,						
	Paraesthesia					
PER ORAL						
			Motrin	C		
			Tylenol	C		
			Xanax	C		
			Zantac	C		

Date:03/30/98ISR Number: 3145770-8Report Type:Periodic Company Report #ZANA0319980326
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Muscle Spasms	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
4 MG DAILY,						

PER ORAL

			Septra	C		
			Progesterone	C		

Date:03/30/98ISR Number: 3145775-7Report Type:Periodic Company Report #ZANA0319980327
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Oedema	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	1) 4 MG DAILY, PER ORAL; 2) PER ORAL	
			Vanceril	C				
			Proventil	C				
			Prednisone	C				
			Bactrim	C				

Date:03/30/98ISR Number: 3145779-4Report Type:Periodic Company Report #ZANA0319980329
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasms	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	1) PER ORAL; 2) UNK	

Date:03/30/98ISR Number: 3145782-4Report Type:Periodic Company Report #ZANA0319980335
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation Liver Function Test	Consumer	Zanaflex (Tizanidine					

	Abnormal		Hydrochloride)	PS		ORAL
PER ORAL						
	Nausea		Betaseron	C		
	Sedation		Baclofen	C		
			Cylert	C		
			Ambien	C		
			Nortriptyline	C		

Date:03/30/98ISR Number: 3145783-6Report Type:Periodic Company Report #ZANA0319980336
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Stupor	Health	Zanaflex (Tizanidine			
		Professional	Hydrochloride)	PS		ORAL
PER ORAL						
			Marcaine	C		
			Fentanyl	C		
			Valium	C		
			Narcan	C		

Date:03/30/98ISR Number: 3145784-8Report Type:Periodic Company Report #ZANA0319980337
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Apnoea	Health	Zanaflex (Tizanidine			
	Stupor	Professional	Hydrochloride)	PS		ORAL
PER ORAL						
			Fentanyl	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/30/98ISR Number: 3145785-XReport Type:Periodic Company Report #ZANA0319980338
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pruritus	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY,	PER ORAL

Date:03/30/98ISR Number: 3145786-1Report Type:Periodic Company Report #ZANA0319980339
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	
	Dizziness							
	Sedation		Baclofen	C				
	Speech Disorder		Copaxone	C				
			Birth Control Pills	C				

Date:03/30/98ISR Number: 3145787-3Report Type:Periodic Company Report #ZANA0319970196
Age:64 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Oliguria	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	24 MG DAILY,	PER ORAL
			Vitamins	C				
			Sulfasalazine	C				

Date:04/03/98ISR Number: 3061346-5Report Type:Expedited (15-DaCompany Report #ZANA0319980349
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Myocardial Infarction	Consumer	Zanaflex	PS		ORAL
PER ORAL						
			Insulin	C		
			Baclofen	C		
			Amantadine	C		
			Isoptin	C		

Date:04/06/98ISR Number: 3062955-XReport Type:Expedited (15-DaCompany Report #ZANA0319980351
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Dizziness	Health	Zanaflex	PS		ORAL
18 MG DAILY						
Initial or Prolonged	Dizziness Postural	Professional	Baclofen	C		
	Faeces Discoloured		Methotrexate	C		
	Haemoglobin Decreased		Amitriptyline	C		
	Pain		Solu-Medrol	C		
	Ulcer					

Date:04/14/98ISR Number: 3064332-4Report Type:Expedited (15-DaCompany Report #1998-00894
Age:65 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Blister
Initial or Prolonged	Blood Creatine
	Phosphokinase Increased
	Blood Creatinine

	Increased Blood Pressure Decreased Blood Urea Increased Dermatitis	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Eosinophil Count	Foreign	Mexitil	PS		ORAL	300 MG/PO
	Increased	Health	Norvasc	SS		ORAL	5 MG/PO
	Face Oedema	Professional	Lasix	SS		ORAL	40 MG/PO
	Fatigue		Ternelin	SS		ORAL	3 MG/PO
	Haematuria		Depas	C		ORAL	1 MG/PO
	Liver Function Test		Glekay	C		ORAL	45 MG/PO
	Abnormal Purpura Pyrexia Rash Erythematous Skin Ulcer White Blood Cell Count Increased						

Date:04/17/98ISR Number: 3068702-XReport Type:Expedited (15-DaCompany Report #ZANA0319980368
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Asthenia	Foreign	Sirdalud	PS		ORAL	2 MG DAILY,
	Hypotonia	Distributor					PER ORAL

Date:04/17/98ISR Number: 3068703-1Report Type:Expedited (15-DaCompany Report #ZANA0319980369
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Bundle Branch Block Left	Foreign	Sirdalud	PS		ORAL	4 MG DAILY,
	Drug Level Below	Distributor					PER ORAL

	Therapeutic		Acetyligoxin	C		
			Cibacalcin	C		
			Sarotin	C		

Date:04/17/98ISR Number: 3068704-3Report Type:Expedited (15-DaCompany Report #ZANA0319980370
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Blood Bilirubin Increased	Foreign	Ternelin	PS		ORAL	PER ORAL
Hospitalization - Initial or Prolonged	Blood Creatine Increased	Distributor	Voltaren	SS			
	Hepatitis Fulminant						
	Renal Failure Acute						
	Rhabdomyolysis						

Date:04/17/98ISR Number: 3068973-XReport Type:Expedited (15-DaCompany Report #ZANA0319980352
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Asthenia	Health Professional	Zanaflex	PS		ORAL	12 MG DAILY PER ORAL;
	Bone Pain						
	Confusional State		Morphine	C			
	Haemorrhoids		Vicodin	C			
	Hepatomegaly		Xanax	C			
	Lethargy		Glipizide	C			
	Rectal Haemorrhage		Carafate	C			
			Prozac	C			
			Plaquenil	C			

				Ritalin	C		
				Prilosec	C		

Date:05/05/98ISR Number: 3073583-4Report Type:Expedited (15-DaCompany Report #98J-10112
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Blood Bilirubin Increased	Foreign	Voltaren	PS		ORAL	75 MG, DAILY,
Hospitalization -	Blood Creatinine	Health					ORAL
Initial or Prolonged	Increased	Professional	Ternelin	SS		ORAL	3 MG,DAILY,
	Disseminated						ORAL
	Intravascular Coagulation						
	Hepatic Failure						
	Hepatitis						
	Hepatitis Fulminant						
	Pallor						
	Renal Failure Acute						
	Rhabdomyolysis						

Date:05/15/98ISR Number: 3079752-1Report Type:Expedited (15-DaCompany Report #ZANA0319980377
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Chorea	Health	Zanaflex	PS		ORAL	360MG DAILY,
Initial or Prolonged	Coma	Professional					PER ORAL
Other	Depressed Level Of Consciousness						
	Intentional Misuse						
	Muscle Rigidity						

Date:05/18/98ISR Number: 3079354-7Report Type:Direct Company Report #
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Hypertension		Tizanidine	PS	Athena Labs	ORAL	2 MG BID PO	2 DOSES

Date:05/18/98ISR Number: 3079870-8Report Type:Expedited (15-DaCompany Report #ZANA0319980370
Age:21 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anorexia	Foreign	Ternelin	PS		ORAL	3.0 MG DAILY	
Hospitalization - Initial or Prolonged	Blood Creatinine Increased Disseminated Intravascular Coagulation Hepatic Failure Hepatitis Hepatitis Fulminant Malaise Pallor Pyrexia Renal Failure Acute Rhabdomyolysis	Distributor	Voltaren	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/18/98ISR Number: 3080088-3Report Type:Expedited (15-DaCompany Report #ZANA0319980379
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Complications Of Maternal Exposure To Therapeutic Drugs Small For Dates Baby	Foreign Distributor	Sirdalud	PS		ORAL	12.0 MG DAILY PER ORAL

Date:05/27/98ISR Number: 3088209-3Report Type:Expedited (15-DaCompany Report #1998-000894
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Blister	Foreign	Mexitil	PS		ORAL	300 MG
Hospitalization - Initial or Prolonged	Dermatitis Fatigue Haematuria Oedema Pyrexia Rash Erythematous	Health Professional	Norvasc (Amlodipine Besilate) Ternelin (Tizanidine Hydrochloride) Lasix (Furosemide) Depas(Etizolam) Ternelin(Tizanidine Hydrochloride) Glakay (Menatetrenone) Depas(Etizolam)	SS SS SS C C C C		ORAL	5 MG

Date:05/28/98ISR Number: 3084810-1Report Type:Expedited (15-DaCompany Report #98J--10112
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Disseminated	Foreign	Voltaren	PS		ORAL	75 MG, DAILY
Hospitalization - Initial or Prolonged	Intravascular Coagulation Hepatic Failure	Health Professional	Ternelin	SS		ORAL	ORAL 3 MG, DAILY

	Hepatitis Fulminant					
ORAL						
	Pallor					
	Renal Failure Acute					
	Rhabdomyolysis					

Date:06/01/98ISR Number: 3087787-8Report Type:Expedited (15-DaCompany Report #ZANA0319980383
Age:2 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Foreign	Ternelin	PS		ORAL	0.33 MG	
	Bronchospasm	Literature					DAILY, PER	
	Dyspnoea						ORAL	
	Foreign Body Aspiration		Tricloryl	SS				
	Intercostal Retraction		Antitussive Agent	C				
	Respiratory Distress		Antihistamine	C				
	Stridor		Expectorant	C				
	Vomiting							

Date:06/01/98ISR Number: 3087791-XReport Type:Expedited (15-DaCompany Report #ZANA0319980377
Age:33 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Athetosis
	Chorea
Other	Coma

	Depressed Level Of Consciousness						
	Depressed Mood	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Muscle Rigidity	Health	Zanaflex	PS		ORAL	12 MG DAILY,
	Overdose	Professional					PER ORAL
	Polyuria		Thorazine	C			
	Suicide Attempt						

Date:06/01/98ISR Number: 3088607-8Report Type:Expedited (15-DaCompany Report #ZANA0319980384
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Jaundice	Foreign	Sirdalud	PS		ORAL	6 MG DAILY,
	Renal Failure Acute	Distributor					PER ORAL
			Gastrozepin	C			
			Pankreon	C			
			Chloraldurat	C			

Date:06/02/98ISR Number: 3088567-XReport Type:Expedited (15-DaCompany Report #98J--10112
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Disseminated	Foreign	Voltaren	PS		ORAL	75 MG, DAILY,
Hospitalization -	Intravascular Coagulation	Health					ORAL
Initial or Prolonged	Hepatic Failure	Professional	Ternelin	SS		ORAL	3 MG, DAILY,
	Hepatitis Fulminant						ORAL
	Pallor		Stac-Eve	SS			
	Renal Failure Acute						
	Rhabdomyolysis						

Date:06/11/98ISR Number: 3095951-7Report Type:Periodic Company Report #316740
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills Dermatitis Dermatitis Bullous Eosinophilia Mucous Membrane Disorder Oedema Pharyngitis Pruritus Purpura Pyrexia Rash Erythematous Rash Maculo-Papular Stevens-Johnson Syndrome Urticaria White Blood Cell Disorder	Health Professional	Macrodantin Capsules, 100 Mg (Nitrofurantoin Macrocrystals) Tizanidine Hydrochloride Bisacodyl Chloral Hydrate Docusate Sodium Elase Eucerin Creme (Wool Fat) Hydrogen Peroxide Milk Of Magnesia (Magnesium Hydroxide) Multivit Oxybutynin Phenazopyridine Tizanidine	PS SS C C C C C C C C C C		ORAL ORAL	100 MG 2 MG BID	Q6HR-QID-Q6HR ; ORAL TITRATED TO 8 MG Q8; ORAL

			Hydrochloride	C		
			Tramadol	C		
			Tylenol (Paracetamol)	C		
			Zoloft (Sertraline Hydrochloride)	C		

Date:06/23/98ISR Number: 3097365-2Report Type:Expedited (15-DaCompany Report #ZANA 319980391
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anuria Blood Creatinine Increased Overdose Renal Failure Stupor	Health Professional	Zanaflex	PS		ORAL	PER ORAL	

Date:06/29/98ISR Number: 3099561-7Report Type:Expedited (15-DaCompany Report #ZANA0319980390
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cyanosis Dyspnoea	Foreign Distributor	Ternelin	PS		ORAL	3.0 MG DAILY, PER ORAL	
			Draganon	SS				
			Loxonin	C				
			Methycool	C				
			Bufferin	C				
			Trental	C				
			Nitroderm Tts	C				

Date:06/29/98ISR Number: 3099611-8Report Type:Expedited (15-DaCompany Report #ZANA0319970256
Age:73 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Life-Threatening	Agranulocytosis	Foreign	Ternelin	PS	ORAL
2 MG DAILY,					
Hospitalization -	Blood Pressure Decreased	Distributor			
PER ORAL					
Initial or Prolonged	Bronchitis Acute		Depas	SS	
	Depressed Level Of		Clinoril	SS	
	Consciousness		Cefzon	C	
	Disseminated		Lasix	C	
	Intravascular Coagulation		Theo-Dur	C	
	Haemorrhage		Noleptan	C	
	Hypotension		Ulgut	C	
	Neutropenia		Sigmart	C	
	Platelet Disorder		Cefzon	C	
	Pneumonia		Lasix	C	
	Prothrombin Time		Theo-Dur	C	
	Prolonged		Noleptan	C	
	Respiratory Disorder		Ulgut	C	
	Sepsis		Sigmart	C	
	Thrombocytopenia		Neuquinon	C	
	Vomiting				
	White Blood Cell Count				
	Decreased				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/29/98ISR Number: 3099614-3Report Type:Expedited (15-DaCompany Report #ZANA0319970264
Age:80 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Systolic Increased	Foreign Distributor	Ternelin	PS		ORAL	1.0 MG DAILY,	PER ORAL
	Cold Sweat		Soleton	SS				
	Nausea							
	Shock							

Date:06/30/98ISR Number: 3099957-3Report Type:Expedited (15-DaCompany Report #1998-000894
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blister	Foreign	Mexitil	PS		ORAL	10 MG/CAP,	
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Health Professional	Norvasc	SS		ORAL	300 MG PO 5 MG/PO	
	Blood Lactate		Lasix	SS		ORAL	40 MG/PO	
	Dehydrogenase Increased		Depas	SS		ORAL	1 MG/PO	
	Blood Urea Increased		Ternelin	SS		ORAL	3 MG/PO	
	Dermatitis		Glakay	SS		ORAL	45 MG/PO	
	Erythema							
	Face Oedema							
	Fatigue							
	Haematuria							
	Hypotension							
	Purpura							
	Pyrexia							
	Rash Papular							
	Skin Ulcer							
	White Blood Cell Count Increased							

Date:07/01/98ISR Number: 3100878-8Report Type:Periodic Company Report #ZANA0319980364
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	
			Dantrium	C				
			Baclofen	C				
			Steroids	C				
			Amitriptyline	C				
			Trental	C				
			Pepcid	C				
			Synthroid	C				
			Bumex	C				
			Lasix	C				

Date:07/01/98ISR Number: 3100880-6Report Type:Periodic Company Report #ZANA0319980343
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	12 MG DAILY, PER ORAL	
			Tegretol	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/01/98ISR Number: 3100882-XReport Type:Periodic Company Report #ZANA0319980344
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Urine Abnormality	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	6 MG DAILY,	PER ORAL
			Baclofen	C				
			Clonazepam	C				
			Estrace	C				
			Tetrabenazine	C				

Date:07/01/98ISR Number: 3100883-1Report Type:Periodic Company Report #ZANA0319980345
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination Insomnia	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	
	Paranoia		Prozac	C				
			Amitriptyline	C				
			Talacen	C				
			Baclofen	C				
			Luvox	C				

Date:07/01/98ISR Number: 3101046-6Report Type:Periodic Company Report #ZANA0319980346
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Speech Disorder	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	
			Baclofen	C				
			Tegretol	C				

Date:07/01/98ISR Number: 3101047-8Report Type:Periodic Company Report #ZANA0319980347
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY,	
	Headache						PER ORAL	
	Insomnia							
	Muscle Spasms		Maxzide	C				
			Paxil	C				
			Xanax	C				
			Prempro	C				
			Imipramine	C				

Date:07/01/98ISR Number: 3101048-XReport Type:Periodic Company Report #ZANA0319980348
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pain	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	18 MG DAILY,	
							PER ORAL	
			Amitripyline	C				
			Synthroid	C				
			Baclofen	C				
			Prempro	C				
			Fosamax	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/01/98ISR Number: 3101049-1Report Type:Periodic Company Report #ZANA0319980353
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apathy Hallucination	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	8 MG DAILY,	PER ORAL
			Amitriptyline	C				
			Baclofen	C				
			Avonex	C				
			Neurontin	C				
			Cylert	C				
			Naproxen	C				

Date:07/01/98ISR Number: 3101050-8Report Type:Periodic Company Report #ZANA0319980354
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acne	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	8 MG DAILY,	PER ORAL
			Xanax	C				

Date:07/01/98ISR Number: 3101052-1Report Type:Periodic Company Report #ZANA0319980355
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pain	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	18 MG DAILY,	PER ORAL
			Baclofen	C				
			Methotrexate	C				
			Amitriptyline	C				
			Solu-Medrol	C				

Date:07/01/98ISR Number: 3101053-3Report Type:Periodic Company Report #ZANA0319980356
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Urinary Incontinence	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	8 MG DAILY,	PER ORAL
			Depakote	C				

Date:07/01/98ISR Number: 3101054-5Report Type:Periodic Company Report #ZANA0319980357
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis Face Oedema	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY,	PER ORAL
			Ditropan	C				
			Lotensin	C				
			Nitroglycerin	C				
			Dantrium	C				
			Daypro	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/01/98ISR Number: 3101056-9Report Type:Periodic Company Report #ZANA0319980358
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY,	PER ORAL
			Betaseron	C				
			Procardia	C				

Date:07/01/98ISR Number: 3101060-0Report Type:Periodic Company Report #ZANA0319980359
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	
	Dry Mouth							
	Hallucination		Baclofen	C				
	Pollakiuria		Glyburide	C				
			Os-Cal	C				
			Imiprmine	C				
			Didronel	C				
			Coumdin	C				

Date:07/01/98ISR Number: 3101062-4Report Type:Periodic Company Report #ZANA0319980360
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Increased Appetite	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY,	PER ORAL
	Polyuria							
	Pyrexia							
			Baclofen	C				
			Diabinese	C				
			Zocor	C				
			Trinex	C				
			Claritin	C				

Date:07/01/98ISR Number: 3101064-8Report Type:Periodic Company Report #ZANA0319980365
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Mouth	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	16 MG DAILY,	

PER ORAL

Date:07/01/98ISR Number: 3101066-1Report Type:Periodic Company Report #ZANA0319980366
Age:37 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amenorrhoea	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	8 MG DAILY,	

PER ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/01/98ISR Number: 3101070-3Report Type:Periodic Company Report #ZANA0319980367
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY,	PER ORAL
			Baclofen	C				

Date:07/01/98ISR Number: 3101071-5Report Type:Periodic Company Report #ZANA0319980371
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amblyopia	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL		PER ORAL
	Deafness							
	Dizziness		Zoloft	C				
	Dry Mouth		Oral Contraceptives	C				
	Nystagmus							
	Palpitations							
	Sedation							
	Stupor							
	Syncope							
	Tinnitus							
	Vertigo							

Date:07/01/98ISR Number: 3101072-7Report Type:Periodic Company Report #ZANA0319980372
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Mouth	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	16 MG DAILY,	PER ORAL
	Muscle Spasms							
	Sedation							

Date:07/01/98ISR Number: 3101073-9Report Type:Periodic Company Report #ZANA0319980375
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Dreams Hyperhidrosis Sedation	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY, PER ORAL	
			Zocor	C				
			Synthroid	C				
			Estratest	C				
			Valium	C				

Date:07/01/98ISR Number: 3101074-0Report Type:Periodic Company Report #ZANA0319980378
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Insomnia	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	6 MG DAILY, PER ORAL	
			Hctz	C				
			Procardia	C				
			Allegra	C				
			Motrin	C				
			Hyoscyamine	C				
			Premarin	C				

				Betaseron	C		

Date:07/01/98ISR Number: 3101076-4Report Type:Periodic Company Report #ZANA0319980380
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective Muscle Spasms	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	24 MG DAILY,	PER ORAL
			Elavil	C				
			Neurontin	C				
			Valium	C				
			Naprelan	C				

Date:07/01/98ISR Number: 3101079-XReport Type:Periodic Company Report #ZANA0319980381
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis Glossitis Hyperhidrosis	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	8 MG DAILY,	PER ORAL
			Tegretol	C				
			Ogen	C				
			Synthroid	C				

Date:07/01/98ISR Number: 3101082-XReport Type:Periodic Company Report #ZANA0319980386
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test Abnormal	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	16 MG DAILY,	PER ORAL

			Klonopin	C		
			Elavil	C		

Date:07/01/98ISR Number: 3101084-3Report Type:Periodic Company Report #ZANA0319980387
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasms	Health	Zanaflex (Tizanidine					
	Tremor	Professional	Hydrochloride)	PS		ORAL	PER ORAL	

Date:07/01/98ISR Number: 3101085-5Report Type:Periodic Company Report #ZANA0319980388
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Zanaflex (Tizanidine					
	Oedema		Hydrochloride)	PS		ORAL	PER ORAL	
			Dilantin	C				
			Claritin	C				
			Prozac	C				
			Lorazepam	C				
			Volmax	C				
			Ativan	C				
			Prilosec	C				
			Flovent	C				

			Flonase	C		

Date:07/09/98ISR Number: 3103518-7Report Type:Expedited (15-DaCompany Report #ZANA0319980393
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Other	Dysarthria	Foreign	Sirdalud	PS		ORAL 4 MG, PER
	Hypotension	Distributor				ORAL
	Malaise		Norvasc (Amlodipine Besilate)	C		
	Pallor		Zocor (Simvastatin)	C		
	Sedation		Nootropil	C		
	Vertigo		Relifex (Nabumetone)	C		
			Ulceran (Ranitidine)	C		

Date:07/13/98ISR Number: 3104744-3Report Type:Expedited (15-DaCompany Report #ZANA0319980379
Age:34 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Complications Of Maternal Exposure To Therapeutic Drugs	Foreign	Sirdalud	PS		ORAL 12 MG DAILY, PER ORAL
	Foetal Growth Retardation	Distributor				
	Hepatitis Neonatal					
	Hypoglycaemia					
	Polycythaemia					
	Thrombocytopenia					

Date:07/21/98ISR Number: 3107331-6Report Type:Expedited (15-DaCompany Report #ZANA0319980395
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Life-Threatening	Abdominal Pain	Foreign	Ternelin	PS		ORAL 1 MG DAILY

	Cold Sweat	Health					
PER ORAL							
	Diarrhoea	Professional	Calslot	SS			
	Hypotension	Distributor	Soleton				
	Palpitations		(Zaltoprofen)	C			
	Shock		Gefanil (Gefarnate)	C			

Date:07/30/98ISR Number: 3111570-8Report Type:Direct Company Report #
Age:87 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Blood Pressure Decreased		Zanaflex	PS		
TWICE A DAY						
Other	Fluid Retention					
VIA PEG TUBE						
Required			Betopic	C		
Intervention to			Sinemet	C		
Prevent Permanent			Levoxyl	C		
Impairment/Damage			Depakene	C		
			Jevity	C		

Date:08/03/98ISR Number: 3112645-XReport Type:Expedited (15-DaCompany Report #WAES 98070066
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agranulocytosis	Other	Clinoril	PS		ORAL	PO; TAB	
Hospitalization -	Blood Pressure Decreased		Ternelin	SS		ORAL	2 MG/DAILY/PO	
Initial or Prolonged	Bronchitis Acute		Depas	SS				
	C-Reactive Protein Increased		Lasix	C				
	Depressed Level Of Consciousness		Noleptan	C				
	Disseminated Intravascular Coagulation		Sigmart	C				
	Epistaxis		Theo-Dur	C				
	Laboratory Test Abnormal		Ulgut	C				
	Platelet Count Decreased							
	Pneumonia							
	Prothrombin Time Prolonged							
	Respiratory Rate Decreased							
	Sepsis							
	Thrombocytopenia							
	Vomiting							
	White Blood Cell Count Increased							

Date:08/05/98ISR Number: 3113385-3Report Type:Expedited (15-DaCompany Report #ZANA0319980400
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health Professional	Zanaflex	PS		ORAL	ORAL	

Date:08/21/98ISR Number: 3123365-XReport Type:Expedited (15-DaCompany Report #ZANA0319980403
Age:19 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatine	Health	Zanaflex	PS			6 MG DAILY	
	Phosphokinase Increased	Professional	Depakene	C				
	Disseminated		Multivitamin	C				
	Intravascular Coagulation		Milk Of Magnesia	C				
	Euphoric Mood		Proventil	C				
	Haemorrhage		Biaxin	C				
	Hyperpyrexia		Entex	C				
	Hypotension							
	Oxygen Saturation Decreased							
	Respiratory Distress							
	Rhabdomyolysis							
	Sepsis							
	Tachycardia							
	Tachypnoea							

Date:08/24/98ISR Number: 3120845-8Report Type:Expedited (15-DaCompany Report #ZANA0319980403
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatine Phosphokinase Increased	Health Professional	Zanaflex	PS			6 MG DAILY;	GT
	Disseminated		Depakene	C				
	Intravascular Coagulation		Multivitamin	C				
	Haemorrhage		Milk Of Magnesia	C				
	Hyperpyrexia		Proventil	C				
	Hypotension		Biaxin	C				
	Inappropriate Affect		Entex	C				
	Oxygen Saturation Decreased							
	Respiratory Distress							
	Respiratory Rate Increased							
	Rhabdomyolysis							
	Sepsis							
	Tachycardia							

Date:08/28/98ISR Number: 3122548-2Report Type:Expedited (15-DaCompany Report #ZANA0319980401
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pneumonia	Health Professional	Zanaflex	PS		ORAL	16 MG DAILY,	PER ORAL
			Cefuroxime	C				
			Albuterol	C				
			Restoril	C				
			Klonopin	C				
			Percocet	C				
			Acetaminophen	C				
			Milk Of Magnesia	C				
			Docusate	C				
			Acetylcysteine	C				
			Silver Sulfadiazine	C				
			Guaifenesin	C				
			Bisacodyl	C				

			Hydroxyzine	C		

Date:09/04/98ISR Number: 3126189-2Report Type:Expedited (15-DaCompany Report #ZANA0319980407
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Pain	Health	Zanaflex	PS		ORAL	32 MG DAILY,	
	Platelet Count Decreased	Professional					PER ORAL	
	Thrombocytopenia		Avonex	SS			UNK	
			Neurontin	C				
			Tranylcypromine Sulfate	C				
			Ibuprofen	C				

Date:09/04/98ISR Number: 3126387-8Report Type:Expedited (15-DaCompany Report #ZANA0319980400
Age:38 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Zanaflex	PS		ORAL	PER ORAL	
		Professional						

Date:09/23/98ISR Number: 3134020-4Report Type:Expedited (15-DaCompany Report #ZANA 0319980401
Age:31 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bronchospasm	Health	Zanaflex	PS		ORAL	16 MG DAILY, PER ORAL	
	Chills	Professional						
	Cough		Cefuroxime	C				
	Pneumonia		Albuterol	C				
	Productive Cough		Restoril	C				
	Rhonchi		Klonopin	C				
			Percocet	C				
			Acetaminophen	C				
			Milk Of Magnesia	C				
			Docusate	C				
			Acetylcysteine	C				
			Silver Sulfadiazine	C				
			Guaifenesin	C				
			Bisacodyl	C				
			Hydroxyzine	C				
			Ceftin	C				
			Benadryl	C				
			Baclofen Pump	C				

Date:09/23/98ISR Number: 3134214-8Report Type:Direct Company Report #
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypotension		Zanaflex	PS		ORAL	4MG BID PO	4 DAY
	Oxygen Saturation Decreased		Lopressor	SS		ORAL	25MG BID PO	
	Sedation							

Date:09/23/98ISR Number: 3134477-9Report Type:Expedited (15-DaCompany Report #ZANA 319980400
Age:38 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Intentional Misuse	Health Professional	Zanaflex	PS		ORAL

Date:09/24/98ISR Number: 3134982-5Report Type:Direct Company Report #
Age:48 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness		Zanaflex	PS		ORAL	8MG, TID, PO	6 MON
	Hallucination, Visual		Neuronitin	C			600MG QID	
	Hypotension		Nascobal	C			1X/WK	
	Sedation		Oxybutinin	C			5MG QID	
			Ultram	C			50MG QD	

Date:10/01/98ISR Number: 3136998-1Report Type:Direct Company Report #
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea		Zanaflex	PS		ORAL	14MG /DAY	
	Pyrexia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/01/98ISR Number: 3263113-6Report Type:Periodic Company Report #ZANA0319980389
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination	Health Professional	Zanaflex (Tizanidine Hyrochloride)	PS		ORAL	8 MG DAILY	
			Antidepressant	C				

Date:10/01/98ISR Number: 3263117-3Report Type:Periodic Company Report #ZANA0319980392
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Myasthenic Syndrome	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	24 MG DAILY	
			Avonex	C				
			Valium	C				
			Tegretol	C				
			Ditropan	C				
			Tofranil	C				

Date:10/01/98ISR Number: 3263119-7Report Type:Periodic Company Report #ZANA0319980394
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Oedema	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL		
			Methadone	C				
			Diazepam	C				
			Dalmane	C				
			Allopurinol	C				

Date:10/01/98ISR Number: 3263122-7Report Type:Periodic Company Report #ZANA0319980396
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Angioneurotic Oedema	Health	Zanaflex (Tizanidine			
	Urticaria	Professional	Hydrochloride)	PS		ORAL
			Aspirin	C		

Date:10/01/98ISR Number: 3263126-4Report Type:Periodic Company Report #ZANA0319980397
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Dermatitis	Health	Zanaflex (Tizanidine			
	Dry Skin	Professional	Hydrochloride)	PS		ORAL
8 MG DAILY						
	Urticaria		Antidepressant	C		

Date:10/01/98ISR Number: 3263129-XReport Type:Periodic Company Report #ZANA0319980399
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Muscle Spasms	Health	Zanaflex (Tizanidine			
		Professional	Hydrochloride)	PS		ORAL
36 MG DAILY						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/01/98ISR Number: 3263131-8Report Type:Periodic Company Report #ZANA0319980402
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY	
			Baclofen	C				
			Ambien	C				
			Bactrim	C				

Date:10/01/98ISR Number: 3263133-1Report Type:Periodic Company Report #ZANA0319980404
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nausea	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY	

Date:10/01/98ISR Number: 3263136-7Report Type:Periodic Company Report #ZANA0319980405
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Herpes Zoster	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL		
	Sedation		Baclofen	C				
			Prozac	C				
			Ditropan	C				
			Nitrofurantoin	C				
			Neurontin	C				
			Estrace	C				
			Prolific	C				

Date:10/01/98ISR Number: 3263139-2Report Type:Periodic Company Report #ZANA0319980410
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Dysgeusia	Health	Zanaflex (Tizanidine				
	Hyperhidrosis	Professional	Hydrochloride)	PS			ORAL
4 MG DAILY							

Date:10/01/98ISR Number: 3263140-9Report Type:Periodic Company Report #ZANA0319980411
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coagulation Time	Health	Zanaflex (Tizanidine					
	Prolonged	Professional	Hydrochloride)	PS		ORAL		
12 MG DAILY								
			Coumadin	C				
			Mevacor	C				
			Vasotec	C				

Date:10/13/98ISR Number: 3142382-7Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT
Disability	Blood Pressure Decreased
	Dizziness
	Headache
	Hyperhidrosis
	Nausea

	Tremor						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Health	Zanaflex	PS			4 MG EVERY 4
		Professional					HOURS

Date:10/29/98ISR Number: 3149344-4Report Type:Expedited (15-DaCompany Report #ZANA0319980420
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Death	Health	Zanaflex	PS		ORAL	PER ORAL
	Overdose	Professional	Oxycodone	SS			

Date:11/04/98ISR Number: 3152429-XReport Type:Expedited (15-DaCompany Report #ZANA0319980421
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign	Ternelin	PS		ORAL	3.0 MG DAILY, PER ORAL
		Health					
		Professional	Disopain	SS			
		Distributor	Aplace	C			

Date:11/06/98ISR Number: 3153181-4Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent	Dysarthria		Zanaflex	PS		ORAL	8 MG PO Q 4 HOURS; DOSAGE INCREASED 4
	Hypotension						

Impairment/Damage
WEEKS PRIOR

TO ADR

Docusate Sodium	C
Kcl	C
Bisacodyl	C
Multivitamins	C
Vitamin C	C
Zinc	C
Omeprazole	C
Vancomycin	C
Flagyl	C
Aztreonam	C
Baclofen	C

Date:11/17/98ISR Number: 3158794-1Report Type:Expedited (15-DaCompany Report #ZANA0319980426
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Asthenia	Foreign	Ternelin	PS		ORAL	2 MG DAILY,	
	Monoparesis	Health					PER ORAL	
	Muscle Atrophy	Professional	Infree	SS				
	Neuropathy Peripheral	Distributor	Chondroitin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/04/98ISR Number: 3167347-0Report Type:Expedited (15-DaCompany Report #ZANA0319980426
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Asthenia	Foreign	Ternelin	PS		ORAL	2 MG DAILY,
	Intervertebral Disc	Health					PER ORAL
	Protrusion	Professional	Infree	SS			
	Monoparesis	Distributor	Chondroitin				
	Movement Disorder		(Chpondroitin				
	Muscle Atrophy		Sulfate)	C			
	Nerve Compression						
	Nerve Root Injury						
	Neuropathy Peripheral						

Date:12/10/98ISR Number: 3168983-8Report Type:Direct Company Report #
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Convulsion	Health	Tizanidine Hcl	PS		ORAL	8 MG TID PO
Intervention to	Headache	Professional	Amoxicillin	C			
Prevent Permanent	Lethargy		Ibuprofen	C			
Impairment/Damage	Vomiting		Guafenasin	C			
			Divalproate	C			

Date:12/15/98ISR Number: 3171078-0Report Type:Expedited (15-DaCompany Report #ZANA0319980433
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Blood Creatine	Health	Zanaflex	PS		ORAL	PER ORAL
Initial or Prolonged	Phosphokinase Increased	Professional					
	Pyrexia						

Date:12/15/98ISR Number: 3171237-7Report Type:Expedited (15-DaCompany Report #ZANA0319980429
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hallucination	Health	Zanaflex	PS		ORAL	PER ORAL	
		Professional	Ms Contin	C				
			Benzodiazepine	C				

Date:12/17/98ISR Number: 3171722-8Report Type:Expedited (15-DaCompany Report #ZANA0319980429
Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Agitation	Health	Zanaflex	PS		ORAL	PER ORAL	
	Confusional State	Professional	Ms Contin	C				
	Depressed Level Of Consciousness		Smir	C				
			Verapamil	C				
	Disorientation		Prozac	C				
	Hallucination		Ativan	C				
	Medication Error							
	Sedation							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/29/98ISR Number: 3176397-XReport Type:Expedited (15-DaCompany Report #ZANA0319980435
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	

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

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

Date:01/06/99ISR Number: 3192622-3Report Type:Periodic Company Report #ZANA0319980432
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperhidrosis	Health Professional	Zanaflex	PS		ORAL	PER ORAL	
	Oedema							
	Vasodilatation							

Date:01/06/99ISR Number: 3192628-4Report Type:Periodic Company Report #ZANA0319980428
Age:50 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Health	Zanaflex (Tizanidine					
	Tremor	Professional	Hydrochloride)	PS		ORAL	PER ORAL	

Date:01/06/99ISR Number: 3192632-6Report Type:Periodic Company Report #ZANA0319980425
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Health	Zanaflex (Tizanidine					
		Professional	Hydrochloride)	PS		ORAL	8 MG , PER	
							ORAL	
			Coumadin	C				
			Depo-Provera	C				
			Baclofen	C				
			Diazepam	C				
			Amitriptyline	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/06/99ISR Number: 3192636-3Report Type:Periodic Company Report #ZANA0319980424
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasms	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	

Date:01/06/99ISR Number: 3192641-7Report Type:Periodic Company Report #ZANA0319980422
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated Muscle Spasms	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY, PER ORAL	

Date:01/06/99ISR Number: 3192646-6Report Type:Periodic Company Report #ZANA0319980419
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	12 MG DAILY, PER ORAL	
			Valium	C				
			Hydrochlorothiazide	C				
			Lisinopril	C				
			Labetalol	C				

Date:01/06/99ISR Number: 3192650-8Report Type:Periodic Company Report #ZANA0319980415
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Zanaflex (Tizanidine					

	Sedation		Hydrochloride)	PS		ORAL
10 MG DIALY,						
	Urinary Incontinence					
PER ORAL						
			Morphine	C		
			Percocet	C		
			Terazosin	C		
			Lopressor	C		
			Naprosyn	C		

Date:01/06/99ISR Number: 3192656-9Report Type:Periodic Company Report #ZANA0319980413
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Abnormal Faeces	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
4 MG DAILY,						
PER ORAL						
			Percocet	C		
			Trilisate	C		
			Zoloft	C		

Date:01/06/99ISR Number: 3192661-2Report Type:Periodic Company Report #ZANA0319980412
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Sedation	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
2 MG DAILY,						

PER ORAL

			Methotrexate	C		
			Avonex	C		

Date:01/25/99ISR Number: 3185399-9Report Type:Expedited (15-DaCompany Report #JAKYO-41666
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Angina Pectoris	Foreign	Itraconazole	PS	Janssen	ORAL	50 MG DAILY	
	Back Pain	Health				ORAL		
	Drug Interaction	Professional	Tizanidine Hydrochloride					
	Drug Level Above Therapeutic		(Tizanidine) Tablet	SS		ORAL	3 MG DAILY	
						ORAL		
			Etodolac	C				
			Terbinafine Hydrochloride	C				
			Misoprostol	C				

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

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

Date:02/03/99ISR Number: 3191336-3Report Type:Expedited (15-DaCompany Report #ZANA0319990440
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Urinary Retention	Foreign	Ternelin	PS		ORAL	PER ORAL	
		Health Professional Distributor	Madopar	C				
			Symmetrel (Amantadine Hydrochloride)	C				
			Aspirin	C				

Date:02/16/99ISR Number: 3199743-XReport Type:Expedited (15-DaCompany Report #ZANA0319990442
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	360 MG DAILY, PER ORAL	
Hospitalization - Initial or Prolonged	Cyanosis							
	Feeling Cold							
Other	Hypotension		Alprazolam	C				
	Intentional Misuse		Trazodone	C				
	Lung Infiltration		Dicyclomine	C				
	Pneumonia Aspiration		Prozac	C				
	Sedation		Percocet	C				

Date:02/19/99ISR Number: 3203503-0Report Type:Expedited (15-DaCompany Report #ZANA0319990443
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Cardiac Failure	Foreign	Ternelin				
	Depressed Level Of Consciousness	Health Professional	(Tizandinine Hydrochloride)	PS		ORAL	284.0 MG
	Drug Level Above Therapeutic	Distributor					DAILY, PER ORAL
	Overdose		Myonal (Eperisone				
	Respiratory Depression		Hydrochloride)	SS			

Date:03/03/99ISR Number: 3211614-9Report Type:Expedited (15-DaCompany Report #ZANA0319990440
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abdominal Distension	Foreign	Ternelin (Tizanidine				
	Abdominal Pain	Health	Hydrochloride)	PS		ORAL	3 MG DAILY
	Decreased Appetite	Professional					PER ORAL
	Urinary Retention	Distributor	Peon (Zaltoprofen)	SS			
			Marzulen-S (Marzulene-S)	SS			
			Dasen (Serrapeptase)	SS			
			Madopar	C			
			Baylotensin	C			
			Symmetrel	C			
			Aspirin	C			
			Parlodel	C			

Date:03/03/99ISR Number: 3211617-4Report Type:Expedited (15-DaCompany Report #ZANA0319990448
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Hyperpyrexia	Health	Zanaflex (Tizanidine				

Initial or Prolonged	Pneumonia	Professional	Hydrochloride)	PS		ORAL

36 MG DAILY

PER ORAL

Date:03/03/99ISR Number: 3211620-4Report Type:Expedited (15-DaCompany Report #ZANA0319990445
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Amnesia	Consumer	Zanaflex (Tizanidine			
Initial or Prolonged	Asthenia		Hydrochloride)	PS		ORAL

PER ORAL

Coma
Fatigue
Hallucination, Visual
Multiple Sclerosis
Muscle Rigidity
Muscle Spasticity
Panic Attack
Visual Disturbance

Date:03/04/99ISR Number: 3212336-0Report Type:Direct Company Report #
Age:54 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Abdominal Pain Upper
Initial or Prolonged	Gallbladder Disorder

	Hepatotoxicity Jaundice Liver Function Test	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Abnormal	Health Professional	Zanaflex	PS			4MG Q6 ; ON AT HOME NOT SURE HOW LONG

Date:03/04/99ISR Number: 3212864-8Report Type:Expedited (15-DaCompany Report #ZANA0319990449
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Cardio-Respiratory Arrest	Company Representative	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL

Date:03/12/99ISR Number: 3219247-5Report Type:Expedited (15-DaCompany Report #ZANA0319990443
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Cardiac Failure Depressed Level Of Consciousness Electrocardiogram Qt Prolonged Electrocardiogram St Segment Elevation Hypothermia Loss Of Consciousness Nausea Overdose Respiratory Depression Suicide Attempt Vomiting	Foreign Health Professional Distributor	Ternelin (Tizanidine Hydrochloride) Myonal (Eperisone Hydrochloride)	PS SS		ORAL	284.0 MG DAILY, PER ORAL

Date:03/12/99ISR Number: 3219425-5Report Type:Expedited (15-DaCompany Report #ZANA0319990454
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour	Foreign	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	
			Tramadol	SS		ORAL	PER ORAL	
			Baclofen	C				
			Diazepam	C				
			Diconal	C				
			Moduretic	C				

Date:03/12/99ISR Number: 3219466-8Report Type:Expedited (15-DaCompany Report #ZANA0319990453
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Rigidity Tremor	Foreign	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	12 MG DAILY, PER ORAL	
			Baclofen	C				
			Cinnarizine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/12/99ISR Number: 3219469-3Report Type:Expedited (15-DaCompany Report #ZANA0319990452
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Failure	Foreign	Zanaflex	PS		ORAL	32 MG DAILY,	
	Congestive						PER ORAL	
	Creatine Phosphokinase Decreased		Lansoprazole	C				
	Crepitations							
	Dyspnoea							
	Dyspnoea Paroxysmal Nocturnal							

Date:03/12/99ISR Number: 3219471-1Report Type:Expedited (15-DaCompany Report #ZANA0319990451
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Foreign	Zanaflex	PS		ORAL	2-4 MG DAILY,	
	Muscle Spasticity						PER ORAL	
	Quadriplegia		Carbarmazepine	C				
			Baclofen	C				

Date:04/01/99ISR Number: 3232648-4Report Type:Periodic Company Report #ZANA0319980434
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Urinary Incontinence	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY,	
							PER ORAL	
			Cosamin	C				

Date:04/01/99ISR Number: 3232650-2Report Type:Periodic Company Report #ZANA0319980436
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accident	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY,	
	Muscle Spasms						PER ORAL	
			Primidone	C				
			Diazepam	C				

Date:04/01/99ISR Number: 3232653-8Report Type:Periodic Company Report #ZANA0319990437
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Mouth	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	
	Sedation							
	Sinusitis		Permax	C				
			Zocor	C				
			Hytrin	C				

Date:04/01/99ISR Number: 3232656-3Report Type:Periodic Company Report #ZANA0319990439
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nausea	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY,	
	Pyrexia							

PER ORAL

			Neurontin	C		

Date:04/01/99ISR Number: 3232658-7Report Type:Periodic Company Report #ZANA0319990446
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	6 MG DAILY,	

PER ORAL

			Anti-Hypertensives	C		

Date:04/01/99ISR Number: 3232660-5Report Type:Periodic Company Report #ZANA0319990447
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	30 MG DAILY,	

PER ORAL

			Zithromax	C		

Date:04/01/99ISR Number: 3232661-7Report Type:Periodic Company Report #ZANA0319980380
Age:44 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective Muscle Spasms	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	24 MG DAILY,	

PER ORAL

			Elavil	C		
			Neurontin	C		
			Valium	C		
			Naprelan	C		

Date:06/07/99ISR Number: 3277525-8Report Type:Expedited (15-DaCompany Report #ZANA0319990489
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Fall	Health	Zanaflex (Tizanidine					
Hospitalization -	Hypotension	Professional	Hydrochloride)	PS		ORAL	16 MG DAILY,	
Initial or Prolonged	Liver Function Test						PER ORAL	
	Abnormal							
	Renal Failure Acute							

Date:06/24/99ISR Number: 3291137-1Report Type:Expedited (15-DaCompany Report #JRFBEL1999000365
Age:73 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bradycardia	Foreign	Prepulsid					
Initial or Prolonged	Cardiac Failure	Health	(Unspecified)					
	Electrocardiogram Qt	Professional	(Cisapride)	PS		ORAL	MG, DAILY	
	Corrected Interval						ORAL	
	Prolonged		Sirdalud Retard (Tizanidine Hydrochloride)	SS		ORAL	MG, DAILY,	
							ORAL	
			Sirdalud (Tizanidine Hydrochloride)	SS		ORAL	MG, DAILY,	

ORAL							
			Cozaar	C			
			Emconcor	C			
			Salazopyrin	C			
			Digoxin	C			
			Furesis	C			
			Lanzo	C			
			Para-Tabs	C			
			Tramal	C			
			Cipramil	C			
			Fosamax	C			
			Progynova	C			
			Miacalcic Nasal	C			
			Tenox	C			
			Oxepam	C			

Date:07/01/99ISR Number: 3298847-0Report Type:Expedited (15-DaCompany Report #JRFBEL1999000365
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Back Pain	Foreign	Prepulsid				
	Bradycardia	Health	(Unspecified)				
	Cardiac Failure	Professional	(Cisapride)	PS		ORAL	5MG 3 IN 1
	Electrocardiogram Qt						DAYS (S) ORAL
	Prolonged		Sirdalud Retard				
	Fracture		(Tizanidine				
	Heart Rate Increased		Hydochloride)	SS		ORAL	MG DAILY ORAL
	Osteoporosis		Sirdalud	SS		ORAL	MG DAILY ORAL
	Pain		Salazopyrin	C			
			Cozaar	C			
			Emconcor	C			

Date:07/01/99ISR Number: 3303393-1Report Type:Periodic Company Report #ZANA0319990480
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Hypersensitivity	Consumer	Zanaflex (Tizanidine				

	Paraesthesia		Hydrochloride)	PS		ORAL
2 MG DAILY,						
	Skin Ulcer					
PER ORAL						
	Urticaria					

Date:07/01/99ISR Number: 3303406-7Report Type:Periodic Company Report #ZANA0319990481
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Liver Function Test	Health	Zanaflex (Tizanidine			
	Abnormal	Professional	Hydrochloride)	PS		ORAL
36 MG DAILY,						
PER ORAL						

Date:07/01/99ISR Number: 3303411-0Report Type:Periodic Company Report #ZANA0319990482
Age:81 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Pruritus	Health	Zanaflex (Tizanidine			
	Rash Maculo-Papular	Professional	Hydrochloride)	PS		ORAL
4 MG DAILY,						
PER ORAL						
			Vasotec	C		
			Biaxin	C		

				Digoxin	C		

Date:07/01/99ISR Number: 3303415-8Report Type:Periodic Company Report #ZANA0319990483
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Rash Pruritic	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4-6 MG DAILY,	PER ORAL

Date:07/01/99ISR Number: 3303418-3Report Type:Periodic Company Report #ZANA0319990486
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness Myasthenic Syndrome Sedation	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL; 4 MG DAILY, PER	ORAL

Date:07/01/99ISR Number: 3303421-3Report Type:Periodic Company Report #ZANA0319990487
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia Sedation	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	6 MG DAILY,	PER ORAL
			Baclofen	C				
			Naproxen Sodium	C				
			Ditropan Excel	C				

Date:07/01/99ISR Number: 3303449-3Report Type:Periodic Company Report #ZANA0319990490
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pain	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	

Date:07/01/99ISR Number: 3303455-9Report Type:Periodic Company Report #ZANA0319990491
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	12 MG DAILY,	
							PER ORAL	
			Clonipen	C				
			Imuran	C				
			Prednisone	C				

Date:07/01/99ISR Number: 3303460-2Report Type:Periodic Company Report #ZANA0319990493
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	
	Dry Mouth							
			Synthroid	C				

			Provera	C			
			Hctz	C			
			Zestril	C			

Date:07/01/99ISR Number: 3303465-1Report Type:Periodic Company Report #ZANA0319990494
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Zanaflex (Tizanidine					
	Hallucination		Hydrochloride)	PS		ORAL	36 MG DAILY,	
	Myasthenic Syndrome						PER ORAL	
	Sedation		Baclofen	C				

Date:07/01/99ISR Number: 3303468-7Report Type:Periodic Company Report #ZANA0319990497
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Consumer	Zanaflex (Tizanidine					
	Abnormal Faeces		Hydrochloride)	PS		ORAL	PER ORAL; 1.5	
	Nausea						MG DAILY, PER	
							ORAL	
			Tegretol	C				
			Mysoline	C				
			Multivitamins	C				
			Calcium Gluconate	C				
			Milk Of Magnesia	C				

Date:07/09/99ISR Number: 3300473-1Report Type:Expedited (15-DaCompany Report #ZANA0319990507
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Pemphigoid		Zanaflex (Tizanidine					

Initial or Prolonged			Hydrochloride)	PS			ORAL
PER ORAL							
			Baclofen	C			
			Frusemide	C			
			Thyroxine	C			
			Spironolactone	C			
			Amlodipine	C			
			Lisinopril	C			
			Simvastatin	C			
			Aspirin	C			
			Diazepam	C			
			Hydroxyzine	C			
			Praxilene	C			

Date:07/13/99ISR Number: 3302773-8Report Type:Expedited (15-DaCompany Report #ZANA0319990503
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Bradycardia	Foreign	Sirdalud (Tizanidine				
Initial or Prolonged	Cardiac Failure	Distributor	Hydrochloride)	PS		ORAL	6.0 MG DAILY,
	Congestive						
PER ORAL							
	Condition Aggravated		Sirdalud Mr	SS		ORAL	UNKNOWN PER
	Electrocardiogram Qt						
ORAL							
	Prolonged		Lansoprazole	SS			
			Prepulsid				
			(Cisapride)	SS		ORAL	
PER ORAL							

			Sulfasalazine	C		
			Cozaar	C		
			Bisoprolol	C		
			Digoxin	C		
			Furosemide	C		

Date:07/23/99ISR Number: 3309826-9Report Type:Expedited (15-DaCompany Report #ZANA0319990509
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia	Health	Sirdalud (Tizanidine					
	Depressed Level Of Consciousness	Professional	Hydrochloride)	PS		ORAL	3.0 MG DAILY;	PER ORAL 711 DAY
	Heart Rate Decreased		Lendormin	C				
	Sedation		Sedes	C				
	Sick Sinus Syndrome		Merislon	C				
			Selbex	C				

Date:07/23/99ISR Number: 3310019-XReport Type:Expedited (15-DaCompany Report #ZANA0319990509
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia	Foreign	Sirdalud (Tizanidine					
	Depressed Level Of Consciousness	Health Professional	Hydrochloride)	PS		ORAL	3.0 MG DAILY,	PER ORAL
	Sedation	Distributor	Merislon	SS				
	Sick Sinus Syndrome		Lendormin	C				
			Selbex	C				
			Sedes	C				

Date:07/30/99ISR Number: 3315221-9Report Type:Expedited (15-DaCompany Report #ZANA0319990511
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign Health	Ternelin (Tizanidine Hydrochloride)	PS	ORAL 3.0 MG DAILY,
	Extensor Plantar Response	Professional			PER ORAL
	Hypertension	Distributor	Aspirine	C	
	Hypoxia		Sarpul	C	
	Respiratory Failure		Trental	C	
	Respiratory Rate Decreased				
	Sedation				
	Shock				
	Stridor				

Date:07/30/99ISR Number: 3315224-4Report Type:Expedited (15-DaCompany Report #ZANA0319990511
Age:70 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Cerebrovascular Accident
	Depressed Level Of Consciousness
	Extensor Plantar Response
	Hypopnoea
	Hypotension
	Hypoxia

	Medication Error					
	Rash Macular					
	Respiratory Failure	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Sedation	Health	Ternelin (Tizanidine			
	Shock	Professional	Hydrochloride)	PS		ORAL
3.0 MG DAILY						
	Stridor		Aspirine	C		
			Sarpul	C		
			Trental	C		

Date:08/19/99ISR Number: 3330238-6Report Type:Expedited (15-DaCompany Report #ZANA0319990520
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Hypotension	Health	Zanaflex (Tizanidine			
	Sudden Death	Professional	Hydrochloride)	PS		ORAL
32 MG DAILY,						
	Syncope					
PER ORAL						
			Amitriptyline	C		
			Baclofen	C		

Date:08/19/99ISR Number: 3330239-8Report Type:Expedited (15-DaCompany Report #ZANA0319990518
Age: Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Bradycardia	Consumer	Zanaflex (Tizanidine			
Initial or Prolonged	Hallucination		Hydrochloride)	PS		ORAL
36 MG DAILY,						
PER ORAL						

Date:09/03/99ISR Number: 3341141-XReport Type:Expedited (15-DaCompany Report #ZANA0319990521
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Chromaturia	Health	Zanaflex (Tizanidine			

	Condition Aggravated	Professional	Hydrochloride)	PS		ORAL
4 MG DAILY,						
	Fatigue					
PER ORAL						
	Haematuria		Baclofen	C		
	Muscle Spasms		Allopurinol	C		
			Atenolol	C		
			Tamsulosin	C		
			Fluoxetine	C		

Date:09/15/99ISR Number: 3348801-5Report Type:Expedited (15-DaCompany Report #99J--10282
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Liver Disorder	Foreign	Voltaren Suppository			
Initial or Prolonged	Oculomucocutaneous	Health	(Diclofenac Sodium)	PS		
RECTAL UNK, DAILY,						
	Syndrome	Professional				
RECTAL						
		Other	Bufferin Unknown			
			(Bufferin)	SS		
			Mucodyne Unknown			
			(Carbocisteine)	SS		
			Pl Granulate (Pl			
			Granules)	SS		
			Loxonin Unknown			
			(Loxoprofen Sodium)	SS		
			Tizanidine			
			Hydrochloride Tablet			

			(Tizanidine Hydrochloride)	SS			ORAL
UNK, UNK, ORAL							
			Klaricid Unknown (Clarithromycin)	SS			

Date:09/15/99ISR Number: 3348815-5Report Type:Expedited (15-DaCompany Report #99J--10282
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Liver Disorder Oculomucocutaneous Syndrome	Foreign Health Professional	Voltaren Suppository (Diclofenac Sodium)	PS		RECTAL	UNK, DAILY, RECTAL	
		Other	Bufferin Unknown (Bufferin)	SS				
			Mucodyne Unknown (Carbocisteine)	SS				
			Tizanidine Hydrochloride Tablet (Tizanidine Hydrochloride)	SS		ORAL	UNK, UNK, ORAL	
			Klaricid Unknown (Clarithromycin)	SS				
			Pl Granulate (Pl Granules)	SS				
			Loxonin Unknown (Loxoprofen Sodium)	C				

Date:09/17/99ISR Number: 3350546-2Report Type:Expedited (15-DaCompany Report #ZANA0319990522
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthma Dyspepsia	Foreign Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	36 MG DAILY	

	Dyspnoea Exertional	Professional				
PER ORAL						
			Diazepam	C		
			Salbutamol	C		

Date:09/20/99ISR Number: 3350768-0Report Type:Direct Company Report #
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required	Fatigue		Zanaflex 4mg	PS		ORAL
4MG 1 1/2-1T						
Intervention to	Liver Function Test					
PO QD						
Prevent Permanent	Abnormal		Effexor	C		
Impairment/Damage			Motrin	C		

Date:09/22/99ISR Number: 3366706-0Report Type:Periodic Company Report #WAES 99070025
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Delusion	Health	Tab Vioxx	PS		ORAL
	Drug Interaction	Professional	Zanaflex	SS		
	Hallucination	Company				
	Vomiting	Representative				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/01/99ISR Number: 3367908-XReport Type:Periodic Company Report #ZANA0319990499
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	ORAL	
	Sedation							

Date:10/01/99ISR Number: 3367912-1Report Type:Periodic Company Report #ZANA0319990500
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	20 MG DAILY,	
	Muscle Spasms							
	Sedation	Distributor					ORAL	
			Glatiramer Acetate	C				
			Oxybutynin	C				
			Fluoxetine Hydrochloride	C				
			Amantadine	C				
			Fampridine	C				

Date:10/01/99ISR Number: 3367914-5Report Type:Periodic Company Report #ZANA0319990508
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Urinary Retention	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	12 MG DAILY,	
							ORAL	

Date:10/01/99ISR Number: 3367918-2Report Type:Periodic Company Report #ZANA0319990512
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	ORAL	

Date:10/01/99ISR Number: 3367919-4Report Type:Periodic Company Report #ZANA0319990517
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chills	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	12 MG DAILY,	
	Depression						PER ORAL	
	Dry Mouth							
	Hyperhidrosis		Tranxene	C				
	Nausea		Inderal	C				
	Pollakiuria		Estrace	C				
	Sedation		Progesterone	C				
			Zoloft	C				
			Potassium	C				
			Magnesium	C				

Date:10/01/99ISR Number: 3367921-2Report Type:Periodic Company Report #ZANA0319990525
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Gastrointestinal Haemorrhage	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/01/99ISR Number: 3367923-6Report Type:Periodic Company Report #ZANA0319990526
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test Abnormal	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	12 MG DIALY,	PER ORAL
			Fentanyl	C				
			Oxy Ir	C				
			Reglan	C				
			Trilisate	C				
			Trazodone	C				
			Mexelitine	C				

Date:10/01/99ISR Number: 3367970-4Report Type:Periodic Company Report #ZANA0319990527
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	
			Baclofen	C				

Date:10/01/99ISR Number: 3367971-6Report Type:Periodic Company Report #ZANA0319990528
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Laboratory Test Abnormal	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	
			Coumadin	SS				

Date:10/01/99ISR Number: 3367973-XReport Type:Periodic Company Report #ZANA0319990529
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperhidrosis Muscle Spasms Myasthenic Syndrome Sedation	Consumer	Zanaflex (Tizanidine Hydrochloride) Methazolamide Clonidine Voltaren Prinivil Zoloft Percocet Trental Duragesic Darvocet	PS C C C C C C C C C		ORAL	14 MG DAILY, PER ORAL	

Date:10/01/99ISR Number: 3367976-5Report Type:Periodic Company Report #ZANA0319990530
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Zanaflex (Tizanidine Hydrochloride) Mysoline (Primidone) Tablets Tegretol	PS C C		ORAL	PER ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/01/99ISR Number: 3367978-9Report Type:Periodic Company Report #ZANA0319990531
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test Abnormal	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY,	PER ORAL

Date:10/01/99ISR Number: 3367981-9Report Type:Periodic Company Report #ZANA0319990481
Age:23 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test Abnormal	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	36 MG DAILY,	PER ORAL

Date:11/02/99ISR Number: 3386864-1Report Type:Direct Company Report #
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Diarrhoea Pyrexia		Zanaflex 4 Mg	PS		ORAL	1T PO QD	

Date:11/04/99ISR Number: 3388803-6Report Type:Expedited (15-DaCompany Report #ZANA0319990545
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Completed Suicide	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL PER ORAL
			Codeine	C		
			Diazepam	C		

Date:11/04/99ISR Number: 3388841-3Report Type:Expedited (15-DaCompany Report #ZANA0319990545
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death	Completed Suicide Overdose	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL PER ORAL
			Codeine	C		
			Diazepam	C		

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

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

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/27/99ISR Number: 3431650-7Report Type:Expedited (15-DaCompany Report #99J--10454
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Nausea Syncope	Foreign Health Professional	Voltaren Tablet (Diclofenac Sodium)	PS		ORAL	25 MG,	DAILY,ORAL
			Ternelin Tablet (Tizanidine)	SS		ORAL	3 MG DAILY,	ORAL
			Persantine Tablet	C				
			Ambroxol Hydrochlori Tablet	C				
			Neuquinon Tablet	C				
			Aldactone A	C				
			Amlodipine Besilate	C				

Date:12/28/99ISR Number: 3432865-4Report Type:Periodic Company Report #ZANA0319990553
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test Abnormal	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4MG DAILY PER	ORAL
			Effexor	C				
			Baclofen	C				
			Claritin-D	C				

Date:12/28/99ISR Number: 3432884-8Report Type:Periodic Company Report #ZANA0319990534
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypertension	Consumer	Zanaflex (Tizanidine					

	Hypotonia		Hydrochloride)	PS		ORAL
16MG DAILY						
	Muscle Spasms					
PER ORAL						
	Visual Disturbance		Diazepam	C		
			Baclofen	C		

Date:12/28/99ISR Number: 3432891-5Report Type:Periodic Company Report #ZANA0319990535
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Hallucination	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
PER ORAL						
			K-Dur	C		
			Indomethacin	C		
			Oxybutynin	C		
			Nitrofurantoin	C		
			Lactulose	C		
			Bumetide	C		

Date:12/28/99ISR Number: 3432895-2Report Type:Periodic Company Report #ZANA0319990537
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Liver Function Test Abnormal	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
8MG DAILY PER ORAL	4 MON					

			Celebrex	C		

Date:12/28/99ISR Number: 3432898-8Report Type:Periodic Company Report #ZANA0319990541
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Skin Ulcer	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	

Date:12/28/99ISR Number: 3432903-9Report Type:Periodic Company Report #ZANA0319990548
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	
		Distributor						

Date:12/28/99ISR Number: 3432906-4Report Type:Periodic Company Report #ZANA0319990549
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Face Oedema Sedation	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4MG PER ORAL	
			Vioxx	C				
			Oxycontin	C				
			Orthotricyclen	C				
			...	C				
			...	C				

Date:12/28/99ISR Number: 3432907-6Report Type:Periodic Company Report #ZANA0319990550
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension Sedation	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	6MG, PER ORAL	
			Requip	C				
			Norvasc	C				
			Prinivil	C				
			Microk	C				
			Furosemide	C				

Date:12/28/99ISR Number: 3432913-1Report Type:Periodic Company Report #ZANA0319990551
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypertonia Paraesthesia	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	8MG DIALY, PER ORAL	
			Neurontin	C				
			Baclofen	C				
			Dss	C				
			Flexeril	C				
			Ditropan	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/28/99ISR Number: 3432917-9Report Type:Periodic Company Report #ZANA0319990552
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	3MG PER ORAL	
	Asthenia							
	Dyspepsia		Elavil	C				
	Emotional Disorder		Klonopin	C				
	Pollakiuria		Avonex	C				
	Sedation		Prevacid	C				
	Visual Disturbance		Pepcid	C				
			Zyrtec	C				
			Synthroid	C				
			Robitussin	C				
			Vitamins	C				

Date:12/28/99ISR Number: 3432920-9Report Type:Periodic Company Report #ZANA0319990555
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperhidrosis	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2MG PER ORAL	

Date:12/28/99ISR Number: 3432924-6Report Type:Periodic Company Report #ZANA0319990557
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Paralysis	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	6MG PER ORAL	

Date:12/28/99ISR Number: 3432926-XReport Type:Periodic Company Report #ZANA0319990558
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Sedation	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
			Theophylline	C		
			Albuterol	C		

PER ORAL

Date:12/28/99ISR Number: 3432928-3Report Type:Periodic Company Report #ZANA0319990559
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Malaise	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL		

PER ORAL

Date:12/28/99ISR Number: 3432933-7Report Type:Periodic Company Report #ZANA0319990560
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Malaise	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL		

PER ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/28/99ISR Number: 3432937-4Report Type:Periodic Company Report #ZANA0319990561
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	36MG PER ORAL	

Date:12/28/99ISR Number: 3432941-6Report Type:Periodic Company Report #ZANA0319990562
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Mouth Muscle Spasms Paraesthesia	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2MG DAILY PER ORAL	

Date:12/28/99ISR Number: 3432946-5Report Type:Periodic Company Report #ZANA0319990529
Age:78 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperhidrosis Muscle Spasms Myasthenic Syndrome Sedation	Health Professional	Zanaflex (Tizanidine Hydrochloride) Methazolamide Clonidine Voltaren Prinivil Zoloft Percocet Trental Duragesic Darvocet	PS C C C C C C C C C		ORAL	12MG PER ORAL	

Date:01/19/00ISR Number: 3445416-5Report Type:Expedited (15-DaCompany Report #ZANA0319990545 (1)
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Other	Completed Suicide	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	
			Codeine	C				
			Diazepam	C				

Date:01/28/00ISR Number: 3447678-7Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Failure Congestive Dyspnoea		Zanaflex 14mg Talbets-Athena Neurosciences	PS	Athena Neurosciences	ORAL	2MG PO	
	Pulmonary Oedema						1/22-1/24;4MG	
	Respiratory Failure						PO ON 1/25	

Date:02/02/00ISR Number: 3451148-XReport Type:Direct Company Report #
Age:58 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Bradycardia Dizziness Head Injury

Syncope

		Report Source	Product	Role	Manufacturer	Route	Dose	Duration
			Zanaflex Athena	PS	Athena	ORAL	PO	
			Accolate	C				
			Luvox	C				
			Trazedone	C				
			Dicloxacillin	C				
			Diazepam	C				

Date:02/11/00ISR Number: 3456779-9Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Health Professional	Zanaflex	PS			4 MG Q 8 PRN	
	Hypotension							

Date:03/03/00ISR Number: 3469027-0Report Type:Expedited (15-DaCompany Report #ZANA030574 (0)
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Dreams	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	4 MG PER ORAL
	Cold Sweat							
	Confusional State							
	Convulsion		Ultran	C				
	Coordination Abnormal		Neurontin	C				
	Dizziness		Lovox	C				
	Eye Movement Disorder		Celebrex	C				
	Fibromyalgia							
	Hallucination, Olfactory							
	Hallucinations, Mixed							
	Nausea							
	Tinnitus							
	Vision Blurred							

Date:03/17/00ISR Number: 3477320-0Report Type:Expedited (15-DaCompany Report #ZANA030574 (1)
Age:41 YR Gender:Female I/FU:F

Outcome	PT
Other	Abnormal Dreams
	Cold Sweat
	Confusional State
	Convulsion
	Coordination Abnormal
	Dizziness
	Emotional Distress
	Eye Disorder
	Eye Movement Disorder
	Fall
	Fear Of Disease
	Hallucination, Olfactory
	Hallucinations, Mixed
	Irritability
	Multiple Sclerosis
	Nausea
	Paralysis
	Sedation
	Tinnitus

Vision Blurred

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	8MG, PER ORAL; 4 MG, PER ORAL	
			Neurontin	C				
			Luvox	C				
			Celebrex	C				
			Tricor	C				

Date:03/24/00ISR Number: 3543157-7Report Type:Periodic Company Report #WAES 00021615
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction Hallucination	Consumer	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL	25 MG/AM/PO;25 MG/DAILY/PO	
			Zanaflex Unk	SS				

Date:03/27/00ISR Number: 3479959-5Report Type:Direct Company Report #
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nausea Thrombocytopenia Vomiting	Health Professional	Tizanidine	PS			2 MG BID	
			Catapres	C				
			Lotensin	C				
			Darvocet	C				
			Prilosec	C				
			Sinemet	C				

Evista	C	
Synthroid	C	
Lanoxin	C	
Ativan	C	

Date:03/28/00ISR Number: 3480994-1Report Type:Expedited (15-DaCompany Report #ZANA030589 (0)
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Decreased	Health	Zanaflex (Tizanidine					
	Drug Interaction	Professional	Hydrochloride)	PS		ORAL	TWO 4MG DOSES	
	Dysphagia						DAILY, PER	
	Hallucination						ORAL	
	Heart Rate Increased		Vioxx (Rofecoxib)	SS			TWO 25MG	
	Psychotic Disorder						DOSES DAILY	

Date:03/28/00ISR Number: 3480995-3Report Type:Expedited (15-DaCompany Report #ZANA030590 (0)
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Health	Zanaflex (Tizanidine					
	Chest Discomfort	Professional	Hydrochloride)	PS		ORAL	4 MG DAILY,	
	Dizziness						PER ORAL	
	Hypotension		Vioxx	SS			25 MG	

			Maxalt	C			

Date:03/28/00ISR Number: 3480996-5Report Type:Expedited (15-DaCompany Report #ZANA030593 (0)
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Amnesia Conversion Disorder Drug Interaction Feeling Abnormal Hallucination	Health Professional	Zanaflex (Tizanidine Hydrochloride) Zanax Soma Oxycontin Lortab	PS SS C C C		ORAL	4 MG DAILY, PER ORAL	

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

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

			Motilium	C			
			Ephedrine	C			
			Frusemide	C			
			Glycerol	C			
			Maxolon	C			
			Morphine	C			
			Paracetamol	C			
			Potassium Chloride	C			
			Senna	C			
			Cyclizine	C			

Date:04/11/00ISR Number: 3486768-XReport Type:Expedited (15-DaCompany Report #ZANA030606(0)
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Post Procedural Complication	Foreign Health	Zanaflex (Tizanidine Hydrofchloride)	PS		ORAL	10 MG DAILY,	
	Respiratory Failure	Professional					PER ORAL	
			Baclofen	C				
			Dantrolene	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/01/00ISR Number: 3494588-5Report Type:Expedited (15-DaCompany Report #ZANA030609 (0)
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chromaturia Feeling Jittery Hepatic Cirrhosis Hepatic Necrosis Jaundice	Health Professional	Zanaflex (Tizanidine Hydrochloride) Lasix Potassium Supplement Phosphinex	PS C C C		ORAL	12 MG DAILY, PER ORAL	

Date:05/03/00ISR Number: 3495372-9Report Type:Direct Company Report #
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Abdominal Pain Lower Abdominal Pain Upper Back Pain Chills Myalgia Nausea		Zanaflex	PS		ORAL	4MG HS ORAL	

Date:05/08/00ISR Number: 3497679-8Report Type:Expedited (15-DaCompany Report #ZANA030610 (0)
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apnoea Coma Hypotension Sedation	Health Professional	Zanaflex (Tizanidine Hydrochloride) Tramadol Dipyridamole Lisinopril Diazepam	PS C C C C		ORAL	24MG, PER ORAL; 8MG, PER ORAL	

			Lansoprazole	C			
			Venlafaxine	C			
			Aspirin	C			

Date:05/24/00ISR Number: 3504562-8Report Type:Direct Company Report #
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hallucination Hypertension		Zanaflex 4mg (Athena Neuroscience)	PS	Athena Neuroscience			2TT Q 2H
	Intentional Misuse		Duragesic	C				
	Tachycardia		Neurontin	C				
	Tremor		Estrace	C				

Date:05/31/00ISR Number: 3506521-8Report Type:Expedited (15-DaCompany Report #ZANA030626(0)
Age:45 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Anorexia
	Blood Bilirubin Increased
	Hepatic Failure
	Hepatic Necrosis
	Hepatotoxicity
	Liver Function Test

		Abnormal Malaise Nausea Vomiting	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
PER ORAL							
				Thyroid Extract	C		
				Ms Contin	C		
				Dilaudid	C		
				Entex	C		
				Proventil	C		

Date:05/31/00ISR Number: 3507051-XReport Type:Expedited (15-DaCompany Report #ZANA030626(0)
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Anorexia Blood Bilirubin Increased	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
PER ORAL						
	Hepatic Failure		Thyroid Extract	C		
	Hepatic Necrosis		Ms Contin	C		
	Hepatotoxicity		Dilaudid	C		
	Liver Function Test		Entex	C		
	Abnormal		Proventil	C		
	Malaise					
	Vomiting					

Date:05/31/00ISR Number: 3507235-0Report Type:Periodic Company Report #MYST0319990051(0)
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Convulsion	Health Professional	Mysoline (Primidone)	PS	Elan Pharma International Ltd	ORAL
PER ORAL						
			Zanaflex (Tizanidine Hydrochloride)	SS		ORAL
PER ORAL						
			Tegretol	C		

Date:06/01/00ISR Number: 3566351-8Report Type:Periodic Company Report #DS/FC/00/020-ACTQ
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Gait Disturbance	Health	Actiq	PS	Anesta Corp			
	Miosis	Professional	Dilaudid (Hydromorphone)	SS		ORAL	8 MG Q 3 HRS	
			Zanaflex (Tizanidine)	SS			PO	
			Lorazepam	SS				
			Oxycontin (Oxycodone)	SS				

Date:06/08/00ISR Number: 3512446-4Report Type:Expedited (15-DaCompany Report #ZANA030629 (0)
Age:43 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Coma
	Dysphagia
	Hypothermia
	Nervous System Disorder

	Stupor						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Health Professional	Zanaflex	PS		ORAL	16 MG DAILY PER ORAL
			Amitriptyline	C			
			Diclofenac	C			
			Co-Proxamol	C			
			Dantrium	C			

Date:06/08/00ISR Number: 3512447-6Report Type:Expedited (15-DaCompany Report #ZANA030627(0)
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Hallucination Hypertension Hypochloraemia Medication Error Overdose Tachycardia Tremor Vomiting	Health Professional	Zanaflex Duragesic Neurontin	PS C C	Elan Pharma International Ltd	ORAL	30-45 TABLETS DAILY, PER ORAL

Date:06/08/00ISR Number: 3512449-XReport Type:Expedited (15-DaCompany Report #ZANA030627 (0)
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Hallucination Hypertension Hypochloraemia	Health Professional	Zanaflex Duragesic	PS C		ORAL	30-45 TABLETS DAILY PER ORAL

	Insomnia		Neurontin	C			
	Intentional Misuse						
	Tachycardia						
	Tremor						
	Vomiting						

Date:06/08/00ISR Number: 3512469-5Report Type:Expedited (15-DaCompany Report #ZANA030632 (0)
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Difficulty In Walking	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	PER ORAL
	Hypertension						
	Joint Swelling		Elavil	C			
	Pyrexia		Klonopin	C			
	Rheumatic Fever		Morphine	C			
	Rheumatoid Arthritis		Phenergan	C			
	Systemic Lupus Erythematosus		Pain Medication (Unspecified)	C			
			Anti-Hypertensive (Unspecified)	C			
			Steroid (Unspecified)	C			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/08/00ISR Number: 3512476-2Report Type:Expedited (15-DaCompany Report #ZANA030632 (0)
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthritis Difficulty In Walking	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	
	Hypertension		Elavil	C				
	Joint Swelling		Klonopin	C				
	Muscle Disorder		Morphine	C				
	Pain		Phenergan	C				
	Pyrexia		Pain Medication (Unspecified)	C				
	Rheumatic Fever							
	Rheumatoid Arthritis		Anti-Hpertensive (Unspecified)	C				
	Systemic Lupus Erythematosus							
			Steroid (Unspecified)	C				

Date:06/08/00ISR Number: 3512481-6Report Type:Expedited (15-DaCompany Report #ZANA030631 (0)
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Disorder Sedation	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	4 MG THREE TIMES DAILY,	
			Elavil	C			PER ORAL	
			Klonopin	C				
			Morphine	C				
			Phenergan	C				
			Pain Medication (Unspecified)	C				
			Anti-Hypertensive (Unspecified)	C				
			Steroid (Unspecified)	C				

Date:06/08/00ISR Number: 3512486-5Report Type:Expedited (15-DaCompany Report #ZANA030631 (0)
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypertonia Muscle Disorder Sedation	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG THREE TIMES DAILY, PER ORAL	
			Elavir	C				
			Klonopin	C				
			Morphine	C				
			Phenergan	C				
			Pain Medication (Unspecified)	C				
			Anti-Hypertensive (Unspecified)	C				
			Steroid (Unspecified)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/08/00ISR Number: 3512490-7Report Type:Expedited (15-DaCompany Report #ZANA030629 (0)
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign Health	Zanaflex	PS	Elan Pharma International Ltd	ORAL	16 MG DAILY,	
	Dysphagia	Professional					PER ORAL	
	Hypothermia		Amitriptyline	C				
			Diclofenac	C				
			Diclofenac	C				
			Co-Proxamol	C				
			Dantrium	C				

Date:06/13/00ISR Number: 3512784-5Report Type:Expedited (15-DaCompany Report #ZANA030626(1)
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia	Health	Zanaflex	PS	Elan Pharma			
	Blood Bilirubin Increased	Professional			International Ltd	ORAL	PER ORAL	
	Cholangitis		Thyroid Extract	C				
	Cholestasis		Ms Contin	C				
	Hepatic Failure		Dilaudid	C				
	Hepatic Necrosis		Entex	C				
	Hepatitis		Proventil	C				
	Liver Disorder							
	Liver Function Test Abnormal							
	Malaise							
	Nausea							
	Vomiting							

Date:06/19/00ISR Number: 3515172-0Report Type:Direct Company Report #USP 51945
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Gabitril	PS	Abbott			
			Zanaflex (Tizanidine					

			Hydrochloride)	SS	Athena Neurosciences	

Date:06/23/00ISR Number: 3518601-1Report Type:Expedited (15-DaCompany Report #ZANA030638 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Overdose	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL		

Date:06/27/00ISR Number: 3520910-7Report Type:Expedited (15-DaCompany Report #ZANA030639 (0)
Age:41 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Asthenia Dermatitis Exfoliative Diarrhoea Hypersensitivity Inflammation Lip Dry Mucosal Inflammation Photosensitivity Reaction

	Pyrexia					
	Rash Erythematous					
	Rash Maculo-Papular	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Red Blood Cell	Health	Zanaflex	PS	Elan Pharma	
	Sedimentation Rate	Professional			International Ltd	ORAL
4 MG, PER						
	Increased					
ORAL						
	Sedation		Claritin-D	C		
	Skin Chapped		Tiazac	C		
	Stevens-Johnson Syndrome		Darvocet-N 100	C		
	Sunburn		Vicodin	C		
	Urticaria		Ibuprofen	C		

Date:07/27/00ISR Number: 3536575-4Report Type:Expedited (15-DaCompany Report #ZANA030651(0)
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Hypotension	Foreign	Zanaflex	PS	Elan Pharma	
Initial or Prolonged	Syncope	Health			International Ltd	ORAL
10MG DAILY,						
		Professional				
PER ORAL						
			Baclofen	C		
			Oxybutynin	C		
			Ciprofloxacin	C		
			Imipramine	C		
			Mebeverine	C		

Date:07/27/00ISR Number: 3536576-6Report Type:Expedited (15-DaCompany Report #ZANA030651(0)
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Hypotension	Health	Zanaflex (Tizanidine			
Initial or Prolonged	Syncope	Professional	Hydrochloride)	PS		ORAL
10MG DAILY 27 DAY						
			Baclofen	C		
			Oxybutynin	C		
			Ciprofloxacin	C		
			Imipramine	C		

			Mebeverine	C			

Date:08/04/00ISR Number: 3542850-XReport Type:Expedited (15-DaCompany Report #ZANA030653 (0)
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Blood Bilirubin Increased	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	4 MG DAILY
	Hepatic Necrosis						PER ORAL
	International Normalised Ratio Increased		Celebrex	C			
	Liver Function Test Abnormal		Dexedrin	C			
	Prothrombin Time Prolonged		Climara Transdermal	C			
			Prilosec	C			

Date:08/07/00ISR Number: 3542682-2Report Type:Direct Company Report #
Age:75 YR Gender:Male I/FU:I

Outcome
Required
Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Coma		Tizanidine 4mg					
	Hypotension		Athena Neurosciences	PS	Athena Neurosciences	ORAL	2-4MG TID	
ORAL								
			Citalopram	C				
			Famotidine	C				
			Atenolol	C				
			Hydrochlorothiazide	C				
			Docusate Sodium	C				
			Acetaminophen	C				
			Quinipril	C				
			Riluzole	C				
			Heparin	C				

Date:08/14/00ISR Number: 3550484-6Report Type:Expedited (15-DaCompany Report #ZANA030656 (0)
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign	Zanaflex	PS	Elan Pharma International Ltd	ORAL	0.7	
	Hypotonia	Literature					MB/KG/DAY,	
	Medication Error	Health					PER ORAL	
	Sedation	Professional						

Date:08/21/00ISR Number: 3554562-7Report Type:Expedited (15-DaCompany Report #ZANA030664 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Foreign	Zanaflex	PS	Elan Pharma International Ltd	ORAL	4 MG-36 MG AS	
	Movement Disorder	Health					NEEDED, PO	
	Muscle Spasticity	Professional						
			Fentanyl	C				

			Propofol	C		
			Suxamethonium	C		
			Atracurium	C		
			Morphine	C		
			Glycopyrrolate	C		
			Neostigmine	C		
			Interferon Beta	C		
			Co-Dydramol	C		
			Ibuprofen	C		

Date:08/23/00ISR Number: 3556390-5Report Type:Direct Company Report #
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Abdominal Tenderness		Zanaflex 4mg (Elan Pharmaceuticals)	PS	Elan Pharmaceuticals		4MG 1/4 TAB	
	Hepatic Enzyme Increased						QID & 2TT	
	International Normalised Ratio Increased		Climara Patch	C			TABS Q HS	
	Jaundice		Dexedrine	C				
	Pleural Effusion		Celebrex	C				
	Prothrombin Time Prolonged							
	Pyrexia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/08/00ISR Number: 3568305-4Report Type:Direct Company Report #
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Palpitations	Health Professional	Zanaflex 4mg Two Tablets TWO TABLETS ONLY AT BEDTIME	PS				

Date:09/12/00ISR Number: 3570369-9Report Type:Direct Company Report #
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain Ascites Autoimmune Hepatitis Cardio-Respiratory Arrest Culture Urine Positive Escherichia Infection Jaundice Sedation Sepsis Ultrasound Scan Abnormal		Zanaflex	PS			3	WK

Date:09/15/00ISR Number: 3572038-8Report Type:Direct Company Report #
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Asthenia Bradycardia Dizziness Hypertension Hypotension		Zanaflex 4mg Prilosec Paxil Tranxene Vioxx Accupril	PS C C C C C		ORAL	4MG TID ORAL	

Date:09/22/00ISR Number: 3578767-4Report Type:Expedited (15-DaCompany Report #ZANA030653 (1)
Age:59 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	16 MG DAILY	PER ORAL
	Coagulopathy							
	Encephalopathy							
	Hepatic Necrosis		Celebrex	C				
	Hepatotoxicity		Dexedrin	C				
	Hyperbilirubinaemia		Climara Transdermal	C				
	Hypoglycaemia							
	International Normalised Ratio Decreased							
	Jaundice							
	Leukocytosis							
	Liver Function Test Abnormal							
	Pleural Effusion							
	Prothrombin Time Prolonged							
	Pyrexia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/27/00ISR Number: 3581462-9Report Type:Direct Company Report #
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Sedation		Zanaflex / 4 Mg	PS		ORAL	2MG, 4MG 2MG	Required

TID 4MGQH
Intervention to
ORAL
Prevent Permanent
Impairment/Damage

Date:09/29/00ISR Number: 3585127-9Report Type:Expedited (15-DaCompany Report #ZANA030680 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Pain	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	24 MG DAILY,	
	Condition Aggravated						PER ORAL	
	Cough							
	Headache							
	Hepatic Enzyme Increased							
	Hepatomegaly							
	Musculoskeletal Stiffness							
	Myalgia							
	Nausea							
	Nightmare							
	Pyrexia							
	Tachypnoea							
	Tenderness							

Date:10/04/00ISR Number: 3587619-5Report Type:Direct Company Report #
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hepatitis	Health	Tizanidine	PS			1/2 TABLET	

Initial or Prolonged	Hepatotoxicity	Professional				
(2MG) BID						
	Liver Function Test		Tizanidine	SS		
1 & 1/2						
	Abnormal					
TABLET (6 MG)						
	Nausea					
Q HS						
	Vomiting		Morphine	C		
			Hydromorphone	C		
			Premarin	C		
			Maxide	C		
			Zyrtec	C		
			Entex	C		
			Triamcinolone			
			Inhaler	C		
			Albuterol Inhaler	C		

Date:10/06/00ISR Number: 3590648-9Report Type:Expedited (15-DaCompany Report #ZANA030681 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Failure	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	PER ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/06/00ISR Number: 3590815-4Report Type:Expedited (15-DaCompany Report #ZANA030609 (1)
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ammonia Increased	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	12 MG DAILY,	PER ORAL
	Chromaturia							
	Diarrhoea							
	Feeling Jittery		Lasix	C				
	Hepatic Cirrhosis		Potassium Supplement	C				
	Hepatic Necrosis		Phosphinex	C				
	Jaundice							
	Liver Function Test Abnormal							
	Nausea							
	Vomiting							

Date:10/12/00ISR Number: 3595567-XReport Type:Expedited (15-DaCompany Report #ZANA030626 (2)
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	8 MG DAILY,	PER ORAL
	Blood Bilirubin Increased							
	Cholangitis							
	Cholestasis		Thyroid Extract	C				
	Coagulopathy		Ms Contin	C				
	Encephalopathy		Dilaudid	C				
	Hepatic Failure		Entex	C				
	Hepatic Necrosis		Proventil	C				
	Hepatitis		Premarin	C				
	Jaundice		Maxzide	C				
	Liver Function Test Abnormal		Zyrtec	C				
	Malaise		Triamcinolone Inhaler	C				
	Portal Hypertension							
	Vomiting							

Date:10/20/00ISR Number: 3599210-5Report Type:Expedited (15-DaCompany Report #ZANA030680(1)
Age:35 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain Upper
	Antibody Test Positive
	Chest Pain
	Chills
	Condition Aggravated
	Cough
	Cytomegalovirus Infection
	Fibromyalgia
	Gram Stain Positive
	Headache
	Hepatic Enzyme Increased
	Hepatitis
	Hepatitis Infectious
	Hepatomegaly
	Hypokalaemia
	Hypophosphataemia
	Musculoskeletal Stiffness
	Nausea
	Nightmare
	Pyrexia

		Rash Macular Rash Pruritic Tachypnoea	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Viral Infection	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
24 MG DAILY							
PER ORAL							
				Demulin	C		

Date:11/02/00ISR Number: 3607028-XReport Type:Expedited (15-DaCompany Report #ZANA030589 (1)
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Blood Pressure Decreased Drug Interaction	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
8 MG DAILY,						
	Dysphagia					
PER ORAL						
	Hallucination		Vioxx (Rofecoxib)	SS		ORAL
50 MG DAILY,						
	Heart Rate Increased					
PER ORAL						
	Psychotic Disorder Speech Disorder					

Date:11/09/00ISR Number: 3610122-0Report Type:Expedited (15-DaCompany Report #ZANA030701 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Jaundice Liver Function Test	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
12 MG DAILY						
	Abnormal					
PER ORAL 2 MON						

Date:11/13/00ISR Number: 3610726-5Report Type:Expedited (15-DaCompany Report #ZANA030702(0)
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Blood Pressure Decreased Condition Aggravated Confusional State Dysarthria Hypotension	Health Professional	Zanaflex Coumadin Lovenox Atenolol Vioxx Zoloft Quinine Sulfate Hydrochlorothiazide	PS C C C C C C C	Elan Pharma International Ltd	ORAL	4 MG DAILY, PER ORAL	

Date:11/13/00ISR Number: 3610809-XReport Type:Expedited (15-DaCompany Report #ZANA030703 (0)
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Hemiparesis Transient Ischaemic Attack Tremor	Health Professional	Zanaflex Coumadin Dilantin Baclofen Lipitor Zoloft Colace Valium	PS C C C C C C C	Elan Pharma International Ltd	ORAL	24 MG DAILY, PER ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/15/00ISR Number: 3611748-0Report Type:Direct Company Report #
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Balance Disorder		Zanaflex (2mg Tabs)	PS			3TTT A DAY	
	Confusional State						STARTED AT 1T	
	Dysarthria						PER DAY THEN	
	Memory Impairment						GRADUALLY	
							INCREASED TO	
			Vicodin Es	C				

Date:11/16/00ISR Number: 3613012-2Report Type:Expedited (15-DaCompany Report #ZANA030710(0)
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Sudden Death	Foreign Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	24 MG DAILY, PER ORAL	
			Aspirin	C				
			Co-Amilofruse	C				
			Glibenclamide	C				
			Amitriptyline	C				

Date:11/16/00ISR Number: 3613013-4Report Type:Expedited (15-DaCompany Report #ZANA030707(0)
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Cardiac Failure Congestive	Foreign Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	6 MG DAILY, PER ORAL	
	Hypertension							
	Paraplegia		Ciprofloxacin	C				

Date:11/22/00ISR Number: 3617124-9Report Type:Expedited (15-DaCompany Report #ZANA030717 (0)
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Foreign	Zanaflex	PS	Elan Pharma			
	Loss Of Consciousness	Health			International Ltd	ORAL	2 TO 4 MG	
		Professional					DAILY, PER	
							ORAL	

Date:11/22/00ISR Number: 3617809-4Report Type:Expedited (15-DaCompany Report #ZANA030663 (0)
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Health	Zanaflex	PS	Elan Pharma			
	Condition Aggravated	Professional			International Ltd	ORAL	4 MG DAILY,	
	Hypertonia						PER ORAL	
	Muscle Spasms		Ditropan	C				
			Diazepam	C				
			Lipitor	C				
			Aspirin	C				
			Prilosec	C				
			Restoril	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/11/00ISR Number: 3626570-9Report Type:Expedited (15-DaCompany Report #ZANA030701 (1)
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Jaundice	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	12 MG DAILY, PER ORAL	2 MON

Date:12/22/00ISR Number: 3636567-0Report Type:Expedited (15-DaCompany Report #ZANA000694 (0)
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypertension Oedema Peripheral	Foreign Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	24 MG DAILY ORAL	

Date:12/22/00ISR Number: 3636621-3Report Type:Expedited (15-DaCompany Report #ZANA000722 (0)
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Depressed Level Of Consciousness Hypotension	Foreign Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	4 MG DAILY ORAL	
			Methylprednisolone	C				
			Effexor	C				
			Thyroxine I 125	C				

Date:12/26/00ISR Number: 3637972-9Report Type:Expedited (15-DaCompany Report #PHNU2000DE01846
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly Other	Abortion Spontaneous Accidental Exposure Multiple Congenital Abnormalities	Foreign Health Professional Other	Voltaren Sirdalud (Sanofi Winthrop) (Ti Zanidine Hydrochloride, Tizanidine Valoron "Goedecke" (Tilidine Hydrochloride)	PS SS SS	Novartis Pharmaceuticals Corp			

Date:12/26/00ISR Number: 3637973-0Report Type:Expedited (15-DaCompany Report #PHNU2000DE01850
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly Other	Abortion Spontaneous Accidental Exposure Foetal Disorder	Foreign Health Professional Other	Voltaren Sirdalud (Sanofi Winthrop) (Ti Zanidine Hydrochloride) Valoron "Goedecke"(Tilidine Hydrochloride)	PS SS SS	Novartis Pharmaceuticals Corp			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/03/01ISR Number: 3641287-2Report Type:Expedited (15-DaCompany Report #ZANA000742 (0)
Age:85 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Arrest	Foreign Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	2 MG DAILY	ORAL
			Senna	C				
			Aspirin	C				
			Tamsulosin	C				
			Co-Danthramer	C				

Date:01/03/01ISR Number: 3641648-1Report Type:Expedited (15-DaCompany Report #001-0945-M0000196
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthralgia	Consumer	Neurontin	PS	Parke Davis Pharmaceuticals Ltd	ORAL	900 MG(300 MG	
Other	Asthenia						TID):2400MG(8	
	Blood Potassium Decreased						00MG	
	Carpal Tunnel Syndrome						TID):2100MG(7	
	Cholelithiasis						00MG	
	Cholestasis						80 MG PER	
	Decreased Activity		Baclofen	SS		ORAL	ORAL	
	Dental Caries						1600 MG	
	Depression		Ms Contin	SS			2500 MG	
	Difficulty In Walking		Propulsid	SS			1 OR 2 (Q 4 H	
	Dry Mouth		Methadone	SS			PRN)	
	Fall		Percocet	SS				
	Fatigue							

		Gallbladder Disorder	Valium	SS		
80 MG						
		Gallbladder Pain	Zanaflex	SS		ORAL
8 MG PER ORAL						
		Headache	Zoloft	SS		ORAL
200 MG PER						
		Hypoaesthesia				
ORAL						
		Hypothyroidism	Hydrochlorothiazide	SS		ORAL
100 MG PER						
		Joint Dislocation				
ORAL						
		Lethargy	Veetids	SS		ORAL
2000 MG PER						
		Liver Function Test				
ORAL	1	WK				
		Abnormal	Synthroid	SS		
		Lymphadenopathy	Oxy Ir (Oxycodone			
		Malnutrition	Hydrochloride)	SS		
8-10 DAILY						
		Movement Disorder	Lasix	SS		
80 MG						
		Nervous System Disorder	Ritalin	SS		
80 MG						
		Oedema Peripheral	K-Dur	SS		
20 MCG						
		Osteoporosis	Seroquel	SS		
		Ovarian Cyst	Ketamine	SS		
		Pain In Extremity	Klonopin	SS		
		Pruritus	Corgard	SS		
		Skin Discolouration	Relafen	SS		
		Skin Ulcer	Celebrex	SS		
800 MG						
		Tendon Disorder	Carafate	SS		
4 MG						
		Vomiting	Dextromethorphan	SS		
200 MG						
		Weight Decreased	Nadolol	SS		
		Weight Increased	Tegaderm	SS		

Date:01/11/01ISR Number: 3646580-5Report Type:Expedited (15-DaCompany Report #2001010006
Age:74 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Akathisia
	Anorexia

	Anxiety					
	Delirium					
	Movement Disorder	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Muscle Rigidity	Foreign	Doral	PS	Wallace Laboratories	
	Pain In Extremity	Health			Div Carter Wallace	
	Restlessness	Professional			Inc	ORAL
15 MG/D, PO						
	Sedation		Levodopa/Benserazide			
	Tremor		Hcl Tablets	SS		ORAL
3 TABS/D, PO						
	Urinary Incontinence		Pergolide Mesylate	SS		ORAL
SEE IMAGE						
			Tizanidine Hcl	SS		ORAL
3 MG/D, PO						
			Etizolam	SS		ORAL
PO						
			Etilefrine	C		
			Pravastatin Sodium	C		
			Azulene Sulfonate			
			Sodium/L-Glutamine	C		
			Haloperidol	C		
			Tiapride Hcl	C		

Date:01/22/01ISR Number: 3652795-2Report Type:Expedited (15-DaCompany Report #ZANA000723 (0)
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Ammonia Increased	Foreign	Zanaflex	PS	Elan Pharma	
	Blood Urea Increased	Health			International Ltd	ORAL
8 MG DAILY						
	Hypertension	Professional				
ORAL						
	Nephritis Interstitial					
	Oliguria					

Date:02/01/01ISR Number: 3659383-2Report Type:Periodic Company Report #ZANA000696 (0)
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Coagulopathy	Consumer	Zanaflex	PS	Elan Pharma	

					International Ltd	ORAL

ORAL

Verapamil	C
Triamterene/Hydrochlorothiazide	C
Propranolol	C
Esterifield Estrogens	C
Baclofen	C
Clonazepam	C
Donnatal	C
Aspirin	C

Date:02/01/01ISR Number: 3659384-4Report Type:Periodic Company Report #ZANA000698 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	2MG DAILY	

ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659385-6Report Type:Periodic Company Report #ZANA000704 (0)
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension	Health	Zanaflex	PS	Elan Pharma			
	Syncope	Professional			International Ltd	ORAL		
ORAL								
			Trazodone	C				
			Dilantin	C				
			Dulcolax	C				

Date:02/01/01ISR Number: 3659386-8Report Type:Periodic Company Report #ZANA000705 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Mouth	Consumer	Zanaflex	PS	Elan Pharma			
	Sedation				International Ltd	ORAL		
2-8 MG DAILY								
ORAL								

Date:02/01/01ISR Number: 3659387-XReport Type:Periodic Company Report #ZANA000706 (0)
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperhidrosis	Health	Zanaflex	PS	Elan Pharma			
		Professional			International Ltd	ORAL		
ORAL								

Date:02/01/01ISR Number: 3659388-1Report Type:Periodic Company Report #ZANA000709 (0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Consumer	Zanaflex	PS	Elan Pharma			
					International Ltd	ORAL		
ORAL								

Date:02/01/01ISR Number: 3659389-3Report Type:Periodic Company Report #ZANA000713 (0)
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Clonic Convulsion	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	12 MG DAILY	ORAL
			Zyrtec	C				
			Atenolol	C				
			Premarin	C				
			Fiorinal	C				
			Oxycontin	C				
			Tylenol#3	C				

Date:02/01/01ISR Number: 3659390-XReport Type:Periodic Company Report #ZANA000715 (0)
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Laboratory Test Abnormal	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	2 MG DAILY	ORAL
			Vioxx	C				
			Oxycontin	C				
			Percocet	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659391-1Report Type:Periodic Company Report #ZANA000718 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Laboratory Test Abnormal	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	12-16 MG	
		Professional					DAILY ORAL	
			Plexeril	C				

Date:02/01/01ISR Number: 3659392-3Report Type:Periodic Company Report #ZANA000719 (0)
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Laboratory Test Abnormal	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	

Date:02/01/01ISR Number: 3659393-5Report Type:Periodic Company Report #ZANA000683 (0)
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypertonia Muscle Spasms	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	2 MG DAILY	
							ORAL	

Date:02/01/01ISR Number: 3659394-7Report Type:Periodic Company Report #ZANA000684 (0)
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pain	Company Representative	Zanaflex	PS	Elan Pharma International Ltd	ORAL	2 MG DAILY	

ORAL

Date:02/01/01ISR Number: 3659395-9Report Type:Periodic Company Report #ZANA000685 (0)
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL		
ORAL								
			Premarin	C				

Date:02/01/01ISR Number: 3659396-0Report Type:Periodic Company Report #ZANA000686 (0)
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperhidrosis	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL		
	Pain						32 MG	DAILY
	Pruritus							
ORAL								
	Sedation		Paxil	C				
			Claritin-D 24 Hour	C				
			Prilosec	C				
			Celebrex	C				
			Hydroxyzine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659397-2Report Type:Periodic Company Report #ZANA000687 (0)
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Facial Palsy	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	
	Sedation	Health						
	Speech Disorder	Professional	Norvasc	C				
	Stupor		Estrogen Supplement	C				
			Aciphex	C				
			Zovirax	C				
			Vioxx	C				

Date:02/01/01ISR Number: 3659398-4Report Type:Periodic Company Report #ZANA000688 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	
	Dry Mouth							

Date:02/01/01ISR Number: 3659399-6Report Type:Periodic Company Report #ZANA000689 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiovascular Disorder	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	

Date:02/01/01ISR Number: 3659400-XReport Type:Periodic Company Report #ZANA000690(0)
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	6-12 MG DAILY	
	Anorexia							

ORAL						
			Celebrex	C		
			Diuretic	C		

Date:02/01/01ISR Number: 3659401-1Report Type:Periodic Company Report #ZANA000691 (0)
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accident	Health	Zanaflex	PS	Elan Pharma			
	Clonic Convulsion	Professional			International Ltd	ORAL	4 MG DAILY	
	Hypertonia	Distributor				ORAL		
			Luvox	SS		ORAL	200 MG DAILY	
ORAL								
			Anafranil	C				
			Ambien	C				
			Tylox	C				
			Prempro	C				
			Neurontin	C				

Date:02/01/01ISR Number: 3659402-3Report Type:Periodic Company Report #ZANA000692(0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Laboratory Test Abnormal	Health	Zanaflex	PS	Elan Pharma			
		Professional			International Ltd	ORAL		
ORAL								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659403-5Report Type:Periodic Company Report #ZANA000668 (0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	4 MG DAILY,	ORAL

Date:02/01/01ISR Number: 3659404-7Report Type:Periodic Company Report #ZANA000669 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	4 MG DILY	ORAL
			Desyrel	C				

Date:02/01/01ISR Number: 3659405-9Report Type:Periodic Company Report #ZANA000670 (0)
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accident Hallucination Hypotension	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	4 MG DAILY	ORAL
			Norvasc	C				
			Paxil	C				
			Premarin	C				

Date:02/01/01ISR Number: 3659406-0Report Type:Periodic Company Report #ZANA000672 (0)
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	

Date:02/01/01ISR Number: 3659407-2Report Type:Periodic Company Report #ZANA000673 (0)
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia Dizziness	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	6-8MG DILY	
	Nausea						ORAL	
			Oral Contraceptives	C				

Date:02/01/01ISR Number: 3659408-4Report Type:Periodic Company Report #ZANA000674 (0)
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasms Pain	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	
			Dantrium	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659409-6Report Type:Periodic Company Report #ZANA000675 (0)
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	4 MG DAILY	
	Blood Urea Increased					ORAL		
	Hyperkalaemia							

Date:02/01/01ISR Number: 3659410-2Report Type:Periodic Company Report #ZANA000676 (0)
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased		Zanaflex	PS	Elan Pharma International Ltd	ORAL	2 MG DAILY	
	Blood Urea Increased					ORAL		
	Urinary Tract Infection		Hydrocodone	C				

Date:02/01/01ISR Number: 3659411-4Report Type:Periodic Company Report #ZANA000678 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pain Paraesthesia	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	12MG DAILY	
	Sedation					ORAL		
	Tremor							

Date:02/01/01ISR Number: 3659412-6Report Type:Periodic Company Report #ZANA000682 (0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Testicular Disorder	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL

4 MG DAILY

ORAL

Date:02/01/01ISR Number: 3659413-8Report Type:Periodic Company Report #ZANA000648 (0)
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Other	Depressed Level Of Consciousness	Consumer	Zanaflex	PS	Elan Pharma International Ltd	
	Dyspnoea		Vioxx	C		
	Hallucination					
	Sedation					

4 MG DAILY

Date:02/01/01ISR Number: 3659414-XReport Type:Periodic Company Report #ZANA000650 (0)
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Other	Syncope	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
			Methadone	C		

12 MG DAILY

ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659415-1Report Type:Periodic Company Report #ZANA000655 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Mouth	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	0.5 MG DAILY	
		Professional				ORAL		

Date:02/01/01ISR Number: 3659416-3Report Type:Periodic Company Report #ZANA000657 (0)
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL		
ORAL								

Date:02/01/01ISR Number: 3659417-5Report Type:Periodic Company Report #ZANA000658 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abnormal Dreams	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL		
	Dry Mouth					ORAL		
	Sedation							

Date:02/01/01ISR Number: 3659418-7Report Type:Periodic Company Report #ZANA000659 (0)
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accident	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	4 MG DAILY	
	Muscle Spasms							
	Sedation					ORAL		
			Avonex	C				

			Tylenol Pm	C		
			Ditropan	C		
			Vitamin Supplement	C		

Date:02/01/01ISR Number: 3659419-9Report Type:Periodic Company Report #ZANA000660 (0)
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Clonic Convulsion	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	6 MG DAILY	
			Ambien	C		ORAL		
			Tylox	C				
			Luvox	C				
			Clomipramine	C				

Date:02/01/01ISR Number: 3659420-5Report Type:Periodic Company Report #ZANA000661 (0)
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hiccups	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	4 MG DAILY	
			Prednisone	C		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659421-7Report Type:Periodic Company Report #ZANA000662 (0)
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Health	Zanaflex	PS	Elan Pharma			
	Visual Field Defect	Professional			International Ltd	ORAL	2 MG	DAILY
ORAL								
			Duragesic Patch	C				
			Actiq	C				
			Ativan	C				
			Fiorinal	C				

Date:02/01/01ISR Number: 3659422-9Report Type:Periodic Company Report #ZANA000665 (0)
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Consumer	Zanaflex	PS	Elan Pharma			
					International Ltd	ORAL	16 MG	DAILY
ORAL								
			Zoloft	C				
			Oxybutynin	C				
			Contac	C				

Date:02/01/01ISR Number: 3659443-6Report Type:Periodic Company Report #ZANA000579 (0)
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Health	Zanaflex	PS	Elan Pharma			
		Professional			International Ltd	ORAL	8 MG	DAILY
ORAL								

Date:02/01/01ISR Number: 3659444-8Report Type:Periodic Company Report #ZANA000580 (0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Laboratory Test Abnormal	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	
			Baclofen	C				
			Wellbutrin	C				

Date:02/01/01ISR Number: 3659445-XReport Type:Periodic Company Report #ZANA000581 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypersensitivity	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	20 MG DAILY	
			Hyzaar	C			ORAL	
			Prilosec	C				
			Soma	C				

Date:02/01/01ISR Number: 3659446-1Report Type:Periodic Company Report #ZANA000582 (0)
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Akathisia	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	20 MG DAILY	

ORAL

			Klonopin	C		
			Neurontin	C		

Date:02/01/01ISR Number: 3659447-3Report Type:Periodic Company Report #ZANA000583 (0)
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arthralgia	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	8 MG DAILY	
	Arthritis					ORAL		

Date:02/01/01ISR Number: 3659448-5Report Type:Periodic Company Report #ZANA000584 (0)
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dysphagia	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	36 MG DAILY	
	Myasthenic Syndrome							
	Rhinitis					ORAL		
	Sinusitis		Baclofen	C				

Date:02/01/01ISR Number: 3659449-7Report Type:Periodic Company Report #ZANA000585 (0)
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	6 MG DAILY	

ORAL

Date:02/01/01ISR Number: 3659450-3Report Type:Periodic Company Report #ZANA000588 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	2 MG DAILY	
			Diovan	C			ORAL	
			Calcium	C				
			Aspirin	C				
			Acidophilus Tablets	C				
			Clonazepam	C				
			Estradiol	C				
			Pravachol	C				
			Albuterol	C				
			Azmacort	C				
			Serevent	C				
			Alpha Interferon Shots	C				
			B12 Shots	C				
			Multivitamins	C				
			Vitamin C	C				
			Vitamin E	C				
			Imodium	C				
			Compazine	C				
			Lomotil	C				

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Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659451-5Report Type:Periodic Company Report #ZANA000592 (0)
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Dreams Drug Interaction	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	4 MG DAILY	ORAL
			Vioxx	SS			50 MG DAILY	

Date:02/01/01ISR Number: 3659452-7Report Type:Periodic Company Report #ZANA000594 (0)
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia Asthenia Dry Mouth Myasthenic Syndrome	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	

Date:02/01/01ISR Number: 3659453-9Report Type:Periodic Company Report #ZANA000595(0)
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Urinary Retention	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	16 MG DAILY	
			Ms Contin	C			PRN ORAL	
			Hydromorphone	C				
			Klonopin	C				

Date:02/01/01ISR Number: 3659454-0Report Type:Periodic Company Report #ZANA000596(0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypoglycaemia	Consumer Health Professional	Zanaflex Glyburide Glucose	PS C C	Elan Pharma International Ltd	ORAL	16 MG DAILY ORAL	

Date:02/01/01ISR Number: 3659455-2Report Type:Periodic Company Report #ZANA000597(0)
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination	Consumer	Zanaflex Vioxx Neurontin	PS C C	Elan Pharma International Ltd	ORAL	12 MG DAILY ORAL	

Date:02/01/01ISR Number: 3659456-4Report Type:Periodic Company Report #ZANA000598(0)
Age:11 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia Malaise Sedation	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	

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Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659457-6Report Type:Periodic Company Report #ZANA000599(0)
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	4 MG DAILY	
	Cough							
	Dyspnoea							
	Headache							

Date:02/01/01ISR Number: 3659458-8Report Type:Periodic Company Report #ZANA000602(0)
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Twitching	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	6 MG DAILY	
			Baclofen	C				
			Prempro	C				

Date:02/01/01ISR Number: 3659459-XReport Type:Periodic Company Report #ZANA000603(0)
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	
			Avonex	C				
			Baclofen	C				
			Valium	C				

Date:02/01/01ISR Number: 3659460-6Report Type:Periodic Company Report #ZANA000605(0)
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyspnoea Hypertension Pneumonia	Health Professional	Zanaflex Alprazolam Imipramine Procyclidine	PS C C C	Elan Pharma International Ltd	ORAL ORAL	8 MG DAILY	

Date:02/01/01ISR Number: 3659461-8Report Type:Periodic Company Report #ZANA000612(0)
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tongue Oedema	Consumer	Zanaflex Soma Lodine Vitamin E	PS C C C	Elan Pharma International Ltd	ORAL ORAL		

Date:02/01/01ISR Number: 3659462-XReport Type:Periodic Company Report #ZANA000613(0)
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Health Professional	Zanaflex Premarin	PS C	Elan Pharma International Ltd	ORAL ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659487-4Report Type:Periodic Company Report #ZANA000573(0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotension	Company Representative	Zanaflex	PS	Elan Pharma International Ltd	ORAL	60 MG DAILY	ORAL
			Vioxx	SS				

Date:02/01/01ISR Number: 3659488-6Report Type:Periodic Company Report #ZANA000564(0)
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test Abnormal	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	8 MG DAILY	ORAL
			Haldol	C				
			Prevacid	C				
			Norflex	C				
			Paxil	C				
			Colace	C				
			Restoril	C				
			Dulcolax	C				
			Benadryl	C				
			Ativan	C				
			Valium	C				

Date:02/01/01ISR Number: 3659489-8Report Type:Periodic Company Report #ZANA000565 (0)
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Myasthenic Syndrome Oedema Peripheral Paraesthesia	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	12 MG DAILY	ORAL

	Weight Increased		Lotrel	C		
			Depakote	C		
			Prednisone	C		
			Zyrtec	C		
			Synthroid	C		
			Prevacid	C		
			Singulair	C		
			Clonidine	C		
			Roxanol	C		
			Pulmicort	C		
			Atrovent Metered Dose Inhaler	C		
			Atrovent Nasal Spray	C		
			Rhinocort Nasal Spray	C		

Date:02/01/01ISR Number: 3659491-6Report Type:Periodic Company Report #ZANA000567(0)
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Health	Zanaflex	PS	Elan Pharma			
	Hallucination	Professional			International Ltd	ORAL	UNKNOWN	ORAL
	Insomnia		Vioxx	SS		ORAL	25 MG DAILY	
	Nausea					ORAL		
			Neurontin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659493-XReport Type:Periodic Company Report #ZANA000571 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	

Date:02/01/01ISR Number: 3659494-1Report Type:Periodic Company Report #ZANA000572 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	8 MG DAILY	
							ORAL	

Date:02/01/01ISR Number: 3659495-3Report Type:Periodic Company Report #ZANA000575 (0)
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Laboratory Test Abnormal	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	
			Flexeril	C				

Date:02/01/01ISR Number: 3659497-7Report Type:Periodic Company Report #ZANA000576 (0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Laboratory Test Abnormal	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	
			Melatonin	C				

Date:02/01/01ISR Number: 3659498-9Report Type:Periodic Company Report #ZANA000577 (0)
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Delusion Hallucination	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	
			Mirapex	C				
			Elavil	C				
			Prilosec	C				
			Propulsid	C				

Date:02/01/01ISR Number: 3659499-0Report Type:Periodic Company Report #ZANA000578 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	2 MG DAILY	

ORAL

Date:02/01/01ISR Number: 3659530-2Report Type:Periodic Company Report #ZANA000633 (0)
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test Abnormal	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	24 MG DAILY	

ORAL

Date:02/01/01ISR Number: 3659531-4Report Type:Periodic Company Report #ZANA000636 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	
	Emotional Disorder							
	Hyperhidrosis		Clonazepam	C				
	Myalgia		Diovan	C				

Date:02/01/01ISR Number: 3659533-8Report Type:Periodic Company Report #ZANA000637 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arthralgia	Consumer	Zanaflex	PS	Elan Pharma International Ltd		6 MG DAILY	
	Muscle Spasms							
	Nausea							
	Tremor		Avonex	C			ORAL	
			Vicodin	C				
			Soma	C				

Date:02/01/01ISR Number: 3659535-1Report Type:Periodic Company Report #ZANA000640 (0)
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	12 MG DAILY	
			Nortriptyline	C			ORAL	
			Celexa	C				

Date:02/01/01ISR Number: 3659536-3Report Type:Periodic Company Report #ZANA000641 (0)
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	12 MG DAILY	
	Dizziness							
	Dry Mouth						ORAL	
	Headache							

Date:02/01/01ISR Number: 3659537-5Report Type:Periodic Company Report #ZANA000642 (0)
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Deafness	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	12 MG DAILY	
	Dizziness							
	Hallucination						ORAL	
			Baclofen	C				
			Prilosec	C				

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Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659539-9Report Type:Periodic Company Report #ZANA000643 (0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Health	Zanaflex	PS	Elan Pharma			
	Hallucination	Professional			International Ltd	ORAL	10 MG DAILY	
	Nausea						ORAL	
			Vioxx	C				

Date:02/01/01ISR Number: 3659540-5Report Type:Periodic Company Report #ZANA000644 (0)
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Urinary Retention	Health	Zanaflex	PS	Elan Pharma			
		Professional			International Ltd	ORAL	6 MG DAILY	
							LORAL	
			Methadone	C				
			Celexia	C				
			Atenolol	C				
			Prinivil	C				
			Topamax	C				
			Neurontin	C				

Date:02/01/01ISR Number: 3659542-9Report Type:Periodic Company Report #ZANA000645 (0)
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia	Health	Zanaflex	PS	Elan Pharma			
	Sedation	Professional			International Ltd	ORAL	12 MG DAILY	
							ORAL	
			Methadone	SS			30 MG Q 6H	
			Ibuprofen	C				
			Viagra	C				

			Potassium Chloride (Kcl)	C		
			Spironolactone	C		

Date:02/01/01ISR Number: 3659543-0Report Type:Periodic Company Report #ZANA000647 (0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation Sexual Dysfunction	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	2 MG DAILY	ORAL
			Pamelor	C				

Date:02/01/01ISR Number: 3659556-9Report Type:Periodic Company Report #ZANA000720 (0)
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	4 MG DAILY	ORAL
			Vioxx	C				
			Premarin	C				

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Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659557-0Report Type:Periodic Company Report #ZANA000721 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation Sexual Dysfunction	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	4 MG DAILY	ORAL
			Celexa	C				
			Buspar	C				
			Darvocet-N100	C				
			Pepcid Ac	C				
			Premarin	C				
			Progesterone	C				

Date:02/01/01ISR Number: 3659558-2Report Type:Periodic Company Report #ZANA000559 (1)
Age:17 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Malaise	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	

Date:02/01/01ISR Number: 3659559-4Report Type:Periodic Company Report #ZANA000560 (1)
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperacusis Visual Disturbance	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	

Date:02/01/01ISR Number: 3659560-0Report Type:Periodic Company Report #ZANA000615 (0)
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Myasthenic Syndrome	Consumer	Zanaflex	PS	Elan Pharma			

	Sedation				International Ltd	ORAL
2 MG DAILY						
ORAL						

Date:02/01/01ISR Number: 3659561-2Report Type:Periodic Company Report #ZANA000617 (0)
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Gait Disturbance	Health	Zanaflex	PS	Elan Pharma	
	Miosis	Professional			International Ltd	ORAL
ORAL						
			Dilaudid	SS		
			Lorazepam	SS		
			Actiq	SS		
			Oxycontin	SS		

Date:02/01/01ISR Number: 3659562-4Report Type:Periodic Company Report #ZANA000618 (0)
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Dysphagia	Consumer	Zanaflex	PS	Elan Pharma	
	Gait Disturbance				International Ltd	ORAL
8 MG DAILY						
	Sedation					
ORAL						
			Oxyconti N	C		
			Vioxx	C		
			Pamelar	C		

Prempro	C
Prevacid	C
Ritalin	C
Calcium Supplement	C
Multivitamin	C
Vitamin B Complex	C
Glucosamine	C

Date:02/01/01ISR Number: 3659563-6Report Type:Periodic Company Report #ZANA000620 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test Abnormal	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	

Date:02/01/01ISR Number: 3659564-8Report Type:Periodic Company Report #ZANA000621 (0)
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperaesthesia Vasodilatation	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	8 TABS DAILY, ORAL	

Loracet	C
Ambien	C
Elavil	C

Date:02/01/01ISR Number: 3659565-XReport Type:Periodic Company Report #ZANA000622 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test Abnormal	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	

Date:02/01/01ISR Number: 3659566-1Report Type:Periodic Company Report #ZANA000623 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	4 MG DAILY	ORAL

Date:02/01/01ISR Number: 3659567-3Report Type:Periodic Company Report #ZANA000624 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	3 MG DAILY	ORAL
	Confusional State							
	Emotional Disorder							
	Euphoric Mood		Daypro	C				
	Speech Disorder		Effexor	C				
			Xanax	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659568-5Report Type:Periodic Company Report #ZANA000625 (0)
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination	Health	Zanaflex	PS	Elan Pharma			
	Laboratory Test Abnormal	Professional			International Ltd	ORAL	2-4 MG DAILY	
ORAL								
			Baclofen	C				
			Neurontin	C				
			Celebrex	C				
			Pamelor	C				

Date:02/01/01ISR Number: 3659569-7Report Type:Periodic Company Report #ZANA000630 (0)
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Insomnia	Consumer	Zanaflex	PS	Elan Pharma			
	Myalgia				International Ltd	ORAL		
ORAL								
	Neck Pain							
	Tremor							

Date:02/05/01ISR Number: 3663227-2Report Type:Expedited (15-DaCompany Report #ZANA000724 (0)
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma	Foreign	Zanaflex	PS	Elan Pharma			
	Convulsion	Health			International Ltd	ORAL	8 MG DAILY	
	Hemiparesis	Professional						
ORAL								
	Hypotension		Etidronate Disodium	C				
	Hypoxia		Fucidin	C				
			Paracetamol	C				
			Imodium	C				
			Heparin	C				
			Lansoprazole	C				
			Methylphenidate	C				

			Baclofen	C			

Date:02/15/01ISR Number: 3666462-2Report Type:Expedited (15-DaCompany Report #ZANA000726 (0)
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Disability	Foreign Health Professional	Zanaflaex (Tizanidine Hydrochloride)	PS		ORAL	6 MG DAILY	ORAL
			Omeprazole	C				
			Lactulose	C				

Date:02/21/01ISR Number: 3669332-9Report Type:Expedited (15-DaCompany Report #ZANA000727 (0)
Age:37 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Drooling
	Drug Interaction
	Drug Withdrawal Syndrome
	Eye Disorder
	Heart Rate Increased
	Hypertension

	Hypoaesthesia Pain Paraesthesia	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Sedation Vomiting	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL 8-12 MG DAILY ORAL
			Prednisone	C		
			Sulfasalazine	C		
			Vioxx	C		
			Prilosec	C		
			Prozac	C		
			Enbrel	C		
			Betoptic	C		
			Lorcet	C		

Date:02/26/01ISR Number: 3670049-5Report Type:Direct Company Report #
Age:71 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Life-Threatening	Bradycardia		Zanaflex 8 Mg Q6h	PS		ORAL 8MG Q6H PO
	Hypotension					

Date:02/28/01ISR Number: 3672108-XReport Type:Expedited (15-DaCompany Report #ZANA000728 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Other	Hepatic Necrosis Hepatitis	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL 4 MG DAILY ORAL

Date:03/06/01ISR Number: 3674623-1Report Type:Direct Company Report #
Age:46 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Adrenal Insufficiency		Tizanidine (Zanaflex)	PS		ORAL	24 MG PO	
	Bradycardia							
	Decreased Appetite		Synthroid	C				
	Hypotension		Fosamax	C				
	Hypothermia		Depakote	C				
	Hypothyroidism		Colace	C				
	Lethargy		Tegretol	C				
			Vasotec	C				
			Oscal	C				
			Loestrin	C				
			Mvi	C				
			Senokot	C				

Date:03/14/01ISR Number: 3680753-0Report Type:Direct Company Report #
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased		Zanaflex	PS				
	Bradycardia							
	Heart Rate Decreased							
	Hypotension							

Date:03/14/01ISR Number: 3682360-2Report Type:Expedited (15-DaCompany Report #ZANA000729 (0)
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Withdrawal Convulsions	Foreign Health Professional Other	Zanaflex Analgesics (Unspecified)	PS C	Elan Pharma International Ltd	ORAL	12 MG DAILY ORAL

Date:03/15/01ISR Number: 3682206-2Report Type:Expedited (15-DaCompany Report #ZANA000730 (0)
Age:22 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged	Hyperpyrexia Tachycardia	Health Professional	Zanaflex Rocephin Erythromycin Glycopyrrolate Toradol	PS C C C C	Elan Pharma International Ltd	ORAL	2 MG ORAL

Date:03/19/01ISR Number: 3684687-7Report Type:Expedited (15-DaCompany Report #ZANA000732(0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Rhabdomyolysis	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL

Date:03/19/01ISR Number: 3684688-9Report Type:Expedited (15-DaCompany Report #ZANA000731(0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Hypotension	Company	Zanaflex	PS	Elan Pharma		

Initial or Prolonged	Shock	Representative			International Ltd	ORAL
4 MG DAILY						
ORAL						
			Antihypertensive	C		

Date:03/23/01ISR Number: 3705738-7Report Type:Periodic Company Report #WAES 01011445
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Sedation	Health	Vioxx	PS	Merck Research	
	Syncope	Professional			Laboratories Div	
					Merck Co Inc	ORAL
25 MG/BID/PO						
			Tab Zanaflex Unk	SS		
			Acetaminophen (+)			
			Hydrocodone	C		

Date:03/26/01ISR Number: 3689727-7Report Type:Expedited (15-DaCompany Report #ZANA000734 (0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Respiratory Distress	Health	Zanaflex	PS	Elan Pharma	
Hospitalization -		Professional			International Ltd	ORAL
ORAL						
Initial or Prolonged			Unspecified Narcotic	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/26/01ISR Number: 3689730-7Report Type:Expedited (15-DaCompany Report #ZANA000733 (0)
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia	Health	Zanaflex	PS	Elan Pharma			
Hospitalization -	Hypotension	Professional			International Ltd	ORAL	12 MG DAILY	
Initial or Prolonged								
ORAL								
			Luvox	C				
			Prevacid	C				
			Fioricet	C				

Date:03/30/01ISR Number: 3706283-5Report Type:Expedited (15-DaCompany Report #PHHO2000DE01410
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Aphasia	Foreign	Sandoglobulin Or					
Initial or Prolonged	Epilepsy	Study	Placebo (Placebo					
		Health	Placebo)	PS				
INTRAVENOUS	QMO,							
		Professional						
INTRAVENOUS								
		Other	Baclofen (Baclofen)	SS				
			Ds-103-282 (Tizanidine Hydrochloride)	SS				
			Orfiril (Valproate Sodium)	C				
			Neuromet (Oxiracetam)	C				

Date:04/05/01ISR Number: 3698357-2Report Type:Direct Company Report #
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Pressure Decreased		Zanaflex / 2 Mg /					
Initial or Prolonged	Dysarthria		Athena	PS	Athena	ORAL	6 MG 1 DOSE	

	Feeling Abnormal						
ORAL							
	Heart Rate Decreased		Norvasc	C			
	Tongue Oedema		Evista	C			
			Synthroid	C			
			Vioxx	C			

Date:04/05/01ISR Number: 3700145-5Report Type:Direct Company Report #
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bradycardia		Tizanidine	PS				
8 MG PO TID								
Initial or Prolonged	Hypotension							
PTA								
	Mental Impairment		Fluoxetine	C				
			Lansoprazole	C				
			Oxycodone	C				

Date:04/10/01ISR Number: 3702337-8Report Type:Expedited (15-DaCompany Report #ZANA000758 (0)
Age:65 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Alanine Aminotransferase
Initial or Prolonged	Increased
	Aspartate
	Aminotransferase

	Increased Bradycardia Dysarthria Feeling Abnormal	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Hypotension Speech Disorder Tongue Oedema	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
6 MG ORAL						
			Norvasc	C		
			Evista	C		
			Synthroid	C		

Date:04/13/01ISR Number: 3704774-4Report Type:Direct Company Report #
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Liver Disorder		Zanaflex 4mg Athena	PS	Athena	ORAL
2 MG 3 TIMES						
ORAL						
			Estrogen	C		
			Artane	C		
			Neurontin	C		
			Mvi	C		
			Calcium	C		
			Ibuprofen	C		

Date:05/10/01ISR Number: 3721431-9Report Type:Expedited (15-DaCompany Report #TCI2000A02663
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Angina Pectoris	Study	Actos	PS		ORAL
15 MG (15 MG, Initial or Prolonged 1 IN 1 D) 264 DAY	Back Pain	Health				
	Cardiomegaly	Professional	Simvastatin	SS		ORAL
5 MG						
	Chest Pain		Mecobalamin	SS		ORAL
1 TAB						
	Malaise Palpitations		Tizanidine Hydrochloride	SS		ORAL
1 TAB						

			Glibenclamide	SS		ORAL
2.5 MG						
			Basen (Voglibose)	SS		ORAL
0.6 MG						

Date:05/17/01ISR Number: 3724580-4Report Type:Direct Company Report #
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Bradycardia		Zanaflex	PS		ORAL
4 MG PO TID /						
Initial or Prolonged	Hypotension					
SINCE BACK						
	Syncope					
SURGERY						
			Prilosec	C		
			Zoloft	C		
			Baycol	C		
			Vit E	C		
			Calcium	C		
			Vioxx	C		
			Oxycotin	C		

Date:05/21/01ISR Number: 3726541-8Report Type:Expedited (15-DaCompany Report #ZANA000785 (0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Orthostatic Hypotension		Zanaflex	PS	Elan Pharma	
Initial or Prolonged	Rebound Hypertension				International Ltd	ORAL
18 MG DAILY						
	Syncope					
ORAL						

				Zestril	C		
				Lasix	C		

Date:05/23/01ISR Number: 3727129-5Report Type:Expedited (15-DaCompany Report #260011
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia		Panaldine	PS	Roche		1014 DAY	
			Ternelin	SS				
			Itrizole	SS				

Date:05/25/01ISR Number: 3729311-XReport Type:Expedited (15-DaCompany Report #260011
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia	Foreign	Ticlid	PS	Syntex (Usa) Inc Llc	ORAL	100 MG DAILY	
		Health Professional	Ternelin (Tizanidine Hydrochloride)	SS		ORAL	ORAL	
		Other	Itrizole (Itraconazole)	SS		ORAL	ORAL	

Date:06/04/01ISR Number: 3733084-4Report Type:Expedited (15-DaCompany Report #2000011288US
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthralgia	Consumer	Solu-Medrol	PS	Pharmacia And Upjohn Co	INTRAVENOUS	1 G, QD, IV	
	Dysphagia	Other						
	Haemorrhagic Stroke		Solu-Medrol Regime #2	SS		INTRAVENOUS	80 MG,QD, IV	
	Hemiparesis							
	Hypertension		Sol-Medrol Regime #3	SS		INTRAVENOUS	60 MG,QD,IV	
	Injection Site Pain		Sol-Medrol Regimen					

	Speech Disorder		#4	SS		
INTRAVENOUS 40 MG,QD,IV						
	Tendonitis		Prednisone	C		
			Cardizem	C		
			Zanaflex (Tizanidine Hydrochloride)	C		

Date:06/05/01ISR Number: 3734012-8Report Type:Expedited (15-DaCompany Report #WAES 01058223
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Asthenia	Foreign	Vioxx	PS	Merck Research Laboratories Div	
	Drug Interaction	Other				
Other	Fatigue				Merck Co Inc	ORAL
25 MG/DAILY						
	Oedema Peripheral					
PO 5 DAY						
	Sinus Bradycardia		Tab Tizanidine	SS		ORAL
4 MG/DAILY PO 5 DAY						

Date:06/08/01ISR Number: 3736257-XReport Type:Expedited (15-DaCompany Report #ZANA000794 (0)
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Bradycardia	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
	Hypotension					
8 MG DAILY						
	Liver Function Test					
ORAL						
	Abnormal		Oxycontin	C		
	Rebound Hypertension		Prilosec	C		

			Azulfidine	C		

Date:06/11/01ISR Number: 3737262-XReport Type:Periodic Company Report #2000-09-1047
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction Skin Disorder	Consumer	Claritin	PS	Schering Corp Sub Schering Plough Corp	ORAL	10 MG/QD	ORAL
			Zanaflex (Tizanidine Hcl) Tablets	SS		ORAL	4-8 MG/PRN	ORAL
			Dantrium	SS			25 MG/TID	
			Procardia	SS			10 MG/TID	
			Docusate Sodium	SS		ORAL	1/2-2 TSP/BID	ORAL
			Senokot	SS				
			Baclofen	SS			20 MG/QID	
			Milk Of Magnesia	SS			2 TBS/Q3D	
			Simethicone	SS			80-160 MG/QID	
			Entex La Tablets	SS			1/2 TAB/QID	

Date:06/12/01ISR Number: 3738765-4Report Type:Expedited (15-DaCompany Report #PHBS2001JP05015
Age:71 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Exfoliative Rash Pruritic	Foreign Health	Diovan	PS	Novartis Pharmaceuticals Corp	ORAL	40 MG/DAY,	ORAL
	Toxic Epidermal	Professional						

	Necrolysis	Other	Ternelin (Tizanidine Hydrochloride, Tizanidine Hydrochloride)	SS	ORAL
3 MG/DAY, ORAL					
			Proheparum (Cysteine, Choline Bitartrate, Liver Hydrolysate, Inositol)	SS	ORAL
3 DF/DAY,ORAL					
			Diazepam (Diazepam)	SS	ORAL
6 MG/DAY, ORAL					
			Cimetidine (Cimetidine)	SS	ORAL
600 MG/DAY, ORAL					
			Solon (Sofalcone)	C	
			Digestive Enzymes (No Ingredients/Substances)	C	
			Propacall (Ticlopidine Hydrochloride)	C	

Date:06/12/01ISR Number: 3738806-4Report Type:Expedited (15-DaCompany Report #WAES 01058223
Age:45 YR Gender:Female I/FU:F

Outcome
Hospitalization -
Initial or Prolonged

Other

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia	Foreign	Vioxx	PS	Merck Research Laboratories Div			
	Drug Interaction	Other						
	Fatigue				Merck Co Inc	ORAL	25 MG/DAILY	5 DAY
	Oedema Peripheral		Tab Tizanidine	SS		ORAL	4 MG/DAILY	5 DAY
	Sinus Bradycardia							

Date:06/18/01ISR Number: 3741501-9Report Type:Expedited (15-DaCompany Report #ZANA000795 (0)
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neuropathy Peripheral	Foreign	Zanaflex	PS	Elan Pharma International Ltd	ORAL	12 MG DAILY	
		Health Professional						
ORAL								

Date:06/20/01ISR Number: 3742324-7Report Type:Expedited (15-DaCompany Report #260011
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - 1051 DAY	Anaemia		Panaldine	PS	Roche			
Initial or Prolonged			Ternelin	SS				
			Itrizole	SS				
340 DAY								

Date:06/22/01ISR Number: 3745870-5Report Type:Expedited (15-DaCompany Report #260011
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - 100 MG DAILY	Anaemia	Foreign	Ticlid	PS	Syntex (Usa) Inc Llc	ORAL		

Initial or Prolonged		Health				
ORAL						
		Professional Other	Ternelin (Tizanidine Hydrochloride)	SS		ORAL
ORAL						
			Itrizole (Itraconazole)	SS		ORAL
200 MG DAILY						
ORAL						

Date:06/28/01ISR Number: 3749927-4Report Type:Expedited (15-DaCompany Report #ZANA000798 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Hepatitis	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
8 MG DAILY						
ORAL						

Date:07/09/01ISR Number: 3754488-XReport Type:Direct Company Report #
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Abdominal Pain Upper		Tizanidine	PS		
4 MG QID						
Initial or Prolonged	Chromaturia					
	Hepatotoxicity					
	Jaundice					
	Lethargy					
	Necrosis					

Date:07/10/01ISR Number: 3756280-9Report Type:Expedited (15-DaCompany Report #ZANA000775 (1)
Age:30 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Respiratory Distress Syndrome	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	4-28 MG DAILY	
Hospitalization - Initial or Prolonged	Bradycardia					ORAL		
	Culture Urine Positive		Baclofen	C				
	Hyperglycaemia		Ambien	C				
	Hypotension		Temazepam	C				
	Intentional Misuse							
	Pneumonia							
	Pulmonary Oedema							
	Pyrexia							
	Respiratory Arrest							
	Respiratory Depression							
	Respiratory Distress							
	Sedation							
	Sepsis							
	Staphylococcal Infection							

Date:07/10/01ISR Number: 3756281-0Report Type:Expedited (15-DaCompany Report #ZANA000788 (0)
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	16 MG DAILY	
	Bradycardia							
	Dizziness					ORAL		
	Dry Mouth		Celebrex	C				
	Fatigue		Pamelor	C				
	Headache		Darvocet-N	C				
	Heart Rate Decreased							
	Hypertension							
	Hypoaesthesia							
	Hypotension							
	Lethargy							
	Sedation							
	Skin Warm							
	Tremor							

Vision Blurred

Date:07/10/01ISR Number: 3756282-2Report Type:Expedited (15-DaCompany Report #ZANA000808 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arthralgia	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL	24 MG DAILY	
	Back Pain							
	Bronchospasm						ORAL	
	Cognitive Disorder		Duragesic	C				
	Dermatitis		Celebrex	C				
	Diplopia		Morphine	C				
	Neck Pain							
	Neuropathy Peripheral							
	Oedema							
	Urinary Incontinence							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/18/01ISR Number: 3760960-9Report Type:Expedited (15-DaCompany Report #ZANA000815 (0)
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Peripheral Ischaemia	Foreign Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	16 MG DAILY	ORAL
			Co-Proxamol	C				
			Acetylsalicylic Acid	C				
			Lactulose	C				

Date:07/20/01ISR Number: 3762665-7Report Type:Expedited (15-DaCompany Report #ZANA000818 (0)
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Autoimmune Disorder	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	ORAL	
	Condition Aggravated							
	Diabetes Mellitus		Ditropan	C				
	Hallucination		Prozac	C				
	Hypertonia		Baclofen	C				
	Pyrexia		Betaseron	C				
			Synthroid	C				
			Insulin	C				

Date:07/26/01ISR Number: 3766155-7Report Type:Expedited (15-DaCompany Report #ZANA000821 (0)
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Liver Function Test Abnormal	Foreign Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	36 MG DAILY	ORAL
	Malaise							
			Imipramine	C				
			Senna	C				
			Lactulose	C				
			Baclofen	C				

			Prednisolone	C		
			Arachis Oil	C		

Date:08/06/01ISR Number: 3772111-5Report Type:Expedited (15-DaCompany Report #ZANA000823 (0)
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	56 MG	DAILY
	Dizziness							
	Drug Dependence							
	Drug Withdrawal Syndrome		Premarin	C				
	Fall		Vicodin	C				
	Feeling Jittery		Dilaudid	C				
	Hypertension							
	Tremor							

Date:08/09/01ISR Number: 3775057-1Report Type:Expedited (15-DaCompany Report #ZANA000829 (0)
Age:16 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Pressure Decreased
	Bradycardia
	Heart Rate Decreased

Hypothermia

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
2 MG DAILY		Foreign Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
ORAL			Clonazepam	C		
			Epilim	C		
			Baclofen	C		

Date:08/13/01ISR Number: 3777130-0Report Type:Expedited (15-DaCompany Report #PHBS2001JP05015
Age:71 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening Hospitalization -	Toxic Epidermal Necrolysis	Foreign Health Professional	Diovan	PS	Novartis Pharmaceuticals Corp	ORAL
40 MG/DAY, Initial or Prolonged						
ORAL						
			Proheparum (Cysteine, Choline Bitartrate, Liver Hydrolysate, Inositol)	SS		ORAL
3 DF/DAY,						
ORAL						
			Diazepam (Diazepam)	SS		ORAL
6 MG/DAY,						
ORAL						
			Cimetidine (Cimetidine)	SS		ORAL
600 MG/DAY,						
ORAL						
			Solon (Sofalcon)	SS		
			Digestive Enzymes (No Ingredients/Substanc			

			es)	SS		ORAL	3 DOSAGES/DAY, ORAL
			Harnal (Tamsulosin Hydrochloride)	SS		ORAL	0.2 MG/DAY, ORAL
			Eviprostat	SS		ORAL	6 DOSAGES/DAY,ORAL
			Ternelin (Tizanidine Hydrochloride, Tizanidine Hydrochloride)	SS		ORAL	3 MG/DAY, ORAL
			Propacall (Ticlopidine Hydrochloride)	C			

Date:08/15/01ISR Number: 3778252-0Report Type:Expedited (15-DaCompany Report #ZANA000828 (0)
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Convulsion	Foreign Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL	12 MG DAILY ORAL
			Prolopa	C			
			Selegiline	C			

			Levothyroxine	C		

Date:08/16/01ISR Number: 3779082-6Report Type:Expedited (15-DaCompany Report #ZANA000830 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Difficulty In Walking	Consumer	Zanaflex	PS	Elan Pharmaceuticals	ORAL	24 MG DAILY
	Hypotonia						ORAL

Date:08/17/01ISR Number: 3778997-2Report Type:Direct Company Report #
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Muscle Spasms		Zanaflex 2mg	PS			2MG 1 QHS

Date:08/17/01ISR Number: 3781222-XReport Type:Expedited (15-DaCompany Report #PHBS2001JP05015
Age:71 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Toxic Epidermal	Foreign	Diovan	PS	Novartis		
Hospitalization -	Necrolysis	Health			Pharmaceuticals Corp	ORAL	40 MG/DAY,
Initial or Prolonged		Professional					ORAL
		Other	Proheparum(Cysteine, Choline Bitartrate, Liver Hydrolysate, Inositol)	SS		ORAL	3 DF/DAY,ORAL
			Diazepam (Diazepam)	SS		ORAL	6 MG/DAY,
							ORAL
			Cimetidine				

	(Cimetidine)	SS	ORAL
600 MG/DAY,			
ORAL			
	Solon(Sofalcone)	SS	
	Digestive Enzymes(No Ingredients/Substances)	SS	ORAL
3			
DOSAGES/DAY,			
ORAL			
	Eviprostat(Chimaphila Umbellata, Populus Tremuloides, Sodium Taurocholate, Pulsatilla	SS	ORAL
6			
DOSAGES/DAY,			
ORAL			
	Ternelin(Tizanidine Hydrochloride, Tizanidine Hydrocholoride)	SS	ORAL
3 MG/DAY,			
ORAL			
	Harnal (Tamsulosin Hydrochloride)	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/21/01ISR Number: 3780457-XReport Type:Direct Company Report #
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Decreased		Zanaflex 4 Mg					
	Dizziness		(Sandoz)	PS	Sandoz	ORAL	2 MG PO.	4 MG
	Fatigue						PO	8 HRS
	Heart Rate Decreased						LATER	
	Respiratory Rate		Cardiozem	C				
	Decreased		Vasotec	C				
	Sedation		Hydrodiuril	C				

Date:08/22/01ISR Number: 3781638-1Report Type:Direct Company Report #
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dysphagia		Zanaflex 4 Mg	PS			1 TAB TAKEN	
	Sedation						AT BEDTIME	
			Estrace	C				

Date:08/22/01ISR Number: 3781932-4Report Type:Direct Company Report #
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hepatitis		Zanaflex	PS		ORAL	4 MG DAILY PO	
Initial or Prolonged			Glucophage	C				
			Glucotrol Xl	C				
			Neurontin	C				
			Cipro	C				

Date:08/31/01ISR Number: 3786636-XReport Type:Direct Company Report #
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Liver Function Test		Zanaflex 4 Mg	PS		ORAL	4 MG PO Q 8H	
	Abnormal						PRN	
			Nitroglycerin O	C				
			Premarin	C				
			Lopressor	C				
			Endocet	C				
			Aciphex	C				
			Baclofen	C				
			Paxil	C				
			Levothroid	C				
			Lorazepam	C				
			Methadone Hcl	C				

Date:09/12/01ISR Number: 3792306-4Report Type:Expedited (15-DaCompany Report #ZANA000835 (0)
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Other	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	ORAL	
	Delirium							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/17/01ISR Number: 3794327-4Report Type:Expedited (15-DaCompany Report #ZANA000834 (0)
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Hyperhidrosis	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY	
Other	Hypotension					ORAL		
	Pallor		Sporanox	C				
	Syncope		Protonix	C				
			Estratest	C				
			Vioxx	C				
			Synthroid	C				
			Ditropan	C				

Date:09/18/01ISR Number: 3795227-6Report Type:Expedited (15-DaCompany Report #ZANA000841 (0)
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	24 MG DAILY	
	Bradycardia					ORAL		
	Drug Withdrawal Syndrome		Novantrone	C				
	Nausea		Baclofen	C				
	Orthostatic Hypotension							
	Rebound Hypertension							
	Sedation							
	Tremor							
	Vomiting							

Date:09/21/01ISR Number: 3797301-7Report Type:Expedited (15-DaCompany Report #ZANA000843 (0)
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization -	Blood Pressure Systolic Increased	Literature Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL		
ORAL								

Initial or Prolonged	Clonic Convulsion	Professional	Selegiline	C			
	Loss Of Consciousness		Ropinirole	C			
	Pyrexia		Bromocriptine	C			
	Sinus Tachycardia		Tolcapone	C			
	Vomiting		Levodopa	C			
			Sinemet	C			
			Amitriptyline	C			
			Lorazepam	C			
			Clonazepam	C			
			Hydrochlorothiazide	C			
			Potassium Chloride	C			
			St. John'S Wort	C			

Date:10/05/01ISR Number: 3806714-6Report Type:Expedited (15-DaCompany Report #ZANA000851(0)
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrial Fibrillation Hypertension	Consumer	Zanaflex	PS		ORAL	8 MG DAILY	ORAL
Other	Speech Disorder Transient Ischaemic Attack		Synthroid	C				
			Glucophage	C				
			Estradiol	C				
			Propoxyphene	C				
			Zestril	C				

			Atenolol	C		

Date:10/12/01ISR Number: 3808762-9Report Type:Expedited (15-DaCompany Report #01P-151-0111184-00
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Interaction Hypotension Sedation	Foreign Health Professional Other	Depakine (Depakene) (Sodium Valproate/ Valproic Acid) (Sodium	PS		ORAL	500 MG, 1 I 1 D, PER ORAL
			Tizanidine Hydrochloride Paracetamil	SS		ORAL	2 MG, 1 IN 1 D, PER ORAL
			Paracetamol	C			

Date:10/12/01ISR Number: 3810672-8Report Type:Expedited (15-DaCompany Report #001-0945-M0101183
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Amnesia Blood Pressure Increased	Consumer	Neurontin (Gabapentin)	PS		ORAL	300 MG PER Other ORAL
	Dry Mouth Dysarthria Dysuria Fatigue Miosis Nausea		Vioxx (Rofecoxib) Zanaflex (Tizanidine)	SS SS			

Date:10/17/01ISR Number: 3810595-4Report Type:Expedited (15-DaCompany Report #ZANA000856 (0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Fall	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY	
	Hypotension							
	Rib Fracture							
			Antihypertensive Medication	C				

Date:10/17/01ISR Number: 3810616-9Report Type:Expedited (15-DaCompany Report #ZANA000862 (0)
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Stevens-Johnson Syndrome	Health Professional	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL	ORAL	
		Distributor	Ponstan (Mefenamic Acid)	SS		ORAL	1000 MG DAILY	
							ORAL	
			Atorvastatin	C				
			Pradif	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/17/01ISR Number: 3810617-0Report Type:Expedited (15-DaCompany Report #ZANA000853 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Drug Dependence	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	17 TABS DAILY
	Hypertension						
	Hypotension						
ORAL							

Date:10/17/01ISR Number: 3810857-0Report Type:Expedited (15-DaCompany Report #ZANA000857 (0)
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY
	Fatigue	Health Professional					
Other	Oedema Peripheral						
ORAL							
	Sinus Bradycardia	Distributor	Vioxx (Rofecoxib)	SS		ORAL	25 MG DAILY
ORAL							

Date:10/17/01ISR Number: 3810990-3Report Type:Expedited (15-DaCompany Report #2001076005CH
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Complications Of Maternal Exposure To Therapeutic Drugs	Foreign Other	Celebrex(Celecoxib)Capsule	PS		ORAL	200 MG, TID,
ORAL							
			Doxycycline (Doxycycline)	SS			100 MG, QD
			Sirdalud(Tizanidine Hydrochloride)	SS			4 MG, BID

			Noroxin(Norfloxacin)	SS		
400 MG, BID						
			Valium (Diazepam)	SS		
SUBCUTANEOUS	1 INJ,					
SUBCUTANEOUS						
			Morphine	C		
			Tramadol	C		
			Paracetamol	C		
			Tetrazepam	C		

Date:10/18/01ISR Number: 3811501-9Report Type:Expedited (15-DaCompany Report #WAES 00050132
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Blood Pressure Decreased	Health	Tab Vioxx	PS		ORAL
PO						
	Drug Interaction	Professional	Zanaflex	SS		
	Dysphagia	Other				
	Hallucination					
	Psychotic Disorder					
	Tachycardia					

Date:10/18/01ISR Number: 3811551-2Report Type:Expedited (15-DaCompany Report #WAES 00050131
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Bradycardia	Health	Tab Vioxx	PS		ORAL
PO						
	Chest Pain	Professional	Zanaflex	SS		
	Dizziness	Other	Maxalt (Rizatriptan			
	Drug Interaction		Benzoate	C		
	Hypotension					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/22/01ISR Number: 3812487-3Report Type:Expedited (15-DaCompany Report #ZANA000865 (0)
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Joint Dislocation	Foreign Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	12 MG DAILY ORAL
			Naudicelle	C			
			Desmopressin	C			

Date:10/24/01ISR Number: 3814605-XReport Type:Expedited (15-DaCompany Report #ZANA000861 (0)
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Abdominal Pain Diarrhoea	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY ORAL
	Feeling Hot And Cold						
	Gastrointestinal Disorder		Pamelor	C			
	Nightmare		Neurontin	C			
	Sleep Talking		Maxalt	C			
			Esgic	C			
			Lozol	C			
			Prilosec	C			
			Loestrin Fe 1.5/30	C			

Date:10/31/01ISR Number: 3820271-XReport Type:Periodic Company Report #2001073793US
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Complications Of Maternal Exposure To Therapeutic Drugs	Consumer	Celebrex	PS		ORAL	200 MG, QD, ORAL
			Neurontin(Gabapentin)	SS		ORAL	750 MG, BID,

ORAL

	Elavil (Amitriptyline Hydrochloride)	SS
	Zanaflex (Tizanidine Hydrochloride)	SS
	Oral Contraceptive Nos (Oral Contraceptive Nos)	SS

Date:11/02/01ISR Number: 3819704-4Report Type:Expedited (15-DaCompany Report #2001AP05083
Age:10 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Crying
	Depressed Level Of Consciousness
	Drug Interaction
	Electrocardiogram Abnormal
	Encephalopathy
	Heart Rate Increased
	Hypertension
	Hypotension
	Joint Stiffness
	Pallor

Sedation

			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Literature	Lisinopril	PS		
10	MON						
			Health	Lisinopril	SS		
			Professional	Tizanidine	SS		
1	WK						
				Valium	C		
				Clonazepam	C		
				Valproic Acid	C		

Date:11/05/01ISR Number: 3821962-7Report Type:Expedited (15-DaCompany Report #ZANA000870 (0)
Age:78 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Cerebrovascular Accident	Foreign	Zanaflex (Tizanidine			
			Health	Hydrochloride)	PS		ORAL
24 MG DAILY							
			Professional				
ORAL							
				Aspirin	C		
				Co-Amilofruse	C		
				Glibenclamide	C		

Date:11/09/01ISR Number: 3823151-9Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Erectile Dysfunction		Zanaflex	PS		
				Prevacid	C		

Date:11/13/01ISR Number: 3824881-5Report Type:Expedited (15-DaCompany Report #ZANA000875 (0)
Age:66 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Disability		Condition Aggravated	Consumer	Zanaflex (Tizanidine			

Other	Difficulty In Walking		Hydrochloride)	PS		ORAL
4 MG DAILY						
	Dyspnoea					
ORAL						
	Muscle Spasms		Toprol Xl	C		
	Pain		Babypyrin	C		
			Lipitor	C		

Date:11/29/01ISR Number: 3832724-9Report Type:Expedited (15-DaCompany Report #001-0945-M0101183
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Amnesia	Consumer	Neurontin			
Initial or Prolonged	Blood Pressure Increased	Health	(Gabapentin)	PS		ORAL
600 MG (BID),						
Disability	Depressed Level Of	Professional				
PER ORAL						
Other	Consciousness		Vioxx (Rofecoxib)	SS		
	Dry Mouth		Zanaflex			
	Dysarthria		(Tizanidine)	SS		
	Dysuria					
	Fatigue					
	Gait Disturbance					
	Lethargy					
	Miosis					
	Nausea					
	Sedation					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/12/01ISR Number: 3839471-8Report Type:Expedited (15-DaCompany Report #ZANA000880 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Flushing Headache Migraine Rebound Hypertension Tremor	Consumer	Zanaflex (Tizanidine Hydrochloride) Theophylline Xr (Theophylline) Albuterol (Salbutamol) Celebrex "Steroid Spinal Injections"	PS SS SS C C		ORAL	2 MG DAILY ORAL	

Date:12/13/01ISR Number: 3840412-8Report Type:Expedited (15-DaCompany Report #200111032BNE
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia Hypotension Hypotonia	Foreign Health Professional Other	Ciprofloxacin Tizanidine	PS SS			500 MG DAILY	

Date:12/17/01ISR Number: 3840878-3Report Type:Expedited (15-DaCompany Report #ZANA000885 (0)
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electrocardiogram Qt Prolonged Syncope	Foreign Health Professional	Zanaflex (Tizanidine Hydrochloride) Prozac Vioxx Neurontin	PS C C C		ORAL	4 MG DAILY ORAL	

Date:12/20/01ISR Number: 3843372-9Report Type:Expedited (15-DaCompany Report #HQ9319810DEC2001
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability Other	Bradycardia Coma Hypotension	Foreign Health Professional Other	Cordarone (Amiodarone, Tablet) Sirdalud (Tizanidine Hydrochloride,)	PS SS		ORAL	8 MG 1 X PER 1 DAY	1 DAY
			Tramal-Slow Release (Tramadol Hydrochloride)	SS		ORAL		

Date:12/24/01ISR Number: 3844568-2Report Type:Expedited (15-DaCompany Report #ZANA000891(0)
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Confusional State Disturbance In Attention Fatigue Hallucination, Visual	Foreign Health Professional	Zanaflex (Tizanidne Hydrochloride)	PS		ORAL	16 MG DAILY ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/26/01ISR Number: 3844975-8Report Type:Expedited (15-DaCompany Report #ZANA000892 (1)
Age:46 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Acute Respiratory Failure	Health	Zanaflex (Tizanidine				
Hospitalization -	Hepatic Failure	Professional	Hydrochloride)	PS		ORAL	ORAL
Initial or Prolonged	Loss Of Consciousness		Lipitor				
	Renal Failure Acute		(Atorvastatin)	SS		ORAL	ORAL
	Respiratory Failure		Atenolol	C			
	Rhabdomyolysis		Toradol	C			
			Lidoderm Patch	C			

Date:12/26/01ISR Number: 3845205-3Report Type:Expedited (15-DaCompany Report #ZANA000892 (0)
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Acute Respiratory Failure	Health	Zanaflex (Tizanidine				
Hospitalization -	Coma	Professional	Hydrochloride)	PS		ORAL	ORAL
Initial or Prolonged	Hepatic Failure		Lipitor				
	Loss Of Consciousness		(Atorvastatin)	SS		ORAL	ORAL
	Renal Failure Acute		Atenolol	C			
	Respiratory Failure		Toradol	C			
	Rhabdomyolysis		Lidoderm Patch	C			

Date:12/26/01ISR Number: 3845216-8Report Type:Expedited (15-DaCompany Report #001-0945-M0101183
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Amnesia	Consumer	Neurontin				
Initial or Prolonged	Blood Pressure Increased	Health	(Gabapentin)	PS		ORAL	300 MG
Disability	Confusional State	Professional					(ONCE), PER
Other	Difficulty In Walking						ORAL

	Dysarthria		Vioxx (Rofecoxib)	SS		ORAL
50 MG (ONCE),						
	Dysuria					
PER ORAL						
	Fatigue		Zanaflex			
	Gait Disturbance		(Tizanidine)	SS		ORAL
2 MG (ONCE),						
	Hemiparesis					
PER ORAL						
	Lethargy		(Clopidogrel)	C		
	Loss Of Consciousness					
	Memory Impairment					
	Mental Status Changes					
	Miosis					
	Nausea					
	Photophobia					
	Somnolence					
	Speech Disorder					

Date:12/27/01ISR Number: 3864582-0Report Type:Periodic Company Report #WAES 01112908
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Asthenia	Health	Tab Vioxx	PS		ORAL
25 MG/ PO						
	Drug Interaction	Professional	Ultram	SS		
	Fatigue	Company	Zanaflex	SS		
		Representative	Neurontin	SS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/28/01ISR Number: 3845935-3Report Type:Direct Company Report #CTU 157992
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Nystagmus		Tizanidine(2 Mg)					
Required	Vertigo		(Athena					
Intervention to			Neurosciences Inc)	PS	Athena Neurosciences	ORAL	2 MG QHS ORAL	
Prevent Permanent			Amitriptyline	C				
Impairment/Damage			Sertraline	C				
			Gabapentin	C				
			Methadone	C				

Date:12/31/01ISR Number: 3846940-3Report Type:Expedited (15-DaCompany Report #EMADSS2001007513
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Accidental Overdose	Foreign	Tramadol					
Initial or Prolonged	Bradycardia	Health	Hydrochloride	PS		ORAL	100 MG, 3 IN	
	Coma	Professional					1 DAY(S),	
	Drug Interaction						ORAL	
	Hypotension		Sirdalud (Tizanidine					
	Spinal Fracture		Hydrochloride)	SS			16-OCT-2001	
HE WAS FIRST								
GIVEN								
			Cordarone					
			(Amiodarone					
			Hydrochloride)	SS		ORAL	ORAL	

Date:01/07/02ISR Number: 3849534-9Report Type:Expedited (15-DaCompany Report #200111032BNE
Age:38 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia	Foreign	Ciprofloxacin	PS		ORAL	500 MG BID	
Other	Bradycardia	Health				ORAL		
	Drug Interaction	Professional	Tizanidine	SS		ORAL	6 MG QID	ORAL 4 YR
	Potentiation	Other	Oxybutynin	C				
	Hypotension		Mitozantrone	C				
	Hypotonia							
	Muscular Weakness							

Date:01/08/02ISR Number: 3849864-0Report Type:Expedited (15-DaCompany Report #PHBS2001JP11095
Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased	Foreign Health Professional	Lamisil (Terbinafine Hydrochloride) Tablet	PS		ORAL	125 MG/D,	ORAL
	Blood Creatine Phosphokinase Increased	Other	Lornoxicam(Lornoxicam)	SS		ORAL	4 MG/D,	ORAL 10 DAY
Disability	Blood Lactate Dehydrogenase Increased		Ternelin (Tizanidine Hydrochloride, Tizanidine Hydrochloride)	SS		ORAL	1 MG/D,	ORAL 10 DAY
	Malaise		Mucosta (Rebamipide)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/09/02ISR Number: 3850482-9Report Type:Direct Company Report #CTU 158728
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hypotension		Zanaflex (4mg)	PS			4MG 2 TAB PO	Initial or Prolonged
								TID
			Celebrex	C				
			Naproxen	C				
			Prilosec	C				
			Orphenadrine	C				
			Synthroid	C				
			Triam/Hctz	C				
			Atenolol	C				
			Lotrel	C				

Date:01/09/02ISR Number: 3851034-7Report Type:Expedited (15-DaCompany Report #ZANA000873 (0)
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Foreign Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	24 MG DAILY	
	Aspartate Aminotransferase Increased						ORAL	
	Blood Bilirubin Increased		Oxybutynin	C				
	Blood Lactate Dehydrogenase Increased							
	Decreased Appetite							
	Gamma-Glutamyltransferase Increased							
	Jaundice							
	Liver Function Test Abnormal							
	Nausea							
	Prothrombin Time Prolonged							

Date:01/14/02ISR Number: 3852910-1Report Type:Expedited (15-DaCompany Report #A200378
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bradycardia	Foreign	Feldene Capsules	PS			INTRAMUSCULAR	40.00 MG
Initial or Prolonged	Confusional State	Health					TOTAL:DAILY:I	
	Drug Interaction	Professional					NTRAMUSCULAR	
	Dysarthria		Tizanidin	SS			12.00 MG	
	Dysphagia						TOTAL:DAILY	
	Hallucination		Seropram	C				
	Hypertension		Neurontin	C				
	Hypotension		Voltaren	C				
	Hypovolaemia		Vioxx	C				

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

Outcome	PT
Hospitalization -	Bradycardia
Initial or Prolonged	Drug Interaction
	Hypotension
	Hypotonia

Malaise

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional	Ciflox (Ciprofloxacin)	PS		ORAL	1000 MG DAILY	
Other				ORAL		
	Sirdalud (Tizanidine Hydrochloride)	SS		ORAL	SEE IMAGE	
	Lioresal (Baclofen)	SS		ORAL	SEE IMAGE	
	Myolastan (Tetrazepam)	SS		ORAL	75 MG DAILY	
				ORAL		
	Voltarene	C				
	Zyloric	C				
	Verospiron	C				
	Pantozol	C				
	L!Snesium	C				
	Melperon	C				
	Zocor	C				

Date:01/17/02ISR Number: 3854822-6Report Type:Expedited (15-DaCompany Report #ZANA000896 (0)
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia	Foreign	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	24 MG DAILY	
	Drug Effect Increased	Health Professional				ORAL		
	Drug Interaction							
	Hypotension		Ciproxin (Ciprofloxacin)	SS		ORAL	1,000 MG DAILY	
	Muscular Weakness					ORAL		
			Oxybutynin	C				
			Mitoxantrone	C				

Date:01/17/02ISR Number: 3855884-2Report Type:Expedited (15-DaCompany Report #ZANA000897 (0)
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hypotension Sepsis	Foreign Health Professional	Zanaflex (Tizanidine Hydrochloride) Enoxaparin Sodium Frusemide Atenolol	PS C C C		ORAL 	6 MG DAILY ORAL	

Date:01/25/02ISR Number: 3860390-5Report Type:Expedited (15-DaCompany Report #PHRM2002FR00519
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradypnoea Drug Interaction Hypotension Hypotonia Malaise Skin Infection	Foreign Health Professional Other	Lioresal(Baclofen)Tablet Sirdalud(Tizanidine Hydrochloride) Myolastan(Tetrazepam) Ciflox(Ciprofloxacin	PS SS SS 		ORAL ORAL ORAL 	30 MG DAILY, ORAL 12 MG DAILY, ORAL 75 MG PER DAY, ORAL	

			)Tablet	SS			
1 G DAILY							
			Voltarene Lp (Diclofenac Sodium)	C			

Date:01/30/02ISR Number: 3862222-8Report Type:Expedited (15-DaCompany Report #A200378
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Foreign Health Professional	Feldene Capsules	PS		INTRAVENOUS	40.00 MG TOTAL; DAILY; INTRAVENOUS	
	Confusional State							
	Drug Abuser							
	Drug Interaction		Gabapentin	SS		ORAL	2200.00 MG TOTAL; ORAL	
	Drug Level Increased							
	Dysarthria		Tizanidine	SS		ORAL	12.00 MG TOTAL; ORAL	
	Dysphagia							
	Hallucination		Seropram	C				
	Hypertension		Voltaren	C				
	Hypotension		Vioxx	C				
	Hypovolaemia							

Date:02/04/02ISR Number: 3865091-5Report Type:Expedited (15-DaCompany Report #ZANA000901 (0)
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hyperpyrexia	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	18 MG DAILY ORAL	
			Neurontin	C				
			Oxycontin	C				

Date:02/06/02ISR Number: 3865672-9Report Type:Expedited (15-DaCompany Report #ZANA000902 (0)
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dysphemia	Health Professional	Zanaflex (Tizandine Hydrochloride)	PS		ORAL	6 MG	ORAL
			Vioxx	C				

Date:02/07/02ISR Number: 3867637-XReport Type:Expedited (15-DaCompany Report #PHBS2001JP11095
Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Aspartate Aminotransferase Increased	Foreign Health Professional	Lamisil (Terbinafine Hydrochloride) Tablet	PS		ORAL	125 MG/D,	ORAL
	Blood Creatine Phosphokinase Increased	Other						
	Blood Lactate Dehydrogenase Increased		Lornoxicam (Lornoxicam)	SS		ORAL	4 MG/D,	ORAL 10 DAY
	Malaise		Ternelin (Tizanidine Hydrochloride, Tizanidine Hydrochloride)					
			Unknown	SS		ORAL	1 MG/D,	ORAL 10 DAY
			Mucosta (Rebamipide)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/08/02ISR Number: 3866916-XReport Type:Direct Company Report #CTU 161325
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bladder Pain		Zanaflex 4 Mg	PS		ORAL	4 MG	3X A
Required	Blood Cholesterol						DAY	ORAL
Intervention to Prevent Permanent Impairment/Damage	Increased Blood Triglycerides							
	Increased Dysuria							
	Hepatomegaly							

Date:02/08/02ISR Number: 3867329-7Report Type:Expedited (15-DaCompany Report #PHRM2002FR00519
Age:24 YR Gender:Male I/FU:F

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

Date:02/08/02ISR Number: 3868545-0Report Type:Expedited (15-DaCompany Report #ZANA000910 (0)
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypersensitivity	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	8-16 MG DAILY	
			Vicodin	C		ORAL		
			Keflex	C				
			Ortho-Novum	C				
			Diazepam	C				
			Percocet	C				
			Ibuprofen	C				

Date:02/11/02ISR Number: 3868898-3Report Type:Expedited (15-DaCompany Report #ZANA000908 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Withdrawal Syndrome	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	ORAL	
	Overdose							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/20/02ISR Number: 3873847-8Report Type:Expedited (15-DaCompany Report #041-0945-M0200003
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Bradycardia Confusional State Drug Abuser Drug Interaction Drug Level Above Therapeutic Dysarthria Dysphagia Hallucination Hypertension Hypotension Hypovolaemia	Foreign Health Professional	Neurontin (Gabapentin) (Piroxicam) (Tizanidine Hydrochloride) (Citalopram Hydrobromide) (Diclofenac Sodium) (Rofecoxib)	PS SS SS SS C C		ORAL INTRAMUSCULAR ORAL ORAL PER ORAL	2200 MG (DAILY), PER ORAL 40 MG , INTRAMUSCULAR 12 MG, PER ORAL

Date:02/21/02ISR Number: 3872735-0Report Type:Direct Company Report #CTU 162008
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Dizziness Electrocardiogram Qt Prolonged		Zanaflex (4mg)	PS		ORAL	4MG PO QID

Date:02/22/02ISR Number: 3875053-XReport Type:Expedited (15-DaCompany Report #ZANA000914 (0)
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Ammonia Increased	Health	Zanaflex (Tizanidine				

Hospitalization - 4 - 6 MG Initial or Prolonged DAILY ORAL	Hallucination, Visual Hepatitis Hyperglycaemia	Professional	Hydrochloride) Ascriptin Norvasc Lopressor	PS C C C		ORAL

Date:02/28/02ISR Number: 3877971-5Report Type:Expedited (15-DaCompany Report #200211271BWH
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Fatigue Speech Disorder	Consumer Other	Cipro (Ciprofloxacin Hydrochloride)	PS		ORAL	500 MG BID; ORAL	
			Zanaflex (Tizanidine Hydrochloride)	SS		ORAL	4 MG DAILY; ORAL	
			Fibercon Vit C Multivitamin Mevacor Tylenol	C C C C C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/28/02ISR Number: 3889406-7Report Type:Periodic Company Report #001-0945-M0100756
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Consumer	Neurontin					
	Asthenia	Health	(Gabapentin)	PS			900 MG TID	
	Burning Sensation	Professional	Tizanidine					
	Drug Ineffective		Hydrochloride	SS				
	Heart Rate Decreased		Voixx (Rofecoxib)	C				
	Hypoaesthesia							
	Hypotension							
	Insomnia							
	Paraesthesia							
	Pruritus							
	Tremor							

Date:03/01/02ISR Number: 3877598-5Report Type:Expedited (15-DaCompany Report #A200378
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bradycardia	Foreign	Feldene Capsules	PS			INTRAMUSCULAR 40.00 MG	
Initial or Prolonged	Confusional State	Health					TOTAL:DAILY:I	
	Drug Interaction	Professional					NTRAMUSCULAR	
	Drug Level Above		Gabapentin	SS		ORAL	2200.00 MG	
	Therapeutic						TOTAL:ORAL	
	Dysarthria		Tizanidine	SS		ORAL	12.00 MG	
	Dysphagia						TOTAL:ORAL	
	Hallucination		Citalopram	SS			20.00 MG	
	Hypertension						TOTAL	
	Hypotension		Voltaren	C				
	Hypovolaemia		Vioxx	C				
	Medication Error							

Date:03/05/02ISR Number: 3877686-3Report Type:Expedited (15-DaCompany Report #WAES 0202CAN00128
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Paralysis	Health Professional	Vioxx	PS		ORAL		
			Tizanidine Hydrochloride	SS		ORAL	9	WK
			Tolterodine Tartrate	C	Merck & Co., Inc	ORAL		

Date:03/07/02ISR Number: 3881712-5Report Type:Expedited (15-DaCompany Report #ZANA000918 (0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Blood Magnesium Decreased Blood Potassium Decreased Torsade De Pointes	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	24 MG DAILY	ORAL
	Urinary Tract Infection		Baclofen	C				
	Ventricular Tachycardia		Gabapentin	C				
			Methadone	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/08/02ISR Number: 3880927-XReport Type:Expedited (15-DaCompany Report #ZANA000919(0)
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Foreign Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	32 MG DAILY ORAL	
			Interferon	C				
			Fluoxetine	C				
			Baclofen	C				

Date:03/11/02ISR Number: 3882291-9Report Type:Expedited (15-DaCompany Report #WAES0202CAN00128
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Paralysis	Foreign Other	Tab Vioxx (Rofecoxib)	PS		ORAL	25 MG/DAILY PO	
			Tizanidine Hydrochloride	SS		ORAL	8 MG/DAILY PO	
			Tolterodine Tartrate	C				

Date:03/18/02ISR Number: 3884740-9Report Type:Expedited (15-DaCompany Report #ZANA000925 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination, Auditory	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	ORAL	
			Percocet	C				

Date:03/19/02ISR Number: 3885517-0Report Type:Expedited (15-DaCompany Report #WAES 01058223
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Foreign	Tab Vioxx (Rofecoxib)	PS		ORAL	25 MG/DAILY	
Other	Drug Interaction	Other						
	Fatigue							
PO							5	DAY
	Oedema Peripheral		Tab Tizanidine	SS		ORAL	4 MG/DAILY	5 DAY
	Sinus Bradycardia							

Date:03/21/02ISR Number: 3887412-XReport Type:Expedited (15-DaCompany Report #ZANA000930 (0)
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	ORAL	
	Bacteraemia							
	Cough		Low-Ogestrel	C				
	Headache		Steroid Epidural	C				
	Infection		Ibuprofen	C				
	Inflammation							
	Influenza Like Illness							
	Malaise							
	Nausea							
	Pain							
	Procedural Complication							
	Pyrexia							
	Urinary Tract Infection							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/21/02ISR Number: 3887461-1Report Type:Expedited (15-DaCompany Report #ZANA000928 (0)
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Crying	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL		
	Headache							
	Influenza Like Illness		Low -Ogestrel	C				
	Malaise		Steroid Epidural	C				
	Nausea							
	Pain							
	Urinary Tract Infection							
	Vomiting							

Date:03/28/02ISR Number: 3890402-4Report Type:Direct Company Report #USP 54808
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Zanaflex	PS	Athena			
			Gabitril	SS	Cephalon			

Date:04/18/02ISR Number: 3902957-1Report Type:Expedited (15-DaCompany Report #ZANA000939 (0)
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Withdrawal Syndrome	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	16 MG DAILY	
	Rebound Hypertension							
						ORAL		
			Baclofen	C				

Date:04/19/02ISR Number: 3903930-XReport Type:Expedited (15-DaCompany Report #ZANA000910 (1)
Age:34 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Hypersensitivity	Health	Zanaflex (Tizanidine					

Other		Professional	Hydrochloride)	PS		ORAL
8 MG DAILY						
ORAL						
			Vicodin	C		
			Keflex	C		
			Ortho-Novum	C		

Date:04/22/02ISR Number: 3904511-4Report Type:Direct Company Report #CTU 166324
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Confusional State		Zanaflex	PS		
TWICE/DAY						
	Depression		Atenolol	C		
	Disorientation		Neurontin	C		
			Lorazepam	C		
			Pravachol	C		
			Aciphex	C		

Date:04/22/02ISR Number: 3905326-3Report Type:Expedited (15-DaCompany Report #200210184BNE
Age:81 YR Gender:Male I/FU:I

Outcome	PT	Report Source
Other	Lymphoma	Foreign
	Skin Disorder	Health

Professional
Other

Product	Role	Manufacturer	Route	Dose	Duration
Nifedipine	PS		ORAL	30 MG DAILY	ORAL
Betaxolol	SS				
Allopurinol	SS			100 MG DAILY	
Simvastatin	SS			10 MG DAILY	
Enalapril	SS			20 MG DAILY	
Nizatidine	SS			150 MG DAILY	
Aspirin (Acetylsalicylic Acid)	SS			75 MG DAILY	
Paracetamol	SS				
Tizanidine	SS			2 MG DAILY	
Prazosin	SS			500 UG TID	

Date:04/25/02ISR Number: 3907853-1Report Type:Expedited (15-DaCompany Report #ZANA000941 (0)
Age:81 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Lymphoma Skin Disorder	Foreign Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY	ORAL
			Betaxolol (Betaxolol)	SS			OPHTHALMIC	OPHTH
			Allopurinol (Allopurinol)	SS			100 MG DAILY	
			Simvastatin					

			(Simvastatin)	SS		
10 MG DAILY						
			Enalapril (Enalapril)	SS		
20 MG DAILY						
			Nifedipine (Nifedipine)	SS		
30 MG DAILY						
			Nizatidine (Nizatidine)	SS		
150 MG DAILY						
			Aspirin (Acetylsalicylic Acid)	SS		
75 MG DAILY						
			Paracetamol (Paracetamol)	SS		
2 PRN						
			Prazosin (Prazosin)	SS		
500 MCG DAILY						

Date:04/25/02ISR Number: 3907899-3Report Type:Expedited (15-DaCompany Report #ZANA000940 (0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Psychosis	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	36 MG DAILY	
	Agitation							
	Arthralgia						ORAL	
	Confusional State		Baclofen	C				
	Fall		Oxycontin	C				
	Hallucination							
	Insomnia							
	Urinary Tract Infection							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/25/02ISR Number: 3907906-8Report Type:Expedited (15-DaCompany Report #ZANA000942 (0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Urinary Tract Infection	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	6 MG DAILY	
			Baclofen	C		ORAL		
			Oxycontin	C				

Date:04/26/02ISR Number: 3908302-XReport Type:Expedited (15-DaCompany Report #2002000069
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Lymphoma	Foreign	Prazosin (Prazosin)	PS			1.5 MG (TID)	
		Health Professional	Nifedipine(Nifedipine)	SS			30 MG (DAILY)	
		Other	Allopurinol	SS			100 MG	(DAILY)
			Simvastatin	SS			10 MG (DAILY)	
			Enalapril	SS			20 MG (DAILY)	
			Betaxolol	SS		OPHTHALMIC	(BID)	
			Acetylsalicylic Acid	SS		OPHTHALMIC	75 MG (DAILY)	
			Paracetamol	SS				
			Tizanidine	SS			2 MG (DAILY)	
			Nizatidine	SS			150 MG	(DAILY)

Date:04/30/02ISR Number: 3910374-3Report Type:Expedited (15-DaCompany Report #PHBS2002JP04033
Age:63 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema Erythema Multiforme Face Oedema Pruritus	Foreign Health Professional Other	Diovan (Valsartan) Tablet	PS		ORAL	40 MG, QD, ORAL	
			Osteluc (Etodolac)	SS		ORAL	100 MG, TID, ORAL	
			Mecobamide (Mecobalamin)	SS		ORAL	500 UG, TID, ORAL	
			Ternelin (Tizanidine Hydrochloride)	SS		ORAL	0.5 MG, TID, ORAL	

Date:04/30/02ISR Number: 3911321-0Report Type:Expedited (15-DaCompany Report #TCI2002A00557
Age:68 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Distension Abdominal Pain Hepatic Neoplasm Malignant Hepatic Steatosis	Study Health Professional	Actos Tablets 30 (Pioglitazone Hydrochloride)	PS		ORAL	30 MG	582 DAY
			Dihydroergocristine Mesilate	SS		ORAL	PER ORAL	4 YR
			Zaltoprofen	SS		ORAL	PER ORAL	946 DAY
			Glibenclamide	SS		ORAL	3.5 MG / 1.25 MG	337 DAY
			Teprenone	SS		ORAL	1.5 GM PER ORAL	946 DAY

					Tizanidine Hydrochloride	SS		ORAL
PER ORAL	673	DAY						
					Ticlopidine Hydrochloride	C		
					Dihydroergocristine Mesilate	C		
					Zaltoprofen	C		
					Tizanidine Hydrochloride	C		
					Teprenone	C		
					Glibenclamide	C		

Date:05/13/02ISR Number: 3915665-8Report Type:Expedited (15-DaCompany Report #ZANA000954 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	8 MG DAILY	
	Bradycardia							
	Dizziness							
	Hallucination		Synthroid	C				
	Heart Rate Increased		Tylenol	C				
	Hypotension							

Date:05/13/02ISR Number: 3916451-5Report Type:Direct Company Report #CTU 167997
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypersensitivity		Zanaflex	PS				
			Baclofen	SS				

Date:05/14/02ISR Number: 3916935-XReport Type:Expedited (15-DaCompany Report #200211271BWH
Age:53 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Consumer	Cipro (Ciprofloxacin					

	Fatigue	Health	Hydrochloride)	PS		ORAL
500 MG BID						
	Speech Disorder	Professional				
ORAL						
		Other	Zanaflex (Tizanidine Hydrochloride)	SS		ORAL
4 MG DAILY						
ORAL						
			Fibercon	C		
			Vit C	C		
			Multivitamin	C		
			Mevacor	C		
			Clonazepam	C		
			Tylenol	C		

Date:05/17/02ISR Number: 3918751-1Report Type:Expedited (15-DaCompany Report #ZANA000955 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Dry Mouth	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
24 MG DAILY	Feeling Abnormal					
	Hallucination, Visual					
ORAL						
	Hypoaesthesia		Valium	C		
			Talwin	C		
			Effexor	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/22/02ISR Number: 3920186-2Report Type:Direct Company Report #USP 54846
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Zanaflex (Tizanidine Hydrochloride)	PS	Athena Neurosciences			
			Anaflex (Salsalate)	SS				

Date:05/22/02ISR Number: 3921212-7Report Type:Expedited (15-DaCompany Report #ZANA000956 (0)
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block First Degree	Consumer Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY	
	Bradycardia	Professional					ORAL	
	Disorientation		Neurontin	C				
	Dry Mouth		Alloprin	C				
	Gait Disturbance		Dyazide	C				
	Heart Rate Increased		Asa	C				
	Hypotension		Vitamin Nos	C				
			Calcium	C				
			Vioxx	C				

Date:05/28/02ISR Number: 3924560-XReport Type:Expedited (15-DaCompany Report #EMADSS2002003182
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Agranulocytosis	Foreign	Sporanox					
	Back Pain	Health	(Unspecified)					
	Bacterial Infection	Professional	(Itraconazole)	PS		ORAL	800 MG,	
	Blood Culture Positive						DAYS(S), ORAL	
	Drug Interaction		Sidalud (Tizanidine)	SS				
	Drug Level Increased		Mst (Morphine					
	Electrocardiogram Qt		Sulfate)	C				
	Prolonged		Maxipime (Cefepime)	C				
	Pancytopenia		Targocid(Teicoplanin					

	Pyrexia		)	C			
	Tooth Infection		Flagyl (Metronidazole)	C			
			Neupogene (Filgrastim)	C			
			Liquemine (Heparin Sodium)	C			
			Antra (Omeprazole)	C			
			Frangulae-Rudolac	C			

Date:05/28/02ISR Number: 3925259-6Report Type:Expedited (15-DaCompany Report #ZANA000959 (0)
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY	
			Vioxx	C		ORAL		
			Dilantin	C				
			Prempro	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/29/02ISR Number: 3926634-6Report Type:Expedited (15-DaCompany Report #ZANA000960(0)
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Contusion	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	12 MG DAILY
Other	Hypersomnia						ORAL
	Psychotic Disorder		Prednisone	C			
	Rib Fracture		Neurontin	C			
	Somnolence		Lopid	C			

Date:06/04/02ISR Number: 3929329-8Report Type:Expedited (15-DaCompany Report #ZANA000965 (0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Amnesia	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2 TABS ORAL
	Catatonia						
	Communication Disorder		Catapres	C			
	Dehydration		Hydrochlorothiazide	C			
	Eating Disorder						
	Mental Status Changes						

Date:06/04/02ISR Number: 3929345-6Report Type:Expedited (15-DaCompany Report #ZANA000966 (0)
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Condition Aggravated	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	ORAL
	Dental Caries						
	Dry Mouth						

Date:06/13/02ISR Number: 3934743-0Report Type:Expedited (15-DaCompany Report #HQ2558304JUN2002
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abdominal Pain Upper	Health						
Hospitalization -	Cardiac Failure	Professional	Hypen (Etodolac, Unspec)	PS		ORAL	400MG DAILY	9 DAY
Initial or Prolonged	Pneumonitis	Other						
	Respiratory Distress		Tizanidine Hydrochloride (Tizanidine Hydrochloride,)	SS		ORAL	2 MG DAILY	9 DAY
			Bendipine Hydrochloride (Benidipine Hydrochloride)	C				
			Ranitidine Hydrochloride (Ranitidine Hydrochloride)	C				
			Digestives, Incl Enzymes (Digestives, Incl Enzymes)	C				
			Lactobacillus Bifidus, Lyophilized (Lactobacillus Bifidus, Lyophilized)	C				
			Furosemide (Furosemide)	C				
			Spironolactone					

				(Spironolactone)	C		
				Misoprostol (Misoprostol)	C		

Date:06/17/02ISR Number: 3935718-8Report Type:Expedited (15-DaCompany Report #ZANA000959 (1)
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY	
			Vioxx	C		ORAL		
			Dilantin	C				
			Prempro	C				

Date:06/18/02ISR Number: 3935263-XReport Type:Direct Company Report #CTU 170348
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Liver Function Test Abnormal		Zanaflex 4mg Athena Neuro	PS	Athena Neuro	ORAL	1-2MG DAY	
			Accolate	C		ORAL		
			Tolectin	C				
			Loestrin	C				
			Proventil	C				

Date:06/19/02ISR Number: 3936502-1Report Type:Expedited (15-DaCompany Report #ZONI000807 (0)
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Glucose Increased Vision Blurred	Health Professional	Zonegran (Zonisamide)	PS		ORAL	200 MG DAILY	

ORAL

Zanaflex (Tizanidine)	SS
Altace	C
Aclovate	C
Proventil Tablet	C
Glucotrol	C
Duragesic	C
Xanax	C
Bentyl	C
Reglan	C
Zoloft	C
Lithium	C
Buspar	C

Date:06/20/02ISR Number: 3937398-4Report Type:Expedited (15-DaCompany Report #ZANA000971 (0)
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Drug Interaction	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	12 MG DAILY	
		Company Representative	Birth Control Pills (Oral Contraceptive Nos)	SS		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/20/02ISR Number: 3937433-3Report Type:Expedited (15-DaCompany Report #ZANA000974 (0)
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aspiration	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	12 MG DAILY	
Other	Drug Ineffective					ORAL		
	Dysphagia		Baclofen	C				
	Eating Disorder							
	Jaw Disorder							
	Muscle Spasticity							
	Weight Decreased							

Date:06/21/02ISR Number: 3937202-4Report Type:Direct Company Report #CTU 170714
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Back Pain		Zanaflex	PS				
	Blood Pressure Increased		Vioxx	SS				
	Ear Infection							
	Fatigue							
	Gastrooesophageal Reflux Disease							
	Sinusitis							
	Tinnitus							
	Visual Acuity Reduced							
	Weight Increased							

Date:06/24/02ISR Number: 3937897-5Report Type:Direct Company Report #CTU 170793
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hallucination		Zanaflex 4mg					
Hospitalization - Initial or Prolonged	Liver Function Test		Novartis	PS	Novartis		1-2 TABS	
Required Intervention to	Abnormal							
	Nausea							
	Tachycardia							

Prevent Permanent Impairment/Damage	Tinnitus
	Vision Blurred

Date:06/24/02ISR Number: 3937899-9Report Type:Direct Company Report #CTU 170794
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Fear		Zanaflex 4mg	PS			2-3 TABS	
	Hallucination							

Date:06/27/02ISR Number: 3978979-1Report Type:Periodic Company Report #WAES 0204USA02209
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hallucination	Health	Tab Vioxx	PS		ORAL	PO	
	Somnolence	Professional Company Representative	Zanaflex	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/28/02ISR Number: 3941537-9Report Type:Direct Company Report #CTU 171244
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis Exfoliative		Zanaflex 4mg	PS		ORAL	ONE 3 TIMES	ORAL

Date:07/01/02ISR Number: 3983822-0Report Type:Periodic Company Report #01100759
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia	Health Professional	Novantrone Strength Unknown	PS			Q 3 MO	
	Infection							
	Liver Function Test		Acetaminophen	SS				
	Abnormal		Tizanidine	SS				
	Surgery		Amantadine	C				
			Oxybutynin	C				
			Baclofen	C				
			4-Aminopyridine	C				
			Fluoxetine	C				

Date:07/09/02ISR Number: 3945469-1Report Type:Direct Company Report #CTU 171933
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety		Zanaflex	PS		ORAL	2 TABS PO QHS	
	Hallucination						SINGLE DOSE	
	Insomnia		Epidural Steroid	SS				

Date:07/17/02ISR Number: 3950444-7Report Type:Expedited (15-DaCompany Report #2002000069
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Lymphoma	Foreign	Prazosin(Prazosin)	PS			1.5 MG(TID)	
		Health Professional	Nifedipine(Nifedipine)	SS			30 MG(DAILY)	
			Allopurinol	SS			100 MG	(DAILY)
			Simvastatin	SS			10 MG (DAILY)	
			Enalapril	SS			20 MG(DAILY)	
			Betaxolol	SS			OPHTHALMIC	UNK(BID),
			Acetylsalicylic Acid	SS			OPHTHALMIC	
			Paracetamol	SS			75 MG(DAILY)	
			Tizanidine	SS			2 MG (DAILY)	
			Nizatidine	SS			150 MG(DAILY)	

Date:07/24/02ISR Number: 3954308-4Report Type:Expedited (15-DaCompany Report #ZANA000984 (0)
Age:47 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Dialysis
	Hypotension
	Loss Of Consciousness
	Nephritis Allergic
	Rash
	Renal Failure
	Sepsis

	Vasculitis						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	10 MG DAILY ORAL
			Hydrochlorothiazide (Hydrochlorothiazide)	SS		ORAL	25 MG DAILY ORAL
			Desyrel	C			
			Oxycontin	C			
			Celexa	C			

Date:08/09/02ISR Number: 3961479-2Report Type:Expedited (15-DaCompany Report #ZONI000844 (0)
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Pressure Increased	Consumer	Zonegran (Zonisamide)	PS		ORAL	400 MG DAILY ORAL
	Orthostatic Hypotension						
	Tachycardia						
	Urinary Retention		Zanaflex (Tizanidine Hydrochloride)	SS		ORAL	ORAL
			Oxycontin	C			

Date:08/14/02ISR Number: 3963199-7Report Type:Expedited (15-DaCompany Report #ZANA000985(0)
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death Disability	Gastrointestinal Haemorrhage	Foreign Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	8 MG DAILY

	Myocardial Infarction	Professional					
ORAL							
			Senna	C			
			Quinine	C			
			Carbamazepine	C			
			Docusate	C			
			Baclofen	C			
			Ipratropium	C			
			Aspirin	C			
			Paracetamol	C			

Date:08/15/02ISR Number: 3962334-4Report Type:Direct Company Report #CTU 174198
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction		Cipro (Ciprofloxacin Hydrochloride)	PS		ORAL	500MG BID	
	Fatigue							
	Speech Disorder							
ORAL								
			Zanaflex (Tizanidine Hydrochloride)	SS		ORAL	4MG DAILY	
ORAL								
			Fibercon	C				
			Vit C	C				
			Multivitamin	C				
			Mevacor	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/19/02ISR Number: 3963437-0Report Type:Direct Company Report #CTU 174417
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pharmaceutical Product Complaint		Zanoflex 2mg (Bd) Generic And Brand Name	PS				
			Tiziainidine (Gen)	SS				

Date:08/21/02ISR Number: 3965831-0Report Type:Expedited (15-DaCompany Report #ZANA000986 (0)
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Orthostatic Hypotension Syncope	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	8 MG DAILY	ORAL
			Effexor	C				
			Fiorinal	C				
			Evista	C				
			Desyrel	C				

Date:08/21/02ISR Number: 3965879-6Report Type:Expedited (15-DaCompany Report #ZANA000987 (0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	16 MG DAILY	ORAL

Date:08/21/02ISR Number: 3966130-3Report Type:Expedited (15-DaCompany Report #ZANA000988 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Cardiomyopathy	Health	Zanaflex (Tizanidine			
	Cerebrovascular Accident	Professional	Hydrochloride)	PS		ORAL
ORAL						

Date:08/23/02ISR Number: 3967355-3Report Type:Expedited (15-DaCompany Report #ZANA000989 (0)
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Anaemia	Health	Zanaflex (Tizanidine			
Initial or Prolonged	Arrhythmia	Professional	Hydrochloride)	PS		ORAL
12 MG DAILY						
	Gastric Ulcer Haemorrhage					
ORAL						
	Pain		Duragesic Patch	C		
	Torsade De Pointes		Metoprolol	C		
	Ulcer Haemorrhage		Darvocet-N	C		
	Ventricular Tachycardia					

Date:08/27/02ISR Number: 3967782-4Report Type:Direct Company Report #CTU 175180
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Anaphylactic Shock		Zanaflex 2mg (Bd)	PS		
	Pharmaceutical Product		Tizanidine (Gen)	SS		
	Complaint					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/03/02ISR Number: 3970040-5Report Type:Direct Company Report #CTU 175545
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Drug Effect Decreased		Trizantadine 4 Mg					
	Mobility Decreased		Holt	PS	Holt	ORAL	4 MG 4 TIMES	
	Pharmaceutical Product						DAY ORAL	
	Complaint							

Date:09/04/02ISR Number: 3971368-5Report Type:Expedited (15-DaCompany Report #2001076005CH
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Complications Of Maternal Exposure To Therapeutic Drugs	Foreign Study Health Professional Other	Celebrex (Celecoxib) Capsule	PS		ORAL	200 MG, TID, ORAL	
	Pregnancy		Doxycycline (Doxycycline)	SS			100 MG, QD	
			Sirdalud (Tizanidine Hydrochloride)	SS			4 MG, BID	
			Noroxin (Norfloxacin)	SS			400 MG, BID	
			Valium (Diazepam)	SS			SUBCUTANEOUS	1 INJ, SUBCUTANEOUS
			Morphine	C				
			Tramadol	C				
			Paracetamol	C				
			Tetrazepam	C				

Date:09/09/02ISR Number: 3974562-2Report Type:Direct Company Report #CTU 176003
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Abdominal Pain		Zanaflex 4mg	PS			1 1/2 TAB	
Required Intervention to Prevent Permanent Impairment/Damage	Liver Function Test						DAILY	
	Abnormal		Phenobarbital	C				
	Malaise		Synthroid	C				
	Nausea		Zyrtec	C				

Date:09/10/02ISR Number: 3974113-2Report Type:Direct Company Report #CTU 176038
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia		Tizanidine (Zanaflex)	PS			2MG 1ST X 3	
	Diplopia							
	Dizziness						WEEKS; 4MG	
	Dry Mouth						NOW	
	Dysarthria		Zantac	C				
	Paraesthesia		Vioxx	C				
			Estrogen	C				

Date:09/13/02ISR Number: 3976139-1Report Type:Expedited (15-DaCompany Report #MK200209-0108-1
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Movement Disorder	Foreign Study	Anafranil Capsules 100	PS				
			Depakene R	SS				

			Ternelin	SS			
			Lochol	SS			

Date:09/16/02ISR Number: 3975911-1Report Type:Expedited (15-DaCompany Report #USA-2002-0002143
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Health Professional	Oxyir Capsules 5 Mg (Oxycodone Hydrochloride) Ir					
	Neuroleptic Malignant Syndrome							
	Postoperative Infection		Capsule	PS		ORAL	MG, ORAL	
	Respiratory Arrest		Zyvox (Linezolid)					
	Respiratory Depression		Tablet	SS		ORAL	MG, ORAL	
			Methadone (Methadone) Unknown	SS		ORAL	MG, ORAL	
			Vancomycin (Vancomycin) Unknown	SS			MG	
			Zanaflex (Tizanidine Hydrochloride) Tablet	SS		ORAL	MG, ORAL	
			Remeron (Mirtazapine) Tablet	SS		ORAL	MG, ORAL	
			Effexor (Venlafaxine Hydrochloride) Tablet	SS		ORAL	MG, ORAL	
			Gabitril (Tiagabine Hydrochloride) Tablet	SS		ORAL	MG, ORAL	

Date:09/20/02ISR Number: 3977881-9Report Type:Direct Company Report #USP 055217
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Medication Error		Tizanidine Hydrochloride	PS	Par		
			Nizatidine	SS	Mylan		

Date:09/20/02ISR Number: 3979356-XReport Type:Expedited (15-DaCompany Report #ZANA001010 (0)
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills Hepatitis	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	24-32 MG	DAILY; ORAL
	Influenza Like Illness							
	Nausea		Relafen	C				
	Prothrombin Time Prolonged		Cipro	C				
	Serum Ferritin Increased		Tylenol	C				
	Tremor							
	Urinary Tract Infection							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/24/02ISR Number: 3981881-2Report Type:Expedited (15-DaCompany Report #ZANA001013 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Cardiac Disorder Coma Rhabdomyolysis	Health Professional Company Representative	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	ORAL

Date:09/25/02ISR Number: 3980226-1Report Type:Direct Company Report #CTU 177090
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Dizziness Hypotension		Zanaflex Amitryptiline Neurontin Bumex Lisonopril	PS C C C C			4MG QD OR BID

Date:09/27/02ISR Number: 3984292-9Report Type:Expedited (15-DaCompany Report #PHBS2002JP04033
Age:63 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Erythema Multiforme Face Oedema Pruritus	Foreign Health Professional Other	Diovan (Valsartan) Tablet Ternelin (Tizanidine Hydrochloride, Tizanidine Hydrochloride) Unknown Osteluc (Etodolac)	PS SS SS		ORAL ORAL	40 MG, QD, ORAL 0.5 MG, TID, ORAL 100 MG, TID,

ORAL							
				Mecobamide (Mecobalamin)	SS		ORAL
500 UG, TID,							
ORAL							

Date:11/01/02ISR Number: 4005575-2Report Type:Expedited (15-DaCompany Report #2002AP03571
Age:47 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Misuse	Literature	Metoprolol	PS				
	Suicide Attempt	Health Professional	Salicylate	SS				
			Tizanidine	SS				

Date:11/12/02ISR Number: 4011639-XReport Type:Expedited (15-DaCompany Report #ZANA001033 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL		
	Hypotension							
Required Intervention to Prevent Permanent Impairment/Damage	Myocardial Infarction		Neurontin	C		ORAL		
	Syncope							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/14/02ISR Number: 4012571-8Report Type:Expedited (15-DaCompany Report #ZANA000971 (1)
Age:37 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia	Health	Zanaflex (Tizanidine					
Hospitalization -	Drug Interaction	Professional	Hydrochloride)	PS			8 MG DAILY	
Initial or Prolonged	Hypotension						ORAL	
			Ortho-Novum 777 (Norethindrone/ Estradiol)	SS			1 TABLET	DAILY
			Vioxx	C				
			Darvocet-N	C				

Date:11/14/02ISR Number: 4012577-9Report Type:Expedited (15-DaCompany Report #ZANA001028 (1)
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Akinesia	Consumer	Zanaflex (Tizanidne					
Initial or Prolonged	Asthenia		Hydrochloride)	PS		ORAL	6 MG DAILY	
Other	Decreased Activity						ORAL	
	Difficulty In Walking		Baclofen	C				
	Hypotension							
	Motor Dysfunction							
	Somnolence							
	Stupor							

Date:11/15/02ISR Number: 4011395-5Report Type:Direct Company Report #CTU 181034
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anger		Zanaflex 4g	PS		ORAL	4MG TID ORAL	
Hospitalization -	Blood Glucose Decreased							

Initial or Prolonged	Chest Pain					
	Flushing					
	Hallucinations, Mixed					
	Incoherent					
	Insomnia					
	Memory Impairment					
	Mental Status Changes					
	Nausea					
	Nightmare					
	Palpitations					
	Psychotic Disorder					
	Urinary Incontinence					
	Vomiting					

Date:11/19/02ISR Number: 4012850-4Report Type:Direct Company Report #CTU 181349
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Pressure Decreased Hypertension		Tizanidine 4 Mg Tablets Clonidine 0.1 Mg Tablets Paxil Remeron	PS SS C C			8 MG 3 TIMES DAILY 0.1 MG -2 DOSES	

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				Colace	C		
				Metamucil	C		
				Intrathecal Pump (Clonidine Baclofen Morphene)	C		
				Neurontin	C		
				Lipitor	C		

Date:11/20/02ISR Number: 4012673-6Report Type:Direct Company Report #CTU 181395
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Pressure Decreased Hypertension		Tizanidine 4mg Tablets	PS			8MG 3 TIMES DAILY	
			Clonidine 0.1mg Tablets	SS			0.1MG -2 DOSES	
			Paxil	C				
			Colace	C				
			Metamucil	C				
			Neurontin	C				
			Lipitor	C				
			Clonidine	C				
			Baclotch	C				
			Morphine	C				

Date:11/21/02ISR Number: 4016887-0Report Type:Expedited (15-DaCompany Report #NSADSS2002042283
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Bradycardia Drug Interaction Hypotension	Health Professional	Ortho-Novum 7/7/7(Tablet) (Ethinylestradiol/Norethindrone)	PS		ORAL	1 TABLET,	

DAILY, ORAL

Zanaflex (Tizanidine Hydrochloride)	SS	ORAL

8 MG, 1 IN 1

DAILY, ORAL

Vioxx (Rofecoxib)	C	
Darvocet-N (Di-Gesic)	C	

Date:11/22/02ISR Number: 4013851-2Report Type:Expedited (15-DaCompany Report #WAES 0211USA01696
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Somnolence		Vioxx	PS	Merck & Co., Inc	ORAL		
			[Composition Unspecified]	SS				
			Zanaflex	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/26/02ISR Number: 4017976-7Report Type:Expedited (15-DaCompany Report #12115150
Age:47 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Metoprolol Tartrate	PS		ORAL		
Other	Overdose	Health Professional	Salicylate (Salicylate Salts)	SS		ORAL		
			Tizanidine (Tizanidine Hcl)	SS		ORAL		

Date:11/26/02ISR Number: 4018026-9Report Type:Expedited (15-DaCompany Report #ZANA001039
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Hypotension Loss Of Consciousness Memory Impairment	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	12 MG DAILY	
			Estrace (Estradiol Valerate)	SS		ORAL	1 MG DAILY	
			Plaquenil	C				
			Vioxx	C				
			Prozac	C				

Date:11/26/02ISR Number: 4018108-1Report Type:Expedited (15-DaCompany Report #ZANA001037
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Biliary Tract Disorder Cholangitis Acute Eosinophilia	Literature Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	16 MG DAILY	

	Hepatic Congestion		Oxycodone	C		
	Hepatic Failure					
	Hepatic Fibrosis					
	Hepatic Haemorrhage					
	Hepatic Steatosis					
	Hepatocellular Damage					

Date:11/29/02ISR Number: 4018276-1Report Type:Expedited (15-DaCompany Report #ZANA001043
Age:47 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Zanaflex (Tizanidine					
		Health	Hydrochloride)	PS		ORAL	ORAL	
		Professional	Metoprolol					
			(Metoprolol)	SS		ORAL	ORAL	
			Salicylate	C				

Date:11/29/02ISR Number: 4018348-1Report Type:Expedited (15-DaCompany Report #ZANA001042
Age:43 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Zanaflex (Tizanidine					
	Completed Suicide	Health	Hydrochloride)	PS		ORAL	ORAL	
		Professional						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/02/02ISR Number: 4018381-XReport Type:Direct Company Report #CTU 181893
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Tardive Dyskinesia		Zanaflex	PS		SEE DESCRIPTION		

Date:12/04/02ISR Number: 4022020-1Report Type:Expedited (15-DaCompany Report #ZANA001045
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Ankle Fracture Dizziness Fall Middle Insomnia	Health Professional Company Representative	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY	ORAL

Date:12/09/02ISR Number: 4020891-6Report Type:Direct Company Report #CTU 182319
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Effect Decreased Pharmaceutical Product Complaint		Tizanidine 4 Mg Teva	PS	Teva		3 PILLS EVERY NIGHT	

Date:12/16/02ISR Number: 4023957-XReport Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12129474
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bradycardia	Health	Estrace Tabs 1 Mg	PS	Apothecon	ORAL		

Initial or Prolonged	Drug Interaction	Professional	Plaquenil	C		
	Hypotension		Vioxx	C		
	Loss Of Consciousness		Prozac	C		
	Memory Impairment		Zanaflex	I		ORAL

Date:12/18/02ISR Number: 4029340-5Report Type:Expedited (15-DaCompany Report #ZANA001049
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Tardive Dyskinesia	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
24 MG DAILY						
ORAL						
			Milk Of Magnesia	C		
			Ducolax	C		
			Lacri-Lube	C		

Date:12/18/02ISR Number: 4029343-0Report Type:Expedited (15-DaCompany Report #ZANA001013
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Cardiac Disorder	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
ORAL						
	Coma					
	Drug Interaction					
	Nervous System Disorder					
	Respiratory Disorder					
	Rhabdomyolysis					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/19/02ISR Number: 4030130-8Report Type:Expedited (15-DaCompany Report #ZANA001045
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ankle Fracture	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	6 MG DAILY	
Required	Dizziness Postural						ORAL	
Intervention to Prevent Permanent Impairment/Damage	Fall							
	Middle Insomnia		Klonopin	C				
			Celexa	C				
			Estrogen	C				

Date:12/24/02ISR Number: 4033743-2Report Type:Expedited (15-DaCompany Report #ZANA001052
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	12 MG DAILY	
							ORAL	
			Effexor	C				
			Depakote	C				
			Vitamins Nos	C				

Date:12/24/02ISR Number: 4033769-9Report Type:Expedited (15-DaCompany Report #ZANA001051
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	12 MG DAILY	
	Alanine Aminotransferase Increased						ORAL	
	Aspartate Aminotransferase Increased		Depakote	C				
			Effexor	C				
			Botox	C				
	Convulsion		Prometrium	C				
	Headache		Vitamins Nos	C				

	Oedema Peripheral Rebound Hypertension Vomiting					

Date:12/31/02ISR Number: 4040235-3Report Type:Expedited (15-DaCompany Report #SAG/INT-10/0/13/10/1
Age:58 YR Gender:Male I/FU:F

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

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/03/03ISR Number: 4039017-8Report Type:Expedited (15-DaCompany Report #ZANA001053
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Pressure Increased Hallucination	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	ORAL
	Lethargy		Cozaar	C			
	Medication Error		Lisinopril	C			
	Neuroleptic Malignant Syndrome		Lopressor	C			

Date:01/03/03ISR Number: 4039033-6Report Type:Expedited (15-DaCompany Report #ZANA001054
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Death	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY
		Company					ORAL
		Representative	Opioids (Unspecified)	C			

Date:01/10/03ISR Number: 4041180-XReport Type:Expedited (15-DaCompany Report #2002AP04402
Age:44 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Autoimmune Hepatitis Tension Headache	Foreign Health	Zomig	PS		ORAL	2.5 MG DAILY PO
Required Intervention to Prevent Permanent Impairment/Damage		Professional Other	Imigran	SS		ORAL	50 MG DAILY PO
			Imigran	SS		ORAL	50 MG DAILY PO

			Ternelin	SS		ORAL 3 MG DAILY PO
			Arofuto	SS		ORAL 60 MG DAILY PO
			Migristene	C		ORAL 60 MG DAILY PO

Date:01/23/03ISR Number: 4046403-9Report Type:Expedited (15-DaCompany Report #2002AP04402
Age:44 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Autoimmune Hepatitis Cholelithiasis	Foreign Health Professional	Zomig	PS		ORAL 2.5 MG DAILY PO
Required Intervention to Prevent Permanent Impairment/Damage	Chronic Hepatitis Hepatitis Tension Headache	Professional Other	Imigran	SS		ORAL 50 MG DAILY PO
			Imigran	SS		ORAL 50 MG DAILY PO
			Migristene	SS		ORAL 60 MG DAILY PO
			Arofuto	SS		ORAL 60 MG DAILY PO
			Ternelin	SS		ORAL 3 MG DAILY PO

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/28/03ISR Number: 4048741-2Report Type:Direct Company Report #CTU 185382
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Dry Mouth		Tizanidine	PS			8 MG TID	
	Hypotension		Simvastatin	C				
			Metformin Hcl	C				
			Atenolol	C				
			Glipizide	C				
			Lisinopril	C				
			Rofecoxib	C				
			Acetaminophen	C				
			Ranitidine	C				

Date:01/28/03ISR Number: 4049722-5Report Type:Expedited (15-DaCompany Report #ZANA001053
Age:55 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Increased	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	UNK	ORAL
	Cerebral Infarction							
	Convulsion		Cozaar	C				
	Escherichia Infection		Lisinopril	C				
	Hallucination		Lopressor	C				
	Lethargy							
	Medication Error							
	Nervous System Disorder							
	Pneumonia Klebsiella							
	Sinus Tachycardia							
	Status Epilepticus							
	Urinary Tract Infection							
	Vasculitis							

Date:01/28/03ISR Number: 4049768-7Report Type:Expedited (15-DaCompany Report #ZANA001033
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia	Health	Zanaflex (Tizanidine					

Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Cardiac Arrest Hypotension Myocardial Infarction Syncope Ventricular Fibrillation	Professional	Hydrochloride) Neurontin Climara Klonopin	PS C C C		ORAL 32 MG DAILY ORAL

Date:01/28/03ISR Number: 4049774-2Report Type:Expedited (15-DaCompany Report #ZANA001010
Age:37 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Hepatitis Influenza Like Illness Serum Ferritin Increased Transferrin Abnormal Urinary Tract Infection	Health Professional	Zanaflex (Tizanidine Hydrochloride) Relafen Cipro Tylenol	PS C C C		ORAL 24-32 MG DAILY ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/29/03ISR Number: 4050764-4Report Type:Periodic Company Report #ZANA000920
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotension	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY	
ORAL								

Date:01/29/03ISR Number: 4050765-6Report Type:Periodic Company Report #ZANA000948
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotension	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY	
ORAL								
			Vicodin	C				

Date:01/29/03ISR Number: 4050769-3Report Type:Periodic Company Report #ZANA000981
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL		
ORAL								
			Birth Control Pills	C				

Date:02/03/03ISR Number: 4051426-XReport Type:Expedited (15-DaCompany Report #2002AP04402
Age:44 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Autoimmune Hepatitis	Foreign	Zomig	PS		ORAL	2.5 MG DAILY	

Initial or Prolonged	Cholelithiasis	Health				
PO						
Required	Chronic Hepatitis	Professional	Imigran	SS		ORAL
50 MG DAILY						
Intervention to	Hepatitis	Other				
PO						
Prevent Permanent			Imigran	SS		ORAL
50 MG DAILY						
Impairment/Damage						
PO						
			Migristene	SS		ORAL
60 MG DAILY						
PO						
			Arofuto	SS		ORAL
60 MG DAILY						
PO						
			Ternelin	SS		ORAL
3 MG DAILY PO						

Date:02/03/03ISR Number: 4052066-9Report Type:Periodic Company Report #A0373546A
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Chest Discomfort	Health	Lamictal			
Required	Chest Pain	Professional	(Lamotrigine)	PS		ORAL
25 MG ORAL						
Intervention to	Skin Discolouration		Tizanidine			
Prevent Permanent	Swelling Face		Hydrochloride			
Impairment/Damage	Swollen Tongue		(Tizanidine			
	Urticaria		Hydrochloride)	SS		ORAL
ORAL						
	Wheezing		Pirbuterol Acetate	C		
			Tramadol			
			Hydrochloride	C		
			Fluticasone+Salmeter			
			ol	C		
			Salbutamol Sulphate	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/03ISR Number: 4052829-XReport Type:Expedited (15-DaCompany Report #ZANA001057
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Health	Zanaflex (Tizanidine					
Hospitalization - Initial or Prolonged	Pancreatitis	Professional	Hydrochloride)	PS		ORAL	ORAL	

Date:02/07/03ISR Number: 4053906-XReport Type:Expedited (15-DaCompany Report #2002AP03571
Age:47 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Metoprolol	PS				
	Intentional Misuse	Health	Salicylate	SS				
		Professional	Tizanidine	SS				

Date:02/07/03ISR Number: 4054749-3Report Type:Expedited (15-DaCompany Report #03-00259
Age:43 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Tizanidine	PS				
	Intentional Misuse	Health						
		Professional						
		Other						

Date:02/07/03ISR Number: 4055131-5Report Type:Expedited (15-DaCompany Report #03-00225
Age:47 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Tizanidine	PS				
	Intentional Misuse	Health	Metoprolol	C			UNKNOWN	UNKNOWN
		Professional	Salicylate	C				
		Other						

Date:02/11/03ISR Number: 4056957-4Report Type:Expedited (15-DaCompany Report #DEU-2003-0000272
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression Hyperhidrosis Insomnia	Foreign Health Professional Other	Oxycodone Hydrochloride Cr Tablets (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL	20 MG, DAILY,	ORAL
			Cosaar (Losartan Potassium)	SS		ORAL	50 MG, DAILY,	ORAL
			Sirdalud (Tizanidine Hydrochloride)	SS		ORAL	8 MG, DAILY,	ORAL
			Fluoxetine (Fluoxetine)	SS		ORAL	20 MG, DAILY,	ORAL
			Pantozol(Pantoprazole Sodium)	SS		ORAL	20 MG, DAILY,	ORAL
			Diclofenac (Diclofenac)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/19/03ISR Number: 4059873-7Report Type:Expedited (15-DaCompany Report #2003-02-0499
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaphylactic Shock	Foreign Health Professional	Diprospan (Betamethasone Sodium Phosphate/Dipropionate) Injectable	PS			1 ML	
			Lornoxicam (Chlorotenoxipam)	SS			8 MG BID	2 DAY
			Milgamma (Pyridoxine/Benfotiamine)	SS			2 ML QD	3 DAY
			Sirdalud	SS			4 MG TID	10 DAY
			Trental	SS			400 MG BID	10 DAY

Date:02/27/03ISR Number: 4067688-9Report Type:Expedited (15-DaCompany Report #ZANA001057
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Cholelithiasis Coma Pancreatitis	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	ORAL	

Date:03/18/03ISR Number: 4075176-9Report Type:Direct Company Report #CTU 188897
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Electrocardiogram Qt Prolonged		Tegaserod (Zelnorm) Samples	PS			UNKNOWN	UNKNOWN
	Syncope						(SAMPLES)	

			Tizanidine (Ranatlex) 4 Mg Tid Prn	SS		ORAL	4 MG PO TID PRN
			Valium	C			
			Xanax	C			
			Prozac	C			
			Nodete	C			
			Zanatlex	C			
			Albuterol	C			

Date:03/18/03ISR Number: 4078191-4Report Type:Expedited (15-DaCompany Report #PHBS2003JP02453
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Dependence	Foreign Literature Health Professional	Tizanidine Hydrochloride (Tizanidine Hydrochloride)	PS		ORAL	3 MG/DAY, ORAL
		Other	Carbamazepine(Carbamazepine) Unknown	SS		ORAL	400 MG/DAY, ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/18/03ISR Number: 4079748-7Report Type:Expedited (15-DaCompany Report #US-SHR-03-001871
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Hepatic Failure Multiple Sclerosis	Consumer Health Professional	Betaseron (Interferon Beta - 1b)Injection	PS		SUBCUTANEOUS	SUBCUTANEOUS	
			Zanaflex(Tizanidine Hydrochloride)	SS				

Date:03/19/03ISR Number: 4076379-XReport Type:Direct Company Report #CTU 189056
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Dehydration		Tizanidine -Zanaflex-	PS		ORAL	4MG QD ORAL	
	Dizziness		Atenolol	SS		ORAL	50 QD ORAL	
	Drug Interaction		Lexapro	SS		ORAL	10MG QD ORAL	
	Hypotension		Diovan	C				
	Lethargy		Norvasc	C				
	Renal Failure		Vioxx	C				
			Aspirin	C				
			Hydrochlorothiazide	C				
			Temazepam	C				

Date:03/20/03ISR Number: 4078196-3Report Type:Direct Company Report #USP 55504
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error Somnolence		Zofran Tizanide	PS SS	Glaxo Welcome Eon			

Date:03/20/03ISR Number: 4080622-0Report Type:Expedited (15-DaCompany Report #USA-2002-0001447
Age:38 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Accident
	Anxiety
	Arthralgia
	Asthenia
	Chest Pain
	Chills
	Coagulopathy
	Confusional State
	Coordination Abnormal
	Cushingoid
	Dehydration
	Drug Withdrawal Syndrome
	Duodenal Ulcer
	Dyspnoea
	Emotional Disorder
	Emotional Distress
	Feeling Of Body Temperature Change
	Hallucination
	Hepatitis
	Hyperhidrosis
	Hypertonia
	Insomnia

	Liver Disorder Migraine Muscle Contractions Involuntary Muscle Twitching Oedema Peripheral Palpitations Pancreatitis Pyrexia Skin Discolouration Speech Disorder Syncope Tremor Vision Blurred Visual Disturbance	Report Source Consumer Health Professional Other	Product Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet Zanaflex (Tizanidine Hydrochloride) Tablet Depakote(Valproate Semisodium) Tablet Motrin Tablet Demerol (Pethidine Hydrochloride) Injectable Phenergan"Wyeth-Ayerst" (Promethazine Hydrochloride) Injectable Elavil (Amitriptyline Hydrochloride) Tablet Xanax (Aprazolam) Prednisone (Prednisone) Tablet Zyprexa (Olanzapine) Tablet Skelaxin (Metaxalone) Tablet Robaxin (Methocarbamol) Tablet Bactrium Ds(Sulfamethoxazole, Trimethoprim) Tablet Vicodin Tablet Neurontin (Gabapentin) Tablet	Role PS SS C C C C C C C C C C C	Manufacturer	Route ORAL ORAL	Dose 40 MG, BID, 12 MG, TID,	Duration

Reglan Tablet	C
Stadol Ns (Butorphanol Tartrate) Spray	C
Doxepin (Doxepin) Tablet	C
Thorazine (Chlorpromazine Hydrochloride) Tablet	C
Flexeril (Ciclobenzaprine Hydrochloride) Tablet	C
Orphenadrine (Orphenadrine) Tablet	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/26/03ISR Number: 4084151-XReport Type:Expedited (15-DaCompany Report #ZANA001062
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Loss Of Consciousness	Foreign Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	8 MG DAILY	
			Thyroxine	C				
			Premarin	C				
			Codeine	C				

Date:04/02/03ISR Number: 4088558-6Report Type:Expedited (15-DaCompany Report #JP-SHR-03-002988
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haemolytic Anaemia	Foreign Health Professional Other	Betaferon (Interferon Beta-1b) Injection	PS		SUBCUTANEOUS	4 MIU, EVERY 2 D,	
			Zantac (Ranitidine Hydrochloride) Tablet	SS		ORAL	300 MG, ORAL	
			Mucosta (Rebamipide) Tablet	SS		ORAL	300 MG, ORAL	
			Ternelin (Tizanidine Hydrochloride) Tablet	SS		ORAL	2 MG, ORAL	
			Prednisolone	C				
			Voltaren "Ciba-Geigy" (Diclofenac Sodium)	C				
			Tegretol (Carbamazepine)	C				
			Takepron					

(Lansoprazole)	C	
Solu-Medrol (Methylprednisolone Sodium Succinate)	C	
Vitamedin S (Hydroxocobalamin)	C	
Gaster (Famotidine)	C	

Date:04/03/03ISR Number: 4087134-9Report Type:Direct Company Report #CTU 190118
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Increased		Zanaflex 4 Mg	PS		ORAL	4 MG 1-1-1-2-	
	Eye Swelling					ORAL		
	Oedema		Fleets Phosphosoda Ginger Lemon Flavor	SS		ORAL	1.5 OZ TWICE	

Date:04/04/03ISR Number: 4090070-5Report Type:Expedited (15-DaCompany Report #PHBS2003JP02453
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Drug Dependence	Foreign Literature

		Health Professional Other	Product	Role	Manufacturer	Route
Dose	Duration					
			Tizanidine Hydrochloride (Tizanidine Hydrochloride)	PS		ORAL
3 MG/DAY,						
ORAL						
			Carbamazepine(Carbamazepine)	SS		ORAL
SEE IMAGE						

Date:04/04/03ISR Number: 4090503-4Report Type:Expedited (15-DaCompany Report #PHBS2003JP02453
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Drug Dependence	Foreign Literature Health Professional Other	Tizanidine Hydrochloride (Tizanidine Hydrochloride)Unknown	PS		ORAL
3 MG/DAY,						
ORAL						
			Caqrbamazepine (Carbamazepine)Unknown	SS		ORAL
500 MG/DAY,						
ORAL						

Date:04/22/03ISR Number: 4097287-4Report Type:Direct Company Report #CTU 191425
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Nausea		Xanaflex	PS		
25 MG (2 Q 8						

	Nervousness					
H)						
	Pharmaceutical Product Complaint					

Date:04/22/03ISR Number: 4097289-8Report Type:Direct Company Report #CTU 191426
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated		Tizanidine 4mg	PS				
12 Q 6 HOUR								
	Muscle Spasms							
PRN								
	Pharmaceutical Product Complaint							

Date:04/24/03ISR Number: 4102202-0Report Type:Expedited (15-DaCompany Report #200310010BYL
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema Multiforme	Foreign Health Professional	Bayaspirin (Acetylsalicylic Acid)	PS		ORAL		
ORAL								
		Other	Celgotin S (Nicergoline)	SS		ORAL		
ORAL								
			Enchinin (Tizanidine Hydrochloride)	SS		ORAL		
ORAL								
			Diasera L	C				
			Alfarol	C				

			Inderal	C			
			Norvasc	C			

Date:04/24/03ISR Number: 4102658-3Report Type:Expedited (15-DaCompany Report #ZANA001068
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Clonic Convulsion	Literature	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL		
	Condition Aggravated	Health						
	Dyspnoea	Professional	Baclofen (Baclofen)	SS		INTRATRACHEAL	INTHC	
	Hyperpyrexia		Lorazepam	C				
	Mechanical Complication Of Implant		Clonazepam	C				
	Medical Device Complication							
	Muscle Spasms							
	Respiratory Rate Increased							

Date:04/28/03ISR Number: 4104230-8Report Type:Expedited (15-DaCompany Report #PHBS2003JP02453
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Dependence	Foreign	Tizanidine Hydrochloride (Tizanidine Hydrochloride)	PS		ORAL	3 MG/DAY,	ORAL
		Literature						
		Health						
		Professional						
		Other	Carbamazepine (Carbamazepine)	SS		ORAL	SEE IMAGE	

Date:04/30/03ISR Number: 4104792-0Report Type:Expedited (15-DaCompany Report #200310010BYL
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema Multiforme Nasopharyngitis	Foreign Health Professional	Bayaspirin (Acetylsalicylic Acid)	PS		ORAL		
			Celgotin S (Nicergoline)	SS		ORAL		
			Enchinin (Tizanidine Hydrochloride)	SS		ORAL		
			Diasera	C				
			Alfarol	C				
			Inderal	C				
			Norvasc	C				

Date:05/01/03ISR Number: 4107308-8Report Type:Periodic Company Report #ZONI001060
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hyperbilirubinaemia	Health Professional	Zonegran (Zonisamide)	PS		ORAL		
			Zanaflex (Tizanidine Hydrochloride)	SS		ORAL	12 MG DAILY	
			Elavil	C				

				Darvocet	C		
				Phrenilin	C		

Date:05/02/03ISR Number: 4106520-1Report Type:Expedited (15-DaCompany Report #ZANA001075
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cerebrovascular Accident	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	ORAL	

Date:05/02/03ISR Number: 4106883-7Report Type:Expedited (15-DaCompany Report #PHBS2003JP01063
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alanine Aminotransferase Increased	Foreign	Tegretol(Carbamazepine)Tablet	PS		ORAL	SEE IMAGE	
Hospitalization - Initial or Prolonged	Blood Alkaline Phosphatase Increased	Professional Other	Ternelin(Tizanidine Hydrochloride)	SS				
	Gamma-Glutamyltransferase Increased		Gaster(Famotidine)	SS				
	Hepatic Function Abnormal		Predonine	C				
	Hypogammaglobulinaemia		Selbex (Teprenone)	C				
	Immunodeficiency		Rize (Clotiazepam)	C				
	Pneumonia							
	Productive Cough							
	Pyrexia							
	Rash Generalised							
	Upper Respiratory Tract Infection							

Date:05/02/03ISR Number: 4107150-8Report Type:Expedited (15-DaCompany Report #2002066682
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Carpal Tunnel Syndrome	Consumer	Neurontin					

Initial or Prolonged	Cognitive Deterioration	Health	(Gabapentin)	PS	ORAL
400 MG					
Other	Condition Aggravated	Professional			
(DAILY), ORAL					
	Confusional State		Anxiolytics	SS	
	Disturbance In Attention		Tizanidine Hydrochloride		
	Drug Interaction		(Tizanidine Hydrochloride)	SS	
	Encephalopathy		Tramadol Hydrochloride (Tramadol Hydrochloride)	SS	
			Alprazolam (Alpazolam)	C	
			Oxycodone Hydrochloride (Oxycodone Hydrochloride)	C	
			Hypnotics And Sedatives	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/05/03ISR Number: 4105660-0Report Type:Direct Company Report #CTU 192289
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nausea		Xanaflex	PS			25 MG (2 Q	8H)
	Nervousness							
	Pharmaceutical Product Complaint							

Date:05/06/03ISR Number: 4108799-9Report Type:Expedited (15-DaCompany Report #ZANA001077
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiotoxicity	Literature	Zanaflex (Tizanidine					
	Ejection Fraction	Health	Hydrochloride)	PS		ORAL	ORAL	
	Decreased	Professional	Mitoxantrone (Mitoxantrone)	SS				
			Amantadine	C				
			Indocin	C				
			Corticosteroid Nos	C				

Date:05/06/03ISR Number: 4108801-4Report Type:Expedited (15-DaCompany Report #ZANA001078
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiotoxicity	Literature	Zanaflex (Tizanidine					
		Health	Hydrochloride)	PS		ORAL	ORAL	
		Professional	Mitoxantrone (Mitoxantrone)	SS			12.5 MG/M2	
			Betaseron	C				
			Fosamax	C				
			Corticosteroid Nos	C				

Date:05/13/03ISR Number: 4108166-8Report Type:Expedited (15-DaCompany Report #CH-BRISTOL-MYERS SQUIBB COMPANY-12119780
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Induced	Health	Selipran	PS	Bristol-Myers Squibb			
	Complications Of Maternal	Professional			Company	ORAL		YR
	Exposure To Therapeutic		Seropram	SS		ORAL		YR
	Drugs		Sirdalud	SS		ORAL	2	WK
	Maternal Drugs Affecting		Ponstan	SS		ORAL	7	DAY
	Foetus		Brufen	SS		ORAL	7	DAY
	Pregnancy							

Date:05/13/03ISR Number: 4111600-0Report Type:Expedited (15-DaCompany Report #OXYS000009
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Literature	Roxicodone (Oxycodone Hcl)	PS		ORAL	30 ML MONTHLY	
	Eosinophilia	Health						ORAL
	Pleural Effusion	Professional	Zanaflex (Tizanidine Hydrochloride)	SS		ORAL	4 MG Q 8 HR	
								ORAL
			Duraclon (Clonidine Hydrochloride)	SS			900 MCG DAILY	
								INTHC

			Morphine	C		
			Bupivacaine	C		
			Fentanyl	C		
			Morphine Sulfate	C		
			Gabapentin	C		
			Fluoxetine	C		
			Baclofen	C		

Date:05/13/03ISR Number: 4111637-1Report Type:Expedited (15-DaCompany Report #CLON000028
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Breath Sounds Decreased Diarrhoea	Literature Health	Duraclon (Clonidine Hydrochloride)	PS		INTRATHECAL	900 MCG DAILY	
	Muscle Spasms Nausea Pleural Effusion Vomiting	Professional	Zanaflex (Tizanidine Hydrochloride)	SS		ORAL	2 MG Q 8 HR	
			Morphine	C				
			Bupivacaine	C				
			Fentanyl	C				

Date:05/13/03ISR Number: 4111638-3Report Type:Expedited (15-DaCompany Report #ZANA001079
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Breath Sounds Decreased Condition Aggravated	Literature Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2MG Q 8 HR	
	Diarrhoea Muscle Spasms Nausea Pleural Effusion	Professional	Duraclon (Clonidine Hydrochloride)	SS		INTRATHECAL	900 MCG DAILY	
			Morphine	C				

			Bupivacaine	C		
			Fentanyl Patch	C		

Date:05/14/03ISR Number: 4114120-2Report Type:Direct Company Report #CTU 193070
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Condition Aggravated		Tizanidine (Generic)	PS		
8MG QID						
	Drug Ineffective		Ambien	C		
	Headache		Prevacid	C		
	Loss Of Consciousness		Oxycontin	C		
	Pancreatic Disorder		Xanax	C		
	Pharmaceutical Product		Advair	C		
	Complaint		Imitrex	C		
			Tylox	C		
			O2	C		

Date:05/15/03ISR Number: 4113569-1Report Type:Direct Company Report #CTU 193144
Age: Gender:Female I/FU:I

Outcome	PT
Other	Condition Aggravated
	Drug Ineffective
	Headache

		Loss Of Consciousness Pancreatic Disorder Pharmaceutical Product Complaint	Report Source	Product Tizanidine (Generic) Eon Lab Ambien Prevacid Oxycontin Xanax Advair Imitrex Tylox O2	Role PS C C C C C C C C	Manufacturer Eon Lab	Route
Dose	Duration						
8 MG QID							

Date:05/21/03ISR Number: 4116375-7Report Type:Expedited (15-DaCompany Report #S03-SWI-02123-01
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Disability	Abortion Induced Arthralgia	Foreign Other	Seropram (Citalopram Hybrobromide)	PS		
20 MG QD PO						
	Complications Of Maternal Exposure To Therapeutic Drugs Drug Exposure During Pregnancy Limb Injury Maternal Drugs Affecting Foetus		Selipran (Pravastatin Sodium) Sirdalud (Tizanidine Hydrochloride) Ponstan (Mefenamic Acid) Brufen (Ibuprofen)	SS SS SS SS		
2 MG QD PO						
500 MG QD PO						

Date:05/27/03ISR Number: 4117342-XReport Type:Direct Company Report #CTU 194045
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Nausea		Xanaflex	PS		
25 MG (2 Q						

	Necrosis
8H)	
	Pharmaceutical Product Complaint

Date:05/27/03ISR Number: 4118061-6Report Type:Expedited (15-DaCompany Report #001-0945-950345
Age: Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Discomfort
	Anticonvulsant Drug Level Increased
Other	Asthenia
	Cervical Vertebral Fracture
	Chest Discomfort
	Convulsion
	Deafness
	Deafness Neurosensory
	Dental Plaque
	Difficulty In Walking
	Dizziness
	Dysstasia
	Feeling Abnormal
	Hypoaesthesia

		Injury Joint Stiffness Muscle Spasms	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Paralysis Road Traffic Accident	Consumer Health	Neurontin (Gabapentin)	PS		ORAL
UNKNOWN		Somnolence	Professional				
(UNKNOWN),		Spinal Cord Injury					
ORAL		Tinnitus Tooth Discolouration		Dilantin Kapseals (Phenytoin Sodium)	SS		ORAL
UNKNOWN		Tooth Disorder					
(UNKNOWN),		Visual Acuity Reduced					
ORAL				Zoloft	SS		ORAL
UNKNOWN							
(UNKNOWN),							
ORAL				Lamotrigine (Lamotrigine)	SS		
UNKNOWN	UNKNOWN						
(UNKNOWN),							
UNKNOWN				Topiramate (Topiramate)	SS		
UNKNOWN	UNKNOWN						
(UNKNOWN),							
UNKNOWN				Tizanidine Hydrochloride (Tizanidine Hydrochloride)	SS		ORAL
UNKNOWN							
(UNKNOWN),							
ORAL							

			Cefuroxime Axetil	C		
			Fluoxetine Hydrochloride	C		
			Citalopram Hydrobromide	C		
			Levetiracetam	C		
			Lactulose	C		
			Lorazepam	C		

Date:06/02/03ISR Number: 4122164-XReport Type:Direct Company Report #USP 55884
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Zanaflex	PS	Athena Neurosciences		TABLET	
			Gabitril	SS	Abbott		TABLET	

Date:06/04/03ISR Number: 4124502-0Report Type:Expedited (15-DaCompany Report #ZANA001075
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG BID ORAL	
	Blood Cholesterol Increased		Lortab	C				
	Blood Pressure Increased							
	Cerebrovascular Accident							
	Headache							
	Nausea							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/12/03ISR Number: 4129145-0Report Type:Expedited (15-DaCompany Report #USA-2002-0001447
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Alanine Aminotransferase Increased Anorexia Anxiety Arthralgia Aspartate Aminotransferase Increased Asthenia Back Pain Bile Duct Obstruction Chest Pain Chills Coagulopathy Condition Aggravated Coordination Abnormal Cushingoid Dehydration Disorientation Dizziness Postural Drug Withdrawal Syndrome Duodenal Ulcer Dysphemia Dyspnoea Emotional Distress Fatigue Fear Feeling Cold Hallucination Hepatotoxicity Hyperhidrosis Insomnia Loss Of Consciousness Migraine Muscle Spasms Muscle Twitching Nausea	Consumer Health Professional Other	Oxycontin (Oxycodone Hydrochloride) Cr Zanaflex (Tizanidine Hydrochloride) Depakote (Valproate Semisodium) Motrin Tablet Demerol (Pethidine Hydrochloride) Injectable Phenergan (Promethazine Hydrochloride) Injectable Elavil (Amitriptyline Hydrochloride) Tablet Xanax (Alprazolam) Prednisone (Prednisone) Tablet Zyprexa (Olanzapine) Tablet Skelaxin (Metaxalone) Tablet Robaxin (Methocarbamol) Tablet Bactrium Ds (Sulfamethoxazole, Trimethoprim) Tablet Vicodin Tablet Neurontin (Gabapentin) Tablet	PS SS C C C C C C C C C C C	Wyeth-Ayerst	ORAL ORAL	40 MG, BID, 12 MG, TID,	

Neck Pain	Reglan Tablet	C
Oedema Peripheral	Stadol Ns	
Oral Intake Reduced	(Butorphanol	
Pain	Tartrate) Spray	C
Palpitations	Doxepin (Doxepin)	
Pancreatitis	Tablet	C
Prothrombin Time	Thorazine	
Prolonged	(Chlorpromazine	
Pyrexia	Hydrochloride)	
Road Traffic Accident	Tablet	C
Skin Discolouration	Flexeril	
Tremor	(Cyclobenzaprine	
Vision Blurred	Hydrochloride)	
Vomiting	Tablet	C
	Orphenadrine	
	(Orphenadrine)	
	Tablet	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/17/03ISR Number: 4130541-6Report Type:Direct Company Report #CTU 195994
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasms		Tizanidine Hcl 4 Mg Pharmaceutical Product Teva Brand	PS	Teva		1/2 TAB AT BEDTIME	
	Complaint							
	Tremor							

Date:06/17/03ISR Number: 4131733-2Report Type:Expedited (15-DaCompany Report #USA-2002-001447
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia	Consumer	Oxycontin Tablets Cr	PS		ORAL	40 MG, BID, ORAL	
	Anxiety	Health						
	Arthralgia	Professional	Zanaflex (Tizanidine Hydrochloride) Tablet	SS		ORAL	12 MG, TID, ORAL	
	Bile Duct Obstruction	Other						
	Chest Pain							
	Chills							
	Condition Aggravated							
	Confusional State		Depakote (Valproate Semisodium)	C				
	Coordination Abnormal		Motrin	C				
	Cushingoid		Demerol (Pethidine Hydrochoride) Injectable	C				
	Dehydration							
	Disorientation							
	Dizziness Postural							
	Drug Withdrawal Syndrome		Phenergan "Wyeth Ayerst" (Promethazine Hydrochloride) Injectable	C	Wyeth Ayerst			
	Duodenal Ulcer							
	Dyspnoea							
	Emotional Distress							
	Fear							
	Feeling Of Body Temperature Change		Elavil (Amitriptyline Hydrochloride) Tablet	C				
	Hallucination							
	Hepatitis							
	Hepatotoxicity		Xanax (Alprazolam)	C				
	Hyperhidrosis		Prednisone					

Insomnia	(Prednisone) Tablet	C
Intervertebral Disc Disorder	Zyprexa (Olanzapine) Tablet	C
Irritability	Skelaxin	
Migraine	(Metaxalone) Tablet	C
Muscle Contractions Involuntary	Robaxin (Methocarbamol)	
Muscle Spasms	Tablet	C
Nervousness	Bactrium Ds	
Oedema Peripheral	(Sulfamethoxazole,	
Pain	Trimethoprim) Tablet	C
Palpitations	Vicodin Tablet	C
Pancreatitis	Neurontin	
Prothrombin Time	(Gabapentin) Tablet	C
Prolonged	Reglan Tablet	C
Pyrexia	Stadol Ns	
Road Traffic Accident	(Butorphanol	
Skin Discolouration	Tartrate) Spray	C
Speech Disorder	Doxepin (Doxepin)	
Syncope	Tablet	C
Tremor	Thorazine	
Vision Blurred	(Chlorpromazine	
Visual Disturbance	Hydrochloride)	
	Tablet	C

			Flexeril (Cyclobenzaprine Hydrochloride) Tablet	C			
			Orphenadrine (Orphenadrine)	C			
			Butalbital, Acetaminophen & Caffeine (Butalbital)	C			
			Zithromax (Azithromycin)	C	Pfizer		

Date:06/24/03ISR Number: 4135851-4Report Type:Expedited (15-DaCompany Report #S03-USA-02601-01
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia	Health	Lexapro					
Hospitalization -	Electrocardiogram Qt	Professional	(Escitalopram)	PS		ORAL	10 MG QD PO	
Initial or Prolonged	Prolonged Torsade De Pointes		Zanaflex (Tizanidine Hydrochloride)	SS				
			Zanaflex (Tizanidine Hydrochloride)	SS				

Date:06/24/03ISR Number: 4135866-6Report Type:Expedited (15-DaCompany Report #USA-2002-0001447
Age:38 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Abdominal Pain
Initial or Prolonged	Anorexia
	Anxiety
	Arthralgia
	Asthenia
	Chest Pain
	Chills
	Coagulopathy
	Coordination Abnormal
	Cushingoid
	Dehydration
	Disorientation

Dizziness Postural
Drug Withdrawal Syndrome
Duodenal Ulcer
Dysphemia
Dyspnoea
Emotional Distress
Fatigue
Fear
Feeling Of Body
Temperature Change
Hallucination
Hepatitis
Hepatotoxicity
Hyperhidrosis
Insomnia
Irritability
Migraine
Muscle Contractions

		Involuntary Muscle Spasms Nausea Nervousness	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Oedema Peripheral Pain Palpitations Pancreatitis	Consumer Health Professional Other	Oxycontin Tablets(Oxycodone Hydrochloride) Cr Tablet	PS		ORAL
40 MG, BID,		Pyrexia					
ORAL							
		Road Traffic Accident Sensory Disturbance Skin Discolouration		Zanaflex(Tizandine Hydrochloride) Tablet	SS		ORAL
12 MG, TID,		Syncope					
ORAL							
		Tremor Vision Blurred Vomiting		Depakote (Valproate Semisodium) Tablet	C		
				Motrin Tablet	C		
				Demerol (Pethidine Hydrochloride) Injectable	C		
				Phenergan "Wyeth-Ayerst" (Promethazine Hydrochloride) Injectablet	C		
				Elavil (Amitriptyline Hydrochlride) Tablet	C		
				Xanax (Alprazolam)	C		
				Prednisone (Prednisone) Tablet	C		
				Zyprexa (Lanzapine) Tablet	C		
				Skelanxin (Metaxalone) Tablet	C		
				Robaxin (Methocarbamol) Tablet	C		
				Bactrium Ds (Sulfamethoxazole, Trimethoprim) Tablet	C		
				Vicodin Tablet	C		
				Neurontin (Gabapentin) Tablet	C		

Reglan Tablet	C
Stadol Ns (Butorphanol Tartrate) Spray	C
Doxepin (Doxepin) Tablet	C
Thorazine (Chlorpromazine Hydrochloride) Tabelt	C
Flexeril (Cyclobenzaprine Hydrochloride) Tablet	C
Orphenadrine (Orphenadrine)	C
Butalbital, Acetaminophen & Caffeine	

			(Butalbital)	C		
			Zithromax "Pfizer" (Azithromycin)	C		

Date:06/26/03ISR Number: 4136019-8Report Type:Expedited (15-DaCompany Report #WAES 0306CHE00020
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Health Professional	Vioxx	PS	Merck & Co., Inc	ORAL	6	DAY
			Tramadol Hydrochloride	SS		ORAL	6	DAY
			Tizanidine Hydrochloride	SS		ORAL	6	DAY

Date:07/01/03ISR Number: 4140379-1Report Type:Expedited (15-DaCompany Report #USA-2002-0001447
Age:38 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain
	Anorexia
	Anxiety
	Arthralgia
	Asthenia
	Bile Duct Obstruction
	Chest Pain
	Chills
	Coagulopathy
	Condition Aggravated
	Coordination Abnormal
	Cushingoid
	Dehydration
	Disorientation
	Dizziness Postural
	Drug Withdrawal Syndrome
	Duodenal Ulcer
	Dysphemia
	Dyspnoea
	Emotional Distress
	Fatigue
	Fear

Feeling Cold
Hallucination
Hepatitis
Hyperhidrosis
Insomnia
Irritability
Loss Of Consciousness
Migraine
Muscle Spasms
Muscle Twitching
Nausea
Nervousness
Oedema Peripheral
Pain
Palpitations
Pancreatitis
Pyrexia
Road Traffic Accident
Skin Discolouration
Tremor

Vision Blurred
Vomiting

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer Health Professional Other	Oxycontin Tablets(Oxycodone Hydrochloride) Cr Tablets	PS		ORAL	40 MG, BID, ORAL	
	Zanaflex (Tizanidine Hydrochloride) Tablet	SS		ORAL	12 MG, TID, ORAL	
	Depakote (Valproate Semisodium)Tablet	C				
	Motrin Tablet	C				
	Demerol (Pethidine Hydrochloride) Injectable	C				
	Phenergan "Wyeth-Ayerst" (Promethazine Hydrochloride)Injectable	C				
	Elavil (Amitriptyline Hydrochloride)Tablet	C				
	Xanax (Alprazolam)	C				
	Prednisone (Prednisone)Tablet	C				
	Zyprexa (Olanzapine)Tablet	C				
	Skelaxin (Metaxalone) Tablet	C				
	Robaxin (Methocarbamol) Tablet	C				
	Bactrium Ds (Sulfamethoxazole, Trimethoprim) Tablet	C				
	Vicodin Tablet	C				
	Neurontin (Gabapentin) Tablet	C				

Reglan Tablet	C
Stadol Ns (Butorphanol Tartrate) Spray	C
Doxepin (Doxepin) Tablet	C
Thorazine (Chlorpromazine Hydrochloride) Tablet	C
Flexeril (Cyclobenzaprine Hydrochloride) Tablet	C
Orphenadrine (Orphenadrine)	C
Butalbital, Acetaminophen & Caffeine	

(Butalbital)	C
Zithromax "Pfizer" (Azithromycin)	C
Promethazine (Promethazine)	C
Cipro (Ciprofloxacin Hydrochloride)	C
Zydone	C
Triamterene (Triamterene)	C

Date:07/02/03ISR Number: 4141836-4Report Type:Expedited (15-DaCompany Report #ZANA001086
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Bradycardia Electrocardiogram Abnormal Electrocardiogram Qt Corrected Interval Prolonged Electrocardiogram Qt Prolonged Torsade De Pointes	Health Professional Other	Zanaflex (Tizanidine Hydrochloride) Lexapro (Escitalopram)	PS SS		ORAL	10 MG QD ORAL	

Date:07/10/03ISR Number: 4146698-7Report Type:Expedited (15-DaCompany Report #USA-2002-0001447
Age:38 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Anxiety Arthralgia Bile Duct Obstruction Chills Coordination Abnormal Cryptococcosis Cushingoid Dehydration Disorientation Drug Ineffective Drug Withdrawal Syndrome Duodenal Ulcer Dyspnoea

Emotional Distress
Fear
Hallucination
Hepatic Failure
Hepatitis
Hepatotoxicity
Hyperhidrosis
Hypoaesthesia
Insomnia
Intervertebral Disc
Protrusion
Irritability
Loss Of Consciousness
Migraine
Muscle Spasms
Muscle Twitching
Oedema Peripheral
Pain

		Palpitations Pancreatitis Paraesthesia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Pyrexia Road Traffic Accident Skin Discolouration Speech Disorder	Consumer Health Professional Other	Oxycontin Tablets(Oxycodone Hydrochloride) Cr Tablet	PS		ORAL
40 MG, BID,		Spinal Column Stenosis					
ORAL		Spinal Osteoarthritis Tremor Vision Blurred		Zanaflex(Tizanidine Hydrochloride) Tablet	SS		ORAL
12 MG, TID,							
ORAL							
				Depakote (Valproate Semisodium)	C		
				Motrin	C		
				Demerol (Pethidine Hydrochloride)	C		
				Phenergan Wyeth-Ayerst (Promethazine Hydrochloride)	C		
				Elavil (Amitriptyline Hydrochloride)	C		
				Xanax (Alprazolam)	C		
				Prednisone (Prednisone)	C		
				Zyprexa (Olanzapine)	C		
				Skelaxin (Metaxalone)	C		
				Robaxin (Methocarbamol)	C		
				Bactrium Ds (Sulfamethoxazole, Trimethoprim)	C		
				Vicodin	C		
				Neurontin (Gabapentin)	C		
				Reglan	C		
				Stadol Ns (Butorphanol Tartrate)	C		

Doxepin (Doxepin)	C
Thorazine (Chlorpromazine Hydrochloride)	C
Flexeril (Cyclobenzaprine Hydrochloride)	C
Orphenadrine (Orphenadrine)	C
Butalbital, Acetaminophen & Caffeine (Butalbital)	C
Zithromax Pfizer (Azithromycin)	C
Promethazine (Promethazine)	C
Cipro (Ciprofloxacin Hydrochloride)	C

Zydone	C
Triamterene (Triamterene)	C

Date:07/16/03ISR Number: 4150486-5Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20030701841
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Drug Interaction	Foreign Health Professional	Tramal (Tramadol Hydrochloride)	PS		ORAL	20 GTT, ORAL	
			Vioxx (Rofecoxib)	SS		ORAL	50 MG, ORAL	
			Sirdalud (Tizanidine Hydrochloride)	SS		ORAL	6 MG, 1 IN 1 DAY, ORAL	

Date:07/17/03ISR Number: 4151531-3Report Type:Expedited (15-DaCompany Report #USA-2002-0001447
Age:38 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Anorexia
	Anxiety
	Arthralgia
	Bile Duct Obstruction
	Chest Pain
	Chills
	Coordination Abnormal
	Cushingoid
	Dehydration
	Disorientation
	Dizziness Postural
	Drug Ineffective
	Drug Withdrawal Syndrome
	Duodenal Ulcer
	Dysphemia
	Dyspnoea
	Emotional Distress
	Fatigue
	Fear

Feeling Cold
Gastroenteritis
Cryptococcal
Glucocorticoids Increased
Hallucination
Hepatic Failure
Hepatitis
Hepatotoxicity
Hyperhidrosis
Insomnia
Irritability
Loss Of Consciousness
Migraine
Muscle Spasms
Muscle Twitching
Oedema Peripheral
Oral Intake Reduced
Pain
Palpitations
Pancreatitis
Skin Discolouration

		Spinal Column Stenosis Spinal Osteoarthritis Tremor	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Vision Blurred	Consumer Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL
40 MG, BID,							
ORAL							
				Zanaflex(Tizanidine Hydrochloride)Tablet	SS		ORAL
12 MG, TID,							
ORAL							
				Naprosyn (Naproxen)	C		
				Depakote (Valproate Semisodium)Tablet	C		
				Motrin Tablet	C		
				Demeron (Pethidine Hydrochloride) Injectable	C		
				Phenergan "Wyeth-Ayerst" (Promethazine Hydrochloride)Injectable	C		
				Elavil (Amitriptyline Hydrochloride)	C		
				Xanax (Alprazolam)	C		
				Prednisone (Prednisone)Tablet	C		
				Zyprexa (Olanzaprine)Tablet	C		
				Skelaxin (Metaxalone)Tablet	C		
				Robaxin (Methocarbamol) Tablet	C		
				Bactrium Ds (Sulfamethoxazole, Trimethoprim)Tablet	C		
				Vicodin Tablet	C		
				Neurontin (Gabapentin) Tablet	C		

Reglan Tablet	C
Stadol Ns (Butorphanol Tartrate)Spray	C
Doxepin (Doxepin) Tablet	C
Thorazine (Chlorpromazine Hydrochloride) Tablet	C
Flexeril (Cyclobenzaprine Hydrochloride) Tablet	C
Orphenadrin (Orphenadrine)	C
Butalbital, Acetaminophen & Caffeine	

(Butalbital)	C
Zithromax "Pfizer" (Azithromycin)	C
Promethazine (Promethazine)	C
Cipro (Ciprofloxacin Hydrochloride)	C
Zydone	C
Triamterene (Triamterene)	C

Date:07/21/03ISR Number: 4150972-8Report Type:Expedited (15-DaCompany Report #WAES 0208USA00634
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased		Vioxx	PS	Merck & Co., Inc	ORAL	1	DAY
Hospitalization - Initial or Prolonged	Bradycardia		Zanaflex	SS				
	Chest Pain		Premarin	C				
	Difficulty In Walking		Lidocaine	C				
	Dyspnoea		Alprazolam	C				
	Myocardial Infarction							

Date:07/22/03ISR Number: 4154620-2Report Type:Expedited (15-DaCompany Report #ZANA001087
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Ectopic Pregnancy	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL		
Required ORAL Intervention to Prevent Permanent Impairment/Damage								

Date:07/28/03ISR Number: 4158211-9Report Type:Expedited (15-DaCompany Report #001-0945-950345
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abasia	Consumer	Neurontin					

Initial or Prolonged	Abdominal Discomfort	Health	(Gabapentin)	PS	ORAL
ORAL					
Other	Asthenia	Professional	Dilantin Kapseals		
	Chest Discomfort		(Phenytoin Sodium)	SS	ORAL
ORAL					
	Convulsion		Zoloft (Sertraline)	SS	ORAL
ORAL					
	Deafness		Lamotrigine		
	Dental Plaque		(Lamotrigine)	SS	
	Difficulty In Walking		Topiramate		
	Dizziness		(Topiramate)	SS	
	Hypoaesthesia		Tizanidine		
	Muscle Spasms		Hydrochloride		
	Paralysis		(Tizanidine		
	Road Traffic Accident		Hydrochloride)	SS	ORAL
ORAL					
	Somnolence		Cefuroxime Axetil		
	Spinal Disorder		(Cefuroxime Axetil)	C	
	Tinnitus		Fluoxetine		
	Tooth Discolouration		Hydrochloride		
	Victim Of Abuse		(Fluoxetine		
	Visual Acuity Reduced		Hydrochloride)	C	
			Citalopram		
			Hydrobromide		
			(Citalopram		
			Hydrobromide)	C	

			Levetiracetam (Levetiracetam)	C			
			Lactulose (Lactulose)	C			
			Lorazepam (Lorazepam)	C			

Date:07/29/03ISR Number: 4158537-9Report Type:Expedited (15-DaCompany Report #ZANA001013
Age:49 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Acidosis	Health	Zanaflex (Tizanidine					
Hospitalization -	Acute Respiratory Failure	Professional	Hydrochloride)	PS		ORAL	40 MG DAILY	
Initial or Prolonged	Anuria						ORAL	
	Blood Urine		Toradol (Ketorolac)	SS				
	Cardiac Disorder		Lipitor					
	Coma		(Atorvastatin)	SS				
	Crepitations		Betapace (Sotalol)	C				
	Depressed Level Of Consciousness		Lasix (Furosemide)	C				
	Dialysis		Potassium (Potassium)	C				
	Drug Screen Positive		Synthroid					
	Hyperkalaemia		(Levothyroxine)	C				
	Hypotension		Proventil Inhaler					
	Hypothermia		(Salbutamol)	C				
	Intentional Misuse		Phenergan					
	Nervous System Disorder		(Promethazine)	C				
	Pneumonia Aspiration							
	Respiratory Rate Decreased							
	Rhabdomyolysis							
	Suicide Attempt							

Date:08/04/03ISR Number: 4161088-9Report Type:Direct Company Report #USP 55987
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Zanaflex	PS	Athena Neurosciences	TAB		

			Gabatril	SS	Cephalon	

TAB

Date:08/07/03ISR Number: 4165028-8Report Type:Direct Company Report #CTU 199561
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Abnormal Behaviour		Zanaflex	PS		
	Conversion Disorder					
	Crying					
	Euphoric Mood					
	Excitability					
	Fall					
	Feeling Abnormal					
	Feeling Of Despair					
	Formication					
	Headache					
	Loss Of Consciousness					
	Self-Injurious Ideation					
	Vertigo					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/12/03ISR Number: 4168515-1Report Type:Expedited (15-DaCompany Report #2003AP02691
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Drug Interaction	Foreign	Zestril	PS		ORAL	10 MG DAILY
Intervention to	Hypotension	Health					PO
Prevent Permanent		Professional	Sirdalud	SS		ORAL	2 MG DAILY PO
Impairment/Damage		Other	Senokot	C			
			Magnesium Oxide	C			
			Amikin	C			
			Trandate	C			
			Nimotop	C			
			Well-Well	C			
			Glycerol	C			
			Mucosolvan	C			
			Clincin	C			
			Ofloxacin	C			

Date:08/20/03ISR Number: 4173184-0Report Type:Expedited (15-DaCompany Report #ZANA001090
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Anaphylactic Reaction	Health	Zanaflex (Tizanidine				
Initial or Prolonged		Professional	Hydrochloride)	PS		ORAL	ORAL

Date:08/21/03ISR Number: 4173426-1Report Type:Direct Company Report #CTU 200454
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Abnormal Behaviour		Zanaflex	PS			
	Crying						
	Drug Ineffective						
	Insomnia						
	Pharmaceutical Product Complaint						

Date:09/05/03ISR Number: 4180645-7Report Type:Direct Company Report #CTU 201335
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective Infection Pharmaceutical Product Complaint		Tizanidine (Generic Zanaflex) 4 Mg Q6	PS		ORAL	4 MG Q 6 PO	

Date:09/05/03ISR Number: 4181550-2Report Type:Direct Company Report #CTU 201346
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective Infection Pharmaceutical Product Complaint		Tizanidine (Generic Zanaflex) 4mg Q 6 Hrs	PS		ORAL	4MG Q 6 HRS PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/08/03ISR Number: 4185781-7Report Type:Expedited (15-DaCompany Report #ZANA001092
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse Loss Of Consciousness Respiratory Rate Decreased	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG	

Date:09/11/03ISR Number: 4187786-9Report Type:Direct Company Report #USP 56044
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Hydrocodone /Apap 10/325	PS	Mallinckrodt	TABLET		
			Tizanidine 4 Mg	SS	Teva	TABLET		

Date:09/11/03ISR Number: 4200753-1Report Type:Periodic Company Report #2003163149US
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Failure Acute	Health Professional	Bextra (Valdecoxib) Tablet	PS		ORAL	10 MG, BID;	ORAL 365 DAY
			Glucophage (Metformin Hydrochloride)	SS		ORAL	500 MG, BID;	ORAL
			Valium (Diazepam)	SS		ORAL	UNK, UNK;	ORAL

UNKNOWN	UNK, UNK, UNK	Baclofen (Baclofen)	SS	
UNKNOWN	UNK, UNK, UNK	Diovan (Valsartan)	SS	
UNK, UNK; ORAL		Zanaflex (Tizanidine Hydrochloride)	SS	ORAL
UNKNOWN	UNK, UNK, UNK	Hydrocodone (Hydrocodone)	SS	
250 MG, QD; ORAL		Niacin (Nicotinic Acid)	SS	ORAL
10 UNK, UNK; ORAL		Vasotec (Enalapril Maleate)	SS	ORAL
8 UNK, BID; ORAL		Potassium Chloride (Potassium Chloride)	SS	ORAL
		Tolterodine L-Tartrate	C	
		Ultram (Tramadol Hydrochloride)	C	
		Protonix (Pyritinol)	C	
		Lasix	C	
		Norvasc (Amlodipine Besilate)	C	
		Lortab	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/24/03ISR Number: 4193327-2Report Type:Expedited (15-DaCompany Report #WAES 0309ITA00012
Age:76 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Face Oedema	Health	Vioxx	PS		ORAL	4	DAY
	Tongue Oedema	Professional	Tizanidine Hydrochloride	SS		ORAL	2	DAY
	Urticaria		Cozaar	C	Merck & Co., Inc	ORAL	363	DAY

Date:09/26/03ISR Number: 4199610-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030904656
Age:30 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Literature	Tylox (Oxycodone/ Acetaminophen)					
		Health						
		Professional	Capsules	PS		ORAL	ORAL	
		Distributor	Oxycodone(Oxycodone)	SS				
			Tizanidine (Tizanidine)	SS				

Date:10/06/03ISR Number: 4204974-3Report Type:Expedited (15-DaCompany Report #ZANA001098
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Rebound Hypertension	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	10 MG DAILY	
	Somnolence							
	Tremor						ORAL	
			Vioxx (Rofecoxib)	C				
			Vicodin (Paracetamol)	C				
			Vicodin (Paracetamol)	C				

Date:10/06/03ISR Number: 4204989-5Report Type:Expedited (15-DaCompany Report #ZANA001097
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hallucinations, Mixed	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	8 MG DAILY	ORAL
			Ambien (Zolpidem)	C				

Date:10/10/03ISR Number: 4208761-1Report Type:Expedited (15-DaCompany Report #2003110069
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bladder Spasm Complex Regional Pain Syndrome Condition Aggravated Feeling Abnormal Laboratory Test Abnormal Medication Error Vaginitis Bacterial White Blood Cell Count Decreased	Health Professional	Neurontin (Gabapentin) Zonisamide (Zonisamide) Ropinirole Hydrochloride (Ropinirole Hydrochloride) Tizanidine Hydrochloride (Tizanidine	PS SS SS		ORAL	300 MG (TID), ORAL	

Hydrochloride)	SS
Montelukast Sodium (Montelukast Sodium)	C
All Other Therapeutic Products	C
Multivitiams (Ergocalciferol, Ascorbic Acid, Folic Acid, Thiamine Hydrochloride,	C
Magnesium (Magnesium)	C
Calcium (Calcium)	C
Ascorbic Acid (Ascorbic Acid)	C
Zinc (Zinc)	C
Chromium (Chromium)	C
Policosanol (Policosanol)	C
Lactobacillus Acidophilus (Lactobacillus Acidophilus)	C

Date:10/10/03ISR Number: 4208962-2Report Type:Direct Company Report #CTU 203594
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Generalised Oedema		Zanaflex 2mg	PS		ORAL	2MG-16MG	QHS

Date:10/16/03ISR Number: 4210563-7Report Type:Direct Company Report #CTU 203921
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pharmaceutical Product		Tizanidine 2 Mg	PS			2 MG	BID
	Complaint		Baclofen	C				

Retching
Vomiting

Date:10/17/03ISR Number: 4214030-6Report Type:Expedited (15-DaCompany Report #ZANA001013
Age:49 YR Gender:Female I/FU:F

Outcome	PT
Life-Threatening	Acidosis
Hospitalization - Initial or Prolonged	Acute Respiratory Failure
	Anuria
	Blood Creatine Phosphokinase
	Blood Urine
	Cardiac Disorder
	Coma
	Crackles Lung
	Depressed Level Of Consciousness
	Dyspnoea
	Haemodynamic Instability

		Hyperkalaemia Hypotension Hypothermia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Overdose Pneumonia Aspiration Renal Failure Acute	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
40 MG DAILY							
		Rhabdomyolysis					
ORAL							
		Suicide Attempt Urine Abnormality		Toradol (Ketorolac)	SS		
				Lipitor (Atorvastatin)	SS		
				Betapace (Sotalol)	C		
				Lasix (Furosemide)	C		
				Potassium (Potassium)	C		
				Synthroid (Levothyroxine)	C		
				Proventil Inhaler (Salbutamol)	C		
				Phenergan (Promethazine)	C		

Date:10/21/03ISR Number: 4216029-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030904656
Age:30 YR Gender:Male I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Alcohol Use Blood Bicarbonate Decreased	Literature Health Professional	Tylox (Oxycodone/Acetamino phen) Capsules	PS		ORAL
ORAL							
		Blood Creatine Phosphokinase Increased Blood Creatine Phosphokinase Mb Increased Blood Ph Decreased Blood Potassium Increased Blood Pressure Systolic Increased Body Temperature Increased Cardio-Respiratory Arrest	Distributor	Oxycodone (Oxycodone)	SS		
				Tizanidine (Tizanidine)	SS		
				Ethanol (Ethanol)	SS		
				Corticosteroid (Corticosteroids)	SS		

Coma
Diabetes Insipidus
Heart Rate Increased
Hypotension
Muscle Rigidity
Nausea
Overdose
Po2 Increased
Posturing
Tachycardia
Vomiting

Date:10/22/03ISR Number: 4215284-2Report Type:Direct Company Report #CTU 204295
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse		Zanaflex	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/22/03ISR Number: 4217003-2Report Type:Expedited (15-DaCompany Report #KII-2003-0002484
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Multiple Drug Overdose Suicide Attempt Tachycardia	Health Professional	Oxycodone Hcl Ir Capsules (Oxycodone Hydrochloride) Ir Capsule	PS		ORAL	5 MG, SEE TEXT,	ORAL
			Ms Contin Tablets(Morphine Sulfate) Cr Tablet	SS		ORAL	40 MG, ORAL	
			Zanaflex (Tizanidine Hydrochloride)	SS		ORAL	SEE TEXT,	ORAL

Date:10/27/03ISR Number: 4221012-7Report Type:Expedited (15-DaCompany Report #ZANA001103
Age:48 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Multiple Drug Overdose	Literature Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS				
			Propoxyphene/Acetaminophen (Dextropropoxyphene)	SS				
			Venlafaxine (Venlafaxine)	SS				

Date:10/30/03ISR Number: 4223831-XReport Type:Expedited (15-DaCompany Report #ZANA001106
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Angioneurotic Oedema Hypersensitivity	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS			12 TO 24 MG	

Pharmaceutical Product
DAILY
Complaint

Date:10/30/03ISR Number: 4223835-7Report Type:Expedited (15-DaCompany Report #ZANA001105
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Drug Withdrawal Syndrome Medication Error	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	48 MG DAILY
			Baclofen (Baclofen)	C		ORAL	

Date:10/30/03ISR Number: 4223838-2Report Type:Expedited (15-DaCompany Report #ZANA001104
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Pressure Increased Myocardial Infarction	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2-5 MG DAILY
			Vioxx (Rofecoxib)	C		ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/30/03ISR Number: 4223990-9Report Type:Expedited (15-DaCompany Report #S03-USA-02601-01
Age:49 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia	Health	Lexapro					
Hospitalization -	Electrocardiogram Qt	Professional	(Escitalopram)	PS		ORAL	10 MG QD PO	
Initial or Prolonged	Prolonged		Zanaflex (Tizanidine					
	Torsade De Pointes		Hydrochloride)	SS				
			Zanaflex (Tizanidine					
			Hydrochloride)	SS				

Date:10/30/03ISR Number: 4224110-7Report Type:Expedited (15-DaCompany Report #OXYT000102
Age:30 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature	Roxicodone					
	Multiple Drug Overdose	Health	(Oxycodone Hcl)	PS				
		Professional	Zanaflex					
			(Tizanidine					
			Hydrochloride)	SS				
			Acetaminophen/Oxycod					
			one					
			(Acetaminophen/Oxyco					
			done)	SS				

Date:10/30/03ISR Number: 4224269-1Report Type:Expedited (15-DaCompany Report #KII-2003-0003787
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error	Health	Oxycontin Tablets					
	Respiratory Rate	Professional	(Oxycodone					
	Increased		Hydrochloride) Cr					
			Tablet	PS		ORAL	SEE IMAGE	1 DAY
			Zaroxolyn					
			(Metolazone)	SS		ORAL	7.5 MG, SEE	

TEXT, ORAL

Lipitor (Atorvastatin)	SS	ORAL	10 MG, SEE TEXT, ORAL
Slow-Mag (Magnesium Chloride Anhydrous)	SS	ORAL	SEE TEXT, ORAL
Aldactone (Spironolactone)	SS	ORAL	25 MG, SEE TEXT, ORAL
Oscal (Calcium Carbonate)	SS	ORAL	500 MG, SEE TEXT, ORAL
Cleocin (Clindamycin Hydrochloride)	SS	ORAL	150 MG, SEE TEXT, ORAL
K-Dur (Potassium Chloride)	SS	ORAL	20 MEQ, SEE TEXT, ORAL
Zanaflex (Tizanidine Hydrochloride)	SS	ORAL	4 MG, SEE TEXT, ORAL
Lasix (Furosemide)	SS	ORAL	160 MG, SEE TEXT, ORAL
Atarax (Hydroxyzine			

			Hydrochloride)	SS	ORAL
25 MG, SEE					
TEXT, ORAL					
			Skelaxin (Metaxalone)	SS	ORAL
400 MG, SEE					
TEXT, ORAL					
			Premarin (Estrogens Conjugated)	SS	ORAL
1.25 MG, SEE					
TEXT, ORAL					
			Prozac (Fluoxetine Hydrochloride)	SS	ORAL
10 MG, SEE					
TEXT, ORAL					
			Zantac (Ranitidine Hydrochloride)	SS	ORAL
150 MG, SEE					
TEXT, ORAL					
			Colace (Docusate Sodium)	SS	ORAL
100 MG, SEE					
TEXT, ORAL	1	DAY			
			Dilantin (Phenytoin Sodium)	SS	
100 MG	1	DAY			
			Valium (Diazepam)	SS	
5 MG	1	DAY			
			Cardizem (Diltiazem Hydrochloride)	SS	
300 MG	1	DAY			
			Antivert (Meclozine Hydrochloride, Nicotinic Acid)	SS	
20 MG	1	DAY			
			Niferex (Polysaccharide-Iron Complex)	SS	
150 MG	1	DAY			
			Lovenox (Heparin-Fraction,		

Sodium Salt) SS

SUBCUTANEOUS 30 MG,

SUBCUTANEOUS 1 DAY

Date:10/31/03ISR Number: 4224878-XReport Type:Expedited (15-DaCompany Report #KII-2003-0004112
Age:43 YR Gender:Male I/FU:I

Outcome	PT
Death	Acid Base Balance
Life-Threatening	Abnormal
Hospitalization -	Blood Glucose Abnormal
Initial or Prolonged	Blood Lactic Acid
Other	Increased
	Blood Pressure Decreased
	Blood Pressure Increased
	Body Temperature
	Increased
	Bradycardia
	Cardiac Arrest
	Coma
	Depression
	Electrocardiogram Qt
	Corrected Interval
	Prolonged
	Electroencephalogram
	Abnormal
	Heart Rate Increased
	Miosis
	Multiple Drug Overdose
	Muscle Twitching
	Mydriasis
	Posturing

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pupil Fixed Respiratory Rate Decreased							
	Respiratory Rate Increased	Health Professional Other	Oxycontin Cr	PS			400 MG	
			Methadone (Methadone)	SS			200 MG	
			Trazodone(Trazodone)	SS			20 MG	
			Gabapentin(Gabapentin)	SS			1 MG	
			Quetiapine(Quetiapine)	SS			4 MG, ORAL	
			Citalopram(Citalopram)	SS			150 MG	
			Clonazepam (Clonazepam)	SS			10 MG	
			Zanaflex(Tizanidine Hydrochloride)	SS		ORAL	50 MG	
			Bupropion(Amfebutamone)	SS				
			Cyclobenazprine(Cyclobenzaprine)	SS				
			Amitriptyline(Amitriptyline)	SS				
			Estalopram()	SS				

Date:11/04/03ISR Number: 4227704-8Report Type:Direct Company Report #CTU 205236
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zanaflex 4mg	PS			2 TID	
	Pharmaceutical Product Complaint							

Date:11/06/03ISR Number: 4228244-2Report Type:Direct Company Report #CTU 205409
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour		Zanaflex	PS		ORAL	4 MG BID PO	
	Confusional State		Aciphex	C				
	Crying		Trazodone	C				
	Feeling Abnormal		Paxil	C				
	Paranoia		Zyprexa	C				
	Urinary Tract Infection		Atenolol	C				
			Ms Contin	C				
			Neurontin	C				

Date:11/07/03ISR Number: 4232128-3Report Type:Expedited (15-DaCompany Report #A01200304976
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Health	Clopidogrel Sulfate	PS		ORAL	75 MG QD, ORAL	
	Aspartate Aminotransferase Increased	Professional Other	Stilnox - (Zolpidem)	SS		ORAL	10 MG QD, ORAL	
	Stevens-Johnson Syndrome		Phenhydan - (Phenytoin)	SS		ORAL	300 MG QD, ORAL	
	Toxic Epidermal Necrolysis		Ritrovil -					

				(Lonazepam)	SS			
INTRAVENOUS	0.5 MG,							
INTRAVENOUS								
NOS	1	DAY						
				Frisium - (Clobazam)	SS			ORAL
20 MG QD,								
ORAL	2	DAY						
				Clont - (Metronidazole)	SS			ORAL
500 MG QD,								
ORAL	9	DAY						
				Klacid -(Clarithromycin)	SS			ORAL
500 MG QD,								
ORAL	9	DAY						
				Pantozol - (Pantoprazole Sodium)	SS			ORAL
40 MG QD,								
ORAL	9	DAY						
				Sirdalud - (Tizanidine Hydrochloride)- Unknown	SS			ORAL
4 MG QD ORAL								
				Metronidazole	C			
				Clarithromycin	C			
				Pantoprazole	C			

Date:11/10/03ISR Number: 4232803-0Report Type:Direct Company Report #CTU 205667
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Pressure Decreased		Zanaflex	PS				
ANY								
	Loss Of Consciousness							

Date:11/10/03ISR Number: 4233547-1Report Type:Expedited (15-DaCompany Report #200306791
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Failure	Foreign	Unspecified Paracetamol Product					
Required	Hepatic Necrosis	Literature						
	Hepatic Steatosis	Other	(Paracetamol)	PS		ORAL	35 G PO	
Intervention to Prevent Permanent Impairment/Damage	Nausea		Tizanidine	SS		ORAL	PO	
	Overdose		Alcohol	SS				
	Vomiting							

Date:11/13/03ISR Number: 4236035-1Report Type:Expedited (15-DaCompany Report #KII-2003-0005736
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Screen Positive	Study	Morphine Sulfate(Similar To Nda 19-516)(Morphine Sulfate) Unknown	PS				
Other	Hyperhidrosis	Health Professional Other						
	Hyperpyrexia							
	Medication Error		Soma (Carisoprodol)	SS				
	Multiple Drug Overdose		Valium(Diazepam)	SS				
	Sinus Tachycardia		Ace Inhibitor Nos()	SS				
	Somnolence		Antihistamine()	SS				
	White Blood Cell Count		Nortriptyline(Nortriptyline)	SS				
			Biguandes()	SS				
			Anticonvulsant()	SS				
			Ssri()	SS				
			Acetaminophen(Parace					

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

Date:11/14/03ISR Number: 4235450-XReport Type:Direct Company Report #CTU 206114
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Insomnia		Zanaflex 2 Mg Par	PS	Par	ORAL	1-2 TABLET 2	
	Restlessness						HRS B4 BE	
							ORAL	

Date:11/18/03ISR Number: 4237313-2Report Type:Direct Company Report #CTU 206352
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zanaflex 4 Mg One					
	Pharmaceutical Product		Tid	PS			4 MG ONE TID	
	Complaint						BY MOUTH	

Date:11/19/03ISR Number: 4238269-9Report Type:Direct Company Report #CTU 206452
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dizziness		Zanaflex 4 Mg	PS		ORAL	4 MG PO QHS	
Hospitalization -	Heart Rate Decreased						[LESS THAN 1	
Initial or Prolonged	Loss Of Consciousness						WEEK]	

Date:11/26/03ISR Number: 4241958-3Report Type:Expedited (15-DaCompany Report #PHBS2003JP12830
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Deafness		Diovan	PS	Novartis Sector: Pharma	ORAL		
			Ternelin	SS		ORAL		
			Gasmotin	C		ORAL		
			Norvasc /Den/	C				

Date:11/28/03ISR Number: 4245360-XReport Type:Expedited (15-DaCompany Report #2003110069
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bladder Spasm Feeling Abnormal Nervousness Vaginitis Bacterial White Blood Cell Count Decreased	Health Professional	Neurontin (Gabapentin)	PS		ORAL	300 MG (TID), ORAL	
			Zonisamide (Zonisamide)	SS				
			Ropinirole Hydrochloride (Ropinirole Hydrochloride)	SS				

Tizanidine Hydrochloride (Tizanidine Hydrochloride)	SS
Montelukast Sodium (Montelukast Sodium)	C
All Other Therapeutic Products	C
Multivitamins (Ergocalciferol, Ascorbic Acid, Folic Acid, Thiamine Hydrochloride,	C
Magnesium (Magnesium)	C
Calcium (Calcium)	C
Ascorbic Acid (Ascorbic Acid)	C
Zinc (Zinc)	C
Chromium (Chromium)	C
Policosanol (Policosanol)	C
Lactobacillus Acidophilus (Lactobacillus Acidophilus)	C

Date:12/02/03ISR Number: 4244848-5Report Type:Direct Company Report #CTU 207204
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Dreams		Tizanidine Hcl					
	Chest Discomfort		(Zanaflex)	PS			2 MG Q HS,	
	Convulsion						TAPERED UP TO	
	Depression						8 MG/ SEE B5	6 MON
	Dizziness		Lipitor	C				
	Eye Pain		Vioxx	C				
	Hyperhidrosis		Toprol Xl	C				
	Movement Disorder		Aspirin	C				
	Muscle Spasms		Hctz	C				
	Muscular Weakness		Clarinex	C				

Paraesthesia
Paralysis
Rash
Somnolence
Syncope
Tinnitus
Tremor
Vision Blurred
Visual Disturbance

Date:12/02/03ISR Number: 4246497-1Report Type:Expedited (15-DaCompany Report #200306791
Age:46 YR Gender:Female I/FU:F

Outcome
Hospitalization -
Initial or Prolonged
Required
Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dialysis	Foreign	Unspecified					
	Hepatic Necrosis	Literature	Paracetamol Product					
	Hepatic Steatosis	Other	(Paracetamol)	PS		ORAL	35 G PO	
	Nausea		Tizanidine	SS		ORAL	PO	
	Overdose		Alcohol	SS				
	Suicide Attempt							
	Vomiting							

Date:12/17/03ISR Number: 4254974-2Report Type:Expedited (15-DaCompany Report #PERC20030095
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alcohol Use	Literature	Percocet	PS	Endo	ORAL	PO	
Life-Threatening	Blood Creatine	Health	Oxycodone	SS		ORAL	PO	
Hospitalization -	Phosphokinase Increased	Professional	Tizanidine	SS		ORAL	PO	
Initial or Prolonged	Blood Creatine		Ethanol	SS		ORAL	PO	
	Phosphokinase Mb		Corticosteroid	SS			ONCE INJ	
	Increased							
	Blood Potassium Increased							
	Blood Pressure Systolic							
	Increased							
	Body Temperature							
	Increased							
	Cardiac Arrest							
	Coma							
	Diabetes Insipidus							
	Hypotension							
	Muscle Rigidity							
	Nausea							
	Respiratory Arrest							
	Tachycardia							
	Troponin Increased							
	Vomiting							

Date:12/17/03ISR Number: 4254987-0Report Type:Expedited (15-DaCompany Report #ZANA001112
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Interaction	Health	Zanaflex (Tizanidine					
Other	Haemolysis	Professional	Hydrochloride)	PS		ORAL	36 MG	ORAL
			Baclofen (Baclofen)	SS				
			Neurontin (Gabapentin)	C				
			Ditropan (Oxybutynin)	C				
			Prednisone (Prednisone)	C				

Date:12/17/03ISR Number: 4268306-7Report Type:Periodic Company Report #USA-2003-0006530
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source
Death	Accidental Overdose	Health
	Multiple Drug Overdose	Professional
		Company

Representative
Other

Product	Role	Manufacturer	Route	Dose	Duration
Oxycontin Tablets (Oxycodone Hydrochloride)	PS			20 MG, Q12H	
Reglan (Metoclopramide)	SS			10 MG, QID	PRN
Lexapro (Citalopram)	SS			10 UNK, DAILY	
Percocet (Paracetamol, Oxycodone Hydrochloride)	SS			5 MG, Q4H PRN	
Zantac (Ranitidine Hydrochloride)	SS			300 MG, BID,	PRN
Zanaflex (Tizanidine Hydrochloride)	SS				
Flagyl (Metronidazole)	SS			500 MG, BID	

Date:12/17/03ISR Number: 4271088-6Report Type:Periodic Company Report #KII-2003-0004072
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Bradycardia Hypertension Multiple Drug Overdose	Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride)	PS		ORAL		
			Tizanidine (Tizanidine)	SS		ORAL	2 MG, SEE TEXT, ORAL	

			Clonazepam (Clonazepam)	SS		ORAL
ORAL						

Date:12/17/03ISR Number: 4271091-6Report Type:Periodic Company Report #KII-2003-0003784
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Multiple Drug Overdose	Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride)	PS		
Other SEE TEXT						
			Flexeril (Cyclobenzaprine Hydrochloride)	SS		
SEE TEXT						
			Tizanidine (Tizandine)	SS		
SEE TEXT						

Date:12/22/03ISR Number: 4256059-8Report Type:Direct Company Report #CTU 208553
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Asthenia		Zanaflex 16 Mg Po Bid	PS		ORAL
16 MG PO BID	Dysarthria					
	Swollen Tongue					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/22/03ISR Number: 4256944-7Report Type:Direct Company Report #CTU 208592
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Activities Of Daily		Tizanidine (Athema					
Other	Living Impaired		Neurosuane)	PS	Athena Neuroscience			1 MON
	Anxiety							
	Depression							
	Drug Ineffective							
	Pain							
	Pharmaceutical Product Complaint							

Date:12/23/03ISR Number: 4258022-XReport Type:Expedited (15-DaCompany Report #200310834BCA
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Apnoea	Foreign	Cipro (Ciprofloxacin					
Other	Blood Pressure Decreased	Health	Hydrochloride)	PS		ORAL	500 MG, BID,	
	Blood Pressure Increased	Professional					ORAL	
	Coma	Other	Tizanidine	SS			SEE IMAGE	
	Dehydration		Fucidine	C				
	Heart Rate Decreased		Altace	C				
	Heart Rate Increased		Metoprolol	C				
	Hypoventilation		Hydrochlorothiazide	C				
	Pallor		Zanaflex	C				
	Respiratory Depression		Ramipril	C				
			Clindamycin	C				

Date:12/29/03ISR Number: 4261566-8Report Type:Expedited (15-DaCompany Report #FI-JNJFOC-20031204242
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression	Foreign	Tramal					
	Psychiatric Symptom	Health	(Tramadol					
		Professional	Hydrochloride)	PS				

			Sirdalud (Tizanidine Hydrochloride)	SS		

Date:12/30/03ISR Number: 4262147-2Report Type:Expedited (15-DaCompany Report #ZANA001116
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Insipidus	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY	ORAL
			Copaxone (Glatiramer)	C				

Date:12/30/03ISR Number: 4262511-1Report Type:Expedited (15-DaCompany Report #ZANA001117
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source
Other	Bradycardia	Foreign
	Fatigue	Health Professional
	Oxygen Saturation Decreased	Company Representative
	Palpitations	

Other

Dose	Duration	Product	Role	Manufacturer	Route
2 MG DAILY		Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
ORAL		Atenolol (Atenolol)	C		
		Aspirine (Acetylsalicylic Acid)	C		
		Nifedipine (Nifedipine)	C		
		Simvastatin (Simvastatin)	C		
		Aspirine (Acetylsalicylic Acid)	C		
		Methocarbamol (Methocarbamol)	C		

Date:01/02/04ISR Number: 4263784-1Report Type:Expedited (15-DaCompany Report #ZANA001112
Age:32 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Glucose-6-Phosphate Dehydrogenase Deficiency	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	36 MG ORAL	
Other	Haemolysis		Baclofen (Baclofen)	SS				
	Refusal Of Treatment By Patient		Neurontin (Gabapentin)	C				
			Ditropan (Oxybutynin)	C				
			Predenisone (Prednisone)	C				

Date:01/07/04ISR Number: 4267039-0Report Type:Expedited (15-DaCompany Report #ZANA001119
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acinetobacter Infection	Literature	Zanaflex (Tizanidine					
	Asthenia	Health	Hydrochloride)	PS				
	Catheter Related	Professional	Ms Contin (Morphine)	SS		ORAL	90 MG DAILY	
	Infection					ORAL		
	Constipation							
	Faecal Incontinence							
	Myelitis Transverse							
	Paraesthesia							
	Urinary Incontinence							

Date:01/07/04ISR Number: 4267041-9Report Type:Expedited (15-DaCompany Report #ZANA001118
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Catheter Related	Literature	Zanaflex (Tizanidine					
	Infection	Health	Hydrochloride)	PS		ORAL	4 TO 8 MG PO	
	Dependence	Professional					AT BEDTIME	
						ORAL		
			Ms Contin (Morphine					
			Sulfate)	SS		ORAL	90 MG DAILY	

ORAL

Date:01/14/04ISR Number: 4270761-3Report Type:Expedited (15-DaCompany Report #JP-ROCHE-353443
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alanine Aminotransferase	Health	Panaldine	PS	Roche	ORAL		
Hospitalization - Initial or Prolonged	Increased	Professional	Euglucon	SS	Roche	ORAL		
	Aspartate		Basen	SS		ORAL		
	Aminotransferase		Ternelin	SS		ORAL		
	Increased		Adalat L	C		ORAL		
	Hepatic Function Abnormal		Takepron	C		ORAL		
	Lymphocyte Stimulation		Cardenalin	C		ORAL		
	Test Positive		Caltan	C		ORAL		
	Pneumonia							

Date:01/23/04ISR Number: 4279306-5Report Type:Expedited (15-DaCompany Report #ZANA001125
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Literature	Zanaflex (Tizanidine					
	Overdose	Health	Hydrochloride)	PS		ORAL	120 MG ORAL	
		Professional						

Date:01/23/04ISR Number: 4279318-1Report Type:Expedited (15-DaCompany Report #ZANA001124
Age:2 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Literature	Zanaflex (Tizanidine					
	Overdose	Health	Hydrochloride)	PS		ORAL	16 MG ORAL	
		Professional						

Date:01/23/04ISR Number: 4279321-1Report Type:Expedited (15-DaCompany Report #ZANA001123
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension Overdose	Literature Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	28 MG ORAL	

Date:01/26/04ISR Number: 4278949-2Report Type:Expedited (15-DaCompany Report #JP-ROCHE-353443
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Dialysis Hepatic Enzyme Increased Hepatic Function Abnormal Lymphocyte Stimulation Test Positive Pneumonia	Health Professional	Panaldine Euglucon Basen Ternelin Adalat L Takepron Cardenalin Caltan	PS SS SS SS C C C C	Roche Roche	ORAL ORAL ORAL ORAL ORAL ORAL ORAL ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/26/04ISR Number: 4278992-3Report Type:Expedited (15-DaCompany Report #WAES 0306CHE00020
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bradycardia	Health	Vioxx	PS	Merck & Co., Inc	ORAL		6 DAY
Initial or Prolonged		Professional	Tizanidine Hydrochloride	SS		ORAL		6 DAY
			Tramadol Hydrochloride	SS		ORAL		6 DAY

Date:01/27/04ISR Number: 4280390-3Report Type:Expedited (15-DaCompany Report #200322722GDDC
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alanine Aminotransferase Increased	Foreign	Glibenclamide (Euglucon) Tablets	PS		ORAL	0.625 MG QD	
Hospitalization -	Aspartate Aminotransferase Increased	Health						
Initial or Prolonged	Blood Alkaline Phosphatase Increased	Professional						
	Blood Bilirubin Increased	Other	Ticlopidine Hydrochloride (Panaldine)	SS		ORAL	200 MG/DAY PO	11 WK
	Dialysis		Voglibose (Basen)	SS		ORAL	PO	28 WK
	Hepatic Function Abnormal		Tizanidine Hydrochloride (Ternelin)	SS		ORAL	PO	19 WK
	Lymphocyte Stimulation Test Positive		Nifedipine (Adalat L)	C				
	Pneumonia		Lansoprazole (Takepron)	C				
			Doxazosin Mesilate (Cardenalin)	C				
			Calcium Carbonate	C				

Date:01/27/04ISR Number: 4280642-7Report Type:Expedited (15-DaCompany Report #ZONI001246
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Carotid Artery Stenosis	Health	Zonegran					
Hospitalization -	Cerebrovascular Accident	Professional	(Zonisamide)	PS		ORAL	200 MG DAILY	
Initial or Prolonged	Palpitations							
			Zanaflex (Tizanidine Hydrochloride)	SS		ORAL	2 MG DAILY	
			Vioxx (Rofecoxib)	C		ORAL		
			Nexium (Esomeprazole Magnesium)	C				
			Skelaxin (Metaxalone)	C				
			Ultracet (Tramadol Hydrochloride/Acetaminophen)	C				
			Ketoprofen (Ketoprofen)	C				

Date:01/28/04ISR Number: 4280419-2Report Type:Direct Company Report #CTU 210961
Age: Gender:Male I/FU:I

Outcome	PT
	Irritability
	Pharmaceutical Product

Complaint

		Report Source	Product	Role	Manufacturer	Route	Dose	Duration
			Generic Zanaflex	PS		ORAL	6 MG PO QID	

Date:01/28/04ISR Number: 4281937-3Report Type:Expedited (15-DaCompany Report #ZANA001121
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Apnoea	Foreign	Zanaflex (Tizanidine					
Required	Cellulitis	Health	Hydrochloride)	PS		ORAL	16 MG/DAY	
Intervention to	Coma	Professional				ORAL		
Prevent Permanent	Dehydration		Ramipril (Ramipril)	C				
Impairment/Damage	Hypotension		Metoprolol					
	Pallor		(Metoprolol)	C				
	Respiratory Arrest		Fucidine (Fusidate					
	Urinary Tract Infection		Sodium)	C				
			Clindamycin					
			(Clindamycin)	C				

Date:01/28/04ISR Number: 4281939-7Report Type:Expedited (15-DaCompany Report #ZANA001122
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Apnoea	Foreign	Zanaflex (Tizanidine					
Hospitalization -	Blood Pressure Increased	Health	Hydrochloride)	PS		ORAL	16 MG/DAY	
Initial or Prolonged	Bradycardia	Professional				ORAL		
	Coma		Ramipril (Ramipril)	C				
	Pallor		Metoprolol					
			(Metoprolol)	C				
			Fucidin (Fusidic					
			Acid)	C				
			Clindamycin					
			(Clindamycin)	C				

Date:01/29/04ISR Number: 4283003-XReport Type:Expedited (15-DaCompany Report #ZANA001126
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperreflexia Labile Blood Pressure	Literature Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL		
			Baclofen (Baclofen0	C				
			Senna Concentrate (Senna Concentrate)	C				
			Gabapentin (Gabapentin)	C				
			Calcium Carbonate (Calcium Carbonate)	C				
			Glyburide (Glibenclamide)	C				
			Fluoxetine (Fluoxetine)	C				
			Lovastatin (Lovastatin)	C				
			Aspirin "Bayer" (Acetylsalicylic Acid)	C				
			Ascorbic Acid					

			(Ascorbic Acid)	C		
			Multi-Vitamins (Multi-Vitamins)	C		

Date:01/29/04ISR Number: 4283074-0Report Type:Expedited (15-DaCompany Report #ZANA001127
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	ORAL	
	Drug Interaction		Gabitril (Tiagabine)	SS		ORAL	12 MG QD ORAL	
	Dyskinesia	Other	Klonopin (Clonazepam)	C				
	Extrapyramidal Disorder							

Date:01/30/04ISR Number: 4283016-8Report Type:Expedited (15-DaCompany Report #WAES 0401USA01663
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dizziness		Vioxx	PS	Merck & Co., Inc	ORAL	1	DAY
	Dry Mouth		Zanaflex	SS				
	Hyperhidrosis		Ultracet	C				
	Hypotension							
	Somnolence							
	Speech Disorder							
	Vision Blurred							

Date:01/30/04ISR Number: 4289028-2Report Type:Periodic Company Report #ZANA001044
Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test Abnormal	Health Professional	Zanaplex (Tizanidine Hydrochloride)	PS		ORAL	8 MG DAILY	
							ORAL	
			Neurontin					

(Gabapentin)	C
Albuterol (Salbutamol)	C
Ativan (Lorazepam)	C
Senokot (Senna)	C
Diastat (Pectin)	C
Robitussin (Guaifenesin)	C
Synthroid (Levothyroxine Sodium)	C
Vitamin C (Ascorbic Acid)	C
Magnesium (Magnesium Oxide)	C
Keppra (Levetiracetam)	C
Dulcolax (Bisacodyl)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/03/04ISR Number: 4285181-5Report Type:Direct Company Report #CTU 211400
Age:21 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alcohol Use		Paroxetine	PS		ORAL	1200 MG	PO
Hospitalization - Initial or Prolonged	Intentional Misuse							
	Suicide Attempt		Zanaflex	SS				
			Rum	SS				

Date:02/04/04ISR Number: 4286811-4Report Type:Expedited (15-DaCompany Report #200322722GDDC
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alanine Aminotransferase Increased	Foreign Health Professional	Glibenclamide (Euglucon) Tablets	PS		ORAL	0.625 MG QD	
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased	Other	Ticlopidine Hydrochloride (Panaldine)	SS		ORAL	200 MG/DAY PO	78 DAY
	Hepatic Function Abnormal		Voglibose (Basen)	SS		ORAL	PO	199 DAY
	Lymphocyte Stimulation		Tizanidine Hydrochloride (Ternelin)	SS		ORAL	PO	138 DAY
	Test Positive		Nifedipine (Adalat L)	C				
	Pneumonia		Lansoprazole (Takepron)	C				
			Doxazosin Mesilate (Cardenalin)	C				
			Calcium Carbonate	C				

Date:02/12/04ISR Number: 4296016-9Report Type:Expedited (15-DaCompany Report #ZONI001246
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia	Health	Zonegran					
Hospitalization -	Balance Disorder	Professional	(Zonisamide)	PS		ORAL	200 MG DAILY	
Initial or Prolonged	Carotid Artery Stenosis	Company					ORAL	
	Cerebrovascular Accident	Representative	Zanaflex (Tizanidine					
	Coordination Abnormal		Hydrochloride)	SS		ORAL	2 MG DAILY	
	Dysarthria						ORAL	
	Monoplegia		Vioxx (Rofecoxib)	C				
	Nausea		Nexium (Esomeprazole					
	Palpitations		Magnesium)	C				
			Skelaxin					
			(Metaxalone)	C				
			Ultracet (Tramadol					
			Hydrochloride/Acetam					
			inophen)	C				
			Ketoprofen					
			(Ketoprofen)	C				

Date:02/17/04ISR Number: 4299044-2Report Type:Expedited (15-DaCompany Report #ZANA001129
Age:61 YR Gender:Female I/FU:I

Outcome	PT
Death	Myocardial Infarction
	Rash
	Urticaria

Ventricular Fibrillation

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Foreign Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY	
		Distributor	Vancocyn (Vancomycin)	C			ORAL	
			Flagyl (Metronidazole)	C				
			Tylenol (Acetaminophen)	C				
			Neurontin (Gabapentin)	C				
			Ativan (Lorazepam)	C				
			Valium (Diazepam)	C				
			Diovol (Magnesium Hydroxide)	C				
			Lovenox (Enoxaparin)	C				

Date:02/24/04ISR Number: 4303810-4Report Type:Direct Company Report #CTU 213047
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Dyspepsia Nausea Pharmaceutical Product Complaint Rash		Tizanidine	PS			4 MG 1-1 1/2 Q4-6 HR	

Date:02/24/04ISR Number: 4304359-5Report Type:Expedited (15-DaCompany Report #ZANA001130
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Increased	Consumer	Zanaflex (Tizanidine					

	Chest Pain		Hydrochloride)	PS			ORAL
18 MG DAILY							
	Coma						
ORAL							
	Convulsion		Accupril (Quinapril				
	Dizziness		Hydrochloride)	C			
	Dyspepsia		Vioxx (Rofecoxib)	C			
	Epistaxis		Zocor (Simvastatin)	C			
	Feeling Abnormal						
	Hyperacusis						
	Hypoaesthesia						
	Loss Of Consciousness						
	Nasal Dryness						
	Paraesthesia						
	Rhinorrhoea						

Date:02/25/04ISR Number: 4304819-7Report Type:Direct Company Report #CTU 213181
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia		Tizanidine 52mg	PS		ORAL	1/2 PO BID	
	Fatigue						AND 1 PO QHS	
	Feeling Abnormal							
	Pharmaceutical Product Complaint							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/02/04ISR Number: 4310883-1Report Type:Direct Company Report #CTU 213607
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia		Tizanidine 2mg	PS		ORAL	1/2 PO BID	
	Fatigue						AND 1 PO QHS	
	Feeling Abnormal							
	Pharmaceutical Product Complaint							

Date:03/02/04ISR Number: 4310887-9Report Type:Direct Company Report #CTU 213609
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective		Zanaflex 4 Mg 1 -Bid					
	Dysuria		Ndc -59075-0594-15	PS		ORAL	4 MG PO BID	
	Pharmaceutical Product Complaint							

Date:03/09/04ISR Number: 4315698-6Report Type:Expedited (15-DaCompany Report #US-SHR-04-021606
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Health Professional	Betaseron (Interferon Beta-1b) Injection, 250ug	PS		SUBCUTANEOUS	8 MIU, EVERY 2D,	
	Aspartate Aminotransferase Increased					SUBCUTANEOUS		
	Blood Bilirubin Increased		Zanaflex (Tizanidine Hydrochloride)	SS		ORAL	ORAL	
			Neurontin /Unk/(Gabapentin)	SS		ORAL	ORAL	

			Potassium (Potassium)	SS		ORAL
ORAL						

Date:03/17/04ISR Number: 4320171-5Report Type:Expedited (15-DaCompany Report #ZANA001142
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Blood Pressure Increased	Foreign	Sirdalud (Tizanidine			
	Cognitive Disorder	Consumer	Hydrochloride)	PS		ORAL
6 MG DAILY						
	Hypoaesthesia Oral	Other				
ORAL						
	Somnolence		Flotac (Diclofenac)	C		
			Enalapril	C		
			Dexamethasone	C		

Date:03/17/04ISR Number: 4320172-7Report Type:Expedited (15-DaCompany Report #ZANA001143
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Bradycardia	Foreign	Sirdalud (Tizanidine			
	Dry Mouth	Health	Hydrochloride)	PS		ORAL
2 MG DAILY						
	Hypotension	Professional				
ORAL						
		Other	Estalis (Norethisterone)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/17/04ISR Number: 4320215-0Report Type:Expedited (15-DaCompany Report #ZANA001134
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bronchopneumonia	Foreign Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY	ORAL
		Other	Hypromellose (Hypromellose)	C				
			Perindopril (Perindopril)	C				
			Paracetamol (Paracetamol)	C				
			Lactulose (Lactulose)	C				

Date:03/17/04ISR Number: 4320216-2Report Type:Expedited (15-DaCompany Report #ZANA001135
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Function Abnormal	Foreign Health Professional	Ternalin (Tizanidine Hydrochloride)	PS		ORAL	3 MG DAILY	ORAL
	Pruritus							
	Rash							
		Other	Loxonin (Loxoprofen Sodium)	SS		ORAL	180 MG DAILY	ORAL
			Mucosta (Rebamipide)	SS		ORAL	300 MG DAILY	ORAL
			Voltaren (Diclofenac Sodium)	SS		RECTAL	50 MG ONCE	RECTAL
			Magnesium Oxide					

			(Magnesium Oxide)	SS		ORAL	2 G DAILY
			Pursennid (Senna)	SS		ORAL	12 MG ONCE
			Juvela (Tocopheryl Nicotinate)	SS		ORAL	600 MG DAILY
			Mohrus	SS		ORAL	
TOPICAL	TOPICAL		Xylocaine (Lidocaine Hydrochloride)	C			

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

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

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/17/04ISR Number: 4320218-6Report Type:Expedited (15-DaCompany Report #ZANA001140
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia Aptyalism	Foreign Health	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY	
	Dizziness Postural	Professional						
ORAL								
		Other	Rytmonorm (Propafenone Hydrochloride)	C				
			Norvasc (Amlodipine Besilate)	C				
			Ticlopidine (Ticlopidine Hydrochloride)	C				
			Losartan (Losartan Potassium)	C				
			Hydrochlorothiazide (Hydrochlorothiazide)	C				

Date:03/18/04ISR Number: 4318539-6Report Type:Expedited (15-DaCompany Report #PHBS2003JP01063
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization -	Hepatic Function Abnormal Hypogammaglobulinaemia		Tegretol	PS	Novartis Sector: Pharma	ORAL	200 mg, BID	36000MIN
Initial or Prolonged	Immune System Disorder Pneumonia		Tegretol	SS	Novartis Sector: Pharma	ORAL	200 mg, TID	5760 MIN
	Productive Cough Pyrexia		Tegretol	SS	Novartis Sector: Pharma	ORAL	200 mg, QID	25920MIN
	Rash Generalised Upper Respiratory Tract		Tegretol	SS	Novartis Sector: Pharma		200 mg, TID	60480MIN
	Infection		Tegretol	SS	Novartis Sector: Pharma	ORAL	200 mg, BID	40320MIN

			Gaster	SS			
UNKNOWN							
			Ternelin	SS			
UNKNOWN							
			Predonine	C			ORAL
15 mg/day							
			Selbex	C			ORAL
150 mg/day							
			Rize	C			ORAL
5 mg/day							

Date:03/19/04ISR Number: 4322313-4Report Type:Expedited (15-DaCompany Report #ZANA001144
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia Gastritis	Foreign Health Professional Other	Sirdalud (Tizanidine Hydrochloride) Oxaprozin (Oxaprozin)	PS SS		ORAL ORAL	8 MG DAILY 1200 MG DAILY	ORAL ORAL

Date:03/19/04ISR Number: 4322314-6Report Type:Expedited (15-DaCompany Report #ZANA001146
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Condition Aggravated Hepatitis B	Foreign Health
Other	Treatment Noncompliance	Professional

Other

Dose	Duration	Product	Role	Manufacturer	Route
3 MG DAILY		Ternalin (Tizanidine Hydrochloride)	PS		ORAL
ORAL		Takepron (Lansoprazole)	C		
		Methotrexate (Methotrexate)	C		
		Foliamin (Folic Acid)	C		
		Predonine (Prednisolone)	C		
		Flucam (Ampiroxicam)	C		
		Cytotec (Misoprostol)	C		
		Depas (Etizolam)	C		
		Biofermin R (Streptococcus Faecalis)	C		
		Selbex (Teprenone)	C		
		Berizym (Enzymes Nos)	C		
		Gasmotin	C		
		Alinamin F (Fursultiamine)	C		
		Cerekinon (Trimebutine Maleate)	C		

Date:03/19/04ISR Number: 4322349-3Report Type:Expedited (15-DaCompany Report #ZANA001141
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination Murder Restlessness Suicidal Ideation	Foreign Literature Health Professional Other	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL	ORAL	

Date:03/19/04ISR Number: 4322350-XReport Type:Expedited (15-DaCompany Report #ZANA001145
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased	Foreign Health Professional	Ternalin (Tizanidine Hydrochloride)	PS		ORAL	1 MG DAILY	
	Blood Creatine Phosphokinase Increased	Other	Lamisil (Terbinafine Hydrochloride)	SS		ORAL	125 GM DAILY	
	Blood Lactate Dehydrogenase Increased		Lornoxicam (Lornoxicam)	SS		ORAL	4 MG DAILY	
	Malaise		Mucosta (Rebamipide)	C		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/19/04ISR Number: 4322351-1Report Type:Expedited (15-DaCompany Report #ZANA001136
Age:24 YR Gender:Male I/FU:I

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

Date:03/25/04ISR Number: 4327874-7Report Type:Expedited (15-DaCompany Report #ZANA001156
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Hepatitis A Pancreatitis Acute	Foreign Health Professional Other	Sirdalud (Tizanidine Hydrochloride)	PS				
			Saroten (Amitriptyline Hydrochloride)	C				
			Seroxat "Novo Nordisk" (Paroxetine Hydrochloride)	C				

Date:03/25/04ISR Number: 4327877-2Report Type:Expedited (15-DaCompany Report #ZANA001155
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Bradycardia	Foreign Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	8 MG A DAT	
			Digoxin (Digoxin)	SS			125 MCGS	
			Morphine (Morphine)	C				
			Fluoxetine (Fluoxetine)	C				
			Simvastatin (Simvastatin)	C				
			Ramipril (Ramipril)	C				
			Warfarin (Warfarin)	C				
			Gabapentin (Gabapentin)	C				

Date:03/25/04ISR Number: 4327928-5Report Type:Expedited (15-DaCompany Report #2004017487
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Withdrawal Syndrome Dyspnoea Fatigue Myoclonic Epilepsy Nerve Injury Pain Somnolence	Health Professional	Zoloft (Sertraline) Tizanidine Hydrochloride (Tizanidine Hydrochloride) Acetylsalicylic Acid (Acetylsalicylic	PS SS				

Acid)	C
Other Respiratory System Products	C
All Other Therapeutic Products	C
Omeprazole (Omeprazole)	C
Amlodipine Besilate (Amlodipine Besilate)	C
Digoxin (Digoxin)	C

Date:03/25/04ISR Number: 4328337-5Report Type:Periodic Company Report #PHEH2003US08933
Age:5 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Angioneurotic Oedema Pharyngeal Oedema Tongue Oedema	Health Professional Company Representative	Trileptal (Oxcarbazepine) Suspension	PS		ORAL	7 ML, Q12H, ORAL	
			Zanaflex (Lic. Athena) (Tizanidine Hydrochloride, Tizanidine Hydrochloride)	SS			2, QHS	
			Klonopin	C				
			Clonidine (Clonidine)	C				
			Risperdal	C				

Date:03/29/04ISR Number: 4329925-2Report Type:Expedited (15-DaCompany Report #ZANA001158
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Foreign Health Professional	Sirdalud (Tizanide Hydrochloride)	PS		ORAL	6 MG DAILY ORAL	

Other Musaril (Tetrazepam) C

Date:03/29/04ISR Number: 4329926-4Report Type:Expedited (15-DaCompany Report #ZANA001157
Age:29 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Alanine Aminotransferase Increased
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased
	Blood Alkaline Phosphatase Increased
	Gamma-Glutamyltransferase Increased
	Hepatic Function Abnormal
	Hypoaesthesia
	Hypogammaglobulinaemia
	Immunodeficiency
	Multiple Sclerosis
	Pneumonia
	Rash Generalised

		Upper Respiratory Tract Infection					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Health Professional Other	Ternalin (Tizanidine Hydrochloride)	PS		
				Tegretol (Carbamazepine)	SS		
400 MG DAILY							
				Predonine (Prednisolone)	C		
				Selbex (Teprenone)	C		
				Rize (Clotiazepam)	C		

Date:04/01/04ISR Number: 4331667-4Report Type:Direct Company Report #CTU 215739
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Required	Deafness Bilateral		Zanaflex 4 Mg Tid	PS		ORAL
4 MG PO TID						
Intervention to Prevent Permanent Impairment/Damage	Deafness Neurosensory		Prednisone	C		
	Tinnitus		Synthroid	C		
			Premarin	C		
			Nexium	C		
			Lipitor	C		
			Topomax	C		
			Fluoxetine	C		
			Toprol Xl	C		
			Wellbutrin	C		
			Flexeril	C		
			Duragesic	C		

Date:04/02/04ISR Number: 4333989-XReport Type:Expedited (15-DaCompany Report #ZANA001158
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Bradycardia	Foreign	Sirdalud (Tizanidine			
	Hypotension	Health	Hydrochloride)	PS		ORAL
6 MG DAILY						
	Nausea	Professional				
ORAL						

		Other	Musaril (Tetrazepam)	C		

Date:04/08/04ISR Number: 4336984-XReport Type:Expedited (15-DaCompany Report #US-SHR-04-021606
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Health Professional	Betaseron (Interferon Beta-1b) Injection, 250ug	PS		SUBCUTANEOUS	8 MIU, EVERY 2D,	
	Aspartate Aminotransferase Increased					SUBCUTANEOUS		
	Blood Bilirubin Increased		Zanaflex (Tizanidine Hydrochloride)	SS		ORAL		
	Liver Function Test Abnormal		Neurontin /Unk/ (Gabapentin)	SS		ORAL		
			Potassium (Potassium)	SS		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/12/04ISR Number: 4337502-2Report Type:Direct Company Report #CTU 216446
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Ventricular Extrasystoles		Tizanidine 4 Mg Tab	PS		ORAL	4 MG 2 TABS	HS ORAL

Date:04/13/04ISR Number: 4341009-6Report Type:Expedited (15-DaCompany Report #ZANA001161
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Foreign	Sirdalud (Tizanidine					
	Body Temperature	Consumer	Hydrochloride)	PS		ORAL	2 DF/DAY ORAL	
	Increased	Other	Vioxx (Rofecoxib)	SS		ORAL	25 MG/DAY	
	Dermatitis Bullous						ORAL	
	Exanthem							
	Rash Macular							

Date:04/13/04ISR Number: 4342443-0Report Type:Expedited (15-DaCompany Report #ZANA001162
Age:11 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Apathy	Foreign	Sirdalud (Tizanidine					
Initial or Prolonged	Medication Error	Health	Hydrochloride)	PS		OTHER	4MG	
	Somnolence	Professional					ONCE/SINGLE	
		Other					OTHER	

Date:04/15/04ISR Number: 4342039-0Report Type:Expedited (15-DaCompany Report #2004017487
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aphasia	Health Professional	Zoloft (Sertraline)	PS				
	Convulsion		Tizanidine Hydrochloride (Tizanidine Hydrochloride)	SS				
	Drug Withdrawal Syndrome		Acetylsalicylic Acid (Acetylsalicyklic Acid)	C				
	Dyskinesia		Other Respiratory System Products (Other Respiratory System Products)	C				
	Dyspnoea		Omeprazole (Omeprazole)	C				
	Fatigue		Amlodipine Besilate (Amlodipine Besilate)	C				
	Hypoaesthesia		Digoxin (Digoxin)	C				
	Muscle Rigidity		Trazodone (Trazodone)	C				
	Myotonia		Oxycodone Hydrochloride (Oxycodone Hydrochloride)	C				
	Nerve Injury		Diazepam (Diazepam)	C				
	Paraesthesia		Furosemide (Furosemide)	C				
	Paralysis							
	Procedural Complication							
	Respiratory Rate Increased							
	Somnolence							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/21/04ISR Number: 4346150-XReport Type:Expedited (15-DaCompany Report #2004024490
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability Other	Embolia Cutis Medicamentosa Gait Disturbance Injection Site Irritation Injection Site Pain Medication Error Muscle Spasms Necrosis	Consumer	Vistaril (Im) (Hydroxyzine Hydrochloride) Neurontin (Gabapentin) Pethidine Hydrochloride (Pethidine Hydrochloride) Oxycodone Hydrochloride (Oxycodone Hydrochloride) Tizanidine Hydrochloride (Tizanidine Hydrochloride)	PS SS SS SS		ORAL ORAL ORAL ORAL	300 MG, ORAL ORAL 20 MG 2 MG	(UNKNOWN), (UNKNOWN),

Date:04/26/04ISR Number: 4349347-8Report Type:Expedited (15-DaCompany Report #ZANA001163
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Screen Positive Medication Error Somnolence	Foreign Health Professional	Ternelin (Tizanidine Hydrochloride) Rohypnol	PS		ORAL ORAL		

		Other	(Flunitrazepam)	SS		ORAL
4 TABLETS						
ORAL						
			Depas (Etizolam)	C		
			Solanax (Alprazolam)	C		
			Benzalin (Nitrazepam)	C		

Date:05/04/04ISR Number: 4355103-7Report Type:Expedited (15-DaCompany Report #200410240BYL
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Jaundice	Foreign Health Professional	Bayaspirin (Acetylsalicylic Acid)	PS		ORAL
ORAL						
		Other	Nitorol R (Isosorbide Dinitrate)	SS		ORAL
ORAL						
			Spelear (Fudosteine)	SS		ORAL
ORAL						
			Osteluc (Etodolac)	SS		ORAL
ORAL						
			Ternelin (Tizanidine Hydrochloride)	SS		ORAL
ORAL						
			Mucosta	C		
			Empynase P	C		
			Resplen	C		

Date:05/05/04ISR Number: 4355461-3Report Type:Expedited (15-DaCompany Report #ZANA001244
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatitis Toxic	Foreign Other	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL	12 MG/D	ORAL
			Homeopathic Preparation (Unspecified) (Homeopathic Preparation	C				

Date:05/05/04ISR Number: 4355931-8Report Type:Expedited (15-DaCompany Report #ZANA001216
Age:6 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Blood Uric Acid Increased Bronchitis Cardio-Respiratory Arrest	Foreign Health Professional	Ternelin (Tizanidine Hydrochloride)	PS		ORAL	0.6 MG	DAILY ORAL
	Dehydration Insomnia Musculoskeletal Stiffness Pyrexia White Blood Cell Count Increased	Other	Hyserenin (Valproate Sodium) Depas (Etizolam) Theodur (Theophylline)	C C C				

Date:05/12/04ISR Number: 4358565-4Report Type:Expedited (15-DaCompany Report #ZANA001156
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Hepatitis A Pancreatitis Acute	Foreign Health Professional Other	Sirdalud (Tizanidine Hydrochloride) Saroten (Amitriptyline Hydrochloride) Seroxat "Novo	PS C		ORAL		ORAL

				Nordisk" (Paroxetine Hydrochloride)	C		

Date:05/17/04ISR Number: 4361416-5Report Type:Expedited (15-DaCompany Report #ZANA001286
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Rash Maculo-Papular	Foreign	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	8 MG DAILY	
	Viral Rash	Health Professional					ORAL	
		Other	Paracetamol (Paracetamol)	C				
			Citalopram (Citalopram)	C				

Date:05/17/04ISR Number: 4362226-5Report Type:Expedited (15-DaCompany Report #ZANA001290
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source
Other	Jaundice	Foreign
	Laboratory Test Abnormal	Health Professional

Other

Dose	Duration	Product	Role	Manufacturer	Route
		Ternelin (Tizanidine Hydrochloride)	PS		ORAL
2 MG DAILY					
ORAL					
		Mucosta (Rebamipide)	C		
		Osteluc (Etodolac)	C		
		Nitrendipine (Nitrendipine)	C		
		Bayaspirina (Acetylsalicylic Acid)	C		
		Resplen (Eprazinone Hydrochloride)	C		
		Empynase (Pronase)	C		
		Spelear (Fudosteine)	C		

Date:05/18/04ISR Number: 4363007-9Report Type:Expedited (15-DaCompany Report #ZANA001309
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Foreign	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL	2-4 MG/DAY	
	Coordination Abnormal	Health						
	Disorientation	Professional						
	Drug Interaction	Other	Entumin (Clotiapine)	SS		ORAL	40-80 MG/DAY	
	Gait Disturbance							
			Lorazepam (Lorazepam)	SS		ORAL	4.5 MG/DAY	
			Seroquel (Quetiapine Fumarate)	SS		ORAL	50-700 MG/DAY	

ORAL

			Nozinan (Levomepromazine)	SS		ORAL	50 MG, QD
			Orfiril (Valproate Sodium)	SS		ORAL	1000 MG/DAY

Date:05/18/04ISR Number: 4363008-0Report Type:Expedited (15-DaCompany Report #ZANA001216
Age:6 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Abdominal Distension	Foreign	Ternelin (Tizanidine Hydrochloride)	PS		ORAL	1.2 MG DAILY
Hospitalization - Initial or Prolonged	Anuria	Health Professional					
	Blood Uric Acid Increased						
	Bronchitis	Other	Hyserenin (Valproate Sodium)	C			
	Cardio-Respiratory Arrest		Depas (Etizolam)	C			
	Dehydration		Theodur (Theophylline)	C			
	Insomnia		Phenobal (Phenobarbital)	C			
	Musculoskeletal Stiffness		Gabalon (Baclofen)	C			
	Ocular Hyperaemia		Meptin (Procaterol Hydrochloride)	C			
	Oculogyration		Mucodyne (Carbocisteine)	C			
	Pyrexia		Tricloryl (Triclofos				
	White Blood Cell Count Increased						

				Sodium)	C		
				Racol (Racol)	C		

Date:05/18/04ISR Number: 4363009-2Report Type:Expedited (15-DaCompany Report #ZANA001306
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthralgia	Foreign	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL	2 MG/D	ORAL
	Bacteria Urine Identified	Health						
	Diarrhoea	Professional	Trasicor (Oxprenolol Hydrochloride)	SS		ORAL	20 MG/D	ORAL
	Drug Interaction	Other						
	Pyelocaliectasis		Alzodone (Butizide)	SS		ORAL	27.5 MG, QW3	ORAL
	Renal Failure Acute							
			Celebrex (Celecoxib)	SS		ORAL	200 MG/D	ORAL
			Vioxx (Rofecoxib)	SS		ORAL		ORAL
			Becozyme Forte (Pyridoxine)	C				
			Bioflorin (Lactobacillus Acidophilus)	C				

Date:05/20/04ISR Number: 4365769-3Report Type:Expedited (15-DaCompany Report #ZANA001307
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pneumonia Aspiration	Foreign Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	ORAL	

Date:05/21/04ISR Number: 4363035-3Report Type:Direct Company Report #USP 56480
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Medication Error		Gabitril	PS	Cephalon	
TABLET						
			Tizanidine	SS		
TABLET						

Date:05/21/04ISR Number: 4363044-4Report Type:Direct Company Report #USP 56478
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Medication Error		Gabitril	PS	Cephalon	
TABLET						
			Tizanidin	SS		
TABLET						

Date:05/21/04ISR Number: 4363810-5Report Type:Expedited (15-DaCompany Report #ZANA001296
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Hepatic Fibrosis	Foreign	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL
6 MG DAILY	Hepatocellular Damage	Health				
ORAL	Liver Function Test	Professional				
	Abnormal	Other	Panacod (Codeine Phosphate)	C		
			Prednisone (Prednisone)	C		
			Miacalcic (Calcitonin, Salmon)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/26/04ISR Number: 4366388-5Report Type:Direct Company Report #CTU 219597
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pharmaceutical Product Complaint		Zanaflex (Generic Only)	PS			4 MG 2 QID	

Date:05/26/04ISR Number: 4366390-3Report Type:Direct Company Report #CTU 219591
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Nausea		Tizanidine	PS			4 MG 1 - 1 1/2 Q 4-6 H PRN SPASMS	
	Pharmaceutical Product Complaint							
	Rash							
	Stomach Discomfort							

Date:05/26/04ISR Number: 4372801-XReport Type:Expedited (15-DaCompany Report #ZANA001308
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delusion	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY	
	Hallucination							
							ORAL	
			Requip (Ropinirole)	C				
			Sinemet (Levodopa)	C				
			Mirapex (Pramipexole Dihydrochloride0	C				

Date:05/27/04ISR Number: 4370131-3Report Type:Expedited (15-DaCompany Report #ZANA001279
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Foreign Health Professional	Ternelin (Tizanidine Hydrochloride)	PS		ORAL	6 MG DAILY	
	Aspartate Aminotransferase Increased	Other	Halfdigoxin-Ky (Digoxin)	C				
	Blood Lactate Dehydrogenase Increased		Warfarin (Warfarin)	C				
	Hepatic Function Abnormal		Tenormin (Atenolol)	C				

Date:06/03/04ISR Number: 4373335-9Report Type:Expedited (15-DaCompany Report #ZANA001311
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Dry Mouth Dysarthria Facial Palsy	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	8 MG DAILY	

Date:06/08/04ISR Number: 4399760-8Report Type:Periodic Company Report #FROV000184
Age:18 YR Gender:Female I/FU:I

Outcome	PT
	Dysarthria
	Mental Impairment

	Somnolence					
		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Consumer	Frova (Frovatriptan Succinate)	PS		ORAL
2.5 MG ORAL						
			Zanaflex (Tizanidine Hydrochloride)	SS		ORAL
16MG DAILY						
ORAL						
			Wellbutrin Xl (Wellbutrin Xl)	C		
			Coreg (Carvedilol)	C		

Date:06/08/04ISR Number: 4399761-XReport Type:Periodic Company Report #FROV000185
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Dysarthria	Consumer	Frova (Frovatriptan			
	Mental Impairment		Succinate)	PS		ORAL
2.5 MG ORAL						
	Somnolence		Zanaflex (Tizanidine Hydrochloride)	SS		ORAL
16 MG ORAL						
			Wellbutrin Xl (Wellbutrin Xl)	C		
			Coreg (Carvedilol)	C		

Date:06/10/04ISR Number: 4378813-4Report Type:Expedited (15-DaCompany Report #ZANA001286
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Rash Maculo-Papular	Foreign	Zanaflex (Tizanidine			
	Viral Rash	Health	Hydrochloride)	PS		ORAL
8 MG DAILY						
		Professional				
ORAL						
			Paracetamol (Paracetamol)	C		

			Citalopram (Citalopram)	C		

Date:06/14/04ISR Number: 4379978-0Report Type:Expedited (15-DaCompany Report #ZANA001216
Age:6 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Distension	Foreign	Ternelin (Tizanidine Hydrochloride)	PS		ORAL	1.2 MG DAILY	
Hospitalization - Initial or Prolonged	Anuria	Health Professional						
	Blood Uric Acid Increased							
	Bronchitis	Other	Hyserenin (Valproate Sodium)	C				
	Cardio-Respiratory Arrest		Depas (Etizolam)	C				
	Cardiovascular Disorder		Theodur (Theophylline)	C				
	Dehydration		Phenobal (Phenobarbital)	C				
	General Physical Condition Abnormal		Gabalon (Baclofen)	C				
	Insomnia		Meptin (Procaterol Hydrochloride)	C				
	Musculoskeletal Stiffness		Mucodyne (Carbocisteine)	C				
	Ocular Hyperaemia		Tricloryl (Triclofos Sodium)	C				
	Oculogyration		Racol (Racol)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/15/04ISR Number: 4381931-8Report Type:Expedited (15-DaCompany Report #ZANA001315
Age:38 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration	Foreign Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY	
	Fatigue							
	Liver Function Test						ORAL	
	Abnormal		Baclofen (Baclofen)	C				
	Somnolence		Oxybutynin (Oxybutynin)	C				
			Carbamazepine (Carbamazepine)	C				
			Pyridoxine (Pyridoxine)	C				
			Isoniazid (Isoniazid)	C				
			Ascorbic Acid (Ascorbic Acid)	C				
			Warfarin (Warfarin)	C				
			Zinc Sulphate (Zinc Sulphate)	C				

Date:06/15/04ISR Number: 4381932-XReport Type:Expedited (15-DaCompany Report #ZANA001314
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Decreased	Foreign Consumer Other	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY	
	Dizziness							
	Jaundice						ORAL	
	Tachycardia							

Date:06/15/04ISR Number: 4382207-5Report Type:Expedited (15-DaCompany Report #ZANA001313
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Dreams	Consumer	Zanaflex (Tizanidine					

Initial or Prolonged	Heart Rate Irregular	Health	Hydrochloride)	PS		ORAL
ORAL						
	Nasal Dryness	Professional	Evoxac (Cevimeline			
	Orthostatic Hypotension		Hydrochloride)	C		
	Respiratory Disorder					
	Tachycardia					

Date:06/16/04ISR Number: 4380826-3Report Type:Expedited (15-DaCompany Report #ZANA001317
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Alpha 1 Foetoprotein	Foreign	Sirdalud (Tizanidine			
	Increased	Health	Hydrochloride)	PS		ORAL
12 MG DAILY						
	Hepatitis	Professional				
ORAL						
	Serum Ferritin Increased	Other	Mercurius Solution			
			(Mercurous Nitrate)	C		

Date:06/16/04ISR Number: 4381375-9Report Type:Expedited (15-DaCompany Report #ZONI001444
Age:55 YR Gender:Male I/FU:I

Outcome	PT
Other	Agitation
	Asthenia

	Confusional State Disturbance In Attention Dry Mouth	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Dysgeusia Dysphasia	Consumer	Zonegran (Zonisamide)	PS		ORAL	200 MG DAILY
	Irritability					ORAL	
	Memory Impairment Mental Impairment Pruritus Somnolence Vision Blurred		Zanaflex (Tizanidine Hydrochloride) Clonidine (Clonidine) Avinza (Morphine Sulafte) Provigil (Modafinil) Melatonin (Melatonin) Androgel (Testosterone Gel)	SS C C C C			

Date:06/18/04ISR Number: 4383593-2Report Type:Expedited (15-DaCompany Report #ZANA001318
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Interaction Hepatitis Acute	Foreign Health Professional	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL	18 MG DAILY
						ORAL	
		Other	Noroxin (Norfloxacin) Lioresal (Baclofen) Daonil (Glibenclamide) Metformin (Metformin) Spasmo-Urgenin N (Trospium Chloride) Valium (Diazepam) Aspirine (Acetylsalicylic Acid) Blopress	SS C C C C C C			

(Candesartan Cilexetil)	C
Borage Oil (Borage Oil)	C

Date:06/18/04ISR Number: 4383596-8Report Type:Expedited (15-DaCompany Report #ZANA001316
Age:55 YR Gender:Male I/FU:I

Outcome	PT
Other	Agitation
	Asthenia
	Confusional State
	Disturbance In Attention
	Dry Mouth
	Dysgeusia
	Hyperaesthesia
	Irritability
	Memory Impairment
	Pruritus
	Somnolence

	Speech Disorder Vision Blurred						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	100 MG ORAL
			Zonegran (Zonisamide)	SS		ORAL	200 MG ORAL
			Clonidine (Clonidine)	C			
			Provigil (Modafinil)	C			
			Melatonin (Melatonin)	C			
			Avinza (Morphine Sulfate)	C			
			Androgel (Testosterone)	C			

Date:06/28/04ISR Number: 4389302-5Report Type:Expedited (15-DaCompany Report #ZANA001313
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abnormal Dreams Blood Pressure Orthostatic Decreased Dehydration Nasal Dryness Pulse Abnormal Respiration Abnormal Tachycardia	Consumer Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	ORAL
			Evoxac (Cevimeline Hydrochloride)	C			
			Bentyl (Dicycloverine)	C			
			Synthroid (Levothyroxine)	C			
			Extex Pse (Guaifenesin)	C			
			Prevacid (Lansoprazole)	C			
			Lipitor (Atorvastatin)	C			

Date:06/29/04ISR Number: 4388210-3Report Type:Direct Company Report #CTU 221765
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated		Tizanidine	PS				
	Pharmaceutical Product		Ambien	C				
	Complaint		Nexium	C				
	Unevaluable Event		Xanax	C				
			Oxycontin	C				
			Tylox	C				
			Advair	C				
			Valiium	C				

Date:07/07/04ISR Number: 4394843-0Report Type:Expedited (15-DaCompany Report #ZANA001321
Age:37 YR Gender:Female I/FU:I

Outcome	PT
Other	Amnesia
	Crying
	Feeling Cold
	Lethargy
	Sedation

	Self-Medication Somnolence						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Other	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL	2 DF/D; ORAL
			Bromazepam	C			
			Cipramil (Citalopram Hydrobromide)	C			
			Omeprazle	C			
			Cipramil (Citalopram Hydrobromide)	C			

Date:07/07/04ISR Number: 4395286-6Report Type:Expedited (15-DaCompany Report #ZANA001315
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Dehydration Fatigue Liver Function Test Abnormal Somnolence	Foreign Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY ORAL
			Baclofen (Baclofen)	C			
			Oxybutynin (Oxybutynin)	C			
			Carbamazepine (Carbamazepine)	C			
			Pyridoxine (Pyridoxine)	C			
			Isoniazid (Isoniazid)	C			
			Ascorbic Acid (Ascorbic Acid)	C			
			Warfarin (Warfarin)	C			
			Zinc Sulphate (Zinc Sulphate)	C			

Date:07/07/04ISR Number: 4395287-8Report Type:Expedited (15-DaCompany Report #ZANA001320
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Disease Progression	Foreign	Sirdalud (Tizanidine					
	Hyperhidrosis	Health	Hydrochloride)	PS		ORAL	4 MG BID ORAL	
	Pneumonia	Professional						
	Vomiting	Other						

Date:07/13/04ISR Number: 4398016-7Report Type:Direct Company Report #CTU 222670
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pharmaceutical Product		Zanaflex 4 Mg 1 Tid	PS			4 MG 1 TID	
	Complaint							

Date:07/14/04ISR Number: 4398090-8Report Type:Direct Company Report #CTU 222795
Age: Gender:Male I/FU:I

Outcome
Life-Threatening
Hospitalization -
Initial or Prolonged

Required Intervention to Prevent Permanent Impairment/Damage	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Acute Myocardial Infarction Angina Unstable		Zanaflex	PS			4 MG	

Date:07/14/04ISR Number: 4399990-5Report Type:Expedited (15-DaCompany Report #ZANA001322
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	C-Reactive Protein Increased	Foreign Literature	Ternelin (Tizanidine Hydrochloride)	PS		ORAL	ORAL	
	Erythema Multiforme Hepatic Function Abnormal	Health Professional	Tegretol (Carbamazepine)	SS		ORAL	ORAL	
	Human Herpes Virus 6 Serology Positive Hypersensitivity Interleukin Level Increased Leukocytosis Lymphocyte Stimulation Test Positive Pyrexia Skin Test Positive Therapy Non-Responder White Blood Cell Count Increased	Other	Loxonin (Loxoprofen Sodium)	C				

Date:07/15/04ISR Number: 4406699-8Report Type:Expedited (15-DaCompany Report #ZANA001323
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Visual Disturbance	Foreign Health Professional	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL	ORAL	

Other

Date:07/16/04ISR Number: 4406642-1Report Type:Expedited (15-DaCompany Report #DRON00204002327
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Circulatory Collapse	Foreign	Marinol (Dronabinol)	PS		ORAL	2.5 MG BID,	
	Confusional State	Study					PO	
	Somnolence	Health	Amitripytline					
	Speech Disorder	Professional	(Amitriptyline)	SS		ORAL	200 MG DAILY	
		Other					PO	
			Baclofen (Baclofen)	SS		ORAL	70 MG DAILY	
							PO	
			Tizanidine					
			(Tizanidine)	SS		ORAL	32 MG DAILY	
							PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/20/04ISR Number: 4405375-5Report Type:Expedited (15-DaCompany Report #ZANA001314
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Decreased	Foreign	Sirdalud (Tizanidine					
	Dizziness	Consumer	Hydrochloride)	PS		ORAL	2 MG DAILY	
	Jaundice	Other					ORAL	
	Tachycardia							

Date:07/26/04ISR Number: 4407380-1Report Type:Expedited (15-DaCompany Report #PHBS2004US09673
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Haemoglobin Decreased	Health	Baclofen	PS	Novartis Sector:			
Other	Haemolysis	Professional			Pharma			
			Zanaflex $El	SS		ORAL	36 mg/d	
			Neurontin	C			UNKNOWN	
			Ditropan	C			UNKNOWN	

Date:07/29/04ISR Number: 4412075-4Report Type:Direct Company Report #CTU 223860
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zanaflex 4 Mg	PS			FOOT DROP	
	Pharmaceutical Product						LEFT FOOT	
	Complaint						MUSCLE SPASM	

Date:07/29/04ISR Number: 4413578-9Report Type:Expedited (15-DaCompany Report #ZANA001324
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dyspnoea Sensation Of Foreign Body	Foreign Health Professional	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY	ORAL
		Other	Panadol (Paracetamol)	SS		ORAL	250 MG DAILY	ORAL
			Mercilon (Desogestrel)	C				
			Beklometasone Dipropionate (Beclometasone Dipropionate)	C				

Date:07/30/04ISR Number: 4411586-5Report Type:Expedited (15-DaCompany Report #PHBS2003JP01063
Age:29 YR Gender:Female I/FU:F

Outcome	PT
Life-Threatening Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Alkaline Phosphatase Increased Gamma-Glutamyltransferase Increased Hepatic Function Abnormal

	Hypogammaglobulinaemia Multiple Sclerosis Myotonia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Pneumonia Productive Cough		Tegretol	PS	Novartis Sector: Pharma	ORAL	200 mg, BID 36000MIN
	Pyrexia Rash Generalised		Tegretol	SS	Novartis Sector: Pharma	ORAL	200 mg, TID 5760 MIN
	Upper Respiratory Tract Infection		Tegretol	SS	Novartis Sector: Pharma	ORAL	200 mg, QID 25920MIN
			Tegretol	SS	Novartis Sector: Pharma		200 mg, TID 60480MIN
			Tegretol	SS	Novartis Sector: Pharma	ORAL	200 mg, BID 40320MIN
			Gaster	SS			UNKNOWN
			Ternelin	SS			UNKNOWN
			Predonine	C		ORAL	15 mg/day
			Selbex	C		ORAL	150 mg/day
			Rize	C		ORAL	5 mg/day

Date:08/05/04ISR Number: 4422425-0Report Type:Expedited (15-DaCompany Report #PHBS2004US09673
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Glucose-6-Phosphate Dehydrogenase Deficiency Haemoglobin Decreased	Foreign Health Professional	Zanaflex $El (Tizanidine Hydrochloride)	PS		ORAL	36 MG/D
	Haemolysis	Other	Baclofen (Baclofen)	SS			
			Neurontin (Gabapentin)	C			
			Ditropan (Oxybutynin Hydrochloride)	C			

Date:08/06/04ISR Number: 4416952-XReport Type:Expedited (15-DaCompany Report #PHBS2003JP01063
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Eosinophilia		Tegretol	PS	Novartis Sector:			
Hospitalization -	Erythema				Pharma	ORAL	200 mg, BID	36000MIN
Initial or Prolonged	Hepatic Function Abnormal		Tegretol	SS	Novartis Sector:			
	Hypogammaglobulinaemia				Pharma	ORAL	200 mg, TID	5760 MIN
	Lung Infiltration		Tegretol	SS	Novartis Sector:			
	Pneumonia				Pharma	ORAL	200 mg, QID	25920MIN
	Productive Cough		Tegretol	SS	Novartis Sector:			
	Pyrexia				Pharma		200 mg, TID	60480MIN
	Rales		Tegretol	SS	Novartis Sector:			
	Rash Generalised				Pharma	ORAL	200 mg, BID	40320MIN
	Skin Exfoliation		Gaster	SS			UNKNOWN	
	Upper Respiratory Tract		Ternelin	SS			UNKNOWN	
	Infection		Predonine	C		ORAL	15 mg/day	
			Selbex	C		ORAL	150 mg/day	
			Rize	C		ORAL	5 mg/day	

Date:08/11/04ISR Number: 4426146-XReport Type:Expedited (15-DaCompany Report #ZANA001325
Age:44 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Acute Myocardial
Initial or Prolonged	Infarction

	Angina Unstable					
	Back Pain					
	Chest Pain	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Condition Aggravated	Health	Zanaflex (Tizanidine			
	Coronary Artery Disease	Professional	Hydrochloride)	PS		ORAL
4 MG DAILY						
	Muscle Spasms					
ORAL						
	Nerve Compression		Vicodin			
	Pain		(Paracetamol)	C		
	Pain In Jaw		Accupril (Quinapril)	C		
	Treatment Noncompliance		Zoloft (Sertraline)	C		
			Klonopin			
			(Clonazepam)	C		

Date:08/18/04ISR Number: 4432526-9Report Type:Expedited (15-DaCompany Report #ZANA001328
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Amnesia	Health	Zanaflex (Tizanidine			
Initial or Prolonged	Angiopathy	Professional	Hydrochloride)	PS		ORAL
4 MG ORAL						
Other	Blood Creatine	Other	Copaxone (Glatiramer			
	Phosphokinase Increased		Acetate)	SS		
	Carotid Artery Stenosis					
	Confusional State					
	Encephalopathy					
	Mental Status Changes					
	Overdose					
	Sleep Disorder					
	Urinary Tract Infection					

Date:08/18/04ISR Number: 4432541-5Report Type:Expedited (15-DaCompany Report #ZANA001332
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Depression	Literature	Zanaflex (Tizanidine			
Initial or Prolonged	General Physical Health	Health	Hydrochloride)	PS		
Other	Deterioration	Professional	Hydrocodone			
	Hip Fracture		(Hydrocodone)	C		

	Orthostatic Hypotension		Acetaminophen (Paracetamol)	C			
			Carbamazepine (Carbamazepine)	C			
			Aspirin (Acetylsalicylic Acid)	C			
			Unspecified Antihypertensive (Unspecified Antihypertensive)	C			

Date:08/23/04ISR Number: 4432952-8Report Type:Expedited (15-DaCompany Report #ZANA001335
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Screen Positive	Foreign	Zanaflex (Tizanidine					
Hospitalization -	Respiratory Depression	Health	Hydrochloride)	PS		ORAL	32 MG DAILY	
Initial or Prolonged	Urinary Tract Infection	Professional				ORAL		
			Methadone (Methadone)	SS			50 MG DAILY	

			Rivotril (Clonazepam)	C			
			Coumadin (Warfarin)	C			
			Vioxx (Rofecoxib)	C			
			Neurontin (Gabapentin)	C			
			Baclofen (Baclofen)	C			
			Bactrim (Sulfamethoxazole)	C			
			Phencyclidine (Phencyclidine)	C			

Date:08/23/04ISR Number: 4432954-1Report Type:Expedited (15-DaCompany Report #ZANA001333
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hospitalisation	Foreign Health Professional Other	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	6 MG ORAL	
			Baclofen (Baclofen)	C				
			Ranitidine (Ranitidine)	C				
			Paracetamol (Paracetamol)	C				
			Atorvastatin (Atorvastatin)	C				
			Oxybutynin (Oxybutynin)	C				
			Amitriptyline (Amitriptyline)	C				
			Warfarin (Warfarin)	C				
			Zopiclone (Zopiclone)	C				
			Carbamazepine (Carbamazepine)	C				

Date:08/23/04ISR Number: 4432955-3Report Type:Expedited (15-DaCompany Report #ZANA001157
Age:29 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Alanine Aminotransferase
Hospitalization -	Increased

Initial or Prolonged	Aspartate Aminotransferase Increased B-Lymphocyte Abnormalities Eosinophilia Extensor Plantar Response Gamma-Glutamyltransferase Increased Hepatic Enzyme Increased Hepatic Function Abnormal Hyperreflexia Hypoaesthesia Hypogammaglobulinaemia Immunodeficiency Multiple Sclerosis Pneumonia Rash Generalised

		Skin Exfoliation Upper Respiratory Tract Infection	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Upper Respiratory Tract Inflammation	Foreign Literature Health Professional Other	Ternelin (Tizanidine Hydrochloride) Tegretol (Carbamazepine)	PS SS		ORAL
400 MG DAILY ORAL							
				Gaster (Famotidine) Predonine (Prednisolone) Selbex (Teprenone) Rize (Clotiazepam)	SS C C C		

Date:08/23/04ISR Number: 4433088-2Report Type:Expedited (15-DaCompany Report #ZANA001328
Age:69 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization - Initial or Prolonged		Amnesia Blood Creatine Phosphokinase Increased	Health Professional Other	Zanaflex (Tizanidine Hydrochloride) Copaxone (Glatiramer Acetate)	PS SS		ORAL
4 MG ORAL Other SUBCUTANEOUS	20 MG DAILY,	Carotid Artery Stenosis Confusional State					
SUBCUTANEOUS		Delirium Encephalopathy Mental Status Changes Overdose Pain In Extremity Urinary Tract Infection		Baclofen (Baclofen)	SS		ORAL
14 TO 20 MG TABLETS, ORAL							

Date:08/25/04ISR Number: 4433560-5Report Type:Direct Company Report #CTU 225635
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Discomfort		Zanaflex 4 Mg	PS			1 TWICE DAILY	
Hospitalization - Initial or Prolonged	Loss Of Consciousness Myocardial Infarction							
Other	Pain							
Required Intervention to Prevent Permanent Impairment/Damage	Thrombosis							

Date:09/01/04ISR Number: 4441807-4Report Type:Expedited (15-DaCompany Report #ZANA001338
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hypotension	Foreign Health Professional	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY	
		Other	Brufen (Ibuprofen)	C			ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/01/04ISR Number: 4443131-2Report Type:Expedited (15-DaCompany Report #ZANA001323
Age:40 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Visual Disturbance	Foreign Health Professional Other	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL	8 MG DAILY	ORAL

Date:09/02/04ISR Number: 4441090-XReport Type:Direct Company Report #CTU 226225
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Drug Ineffective Pharmaceutical Product Complaint		Zanaflex 8 Mg Tid - Qid	PS			8 MG TID - QID	
			Ultracet	C				

Date:09/03/04ISR Number: 4440511-6Report Type:Expedited (15-DaCompany Report #PHBS2004US11398
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depressed Level Of Consciousness	Health Professional	Baclofen	PS	Novartis Sector: Pharma		UNKNOWN	
	Dizziness Tachycardia		Tizanidine Hydrochloride	SS			UNKNOWN	
			Nortriptyline Hydrochloride	SS			UNKNOWN	
			Gabapentin	SS			UNKNOWN	
			Phenelzine	SS			UNKNOWN	

			Ketorolac	SS			UNKNOWN
			Bethanechol	SS			UNKNOWN
			Olanzapine	SS			UNKNOWN

Date:09/03/04ISR Number: 4444842-5Report Type:Expedited (15-DaCompany Report #2004PK01436
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Confusional State	Foreign	Seroquel	PS		ORAL	700 MG DAILY
Intervention to	Coordination Abnormal	Health					PO
Prevent Permanent	Drug Interaction	Professional	Sirdalud	SS		ORAL	4 MG DAILY PO
Impairment/Damage		Other	Entumin	SS		ORAL	80 MG DAILY
							PO
			Orfiril	SS		ORAL	1 G DAILY PO
			Lorazepam	SS		ORAL	4.5 MG DAILY
							PO

Date:09/03/04ISR Number: 4445304-1Report Type:Expedited (15-DaCompany Report #ZANA001342
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Blood Pressure Systolic	Foreign	Ternelin (Tizanidine				
Initial or Prolonged	Decreased	Health	Hydrochloride)	PS		ORAL	3 MG ORAL
	Heart Rate Decreased	Professional	Loxonin (Loxoprofen				
		Other	Sodium)	SS		ORAL	180 MG
			Mucosta(Rebamipide)	SS		ORAL	300 MG ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/08/04ISR Number: 4444172-1Report Type:Expedited (15-DaCompany Report #CH-MERCK-0409CHE00009
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Health Professional	Vioxx	PS	Merck & Co., Inc	ORAL		8 DAY
	Aspartate Aminotransferase Increased		Diclofenac Sodium	SS		ORAL		
			Tizanidine Hydrochloride	SS		ORAL		3 DAY
	Blood Alkaline Phosphatase Increased		Herbs (Unspecified)	C		ORAL		
	Bradycardia							
	Gamma-Glutamyltransferase Increased							

Date:09/14/04ISR Number: 4448421-5Report Type:Expedited (15-DaCompany Report #PHBS2004CH11775
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased		Voltaren	PS	Novartis Sector: Pharma		UNKNOWN	4320 MIN
Other	Aspartate Aminotransferase Increased		Sirdalud	SS			UNKNOWN	6 mg/day 4320 MIN
			Vioxx	SS			UNKNOWN	4320 MIN
			Herbal Extracts Nos	SS				
	Blood Alkaline Phosphatase Increased							
	Bradycardia							
	Chest Discomfort							
	Diarrhoea							
	Drug Interaction							
	Dyspnoea							
	Fibrin D Dimer Increased							
	Gamma-Glutamyltransferase Increased							
	Haemangioma Of Liver							
	Hepatic Enzyme Increased							
	Hepatic Lesion							
	Hyperhidrosis							

	Liver Disorder						
	Pleural Effusion						
	Pulmonary Hypertension						
	Vomiting						

Date:09/14/04ISR Number: 4450215-1Report Type:Expedited (15-DaCompany Report #ZANA001322
Age:59 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Biopsy Skin Abnormal	Foreign	Ternelin (Tizanidine Hydrochloride)	PS		ORAL	ORAL
	C-Reactive Protein Increased	Literature					
	Eosinophilia	Health Professional	Tegretol (Carbamazepine)	SS		ORAL	ORAL
	Erythema Multiforme	Other	Loxonin (Loxoprofen Sodium)	C			
	Hepatic Function Abnormal		Prednisolone	C			
	Human Herpes Virus 6						
	Serology Positive						
	Hypersensitivity						
	Leukocytosis						
	Lymphocyte Stimulation						
	Test Positive						
	Purpura						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/14/04ISR Number: 4450216-3Report Type:Expedited (15-DaCompany Report #ZANA001290
Age:74 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	False Positive Laboratory Result	Foreign Health Professional	Ternelin (Tizanidine Hydrochloride)	PS		ORAL	2 MG DAILY	
	Hepatitis Cholestatic					ORAL		
	Laboratory Test Abnormal	Other	Mucosta (Rebamipide)	SS				
	Lymphocyte Stimulation Test Positive		Osteluc (Etodolac)	C				
	Urticaria		Nitrendipine	C				
			Bayaspirina (Acetylsalicylic Acid)	C				
			Resplen (Eprazinone Hydrochloride)	C				
			Empynase (Pronase)	C				
			Spelear (Fudosteine)	C				
			Nitorol (Isosorbide Dinitrate)	C				

Date:09/14/04ISR Number: 4450218-7Report Type:Expedited (15-DaCompany Report #ZANA001344
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Decreased Dehydration	Foreign Health Professional Other	Ternelin (Tizanidine Hydrochloride)	PS		ORAL	ORAL	
			Depromel (Fluvoxamine)	C				
			Wypax (Lorazepam)	C				
			Amoxan (Amoxapine)	C				

Date:09/15/04ISR Number: 4452325-1Report Type:Expedited (15-DaCompany Report #ZANA001309
Age:32 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Foreign	Sirdalud (Tizanidine					

	Coordination Abnormal	Health	Hydrochloride)	PS	ORAL
2-4 MG/DAY					
	Depressive Delusion	Professional			
ORAL					
	Disease Recurrence	Other	Entumin (Clotiapine)	SS	ORAL
40-80 MG/DAY					
	Disorientation				
ORAL					
	Drug Interaction		Lorazepam		
	Gait Disturbance		(Lorazepam)	SS	ORAL
4.5 MG/DAY					
	Sleep Disorder				
ORAL					
			Seroquel (Quetiapine		
			Fumarate)	SS	ORAL
100 - 700					
MG/DAY ORAL					
			Nozinan		
			(Levomepromazine)	SS	ORAL
50 MG DAILY					
ORAL					
			Orfiril (Valproate		
			Sodium)	SS	ORAL
1000 MG/DAY					
ORAL					

Date:09/15/04ISR Number: 4452379-2Report Type:Expedited (15-DaCompany Report #ZANA001345
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Hepatitis Acute	Foreign Health

		Professional Other				
			Product	Role	Manufacturer	Route
Dose	Duration					
			Ternelin (Tizanidine Hydrochloride)	PS		ORAL
3 TABLETS/DAY, ORAL						
			Cerocral (Ifenprodil Tartrate)	SS		ORAL
3 TABLETS/DAY, ORAL						
			Methycobal (Mecobalamin)	C		

Date:09/17/04ISR Number: 4456374-9Report Type:Expedited (15-DaCompany Report #DSA_24963_2004
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Confusional State	Foreign	Temesta	PS		ORAL
4.5 MG Q DAY PO	Coordination Abnormal	Health				
	Sleep Disorder	Professional	Seroquel	SS		ORAL
700 MG Q DAY PO		Other				
			Sirdalud	SS		ORAL
4 MG Q DAY PO						
			Entumin	SS		ORAL
80 MG Q DAY PO						
			Orfiril "Desitin"	SS		ORAL
1 G QD PO						

Date:09/23/04ISR Number: 4460500-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040903505
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged Other	Aggression Aspiration Drug Interaction Potentiation	Literature Health Professional	Cyclobenzaprine (Cyclobenzaprine Hydrochloride) Unknown	PS		ORAL	300 MG, 1 IN	1 DAY, ORAL
	Drug Screen Positive Drug Toxicity Lung Disorder		Acetaminophen/Tramadol (Tramadol/Apap)	SS			30 G/3 G	
	Multiple Drug Overdose Sedation		Amitriptyline (Amitriptyline)	SS		ORAL	700 MG, 1 IN	1 DAY, ORAL
	Self-Medication Suicide Attempt Vomiting		Tizanidine (Tizanidine)	SS		ORAL	120 MG, 1 IN	1 DAY, ORAL
			Rofecoxib (Rofecoxib)	SS		ORAL	750 MG, 1 IN	1 DAY, ORAL
			Omeprazole (Omeprazole)	SS		ORAL	300 MG, 1 IN	1 DAY, ORAL

Date:09/24/04ISR Number: 4457840-2Report Type:Expedited (15-DaCompany Report #US-MERCK-0409USA01708
Age:21 YR Gender:Female I/FU:I

Outcome
Death
Hospitalization -
Initial or Prolonged

Other

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Aggression	Health	Vioxx	PS	Merck & Co., Inc	ORAL		
	Aspiration	Professional	Acetaminophen And Tramadol Hydrochloride	SS		UNKNOWN		
	Completed Suicide							
	Depressed Level Of Consciousness		Elavil	SS		ORAL		
	Drug Toxicity		Tizanidine Hydrochloride	SS		ORAL		
	Intentional Misuse		Flexeril	SS		ORAL		
	Vomiting		Omeprazole	SS		ORAL		

Date:09/24/04ISR Number: 4462090-XReport Type:Direct Company Report #CTU 228006
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasticity		Tizanidine 2mg	PS			2 MG BID	
	Pharmaceutical Product Complaint		Baclofen	C				
	Retching							
	Vomiting							

Date:09/28/04ISR Number: 4462613-0Report Type:Expedited (15-DaCompany Report #200412698GDS
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Foreign Health	Ciproxine (Ciprofloxacin)	PS		ORAL	500 MG, BID,	
	Bradycardia	Professional						
	Electrocardiogram Qt Prolonged	Other	Propanolol	SS		ORAL	20 MG, BID,	
	Hypotension		Tizanidine	SS		ORAL	4 MG, TOTAL	

	Sinus Arrest					
DAILY, ORAL						
			Aspirin	C		
			Irbesartan	C		
			Simvastatin	C		
			Oxazepam	C		
			Dextran Sulfate	C		
			Tramadol	C		

Date:09/30/04ISR Number: 4465441-5Report Type:Expedited (15-DaCompany Report #ZANA001349
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Blood Pressure Systolic Increased	Foreign Health Professional	Ternelin (Tizanidine Hydrochloride)	PS		ORAL
3 TABLETS						
DAILY ORAL	Epilepsy	Other	Luvox (Fluvoxamine Maleate)	C		
			Myslee (Zolpidem Tartrate)	C		
			Gasmotin (Mosapride Citrate)	C		
			Promac (Polaprezinc)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/30/04ISR Number: 4465452-XReport Type:Expedited (15-DaCompany Report #ZANA001348
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Enzymes Increased	Foreign	Sirdalud (Tizanidine					
	Cardiac Failure	Health	Hydrochloride)	PS		ORAL	ORAL	
		Professional						
		Other						

Date:09/30/04ISR Number: 4465453-1Report Type:Expedited (15-DaCompany Report #ZANA001347
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase	Foreign	Ternelin (Tizanidine					
Initial or Prolonged	Increased	Health	Hydrochloride)	PS		ORAL	3 MG DAILY	
	Aspartate	Professional					ORAL	
	Aminotransferase	Other	Ketas (Ibudilast)	SS		ORAL	30 MG DAILY	
	Increased						ORAL	
	Blood Alkaline		Gasmotin (Mosapride					
	Phosphatase Increased		Citrate)	SS		ORAL	15 MG DAILY	
	Blood Lactate						ORAL	
	Dehydrogenase Increased		Chinese Medication	C				
	Gamma-Glutamyltransferase							
	Increased							
	Hypoaesthesia							
	Liver Disorder							
	Therapy Non-Responder							

Date:10/04/04ISR Number: 4467946-XReport Type:Expedited (15-DaCompany Report #200412698GDS
Age:71 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Blood Creatinine
Initial or Prolonged	Increased

Bradycardia
Delirium
Drug Level Increased
Electrocardiogram Qrs
Complex Prolonged
Electrocardiogram Qt
Prolonged
Fall
General Physical Health
Deterioration
Haemoglobin Decreased
Headache
Hypotension
Loss Of Consciousness
Mental Disorder Due To A
General Medical Condition
Myoclonus
Psychomotor Retardation
Pulse Absent
Sinus Arrest
Sinus Bradycardia
Somnolence
Therapeutic Agent
Toxicity
Thirst
Traumatic Brain Injury

	Tremor Urinary Tract Infection						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Health Professional	Ciproxine (Ciprofloxacin)	PS		ORAL	500 MG, BID, ORAL
		Other	Inderal (Propranolol Hydrochloride)	SS		ORAL	20 MG, BID, ORAL
			Sirdalud (Tizanidine Hydrochloride)	SS		ORAL	4 MG, TOTAL DAILY, ORAL
			Aspirin Cardio	C			
			Coaprovel	C			
			Simcora	C			
			Quilinorm	C			
			Surmontil	C			
			Seresta	C			
			Neurontin	C			
			Celebrex	C			
			Tramal	C			
			Phlebodril N	C			

Date:10/05/04ISR Number: 4469462-8Report Type:Expedited (15-DaCompany Report #ZANA001350
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Foreign Health Professional	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL	4 MG DAILY ORAL
	Delirium						
	Electrocardiogram Qrs Complex Prolonged	Other	Inderal (Propranolol Hydrochloride)	SS		ORAL	40 MG DAILY ORAL
	Electrocardiogram Qt						

	Prolonged	Ciproxin	
	Electrocardiogram	(Ciprofloxacin)	SS
1000 MG DAILY			
	Repolarisation	Aspirin	
	Abnormality	(Acetylsalicylic	
	Fall	Acid)	C
	General Physical Health	Coaprovel	
	Deterioration	(Irbesartan)	C
	Haemoglobin Decreased	Simvastatin	
	Headache	(Simvastatin)	C
	Hypotension	Seresta (Oxazepam)	C
	Loss Of Consciousness	Phlebodril N (Ruscus	
	Myoclonus	Aculeatus Melilotus	
	Personality Change	Officinalis)	C
	Polydipsia	Tramal (Tramadol	
	Pulse Absent	Hydrochloride)	C
	Pyrexia	Quilonorm (Lithium	
	Sinus Arrest	Acetate)	C
	Sinus Bradycardia	Surmontil	
	Somnolence	(Trimipramine	
	Therapeutic Agent	Maleate)	C
	Toxicity	Neurontin	
	Tremor	(Gabapentin)	C
	Urine Abnormality	Celebrex (Celecoxib)	C
		Cipralex	
		(Escitalopram)	C
		Lithium (Lithium)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/05/04ISR Number: 4470593-7Report Type:Expedited (15-DaCompany Report #ZANA001346
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Health Professional	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL	6 MG DAILY	
Other	Aspartate Aminotransferase Increased	Other	Voltaren (Diclofenac Sodium)	SS		ORAL		
	Blood Alkaline Phosphatase Increased		Vioxx (Rofecoxib)	SS				
	Bradycardia		Herbal Extracrs Nos (Herbal Extracts Nos)	SS				
	Chest Discomfort							
	Diarrhoea							
	Drug Interaction							
	Drug Level Increased							
	Dyspnoea							
	Fibrin D Dimer Increased							
	Gamma-Glutamyltransferase Increased							
	Haemangioma							
	Hepatic Enzyme Increased							
	Hyperhidrosis							
	Hypoperfusion							
	Pleural Effusion							
	Pulmonary Hypertension							
	Vomiting							

Date:10/06/04ISR Number: 4470653-0Report Type:Direct Company Report #CTU 228942
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pharmaceutical Product Complaint		Zanaflex (Tizanidine)	PS			4 MG FOR QJS	6 MON
			Flexent	C				
			Clonazepam	C				
			Wellbutrin Sr	C				
			Gabitrol	C				
			Duragesic	C				

Date:10/06/04ISR Number: 4471368-5Report Type:Expedited (15-DaCompany Report #2004UW19873
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Chest Sound	Literature	Elavil	PS		ORAL	700 MG DAILY;	
Hospitalization - Initial or Prolonged	Aggression	Health Professional	Vioxx	SS		ORAL	750 MG DAILY;	
Required Intervention to Prevent Permanent Impairment/Damage	Aspiration		Flexeril	SS		ORAL	300 MG DAILY;	
	Completed Suicide							
	Depressed Level Of Consciousness		Acetaminophen	SS			30 G	
	Drug Toxicity		Tramadol Hydrochloride	SS			3G	
	Intentional Misuse		Tizanidine Hydrochloride	SS		ORAL	120 MG DAILY;	
	Sedation		Omeprazole	SS		ORAL	300 MG DAILY;	
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/07/04ISR Number: 4471850-0Report Type:Expedited (15-DaCompany Report #ZANA001353
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Foreign	Zanaflex (Tizanidine					
	Nausea	Health	Hydrochloride)	PS		ORAL	16 MG DAILY	
	Orthostatic Hypotension	Professional					ORAL	
	Vomiting	Other	Avonex (Interferon)	C				
	Weight Decreased		Sandostatin (Octreotide)	C				

Date:10/12/04ISR Number: 4475626-XReport Type:Expedited (15-DaCompany Report #ST-2004-008072
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anorexia	Foreign	Olmetec	PS		ORAL	20 MG QD PO	
Initial or Prolonged	Dizziness	Health	Diovan	SS	Novartis	ORAL	80 MG QD PO	
	Hepatic Function Abnormal	Professional	Niflan	SS		ORAL	7.5 MG TID PO	
	Malaise	Company	Enchinin	SS		ORAL	1 MG TID PO	
		Representative	Iotrol	C				
		Other	Renivace	C				
			Halcion	C				
			Methycool	C				
			Norvasc	C				

Date:10/12/04ISR Number: 4475637-4Report Type:Expedited (15-DaCompany Report #ZANA001352
Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation	Foreign	Zanaflex (Tizanidine					
	Hepatic Enzyme Increased	Other	Hydrochloride)	PS		ORAL	1 MG DAILY	
	Liver Disorder						ORAL	

	Pyrexia		Baclofen (Baclofen)	C		
	Rash Erythematous		Heparin (Heparin)	C		
			Risperidone (Risperidone)	C		

Date:10/12/04ISR Number: 4476942-8Report Type:Expedited (15-DaCompany Report #KII-2004-0013534
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Aggression	Study	Morphine Sulfate (Morphine Sulfate)	PS		
Other	Agitation	Health Professional	Other Hypnotics And Sedatives ()	SS		
	Alkalosis	Other	Muscle Relaxants ()	SS		
	Areflexia		Tizanidine (Tizanidine)	SS		
	Back Pain		Cyclobenzaprine (Cyclobenzaprine)	SS		
	Blood Ph Decreased		Benzodiazepine Derivatives ()	SS		
	Coma		Amitriptyline (Amitriptyline)	SS		
	Headache					
	Muscle Twitching					
	Myocardial Infarction					
	Neck Pain					
	Pericarditis					
	Pneumonia Aspiration					
	Pyrexia					
	Restlessness					
	Viral Infection					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/12/04ISR Number: 4477557-8Report Type:Expedited (15-DaCompany Report #2004070988
Age:43 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Doxepin (Caps)					
Other	Completed Suicide	Health Professional	(Doxepin)	PS				
			Oxycodone (Oxycodone)	SS				
			Tizanidine (Tizanidine)	SS				
			All Other Therapeutic Products (All Other Therapeutic Products)	SS				

Date:10/13/04ISR Number: 4474169-7Report Type:Direct Company Report #CTU 229457
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Nausea		Tizanidine	PS			4 MG 1 - 1/2 Q 6 H	
	Rash							
	Stomach Discomfort							

Date:10/14/04ISR Number: 4475455-7Report Type:Direct Company Report #CTU 229593
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated		Tizanidine	PS				
CHANGE TO ZANAFLEX BMN	Muscle Spasms							

[LIFETIME]

Date:10/14/04ISR Number: 4678669-6Report Type:Direct Company Report #CTU 239853
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Tizanidine 4 Mg	PS			4 MG DAILY	
	Therapeutic Response							
	Unexpected With Drug							
	Substitution							

Date:10/15/04ISR Number: 4476649-7Report Type:Direct Company Report #CTU 229667
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depressed Level Of		Zanaflex 4 Mg	PS			NIGHTLY	
	Consciousness							
	Hallucination							
	Hallucination, Visual							
	Nightmare							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/20/04ISR Number: 4482108-8Report Type:Expedited (15-DaCompany Report #ACO_0006_2004
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis Acute	Foreign	Ternelin	PS		ORAL	3 TAB QDAY PO	
	Malaise	Health Professional	Cerocral	SS		ORAL	3 TAB QDAY PO	
			Methycobal	C				

Date:10/20/04ISR Number: 4483459-3Report Type:Expedited (15-DaCompany Report #ACO_0007-2004
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Myocardial Infarction	Health Professional	Sirdalud	PS		ORAL	2 MG QDAY PO	

Date:10/21/04ISR Number: 4486099-5Report Type:Expedited (15-DaCompany Report #HQWYE706312OCT04
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatinine Increased	Health Professional	Inderal (Propranolol Hydrochloride, Tablet)	PS		ORAL	40 MG 1X PER	
Hospitalization - Initial or Prolonged	Bradycardia	Other						
Other	Drug Interaction						1 DAY ORAL	7 DAY
	Electrocardiogram Qt Prolonged		Ciproxin (Ciprofloxacin,)	SS		ORAL	1 G 1X PER 1	
	Hypotension						DAY	4 DAY
	Loss Of Consciousness		Sirdalud - Slow Release (Tizanidine Hydrochloride,)	SS		ORAL	4 MG 1X PER 1	
	Sinus Arrest						DAY ORAL	
			Aspirin "Bayer"					

(Acetylsalicylic Acid)	C
Coaprovel (Irbesartan/Hydrochlorothiazide)	C
Simvastatin (Simvastatin)	C
Seresta (Oxazepam)	C
Phlebodril (Ascorbic Acid/Hesperidin Methyl Chalcone/Ruscus Aculeatus)	C
Tramal (Tramadol Hydrochloride)	C
Lithium (Lithium)	C
Gabapentin (Gabapentin)	C
Celecoxib (Celecoxib)	C
Trimipramine (Trimipramine)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/22/04ISR Number: 4484597-1Report Type:Expedited (15-DaCompany Report #2004AL000677
Age:30 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Multiple Drug Overdose	Literature	Tizanidine Hydrochloride Tablets, 2 Mg And 4 Mg (Purepac)	PS	Purepac	ORAL	PO	
			Valproic Acid	SS		ORAL	PO	

Date:10/22/04ISR Number: 4484598-3Report Type:Expedited (15-DaCompany Report #2004AL000709
Age:39 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Multiple Drug Overdose	Literature	Tizanidine Hydrochloride Tablets, 2 Mg And 4 Mg (Purepac)	PS	Purepac	ORAL	PO	
			Paroxetine	SS		ORAL	PO	

Date:10/22/04ISR Number: 4484604-6Report Type:Expedited (15-DaCompany Report #2004AL000683
Age:43 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Multiple Drug Overdose	Literature	Tizanidine Hydrochloride Tablets, 2 Mg And 4 Mg (Purepac)	PS	Purepac	ORAL	PO	
			Doxepin	SS		ORAL	PO	
			Oxycodone	SS		ORAL	PO	

Date:10/26/04ISR Number: 4486575-5Report Type:Direct Company Report #CTU 230473
Age:94 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dysphagia		Tizanidine	PS				

Date:10/26/04ISR Number: 4489914-4Report Type:Expedited (15-DaCompany Report #ACO_0008_2004
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Overdose Somnolence	Foreign Health Professional Other	Ternelin	PS				

Date:10/27/04ISR Number: 4489642-5Report Type:Expedited (15-DaCompany Report #FLUV00304003016
Age:67 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness Postural Drug Interaction Dysstasia	Foreign Health Professional	Depromel 25 (Fluvoxamine Maleate)	PS		ORAL	50 MILLIGRAM	(S) BID ORAL
	Fall Muscular Weakness Orthostatic Hypotension	Other	Ternelin (Tizanidine Hydrochloride)	SS		ORAL	1 MILLIGRAM	(S) TID ORAL

			Meilax (Ethyl Loflazepate)	C		
			Dogmatyl (Sulpiride)	C		
			Lendormin (Brotizolam)	C		
			Gosha-Jinki-Gan (Gosha-Jinki-Gan)	C		

Date:10/28/04ISR Number: 4490060-4Report Type:Expedited (15-DaCompany Report #2004082345
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cutaneous Lupus Erythematosus	Consumer	Neurontin (Gabapentin)	PS				
	Fibromyalgia		Zoloft (Sertraline)	SS				
	Rheumatoid Arthritis		Methotrexate (Methotrexate)	SS				
	Sjogren'S Syndrome		Infliximab (Infliximab)	SS				
			Hydroxychloroquine Phosphate (Hydroxychloroquine Phosphate)	SS				
			Tizanidine Hydrochloride (Tizanidine Hydrochloride)	SS				
			Morphine Sulfate (Morphine Sulfate)	C				

Date:11/02/04ISR Number: 4491034-XReport Type:Expedited (15-DaCompany Report #US-MERCK-0409USA01708
Age:21 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression		Vioxx	PS	Merck & Co., Inc	ORAL		
Hospitalization - Initial or Prolonged	Aspiration		Flexeril	SS		ORAL		
	Completed Suicide		Acetaminophen And Tramadol Hydrochloride	SS				
Other	Depressed Level Of Consciousness							
UNKNOWN								
	Drug Toxicity		Omeprazole	SS		ORAL		

	Intentional Misuse		Elavil	SS		ORAL
	Vomiting		Tizanidine Hydrochloride	SS		ORAL

Date:11/03/04ISR Number: 4494900-4Report Type:Expedited (15-DaCompany Report #ACO_0009_2004
Age:30 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Tizanidine Hydrochloride	PS			DF	
	Multiple Drug Overdose	Health Professional	Valproic Acid	SS			DF	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/03/04ISR Number: 4495377-5Report Type:Expedited (15-DaCompany Report #ACO_0011_2004
Age:39 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Tizanidine					
	Intentional Misuse	Health	Hydrochloride	PS				
		Professional	Paroxetine	SS				

Date:11/03/04ISR Number: 4495383-0Report Type:Expedited (15-DaCompany Report #ACO_0010_2004
Age:43 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Tizanidine					
	Intentional Misuse	Health	Hydrochloride	PS				
		Professional	Oxycodone	SS				
			Doxepin	SS				

Date:11/05/04ISR Number: 4493790-3Report Type:Expedited (15-DaCompany Report #US-ABBOTT-04P-163-0279307-00
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Valproic Acid	PS		ORAL		
			Tizanidine	SS		ORAL		

Date:11/08/04ISR Number: 4495564-6Report Type:Expedited (15-DaCompany Report #US-ROCHE-384009
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Vertigo		Pegasys	PS	Roche	SUBCUTANEOUS		
			Copegus	SS	Roche	ORAL		
			Topamax	SS		ORAL		
			Zanaflex	SS		ORAL		
			Flomax	C				

Date:11/08/04ISR Number: 4496066-3Report Type:Expedited (15-DaCompany Report #TW-MERCK-0411USA00810
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Areflexia		Prinivil	PS	Merck & Co., Inc	ORAL		
	Cerebral Haemorrhage		Tizanidine Hydrochloride	SS				
	Cerebrovascular Accident							
	Coma		Amlodipine Besylate	C				
	Corneal Reflex Decreased		Ofloxacin	C				
	Decerebration		Biofermin	C				
	Depressed Level Of Consciousness		Theophylline	C				
	Drug Interaction		Nimodipine	C				
	Hypertension		Labetalol Hydrochloride	C				
	Hypotension							
	Movement Disorder							
	Muscle Rigidity							
	Opisthotonus							
	Respiratory Failure							
	Sepsis							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/11/04ISR Number: 4499275-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908829
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression		Ultracet	PS				
OROPHARINGEAL								
	Aspiration		Cyclobenzaprine	SS				
OROPHARINGEAL								
	Completed Suicide		Amitriptyline	SS				
OROPHARINGEAL								
	Depressed Level Of		Tizanidine	SS				
	Consciousness		Rofecoxib	SS				
	Drug Toxicity		Omeprazole	SS				
	Intentional Misuse							
	Lung Crepitation							
	Sedation							
	Vomiting							

Date:11/12/04ISR Number: 4503023-7Report Type:Expedited (15-DaCompany Report #ACO_0013_2004
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dry Mouth	Foreign	Zanaflex	PS		ORAL	2 MG QDAY PO	
	Fatigue	Health	Ibuprofen	C				
	Headache	Professional	Cialis	C				
	Insomnia	Other						
	Muscle Spasms							
	Nightmare							
	Somnolence							

Date:11/15/04ISR Number: 4500819-2Report Type:Expedited (15-DaCompany Report #CH-MERCK-0411CHE00025
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain		Vioxx	PS	Merck & Co., Inc	ORAL		
	Dermatitis Bullous		Tizanidine					
	Pyrexia		Hydrochloride	SS		ORAL		

Date:11/16/04ISR Number: 4504376-6Report Type:Expedited (15-DaCompany Report #ACO_0015_2004
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased	Literature	Tizanidine	PS		ORAL	360 MG ONCE	
	Coma	Health					PO	
	Drug Ineffective	Professional						
	Heart Rate Decreased							
	Miosis							
	Overdose							

Date:11/16/04ISR Number: 4504452-8Report Type:Expedited (15-DaCompany Report #ACO_0016_2004
Age:30 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Blood Pressure Decreased
	Blood Pressure Systolic Increased
	Depressed Level Of Consciousness
	Drug Ineffective
	Heart Rate Decreased
	Heart Rate Increased

	Hypotension Miosis Overdose	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Respiratory Depression	Literature	Tizanidine	PS		ORAL	30 TAB ONCE
		Health					PO
		Professional					

Date:11/16/04ISR Number: 4504993-3Report Type:Expedited (15-DaCompany Report #ACO_0014_2004
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Anxiety	Foreign	Tizandine	PS		ORAL	2000 MG QDAY
Hospitalization -	Convulsion	Literature					PO
Initial or Prolonged	Delirium	Health	Tizanidine	SS		ORAL	12 MG QDAY PO
	Drug Withdrawal Syndrome	Professional	Zolpidem	SS		ORAL	7500 MG QDAY
	Hypotonia	Other					PO
	Medication Error		Zolpidem	SS		ORAL	DF QDAY PO
	Muscle Spasms		Xylometazoline	SS			100 MG QDAY
	Paraesthesia		Xylometazoline	SS			DF QDAY
	Treatment Noncompliance						

Date:11/17/04ISR Number: 4503821-XReport Type:Expedited (15-DaCompany Report #CH-MERCK-0411CHE00026
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Diarrhoea	Health	Vioxx	PS	Merck & Co., Inc	ORAL	21 DAY
Initial or Prolonged	Drug Interaction	Professional	Celecoxib	SS		ORAL	44 DAY

	Renal Failure Acute		Buthiazide	SS		ORAL
6 MON						
			Tizanidine Hydrochloride	SS		ORAL
44 DAY						
			Oxprenolol Hydrochloride	SS		ORAL
6 YR						
			Ascorbic Acid And Vitamin B (Unspecified)	C		
UNKNOWN						
			Enterococcus Faecium (As Drug)	C		
UNKNOWN						

Date:11/17/04ISR Number: 4506997-3Report Type:Expedited (15-DaCompany Report #2004-BP-11398YA
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Health	Harnal (Tamsulosin)	PS		ORAL	0.2 MG PO	
	Aspartate Aminotransferase Increased	Professional Other	Dantrium (Dantrolene Sodium)	SS		ORAL	25 MG PO	
	Blood Bilirubin Increased		Lioresal (Dantrolene Sodium)	SS		ORAL	5 MG PO	
	Blood Lactate Dehydrogenase Increased		Ternelin (Tizanidine Hydrochloride)	SS		ORAL	1 MG PO	
	Gamma-Glutamyltransferase Increased		Vitamedin (Benfotiamine/B6/B12)	C		ORAL		
	Hepatic Function Abnormal		Diazepam (Diazepam)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/18/04ISR Number: 4507134-1Report Type:Expedited (15-DaCompany Report #B0349830A
Age:39 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Proxetine Hydrochloride Tablet-Controlled Release (Generic) (Paroxetine	PS		ORAL	ORAL	
	Drug Level	Health Professional	Tizanidine (Formulation Unknown) (Tizanidine)	SS		ORAL	ORAL	

Date:11/23/04ISR Number: 4512376-5Report Type:Expedited (15-DaCompany Report #ACO_0018_2004
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Decreased	Foreign	Ternelin	PS		ORAL	3 MG QDAY PO	
	Blood Pressure Systolic Increased	Health Professional	Fluvoxamine Maleate	SS		ORAL	150 MG QDAY PO	
	Dehydration	Other	Lorazepam	C				
	Dialysis		Amoxan	C				
	Dialysis Disequilibrium Syndrome		Allopurinol	C				
			Lansoprazole	C				
	Dizziness		Mosapride Citrate	C				
	Nausea		Alfacalcidol	C				
	Somnolence		Calcium Carbonate	C				

Date:11/23/04ISR Number: 4512401-1Report Type:Expedited (15-DaCompany Report #ACO_0017_2004
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase	Foreign	Ternelin	PS		ORAL	2 MG QDAY PO	

Initial or Prolonged	Increased	Health	Ketas	SS		ORAL
30 MG QDAY PO						
	Aspartate	Professional	Gasmotin	SS		ORAL
15 MG QDAY PO						
	Aminotransferase Increased Blood Alkaline Phosphatase Increased Blood Lactate Dehydrogenase Increased Gamma-Glutamyltransferase Increased Hypoaesthesia Limb Discomfort Liver Disorder	Other	Chinese Medicine	C		

Date:11/24/04ISR Number: 4514139-3Report Type:Expedited (15-DaCompany Report #2003AP02691
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Drug Interaction	Foreign	Zestril	PS		ORAL	10 MG DAILY
Intervention to	Hypotension	Literature					PO
Prevent Permanent		Health	Sirdalud	SS		ORAL	2 MG DAILY PO
Impairment/Damage		Professional	Senokot	C			
		Other	Magnesium Oxide	C			
			Amikin	C			
			Trandate	C			

Nimotop	C
Well-Well	C
Glycerol	C
Mucosolvan	C
Clincin	C
Ofloxacin	C
Amlodipine	C
Nimodipine	C
Labetalol	C

Date:12/09/04ISR Number: 4524021-3Report Type:Expedited (15-DaCompany Report #ACO_0028_2004
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased	Foreign	Tizanidine	PS		ORAL	2 MG ONCE PO	
	Depressed Level Of Consciousness	Health Professional Other	Labetalol	C				
			Amlodipine	C				
			Nimodipine	C				
			Lisinopril	C				

Date:12/14/04ISR Number: 4528889-6Report Type:Expedited (15-DaCompany Report #HQWYE762806DEC04
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Serotonin Syndrome	Health Professional Other	Tazobac (Piperacillin/Tazobactam Injection)	PS		INTRAVENOUS	4.5 G 3X PER 1 DAY	25 DAY
			Brufen (Ibuprofen)	SS		ORAL	400 MG 3X PER 1 DAY	
			Garamycin (Gentamicin Sulfate)	SS		INTRAVENOUS DRIP	30 MG 2X PER	

1 DAY			
	Nexium (Esomeprazole)	SS	
40 MG DAILY			
	Sirdalud (Tizanidine Hydrochloride)	SS	ORAL
3 MG DAILY			
	Tramal (Tramadol Hydrochloride)	SS	
50 MG 4X PER			
1 DAY			
	Bactrim (Sulfamethoxazole/Trimethoprim)	SS	
	Zoloft (Sertraline Hydrochloride)	SS	ORAL
50 MG			
	Neurontin (Gabapentin)	C	
	Rivotril (Clonazepam)	C	
	Fraxiparin (Heparin-Fraction, Calcium Salt)	C	
	Benerva (Thiamine Hydrochloride)	C	
	Temesta (Lorazepam)	C	
	Becozyme Forte (Biotin/Calcium Pantothenate/Cyanoco		

				balamin/Nicotinamide /Pyridoxine/	C		
				Mst (Morphine Sulfate)	C		
				Dafalgan (Paracetamol)	C		

Date:12/14/04ISR Number: 4529397-9Report Type:Expedited (15-DaCompany Report #2004PK02050
Age:17 YR Gender:Female I/FU:I

Outcome	Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Required	40 MG DAILY		Agitation	Foreign	Nexium	PS		
Intervention to	200 MG DAILY		Asthenia	Health	Tramal	SS		ORAL
Prevent Permanent	PO		Coordination Abnormal	Professional				
Impairment/Damage	8 MG DAILY PO		Dysaesthesia	Other	Sirdalud	SS		ORAL
			Hyperaesthesia		Zoloft	SS		
	1200 MG DAILY		Motor Dysfunction		Brufen	SS		ORAL
	PO		Pain In Extremity					
	INTRAVENOUS	13.5 G DAILY	Postoperative Infection		Tazobac	SS		
	IV		Pseudomonas Infection					
	INTRAVENOUS	160 MG DAILY	Pyrexia		Gentamicine	SS		
	IV		Sedation					
			Serotonin Syndrome		Neurontin	C		
			Skin Necrosis		Rivotril	C		
			Somnolence		Mst	C		
			Tremor		Dafalgan	C		
					Temesta	C		
					Bactrim	C		
					Fraxiparin	C		
					Benerva	C		
					Becozyme Forte	C		

Date:12/16/04ISR Number: 4531909-6Report Type:Expedited (15-DaCompany Report #2004-BP-12563BP
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chromaturia Diarrhoea Jaundice Nausea Vomiting	Health Professional	Mirapex Tablets (Pramipexole Dihydrochloride)	PS		ORAL	PO (THERAPY DATES: ABOUT ONE YEAR AGO - NR)	
			Metformin (Metformin)	SS				
			Estrogen	SS				
			Zanaflex (Tizanidine Hydrochloride)	SS				
			Rebif (Interferon Beta)	SS				

Date:12/20/04ISR Number: 4536994-3Report Type:Expedited (15-DaCompany Report #2004104140
Age: Gender:Female I/FU:I

Outcome	PT
Other	Agitation
	Asthenia
	Coordination Abnormal
	Diarrhoea
	Dysaesthesia

Hyperaesthesia Myoclonus Neuralgia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Pain	Foreign	Zoloft (Sertraline)	PS		ORAL	(50 MG), ORAL
Postoperative Infection Pseudomonas Infection	Health Professional	Gentamicin (Gentamicin)	SS		INTRAVENOUS	INTRAVENOUS
Serotonin Syndrome Somnolence Tremor		Pip/Tazo (Piperacillin Sodium, Tazobactam Sodium)	SS			
		Ibuprofen (Ibuprofen)	SS			
		Tizanidine Hydrochloride (Tizanidine Hydrochloride)	SS			
		Tramadol Hydrochloride (Tramadol Hydrochloride)	SS			
		Doxorubicin (Doxorubicin)	C			
		Esomeprazole (Esomeprazole)	C			
		Gabapentin (Gabapentin)	C			
		Clonazepam (Clonazepam)	C			
		Morphine Sulfate (Morphine Sulfate)	C			
		Paracetamol (Paracetamol)	C			
		Lorazepam (Lorazepam)	C			
		Bactrim (Sulfamethoxazole, Trimethoprim)	C			
		Heparin-Fraction, Calcium Salt (Heparin-Fraction, Calcium Salt)	C			
		Thiamine Hydrochloride (Thiamine				

				Hydrochloride)	C		
				Becozyme (Magnesium Carbonate, Potassium Iodide, Silicic Acid, Vitamins Nos)	C		

Date:12/21/04ISR Number: 4537410-8Report Type:Expedited (15-DaCompany Report #MK200412-0137-1
Age:43 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Oxycodone Hcl Tabets	PS				
	Multiple Drug Overdose	Health Professional	Doxepine	SS				
			Tizanidine	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/22/04ISR Number: 4538886-2Report Type:Expedited (15-DaCompany Report #ACO_0030_2004
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall Loss Of Consciousness Lower Limb Fracture	Health Professional	Zanaflex	PS		ORAL	DF PO	

Date:12/27/04ISR Number: 4541188-1Report Type:Expedited (15-DaCompany Report #2004-BP-11398YA
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Bilirubin Increased Blood Lactate Dehydrogenase Increased Gamma-Glutamyltransferase Increased Liver Disorder Malaise	Foreign Health Professional Other	Harnal (Tamsulosin) Dantrium (Dantrolene Sodium) Ternelin (Tizanidine Hydrochloride) Vitamedin (Benfotiamine/B6/B12) Diazepam (Diazepam)	PS SS SS C C		ORAL ORAL ORAL	0.2 MG PO 25 MG PO 1 MG TIS (TID) PO	

Date:12/27/04ISR Number: 4541330-2Report Type:Expedited (15-DaCompany Report #ACO_0018_2004
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Balance Disorder Blood Pressure Decreased	Foreign Health	Ternelin Fluovoxamine Maleate	PS SS		ORAL ORAL	3 MG QDAY PO 150 MG QDAY	

	Dehydration	Professional					
PO							
	Dizziness	Other	Lorazepam	C			
	Nausea		Amoxan	C			
	Somnolence		Allopurinol	C			
			Lansoprazole	C			
			Mosapride Citrate	C			
			Alfacalcidol	C			
			Calcium Carbonate	C			

Date:12/27/04ISR Number: 4541332-6Report Type:Expedited (15-DaCompany Report #ACO_0028_2004
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Blood Pressure Decreased	Foreign	Tizanidine	PS		ORAL	2 MG ONCE PO
Initial or Prolonged	Depressed Level Of	Health	Labetalol	C			
	Consciousness	Professional	Amlodipine	C			
		Other	Nimodipine	C			
			Lisinopril	C			

Date:12/27/04ISR Number: 4541346-6Report Type:Expedited (15-DaCompany Report #ACO_0006_2004
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source
Hospitalization -	Hepatitis Acute	Foreign
Initial or Prolonged		Health
		Professional

Other

				Product	Role	Manufacturer	Route
Dose	Duration						
				Ternelin	PS		ORAL
3 TAB QDAY PO							
				Cerocral	SS		ORAL
3 TAB QDAY PO							
				Methycobal	C		

Date:12/27/04ISR Number: 4541347-8Report Type:Expedited (15-DaCompany Report #ACO_0008_2004
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Overdose	Foreign	Ternelin	PS		
	Somnolence	Health Professional Other				

Date:12/27/04ISR Number: 4541351-XReport Type:Expedited (15-DaCompany Report #ACO_0013_2004
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Dry Mouth	Foreign	Zanaflex	PS		ORAL
2 MG QDAY PO						
	Fatigue	Health	Ibuprofen	C		
	Headache	Professional	Cialis	C		
	Insomnia	Other				
	Muscle Spasms					
	Nightmare					
	Somnolence					

Date:12/27/04ISR Number: 4541354-5Report Type:Expedited (15-DaCompany Report #ACO_0014_2004
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Abnormal Behaviour	Foreign	Tizanidine	PS		ORAL
2000 MG QDAY						

Hospitalization - Initial or Prolonged	Anxiety	Literature			
	Convulsion	Health	Tizanidine	SS	ORAL 12 MG QDAY PO
Required Intervention to Prevent Permanent Impairment/Damage	Delirium	Professional	Zolpidem	SS	ORAL 7500 MG QDAY PO
	Drug Withdrawal Syndrome	Other			
	Hypotonia		Zolpidem	SS	ORAL DF QDAY PO
	Muscle Spasms		Xylometazoline	SS	100 MG QDAY
	Paraesthesia		Xylometazoline	SS	DF QDAY
	Social Avoidant Behaviour				
	Treatment Noncompliance				

Date:12/27/04ISR Number: 4541358-2Report Type:Expedited (15-DaCompany Report #ACO_0017_2004
Age:81 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased
	Blood Alkaline Phosphatase Increased
	Blood Lactate Dehydrogenase Increased
	Discomfort

	Gamma-Glutamyltransferase Increased						
	Hypoaesthesia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Liver Disorder	Foreign	Ternelin	PS		ORAL	3 MG QDAY PO
		Health	Ketas	SS		ORAL	30 MG QDAY PO
		Professional	Gasmotin	SS		ORAL	15 MG QDAY PO
		Other	Chinese Medicine	C			

Date:12/27/04ISR Number: 4542153-0Report Type:Expedited (15-DaCompany Report #ACO_0016_2004
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Blood Pressure Increased	Literature	Tizanidine	PS		ORAL	30 TAB ONCE
	Depressed Level Of Consciousness	Health Professional					PO
	Drug Ineffective						
	Heart Rate Decreased						
	Hypotension						
	Intentional Misuse						
	Miosis						
	Respiratory Depression						
	Treatment Noncompliance						

Date:12/27/04ISR Number: 4542155-4Report Type:Expedited (15-DaCompany Report #ACO_0015_2004
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Blood Pressure Decreased	Literature	Tizanidine	PS		ORAL	360 MG ONCE
	Coma	Health Professional					PO
	Drug Ineffective						
	Heart Rate Decreased						
	Miosis						
	Overdose						

Date:12/27/04ISR Number: 4542157-8Report Type:Expedited (15-DaCompany Report #ACO_0007_2004
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cardiac Enzymes Increased	Health	Sirdalud	PS		ORAL	2 MG DAILY PO	
Initial or Prolonged	Myocardial Infarction	Professional						

Date:12/27/04ISR Number: 4542249-3Report Type:Expedited (15-DaCompany Report #ACO_0011_2004
Age:39 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Tizanidine					
	Overdose	Health	Hydrochloride	PS				
		Professional	Paroxetine	SS				

Date:12/27/04ISR Number: 4542417-0Report Type:Expedited (15-DaCompany Report #ACO_0009_2004
Age:30 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Tizanidine					
	Multiple Drug Overdose	Health	Hydrochloride	PS			DF	
		Professional	Valproic Acid	SS			DF	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/27/04ISR Number: 4542420-0Report Type:Expedited (15-DaCompany Report #ACO_0010_2004
Age:43 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Tizanidine					
	Multiple Drug Overdose	Health Professional	Hydrochloride	PS				
			Oxycodone	SS				
			Doxepin	SS				

Date:12/29/04ISR Number: 4542433-9Report Type:Expedited (15-DaCompany Report #2004AP000937
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Pain	Consumer	Tizanidine Hydrochloride Tablets	PS		ORAL	8 MG; EVERY	DAY (DAILY);
	Depressed Level Of Consciousness							
	Dizziness							
	Dizziness Postural							
	Dysstasia		Donnatal Extentabs	C				
	Hallucination, Visual		Ibuprofen	C				
	Overdose							
	Pharmaceutical Product Complaint							
	Sedation							

Date:12/30/04ISR Number: 4541726-9Report Type:Expedited (15-DaCompany Report #JP-SOLVAY-00304004443
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anuria		Fluvoxamine	PS		ORAL	Daily dose:	
	Body Temperature Decreased						150	milligram(s)
	Drug Interaction		Zopiclone	C			UNKNOWN	Daily dose:

Dry Mouth
unknown
Heart Rate Decreased Flunitrazepam C
UNKNOWN Daily dose:

unknown
Candesartan C
UNKNOWN Daily dose:

unknown
Famotidine C
UNKNOWN Daily dose:

unknown
Carbamazepine C
UNKNOWN Daily dose:

unknown
Bezafibrate C
UNKNOWN Daily dose:

unknown
Ticlopidine C
UNKNOWN Daily dose:

unknown
Benidipine C
UNKNOWN Daily dose:

unknown
Tizanidine I
UNKNOWN Daily dose: 3

milligram(s)

Date:12/30/04ISR Number: 4544292-7Report Type:Expedited (15-DaCompany Report #ACO_0034_2004
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aphasia	Foreign	Sirdalud - Slow Release	PS		ORAL	6 MG DAILY PO	
	Drug Interaction	Health						
	Epilepsy	Professional	Sirdalud	SS		ORAL	4 MG DAILY PO	
		Other	Zocor "Merck"	SS	Merck	ORAL	80 MG QDAY PO	

			Zocor "Merck"	SS	Merck	ORAL
40 MG BID PO						

Date:12/30/04ISR Number: 4544293-9Report Type:Expedited (15-DaCompany Report #ACO_0035_2004
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Body Temperature	Foreign	Tizanidine	PS		ORAL
3 MG QDAY PO						
Initial or Prolonged	Decreased	Literature	Fluvoxamine	SS		
150 MG QDAY						
	Dry Mouth	Health	Zopiclone	C		
	Enuresis	Professional	Flunitrazepam	C		
	Heart Rate Decreased	Other	Benidipine	C		
			Candesartan	C		
			Ticlopidine	C		
			Famotidine	C		
			Bezafibrate	C		
			Carbamazepine	C		

Date:12/31/04ISR Number: 4542792-7Report Type:Expedited (15-DaCompany Report #PHBS2004JP16522
Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Alanine Aminotransferase	Health	Voltaren	PS	Novartis Sector:	
Initial or Prolonged	Increased	Professional			Pharma	ORAL
75 mg/day 43200MIN						
	Aspartate		Ternelin	SS		ORAL
3 mg/day 43200MIN						
	Aminotransferase		Mucosta	SS		ORAL
300 mg/day 43200MIN						
	Increased		Mecobalamin	C		ORAL
1000 ug/day						
	Back Pain					
	Condition Aggravated					
	Gamma-Glutamyltransferase Increased					
	Liver Disorder					

Date:01/03/05ISR Number: 4545249-2Report Type:Expedited (15-DaCompany Report #HQWYE762806DEC04
Age:17 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pyrexia Serotonin Syndrome	Health Professional Other	Tazobac (Piperacillin/Tazobactam, Injection)	PS		INTRAVENOUS	4.5 G 3X PER	1 DAY
						INTRAVENOUS	25	DAY
			Brufen (Ibuprofen)	SS		ORAL	400 MG 3X PER	1 DAY
			Garamycin (Gentamicin Sulfate)	SS		INTRAVENOUS DRIP	30 MG 2X PER	1 DAY
			Nexium (Esomeprazole)	SS		INTRAVENOUS DRIP	40 MG DAILY	
			Sirdalud (Tizanidine Hydrochloride)	SS		ORAL	3 MG DAILY	
			Tramal (Tramadol Hydrochloride)	SS		ORAL	50 MG 4X PER	1 DAY
			Zoloft (Sertraline					

	Hydrochloride)	SS	ORAL 50 MG ORAL
	Neurontin (Gabapentin)	C	
	Rivortil (Clonazepam)	C	
	Mst (Morphine Sulfate)	C	
	Dafalgan (Paracetamol)	C	
	Bactrim (Sulfamethoxazole/Trimethoprim)	C	
	Fraxiparin (Heparin-Fraction, Calcium Salt)	C	
	Benerva (Thiamine Hydrochloride)	C	
	Becozyme Forte (Biotin/Calcium Pantothenate/Cyanocobalamin/Nicotinamide/Pyridoxine/Riboflav	C	
	Temesta (Lorazepam)	C	

Date:01/10/05ISR Number: 4551309-2Report Type:Expedited (15-DaCompany Report #ACO_0037_2004
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Foreign	Ternelin	PS		ORAL	DF	QDAY PO
	Respiratory Disorder	Health	Ternelin	SS		ORAL	DF	QDAY PO
	Serotonin Syndrome	Professional	Paxil	SS		ORAL	DF	PO
	Therapy Non-Responder	Other						
	Tremor							

Date:01/12/05ISR Number: 4552849-2Report Type:Direct Company Report #CTU 236460
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Drug Ineffective		Zanaflex	PS		ORAL
4MG TID PO						
	Pharmaceutical Product					
	Complaint					

Date:01/18/05ISR Number: 4555504-8Report Type:Direct Company Report #CTU 237070
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Nephrolithiasis		Tizanidine	PS		

Date:01/21/05ISR Number: 4558654-5Report Type:Direct Company Report #CTU 237527
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required	Nausea		Tizandine	PS		
2-(3 X A DAY						
Intervention to	Pharmaceutical Product					
)(PRN)						
Prevent Permanent	Complaint					
Impairment/Damage	Rash					
	Stomach Discomfort					

Date:01/24/05ISR Number: 4563646-6Report Type:Expedited (15-DaCompany Report #ACO_0036_2004
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Back Pain Liver Disorder Lymphocyte Stimulation Test Positive	Foreign Health Professional Other	Ternelin Voltaren Mucosta Mecobalamin	PS SS SS C		ORAL ORAL ORAL PO	3 MG QDAY 75 MG QDAY 300 MG QDAY PO	PO

Date:01/25/05ISR Number: 4563233-XReport Type:Expedited (15-DaCompany Report #CH-2005-000910
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium Hallucination, Auditory	Foreign Health Professional Other	Sotalol (Sotalol Hydrochloride) Tablet Sirdalud (Tizanidine Hydrochloride) Transtec Tts (Buprenorphine) Torem (Torasemide) Plavix (Clopidogrel Sulfate) Dafalgan Zestril (Lisinopril) Temgesic (Buprenorphine) Aspirin Cardio	PS SS C C C C C C		ORAL ORAL	80 MG, 4 MG, 1X/DAY,	2X/DAY, ORAL ORAL

				(Acetylsalicylic Acid)	C		

Date:01/26/05ISR Number: 4566551-4Report Type:Direct Company Report #CTU 238193
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasms		Tizanidine	PS				

CHANGE TO

ZANAFLEX 73

MN [LIFETIME]

Date:01/31/05ISR Number: 4568451-2Report Type:Expedited (15-DaCompany Report #ACO_0028_2004
Age:48 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Cerebral Haemorrhage
	Cerebral Ventricle Dilatation
	Cerebrovascular Accident
	Coma
	Decerebration
	Drug Interaction
	Hypertension
	Hypotension

	Jaw Disorder						
	Opisthotonus						
	Pain	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Respiratory Failure	Foreign	Tizanidine	PS		ORAL	2 MG ONCE PO
		Literature	Lisinopril	SS		ORAL	10 MG QDAY PO
		Health	Labetalol	C			
		Professional	Amlodipine	C			
		Other	Nimodipine	C			

Date:02/01/05ISR Number: 4601995-3Report Type:Periodic Company Report #ACO_0029_2004
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Alanine Aminotransferase		Zanaflex	PS		ORAL	4 MG TID PO 1 YR
Initial or Prolonged	Increased		Aminopyridine	C			
	Aspartate		Rebif	C			
	Aminotransferase		Mirapex	C			
	Increased		Estrogen	C			
	Blood Bilirubin Increased						
	Chromaturia						
	Jaundice						
	Nausea						
	Vomiting						

Date:02/01/05ISR Number: 4601997-7Report Type:Periodic Company Report #ACO_0019_2004
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Accidental Overdose	Consumer	Zanaflex	PS			DF
Initial or Prolonged	Coma		Baclofen	SS			DF
	Respiratory Distress		Xanax	SS			DF

Date:02/07/05ISR Number: 4576253-6Report Type:Expedited (15-DaCompany Report #ACO_0121_2005
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Cerebral Infarction	Foreign	Sirdalud	PS		ORAL	PO	
	Condition Aggravated	Health Professional	Ciproxin	SS				
	Hypotension							
	Memory Impairment	Other						

Date:02/07/05ISR Number: 4576254-8Report Type:Expedited (15-DaCompany Report #ACO_0037_2004
Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Foreign	Ternelin	PS		ORAL	DF QDAY PO	
	Disease Recurrence	Health	Ternelin	SS		ORAL	DF QDAY PO	
	Drug Interaction	Professional	Paxil	SS		ORAL	35 MG QDAY PO	
	Dyspnoea	Other	Lexotan	SS			DF	
	Epilepsy							
	Hyperventilation							
	Myoclonus							
	Oxygen Saturation Decreased							
	Serotonin Syndrome							
	Therapy Non-Responder							
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/07/05ISR Number: 4576742-4Report Type:Expedited (15-DaCompany Report #ACO_0122_2005
Age:10 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Literature	Zanaflex	PS			DF
		Health	Lisinopril	SS		ORAL	DF PO
	Heart Rate Increased	Professional	Valproic Acid	C			
	Hypotension		Valium	C			
	Musculoskeletal Stiffness		Clonazepam	C			
	Pallor						
	Somnolence						

Date:02/08/05ISR Number: 4576909-5Report Type:Expedited (15-DaCompany Report #05-02-0156
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign	Lisinopril Tablets	PS		ORAL	10MG QD ORAL
		Literature	Tizanidine	SS			2 MG
Other	Drug Interaction		Amlodipine	C			
	Hypotension		Nimopidine	C			
			Labetalol	C			

Date:02/08/05ISR Number: 4579159-1Report Type:Direct Company Report #CTU 239730
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Blood Pressure Decreased		Zanaflex	PS		ORAL	1/2 AT NIGHT
	Heart Rate Decreased						ORAL
	Loss Of Consciousness						

Date:02/09/05ISR Number: 4577958-3Report Type:Expedited (15-DaCompany Report #ACO_0123_2005
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hallucination, Auditory	Foreign	Sirdalud	PS		ORAL	4 MG QDAY PO	
		Health Professional	Sotalex	SS		ORAL	160 MG QDAY PO	
		Other	Buprenorphine	C				
			Torem	C				
			Plavix	C				
			Dafalgan	C				
			Zestril	C				
			Temgesic "Essex Pharma"	C				
			Aspirin Compound	C				

Date:02/09/05ISR Number: 4578634-3Report Type:Direct Company Report #CTU 239962
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Jaundice Myalgia Nausea Vomiting		Tizanidine	PS				
			Zolpidem	C				
			Venlafaxine	C				
			Propanolol	C				
			Levothyroxine	C				
			Ropinirole	C				
			Loratidine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/10/05ISR Number: 4579812-XReport Type:Expedited (15-DaCompany Report #2005PK00214
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Dissociative Disorder	Foreign	Zomig	PS		ORAL	4 DF DAILY PO
Initial or Prolonged	Drug Abuser	Health	Sirdalud	SS		ORAL	4 DF DAILY PO
	Intentional Misuse	Professional	Diflucan	SS		ORAL	1 DF DAILY PO
	Somnolence	Other	Benzodiazepines	SS			
	Stupor						
	Tachycardia						

Date:02/10/05ISR Number: 4579912-4Report Type:Expedited (15-DaCompany Report #2004AL000677
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Bradycardia	Literature	Tizanidine				
Hospitalization -	Cardio-Respiratory Arrest	Health	Hydrochloride				
Initial or Prolonged	Coma	Professional	Tablets, 4 Mg				
	Completed Suicide		(Purepac)	PS	Purepac	ORAL	PO
	Haemodialysis		Valproic Acid	SS		ORAL	PO
	Hypotension						
	Intentional Misuse						
	Mental Status Changes						

Date:02/16/05ISR Number: 4589351-8Report Type:Expedited (15-DaCompany Report #ACO_0128_2005
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Confusional State	Foreign	Sirdalud	PS		ORAL	20 MG QDAY PO
Initial or Prolonged	Gait Disturbance	Health	Oxaprozin	C			
	Vertigo	Professional	Kenacort	C			
		Other					

Date:02/22/05ISR Number: 4591094-1Report Type:Direct Company Report #CTU 241023
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Effect Decreased		Tizanidine	PS	Apo Ti-4	ORAL	4MG AND 8MG	
	Dry Mouth						BID ORAL	
	Fatigue		Copaxone	C				
	Muscle Spasticity		Prevacid	C				
	Pharmaceutical Product		Wellbutrin Sr	C				
	Complaint		Femhrt	C				
			Tizanidine	C				

Date:02/22/05ISR Number: 4591413-6Report Type:Expedited (15-DaCompany Report #2005026143
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dissociative Disorder	Foreign	Diflucan Tablets					
	Drug Abuser	Health	(Fluconazole)	PS		ORAL	ORAL	
	Heart Rate Increased	Professional	Tizanidine					
	Muscle Contracture		Hydrochloride					
	Somnolence		(Tizanidine					
	Stupor		Hydrochloride)	SS		ORAL	16 MG (4 MG,	
							1 IN 1	
							D),ORAL	
			Zolmitriptan					

			(Zolmitriptan)	SS		ORAL
10 MG (2.5 MG, 1 IN 1 D), ORAL						
			Benzodiazepine Derivatives (Benzodiazepine Derivatives)	SS		

Date:02/23/05ISR Number: 4595107-2Report Type:Expedited (15-DaCompany Report #JP-SHR-03-002988
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Haemolytic Anaemia	Foreign	Betaferon			
	Leukopenia	Study	(Interferon Beta-1b)			
	Neutropenia	Health	Injection	PS		
SUBCUTANEOUS SEE IMAGE						
	Relapsing-Remitting Multiple Sclerosis Therapy Non-Responder	Professional Other	Ternelin (Tizanidine Hydrochloride) Tablet	SS		ORAL
2 MG, 1X/DAY, ORAL						
			Zantac (Ranitidine Hydrochloride) Tablet	SS		ORAL
300 MG, 1X/DAY, ORAL						
			Mucosta (Rebamipide) Tablet	SS		ORAL
300 MG, 1X/DAY, ORAL						
			Tegretol (Carbamazepine) Tablet	SS		ORAL
SEE IMAGE						
			Takepron (Lansoprazole)	C		
			Solu-Medrol (Methylprednisolone Sodium Succinate)	C		

Glyceol (Glycerol, Fructose)	C
Predonine	C
Iscotin (Isoniazid)	C
Mucodyne (Carbocisteine)	C
Mucosolvan	C
Rimactane (Rifampicin)	C
Vitamedin (Benfotiamine)	C
Voltaren (Diclofenac Sodium)	C
Gaster D (Famotidine)	C

Date:03/01/05ISR Number: 4598348-3Report Type:Direct Company Report #CTU 241765
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Chest Pain		Tizanidine 4mg	PS		ORAL	PO ONCE	QID
	Dyspnoea		Tizanidine 4mg	SS				
	Feeling Abnormal		Klonopin	C				
	Syncope		Neurontin	C				
			Soma	C				
			Lortabs	C				

			Zomig	C		

Date:03/03/05ISR Number: 4599864-0Report Type:Expedited (15-DaCompany Report #ACO_0130_2005
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Conversion Disorder	Foreign	Sirdalud	PS		ORAL	16 MG QD PO
Initial or Prolonged	Dissociative Disorder	Health	Diflucan	SS		ORAL	1 TAB QDAY PO
	Drug Abuser	Professional	Zomig	SS		ORAL	4 TAB QDAY PO
	Dysphonia	Other	Benzodiazepines	SS			
	Muscle Contracture						
	Somnolence						
	Stupor						
	Tachycardia						

Date:03/03/05ISR Number: 4600212-8Report Type:Expedited (15-DaCompany Report #2005-00682
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Drug Interaction	Foreign	Lisinopril	PS	Watson Laboratories	ORAL	10 MG, DAILY,
Intervention to	Potentiation	Literature				ORAL	
Prevent Permanent	Hypotension	Health	Tizanidine				
Impairment/Damage	Idiosyncratic Drug	Professional	(Tizanidine)	SS			2 MG, SINGLE
	Reaction	Other	Amlodipine				
			(Amlodipine)	C			
			Nimodipine				
			(Nimodipine)	C			
			Labetalol				
			(Labetalol)	C			
			Ofloxacin				
			(Ofloxacin)	C			
			Theophylline	C			
			Biofermin				
			(Lactobacillus				
			Acidophilus,				

			Bacillus Subtilis, Streptococcus	C		

Date:03/07/05ISR Number: 4603071-2Report Type:Expedited (15-DaCompany Report #ACO_0127_2005
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Lymphocyte Stimulation	Foreign	Ternelin	PS		ORAL	PO	
	Test Positive	Health	Peon	SS				
	Toxic Skin Eruption	Professional	Marzulene S	SS				
	Urticaria	Other						

Date:03/09/05ISR Number: 4602775-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908829
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Health	Ultracet	PS		OROPHARINGEAL	30g/3 g	
Hospitalization - Initial or Prolonged		Professional	Cyclobenzaprine	SS		OROPHARINGEAL		
			Amitriptyline	SS				
			Tizanidine	SS				
			Rofecoxib	SS				
			Omeprazole	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Health	Harnal (Tamsulosin)	PS		ORAL	0.2 MG (NR)	PO
Other	Aspartate Aminotransferase Increased	Professional	Dantrium (Dantrolene Sodium) (Nr)	SS		ORAL	25 MG (NR)	PO
	Blood Bilirubin Increased		Lioresal (Dantrolene Sodium) (Nr)	SS		ORAL	6 DF (NR)	PO
	Blood Lactate Dehydrogenase Increased		Ternelin (Tizanidine Hydrochloride) (Nr)	SS		ORAL	1 MG TID (NR, TID)	PO
	Gamma-Glutamyltransferase Increased		Vitamedin (Benfotiamine/B6/B12) (Nr)	C				
	Liver Disorder							
	Lymphocyte Stimulation Test Positive		Diazepam (Diazepam) (Nr)	C				
	Malaise							

Date:03/15/05ISR Number: 4611182-0Report Type:Direct Company Report #CTU 243250
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zanaflex - Generic Form	PS			2 MG	
	Pharmaceutical Product Complaint							

Date:03/15/05ISR Number: 4613238-5Report Type:Expedited (15-DaCompany Report #2005040174
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain	Foreign	Triazolam Tablet					

Initial or Prolonged	Acute Prerenal Failure	Literature	(Triazolam)	PS	ORAL
2.5 MG, ORAL					
Other	Blood Pressure Systolic	Health	Flunitrazepam		
	Increased	Professional	(Flunitrazepam)	SS	ORAL
ORAL					
	Body Temperature		Phenobarbital		
	Decreased		(Phenobarbital)	SS	ORAL
ORAL					
	Dehydration		Lorazepam		
	Haemodialysis		(Lorazepam)		
	Intentional Misuse		(Lorazepam)	SS	ORAL
ORAL					
	Rhabdomyolysis		Tizanidine		
	Suicide Attempt		Hydrochloride		
	Vomiting		(Tizanidine		
			Hydrochloride)	SS	ORAL
ORAL					
			Zopiclone		
			(Zopiclone)	SS	ORAL
ORAL					

Date:03/17/05ISR Number: 4611206-0Report Type:Expedited (15-DaCompany Report #US-MERCK-0409USA01708
Age:21 YR Gender:Female I/FU:F

Outcome	PT
Death	Aggression
Hospitalization -	Aspiration
Initial or Prolonged	Completed Suicide
Other	Depressed Level Of
	Consciousness
	Drug Interaction
	Drug Screen Positive
	Drug Toxicity

		Foreign Body Aspiration Intentional Misuse Lung Crepitation	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Lung Disorder		Vioxx	PS	Merck & Co., Inc	ORAL
		Sedation		Flexeril	SS		ORAL
		Self-Medication		Ultracet	SS		
UNKNOWN							
		Vomiting		Omeprazole	SS		ORAL
				Elavil	SS		ORAL
				Tizanidine Hydrochloride	SS		ORAL

Date:03/17/05ISR Number: 4611425-3Report Type:Expedited (15-DaCompany Report #PHBS2004JP16522
Age:27 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization - Initial or Prolonged		Alanine Aminotransferase Increased		Voltaren	PS	Novartis Sector: Pharma	ORAL
75 mg/day	43200MIN						
		Aspartate Aminotransferase Increased		Ternelin	SS		ORAL
3 mg/day	43200MIN						
				Mucosta	SS		ORAL
300 mg/day	43200MIN						
				Mecobalamin	C		ORAL
1000 ug/day							
		Back Pain Condition Aggravated Gamma-Glutamyltransferase Increased Liver Disorder Lymphocyte Stimulation Test Positive					

Date:03/17/05ISR Number: 4619026-8Report Type:Direct Company Report #CTU 243514
Age: Gender: I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Blood Pressure Systolic Decreased Dizziness		Sirdalud -Tizanidine-	PS		

Drug Effect Increased
Drug Interaction
Drug Interaction
Inhibition
Drug Level Increased
Hypotension
Nervous System Disorder
Somnolence

Date:03/18/05ISR Number: 4613530-4Report Type:Direct Company Report #CTU 243721
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Muscle Spasms		Zanaflex - Generic					
	Pharmaceutical Product		Form 2mg	PS				
	Complaint						ZANAFLEX 2MG	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/23/05ISR Number: 4620308-4Report Type:Direct Company Report #CTU 244097
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium Drug Withdrawal Syndrome Overdose Psychotic Disorder		Tizanidine Hcl	PS		ORAL	4MG 1 TID PRN ORAL	

Date:03/24/05ISR Number: 4617527-XReport Type:Expedited (15-DaCompany Report #PHBS2005BE04067
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser Medication Error		Lamisil	PS	Novartis Sector: Pharma		UNKNOWN	6 x 56 tablets = 336 tablets
			Sirdalud	SS			8 packages of 100 Sirdalud 4 mg tablets	92160MIN
			Sirdalud	SS			UNKNOWN	32 packages of 100 Sirdalud 4 mg tablets	106 DAY
			Methadone	SS			UNKNOWN	10 x 60 tablets = 600	

tablets			
		Serenase	SS
UNKNOWN	3 x 50		
tablets = 150			
tablets			
		Temgesic	SS
UNKNOWN	50 DF,		
ONCE/SINGLE			
		Ranitidine	SS
UNKNOWN	9 x 28 or 56		
tablets			
		Amoxycillin	SS
UNKNOWN	500 mg,		
ONCE/SINGLE			
		Brufen	SS
UNKNOWN	400 mg,		
ONCE/SINGLE			
		Ciproxine	SS
UNKNOWN	3 x 20		
tablets = 60			
tablets			

Date:03/24/05ISR Number: 4620084-5Report Type:Expedited (15-DaCompany Report #2005040174
Age:47 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain
Other	Acute Prerenal Failure
	Aphagia
	Blood Chloride Decreased
	Blood Pressure Systolic Increased
	Blood Sodium Decreased
	Dehydration
	Haemodialysis
	Hepatic Function Abnormal
	Intentional Misuse
	Rhabdomyolysis
	Suicide Attempt

Vomiting

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Literature	Halcion (Triazolam)	PS		ORAL	0.25 MG (0.25 MG,)	
Health Professional	Lorazepam (Lorazepam) (Lorazepam)	SS		ORAL	1 MG (1 MG, QD),	ORAL
	Phenobarbital (Phenobarbital)	SS		ORAL		ORAL
	Zopiclone (Zopiclone)	SS		ORAL		ORAL
	Vegetamin(Chlorpromazine Hydrochloride, Phenobarbital, Promethazine Hydrochloride)	SS		ORAL		ORAL
	Tizanidine Hydrochloride (Tizanidine Hydrochloride)	SS		ORAL		ORAL
	Flunitrazepam (Flunitrazepam)	C		ORAL	2 MG (2 MG, QD),	ORAL
	All Other Therapeutic Products (All Other Therapeutic Products)	C				

Date:04/01/05ISR Number: 4627700-2Report Type:Expedited (15-DaCompany Report #ACO_0132_2005
Age:40 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain
	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased
	Blood Calcium Increased
	Blood Lactate Dehydrogenase Increased
	Blood Potassium Increased
	Blood Pressure Systolic Increased
	Blood Sodium Decreased
	Body Temperature Decreased
	Dry Skin
	Glasgow Coma Scale Abnormal
	Haemodialysis
	Intentional Misuse
	Oedema Peripheral
	Oral Intake Reduced
	Renal Failure Acute
	Rhabdomyolysis

	Somnolence						
	Suicide Attempt						
	Vomiting	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign	Ternelin	PS		ORAL	20 MG ONCE PO
		Health	Rohypnol	SS		ORAL	46 MG ONCE PO
		Professional	Halcion	SS		ORAL	2.5 MG ONCE PO
		Other					
			Wypax	SS		ORAL	20 MG ONCE PO
			Slowheim	SS		ORAL	75 MG ONCE PO
			Vegetamin A	SS		ORAL	600 MG ONCE PO

Date:04/01/05ISR Number: 4628375-9Report Type:Expedited (15-DaCompany Report #ACO_0133_2005
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Amnesia	Health	Zanaflex	PS		ORAL	4 MG PO
	Confusional State	Professional	Trazodone Hydrochloride	SS		ORAL	100 MG PO
	Depression						
	Insomnia		Dilaudid	SS			
	Lethargy		Xanax	SS			
	Muscular Weakness		Quinapril	SS			
			Valium	SS			

Date:04/05/05ISR Number: 4626981-9Report Type:Expedited (15-DaCompany Report #PHBS2005BE04067
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Drug Abuser		Lamisil	PS	Novartis Sector:		

UNKNOWN	6 x 56 tablets = 336 tablets		
		Sirdalud	SS
8 packages of 100 Sirdalud 4 mg tablets	92160MIN		
		Sirdalud	SS
UNKNOWN	32 packages of 100 Sirdalud 4 mg tablets		
	106 DAY		
UNKNOWN	10 x 60 tablets = 600 tablets		
		Methadone	SS
		Serenase	SS
UNKNOWN	3 x 50 tablets = 150 tablets		
		Temgesic	SS
UNKNOWN	50 DF, ONCE/SINGLE		
		Ranitidine	SS
UNKNOWN	9 x 28 or 56 tablets		
		Amoxycillin	SS
UNKNOWN	500 mg, ONCE/SINGLE		
		Brufen	SS
UNKNOWN	400 mg, ONCE/SINGLE		
		Ciproxine	SS
UNKNOWN	3 x 20		

tablets = 60

tablets

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/05/05ISR Number: 4629414-1Report Type:Expedited (15-DaCompany Report #ACO_0135_2005
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Foreign	Zanaflex	PS				
	Dyskinesia	Consumer	Inhaler	C				
	Muscle Spasms	Other						
	Speech Disorder							

Date:04/07/05ISR Number: 4708207-0Report Type:Direct Company Report #USP 57197
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Dispensing Error		Gabitril	PS	Cephalon	TABLET		
	Medication Error		Zanaflex	SS		TABLET		

Date:04/08/05ISR Number: 4633338-3Report Type:Expedited (15-DaCompany Report #ACO-0127_2005
Age:27 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Generalised Erythema	Foreign	Ternelin	PS		ORAL	PO	
	Lymphocyte Stimulation	Health	Peon	SS				
	Test Positive	Professional	Marzulene S	SS				
	Pigmentation Disorder	Other	Dan Rich	SS				
	Rash		Over-The - Counter					
	Toxic Skin Eruption		Antitussives (Nos)	SS				
	Urticaria							

Date:04/12/05ISR Number: 4633339-5Report Type:Expedited (15-DaCompany Report #ACO_0036_2004
Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase	Foreign	Ternelin	PS		ORAL	3 MG QDAY PO	

Initial or Prolonged 75 MG QDAY PO	Increased	Health	Voltaren	SS		ORAL
	Aspartate Aminotransferase Increased Back Pain Gamma-Glutamyltransferase Abnormal Liver Disorder Lymphocyte Stimulation Test Positive	Professional Other	Mucosta Mecobalamin	SS C		ORAL
300 MG QDAY PO						

Date:04/14/05ISR Number: 4636804-XReport Type:Expedited (15-DaCompany Report #ACO_0137_2005
Age:64 YR Gender:Male I/FU:I

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Disability	Confusional State Dyspnoea Loss Of Consciousness Quadriparesis Rales	Foreign Health Professional Other	Sirdalud	PS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/14/05ISR Number: 4636807-5Report Type:Expedited (15-DaCompany Report #ACO_0138_2005
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Foreign	Zanaflex	PS		ORAL	4 MG PO	
		Health Professional	Lamisil	SS				
			Methadone	SS		ORAL	25 MG PO	5 MON
		Other	Serenase	SS		ORAL	2.5 MG PO	
			Temgesic Schering-Plough	SS	Schering-Plough	ORAL	0.2 MG PO	
			Ranitidine	SS		ORAL	300 MG PO	
			Amoxicillin	SS		ORAL	500 MG PO	
			Brufen Abbott	SS	Abbott	ORAL	400 MG PO	
			Ciproxine	SS		ORAL	500 MG PO	

Date:04/14/05ISR Number: 4636822-1Report Type:Expedited (15-DaCompany Report #DSA_26193_2005
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Foreign	Wypax	PS		ORAL	20 MG ONCE PO	
	Blood Potassium Increased	Health Professional	Halicion	SS		ORAL	2.5 MG ONCE PO	
	Blood Pressure Systolic Increased	Other	Rohypnol	SS		ORAL	DF ONCE PO	
	Body Temperature Decreased		Ternelin	SS		ORAL	20 MG ONCE PO	
	Depression		Vegetamin A	SS		ORAL	600 MG ONCE PO	
	Dry Skin		Slowheim	SS		ORAL	75 MG ONCE PO	

	Glasgow Coma Scale		Wypax	SS		ORAL
DF UNK PO						
	Abnormal		Halcion	SS		ORAL
DF UNK PO						
	Haemodialysis		Rohypnol	SS		ORAL
DF UNK PO						
	Hepatic Function Abnormal		Ternelin	SS		ORAL
DF UNK PO						
	Intentional Misuse		Vegetamin A	SS		ORAL
DF UNK PO						
	Oedema Peripheral		Slowheim	SS		ORAL
DF UNK PO						
	Renal Failure Acute					
	Rhabdomyolysis					
	Suicide Attempt					

Date:04/21/05ISR Number: 4643078-2Report Type:Expedited (15-DaCompany Report #ACO_0135_2005
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Back Pain	Foreign	Tizanidine	PS		ORAL	4 MG Q6HR PO
	Dyskinesia	Consumer	Inhaler (Name Unknown)	C			
	Muscle Spasms	Other					
	Speech Disorder						
	Torticollis						

Date:04/21/05ISR Number: 4643080-0Report Type:Expedited (15-DaCompany Report #ACO_0141_2005
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Chest Pain	Foreign	Ternelin	PS			DF
	Peripheral Coldness	Health Professional					
		Other					

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Freedom Of Information (FOI) Report

Date:04/28/05ISR Number: 4649741-1Report Type:Direct Company Report #CTU 247336
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Swelling Face		Zanaflex 4 Mg	PS				

Date:05/02/05ISR Number: 4651569-3Report Type:Expedited (15-DaCompany Report #2005061462
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Bextra (Valdecoxib)	PS		ORAL	20 MG (20 MG, 1 IN 1 D), ORAL	
	Blister							
	Chondropathy							
	Crying		Celebrex (Celecoxib)	SS		ORAL	(1 IN 1 D), ORAL	
	Drug Ineffective							
	Emotional Distress		Tizanidine Hydrochloride (Tizanidine Hydrochloride)	SS				
	Exostosis							
	Fear							
	Herpes Simplex							
	Inadequate Analgesia							
	Intervertebral Disc Disorder							
	Memory Impairment							
	Pruritus							
	Scar							
	Skin Reaction							
	Somnolence							

Date:05/03/05ISR Number: 4652984-4Report Type:Expedited (15-DaCompany Report #KII-2005-0016321
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Sodium Decreased	Study	Oxycodone Hydrochloride					
	Electrocardiogram Qt	Other						

Other	Corrected Interval Prolonged	(Similar To Nda 20-553) (Oxycodone			
	Hypotension	Hydrochloride)	PS		ORAL
ORAL					
	Lethargy	Tizanidine			
	Mental Status Changes	(Tizanidine)	SS		ORAL
ORAL					
	Renal Failure Acute	Benzodiazepine Derivatives (Benzodiazepine			
		Derivatives)	SS		ORAL
ORAL					
		Hydrochlorothiazide (Hydrochlorothiazide			
		)	SS		ORAL
ORAL					
		Ace Inhibitor Nos			
		(Ace Inhibitor Nos)	SS		ORAL
ORAL					

Date:05/05/05ISR Number: 4656450-1Report Type:Expedited (15-DaCompany Report #S05-SWI-01568-01
Age:33 YR Gender:Female I/FU:I

Outcome	PT
Other	Burning Sensation
	Condition Aggravated
	Dizziness
	Dyspnoea
	Fatigue

		Muscular Weakness Somnolence Tongue Disorder	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Health	Cipralex (Escitalopram)	PS		ORAL
10 MG QD PO							
			Professional Other	Sirdalud (Tizanidine Hydrochloride)	SS		
				Felden (Piroxicam)	C		
				Ponstan (Mefenamic Acid)	C		
				Xefo (Lornoxicam)	C		

Date:05/06/05ISR Number: 4656778-5Report Type:Expedited (15-DaCompany Report #2005PK00757
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required Intervention to	Convulsion Sleep Disorder	Foreign Health	Nolvadex Astrazeneca	PS	Astrazeneca	ORAL
20 MG DAILY						
Prevent Permanent		Professional				
PO						
Impairment/Damage		Other	Tramal	SS		ORAL
100 MG DAILY						
PO						
			Sirdalud	SS		ORAL
2 MG DAILY PO						

Date:05/09/05ISR Number: 4658145-7Report Type:Expedited (15-DaCompany Report #2005061462
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Activities Of Daily	Consumer	Bextra (Valdecoxib)	PS		ORAL
20 MG (20 MG,						
	Living Impaired					
1 IN 1 D),						
	Crying					
ORAL						

	Drug Ineffective	Celebrex (Celecoxib)	SS	ORAL 1 IN 1 D,
	Exostosis			ORAL
	Fatigue	Tizanidine Hydrochloride (Tizanidine Hydrochloride)	SS	
	Herpes Simplex			
	Intervertebral Disc Disorder			
	Memory Impairment			
	Oral Mucosal Blistering			
	Pain			
	Pruritus			
	Rash Pruritic			
	Scar			
	Skin Disorder			
	Skin Reaction			
	Somnolence			
	Stress			

Date:05/09/05ISR Number: 4658772-7Report Type:Expedited (15-DaCompany Report #ACO_0143_2005
Age:71 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Anaemia
	Balance Disorder
	Blindness Transient
	Blood Pressure Increased
	Bradycardia
	Cardiomegaly
	Carotid Bruit

	Coronary Artery Stenosis Dizziness Drug Interaction	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Electrocardiogram Poor	Foreign	Tizanidine	PS		ORAL
3 MG QDAY PO 33 DAY						
	R-Wave Progression	Literature	Ticlopidine	SS		ORAL
100 MG TID PO						
	Electrocardiogram St-T Change Glycosylated Haemoglobin Increased Pulse Absent Reflexes Abnormal Sinus Arrhythmia Sinus Bradycardia Ventricular Hypertrophy	Health Professional Other				

Date:05/12/05ISR Number: 4660036-2Report Type:Expedited (15-DaCompany Report #US-2004-BP-12563BP
Age:56 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Chromaturia Diarrhoea Jaundice Nausea Vomiting		Mirapex Tablets Metformin Estrogen Zanaflex Rebif	PS SS SS SS SS	B.I. Pharmaceuticals,Inc. /Ridgefield	ORAL

Date:05/13/05ISR Number: 4663254-2Report Type:Expedited (15-DaCompany Report #ACO_0144_2005
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Burning Sensation	Foreign	Sirdalud	PS		ORAL
4 TAB QDAY PO						
	Dizziness	Health	Cipralex	SS		ORAL
10 MG NIGHTLY						
	Dyspnoea	Professional				
PO						
	Muscular Weakness	Other	Felden	C		

	Somnolence		Ponstan	C
	Sudden Onset Of Sleep		Xefo	C
	Tongue Disorder			

Date:05/16/05ISR Number: 4664015-0Report Type:Direct Company Report #CTU 248634
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Condition Aggravated		Zanaflex Generic					
	Drug Effect Decreased		Form 2mg	PS				
ZANAFLEX 2MG								
	Muscle Spasms							
	Therapeutic Response							
	Unexpected							

Date:05/25/05ISR Number: 4673499-3Report Type:Expedited (15-DaCompany Report #PHBS2005JP06867
Age:62 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Anaphylactic Shock
	Blood Pressure Decreased
	Confusional State
	Erythema

	Vomiting						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Voltaren Sr	PS	Novartis Sector: Pharma	ORAL	75 mg/day
			Ternelin	SS		ORAL	2 mg/day
			Mucosta	SS		ORAL	2 DF/day

Date:06/02/05ISR Number: 4679968-4Report Type:Expedited (15-DaCompany Report #PHFR2005GB01965
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Blood Creatinine		Baclofen	PS	Novartis Sector:		
Hospitalization -	Increased				Pharma	ORAL	40 mg, QD
Initial or Prolonged	Drug Level Increased		Tizanidine	SS		ORAL	36mg/day
Other	Epilepsy		Gabapentin	SS			UNKNOWN 400 mg, BID
	Glasgow Coma Scale		Bendrofluazide	C		ORAL	2.5mg/day
	Abnormal						
	Hallucination						
	Loss Of Consciousness						
	Overdose						
	Renal Failure Acute						
	Urinary Tract Infection						

Date:06/02/05ISR Number: 4681511-0Report Type:Expedited (15-DaCompany Report #ZICO001221
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Anaemia	Health	Prialt (Ziconotide				
Initial or Prolonged	Anxiety	Professional	Intrathecal				
	Blood Albumin Decreased		Infusion)	PS			INTRATHECAL 0.1 MCG/HR

	Blood Creatine		
INTRATHECAL			
	Phosphokinase Increased	Zanaflex	
	Blood Creatine	(Tizanidine)	SS
	Phosphokinase Mb	Neurontin	
	Increased	(Gabapentin)	C
	Dyspnoea	Restoril (Temazepam)	C
	Headache	Wellbutrin	
	Pulmonary Oedema	(Amfebutamone	
		Hydrochloride)	C
		Dilaudid	
		(Hydromorphone	
		Hydrochloride)	C
		Oxybutryn	
		(Oxybutryn)	C
		Protonix(Pantoprazol	
		e)	C
		Zoloft (Sertraline	
		Hydrochloride)	C
		Procrit	
		(Erythropoeitin)	C
		Hydrochlorothiazid	
		(Hydrochlorothiazide	
		)	C
		Levaquin	
		(Levofloxacin)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/02/05ISR Number: 4682499-9Report Type:Direct Company Report #CTU 250170
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Effect Decreased		Tizanidine 4 Mg	PS			3 PER DAY; 1	
	Dry Mouth						3 TIMES PER	
	Headache						DAY	
	Insomnia							
	Pharyngitis Streptococcal							

Date:06/06/05ISR Number: 4682504-XReport Type:Expedited (15-DaCompany Report #CH-MERCK-0409CHE00009
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bradycardia		Vioxx	PS	Merck & Co., Inc	ORAL	8	DAY
Initial or Prolonged	Hepatic Enzyme Increased		Tizanidine Hydrochloride	SS		ORAL	1	DAY
			Tizanidine Hydrochloride	SS		ORAL	1	DAY
			Tizanidine Hydrochloride	SS		ORAL	1	DAY
			Diclofenac Sodium	SS		ORAL		
			Herbs (Unspecified)	C		ORAL		

Date:06/09/05ISR Number: 4688149-XReport Type:Expedited (15-DaCompany Report #430015M05USA
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Idiopathic	Health	Novantrone					
Initial or Prolonged	Thrombocytopenic Purpura	Professional	(Mitoxantrone Hydrochloride)	PS			25 MG/M2, 3	

IN 1 MONTHS

Effexor (Venlafazine Hydrochloride)	SS
Zanaflfex (Tizanidine Hydrochloride)	SS
Neurontin (Gabapentin)	C
Provigil (Modafinil)	C
Inderal (Propranolol Hydrochoride)	C
Clonazepam (Clonazepam)	C
Naprilan (Enalapril)	C
Ambien (Zolipen (Enalapril)	C
Imitrex (Sumatriptan Succinate)	C
Urocholine (All Other Non-Therapeutic Products)	C
Trileptal (Oxycarbazepine)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/09/05ISR Number: 4688206-8Report Type:Expedited (15-DaCompany Report #ACO_0162_2005
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Health	Zanaflex	PS		ORAL	DF	PO
	Paranoia	Professional	Effexor-Xr	SS		ORAL	37.5 MG	ONCE
PO								
			Lexapro	C				
			Duragesic	C				
			Zonegran	C				
			Clonidine	C				
			Ultram	C				

Date:06/14/05ISR Number: 4691907-9Report Type:Expedited (15-DaCompany Report #ACO_0163_2005
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase	Health	Tizanidine	PS		ORAL	DF	PO
Initial or Prolonged	Increased	Professional	Prialt/Ziconotide	SS				
INTRATHORACIC	DF IT							
	Anaemia		Neurontin	C				
	Anxiety		Restoril	C				
	Aspartate							
	Aminotransferase							
	Increased							
	Band Neutrophil							
	Percentage Decreased							
	Blood Alkaline							
	Phosphatase Increased							
	Blood Calcium Decreased							
	Blood Creatine							
	Phosphokinase Increased							
	Blood Creatine							
	Phosphokinase Mb							
	Increased							
	Blood Glucose Increased							
	Blood Iron Decreased							
	Blood Lactate							
	Dehydrogenase Increased							

Drug Screen Positive
Dyspnoea
Haematocrit Decreased
Haemoglobin Decreased
Haptoglobin Increased
Headache
Laboratory Test Abnormal
Lymphocyte Percentage Decreased
Mean Cell Haemoglobin Concentration Decreased
Mean Cell Haemoglobin Decreased
Mean Cell Volume Increased
Neutrophil Count Abnormal
Neutrophil Percentage Increased
Pulmonary Oedema
Red Cell Distribution Width Increased
White Blood Cell Count Increased

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/14/05ISR Number: 4692043-8Report Type:Expedited (15-DaCompany Report #HQWYE133802JUN05
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Idiopathic Thrombocytopenic Purpura	Health Professional	Novantrone (Mitoxantrone Hydrochloride, Injection)	PS			25 MG/M2	EVERY 3 MONTHS
			Effexor (Venlafaxine Hydrochloride, Tablet)	SS				
			Zanaflex (Tizanidine Hydrochloride,)	SS				
			Neurontin (Gabapentin)	C				
			Inderal (Propranolol Hydrochloride)	C				
			Clonazepam (Clonazepam)	C				
			Naprilene (Enalapril Maleate)	C				
			Ambien (Zolpidem Tartrate)	C				
			Imitrex (Sumatriptan Succinate)	C				
			Trileptal (Oxcarbazepine)	C				
			Provigil (Modafinil)	C				

Date:06/14/05ISR Number: 4692169-9Report Type:Expedited (15-DaCompany Report #TZD20050003
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia	Foreign	Tizanidine Hcl	PS		ORAL	3 MG DAILY PO	
	Areflexia	Literature	Ticlopidine Hcl	C				
	Balance Disorder	Health Professional						
	Blindness Transient							

Blood Pressure Diastolic Decreased
Blood Pressure Systolic Increased
Cardiomegaly
Carotid Bruit
Coronary Artery Stenosis
Dizziness
Drug Level Increased
Electrocardiogram Poor R-Wave Progression
Electrocardiogram St-T Change
Glycosylated Haemoglobin Increased
Pulse Absent
Sinus Arrhythmia
Sinus Bradycardia
Ventricular Hypertrophy

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/15/05ISR Number: 4690435-4Report Type:Expedited (15-DaCompany Report #PHBS2004CH11775
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abdominal Pain Upper		Voltaren	PS	Novartis Sector: Pharma			
Hospitalization -	Alanine Aminotransferase							
UNKNOWN							50 mg/d	4320 MIN
Initial or Prolonged	Increased		Sirdalud	SS		ORAL		
6 mg/day	4320 MIN							
Other	Aspartate		Vioxx	SS				
UNKNOWN							25 mg/d	4320 MIN
	Aminotransferase		Herbal Extracts Nos	SS				
	Increased							
	Brain Natriuretic Peptide							
	Increased							
	Chest Discomfort							
	Chest Pain							
	Diarrhoea							
	Drug Interaction							
	Dyspnoea							
	Fibrin D Dimer Increased							
	Gamma-Glutamyltransferase							
	Increased							
	Haemangioma Of Liver							
	Hepatic Enzyme Increased							
	Hepatic Lesion							
	Hepatotoxicity							
	Hyperhidrosis							
	Nausea							
	Pleural Effusion							
	Pulmonary Hypertension							
	Right Ventricular Failure							
	Sinus Bradycardia							
	Vomiting							

Date:06/16/05ISR Number: 4693790-4Report Type:Expedited (15-DaCompany Report #ACO_0166_2005
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Exanthem	Foreign	Ternelin	PS		ORAL		
2 MG QDAY PO								
Initial or Prolonged	Hypotension	Health	Voltaren	SS		ORAL		
75 MG QDAY PO								

	Vomiting	Professional	Mucosta	SS
2 DF QDAY				
		Other		

Date:06/17/05ISR Number: 4695028-0Report Type:Expedited (15-DaCompany Report #ACO_0167_2005
Age:59 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Acute Right Ventricular Failure
Required Intervention to Prevent Permanent Impairment/Damage	Alanine Aminotransferase Increased
	Angiopathy
	Aspartate Aminotransferase Increased
	Blood Pressure Systolic Increased
	Bradycardia
	Drug Interaction
	Gamma-Glutamyltransferase Increased
	Haemangioma Of Liver

	Hepatic Cyst Liver Function Test Abnormal	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Pulmonary Hypertension	Foreign	Sirdalud	PS		ORAL	VAR QDAY PO 3 DAY
	Tachycardia	Literature	Vioxx	SS		ORAL	25 MG QDAY PO
	Ventricular Extrasystoles	Health Professional Other	Voltaren Phytotherapeutics	C C			

Date:06/21/05ISR Number: 4697993-4Report Type:Expedited (15-DaCompany Report #2005084736
Age:53 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Abasia	Foreign	Serlain (Sertraline)	PS		ORAL	50 MG (50 MG,
	Drug Interaction	Health					1 IN 1 D),
	Feeling Abnormal	Professional					ORAL
			Sirdalud (Tizanidine Hydrochloride)	SS		ORAL	ORAL

Date:06/22/05ISR Number: 4699425-9Report Type:Expedited (15-DaCompany Report #ACO_0170_2005
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Blood Pressure Systolic Decreased Intentional Misuse Overdose Somnolence	Foreign Health Professional Other	Ternelin Alcohol	PS SS		ORAL	20 DF ONCE PO

Date:06/22/05ISR Number: 4699426-0Report Type:Expedited (15-DaCompany Report #ACO_0171_2005
Age:8 MON Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Drug Intake By Child Bradycardia Depressed Level Of Consciousness	Foreign Other	Sirdalud	PS		ORAL	32 MG ONCE PO	

Date:06/22/05ISR Number: 4699427-2Report Type:Expedited (15-DaCompany Report #ACO_0169_2005
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Epilepsy	Foreign	Zanaflex	PS		ORAL	36 MG PO	
	Glasgow Coma Scale	Health	Gabapentin	SS		ORAL	800 MG PO	
	Abnormal	Professional	Baclofen	SS		ORAL	40 MG PO	
	Hallucination	Other	Ciprofloxacin	C				
	Intentional Misuse		Bendrofluazide	C				
	Loss Of Consciousness							
	Overdose							
	Renal Failure Acute							
	Urinary Tract Infection							

Date:06/27/05ISR Number: 4701637-2Report Type:Expedited (15-DaCompany Report #2005084736
Age:53 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Abasia	Foreign	Serlain (Sertraline)	PS		ORAL	50 MG (50 MG, 1 IN 1 D),	
	Depression	Health						
	Drug Interaction	Professional					ORAL	
	Feeling Abnormal		Sirdalud (Tizanidine Hydrochloride)	SS		ORAL	ORAL	

Date:06/29/05ISR Number: 4702901-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050606116
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse		Flexeril	PS				
	Loss Of Consciousness		Zanaflex	SS				
			Klonopin	SS				
			No-Doz	SS				
			No-Doz	SS				
			Lexapro	C				
			Depakote	C				

Date:06/29/05ISR Number: 4702997-9Report Type:Expedited (15-DaCompany Report #PHBS2003JP01063
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Eosinophilia		Tegretol	PS	Novartis Sector:			
Hospitalization - Initial or Prolonged	Generalised Erythema				Pharma	ORAL	200 mg, BID	36000MIN
	Hepatic Function Abnormal		Tegretol	SS	Novartis Sector:			
	Hypogammaglobulinaemia				Pharma	ORAL	200 mg, TID	5760 MIN
	Immunodeficiency		Tegretol	SS	Novartis Sector:			
	Lung Infiltration				Pharma	ORAL	200 mg, QID	25920MIN
	Myotonia		Tegretol	SS	Novartis Sector:			

		Pneumonia				Pharma	
200 mg, TID	60480MIN						
		Productive Cough		Tegretol	SS	Novartis Sector:	
		Pyrexia				Pharma	ORAL
200 mg, BID	40320MIN						
		Rales		Gaster	SS		
UNKNOWN							
		Rash Generalised		Ternelin	SS		
UNKNOWN							
		Skin Exfoliation		Predonine	C		ORAL
15 mg/day							
		Upper Respiratory Tract		Selbex	C		ORAL
150 mg/day							
		Infection		Rize	C		ORAL
5 mg/day							
		Upper Respiratory Tract Inflammation					

Date:07/05/05ISR Number: 4708794-2Report Type:Expedited (15-DaCompany Report #ACO_0172_2005
Age:61 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Lethargy	Foreign	Zanaflex	PS		ORAL
2 MG TID PO						
	Myalgia	Health	Zanaflex	SS		ORAL
2 MG QWK PO						
		Professional	Evening Primrose	C		
		Other	Vitamin C	C		
			Ibuprfen	C		
			Imipramine	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/07/05ISR Number: 4708246-XReport Type:Expedited (15-DaCompany Report #PHBS2003JP01063
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Eosinophilia		Tegretol	PS	Novartis Sector:			
Hospitalization -	Generalised Erythema				Pharma	ORAL	200 mg, BID	36000MIN
Initial or Prolonged	Hepatic Function Abnormal		Tegretol	SS	Novartis Sector:			
	Hypogammaglobulinaemia				Pharma	ORAL	200 mg, TID	5760 MIN
	Lung Infiltration		Tegretol	SS	Novartis Sector:			
	Pneumonia				Pharma	ORAL	200 mg, QID	25920MIN
	Productive Cough		Tegretol	SS	Novartis Sector:			
	Pyrexia				Pharma		200 mg, TID	60480MIN
	Rales		Tegretol	SS	Novartis Sector:			
	Rash Generalised				Pharma	ORAL	200 mg, BID	40320MIN
	Upper Respiratory Tract		Gaster	SS			UNKNOWN	
	Infection		Ternelin	SS			UNKNOWN	
			Predonine	C		ORAL	15 mg/day	
			Selbex	C		ORAL	150 mg/day	
			Rize	C		ORAL	5 mg/day	

Date:07/07/05ISR Number: 4709528-8Report Type:Expedited (15-DaCompany Report #ACO_0173_2005
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Screen Positive		Zanaflex	PS		ORAL	DF PO	
Initial or Prolonged	Feelings Of Worthlessness		Klonopin	SS		ORAL	DF PO	
	Loss Of Consciousness		Flexeril	SS			DF PO	
	Multiple Drug Overdose		No-Doz	SS		ORAL	DF PO	
	Polysubstance Abuse		Lexapro	C				

	Somnolence					
	Suicidal Ideation					

Date:07/08/05ISR Number: 4710995-4Report Type:Expedited (15-DaCompany Report #ACO_0166_2005
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Erythema	Health	Ternelin	PS		ORAL	2 MG QDAY PO
	Exanthem	Professional	Voltaren	SS		ORAL	75 MG QDAY PO
	Hypotension		Mucosta	SS			2 DF QDAY
	Vomiting						

Date:07/08/05ISR Number: 4711002-XReport Type:Expedited (15-DaCompany Report #ACO_0174_2005
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Difficulty In Walking	Foreign	Tizanidine	PS		ORAL	2 MG QDAY PO
	Dizziness	Health	Propranol	C			
	Dry Mouth	Professional	Losartan Potassium W/Hydrochlorothiazide	C			
	Feeling Abnormal	Other	Euthyrox	C			
	Speech Disorder						

Date:07/13/05ISR Number: 4715469-2Report Type:Expedited (15-DaCompany Report #KII-2005-0017347
Age:41 YR Gender:Female I/FU:I

Outcome
Hospitalization - Initial or Prolonged

Other

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Intentional Misuse	Study	Morphine Sulfate					
	Multiple Drug Overdose	Health	(Morphine Sulfate)	PS		ORAL	SEE TEXT,	
	Oxygen Saturation	Professional					ORAL	
	Decreased	Other	Tizanidine					
	Polysubstance Abuse		(Tizanidine)	SS		ORAL	SEE TEXT,	
	Respiratory Rate						ORAL	
	Decreased		Diazepam (Diazepam)	SS		ORAL	SEE TEXT,	
	Respiratory Rate						ORAL	
	Increased		Clonazepam					
	Sinus Tachycardia		(Clonazepam)	SS		ORAL	SEE TEXT,	
	Somnolence						ORAL	
			Marijuana (Cannabis)	SS				
RESPIRATORY (INHALATION)						INHALATION		

Date:07/19/05ISR Number: 4718975-XReport Type:Expedited (15-DaCompany Report #ACO_0175_2005
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Body Temperature	Foreign	Ternelin	PS		ORAL	1 MG QDAY; PO	
Hospitalization -	Decreased	Health	Solantal	SS		ORAL	50 MG QDAY;	
Initial or Prolonged	Drug Interaction	Professional					PO	
	Myocardial Infarction	Other	Marzulene	C				

Date:07/20/05ISR Number: 4718400-9Report Type:Expedited (15-DaCompany Report #CH-MERCK-0409CHE00009
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Discomfort		Vioxx	PS	Merck & Co., Inc	ORAL	8	DAY
Initial or Prolonged	Abdominal Pain		Tizanidine Hydrochloride	SS		ORAL	1	DAY
	Acute Right Ventricular Failure		Tizanidine Hydrochloride	SS		ORAL	1	DAY
	Bradycardia		Tizanidine Hydrochloride	SS		ORAL	1	DAY
	Diarrhoea		Diclofenac Sodium	SS		ORAL		
	Hepatic Cyst		Herbs (Unspecified)	C		ORAL		
	Hepatic Enzyme Increased							
	Hyperhidrosis							
	Nausea							
	Pulmonary Hypertension							
	Sinus Bradycardia							
	Vomiting							

Date:07/20/05ISR Number: 4719189-XReport Type:Expedited (15-DaCompany Report #S05-CAN-02441-01
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression	Foreign	Citalopram (Hydrobromide)	PS			40 MG QD	
	Drug Withdrawal Syndrome	Health Professional	Marijuana (Cannabis)	SS			UNKNOWN	UNK
	Personality Change	Other	Topimax (Topiramate)	SS			100 MG QD	
	Psychotic Disorder		Zanaflex (Tizanidine Hydrochloride)	SS			12 MG QD	
	Speech Disorder		Diphenhydramine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/29/05ISR Number: 4733536-4Report Type:Expedited (15-DaCompany Report #ZANA001129
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Myocardial Infarction	Foreign	Zanaflex	PS		ORAL	4 MG QDAY PO	
	Rash	Health	Zanaflex	SS		ORAL	4 MG QDAY PO	
	Respiratory Tract	Professional	Zanaflex	SS		ORAL	0.01 MG TID	
	Infection	Other					PO	38 DAY
	Ventricular Fibrillation		Vancocyn	C				
			Flagyl	C				
			Tylenol	C				
			Neurontin	C				
			Ativan	C				
			Valium	C				
			Diovol	C				
			Lovenox	C				

Date:08/01/05ISR Number: 4733326-2Report Type:Direct Company Report #CTU 254997
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zanaflex	PS		ORAL	4 MG PO BID	
	Pharmaceutical Product Complaint							

Date:08/02/05ISR Number: 4736410-2Report Type:Expedited (15-DaCompany Report #ACO_0170_2005
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Systolic Decreased	Foreign Health	Ternelin	PS		ORAL	20 TAB ONCE PO	
	Coma	Professional	Alcohol	SS				
	Intentional Misuse	Other						

	Intentional Self-Injury					
	Overdose					
	Somnolence					

Date:08/02/05ISR Number: 4736412-6Report Type:Expedited (15-DaCompany Report #ACO_0141_2005
Age:56 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Pain	Foreign	Ternelin	PS				
DF								
	Hypoaesthesia	Health						
	Peripheral Coldness	Professional						
		Other						

Date:08/03/05ISR Number: 4735833-5Report Type:Direct Company Report #CTU 255403
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pharmaceutical Product		Zanaflex	PS				
4MG TID								
	Complaint		Baclofen	C				
	Vomiting		Artane	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/15/05ISR Number: 4744888-3Report Type:Expedited (15-DaCompany Report #US-MERCK-0409USA01708
Age:21 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Chest Sound		Vioxx	PS	Merck & Co., Inc	ORAL		
Hospitalization -	Aggression		Flexeril	SS		ORAL		
Initial or Prolonged	Aspiration		Ultracet	SS				
UNKNOWN								
Other	Completed Suicide		Omeprazole	SS		ORAL		
	Depressed Level Of Consciousness		Elavil	SS		ORAL		
			Tizanidine Hydrochloride	SS		ORAL		
	Drug Interaction							
	Drug Screen Positive							
	Drug Toxicity							
	Intentional Misuse							
	Lung Crepitation							
	Lung Disorder							
	Sedation							
	Self-Medication							
	Vomiting							

Date:08/16/05ISR Number: 4746208-7Report Type:Expedited (15-DaCompany Report #CH-MERCK-0409CHE00009
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain		Vioxx	PS	Merck & Co., Inc	ORAL	8	DAY
Initial or Prolonged	Alanine Aminotransferase Increased		Tizanidine Hydrochloride	SS		ORAL	1	DAY
	Aspartate Aminotransferase Increased		Tizanidine Hydrochloride	SS		ORAL	1	DAY
	Back Pain		Tizanidine Hydrochloride	SS		ORAL	1	DAY
	Blood Alkaline Phosphatase Increased		Diclofenac Sodium	SS		ORAL		
	Bradycardia		Herbs (Unspecified)	C		ORAL		
	Chest Discomfort							
	Diarrhoea							
	Drug Interaction							
	Dyspnoea							

Fibrin D Dimer Increased
Gamma-Glutamyltransferase Increased
Haemangioma Of Liver
Hepatic Cyst
Hepatic Lesion
Hyperhidrosis
Liver Disorder
Liver Function Test Abnormal
Pleural Effusion
Pulmonary Hypertension
Right Ventricular Failure
Sinus Bradycardia
Vomiting

Date:08/18/05ISR Number: 4747990-5Report Type:Expedited (15-DaCompany Report #US-SANOFI-SYNTHELABO-A03200500832
Age: Gender:Female I/FU:F

Outcome PT
Other Abdominal Discomfort
Gastrointestinal

Haemorrhage

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
UNK			Ambien	PS		ORAL
UNK			Plavix	SS		ORAL
UNK			Carafate	SS		ORAL
UNK			Metoclopramide	SS		ORAL
UNK			Darvocet	SS		ORAL
UNK			Mycelex	SS		
UNKNOWN	UNK		Promethazine	SS		ORAL
UNK			Lasix	SS		ORAL
UNK			Tizanidine	SS		ORAL
UNK						

Date:08/18/05ISR Number: 4748218-2Report Type:Expedited (15-DaCompany Report #200516252US
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Abdominal Discomfort Gastrointestinal		Lasix	PS	Aventis Pharmaceuticals Inc.	ORAL
dose: UNKNOWN	Haemorrhage		Ambien	SS		ORAL
dose: UNKNOWN			Plavix	SS		ORAL
dose: UNKNOWN			Carafate	SS		ORAL
dose: UNKNOWN			Metoclopramide	SS		ORAL
dose: UNKNOWN			Darvocet-N	SS		ORAL
dose: UNKNOWN			Mycelex	SS		
dose: UNKNOWN			Promethazine	SS		ORAL
dose: UNKNOWN						

			Tizanidine	SS		ORAL	

dose: UNKNOWN

Date:08/19/05ISR Number: 4749387-0Report Type:Expedited (15-DaCompany Report #CH-MERCK-0409CHE00009
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bradycardia		Vioxx	PS	Merck & Co., Inc	ORAL		8 DAY
Initial or Prolonged	Hepatic Enzyme Increased		Tizanidine Hydrochloride	SS		ORAL		1 DAY
			Tizanidine Hydrochloride	SS		ORAL		1 DAY
			Tizanidine Hydrochloride	SS		ORAL		1 DAY
			Diclofenac Sodium	SS		ORAL		
			Herbs (Unspecified)	C		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Summary report for FOI selections:

Selection by inexact search of active ingredient: TIZANIDINE%

Selection by inexact search of Tradename/Verbatim: ZANAFLEX%

Total number of reports: 1,065

From: 01-NOV-1997 To: Present