Freedom Of Information (FOI) Report

Amitriptyline

Multivitamins

C

C

C

Lasix

Os-Cal

Ecotrin

Date:11/05/97ISR Number: 100000165Report Type:Expedited (15-DaCompany Report #ZANA0319970279

Age: 45 YR Gender: Female I/FU:I

		Zanaflex Valium	PS	ORAL
- 5 4	Professional	Valium		
piratory Depression		Betaseron Darvocet Tylenol Synthroid	C C C C	
I/FU:I		#ZANA0319970282	Role Manufacturer	Route
phagia	Health	Zanaflex	PS	ORAL
	Professional	Ritonavir	С	
· (0000206Report Type:Expedite I/FU:I phagia cle Spasms	0000206Report Type:Expedited (15-DaCompany Report I/FU:I Report Source phagia Cle Spasms Professional	Tylenol Synthroid 0000206Report Type:Expedited (15-DaCompany Report #ZANA0319970282 I/FU:I Report Source Product phagia Health Zanaflex cle Spasms Professional Ritonavir	Tylenol C Synthroid C 0000206Report Type:Expedited (15-DaCompany Report #ZANA0319970282 I/FU:I Report Source Product Role Manufacturer phagia Health Zanaflex PS cle Spasms Professional Ritonavir C

Dyspnoea Hypotension

Pneumothorax Pulmonary Oedema

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration		-			
Hospitalization - 24 MG DAILY,	Abdominal Pain Lower	Health	Zanaflex	PS	ORAL
Initial or Prolonged PER ORAL	Acute Respiratory	Professional			
	Distress Syndrome		Prednisone	C	
	Anxiety		Ditropan	C	
	Constipation		Halcion	C	
	Dehydration		Zantac	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					
Hospitaliza	tion -	Convulsion	Health	Zanaflex	PS	ORAL
PER ORAL						
Initial or	Prolonged		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 -Asthenia Initial or Prolonged Bradycardia

Depressed Level Of

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Dose	Duration	Consciousness Dyspnoea Hyperhidrosis Hypersensitivity	Report Source	Product	Role	Manufacturer	Route
2MG DAILY,	Duracion	Hypotension	Health	Zanaflex	PS		ORAL
ZMG DAIDI,		Pallor	Professional				
PER ORAL				- 1	_		
		Pulse Pressure Decreased		Lasix Codamine Ticlid Zyloprim Cordarone Ativan Paxil Pepcid Multivitamins Metamucil Darvocet-N Ambien	0 0 0 0 0 0 0 0 0 0		
	7ISR Number Gender:Male	: 3008767-4Report Type:Exped I/FU:F	ited (15-DaCompany Re	port #ZANA0319970291			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat 12 MG DAILY	ion -	Convulsion	Health	Zanaflex	PS		ORAL
Initial or P	rolonged	Grand Mal Convulsion	Professional	Baclofen Synthroid Naproxen Hytrin Senokot Depakote Dulcolax	C C C C C 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 O 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 Dose Duratio	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - PER ORAL	Jaundice Cholestatic	Health	Zanaflex	PS	ORAL
Initial or Prolonged	l	Professional	Synthroid	С	
			Prozac	С	
			Avonex	C	

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Zoloft

С

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	

Date:12/24/97ISR Number: 3048850-0Report Type:Periodic Company Report #ZANA0319970243

Age:49 YR Gender:Female I/FU:I

Report Source Role Manufacturer Outcome PTProduct Route

Dose Duration

Muscle Spasticity Other 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 PTReport Source Product Role Manufacturer Route Duration Dose

Hallucination Zanaflex PS ORAL Other Consumer

24 MG DAILY,

PER ORAL

Diflucan С Tylenol С Aspirin С Imipramine С Glucophage С Date:12/24/97ISR Number: 3048858-5Report Type:Periodic Company Report #ZANA0319970245 Age: Gender:Male I/FU:I Outcome PTReport 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 PTReport Source Product Role Manufacturer Outcome Route Duration Dose Muscular Weakness ORAL Other Consumer Zanaflex PS PER ORAL Oliguria Baclofen С Nifedipine С Clonidine С Atenolol С Date:12/24/97ISR Number: 3048866-4Report Type:Periodic Company Report #ZANA0319970248 Age:52 YR Gender:Female I/FU:I

Report Source Role Manufacturer Outcome PTProduct Route Duration Dose

ORAL

Other Asthenia Consumer Zanaflex PS

Coordination Abnormal С Avonex

Urinary Incontinence

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PER ORAL

Freedom Of Information (FOI) Report

Date:12/24/97ISR Number: 3048871-8Report Type:Periodic Company Report #ZANA0319970251

Liver Function Test

Abnormal

Age:52 YR Gender:Female I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 2 MG DAILY,	Daracion	Medication Error	Health	Zanaflex	PS	ORAL
,		Menometrorrhagia	Professional			
PER ORAL						
				Lasix	C	
				Zestril	C	
				Vitamins	С	
Date:12/24/9	7ISR Number	r: 3048939-6Report Type:Period	dic Company Re	port #ZANA0319970252		
	Gender: Fema					
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration	7	II a a l + b	7	Da	ODAT
Other PER ORAL		Anorexia	Health	Zanaflex	PS	ORAL
-		Liver Function Test	Professional	Prednisone	С	
		Abnormal		Solu-Medrol	С	
		Photosensitivity Reaction		Copaxone	С	
		Urinary Tract Infection		Lo-Ovral	С	
		Vasodilatation Weight Decreased		Cipro	С	
	71SR Number Gender:Male	r: 3048946-3Report Type:Period	dic Company Re	eport #ZANA0319970254		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Other PER ORAL		Hypertension	Health	Zanaflex	PS	ORAL
		Keratoconjunctivitis	Professional	Bromfed	С	
		Sicca		Relafen	С	
		Lacrimation Increased				

Age:68 YR Gender:Male I/FU:I Role Manufacturer Report Source Outcome PTProduct Route Dose Duration Other Dry Mouth Consumer Zanaflex PS ORAL 4 MG DAILY, Sedation PER ORAL Cardizem С Vasotec С Isosorbide С Insulin Date:12/24/97ISR Number: 3048955-4Report Type:Periodic Company Report #ZANA0319970258 Gender:Male Age:50 YR I/FU:I

Company Report #ZANA0319970255

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

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Date:12/24/97ISR Number: 3048951-7Report Type:Periodic

Freedom Of Information (FOI) Report

Lo-Estren

Paxil

C

Date:12/24/97ISR Number: 3048959-1Report Type:Periodic Company Report #ZANA0319970259

Age:52 YR Gender: Female I/FU:I

Role Manufacturer Outcome PTReport Source Product Route Duration

Dose

Other Liver Function Test Health Zanaflex PS ORAL

8 MG DAILY,

Abnormal Professional

PER ORAL

Date:12/24/97ISR Number: 3048962-1Report Type:Periodic Company Report #ZANA0319970260

Age: 45 YR Gender: Male I/FU:I

Role Manufacturer PTReport Source Product Outcome Route

Dose Duration

Erectile Dysfunction Other Health Zanaflex PS ORAL

20 MG DAILY, Sedation

Professional

PER ORAL

Diazepam C

Date:12/24/97ISR Number: 3048967-OReport Type:Periodic Company Report #ZANA0319970261

Age: 49 YR Gender: Female

Outcome PTReport Source Product Role Manufacturer Route

Dose Duration

Constipation Other Consumer Zanaflex PS ORAL PER ORAL Prednisone С

Prilosec Macrodantin С Relafen

Date:12/24/97ISR Number: 3048970-0Report Type:Periodic Company Report #ZANA0319970262

Age:37 YR Gender:Female I/FU:I

PT Report Source Product Role Manufacturer Outcome Route Dose Duration

PER ORAL						
				Dantrium	C	
				Zoloft	С	
				Verapamil	C	
				Aspirin	С	
	7ISR Number Gender:Male	:: 3048974-8Report Type:Per e	riodic Company Re	eport #ZANA0319970267		
Outcome	3011401 1141	PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration			0		
Other PER ORAL		Fall	Consumer	Zanaflex	PS	ORAL
1		Sedation		Oxybutynin	С	
				Daypro	С	
1				Prozac	С	
1				Xanax	С	
Age:46 YR (Gender:Male	r: 3048976-1Report Type:Per e I/FU:I PT	riodic Company Re Report Source	eport #ZANA0319970268 Product	Role Manufacturer	Route
Age:46 YR (Outcome Dose		PT	Report Source	Product		
Age:46 YR (Outcome Dose Other	Gender:Male	e I/FU:I			Role Manufacturer PS	Route ORAL
Age:46 YR (Outcome Dose	Gender:Male	PT	Report Source	Product		
Age:46 YR (Outcome Dose Other 12 MG DAILY,	Gender:Male	PT Dyspepsia	Report Source	Product	PS	
Age:46 YR (Outcome Dose Other 12 MG DAILY,	Gender:Male	PT Dyspepsia	Report Source	Product Zanaflex		
Age:46 YR (Outcome Dose Other 12 MG DAILY,	Gender:Male	PT Dyspepsia	Report Source	Product Zanaflex Tegretol	PS C	

Consumer

Zanaflex

PS

ORAL

Other 2 MG DAILY, Fatigue

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Zanaflex

Company Report #ZANA0319970275

PS

ORAL

Date:12/24/97ISR Number: 3048979-7Report Type:Periodic Company Report #ZANA0319970270 Age:24 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Other Dizziness Health Zanaflex PS ORAL 12 MG DAILY, Professional Fatique PER ORAL Insomnia Docusate Darvocet N-100 Date:12/24/97ISR Number: 3048983-9Report Type:Periodic Company Report #ZANA0319970271 Age: 57 YR Gender: Male Role Manufacturer PTReport Source Product Outcome Route Dose Duration

12 MG DAILY,

Eye Irritation Professional

Conjunctival Hyperaemia

Flushing

Other

PER ORAL

riabiliti

Date:12/24/97ISR Number: 3048987-6Report Type:Periodic

Age:20 YR Gender:Male I/FU:I

Health

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

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	С	
				Pamelor	С	
				Betaseron	С	
				Ambien	С	
				Baclofen	C	
	Gender:Fema	r: 3048992-XReport Type:Period ale I/FU:I PT Sedation	dic Company Repo Report Source Health	Product Zanaflex	Role Manufacturer	Route ORAL
			Professional			
PER ORAL						
				Zestril	С	
				Cardizem	С	
				Paxil	C	
				Prozac	C	
				Ibuprofen	C	
				Klonopin	C	
				KIOHOPIH	C	

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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

Company Report #ZANA0319970284

Dose Duration

Other Hypotension Health Zanaflex PS ORAL

4 MG DAILY ,

Professional

PER ORAL

Diovan C
Synthroid C
Premarin C
Progesterone C

Baclofen

Date:12/24/97ISR Number: 3049039-1Report Type:Periodic

Age:55 YR Gender:Male I/FU:I

26 MG DAILY,					
	Abnormal	Professional			
PER ORAL					
			Amantadine	C	
			Avonex	C	
			Advil	C	
			Synthroid	С	
Date:12/24/97ISR Numk Age:50 YR Gender:Fe	ber: 3049044-5Report Typ emale	pe:Periodic Company Re	eport #ZANA0319970285		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration			Z	DG	00.74
Other	Accident		Zanaflex	PS	ORAL
12 MG DAILY,	Influenza Like Illne				
PER ORAL	Influenza bike iiine	:55			
PER ORAL	Sedation		Depakote	С	
	Sedacion		Clonazepam	C	
1			Phenobarbital	C	
I			Lozol	C	
1			Prilosec	C	
I			Premarin	C	
			Premarm	C	

Report Source

Health

Product

Zanaflex

Role Manufacturer

PS

Route

ORAL

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Outcome

Dose

Other

PT

Liver Function Test

Duration

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Date:12/24/97ISR Number: 3049058-5Report Type:Periodic Company Report #ZANA0319970286 Age:63 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Other Muscle Spasms Consumer Zanaflex PS ORAL PER ORAL Sedation Demadex С K-Dur С Lanoxin С Quinidex С Tegretol С Aspirin Date:12/24/97ISR Number: 3049062-7Report Type:Periodic Company Report #ZANA0319970287 Gender:Male I/FU:I Age: Role Manufacturer Outcome PTReport Source Product Route Dose Duration Other Hiccups Health Zanaflex PS ORAL 16 MG DAILY, Professional PER ORAL Valium С Baclofen С Amantadine

			Percocet	C	
	Jumber: 3049067-6Report Type:Per	riodic Company Re	eport #ZANA0319970289		
Outcome Dose Durat	PT ion	Report Source	Product	Role Manufacturer	Route
Other 4 MG DAILY,	Condition Aggravated	Consumer	Zanaflex	PS	ORAL
PER ORAL	Hypertonia				
			Synthroid	С	

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

Company Report #ZANA0319970290

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Muscular Weakness		Zanaflex	PS		ORAL
24 MG DAILY,		Sedation					
PER ORAL					~		
				Baclofen Klonopin	C C		Ţ
				KIOHOPIH	C		
Date:12/24/9 Age:93 YR		:: 3049074-3Report Type:Periodi	ic Company Repor	rt #ZANA0319970293			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 4 MG DAILY,	Duration	Drug Ineffective	Health	Zanaflex	PS		ORAL
4 MG DAILY, PER ORAL		Hypotension	Professional				
				Pepcid	С		
				Ultram	C		
				Parlodel	С		
	7ISR Number Gender:Male	:: 3049077-9Report Type:Periodi	ic Company Repor	rt #ZANA0319970294			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 12 MG DAILY,		Hypotension		Zanaflex	PS		ORAL
PER ORAL		Sedation					
		Stupor		Norvasc	С		
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Zoloft С Coumadin С Pepcid C

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

Outcome

Report Source Role Manufacturer PTProduct Route Dose Duration Health Zanaflex PS ORAL Other Coma 6 MG DAILY,

Drug Effect Decreased Professional

PER ORAL

Hypotension Digoxin Lethargy Verapamil С Haldol

Phenobarbital C

Date:12/24/97ISR Number: 3049132-3Report Type:Periodic Company Report #ZANA0319970296

Gender:Male I/FU:I Age:

PTReport Source Product Role Manufacturer Outcome Route

Dose Duration

Sedation Health Zanaflex ORAL Other PS

16 MG DAILY,

Professional

PER ORAL

Methadone C Diazepam

Date:12/24/97ISR Number: 3049137-2Report Type:Periodic Company Report #ZANA0319970297

Age:41 YR Gender: Female I/FU:I

Outcome PTReport 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 PTReport Source Product Role Manufacturer Route Dose Duration Headache Health Zanaflex ORAL Other PS

Baclofen

С

С

Role Manufacturer

ORAL

16 MG DAILY,

Professional

PER ORAL

Tegretol

Date:12/24/97ISR Number: 3049145-1Report Type:Periodic Company Report #ZANA0319970299

Gender:Male Age: I/FU:I

Report Source Role Manufacturer Outcome PTProduct Route Dose Duration

Gamma-Glutamyltransferase Other Health Zanaflex PS ORAL

PER ORAL Increased Professional Dilantin С

Date:12/24/97ISR Number: 3049149-9Report Type:Periodic Company Report #ZANA0319970300

Age:48 YR Gender:Male I/FU:I

PT

Outcome Report Source Product Route Duration Dose

Hepatitis Health Zanaflex PS Other PER ORAL

Pyrexia Professional Baclofen SS

Sedation Prozac С

Wellbutrin С

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Freedom Of Information (FOI) Report

Company Report #ZANA0319970301

Gender: Unknown Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Other Blood Triglycerides Health Zanaflex PS ORAL PER ORAL Increased Professional Hyperglycaemia Date:12/24/97ISR Number: 3049157-8Report Type:Periodic Company Report #ZANA0319970302 Age: Gender: Unknown I/FU:I РΤ Role Manufacturer Report Source Product Outcome Route Dose Duration Blood Triglycerides Zanaflex Other Health PS ORAL PER ORAL Professional Increased Company Report #ZANA0319970303 Date:12/24/97ISR Number: 3049161-XReport Type:Periodic Gender: I/FU:I Age: Role Manufacturer PTReport Source Product Outcome Route Duration Dose Zanaflex Constipation Health PS ORAL Other PER ORAL Dysphagia Professional Hypertonia Date:12/24/97ISR Number: 3049163-3Report Type:Periodic Company Report #ZANA0319970304 Age:56 YR Gender: Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Asthenia Consumer Zanaflex PS ORAL 4 MG DAILY, Sedation PER ORAL Prozac C Prosom С Baclofen

Date:12/24/97ISR Number: 3049153-0Report Type:Periodic

Date:12/24/97ISR Number: 3049165-7Report Type:Periodic Company Report #ZANA0319970007

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

Stupor

Outcome	Duna ti an	PT	Report Source	Product	Role Manufacturer	Route
Dose Other 4 MG DAILY,	Duration	Asthenia	Consumer	Zanaflex	PS	ORAL
		Coordination Abnormal				
PER ORAL						
		Cyanosis		Baclofen	С	
		Sedation		Methotrexate	С	
				Tegretol	C	
				Betaseron	C	
	97ISR Number Gender:Fema	:: 3049172-4Report Type:Perio	odic Company Re	port #ZANA0319970177		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 4 MG DAILY,	Daracion	Chest Pain	Health	Zanaflex	PS	ORAL
,		Hypotension	Professional			
PER ORAL		пуроссивтои	rioressionar			

С

С

С

С

Estrace Fosamax Prednisone

Promod

Reglan

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Date:12/24/97ISR Number: 3049175-XReport Type:Periodic Company Report #ZANA0319970203

Age:47 YR Gender:Female I/FU:F

Outcome Dose	Duration	PT	Report Sour	cce	Product	Role	Manufacturer	Route
Other PER ORAL		Dysgeusia	Consumer		Zanaflex	PS		ORAL
		Hallucination			Levoxyl	C		
					Ventolin	С		
					Aerobid	C		
					Slo-Bid	C		
					Beconase	C		
					Hismanal	С		
	8ISR Number: Gender:Male	: 3021651-5Report Type:Direct I/FU:I	Com	mpany Report	#			
Outcome Dose	Duration	PT	Report Sour	rce	Product	Role	Manufacturer	Route
Life-Threate		Asthenia Bradycardia			Zanaflex	PS	Athena Neuro Sciences	ORAL
4 MG PO		Chest Pain Hypotension						
	98ISR Number: Gender:Femal	: 3021217-7Report Type:Direct le I/FU:I	Con	mpany Report	#			
					_	_	_	
Outcome Dose	Duration	PT	Report Sour		Product		Manufacturer	Route
Hospitalizat	cion -	Hallucination			Tizanidine	PS		ORAL

Dose Duration		-		
Hospitalization - 4MG X3D; 6MG Initial or Prolonged X2 PO	Hallucination	Tizanidine	PS	ORA:
AZ PO		Fluoxetine	С	
		Oxybutynin	C	
		Nitrofurantoin	C	
		Cipro	C	
ı		Diazepam	C	
		Ibuprofen	C	

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

Gender:Female I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration

Hospitalization -Blood Pressure Decreased Tizanidine Hcl PS ORAL

6 MG PO QD ;4

Initial or Prolonged Heart Rate Decreased

MG PO DID

Syncope

Date:02/18/98ISR Number: 3030594-2Report Type:Expedited (15-DaCompany Report #ZANA0319980328

Age:70 YR Gender:Male I/FU:I

Role Manufacturer Report Source Outcome PTProduct Route

Duration Dose

Life-Threatening Health Asthenia Zanaflex PS ORAL

4 MG DAILY

Hospitalization -Bradycardia Professional

PER ORAL

Initial or Prolonged Chest Pain

Dizziness Hypotension

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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

Erythematosus

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Life-Threatening 3 MG DAILY,	Shock	Foreign	Ternelin	PS	ORAL
J MG DAILI,		Distributor			
PER ORAL					
			Zaltoprofen	С	
			Soleton	С	
Date:03/02/98ISR Numbe Age:47 YR Gender:Mal	er: 3040502-6Report Type:Exp le I/FU:I	pedited (15-DaCompany Ro	eport #ZANA0319980333		
Age 17 IIC Gender Mai	1/10/1				
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Life-Threatening 3.0 MG DAILY	Dysarthria	Foreign	Ternelin	PS	ORAL
Hospitalization - PER ORAL	Face Oedema	Distributor			
Initial or Prolonged	Malaise		Indomethacin	C	
	Oedema Peripheral		Benzbromarone	С	
	Pulmonary Oedema		Camostat	C	
	Weight Increased		Famotidine	C	
			Triazolam	C	
			Foy	С	
Date:03/02/98ISR Numbe Age:31 YR Gender:Fem	er: 3040505-1Report Type:Exp nale I/FU:I	pedited (15-DaCompany Ro	eport #ZANA0319980332		
Outcome .	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration			-1		
Other	Antinuclear Antibody	Foreign	Sirdalud	PS	ORAL
2.0 MG DAILY,	Dogitimo	Digtaibut			
PER ORAL	Positive	Distributor			
PER URAL	Systemic Lupus		Myolastan	С	
	Systemic Lupus		MyOrastall	C	

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

Gender:Male I/FU:I

Outcome PT

Dose Duration

Life-Threatening Convulsion Foreign Sirdalud PS ORAL 2.5 MG DAILY,

Product

Role Manufacturer

Route

Report Source

Hospitalization -Drug Interaction Distributor

PER ORAL

Initial or Prolonged Shock

Date:03/05/98ISR Number: 3050056-6Report Type:Direct Company Report #

Age:40 YR Gender:Female I/FU:I

Report Source Role Manufacturer Outcome PTProduct Route

Duration Dose

Athena/Sandoz Other Anxiety Zanaflex PS

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

Life-Threatening Accidental Overdose

Hospitalization -Arrhythmia

Initial or Prolonged Blood Bilirubin Increased

Hepatic Function Abnormal

Hypotonia

Respiratory Disorder

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Freedom Of Information (FOI) Report

Role Manufacturer

Route

Sedation				
	Report Source	Product	Role Manufacturer	Route
	Foreign	Sirdalud	PS	ORAL
	Distributor			
: 3054310-3Report Type:Experiment	dited (15-DaCompany Re	eport #ZANA0319980342		
PT	Report Source	Product	Role Manufacturer	Route
Hypokalaemia	Foreign	Ternelin	PS	ORAL
Loss Of Consciousness	Distributor			
Sedation		Votraren	С	
: 3055540-7Report Type:Experiment	dited (15-DaCompany Re Report Source	eport #ZANA0319980342 Product	Role Manufacturer	Route
Dizziness	Foreign	Ternelin	PS	ORAL
Hypokalaemia	Distributor			
Hypovolaemia				
Loss Of Consciousness Oral Intake Reduced Sedation		Voltaren Myonal Loxonin Vitamedine Methycobal	SS SS SS C	
=	I/FU:I PT Hypokalaemia Loss Of Consciousness Sedation : 3055540-7Report Type:Experize I/FU:F PT Dizziness Hypokalaemia Hypovolaemia Loss Of Consciousness Oral Intake Reduced	Foreign Distributor 3054310-3Report Type:Expedited (15-DaCompany Refi/FU:I PT Report Source Hypokalaemia Foreign Loss Of Consciousness Distributor Sedation 3055540-7Report Type:Expedited (15-DaCompany Refi/FU:F PT Report Source Dizziness Foreign Hypokalaemia Distributor Hypokalaemia Distributor Hypovolaemia Loss Of Consciousness Oral Intake Reduced	Foreign Sirdalud Distributor 3054310-3Report Type:Expedited (15-DaCompany Report #ZANA0319980342 I/FU:I PT Report Source Product Hypokalaemia Foreign Ternelin Loss Of Consciousness Distributor Sedation Votraren 3055540-7Report Type:Expedited (15-DaCompany Report #ZANA0319980342 I/FU:F PT Report Source Product Dizziness Foreign Ternelin Hypokalaemia Distributor Hypokalaemia Loss Of Consciousness Voltaren Oral Intake Reduced Myonal Sedation Myonal Loxonin	Foreign Sirdalud PS Distributor #ZANA0319980342 I/FU:T PT Report Source Product Role Manufacturer Hypokalaemia Foreign Ternelin PS Loss Of Consciousness Distributor Sedation Votraren C #ZANA0319980342 I/FU:F PT Report Source Product Role Manufacturer #ZANA0319980342 I/FU:F PT Report Source Product Role Manufacturer #ZANA0319980342 I/FU:F PT Report Source Product Role Manufacturer Dizziness Foreign Ternelin PS #Hypokalaemia Distributor #Hypokalaemia Distributor #Hypokalaemia SS Oral Intake Reduced SS Oral Intake Reduced SS Oral Intake Reduced SS Sedation SS SEDATOR SS SE SEDATOR SS SE S

Report Source

Outcome

Dose

PT

Duration

Product

Hospitalizat	tion -		Alanine Aminotransferase	Foreign	Trental	PS	ORAL
300 MG PO	3	MON					
Initial or E	Prolonge	d	Increased	Study	Hextol	SS	ORAL
300 MG	3	MON					
Other			Anorexia	Health	Tegretol	SS	ORAL
ORAL	1	MON					
			Aspartate	Professional	Ternelin	SS	ORAL
ORAL	1	MON					
			Aminotransferase		Basen	C	
			Increased		Kinedak	C	
			Gamma-Glutamyltransferase		Minipress	С	
			Increased				
			Haematocrit Decreased				
			Haemoglobin Decreased				
			Hepatic Function Abnormal				
Date:03/20/9 Age:70 YR			: 3057107-3Report Type:Expedit I/FU:F	ced (15-DaCompany Repor	t #ZANA0319980328		
Outcome	- ·		PT	Report Source	Product	Role Manufacturer	Route
Dose	Durati	on	7. 11. 1	** 7.1	- C1	7.0	0011
Life-Threate 4 MG DAILY,	ening		Asthenia	Health	Zanaflex	PS	ORAL
Hospitalizat PER ORAL	tion -		Bradycardia	Professional			
Initial or E	Prolonge	d	Chest Pain Dizziness				

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Hypotension

Freedom Of Information (FOI) Report

Tylenol

Insulin

Allegra

Resulin

C

C

C

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-Threate PER ORAL		Accidental Overdose	Foreign	Sirdalud	PS		ORAL
Hospitalizat Initial or F		Arrhythmia Asphyxia Bradycardia Hepatic Function Abnormal Hypotonia Respiratory Disorder Sedation Tachycardia	Distributor				
Age:38 YR				t #ZANA0319970306	Dala	Manufachusas	Doube
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 8 MG DAILY,		Asthenia	Health	Zanaflex	PS		ORAL
PER ORAL			Professional				
PER ORAL				Baclofen	С		
				Ativan	C		
				Tessalon	C		
				Cipro	C		
	8ISR Number Gender:Male	: 3140712-3Report Type:Periodic	c Company Repor	t #ZANA0319970307			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 4 MG DAILY,	Duration	Insomnia	Consumer	Zanaflex	PS		ORAL
		Sedation					
PER ORAL							

Date:03/30/98ISR Number: 3140714-7Report Type:Periodic Company Report #ZANA0319970308

Age:59 YR Gender:Male I/FU:I

PTReport Source Product Role Manufacturer Outcome Route Duration Dose Dizziness Consumer Zanaflex PS ORAL Other 16 MG DAILY, Dry Mouth PER ORAL Muscle Spasms Valium С

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

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

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Freedom Of Information (FOI) Report

Role Manufacturer

PS

Route

ORAL

Company Report #ZANA0319970310

Product

Zanaflex

Age:68 YR	Gender:Male	e I/FU:I	are company nep				
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other PER ORAL		Orthostatic Hypotension	Health	Zanaflex	PS		ORAL
		Sedation	Professional	Trazodone Toprol-Xl Cardias Mcd	С С		
	98ISR Number Gender:Fema	r: 3140735-4Report Type:Perio	dic Company Rep	ort #ZANA0319970311			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 8 MG DAILY,		Muscle Spasms	Consumer	Zanaflex	PS		ORAL
0 110 211221,							
PER ORAL		Nausea					
PER ORAL		Nausea		4-Aminopyridine	С		

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,						

Report Source

Consumer

Visual Disturbance PER ORAL

PT

Sedation

Duration

Outcome

4 MG DAILY,

PER ORAL

Dose

Other

Date:03/30/98ISR Number: 3140733-0Report Type:Periodic

Prilosec С Lactulose С Vitamin C С

Role Manufacturer

PS

Route

ORAL

Date:03/30/98ISR Number: 3140743-3Report Type:Periodic

Gender:Female Age:

I/FU:I

Company Report #ZANA0319970314

Product

Zanaflex

Route
ORAL

Report Source

Consumer

Date:03/30/98ISR Number: 3140747-0Report Type:Periodic Company Report #ZANA0319970315

Age:67 YR Gender:Female I/FU:I

Outcome PTDose

Duration

Dizziness Other

PER ORAL

Dry Mouth

Sedation

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Freedom Of Information (FOI) Report

Role Manufacturer

Role Manufacturer

Route

Route

Product

Product

Date:03/30/98ISR Number: 3140773-1Report Type:Periodic Company Report #ZANA0319970316

Age:58 YR Gender:Male I/FU:I

PT

PT

Outcome

Outcome

Dose	Duration					
Other		Abdominal Pain	Consumer	Zanaflex	PS	ORAL
24 MG DAILY,						
		Diarrhoea				
PER ORAL						
1				Pepcid	C	
				Parnate	C	
				Meprobamate	C	
i				Propantheline	C	
1				Sulfonate	C	
1				Tylenol	C	
1				Vitamin B12	C	
1				Hydrochlorothiazide	C	
1				Diazepam	C	
1				Avonex	C	
1				Prazocin		
1				Hydrochloride	C	
1				Potassium Chloride	C	
1				Chlorpheniramine		
1				Maleate	C	
1						
1						
1						
Date:03/30/9	8ISR Number	r: 3140776-7Report Type:	Periodic Company	Report #ZANA0319970317		
Age:58 YR	Gender: Fema	ale I/FU:I				

Report Source

Dose Other PER ORAL	Duration	Drug Ineffective	Consumer	Zanaflex	PS	ORAL
		Sedation		Progesterone	С	

Report Source

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

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

Date:03/30/98ISR Number: 3140782-2Report Type:Periodic Company Report #ZANA0319970319

Age:67 YR Gender:Female I/FU:I

Outcome PTReport Source Product Role Manufacturer Route Duration Dose Dizziness Consumer Zanaflex PS ORAL Other 4 MG DAILY,

Hypertension

PER ORAL

Nausea Desipramine С Zestril С Relafen С

> С Neurontin Lipitor С Clonazepam С

> > Role Manufacturer

Route

Product

Date:03/30/98ISR Number: 3140788-3Report Type:Periodic Company Report #ZANA0319970320

Age:52 YR Gender: Female I/FU:I

PT

Report Source Duration Dose Flatulence Health Zanaflex PS ORAL Other

4 MG DAILY,

Professional

Baclofen С

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PER ORAL

Outcome

Freedom Of Information (FOI) Report

Report Source Company Representative ic Company Report Source Consumer	Product Zanaflex Report #ZANA031998032 Product Zanaflex	PS 2	anufacturer	Route ORAL
Representative ic Company Report Source	Report #ZANA031998032 Product	2 Role Ma	ınufacturer	ORAL
ic Company Report Source	Product	Role Ma	ınufacturer	
Report Source	Product	Role Ma	ınufacturer	
			ınufacturer	
Consumer	Zanaflex	PS		Route
		- 5		ORAL
ic Company	Report #ZANA031998032	3		
Report Source	Product	Role Ma	anufacturer	Route
Consumer	Zanaflex	PS		ORAL
	Oxycontin Baclofen Humibid	С С С		
		Baclofen	Baclofen C	Baclofen C

Outcome PT Report Source Product Role Manufacturer Route

Dose Duration
Other Aphasia Health Zanaflex PS ORAL

4 MG DAILY,

Age: 43 YR Gender: Female

I/FU:I

PER	ORAL

4 MG DAILY,

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Chills

Coordination Abnormal

		Diarrhoea Dizziness Dry Mouth Hyperhidrosis Muscle Spasms Sedation		Klonopin Trimpex	C C		
	SR Number ender:Fema	: 3140803-7Report Type:Pe le I/FU:I	riodic Company R	eport #ZANA0319980325			
Outcome Dose D	uration	PT	Report Source	Product	Role	Manufacturer	Route
Other 4 MG DAILY,	0101011	Muscle Twitching	Consumer	Zanaflex	PS		ORAL
		Paraesthesia					
PER ORAL							
				Motrin	C		
				Tylenol	С		
				Xanax	C		
				Zantac	С		
	SR Number ender:Fema	: 3145770-8Report Type:Pe le I/FU:I	riodic Company Ro	eport #ZANA0319980326			
Outcome Dose D	uration	PT	Report Source	Product	Role	Manufacturer	Route
Other	ALACIOII	Muscle Spasms	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
				<u>, , </u>			~

Baclofen

С

Professional

Freedom Of Information (FOI) Report

PER ORAL

Septra Progesterone

Vanceril

Proventil

Prednisone Bactrim

С

C С

Date: 03/30/98ISR Number: 3145775-7Report Type: Periodic Company Report #ZANA0319980327

Age:30 YR Gender: Female I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration

Zanaflex (Tizanidine Other Oedema Consumer

Hydrochloride) PS ORAL 1) 4 MG

DAILY, PER

ORAL

2) UNK

2) PER ORAL;

Date:03/30/98ISR Number: 3145779-4Report Type:Periodic Company Report #ZANA0319980329

Age:51 YR Gender:Female

Outcome PTReport Source Product Role Manufacturer Route

Dose Duration

Other Muscle Spasms Consumer Zanaflex (Tizanidine PS ORAL

Hydrochloride)

1) PER ORAL;

Date: 03/30/98ISR Number: 3145782-4Report Type: Periodic Company Report #ZANA0319980335

Age:54 YR Gender:Female I/FU:I

Outcome PTReport Source Product Role Manufacturer Route Duration Dose

Other Constipation Consumer Zanaflex Liver Function Test

(Tizanidine

PER ORAL		1101101			117 01 0 0111 01 1 00 7			01412
PER ORAL		Nausea			Betaseron	С		
		Sedation			Baclofen	C		
		Sedacion			Cylert	C		
					Ambien			
						C		
					Nortriptyline	С		
Date:03/30/! Age:	98ISR Number Gender:Male	: 3145783-6Report I/FU:I	Type:Periodic	Company Repo	ort #ZANA0319980336			
_								
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other		Stupor	Health		Zanaflex (Tizanidine			
			Profess	sional	Hydrochloride)	PS		ORAL
PER ORAL								
					Marcaine	C		
					Fentanyl	C		
					Valium	C		
					Narcan	С		
Date:03/30/9 Age:	98ISR Number Gender:Male	: 3145784-8Report I/FU:I	Type:Periodic	Company Repo	ort #ZANA0319980337			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other	Daracron	Apnoea	Health		Zanaflex (Tizanidine			
OCIICI		Stupor	Profess	ional	Hydrochloride)	PS		ORAL
PER ORAL		beapor	110105	FIGHAL	nydroenror ide /	15		ORAL
					Fentanyl	С		
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Hydrochloride)

PS

ORAL

Abnormal

Freedom Of Information (FOI) Report

Company Report #ZANA0319980339

Vitamins Sulfasalazine

C

ORAL

Date:03/30/98ISR Number: 3145785-XReport Type:Periodic Company Report #ZANA0319980338

Gender: Female Age: I/FU:I

Outcome PΤ Report Source Product Role Manufacturer Route

Duration Dose

Other Pruritus Health Zanaflex (Tizanidine ORAL

Professional Hydrochloride) PS

4 MG DAILY,

PER ORAL

Age:40 YR Gender: Female I/FU:I

Report Source Role Manufacturer Outcome PTProduct Route

Duration Dose Asthenia Other

Date:03/30/98ISR Number: 3145786-1Report Type:Periodic

Zanaflex (Tizanidine Consumer Dizziness Hydrochloride) PS ORAL

PER ORAL Sedation Baclofen

C Speech Disorder Copaxone

Birth Control Pills

Date: 03/30/98ISR Number: 3145787-3Report Type: Periodic Company Report #ZANA0319970196

Age:64 YR Gender:Male

Outcome PTReport Source Product Role Manufacturer Route

Dose Duration

Other Oliguria Consumer Zanaflex (Tizanidine Hydrochloride) PS

24 MG DAILY,

PER ORAL

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

Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration

			Amantadine Isoptin	C C	
Date:04/06/98ISR Numbe: Age:69 YR Gender:Malo	r: 3062955-XReport Type:Expe e I/FU:I	edited (15-DaCompany Ro	eport #ZANA0319980351		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - 18 MG DAILY	Dizziness	Health	Zanaflex	PS	ORAL
Initial or Prolonged	Dizziness Postural	Professional	Baclofen	C	
	Faeces Discoloured		Methotrexate	C	
	Haemoglobin Decreased		Amitriptyline	C	
	Pain		Solu-Medrol	C	

Consumer

Zanaflex

Insulin

Baclofen

PS

С С ORAL

Date:04/14/98ISR Number: 3064332-4Report Type:Expedited (15-DaCompany Report #1998-00894

Gender:Female Age:65 YR I/FU:I

Outcome PT

Hospitalization -Blister Initial or Prolonged

Blood Creatine

Ulcer

Phosphokinase Increased

Myocardial Infarction

Blood Creatinine

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Death

PER ORAL

Freedom Of Information (FOI) Report

		Increased Blood Pressure Decreased Blood Urea Increased Dermatitis	Report Source	Product	Pole	Manufacturer	Route
Dose	Duration					Manuracturer	
300 MG/PO		Eosinophil Count	Foreign	Mexitil	PS		ORAL
5 MG/PO		Increased	Health	Norvasc	SS		ORAL
		Face Oedema	Professional	Lasix	SS		ORAL
40 MG/PO		Fatigue		Ternelin	SS		ORAL
3 MG/PO		Haematuria		Donag	С		ORAL
1 MG/PO				Depas	-		ORAL
45 MG/PO		Liver Function Test		Glekay	С		ORAL
		Abnormal Purpura Pyrexia Rash Erythematous Skin Ulcer White Blood Cell Count Increased					
	98ISR Number Gender:Fema	:: 3068702-XReport Type:Exped ale I/FU:I	ited (15-DaCompany Re	port #ZANA0319980368			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Death 2 MG DAILY,	Duracion	Asthenia	Foreign	Sirdalud	PS		ORAL
		Hypotonia	Distributor				
PER ORAL							
Date:04/17/9 Age:74 YR		:: 3068703-1Report Type:Exped ale I/FU:I	ited (15-DaCompany Re	port #ZANA0319980369			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Bundle Branch Block Left	Foreign	Sirdalud	PS		ORAL

Distributor

4 MG DAILY,

PER ORAL

Drug Level Below

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

Report Source Role Manufacturer Outcome PTProduct Route Dose Duration Life-Threatening Blood Bilirubin Increased Foreign Ternelin PS ORAL PER ORAL Hospitalization -Blood Creatine Increased Distributor Voltaren SS Initial or Prolonged 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

PT

Dose Duration Asthenia Hospitalization -Health ORAL Zanaflex PS 12 MG DAILY Initial or Prolonged Bone Pain Professional PER ORAL; Confusional State С Morphine Haemorrhoids Vicodin C Hepatomegaly Xanax С Glipizide С Lethargy Rectal Haemorrhage Carafate С С Prozac

Product

Plaquenil

Report Source

Role Manufacturer

С

Route

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Outcome

Freedom Of Information (FOI) Report

Product

Ternelin

Zanaflex

Ritalin Prilosec С

SS

PS

Role Manufacturer

Route

ORAL

ORAL

Date:05/05/98ISR Number: 3073583-4Report Type:Expedited (15-DaCompany Report #98J-10112

Age:22 YR Gender:Male I/FU:F

Dose Duration Blood Bilirubin Increased Life-Threatening Foreign Voltaren PS ORAL 75 MG, DAILY,

Report Source

Professional

Hospitalization -Blood Creatinine Health

Increased

ORAL

Initial or Prolonged

Outcome

ORAL

Other

3 MG, DAILY,

Disseminated

PT

Intravascular Coaquiation

Hepatic Failure

Hepatitis

Hepatitis Fulminant

Pallor

Renal Failure Acute

Rhabdomyolysis

Date:05/15/98ISR Number: 3079752-1Report Type:Expedited (15-DaCompany Report #ZANA0319980377

Gender:Male Age: I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Health

Dose Duration

Hospitalization -Chorea

360MG DAILY,

Initial or Prolonged Professional Coma PER ORAL

> 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

Date:05/18/98ISR Numbe Age:21 YR Gender:Mal	r: 3079870-8Report Type:Exped: e I/FU:F	ited (15-DaCompany Re	eport #ZANA0319980370		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Life-Threatening 3.0 MG DAILY	Anorexia	Foreign	Ternelin	PS	ORAL
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	

Report Source

Product

Tizanidine

Role Manufacturer

PS

Athena Labs

Route

ORAL

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Outcome

Required

2 DOSES

2 MG BID PO Intervention to

Prevent Permanent Impairment/Damage

Dose

PΤ

Hypertension

Duration

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

Duration

Disseminated

Dose

Life-Threatening

75 MG, DAILY

1/10/1					
PT	Report Source	Product	Role	Manufacturer	Route
Complications Of Maternal	Foreign	Sirdalud	PS		ORAL
Exposure To Therapeutic	Distributor				
Drugs Small For Dates Baby					
r: 3088209-3Report Type:Exped	ited (15-DaCompany Re	eport #1998-000894			
PT	Report Source	Product	Role	Manufacturer	Route
Blister	Foreign	Mexitil	PS		ORAL
Dermatitis Fatigue	Health Professional	Norvasc (Amlodipine Besilate)	SS		ORAL
Haematuria Oedema		Ternelin (Tizanidine Hydrochloride)	SS		
Pyrexia		Lasix (Furosemide)	SS		
Rash Erythematous		Depas(Etizolam) Ternelin(Tizanidine	С		
		Hydrochloride) Glakay	С		
		(Menatetrenone)	C		
		Depas(Etizolam)	С		
r: 3084810-1Report Type:Exped	ited (15-DaCompany Re	eport #98J10112			
PT	Report Source	Product	Role	Manufacturer	Route
	Complications Of Maternal Exposure To Therapeutic Drugs Small For Dates Baby T: 3088209-3Report Type:Exped ale I/FU:F PT Blister Dermatitis Fatigue Haematuria Oedema Pyrexia Rash Erythematous T: 3084810-1Report Type:Exped Exped	Complications Of Maternal Foreign Exposure To Therapeutic Distributor Drugs Small For Dates Baby Therapeutic Distributor Drugs Small For Dates Baby Therapeutic Distributor Drugs Small For Dates Baby Therapeutic Drugs Small For Dates Baby Therapeutic Drugs Report Source Blister Foreign Dermatitis Health Fatigue Professional Haematuria Oedema Pyrexia Rash Erythematous Therapeutic Distributor Report Source Foreign Health Professional Haematuria Oedema Pyrexia Rash Erythematous	PT Report Source Product Complications Of Maternal Foreign Sirdalud Exposure To Therapeutic Distributor Drugs Small For Dates Baby The state of	PT Report Source Product Role Complications Of Maternal Foreign Sirdalud PS Exposure To Therapeutic Distributor Drugs Small For Dates Baby The state of the s	PT Report Source Product Role Manufacturer Complications Of Maternal Foreign Sirdalud PS Exposure To Therapeutic Distributor Drugs Small For Dates Baby The Report Source Product Role Manufacturer PT Report Source Product Role Manufacturer Blister Foreign Mexitil PS Dermatitis Fatigue Professional Besilate) Health Norvasc (Amlodipine Besilate) Fatigue Professional Hydrochloride) Godema Pyrexia Rash Erythematous Role Manufacturer Foreign Mexitil PS Lasix (Furosemide) SS Popas (Etizolam) C Ternelin(Tizanidine Hydrochloride) Glakay (Menatetrenone) C Depas (Etizolam) C Ternelin(Tizanidine Hydrochloride) C Glakay (Menatetrenone) C Depas (Etizolam) C Total (Tizanidine Hydrochloride) C Glakay (Menatetrenone) C Depas (Etizolam) C Total (Tizanidine Hydrochloride) C Depas (Etizolam) C Total (Tizanidine Hydrochloride) C Depas (Etizolam) C Total (Tizanidine Hydrochloride) C Glakay (Menatetrenone) C Depas (Etizolam) C Total (Tizanidine Hydrochloride) C Total (Tizanidine Hydrochlorid

Hospitalization - Intravascular Coagulation Health
ORAL
Initial or Prolonged Hepatic Failure Professional Ternelin SS ORAL
3 MG, DAILY

Voltaren

PS

ORAL

Foreign

Hepatitis Fulminant

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 Duration PT

Report Source

Product

Role Manufacturer

Route

Dose

Anxiety

Foreign

Ternelin

PS

Other 0.33 MG

Bronchospasm

Literature

ORAL

DAILY, PER

Dyspnoea

ORAL

Foreign Body Aspiration

Tricloryl

SS

Intercostal Retraction Respiratory Distress

Antitussive Agent Antihistamine

С

Stridor

Expectorant

С С

Vomiting

Date:06/01/98ISR Number: 3087791-XReport Type:Expedited (15-DaCompany Report #ZANA0319980377

Age:33 YR Gender:Male I/FU:F

Outcome

Other

Hospitalization -Athetosis

Initial or Prolonged

Chorea Coma

PT

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Freedom Of Information (FOI) Report

		Depressed Level Of Consciousness Depressed Mood	Report Source	Product	Role Manufacturer	Route
Dose	Duration	Muscle Rigidity	Health	Zanaflex	PS	ORAL
12 MG DAILY, PER ORAL		Overdose	Professional			
		Polyuria Suicide Attempt		Thorazine	С	
	8ISR Number Gender:Male	:: 3088607-8Report Type:Expedit	ed (15-DaCompany Repor	ct #ZANA0319980384		
Outcome	December 1 and	PT	Report Source	Product	Role Manufacturer	Route
Dose Death	Duration	Jaundice	Foreign	Sirdalud	PS	ORAL
6 MG DAILY,		Renal Failure Acute	Distributor			
PER ORAL				Gastrozepin Pankreon Chloraldurat	C C C	
	8ISR Number Gender:Male	:: 3088567-XReport Type:Expedit				
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Life-Threater 75 MG, DAILY	ning	Disseminated	Foreign	Voltaren	PS	ORAL
Hospitalizati		Intravascular Coagulation	Health			!
Initial or Pr 3 MG, DAILY,	colonged	Hepatic Failure	Professional	Ternelin	SS	ORAL
ORAL		Hepatitis Fulminant				
ONEL		Pallor Renal Failure Acute Rhabdomyolysis		Stac-Eve	SS	

Date:06/11/98ISR Number: 3095951-7Report Type:Periodic Age:36 YR

Gender:Female I/FU:I

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

Company Report #316740

Multivit

Oxybutynin

Tizanidine

Phenazopyridine

С

С

С

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Freedom Of Information (FOI) Report

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

PS

ORAL

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

Age: Gender:Male I/FU:I

Role Manufacturer Outcome PTReport Source Product Route Dose Duration Zanaflex

Health

Hospitalization -

Initial or Prolonged Blood Creatinine Professional

> Increased Overdose Renal Failure

Stupor

Anuria

Date:06/29/98ISR Number: 3099561-7Report Type:Expedited (15-DaCompany Report #ZANA0319980390

Age:83 YR Gender:Male I/FU:I

Role Manufacturer Outcome PTReport Source Product Route Duration Dose ORAL Hospitalization -Cyanosis Foreign Ternelin PS 3.0 MG DAILY,

Initial or Prolonged Dyspnoea Distributor

PER ORAL

PER ORAL

Draganon SS Loxonin С Methycool С Bufferin Trental С Nitroderm Tts

Date:06/29/98ISR Number: 3099611-8Report Type:Expedited (15-DaCompany Report #ZANA0319970256

Age:73 YR Gender: Female I/FU:F

PTReport Source Product Role Manufacturer Route Outcome Dose Duration

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

ORAL

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Freedom Of Information (FOI) Report

Product

Role Manufacturer

Route

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 D	Duration					
Hospitalization 1.0 MG DAILY,	on -	Blood Pressure Systolic	Foreign	Ternelin	PS	ORAL
Initial or Pro PER ORAL	olonged	Increased	Distributor			
		Cold Sweat Nausea Shock		Soleton	SS	

Date:06/30/98ISR Number: 3099957-3Report Type:Expedited (15-DaCompany Report #1998-000894

Age:65 YR Gender:Female I/FU:F

Outcome

PΤ

Dose Duration	1				
Life-Threatening	Blister	Foreign	Mexitil	PS	ORAL
10 MG/CAP,					
Hospitalization - 300 MG PO	Blood Creatine	Health			
Initial or Prolonged 5 MG/PO	Phosphokinase Increased	Professional	Norvasc	SS	ORAL
	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					

Report Source

Erythema Face Oedema Fatique 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 PTReport Source Product Role Manufacturer Route

Dose Duration

Hospitalization -Hepatitis Health Zanaflex (Tizanidine

Initial or Prolonged

PER ORAL

Professional Hydrochloride)

Company Report #ZANA0319980343

Dantrium С Baclofen

С Steroids С

PS

PS

С

ORAL

ORAL

Amitriptyline С Trental С Pepcid С С

Synthroid С Bumex Lasix С

Date:07/01/98ISR Number: 3100880-6Report Type:Periodic

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

PTReport Source Product Role Manufacturer Outcome Route

Duration Dose

Hallucination Zanaflex (Tizanidine Consumer Other

Hydrochloride)

12 MG DAILY,

PER ORAL

Tegretol

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Freedom Of Information (FOI) Report

Baclofen

Tegretol

С

Date:07/01/98ISR Number: 3100882-XReport Type:Periodic Company Report #ZANA0319980344

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

Age:43 YR	Gender:Fema	ile I/FU:I					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Urine Abnormality	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
6 MG DAILY,			FIOLESSIONAL	nydrochioride)	FD		OKAL
PER ORAL				- 1 C	~		
				Baclofen	C		
				Clonazepam	C C		
				Estrace Tetrabenazine	C		
	98ISR Number Gender:Fema	: 3100883-1Report Type:Per le I/FU:I	iodic Company Re	eport #ZANA0319980345			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Hallucination	Health	Zanaflex (Tizanidine			
		Insomnia	Professional	Hydrochloride)	PS		ORAL
PER ORAL		Paranoia		Prozac	С		
		raranora		Amitriptyline	C		
				Talacen	C		
				Baclofen	C		
				Luvox	C		
Date:07/01/9 Age:	98ISR Number Gender:Male	: 3101046-6Report Type:Per	iodic Company Re	eport #ZANA0319980346			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Daracion	Speech Disorder	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
PER ORAL			FIULESSIUMAI		гo		ORAL
				- 1 C	~		

Date:07/01/98ISR Number: 3101047-8Report Type:Periodic Company Report #ZANA0319980347 Age:50 YR Gender: Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Asthenia Consumer Zanaflex (Tizanidine Headache Hydrochloride) PS ORAL 4 MG DAILY, Insomnia PER ORAL Maxzide С Muscle Spasms Paxil С Xanax С Prempro С Imipramine С Date:07/01/98ISR Number: 3101048-XReport Type:Periodic Company Report #ZANA0319980348 Age:59 YR Gender:Female I/FU:I PTReport Source Product Role Manufacturer Outcome Route Duration Dose Zanaflex (Tizanidine Pain Consumer Other Hydrochloride) PS ORAL 18 MG DAILY,

PER ORAL

Amitripyline С Synthroid С Baclofen С

Prempro С Fosamax С

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Freedom Of Information (FOI) Report

Solu-Medrol

Date:07/01/ Age:40 YR	98ISR Number Gender:Male	: 3101049-1Report Type:Peri	odic Company Re	eport #ZANA0319980353			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
)ther		Apathy Hallucination	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
B MG DAILY,				<u>,</u>			
PER ORAL							
				Amitriptyline	С		
				Baclofen	С		
				Avonex	С		
				Neurontin	С		
				Cylert	C		
				Naproxen	C		
Date:07/01/ Age:42 YR Outcome Dose Other 8 MG DAILY,	Gender:Male	:: 3101050-8Report Type:Peri e I/FU:I PT Acne	Report Source Consumer	Product Zanaflex (Tizanidine Hydrochloride) Xanax	Role PS C	Manufacturer	Route ORAL
Date:07/01/ Age:69 YR	98ISR Number Gender:Male	: 3101052-1Report Type:Peri	odic Company Re	eport #ZANA0319980355			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Pain	Congumor	Zanaflex (Tizanidine			
Julier		Palli	Consumer	Hydrochloride)	PS		ORAL
.8 MG DAILY	,			Hydrochioride)	PS		ORAL
PER ORAL							
				Baclofen	С		
				Methotrexate	C		
				Amitriptyline	C		
				Amitriptyime	_		

Date:07/01/98ISR Number: 3101053-3Report Type:Periodic Company Report #ZANA0319980356

Age:29 YR Gender: Female I/FU:I

PTReport Source Product Role Manufacturer Outcome Route

Duration Dose

Urinary Incontinence Zanaflex (Tizanidine Other Consumer Hydrochloride) PS

8 MG DAILY,

PER ORAL Depakote С

Date:07/01/98ISR Number: 3101054-5Report Type:Periodic Company Report #ZANA0319980357

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

Outcome Role Manufacturer PTReport Source Product Route

Dose Duration

Other Dermatitis Health Zanaflex (Tizanidine

Face Oedema Professional Hydrochloride)

PS ORAL

4 MG DAILY,

PER ORAL

Ditropan С Lotensin С Nitroglycerin С ORAL

Dantrium С С

Daypro

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Freedom Of Information (FOI) Report

Baclofen

Zocor

Trinex

Claritin

Diabinese

С

С

C

C

Date:07/01/98ISR Number: 3101056-9Report Type:Periodic Company Report #ZANA0319980358 Age:61 YR Gender: Female I/FU:I Role Manufacturer Outcome PΤ Report Source Product Route Dose Duration Other Sedation Consumer Zanaflex (Tizanidine Hydrochloride) PS ORAL 2 MG DAILY, PER ORAL С Betaseron Procardia Date:07/01/98ISR Number: 3101060-0Report Type:Periodic Company Report #ZANA0319980359 Age:51 YR Gender: Female I/FU:I Report Source Role Manufacturer Outcome PTProduct Route Duration Dose Asthenia Zanaflex (Tizanidine Other Consumer Dry Mouth Hydrochloride) PS ORAL PER ORAL Hallucination Baclofen С Pollakiuria Glyburide C Os-Cal С Imiprmine C Didronel С Coumdin Date:07/01/98ISR Number: 3101062-4Report Type:Periodic Company Report #ZANA0319980360 Age:58 YR Gender: Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Zanaflex (Tizanidine Other Increased Appetite Consumer Polyuria Hydrochloride) PS ORAL 2 MG DAILY, Pyrexia

PER ORAL

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

PS

ORAL

Dose Duration

Other Dry Mouth Consumer Zanaflex (Tizanidine

Hydrochloride)

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 Zanaflex (Tizanidine

Amenormoea mearin Zanarra (12 aniume

Professional Hydrochloride) PS ORAL

8 MG DAILY,

PER ORAL

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Freedom Of Information (FOI) Report

Baclofen

Zanaflex (Tizanidine

Oral Contraceptives

Company Report #ZANA0319980371

С

C

Date:07/01/98ISR Number: 3101070-3Report Type:Periodic Company Report #ZANA0319980367

Age:78 YR Gender: Female I/FU:I

Role Manufacturer Outcome PΤ Report Source Product Route

Dose Duration

Other Sedation Consumer Zanaflex (Tizanidine Hydrochloride) PS ORAL

4 MG DAILY,

PER ORAL

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

Role Manufacturer PTReport Source Product Outcome Route

Dose Duration

Other

Deafness Hydrochloride) PS ORAL

Consumer

PER ORAL

Dizziness Zoloft C

Dry Mouth Nystagmus Palpitations

Amblyopia

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

Role Manufacturer Outcome PTReport Source Product Route

Dose

Duration

Dry Mouth Consumer Zanaflex (Tizanidine

Muscle Spasms Hydrochloride) PS ORAL

16 MG DAILY,

Sedation

PER ORAL

Other

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

Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Abnormal Dreams Consumer Zanaflex (Tizanidine Hyperhidrosis Hydrochloride) PS ORAL 4 MG DAILY, Sedation PER ORAL Zocor С С Synthroid Estratest С Valium С Date:07/01/98ISR Number: 3101074-0Report Type:Periodic Company Report #ZANA0319980378 Age:58 YR Gender:Female I/FU:I Outcome Role Manufacturer PTReport Source Product Route Dose Duration Insomnia Consumer Zanaflex (Tizanidine Other Hydrochloride) PS ORAL 6 MG DAILY, PER ORAL С Hctz

Procardia С С Allegra Motrin С Hyoscyamine С Premarin С

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Freedom Of Information (FOI) Report

Zanaflex (Tizanidine

PS

ORAL

Hydrochloride)

Betaseron C

Outcome Oose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
ther	Duracion	Drug Ineffective Muscle Spasms	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
4 MG DAILY	7.,						
ER ORAL							
				Elavil	C		
				Neurontin	C		
				Valium	C		
				Naprelan	С		
	Gender:Fema	r: 3101079-XReport Type:	1 1	eport #ZANA0319980381			
Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration		Report Source Consumer	Zanaflex (Tizanidine	Role	Manufacturer	Route ORAL
Dose Other		PT Dermatitis Glossitis				Manufacturer	
Dose Other 3 MG DAILY,		PT Dermatitis		Zanaflex (Tizanidine		Manufacturer	
Dose Other 3 MG DAILY,		PT Dermatitis Glossitis		Zanaflex (Tizanidine Hydrochloride) Tegretol	PS C	Manufacturer	
Dose Other 3 MG DAILY,		PT Dermatitis Glossitis		Zanaflex (Tizanidine Hydrochloride) Tegretol Ogen	PS	Manufacturer	
Outcome Dose Other 8 MG DAILY, PER ORAL		PT Dermatitis Glossitis		Zanaflex (Tizanidine Hydrochloride) Tegretol	PS C	Manufacturer	
Dose Other 3 MG DAILY,		PT Dermatitis Glossitis		Zanaflex (Tizanidine Hydrochloride) Tegretol Ogen	PS C C	Manufacturer	
Dose Other 8 MG DAILY, PER ORAL Date:07/01/		PT Dermatitis Glossitis Hyperhidrosis T: 3101082-XReport Type:	Consumer	Zanaflex (Tizanidine Hydrochloride) Tegretol Ogen	PS C C	Manufacturer	
Dose Other 8 MG DAILY, PER ORAL Date:07/01/	98ISR Number	PT Dermatitis Glossitis Hyperhidrosis T: 3101082-XReport Type:	Consumer	Zanaflex (Tizanidine Hydrochloride) Tegretol Ogen Synthroid	PS C C C	Manufacturer	

Health

Professional

PER ORAL

16 MG DAILY,

Liver Function Test

Abnormal

Other

Klonopin С C Elavil

Date:07/01/98ISR Number: 3101084-3Report Type:Periodic

Age: Gender:

PT

I/FU:I

Outcome Dose

Duration

Muscle Spasms

Tremor

Health

Zanaflex (Tizanidine

Professional

Report Source

Report Source

Hydrochloride)

PS

Role Manufacturer

PS

Role Manufacturer

ORAL

Route

Route

PER ORAL

Other

Date:07/01/98ISR Number: 3101085-5Report Type:Periodic

Gender:Female Age:51 YR

Company Report #ZANA0319980388

Company Report #ZANA0319980387

Product

I/FU:I

Outcome

Dose Duration

Asthenia

PT

Oedema

Consumer

Zanaflex (Tizanidine

Product

Hydrochloride)

ORAL

PER ORAL

Other

Dilantin С Claritin С С Prozac С Lorazepam Volmax С С Ativan Prilosec С

Flovent

С

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Freedom Of Information (FOI) Report

Flonase С

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Other	Dysarthria	Foreign	Sirdalud	PS		ORAL
4 MG, PER	Dy Sar Cirr Ia	10101311	DILGGLGG	1.5		0141
·	Hypotension	Distributor				
ORAL						
	Malaise		Norvasc (Amlodipine			
	Pallor		Besilate)	C		
	Sedation		Zocor (Simvastatin)	C		
	Vertigo		Nootropil	C		
			Relifex (Nabumetone)			
			Ulceran (Ranitidine)	C.		
07 (10 (00 Tap at 1						
Age:34 YR Gender:Fe Outcome	er: 3104744-3Report Type:Expedi male I/FU:F PT	ited (15-DaCompany Re Report Source	eport #ZANA0319980379 Product	Role	Manufacturer	Route
Age:34 YR Gender:Fe Outcome Dose Duration	male I/FU:F	Report Source	Product		Manufacturer	
Age:34 YR Gender:Fe Outcome	male I/FU:F			Role PS	Manufacturer	Route ORAL
Age:34 YR Gender:Fe Outcome Dose Duration Hospitalization - 12 MG DAILY, Initial or Prolonged	male I/FU:F	Report Source	Product		Manufacturer	
Age:34 YR Gender:Fe Outcome Dose Duration Hospitalization -	male I/FU:F PT Complications Of Maternal	Report Source Foreign	Product		Manufacturer	

Outcome PTReport Source Product Role Manufacturer Route Dose Duration

Age:77 YR Gender:Female

Thrombocytopenia

I/FU:I

Date:07/21/98ISR Number: 3107331-6Report Type:Expedited (15-DaCompany Report #ZANA0319980395

Foreign Life-Threatening Abdominal Pain Ternelin PS ORAL 1 MG DAILY

Cold Sweat Health Diarrhoea Professional Calslot Hypotension Distributor Soleton

Palpitations

Shock

(Zaltoprofen)

С Gefanil (Gefarnate)

SS

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-Threaten TWICE A DAY	ning	Blood Pressure Decreased		Zanaflex	PS	
Other		Fluid Retention				
VIA PEG TUBE						
Required				Betopic	C	
Intervention	to			Sinemet	C	
Prevent Perma	nent			Levoxyl	C	ļ
Impairment/Dam	mage			Depakene	C	
1				Jevity	C	

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Freedom Of Information (FOI) Report

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 PO; TAB	Agranulocytosis	Other	Clinoril	PS	ORAL
Hospitalization - 2 MG/DAILY/PO	Blood Pressure Decreased		Ternelin	SS	ORAL
Initial or Prolonged	Bronchitis Acute		Depas	SS	
	C-Reactive Protein		Lasix	C	
	Increased		Noleptan	C	
	Depressed Level Of		Sigmart	C	
	Consciousness		Theo-Dur	C	
	Disseminated		Ulgut	C	
	Intravascular Coagulation				
	Epistaxis				
	Laboratory Test Abnormal				
	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	Duration	PT	Report Source	Product	Role Manufacturer	Route
Death	Duration	Overdose	Health	Zanaflex	PS	ORAL
ORAL			Professional			

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

PT	Report Source
Blood Creatine	Health
Phosphokinase Increased Disseminated Intravascular Coagulation Euphoric Mood Haemorrhage Hyperpyrexia Hypotension Oxygen Saturation Decreased Respiratory Distress Rhabdomyolysis Sepsis Tachycardia Tachypnoea	Professional

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Outcome

6 MG DAILY

Duration

Dose

Death

Depakene

Biaxin

Entex

Product

Zanaflex

Multivitamin Milk Of Magnesia Proventil

С С С С С

PS

С

Role Manufacturer

Route

Freedom Of Information (FOI) Report

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

Age:19 IR	Gender · Mare	1/FU-1				
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Death 6 MG DAILY;	2 42 4 5 2 5 1	Blood Creatine	Health	Zanaflex	PS	
		Phosphokinase Increased	Professional			
GT		Disseminated		Depakene	С	
		Intravascular Coagulation		Multivitamin	C	
		Haemorrhage		Milk Of Magnesia	C	
		Hyperpyrexia		Proventil	С	
		Hypotension		Biaxin	C	
Date:08/28/9 Age:31 YR		Inappropriate Affect Oxygen Saturation Decreased Respiratory Distress Respiratory Rate Increased Rhabdomyolysis Sepsis Tachycardia 1: 3122548-2Report Type:Expedit	ted (15-DaCompany Rep	Entex Dort #ZANA0319980401	C	
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration		vebore pource	Troduct	Role Manufacturer	Rouce
Hospitalizat 16 MG DAILY,	,	Pneumonia	Health	Zanaflex	PS	ORAL
Initial or E PER ORAL	Prolonged		Professional			

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

С

Report Source Role Manufacturer Outcome PTProduct Route Duration Dose Hospitalization -Chest Pain Health ORAL Zanaflex PS 32 MG DAILY, Initial or Prolonged Professional Platelet Count Decreased PER ORAL Thrombocytopenia SS Avonex UNK Neurontin С Tranylcypromine Sulfate С Ibuprofen С Date:09/04/98ISR Number: 3126387-8Report Type:Expedited (15-DaCompany Report #ZANA0319980400 Age:38 YR Gender:Male I/FU:F Role Manufacturer Report Source Product Outcome PTRoute Duration Dose Overdose Health Zanaflex Death PS ORAL PER ORAL

Professional

Date:09/04/98ISR Number: 3126189-2Report Type:Expedited (15-DaCompany Report #ZANA0319980407

I/FU:I

Age:59 YR

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Gender:Male

Freedom Of Information (FOI) Report

Date:09/23/98ISR Number: 3134020-4Report Type:Expedited (15-DaCompany Report #ZANA 0319980401

Date:09/23/98ISR Number: 3134477-9Report Type:Expedited (15-DaCompany Report #ZANA 319980400

I/FU:F

Age:38 YR

Gender:Male

Description	utcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Cough			Bronchospasm	Health	Zanaflex	PS		ORAL
Cough	nitial or E		Chills	Professional				
Productive Cough Rhonchi Restoril Rhonchi Rhonchi Restoril Rionopin 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: 3134214-6Report Type:Direct Date:09/23/98ISR Number: 3134214			Cough			С		
Rhonchi Reporcet Chactaminophen Chactamino						С		
Percocet C Acetaminophen C Milk Of Magnesia C Docusate C Acetylcysteine C Acetylcysteine C Silver Sulfadiazine C Guaifenesin C Bisacodyl C Hydroxyzine C Ceftin C Benadryl C Benadryl C Benadryl C Benadryl C Benadryl C Baclofen Pump C PT Report Source Product Role Manufacturer Rou Dose Duration Hypotension Zanaflex PS ORF MG BID PO Oxygen Saturation Lopressor SS ORF								
Acetaminophen C Milk Of Magnesia C Docusate C Acetylcysteine C Silver Sulfadiazine C Guaifenesin C Bisacodyl C Hydroxyzine C Ceftin C Benadryl			Rhonchi					
Milk Of Magnesia C Docusate C Acetylcysteine C Silver Sulfadiazine C Guaifenesin C Bisacodyl C Hydroxyzine C Ceftin C Benadryl C Baclofen Pump C Outcome PT Report Source Product Role Manufacturer Route Company Report # Duration Hypotension Zanaflex PS ORF MMG BID PO 4 DAY Oxygen Saturation Lopressor SS ORF						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 # 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 # Silver Sulfadiazine C Guaifenesin C Bisacodyl C Baclofen Pump C Botton Bisacodyl C Baclofen Pump C Botton Bisacodyl C Baclofen Pump C Baclofen P								
Acetylcysteine C Silver Sulfadiazine C Guaifenesin C Bisacodyl C Hydroxyzine C Ceftin C Benadryl C					Milk Of Magnesia	С		
Silver Sulfadiazine C Guaifenesin C Bisacodyl C Hydroxyzine C Ceftin C Benadryl C Benadr								
Guaifenesin C Bisacodyl C Hydroxyzine C Ceftin C Benadryl C Benadryl C Benadryl C Benadryl C Benadryl C Benadryl C Baclofen Pump C Company Report # Age:71 YR Gender:Male I/FU:I Coutcome PT Report Source Product Role Manufacturer Rout Cose Duration Hypotension Zanaflex PS ORF AMG BID PO 4 DAY Coygen Saturation Lopressor SS ORF Conference Decreased								
Bisacodyl C Hydroxyzine C Ceftin C Benadryl								
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 Dutcome PT Report Source Product Role Manufacturer Rou Dose Duration Hypotension Zanaflex PS ORF 4MG BID PO 4 DAY Oxygen Saturation Lopressor SS ORF								
Ceftin C Benadryl 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 Dutcome PT Report Source Product Role Manufacturer Rou Dose Duration Hypotension Zanaflex PS ORF 4MG BID PO 4 DAY Oxygen Saturation Lopressor SS ORF								
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 Rou Dose Duration Hypotension Zanaflex PS ORF 4MG BID PO 4 DAY Oxygen Saturation Lopressor SS ORF								
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 Rou Dose Duration Hypotension Zanaflex PS ORF 4MG BID PO 4 DAY Oxygen Saturation Lopressor SS ORF								
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 Rou Dose Duration Hypotension Zanaflex PS ORF 4MG BID PO 4 DAY Oxygen Saturation Lopressor SS ORF								
Age:71 YR Gender:Male I/FU:I Outcome PT Report Source Product Role Manufacturer Rou Dose Duration					Baclofen Pump	С		
Dose Duration Hypotension Zanaflex PS ORF 4MG BID PO 4 DAY Oxygen Saturation Lopressor SS ORF 25MG BID PO Decreased				Company Repo	ort #			
Hypotension Zanaflex PS ORA 4MG BID PO 4 DAY Oxygen Saturation Lopressor SS ORA 25MG BID PO Decreased	Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
4MG BID PO 4 DAY Oxygen Saturation Lopressor SS ORA 25MG BID PO Decreased		Duracion	Urmotencion		7anaflev	DQ		ORAL
Oxygen Saturation Lopressor SS ORF 25MG BID PO Decreased		4 DAV			Zanarrex	Pυ		OKAL
25MG BID PO Decreased	Dose	T 1/0.1			Tonraggor	99		ORAL
Decreased	Dose				портеррот	تات		OLVI
	Dose 4MG BID PO		oxygen bacaración					
	Dose 4MG BID PO							
Sedacion	Dose 4MG BID PO							

Outcome PT Report Source Product Role Manufacturer Route
Dose Duration

Death ORAL		Intentional Misuse	Health	Zanaflex	PS	ORAL
ORAL			Professional			
	98ISR Number: Gender:	: 3134982-5Report Type:Direct I/FU:I	Company Repo	rt #		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 8MG, TID, PO		Dizziness		Zanaflex	PS	ORAL
600MG QID		Hallucination, Visual		Neuronitin	С	1
1X/WK		Hypotension		Nascobal	С	1
		Sedation		Oxybutinin	С	1
5MG QID 50MG QD				Ultram	С	
Date:10/01/9 Age:67 YR		: 3136998-1Report Type:Direct	Company Repo	rt #		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other	Duration	Diarrhoea		Zanaflex	PS	ORAL
14MG /DAY		Pyrexia				
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Freedom Of Information (FOI) Report

Product

Role Manufacturer

Route

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	Zanaflex (Tizanidine			
			Professional	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

Age. 56 ik Gender: Female 1/FU:

Outcome

PT

Dose	Duration					
Other		Myasthenic Syndrome	Consumer	Zanaflex (Tizanidine		
				Hydrochloride)	PS	ORAL
24 MG DAILY						
				Avonex	C	
				Valium	C	
				Tegretol	C	
				Ditropan	C	
				Tofranil	C	

Report Source

Date:10/01/98ISR Number: 3263119-7Report Type:Periodic Company Report #ZANA0319980394

Age:47 YR Gender:Male I/FU:I

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

Date:10/01/ Age:	98ISR Number Gender:Fema	: 3263126-4Report Type:Periodi le I/FU:I	.c Company Repor	t #ZANA0319980397			
Outcome	December 1 and	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Dermatitis Dry Skin	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
8 MG DAILY		Urticaria		Antidepressant	С		
Date:10/01/ Age:	98ISR Number Gender:Male	: 3263129-XReport Type:Periodi	.c Company Repor	t #ZANA0319980399			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Muscle Spasms	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL

Zanaflex (Tizanidine

PS

С

ORAL

Hydrochloride)

Aspirin

Health

Professional

36 MG DAILY

Other

Angioneurotic Oedema

Urticaria

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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

Age: 42 YR Gender: Female

Duration

Outcome

Dose

I/FU:I

PT

Dote: Duration Dermatitis Health Zanaflex (Tizanidine Hydrochloride) PS ORAL	Age:33 IK	Gender · Fellia	1/F0·1					
Define Demaitis Health Zanaflex (Tizanidine Hydrochloride) PS ORAL Professional Hydrochloride) PS ORAL Professional Hydrochloride) PS ORAL Professional Hydrochloride) PS ORAL PROFESSIONAL	Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Baclofen C Ambien C Sactrim C	Other		Dermatitis			DQ		ODAT.
Ambien C C Bactrim C C Bactrim C C Company Report #ZANA0319980404 Ambien C C Company Report #ZANA0319980404 Ambien C C C C C C C C C C C C C C C C C C C	2 MG DAILY			FIOLESSIONAL	nydrochroride)	PS		ORAL
Date:10/01/98ISR Number: 3263133-1Report Type:Periodic Company Report #ZANA0319980404 Age:53 YR Gender:Male I/FU:I Doubtcome PT Report Source Product Role Manufacturer Route Dose Duration Cher Nausea Consumer Zanaflex (Tizanidine Hydrochloride) Date:10/01/98ISR Number: 3263136-7Report Type:Periodic Company Report #ZANA0319980405 Age:51 YR Gender:Female I/FU:I Dutcome PT Report Source Product Role Manufacturer Route Dose Duration Cher Professional Hydrochloride) PS ORAL Route Route Route Route Dirropan C Dirropan C Dirropan C Dirropan C Dirropan C Dirropan C Estrace C Prolific C Estrace C Prolific C					Baclofen	С		
Date:10/01/98ISR Number: 3263133-1Report Type:Periodic Company Report #ZANA0319980404 Outcome PT Report Source Product Role Manufacturer Route Dose Duration Ther Nausea Consumer Zanaflex (Tizanidine Hydrochloride) Date:10/01/98ISR Number: 3263136-7Report Type:Periodic Company Report #ZANA0319980405 Outcome PT Report Source Product Role Manufacturer Route Date:10/01/98ISR Number: 3263136-7Report Type:Periodic Company Report #ZANA0319980405 Outcome PT Report Source Product Role Manufacturer Route Dose Duration Other Herpes Zoster Health Zanaflex (Tizanidine Hydrochloride) FS ORAL					Ambien	C		
Age:53 YR Gender:Male I/FU:I Outcome Duration Dither Duration Deher Nausea Consumer Zanaflex (Tizanidine Hydrochloride) PS ORAL Outcome Duration Deher Nausea Consumer Zanaflex (Tizanidine Hydrochloride) PS ORAL Outcome Duration Dither PT Report Source Product Role Manufacturer Route PT Report Source Product Role Manufacturer Route PT Report Source Product Role Manufacturer Route Dither Herpes Zoster Health Zanaflex (Tizanidine Hydrochloride) PS ORAL ORAL PT Report Source Product Role Manufacturer Route Professional Hydrochloride) PS ORAL ORAL Professional Hydrochloride Professional CORAL Report Source Product Role Manufacturer Route Professional Report (Tizanidine Professional CORAL Report Source Product Role Manufacturer Route Ro					Bactrim	С		
Dutcome PT Report Source Product Role Manufacturer Route Dose Duration Other Nausea Consumer Zanaflex (Tizanidine Hydrochloride) PS ORAL Date:10/01/98ISR Number: 3263136-7Report Type:Periodic Company Report #ZANA0319980405 Age:51 YR Gender:Female I/FU:I Dutcome Duration Other PT Report Source Product Role Manufacturer Route Dose Duration Other Herpes Zoster Health Zanaflex (Tizanidine Professional Hydrochloride) PS ORAL Prozac C Prozac C Ditropan C Prozac C Ditropan C Neurontin C Neurontin C Neurontin C Neurontin C Sestrace C Prolific C				c Company Repor	t #ZANA0319980404			
ORAL ORAL ORAL ORAL ORAL ORAL ORAL ORAL	_							
ORAL	Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Age:51 YR Gender:Female I/FU:I Contact Burst Bu		Duration		_				
Age:51 YR Gender:Female I/FU:I Outcome PT Report Source Product Role Manufacturer Route Dose Duration Other Herpes Zoster Health Zanaflex (Tizanidine Sedation Professional Hydrochloride) PS ORAL Baclofen C Prozac C Ditropan C Nitrofurantoin C Neurontin C Estrace C Prolific C	Other		Nausea	Consumer		DG		ORAT.
Age:51 YR Gender:Female I/FU:I Outcome PT Report Source Product Role Manufacturer Route Oose Duration Other Herpes Zoster Health Zanaflex (Tizanidine Sedation Professional Hydrochloride) PS ORAL Baclofen C Prozac C Ditropan C Nitrofurantoin C Neurontin C Estrace C Prolific C	2 MG DAILY				nyaroenioriae,	15		Oldin
Dose Duration Other Herpes Zoster Health Zanaflex (Tizanidine Sedation Professional Hydrochloride) PS ORAL Baclofen C Prozac C Ditropan C Nitrofurantoin C Neurontin C Estrace C Prolific C				c Company Repor	t #ZANA0319980405			
Herpes Zoster Sedation Professional Hydrochloride) Baclofen Prozac Ditropan C Nitrofurantoin C Estrace C Prolific C Prolific C	Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Baclofen C Prozac C Ditropan C Nitrofurantoin C Neurontin C Estrace C Prolific C	Other		Herpes Zoster	Health	Zanaflex (Tizanidine			
Prozac C Ditropan C Nitrofurantoin C Neurontin C Estrace C Prolific C			Sedation	Professional	Hydrochloride)	PS		ORAL
Ditropan C Nitrofurantoin C Neurontin C Estrace C Prolific C					Baclofen	C		
Nitrofurantoin C Neurontin C Estrace C Prolific C					Prozac	C		
Neurontin C Estrace C Prolific C					Ditropan	C		
Estrace C Prolific C					Nitrofurantoin	C		
Prolific C					Neurontin	C		
					Estrace	С		
Date:10/01/98ISR Number: 3263139-2Report Type:Periodic Company Report #ZANA0319980410					Prolific	С		
Date:10/01/98ISR Number: 3263139-2Report Type:Periodic Company Report #ZANA0319980410								
	Date:10/01/9	8ISR Number	: 3263139-2Report Type:Periodi	c Company Repor	t #ZANA0319980410			

Report Source

Product

Role Manufacturer

Route

Date:10/01/98ISR Numbe Age:79 YR Gender:Mai	er: 3263140-9Report Type:Pe: le I/FU:I	riodic Company Ro	eport #ZANA0319980411		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
ose Duration Ther	Coagulation Time Prolonged	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS	ORAL
L2 MG DAILY					
			Coumadin	C	
			Mevacor	C	
			Vasotec	С	
Date:10/13/98ISR Numbe Age: Gender:Ma	er: 3142382-7Report Type:Di: le I/FU:I	rect Company Ro	eport #		

Zanaflex (Tizanidine

PS

ORAL

Hydrochloride)

Health

Professional

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Other

4 MG DAILY

Dysgeusia

Headache Hyperhidrosis

Nausea

Hyperhidrosis

Freedom Of Information (FOI) Report

Tremor	

Prevent Permanent

INCREASED 4

		Tremor				
Dose	Duration		Report Source	Product	Role Manufacture	r Route
4 MG EVERY			Health Professional	Zanaflex	PS	
HOURS						
Date:10/29/ Age:30 YR	98ISR Number Gender:Male	r: 3149344-4Report Type:Exp e I/FU:I	pedited (15-DaCompany Re	eport #ZANA0319980420		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacture	r Route
Death PER ORAL	Death	Death	Health	Zanaflex	PS	ORAL
FER ORAL		Overdose	Professional	Oxycodone	SS	
Age: Outcome Dose Hospitaliza	Gender:Male Duration tion -	PT	Report Source Foreign	Product Ternelin	Role Manufacture	
Dose Hospitaliza 3.0 MG DAIL Initial or 1	tion - Y,	Depressed Level Of Consciousness	Foreign Health	Ternelin	PS	ORAL
PER ORAL	riorongea	Consciousness	Professional Distributor	Disopain Aplace	SS C	
Date:11/06/ Age:	98ISR Number Gender:Male	r: 3153181-4Report Type:Dir e I/FU:I	rect Company Re	eport #		
Outcome	Duration	PT	Report Source	Product	Role Manufacture	r Route
Dose Required 8 MG PO Q 4	Duracion	Dysarthria		Zanaflex	PS	ORAL
Intervention HOURS; DOSA		Hypotension				

TO ADR

Docusate Sodium	С
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 Disability 2 MG DAILY,	Duration	Asthenia	Foreign	Ternelin	PS	ORAL
ŕ		Monoparesis	Health			
PER ORAL		Muscle Atrophy	Professional	Infree	SS	
		- -	Distributor	Chondroitin	C	

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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 Disability 2 MG DAILY,	Duration	Asthenia	Foreign	Ternelin	PS	ORAL
PER ORAL		Intervertebral Disc	Health			
PER URAL		Protrusion Monoparesis Movement Disorder Muscle Atrophy Nerve Compression Nerve Root Injury Neuropathy Peripheral	Professional Distributor	Infree Chondroitin (Chpondroitin Sulfate)	ss	

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 Duratio	on				
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	С	

Date:12/15/98ISR Number: 3171078-0Report Type:Expedited (15-DaCompany Report #ZANA0319980433

Age:20 YR Gender:Female I/FU:I

PTRole Manufacturer Outcome Report Source Product 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

Dobe Dara	Hallucination	Health	Zanaflex	PS	ORAL
PER ORAL		Professional	Ms Contin Benzodiazepine	C C	
	Number: 3171722-8Report Type:Hr:Male I/FU:F	Expedited (15-DaCompany Ro	eport #ZANA0319980429		
Outcome Dose Dura	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - PER ORAL		Health	Zanaflex	PS	ORAL
Initial or Prolon Disability	ged Confusional State Depressed Level Of Consciousness Disorientation Hallucination Medication Error Sedation	Professional	Ms Contin Smir Verapamil Prozac Ativan	C C C C	

Report Source

Product

Role Manufacturer

Route

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Outcome

Dose

PT

Duration

Freedom Of Information (FOI) Report

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

Age: Gender: I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration Other Convulsion Health Zanaflex (Tizanidine

Professional Hydrochloride) PS ORAL

PER ORAL

Date:01/05/99ISR Number: 3192864-7Report Type:Expedited (15-DaCompany Report #ZANA0319990441

Gender:Female Age:1 YR I/FU:I

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

FIULGSSIUMI	DIOLESAI (DACIOLEII)	טט
Distributor	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				

Hyperhidrosis Other Health Zanaflex PS ORAL

PER ORAL Oedema Professional

Vasodilatation

Date:01/06/99ISR Number: 3192628-4Report Type:Periodic Company Report #ZANA0319980428

Age:50 YR Gender:

Outcome PTReport Source Product Role Manufacturer Route

Duration Dose

Sedation Health Zanaflex (Tizanidine Other ORAL

Hydrochloride) Tremor Professional PS

PER ORAL

Date:01/06/99ISR Number: 3192632-6Report Type:Periodic Company Report #ZANA0319980425

Gender: Female I/FU:I Age:

Role Manufacturer PTReport Source Product Outcome Route

Duration Dose

Alopecia Health Zanaflex (Tizanidine Other

Professional Hydrochloride) PS ORAL

8 MG , PER

ORAL

Coumadin С Depo-Provera С

Baclofen С Diazepam

С Amitriptyline С

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Freedom Of Information (FOI) Report

Role Manufacturer

Route

	99ISR Number Gender:Male	: 3192636-3Report Type:Periodi	.C	Company Repor	t #ZANA0319980424			
Outcome		PT	Report	Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Muscle Spasms	Consume	er	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
PER ORAL								
	991SR Number Gender:Fema	: 3192641-7Report Type:Periodi le I/FU:I	.C	Company Repor	t #ZANA0319980422			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other	Duracion	Condition Aggravated Muscle Spasms	Health Profess	sional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
2 MG DAILY,								
PER ORAL								
Date:01/06/9 Age:63 YR		: 3192646-6Report Type:Periodi	.C	Company Repor	t #ZANA0319980419			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other	Daracion	Asthenia	Consume	er	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
12 MG DAILY,					1			
PER ORAL					W-14	C		
					Valium Hydrochlorothiazide	C C		
					Lisinopril	С		
					Labetalol	С		
	00 T.CD - Novelle	: 3192650-8Report Type:Periodi		a 5	t #ZANA0319980415			

Report Source

Consumer

Product

Zanaflex (Tizanidine

PT

Asthenia

Duration

Outcome

Dose

Other

		Sedation		Hydrochloride)	PS	ORAL
10 MG DIALY,				_		
		Urinary Incontinence				
PER ORAL						
				Morphine	C	
				Percocet	C	
				Terazosin	C	
				Lopressor	C	
				Naprosyn	С	
Date:01/06/9	9ISR Number	: 3192656-9Report Type:Period	ic Company Repo	rt #ZANA0319980413		
	Gender:Male		_ <u>. </u>	··		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other		Abnormal Faeces	Health	Zanaflex (Tizanidine		
			Professional	Hydrochloride)	PS	ORAL
4 MG DAILY,						
PER ORAL						
				Percocet	C	
				Trilisate	C	
				Zoloft	C	
		: 3192661-2Report Type:Period	ic Company Repor	rt #ZANA0319980412		
Age:54 YR	Gender:Femal	le I/FU:I				
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other		Sedation	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS	ORAL
2 MG DAILY,				-		
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Freedom Of Information (FOI) Report

Ternelin Unknown (Tizanidine)

SS

ORAL

PER ORAL

Methotrexate C Avonex C

PT	Report Source	Product	Role	Manufacturer	Route
Angina Pectoris	Foreign	Itraconazole	PS	Janssen	ORAL
Back Pain	Health				
Drug Interaction Drug Level Above Therapeutic	Professional	Tizanidine Hydrochloride (Tizanidine) Tablet	SS		ORAL
		(111411141116) 142166			01412
		Etodolac Terbinafine	С		
		Hydrochloride	C		
		Misoprostol	С		
: 3188604-8Report Type:Expe	dited (15-DaCompany Re	eport #98J-10423			
, =					
PT	Report Source	Product	Role	Manufacturer	Route
	Angina Pectoris Back Pain Drug Interaction Drug Level Above Therapeutic : 3188604-8Report Type:Expec	Angina Pectoris Foreign Back Pain Health Drug Interaction Professional Drug Level Above Therapeutic 3188604-8Report Type:Expedited (15-DaCompany Recompany Recompa	Angina Pectoris Foreign Itraconazole Back Pain Health Drug Interaction Professional Tizanidine Hydrochloride (Tizanidine) Tablet Etodolac Terbinafine Hydrochloride Misoprostol ### Standard Hydrochloride ###	Angina Pectoris Foreign Itraconazole PS Back Pain Health Drug Interaction Professional Tizanidine Hydrochloride (Tizanidine) Tablet SS Etodolac C Terbinafine Hydrochloride C Misoprostol C 3188604-8Report Type:Expedited (15-DaCompany Report #98J-10423	Angina Pectoris Foreign Itraconazole PS Janssen Back Pain Health Drug Interaction Drug Level Above Therapeutic February Report #98J-10423 Tizanidine Hydrochloride (Tizanidine) Tablet SS February Report #98J-10423

ORAL

1 MG, DAILY,

ORAL

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

Gender: Female I/FU:I

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

Date:02/16/99ISR Number: 3199743-XReport Type:Expedited (15-DaCompany Report #ZANA0319990442

Gender:Female Age:45 YR I/FU:I

PT

Sedation

Dose	Duration					
Life-Threater	ning	Bradycardia	Health	Zanaflex (Tizanidine		
Hospitalizati 360 MG DAILY,		Cyanosis	Professional	Hydrochloride)	PS	ORAL
Initial or Pr PER ORAL	rolonged	Feeling Cold				
Other		Hypotension		Alprazolam	C	
1		Intentional Misuse		Trazodone	C	
1		Lung Infiltration		Dicyclomine	C	
1		Pneumonia Aspiration		Prozac	C	

Product

Percocet

Role Manufacturer

С

Route

Report Source

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Outcome

Freedom Of Information (FOI) Report

Aspirin Parlodel

Date:02/19/99ISR Number: 3203503-OReport Type:Expedited (15-DaCompany Report #ZANA0319990443

Age:51 YR Gender:Female I/FU:I

Outcome				_	_	
	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration		-	- 1			
Hospitalization -	Cardiac Failure	Foreign	Ternelin			
Initial or Prolonged	Depressed Level Of	Health	(Tizandinine			
Other	Consciousness	Professional	Hydrochloride)	PS		ORAL
284.0 MG	1 -1	- 1 · · · · · · · · · ·				
D. T. T. D.	Drug Level Above	Distributor				
DAILY, PER	m1.					
0.5.1.	Therapeutic					
ORAL	2		27 1 (Do			
	Overdose		Myonal (Eperisone	~~		
	Respiratory Depression		Hydrochloride)	SS		
	- ⁷ - T/DII•D					
Age:69 YR Gender:Fem Outcome	ale I/FU:F PT	Report Source	Product	Role	Manufacturer	Route
Outcome Dose Duration	PT	-		Role	Manufacturer	Route
Outcome Dose Duration Hospitalization -	PT Abdominal Distension	Foreign	Ternelin (Tizanidine		Manufacturer	
Outcome Dose Duration	PT	-		Role	Manufacturer	Route ORAL
Outcome Dose Duration Hospitalization - Initial or Prolonged	PT Abdominal Distension	Foreign	Ternelin (Tizanidine		Manufacturer	
Outcome Dose Duration Hospitalization - Initial or Prolonged	PT Abdominal Distension Abdominal Pain	Foreign Health	Ternelin (Tizanidine		Manufacturer	
Outcome Dose Duration Hospitalization - Initial or Prolonged 3 MG DAILY	PT Abdominal Distension Abdominal Pain	Foreign Health	Ternelin (Tizanidine Hydrochloride) Peon (Zaltoprofen)		Manufacturer	
Outcome Dose Duration Hospitalization - Initial or Prolonged 3 MG DAILY	PT Abdominal Distension Abdominal Pain Decreased Appetite	Foreign Health Professional	Ternelin (Tizanidine Hydrochloride)	PS	Manufacturer	
Outcome Dose Duration Hospitalization - Initial or Prolonged 3 MG DAILY	PT Abdominal Distension Abdominal Pain Decreased Appetite	Foreign Health Professional	Ternelin (Tizanidine Hydrochloride) Peon (Zaltoprofen)	PS SS SS	Manufacturer	
Outcome Dose Duration Hospitalization - Initial or Prolonged 3 MG DAILY	PT Abdominal Distension Abdominal Pain Decreased Appetite	Foreign Health Professional	Ternelin (Tizanidine Hydrochloride) Peon (Zaltoprofen) Marzulen-S	PS SS	Manufacturer	
Outcome Dose Duration Hospitalization - Initial or Prolonged 3 MG DAILY	PT Abdominal Distension Abdominal Pain Decreased Appetite	Foreign Health Professional	Ternelin (Tizanidine Hydrochloride) Peon (Zaltoprofen) Marzulen-S (Marzulene-S)	PS SS SS	Manufacturer	
Outcome Dose Duration Hospitalization - Initial or Prolonged 3 MG DAILY	PT Abdominal Distension Abdominal Pain Decreased Appetite	Foreign Health Professional	Ternelin (Tizanidine Hydrochloride) Peon (Zaltoprofen) Marzulen-S (Marzulene-S) Dasen (Serrapeptase)	PS SS SS SS	Manufacturer	
Outcome Dose Duration Hospitalization - Initial or Prolonged 3 MG DAILY	PT Abdominal Distension Abdominal Pain Decreased Appetite	Foreign Health Professional	Ternelin (Tizanidine Hydrochloride) Peon (Zaltoprofen) Marzulen-S (Marzulene-S) Dasen (Serrapeptase) Madopar	PS SS SS SS C	Manufacturer	

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

Age. 43 IK Gender Mare 1/10.1

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration				

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

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration

Hospitalization -Zanaflex (Tizanidine Amnesia Consumer

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-OReport Type:Direct Company Report #

Age:54 YR Gender:Female I/FU:I

Outcome PT

Abdominal Pain Upper Hospitalization -Initial or Prolonged Gallbladder Disorder

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Freedom Of Information (FOI) Report

Hepatotoxicity Jaundice Liver Function Test Role Manufacturer Report Source Product Route Dose Duration Abnormal Health Zanaflex PS 4MG Q6; ON Professional 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 Report Source Product Role Manufacturer Outcome PTRoute Dose Duration Cardio-Respiratory Arrest Zanaflex (Tizanidine Life-Threatening Company Hydrochloride) Representative 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 Report Source Role Manufacturer Outcome PTProduct Route Dose Duration Hospitalization -Cardiac Failure Ternelin (Tizanidine Foreign Initial or Prolonged Depressed Level Of Health Hydrochloride) PS ORAL 284.0 MG Other Consciousness Professional DAILY, PER Electrocardiogram Qt Distributor ORAL Prolonged Myonal (Eperisone Electrocardiogram St Hydrochloride) SS Segment Elevation Hypothermia Loss Of Consciousness Nausea

Overdose

Vomiting

Respiratory Depression

Suicide Attempt

Date:03/12/99ISR Number: 3219425-5Report Type:Expedited (15-DaCompany Report #ZANA0319990454

Age:61 YR Gender:Female I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P: PER ORAL	ion -	Abnormal Behaviour	Foreign	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
				Tramadol	SS		ORAL
PER ORAL Date:03/12/9	9ISR Number	: 3219466-8Report Type:Expedit	ed (15-DaCompany Repor	Baclofen Diazepam Diconal Moduretic	C C C C		
Age:54 YR	Gender:Male	I/FU:I					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P: 12 MG DAILY,		Muscle Rigidity Tremor	Foreign	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL

PER ORAL

Baclofen C Cinnarizine C

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Freedom Of Information (FOI) Report

C

С

Date:03/12/99ISR Number: 3219469-3Report Type:Expedited (15-DaCompany Report #ZANA0319990452

Age:30 YR Gender:Male I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration

Other Cardiac Failure Foreign Zanaflex PS ORAL

32 MG DAILY,

PER ORAL

Congestive

Creatine Phosphokinase

Lansoprazole

Decreased Crepitations Dyspnoea

Dyspnoea Paroxysmal

Nocturnal

Date:03/12/99ISR Number: 3219471-1Report Type:Expedited (15-DaCompany Report #ZANA0319990451

Gender: Male Age: I/FU:I

Role Manufacturer Route Outcome PTReport Source Product

Dose Duration

Hospitalization -Condition Aggravated Foreign Zanaflex PS ORAL

2-4 MG DAILY,

Initial or Prolonged Muscle Spasticity

PER ORAL

Quadriplegia Carbarmazepine С

Baclofen

Date:04/01/99ISR Number: 3232648-4Report Type:Periodic Company Report #ZANA0319980434

Age:71 YR Gender:Female I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration

Urinary Incontinence Zanaflex (Tizanidine Other Consumer

Hydrochloride) PS ORAL

4 MG DAILY,

PER ORAL Cosamin Date:04/01/99ISR Number: 3232650-2Report Type:Periodic Company Report #ZANA0319980436 Age:48 YR Gender: Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Accident Consumer Zanaflex (Tizanidine Muscle Spasms Hydrochloride) PS ORAL 4 MG DAILY, PER ORAL Primidone С Diazepam С Date:04/01/99ISR Number: 3232653-8Report Type:Periodic Company Report #ZANA0319990437 Age:47 YR Gender:Male I/FU:I Report Source Role Manufacturer Outcome PTProduct Route Dose Duration Zanaflex (Tizanidine Other Dry Mouth Consumer Sedation Hydrochloride) PS ORAL PER ORAL Sinusitis С Permax Zocor С Hytrin

Date:04/01/99ISR Number: 3232656-3Report Type:Periodic Company Report #ZANA0319990439

Age:49 YR Gender:Male I/FU:I

PTReport Source Product Role Manufacturer Outcome Route Duration Dose Zanaflex (Tizanidine Consumer Other Nausea Pyrexia Hydrochloride) PS ORAL

2 MG DAILY,

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Freedom Of Information (FOI) Report

С

С

Neurontin

Valium

Naprelan

PER ORAL

					Neurontin	C		
Date:04/01/ Age:16 YR	99ISR Number Gender:Male	: 3232658-7Report I I/FU:I	'ype:Periodic	Company Report	t #ZANA0319990446			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other	Duracion	Hypotension	Health Profess	ional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
6 MG DAILY,								
PER ORAL					2	G		
					Anti-Hypertensives	С		
Age:33 YR Outcome	Gender:Male	: 3232660-5Report T I/FU:I PT	Type:Periodic Report		t #ZANA0319990447 Product	Role	Manufacturer	Route
Dose Other	Duration	Hypotension	Health		Zanaflex (Tizanidine			
30 MG DAILY	7,		Profess	ional	Hydrochloride)	PS		ORAL
PER ORAL								
					Zithromax	С		
Date:04/01/ Age:44 YR	991SR Number Gender:Male	: 3232661-7Report T I/FU:F	'ype:Periodic	Company Report	t #ZANA0319980380			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other		Drug Ineffective Muscle Spasms	Consume	r	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
24 MG DAILY	7 ,	rasere spasias			nyaroenioi iac /	15		OICAL
PER ORAL						_		
I					Elavil Neurontin	C C		
					Neuronem	~		

Date:06/07/99ISR Number: 3277525-8Report Type:Expedited (15-DaCompany Report #ZANA0319990489

Age:36 YR Gender:Female I/FU:I

Outcome PTReport Source Product Role Manufacturer Route Duration Dose 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

MG, DAILY,

ORAL
Sirdalud (Tizanidine

Hydrochloride) SS ORAL

ORAL

MG, DAILY,

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Freedom Of Information (FOI) Report

Cozaar

Product

ORAL

Outcome

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

С

Role Manufacturer

Route

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

Age:72 YR Gender:Female

PT

	= =				
Dose Duration					
Hospitalization -	Back Pain	Foreign	Prepulsid		
Initial or Prolonged	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	С	
			Cozaar	С	
			Emconcor	С	

Report Source

Date:07/01/99ISR Number: 3303393-1Report Type:Periodic Company Report #ZANA0319990480

ender:Male	I/FU:I					
	PT	Report Source	Product	Role	Manufacturer	Route
	Hypersensitivity	Consumer	Zanaflex (Tiza	nidine		
3	ender:Male Ouration	PT	ender:Male I/FU:I Report Source	ender:Male I/FU:I Report Source Product Ouration	PT Report Source Product Role Duration	ender:Male I/FU:I To the Product Role Manufacturer Duration

		Paraesthesia		Hydrochloride)	PS		ORAL
2 MG DAILY, PER ORAL		Skin Ulcer					
		Urticaria					
	99ISR Number Gender:Male	: 3303406-7Report Type:Per	iodic Company	Report #ZANA0319990481			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Liver Function Test	Health	Zanaflex (Tizanidine			1
36 MG DAILY	,	Abnormal	Professional	Hydrochloride)	PS		ORAL
PER ORAL							
Date:07/01/ Age:81 YR	99ISR Number Gender:	:: 3303411-0Report Type:Per I/FU:I	iodic Company	Report #ZANA0319990482			
Outcome	Describion	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Pruritus Rash Maculo-Papular	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
4 MG DAILY,		Table Table 1					- -
PER ORAL							
PER ORAL				Vasotec Biaxin	C C		
i				Biaxin	C		

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Freedom Of Information (FOI) Report

Digoxin С

ORAL

ORAL

ORAL

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

Age: Gender: I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Duration Dose

Rash Pruritic Health Zanaflex (Tizanidine Other

Professional Hydrochloride) PS

4-6 MG DAILY,

PER ORAL

Date:07/01/99ISR Number: 3303418-3Report Type:Periodic Company Report #ZANA0319990486

Gender: Female I/FU:I Age:

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration

Other Dizziness Consumer Zanaflex (Tizanidine

Myasthenic Syndrome Hydrochloride)

PS PER ORAL; 4

Sedation

MG DAILY, PER

ORAL

Date:07/01/99ISR Number: 3303421-3Report Type:Periodic Company Report #ZANA0319990487

Age:50 YR Gender: Female I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration

Zanaflex (Tizanidine Other Alopecia Consumer

Sedation Hydrochloride) PS

6 MG DAILY,

PER ORAL

Baclofen С

Naproxen Sodium С

Ditropan Excel С Date:07/01/99ISR Number: 3303449-3Report Type:Periodic Company Report #ZANA0319990490

Age:52 YR Gender: Female I/FU:I

Outcome PTReport Source Product Role Manufacturer Route

Dose Duration

Other Professional Hydrochloride) PS ORAL

Pain Health Zanaflex (Tizanidine

PER ORAL

Date:07/01/99ISR Number: 3303455-9Report Type:Periodic Company Report #ZANA0319990491

Age:49 YR Gender: Female I/FU:I

Role Manufacturer Report Source Product Outcome PTRoute

Duration Dose

Alopecia Health Zanaflex (Tizanidine Other

Professional Hydrochloride) PS ORAL

12 MG DAILY,

PER ORAL Clonipen С

Imuran С Prednisone С

Date:07/01/99ISR Number: 3303460-2Report Type:Periodic Company Report #ZANA0319990493

Gender: Female Age: I/FU:I

PTReport Source Product Role Manufacturer Outcome Route

Duration Dose

Dizziness Consumer Zanaflex (Tizanidine Other

Dry Mouth Hydrochloride) PS ORAL

PER ORAL Synthroid С

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Freedom Of Information (FOI) Report

Provera	С
Hctz	C
Zestril	С

Milk Of Magnesia

С

Date:07/01/99ISR Number: 3303465-1Report Type:Periodic Company Report #ZANA0319990494 Gender:Male I/FU:I Age: Role Manufacturer Outcome PTReport Source Product Route Dose Duration Asthenia Zanaflex (Tizanidine Other Consumer Hydrochloride) Hallucination PS ORAL 36 MG DAILY, Myasthenic Syndrome PER ORAL Sedation Baclofen C Date:07/01/99ISR Number: 3303468-7Report Type:Periodic Company Report #ZANA0319990497 Gender: Male Age:9 YR I/FU:I Report Source Role Manufacturer Outcome PΤ Product Route Duration Dose Abdominal Pain Consumer Zanaflex (Tizanidine Other Abnormal Faeces Hydrochloride) PS ORAL PER ORAL; 1.5 Nausea MG DAILY, PER ORAL Tegretol С Mysoline Multivitamins C Calcium Gluconate

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

phigoid Zanaflex (Tizanidine

		SIMVASCACIII	C	
		Aspirin	C	
		Diazepam	C	
			С	
	edited (15-DaCompany Re	eport #ZANA0319990503		
1/FU-1				
PT	Report Source	Product	Role Manufacturer	Route
Bradycardia	Foreign	Sirdalud (Tizanidine		
Cardiac Failure	Distributor	Hydrochloride)	PS	ORAL
		-		
Congestive				
Condition Aggravated		Sirdalud Mr	SS	ORAL
- -				
Electrocardiogram Qt				ļ
-				I
Prolonged		Lansoprazole	SS	
_		Prepulsid		ļ
			aa	ORAL
	PT Bradycardia Cardiac Failure Congestive Condition Aggravated Electrocardiogram Qt	PT Report Source Bradycardia Foreign Cardiac Failure Distributor Congestive Condition Aggravated Electrocardiogram Qt	Aspirin Diazepam Hydroxyzine Praxilene T: 3302773-8Report Type:Expedited (15-DaCompany Report #ZANA0319990503 ale I/FU:I PT Report Source Product Bradycardia Foreign Sirdalud (Tizanidine Cardiac Failure Distributor Hydrochloride) Congestive Condition Aggravated Sirdalud Mr Electrocardiogram Qt Prolonged Lansoprazole Prepulsid	Aspirin C Diazepam C Hydroxyzine C Praxilene C Fraxilene C Fraxilene C Report Type:Expedited (15-DaCompany Report #ZANA0319990503 Report Source Product Role Manufacturer Bradycardia Foreign Sirdalud (Tizanidine Cardiac Failure Distributor Hydrochloride) PS Congestive Condition Aggravated Sirdalud Mr SS Electrocardiogram Qt Prolonged Lansoprazole SS

Hydrochloride)

Spironolactone

Baclofen

Frusemide

Thyroxine

Amlodipine

Lisinopril

Simvastatin

PS

С

С

С

С

С

C C ORAL

Initial or Prolonged

PER ORAL

PER ORAL

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Freedom Of Information (FOI) Report

Sulfasalazine

Cozaar Bisoprolol

Digoxin

Product

С

C C

Role Manufacturer

Route

			Eurogomido	C		
			Furosemide	С		
Date:07/23/99ISR Numbe: Age:78 YR Gender:Mal	r: 3309826-9Report Type:Exp e I/FU:I	pedited (15-DaCompany R	eport #ZANA0319990509			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration		-				
Life-Threatening	Bradycardia	Health	Sirdalud (Tizanidine			
	Depressed Level Of	Professional	Hydrochloride)	PS		ORAL
3.0 MG DAILY;						
	Consciousness					
PER ORAL 711 DAY			+ 1 '	~		
	Heart Rate Decreased		Lendormin	C		
	Sedation		Sedes	C		
	Sick Sinus Syndrome		Merislon Selbex	C C		
Date:07/23/99ISR Numbe: Age:78 YR Gender:Mal	r: 3310019-XReport Type:Exp e I/FU:I	pedited (15-DaCompany R	eport #ZANA0319990509			
Age:/8 ik Gender-Mar	e 1/FU-1					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Bradycardia	Foreign	Sirdalud (Tizanidine			
	Depressed Level Of	Health	Hydrochloride)	PS		ORAL
3.0 MG DAILY,						
	Consciousness	Professional				
PER ORAL	Sedation	Distributor	Merislon	99		
	Sick Sinus Syndrome	DISCLIDUCOL	Merision Lendormin	SS C		
	SICK SILIUS SYLIGIOME		Selbex	C		
			Sedes	C		
			Sedes	C		

Report Source

Date:07/30/99ISR Number: 3315221-9Report Type:Expedited (15-DaCompany Report #ZANA0319990511

I/FU:I

Age:70 YR

Outcome

Dose

Gender:Female

Duration

PT

Hospitalization -	Depressed Level Of	Foreign	Ternelin (Tizanidine	
Initial or Prolonged 3.0 MG DAILY,	Consciousness	Health	Hydrochloride)	PS
•	Extensor Plantar Response	Professional		
PER ORAL				
	Hypertension	Distributor	Aspirine	C
	Нурохіа		Sarpul	C
	Respiratory Failure		Trental	C
	Respiratory Rate			
	Decreased			
	Sedation			
	Shock			
	Stridor			
Date:07/30/99ISR Numbe Age:70 YR Gender:Fem	er: 3315224-4Report Type:Exped: nale I/FU:I	ited (15-DaCompany	Report #ZANA0319990511	
Outcome	PT			
Hospitalization -	Cerebrovascular Accident			
Initial or Prolonged	Depressed Level Of			
	Consciousness			
	Extensor Plantar Response			
	Hypopnoea			

ORAL

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Hypotension Hypoxia

Freedom Of Information (FOI) Report

Role Manufacturer

Route

		Rash Macular					
Dose :	Duration	Respiratory Failure	Report Source	Product	Role	Manufacturer	Route
Dose .	Duracion	Sedation	Health	Ternelin (Tizanidine			
		Shock	Professional	Hydrochloride)	PS		ORAL
3.0 MG DAILY				-			
		Stridor		Aspirine	С		
				Sarpul	C		
				Trental	С		
	ISR Number ender:Fema	: 3330238-6Report Type:Exp	edited (15-DaCompany Re	eport #ZANA0319990520			
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	С		
		: 3330239-8Report Type:Exp SpecifiI/FU:I	edited (15-DaCompany Re	eport #ZANA0319990518			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
	Duration		_	- 63 (-1 13)			
Hospitalizati Initial or Pr 36 MG DAILY,		Bradycardia Hallucination	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
PER ORAL							
	ISR Number ender:Male	: 3341141-XReport Type:Exp	edited (15-DaCompany Re	eport #ZANA0319990521			

Report Source

Health

Product

Zanaflex (Tizanidine

Medication Error

Outcome

Dose

Other

PT

Chromaturia

Duration

Date:09/15/99ISR Numbe	er: 3348801-5Report Type:Ex	pedited (15-DaCompany Ro	eport #99J10282			
Age:33 YR Gender:Fen	male I/FU:I					
Outcome Dose Duration	PT	Report Source	Product	Role M	Manufacturer	Route
Hospitalization - Initial or Prolonged RECTAL UNK,	Liver Disorder Oculomucocutaneous DAILY,	Foreign Health	Voltaren Suppository (Diclofenac Sodium)	PS		
RECTAL	Syndrome	Professional				
		Other	Bufferin Unknown (Bufferin) Mucodyne Unknown (Carbocisteine) Pl Granulate (Pl Granules)	SS SS		
			Loxonin Unknown (Loxoprofen Sodium) Tizanidine Hydrochloride Tablet	SS		

Professional

Hydrochloride)

Baclofen

Atenolol

Tamsulosin

Fluoxetine

Allopurinol

PS

С

С

С

С

С

ORAL

Condition Aggravated

Fatigue

Haematuria

Muscle Spasms

4 MG DAILY,

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PER ORAL

Freedom Of Information (FOI) Report

Hydrochloride)

PS

ORAL

(Tizanidine

Hospitalization -	Asthma	Foreign	Zanaflex (Tizanidine			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Date:09/17/99ISR Number Age:30 YR Gender:Male	r: 3350546-2Report Type:Ex e I/FU:I	pedited (15-DaCompany Re	eport #ZANA0319990522			
			(Loxoprofen Sodium)	С		
			Granules) Loxonin Unknown	SS		
			(Clarithromycin) Pl Granulate (Pl	SS		
ORAL			Klaricid Unknown			
UNK, UNK,			Hydrochloride)	SS		ORAL
			Hydrochloride Tablet (Tizanidine			
			Tizanidine	ಎಎ		
			Mucodyne Unknown (Carbocisteine)	SS		
		Other	Bufferin Unknown (Bufferin)	SS		
RECTAL	Syndrome					
	DAILY,	Professional				
Hospitalization - Initial or Prolonged	Liver Disorder Oculomucocutaneous	Foreign Health	Voltaren Suppository (Diclofenac Sodium)	PS		
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Date:09/15/99ISR Number Age:33 YR Gender:Fema	r: 3348815-5Report Type:Ex ale I/FU:I	pedited (15-DaCompany Re	eport #99J10282			
			(Clarithromycin)	SS		
ORAL			Klaricid Unknown			
UNK, UNK,						
			Hydrochloride)	SS		ORAL

Health

Initial or Prolonged

36 MG DAILY

Dyspepsia

Diazepam Salbutamol С С

Date:09/20/99ISR Number: 3350768-OReport Type:Direct

Age:44 YR Gender:Male I/FU:I

Outcome Dose Duration

PTFatigue Report Source

Company Report #

Zanaflex 4mg

Product

Role Manufacturer

Route ORAL

Required

4MG 1 1/2-1T

Intervention to Liver Function Test

PO OD

Prevent Permanent

Abnormal

Effexor С

Impairment/Damage

Motrin

Company Report #WAES 99070025

С

PS

Date:09/22/99ISR Number: 3366706-0Report Type:Periodic

Gender: Unknown I/FU:I Age:

Outcome

PT

Product

Role Manufacturer

Route

Duration Dose

Delusion

Health

Tab Vioxx Zanaflex

PS

ORAL

Drug Interaction Hallucination

Professional Company

Report Source

SS

Vomiting

Representative

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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

Role Manufacturer Outcome PΤ Report Source Product Route

Dose Duration

Other Asthenia Consumer Zanaflex (Tizanidine

Sedation Hydrochloride) PS ORAL

ORAL

Date:10/01/99ISR Number: 3367912-1Report Type:Periodic Company Report #ZANA0319990500

Age:48 YR Gender:Male I/FU:I

Role Manufacturer Outcome РΤ Report Source Product Route

Dose Duration

Diarrhoea Health Zanaflex (Tizanidine Other

Professional Hydrochloride) PS ORAL Muscle Spasms

20 MG DAILY,

Sedation Distributor

ORAL

Glatiramer Acetate C Oxybutynin C Fluoxetine

Hydrochloride C Amantadine С

Fampridine С

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

Age: Gender: I/FU:I

PΤ Role Manufacturer Outcome Report Source Product Route

Duration Dose

Urinary Retention Zanaflex (Tizanidine Other Health

Professional Hydrochloride) ORAL PS

Company Report #ZANA0319990512

12 MG DAILY,

ORAL

Date:10/01/99ISR Number: 3367918-2Report Type:Periodic

Age:50 YR

Gender: Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other ORAL	Duration	Hypotension	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
	99ISR Number Gender:Fema	r: 3367919-4Report Type:Pe ale I/FU:I	eriodic Company Re	eport #ZANA0319990517			
Outcome	5 1 - 05	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Chills Depression	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
12 MG DAILY,		Dry Mouth		-			
PER ORAL		Hyperhidrosis Nausea Pollakiuria Sedation		Tranxene Inderal Estrace Progesterone Zoloft Potassium Magnesium	0 0 0 0 0 0		
	99ISR Number Gender:	r: 3367921-2Report Type:Pe	eriodic Company Re	eport #ZANA0319990525			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Gastrointestinal Haemorrhage	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
PER ORAL							
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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 Health Zanaflex (Tizanidine

Liver Function Test Health Zanaflex (Tizanidine

Abnormal Professional Hydrochloride) PS ORAL

12 MG DIALY,

PER ORAL

Fentanyl C
Oxy Ir C
Reglan C
Trilisate C
Trazodone C

Mexelitine (

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 Zanaflex (Tizanidine

Professional Hydrochloride) PS ORAL

PER ORAL

Baclofen C

Bactoten

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 Zanaflex (Tizanidine

Other Laboratory Test Abnormal Health Zanaflex (Tizanidine

Professional 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	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
14 MG DAILY,		Mascic spasins		nyaroenror rae /	15		OKAL
11 110 211121 /		Myasthenic Syndrome					
PER ORAL		1					
		Sedation		Methazolamide Clonidine Voltaren Prinivil	C C C		
				Zoloft	C C		
				Percocet	C		
				Trental	C		
				Duragesic	C		
				Darvocet	C		
	991SR Number Gender:Male	: 3367976-5Report Type:Period.	ic Company Repor	rt #ZANA0319990530			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Convulsion	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
PER ORAL				Mysoline (Primidone) Tablets Tegretol	C C		

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Freedom Of Information (FOI) Report

ORAL

Date:10/01/99ISR Number: 3367978-9Report Type:Periodic Company Report #ZANA0319990531

Gender: Male Age:46 YR I/FU:I

Outcome PTReport Source Product Role Manufacturer Route

Dose Duration

Other Liver Function Test Health Zanaflex (Tizanidine

Abnormal Professional Hydrochloride)

ORAL PS

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

Report Source Role Manufacturer Outcome PTProduct Route

Duration Dose

Liver Function Test Health Zanaflex (Tizanidine Other

Abnormal Professional Hydrochloride) PS

36 MG DAILY,

PER ORAL

Date:11/02/99ISR Number: 3386864-1Report Type:Direct Company Report #

Age:34 YR Gender: Female I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration

Life-Threatening

Alanine Aminotransferase Zanaflex 4 Mg PS ORAL 1T PO OD

Hospitalization -Increased

Initial or Prolonged Aspartate

Aminotransferase Increased

Diarrhoea Pyrexia

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

				Codeine Diazepam	C C		
	R Number: der:Femal	: 3388841-3Report Type:Exp le I/FU:I	pedited (15-DaCompany Ro	eport #ZANA0319990545			
Outcome Dose Du	ıration	PT	Report Source	Product	Role	Manufacturer	Route
Death PER ORAL		Completed Suicide Overdose	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
				Codeine Diazepam	C C		
Date:11/23/99IS Age:73 YR Gen		: 3405354-0Report Type:Dir le I/FU:I	rect Company Re	∋port #			
Outcome Dose Du	ıration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatenin 2TABS BID Hospitalization ORAL	ıg	Grand Mal Convulsion		Zanaflex 4mg	PS		ORAL
Initial or Prol 1 TAB TID	onged			Lioresal 20mg	SS		ORAL
ORAL				Diltantin Prozac Kcl	C C C		
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Health Professional Zanaflex (Tizanidine

PS

ORAL

Hydrochloride)

Death

PER ORAL

Completed Suicide

Freedom Of Information (FOI) Report

Date:12/27/99ISR Number: 3431650-7Report Type:Expedited (15-DaCompany Report #99J--10454

Age:53 YR

Gender:Male

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
ife-Threatening	Nausea	Foreign	Voltaren Tablet	Da	00.31
25 MG,	Syncope	Health	(Diclofenac Sodium)	PS	ORAL
.5 MG,		Professional			
DAILY,ORAL		rioressionar			
			Ternelin Tablet		
			(Tizanidine)	SS	ORAL
B MG DAILY,					
DRAL					
			Persantine Tablet	C	
			Ambroxol Hydrochlori		
			Tablet	C	
			Neuquinon Tablet Aldactone A	C C	
			Amlodipine Besilate	С	
	er: 3432865-4Report Type:Pe .e I/FU:I	riodic Company Re	Amlodipine Besilate eport #ZANA0319990553	C	
Age:44 YR Gender:Mal	e I/FU:I		eport #ZANA0319990553		Route
Age:44 YR Gender:Mal Outcome		riodic Company Re Report Source		Role Manufacturer	Route
Age:44 YR Gender:Mal Outcome Dose Duration	e I/FU:I		eport #ZANA0319990553		Route
Age:44 YR Gender:Mal Outcome Dose Duration	e I/FU:I PT	Report Source	eport #ZANA0319990553 Product		Route
Age:44 YR Gender:Mal Outcome Dose Duration Other	PT Liver Function Test	Report Source Health	eport #ZANA0319990553 Product Zanaflex (Tizanidine	Role Manufacturer	
Age:44 YR Gender:Mal Outcome	PT Liver Function Test	Report Source Health	eport #ZANA0319990553 Product Zanaflex (Tizanidine Hydrochloride)	Role Manufacturer	
Age:44 YR Gender:Mal Outcome Dose Duration Other 4MG DAILY PER	PT Liver Function Test	Report Source Health	eport #ZANA0319990553 Product Zanaflex (Tizanidine Hydrochloride) Effexor	Role Manufacturer PS C	
Age:44 YR Gender:Mal Outcome Dose Duration Other 4MG DAILY PER	PT Liver Function Test	Report Source Health	eport #ZANA0319990553 Product Zanaflex (Tizanidine Hydrochloride) Effexor Baclofen	Role Manufacturer PS C C C	
Age:44 YR Gender:Mal Outcome Dose Duration Other 4MG DAILY PER	PT Liver Function Test	Report Source Health	eport #ZANA0319990553 Product Zanaflex (Tizanidine Hydrochloride) Effexor	Role Manufacturer PS C	

Outcome PT Report Source Product Role Manufacturer Route
Dose Duration

Other Hypertension Consumer Zanaflex (Tizanidine

I/FU:I

Hypotonia Hydrochloride) PS ORAL 16MG DAILY Muscle Spasms PER ORAL Visual Disturbance Diazepam С Baclofen Date:12/28/99ISR Number: 3432891-5Report Type:Periodic Company Report #ZANA0319990535 Gender:Male I/FU:I Age: PTReport Source Product Role Manufacturer Outcome Route Duration Dose Hallucination Consumer Zanaflex (Tizanidine Other Hydrochloride) PS ORAL

K-Dur

Indomethacin

Nitrofurantoin

Oxybutynin

Lactulose Bumetide

Product

С

С

С

С

Role Manufacturer

Route

Date:12/28/99ISR Number: 3432895-2Report Type:Periodic Company Report #ZANA0319990537

Gender:Female Age: I/FU:I

Duration

PT

Liver Function Test Health Zanaflex (Tizanidine Other PS ORAL

Abnormal Professional Hydrochloride)

Report Source

8MG DAILY PER

4 ORAL MON

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Outcome

Dose

PER ORAL

Freedom Of Information (FOI) Report

Hydrochloride)

С

PS

ORAL

ORAL

ORAL

Celebrex

Company Report #ZANA0319990541

Age: Gender:Female I/FU:I

Outcome PT Report Source Product Role Manufacturer Route

Dose Duration

Other Skin Ulcer Health Zanaflex (Tizanidine

Professional

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 Zanaflex (Tizanidine

Professional Hydrochloride) PS

PER ORAL

Distributor

Date:12/28/99ISR Number: 3432898-8Report Type:Periodic

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 Health Zanaflex (Tizanidine

Sedation Professional Hydrochloride) PS

4MG PER ORAL

Vioxx C
Oxycontin C
Orthotricyclen C
... C

...

Date:12/28/99ISR Number: 3432907-6Report Type:Periodic Company Report #ZANA0319990550

Age:82 YR Gender:Female I/FU:I

			Requip	C	
			Norvasc	C	
			Prinivil	C	
			Microk	C	
			Furosemide	С	
Date:12/28/99ISR Numbe: Age:44 YR Gender:Mal	r: 3432913-1Report Type:Period e I/FU:I	dic Company Repo	rt #ZANA0319990551		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Other	Hypertonia	Health	Zanaflex (Tizanidine		
		- C ' 1			
	Paraesthesia	Professional	Hydrochloride)	PS	ORAL
8MG DIALY,	Paraesthesia	Professional	Hydrochloride)	PS	ORAL
8MG DIALY, PER ORAL	Paraesthesia	Professional	Hydrochloride)	PS	ORAL
	Paraesthesia	Professional	Hydrochloride) Neurontin	PS C	ORAL
	Paraesthesia	Professional			ORAL
	Paraesthesia	Professional	Neurontin	С	ORAL
8MG DIALY, PER ORAL	Paraesthesia	Professional	Neurontin Baclofen	C C	ORAL

Report Source

Consumer

Product

Zanaflex (Tizanidine

Hydrochloride)

Role Manufacturer

PS

Route

ORAL

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Outcome

Dose

Other

PT

Hypotension

Sedation

Duration

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

Date:12/28/99ISR Number: 3432926-XReport Type:Periodic

PT

I/FU:I

Age: 22 YR Gender: Female

Duration

Outcome

Dose

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Anxiety	Consumer	Zanaflex (Tizanidine			
		Asthenia		Hydrochloride)	PS		ORAL
3MG PER OR	AL						
		Dyspepsia		Elavil	С		
		Emotional Disorder		Klonopin	С		
		Pollakiuria		Avonex	С		
		Sedation		Prevacid	С		
		Visual Disturbance		Pepcid	С		
				Zyrtec	С		
				Synthroid	C		
				Robitussin	C		
				Vitamins	C		
Age:65 YR Outcome Dose	/99ISR Number Gender:Fema Duration	PT	Report Source	eport #ZANA0319990555 Product	Role	Manufacturer	Route
Other		Hyperhidrosis	Consumer	Zanaflex (Tizanidine			0.7.7
2MG PER OR	AL			Hydrochloride)	PS		ORAL
Date:12/28 Age:51 YR	/99ISR Number Gender:Male	: 3432924-6Report Type:Per e I/FU:I		eport #ZANA0319990557			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Paralysis	Health	Zanaflex (Tizanidine			
			Professional	Hydrochloride)	PS		ORAL
6MG PER OR	AL						

Report Source

Company Report #ZANA0319990558

Product

Role Manufacturer

Route

Other		Sedation	Consum	er	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
PER ORAL					Theophylline Albuterol	C C		
Date:12/28/ Age:17 YR	99ISR Number Gender:Fema	: 3432928-3Report 1 le I/FU:I	Type:Periodic	Company Re	eport #ZANA0319990559			
Outcome	.	PT	Report	Source	Product	Role	Manufacturer	Route
Dose Other PER ORAL	Duration	Malaise	Consum	er	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
Date:12/28/ Age:51 YR	99ISR Number Gender:Fema	: 3432933-7Report 7 le I/FU:I	Type:Periodic	Company Re	eport #ZANA0319990560			
Outcome	5	PT	Report	Source	Product	Role	Manufacturer	Route
Dose Other PER ORAL	Duration	Malaise	Consum	er	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL

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Freedom Of Information (FOI) Report

PS

PS

ORAL

ORAL

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

Age: Gender: I/FU:I

Outcome PTReport Source Product Role Manufacturer Route

Duration Dose

Other Drug Ineffective Health Zanaflex (Tizanidine

Professional Hydrochloride)

36MG PER ORAL

Date:12/28/99ISR Number: 3432941-6Report Type:Periodic Company Report #ZANA0319990562

Age: Gender: Female I/FU:I

Outcome РΤ Report Source Product Role Manufacturer Route

Dose Duration

Zanaflex (Tizanidine Other Dry Mouth Consumer

Hydrochloride) Muscle Spasms

ORAL PS

2MG DAILY PER

Paraesthesia

ORAL

Date:12/28/99ISR Number: 3432946-5Report Type:Periodic Company Report #ZANA0319990529

Age:78 YR Gender: Female I/FU:F

Role Manufacturer PTReport Source Product Route Outcome

Dose Duration

12MG PER ORAL

Zanaflex (Tizanidine Other Hyperhidrosis Health Professional Muscle Spasms Hydrochloride)

Myasthenic Syndrome Methazolamide C

Sedation Clonidine С Voltaren C

Prinivil Zoloft С Percocet Trental C

Duragesic C Darvocet

Date:01/19/00ISR Number: 3445416-5Report Type:Expedited (15-DaCompany Report #ZANA0319990545 (1)

Age:45 YR Gender: Female I/FU:F

Dose	Duration		-				
Death Other PER ORAL		Completed Suicide	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
r Bri Orani	PER URAL			Codeine Diazepam	C C		
Date:01/28/ Age:	00ISR Number Gender:Fema	r: 3447678-7Report Type:Direc ale I/FU:I	t Company Re	eport #			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Life-Threat	Duration ening	Cardiac Failure Congestive		Zanaflex 14mg Talbets-Athena	20		
2MG PO		Dyspnoea Pulmonary Oedema		Neurosciences	PS	Athena Neurosciences	ORAL
1/22-1/24;4	MG	Respiratory Failure					
PO ON 1/25		Respiratory Farrure					
	00ISR Number Gender:Male	:: 3451148-XReport Type:Direc	t Company Re	eport #			
Outcome	ochael mare	PT					
Hospitaliza Initial or		Bradycardia Dizziness Head Injury					
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Report Source

Product

Role Manufacturer

Route

Outcome

PT

Freedom Of Information (FOI) Report

Syncope

Dose D	uration		Report Source	Product	Role	Manufacturer	Route
	uracion			Zanaflex Athena	PS	Athena	ORAL
PO				Accolate	С		
				Luvox	C		
				Trazedone	C		
				Dicloxacillin	С		
				Diazepam	С		
Date:02/11/00T	SR Number	: 3456779-9Report Type:Direct	Company Repor	+ #			
	nder:Fema		Company Repor	С #			
Outcome Dose D	uration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization 4 MG Q 8 PRN	n -	Coma	Health	Zanaflex	PS		
Initial or Pro	longed	Hypotension	Professional				
	SR Number nder:Fema	: 3469027-0Report Type:Expedit le I/FU:I	ed (15-DaCompany Repor	t #ZANA030574 (0)			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Double Doub	uration	Abnormal Dreams	Consumer	Zanaflex (Tizanidine			
Other		Cold Sweat	Consumer	Hydrochloride)	PS		ORAL
PER ORAL 4		COIG BWCGC		nyarocnioriae,	15		OICAL
		Confusional State					
MG PER ORAL							
		Convulsion		Ultran	C		
		Coordination Abnormal		Neurontin	С		
		Dizziness		Lovox	C		
		Eye Movement Disorder		Celebrex	С		
		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

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Freedom Of Information (FOI) Report

Vision Blurred

D D			Report S	Source	Product	Role	Manufacturer	Route
Dose D	uration		Health Profess:	ional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
8MG, PER			1101055	Tonar	ny drochroride /	10		Oldin
ORAL; 4 MG,								
PER ORAL								
					Neurontin	C		
					Luvox	C		
					Celebrex	C		
					Tricor	С		
	SR Number ender:Femal	: 3543157-7Report Type:Periodiale I/FU:I	С	Company Report	t #WAES 00021615			
Outcome Dose D	uration	PT	Report S	Source	Product	Role	Manufacturer	Route
		Drug Interaction Hallucination	Consume	r	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL
25							Meren do inc	Oldin
MG/AM/PO;25								
MG/DAILY/PO								
					Zanaflex Unk	SS		
Date:03/27/00I	SR Number	: 3479959-5Report Type:Direct		Company Report	t #			
Age:75 YR Ge	ender:Femal	le I/FU:I						
Outcome Dose D	Ouration	PT	Report S	Source	Product	Role	Manufacturer	Route
Hospitalizatio 2 MG BID	n -	Abdominal Pain	Health		Tizanidine	PS		
Initial or Pro	longed	Nausea	Profess	ional	Catapres	C		
		Thrombocytopenia			Lotensin	C		
		Vomiting			Darvocet	C		
					Prilosec	C		
					Sinemet	C		

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Date:03/28/00ISR Number: 3480994-1Report Type:Expedited (15-DaCompany Report #ZANA030589 (0)

Age:52 YR Gender:Female I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration

Other Blood Pressure Decreased Health Zanaflex (Tizanidine

Drug Interaction Professional Hydrochloride) PS ORAL

TWO 4MG DOSES

Dysphagia

DAILY, PER Hallucination

ORAL

Vioxx (Rofecoxib) Heart Rate Increased SS

TWO 25MG Psychotic Disorder

DOSES DAILY

Date:03/28/00ISR Number: 3480995-3Report Type:Expedited (15-DaCompany Report #ZANA030590 (0)

Gender: Female Age:40 YR I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Duration Dose

Bradycardia Health Zanaflex (Tizanidine Other

ORAL

Chest Discomfort Professional Hydrochloride) PS

4 MG DAILY,

Dizziness

PER ORAL Hypotension Vioxx SS

25 MG

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Freedom Of Information (FOI) Report

Temazepam

Maxalt C

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Mospitalization -	Agitation	Health	Zanaflex (Tizanidine			
nitial or Prolonged MG DAILY,	Amnesia	Professional	Hydrochloride)	PS		ORAL
PER ORAL	Conversion Disorder					
	Drug Interaction Feeling Abnormal Hallucination		Zanax Soma Oxycontin Lortab	SS C C		
Age:19 YR Gender:Fem						
Outcome Oose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening	Agitation Cyanosis	Foreign Health	Baclofen Unknown (Baclofen)	PS		ORAL
30 MG QD,	Hypoxia	Professional				
DRAL	Respiratory Failure	Other	Dantrolene Unknown (Dantrolene)	SS		ORAL
200 MG,			(bancrorene)	טט		OKAL
DAILY, ORAL						
·			Zanaflex Unknown (Tizanidine			
10 MG DAILY,			Hydrochloride)	SS		ORAL
DRAL						
			Voltarol	C		
			Bisacodyl Lactulose	C C		
			Cefuroxime	C		
			COL AL OILLING	~		

Motilium	С
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 -	Post Procedural	Foreign	Zanaflex (Tizanidine		
Initial or Prolonged	Complication	Health	Hydrofchloride)	PS	ORAL
10 MG DAILY,					
	Respiratory Failure	Professional			
PER ORAL					
			Baclofen	C	
			Dantrolene	C	

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Freedom Of Information (FOI) Report

Tramadol Dipyridamole

Diazepam

Lisinopril

С

С

Date:05/01/00ISR Number: 3494588-5Report Type:Expedited (15-DaCompany Report #ZANA030609 (0)

Sedation

PER ORAL

Age:66 YR Gender:Fema	ale I/FU:I	areca (13 Dacompany Re	SPOTE #211111030009 (0)			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Chromaturia	Health	Zanaflex (Tizanidine			
Initial or Prolonged 12 MG DAILY,	Feeling Jittery	Professional	Hydrochloride)	PS		ORAL
	Hepatic Cirrhosis					
PER ORAL						
	Hepatic Necrosis		Lasix	C		
	Jaundice		Potassium Supplement Phosphinex	C C		
Date:05/03/00ISR Number Age:32 YR Gender:Fema	r: 3495372-9Report Type:Dired ale I/FU:I	ct Company Re	eport #			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - 4MG HS ORAL	Abdominal Pain Lower		Zanaflex	PS		ORAL
Initial or Prolonged	Abdominal Pain Upper					
Required	Back Pain					
Intervention to	Chills					
Prevent Permanent	Myalgia					
Impairment/Damage	Nausea					
Date:05/08/00ISR Number Age:65 YR Gender:Male	r: 3497679-8Report Type:Expede	dited (15-DaCompany Re	eport #ZANA030610 (0)			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Apnoea	Health	Zanaflex (Tizanidine			
Ocher	Coma	Professional	Hydrochloride)	PS		ORAL
24MG, PER	Coma	TIOLOGOTOHAT	ny drochioride /	15		OKAL
Zino, i dic	Hypotension					
ORAL; 8MG,	11					
•						

Lansoprazole C
Venlafaxine C
Aspirin C

Date:05/24/00ISR Number: 3504562-8Report Type:Direct

Age: 40 YR Gender: Female I/FU: I

Outcome PT Report Source Product Role Manufacturer Route

Company Report #

Dose Duration

Hospitalization - Hallucination Zanaflex 4mg (Athena

Initial or Prolonged Hypertension 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 - Anorexia

Initial or Prolonged Blood Bilirubin Increased

Hepatic Failure
Hepatic Necrosis
Hepatotoxicity
Liver Function Test

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Freedom Of Information (FOI) Report

		Abnormal Malaise					
		Nausea					
		Vomiting	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						1
			Health	Zanaflex	PS	Elan Pharma	
			Professional			International Ltd	ORAL
PER ORAL							'
				Thyroid Extract	C		'
				Ms Contin	С		ŗ
				Dilaudid	C		,
				Entex	C		ŗ
				Proventil	С		•
	l/00ISR Number Gender:Fema	r: 3507051-XReport Type:Expedi ale I/FU:I	ited (15-DaCompany Re	:port #ZANA030626(0)			
	Gender . I cind				- 1		
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						ŗ
Hospitaliz		Anorexia	Health	Zanaflex	PS	Elan Pharma	
Initial or PER ORAL	r Prolonged	Blood Bilirubin Increased	Professional			International Ltd	ORAL
		Hepatic Failure		Thyroid Extract	С		ļ
I		Hepatic Necrosis		Ms Contin	С		!
l		Hepatotoxicity		Dilaudid	С		ļ
l		Liver Function Test		Entex	C		!
		Abnormal		Proventil	C		
		Malaise					
		Vomiting					l
Date:05/31 Age:9 YR	1/00ISR Number Gender:Male	r: 3507235-0Report Type:Period	lic Company Re	eport #MYST0319990051(0)			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	FI	Report Bource	Troduce	1010	Manuraccurci	10000
Other	Daracron	Convulsion	Health	Mysoline (Primidone)	DG	Elan Pharma	
		CONVUISION	Professional	mysorrine (Frimidone)	FD	International Ltd	ORAL
PER ORAL				7 53 (mii di			
				Zanaflex (Tizanidine			
				Hydrochloride)	SS		ORAL
PER ORAL				Tegretol	С		

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 PTReport Source Product Role Manufacturer Route Dose Duration Gait Disturbance Health Actiq Anesta Corp PS Miosis Professional Dilaudid (Hydromorphone)

Zanaflex

SS

ORAL

8 MG Q 3 HRS

ΡO

(Tizanidine) SS Lorazepam SS Oxycontin (Oxycodone) SS

Date:06/08/00ISR Number: 3512446-4Report Type:Expedited (15-DaCompany Report #ZANA030629 (0)

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

Outcome PTHospitalization -Coma Initial or Prolonged

Dysphagia Hypothermia

Nervous System Disorder

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Freedom Of Information (FOI) Report

Stupor

Dose Duration		Report Source	Product	Role	Manufacturer	Route
		Health	Zanaflex	PS		ORAL
16 MG DAILY		Professional				
PER ORAL			Amitriptyline Diclofenac Co-Proxamol Dantrium	C C C		
Date:06/08/00ISR Numbe: Age:40 YR Gender:Fema	r: 3512447-6Report Type:Exped ale I/FU:I	ited (15-DaCompany Re	eport #ZANA030627(0)			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 30-45 TABLETS	Drug Withdrawal Syndrome Hallucination	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
DAILY, PER	Hypertension Hypochloraemia					
ORAL	пуросптогаешта					
	Medication Error Overdose Tachycardia Tremor Vomiting		Duragesic Neurontin	C C		
Date:06/08/00ISR Numbe: Age:40 YR Gender:Fema	r: 3512449-XReport Type:Exped ale I/FU:I	ited (15-DaCompany Re	eport #ZANA030627 (0)			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 30-45 TABLETS	Drug Withdrawal Syndrome	Health	Zanaflex	PS		ORAL
Initial or Prolonged DAILY PER	Hallucination	Professional				
ORAL	Hypertension					
-	Hypochloraemia		Duragesic	С		

Insomnia Intentional Misuse Tachycardia Tremor

Vomiting

Neurontin

C

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 -	Difficulty In Walking	Health	Zanaflex	PS	Elan Pharma	
Initial or Prolonged	Hypertension	Professional			International Ltd	ORAL
PER ORAL						
	Joint Swelling		Elavil	С		
	Pyrexia		Klonopin	С		
	Rheumatic Fever		Morphine	С		
	Rheumatoid Arthritis		Phenergan	С		
	Systemic Lupus		Pain Medication			
	Erythematosus		(Unspecified)	С		
			Anti-Hypertensive			
			(Unspecified)	С		
			Steroid			
			(Unspecified)	С		

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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

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

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						
Hospitaliz	zation -	Muscle Disorder	Health	Zanaflex	PS	Elan Pharma	
Initial or	r Prolonged	Sedation	Professional			International Ltd	ORAL
4 MG THREE	E						

1 110 111111111

TIMES DAILY,

PER ORAL

Elavil	С
Klonopin	С
Morphine	С
Phenergan	С
Pain Medication	
(Unspecified)	С
Anti-Hypertensive	
(Unspecified)	С
Steroid	
(Unspecified)	C

Age:21 YR Gender:Female I/FU:I Role Manufacturer Outcome Report Source Product PTRoute Dose Duration Hospitalization -Hypertonia Health Zanaflex (Tizanidine Initial or Prolonged Muscle Disorder Professional Hydrochloride) PSORAL 4 MG THREE Sedation

Date:06/08/00ISR Number: 3512486-5Report Type:Expedited (15-DaCompany Report #ZANA030631 (0)

TIMES DAILY,

PER ORAL

Elavir	С
Klonopin	C
Morphine	C
Phenergan	C
Pain Medication	
(Unspecified)	C
Anti-Hypertensive	
(Unspecified)	C
Steroid	
(Unspecified)	C

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Freedom Of Information (FOI) Report

Date:06/08/00ISR Number: 3512490-7Report Type:Expedited (15-DaCompany Report #ZANA030629 (0)

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

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Depressed Level Of	Foreign	Zanaflex	PS	Elan Pharma	
Initial or Prolonged 16 MG DAILY,	Consciousness	Health			International Ltd	ORAL
·	Dysphagia	Professional				
PER ORAL						
	Hypothermia		Amitriptyline	C		
			Diclofenac	С		
			Diclofenac	C		
			Co-Proxamol	C		
			Dantrium	C		
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Anorexia	Health				Route
Initial or Prolonged PER ORAL			Zanaflex	PS	Elan Pharma	Route
	Blood Bilirubin Increased	Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
-	Blood Bilirubin Increased Cholangitis		Zanaflex Thyroid Extract	PS C		
	Cholangitis		Thyroid Extract	С		
	Cholangitis Cholestasis		Thyroid Extract Ms Contin	C C		
	Cholangitis Cholestasis Hepatic Failure		Thyroid Extract Ms Contin Dilaudid	C C		
	Cholangitis Cholestasis Hepatic Failure Hepatic Necrosis		Thyroid Extract Ms Contin Dilaudid Entex	C C C		
	Cholangitis Cholestasis Hepatic Failure Hepatic Necrosis Hepatitis		Thyroid Extract Ms Contin Dilaudid Entex	C C C		
	Cholangitis Cholestasis Hepatic Failure Hepatic Necrosis Hepatitis Liver Disorder		Thyroid Extract Ms Contin Dilaudid Entex	C C C		

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

Nausea Vomiting

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

Hydrochloride) SS Athena Neurosciences

ORAL

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 - Bradycardia Health Zanaflex PS Elan Pharma

Initial or Prolonged Overdose Professional International Ltd

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 - Asthenia

Initial or Prolonged Dermatitis Exfoliative

Diarrhoea

Hypersensitivity Inflammation

Lip Dry

Mucosal Inflammation
Photosensitivity Reaction

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Freedom Of Information (FOI) Report

		Pyrexia					
		Rash Erythematous	_	_	_	_	
_		Rash Maculo-Papular	Report Source	Product	Role	Manufacturer	Route
Dose	Duration		77 7 1 2	- C1	D.C.	E. D.	
		Red Blood Cell	Health	Zanaflex	PS	Elan Pharma	0011
4 140 555		Sedimentation Rate	Professional			International Ltd	ORAL
4 MG, PER		_ 1					
0		Increased					
ORAL		a 1		63 Lul 5	~		
		Sedation		Claritin-D	C		
		Skin Chapped		Tiazac	C		
		Stevens-Johnson Syndrome		Darvocet-N 100	C		
		Sunburn		Vicodin	C		
i		Urticaria		Ibuprofen	С		
	00ISR Number Gender:Male	: 3536575-4Report Type:Expedi	ted (15-DaCompany Rep	oort #ZANA030651(0)			
Outcome		PT	Report Source	Product	Dolo.	Manufacturer	Route
Dose	Duration	PI	Report Source	Product	KOTE	Manuracturer	Route
Dose Hospitaliza		Urmetengien	Earaign	Zanaflex	PS	Elan Pharma	
Initial or I		Hypotension	Foreign Health	Zanarrex	PS		ODAT
	Protonged	Syncope	неатсп			International Ltd	ORAL
10MG DAILY,			D				
			Professional				
PER ORAL				D 1.6	a		
				Baclofen	C		
				Oxybutynin	С		
				Ciprofloxacin	C		
				Imipramine	C		
				Mebeverine	С		
Date:07/27/0 Age:45 YR	001SR Number Gender:Male	: 3536576-6Report Type:Expedi I/FU:I	ted (15-DaCompany Rep	oort #ZANA030651(0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat		Hypotension	Health	Zanaflex (Tizanidine			
Initial or 1 10MG DAILY	Prolonged 27 DAY	Syncope	Professional	Hydrochloride)	PS		ORAL
				Baclofen	С		
				Oxybutynin	С		
				Ciprofloxacin	C		
				Imipramine	C		
1					-		
i							

Pyrexia

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 -	Abdominal Pain Upper Blood Bilirubin Increased	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
Initial or Prolonged MG DAILY	Blood Billrubin increased	Professional			International Ltd	URAL
	Hepatic Necrosis					
PER ORAL						
	International Normalised		Celebrex	С		
	Ratio Increased		Dexedrin	С		
	Liver Function Test		Climara Transdermal	С		
	Abnormal		Prilosec	C		
	Prothrombin Time					
	Prolonged					

Company Report #

Date:08/07/00ISR Number: 3542682-2Report Type:Direct

Age:75 YR Gender:Male I/FU:I

Outcome Required Intervention to

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Freedom Of Information (FOI) Report

Fentanyl

Prevent Permanent Impairment/Damage

rce Product Role Manufacturer Rou Tizanidine 4mg Athena Neurosciences PS Athena Neurosciences ORA	ıte
Athena Neurosciences PS Athena Neurosciences ORA	_
	ΔL
Citalopram C Famotidine C Atenolol C Hydrochlorothiazide C Docusate Sodium C Acetaminophen C Quinipril C Riluzole C Heparin C	
mpany Report #ZANA030656 (0)	
rce Product Role Manufacturer Rou	ıte
Zanaflex PS Elan Pharma International Ltd ORA	ΑL
al	
mpany Report #ZANA030664 (0)	
rce Product Role Manufacturer Rou	ıte
Zanaflex PS Elan Pharma International Ltd ORA	ΔL
	_
ou: e ona	Famotidine C Atenolol C Hydrochlorothiazide C Docusate Sodium C Acetaminophen C Quinipril C Riluzole C Heparin C Company Report #ZANA030656 (0) Company Report #ZANA030664 (0)

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

Role Manufacturer

Route

Product

Date:08/23/00ISR Number: 3556390-5Report Type:Direct Company Report #

Age:59 YR Gender:Female I/FU:I

PT

Pyrexia

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

Report Source

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Outcome

Freedom Of Information (FOI) Report

Role Manufacturer

С

Route

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 - Dyspnoea Health Zanaflex 4mg Two

Initial or Prolonged Palpitations Professional Tablets PS

TWO TABLETS

ONLY AT

BEDTIME

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 Zanaflex PS

3 WK

Outcome

Impairment/Damage

Ascites

Autoimmune Hepatitis
Cardio-Respiratory Arrest
Culture Urine Positive
Escherichia Infection

Jaundice Sedation Sepsis

PT

Ultrasound Scan Abnormal

Date:09/15/00ISR Number: 3572038-8Report Type:Direct Company Report #

Age:57 YR Gender:Male I/FU:I

Dose Duration				
Hospitalization -	Asthenia	Zanaflex 4mg	PS	ORAL
4MG TID ORAL				
Initial or Prolonged	Bradycardia	Prilosec	C	
Required	Dizziness	Paxil	C	
Intervention to	Hypertension	Tranxene	C	
Prevent Permanent	Hypotension	Vioxx	C	

Product

Accupril

Report Source

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 16 MG DAILY	Abdominal Pain Upper Coagulopathy	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
	Encephalopathy					
PER ORAL						
	Hepatic Necrosis		Celebrex	С		
	Hepatotoxicity		Dexedrin	С		
	Hyperbilirubinaemia		Climara Transdermal	С		
	Hypoglycaemia					
	International Normalised					
	Ratio Decreased					
	Jaundice					
	Leukocytosis					
	Liver Function Test					
	Abnormal					
	Pleural Effusion					
	Prothrombin Time					
	Prolonged					
	Pyrexia					

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Freedom Of Information (FOI) Report

ORAL

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 - Chest Pain Health Zanaflex PS Elan Pharma

Initial or Prolonged Condition Aggravated Professional International Ltd

24 MG DAILY,

•

Cough

PER ORAL

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 (2MG) BID	Hepatotoxicity	Professional		
	Liver Function Test		Tizanidine	SS
1 & 1/2				
	Abnormal			
TABLET (6 MG)				
	Nausea			
Q HS				
	Vomiting		Morphine	С
			Hydromorphone	С
			Premarin	C
			Maxide	C
			Zyrtec	C
			Entex	C
			Triamcinolone	
			Inhaler	С
			Albuterol Inhaler	С
	er: 3590648-9Report Type:Ex nale I/FU:I	pedited (15-DaCompany Rep	port #ZANA030681 (0)	
J	·			
Outcome	PT	Report Source	Product	Role

Manufacturer Route Dose Duration Hospitalization -Hepatic Failure Health Zanaflex Elan Pharma PS Initial or Prolonged Professional International Ltd ORAL

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PER ORAL

Freedom Of Information (FOI) Report

Ms Contin

Dilaudid

Proventil

Triamcinolone

Premarin

Maxzide

Zyrtec

Inhaler

Entex

С

С

С

С

С

С

С

Date:10/06/00ISR Number: 3590815-4Report Type:Expedited (15-DaCompany Report #ZANA030609 (1)

Age:60 YR Gender:Female I/FU:F

Coagulopathy

Hepatitis

Jaundice

Abnormal Malaise

Vomiting

Encephalopathy

Hepatic Failure

Hepatic Necrosis

Liver Function Test

Portal Hypertension

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged 12 MG DAILY,	Ammonia Increased Chromaturia Diarrhoea	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
PER ORAL	Feeling Jittery Hepatic Cirrhosis Hepatic Necrosis Jaundice Liver Function Test Abnormal Nausea Vomiting		Lasix Potassium Supplement Phosphinex	С С С		
Date:10/12/00ISR Numbe Age:45 YR Gender:Fen	er: 3595567-XReport Type:Expedinale I/FU:F	ited (15-DaCompany Re	eport #ZANA030626 (2)			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 8 MG DAILY,	Anorexia Blood Bilirubin Increased	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
PER ORAL	Cholangitis					
	Cholestasis		Thyroid Extract	С		

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

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Freedom Of Information (FOI) Report

		Rash Macular Rash Pruritic Tachypnoea	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Winel Infortion	II.a.l.b	Zanaflex	Da	Elan Dharma	
		Viral Infection	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
24 MG DAILY							
PER ORAL							
				Demulin	С		
Date:11/02/0	OOTSR Number	r: 3607028-XReport Type:Exped	lited (15-DaCompany Re	eport #ZANA030589 (1)			
Age:52 YR	Gender:Fema		reca (13 bacompany no	SPOTE HEIMIOSOSOS (I)			
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,			rroressionar			incernacional nea	Oldin
		Dysphagia					
PER ORAL		Hallucination		Vioxx (Rofecoxib)	SS		ORAL
50 MG DAILY		nallucinacion		VIOXX (ROIECOXID)	55		UKAL
00 110 211221	,	Heart Rate Increased					
PER ORAL							
		Psychotic Disorder Speech Disorder					
Date:11/09/0 Age:	00ISR Numbe: Gender:Fema	r: 3610122-0Report Type:Exped ale I/FU:I	ited (15-DaCompany Re	eport #ZANA030701 (0)			
Outcome	.	PT	Report Source	Product	Role	Manufacturer	Route
Dose Death	Duration	Jaundice	Health	Zanaflex	PS	Elan Pharma	
Deach		Liver Function Test	Professional	Zanariex	FD	International Ltd	ORAL
12 MG DAILY							
PER ORAL	2 MOI	Abnormal N					

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

Role	_	
11010	Manufacturer	Route
PS	Elan Pharma	
15	International Ltd	ORAL
C		
C		
C		
C		
C		
С		
C		
Role	Manufacturer	Route
		Route
Role PS	Elan Pharma	
		Route ORAL
	Elan Pharma	
PS	Elan Pharma	
PS C	Elan Pharma	
PS C C	Elan Pharma	
PS C C C	Elan Pharma	
PS C C C	Elan Pharma	
PS C C C C	Elan Pharma	
PS C C C	Elan Pharma	
	C C C C	International Ltd C C C C C C

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Freedom Of Information (FOI) Report

	001SR Number Gender:Male	c: 3611748-OReport Type:Direct	Company Repor	rt #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 3TTT A DAY	Duracion	Balance Disorder		Zanaflex (2mg Tabs)	PS		
STARTED AT	lT	Confusional State					
PER DAY THE	Ŋ	Dysarthria					
GRADUALLY		Memory Impairment					
INCREASED TO)			Vicodin Es	С		
	00ISR Number Gender:Fema	r: 3613012-2Report Type:Expediate	ted (15-DaCompany Repor	rt #ZANA030710(0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	2 42 4 5 2 5 1	Sudden Death	Foreign Health	Zanaflex	PS	Elan Pharma International Ltd	ORAL
24 MG DAILY	,		Professional				
PER ORAL				Aspirin Co-Amilofruse Glibenclamide Amitriptyline	C C C		
	001SR Number Gender:Male	a: 3613013-4Report Type:Expedi	ted (15-DaCompany Repor	rt #ZANA030707(0)			
Outcome	Dunahian	PT	Report Source	Product	Role	Manufacturer	Route
Dose Disability	Duration	Cardiac Failure Congestive	Foreign Health	Zanaflex	PS	Elan Pharma International Ltd	ORAL
6 MG DAILY,		Hypertension	Professional				
PER ORAL		Paraplegia		Ciprofloxacin	С		

Date:11/22/00ISR Number: 3617124-9Report Type:Expedited (15-DaCompany Report #ZANA030717 (0)

Age:67 YR Gender:Male I/FU:I

PTReport Source Product Role Manufacturer Outcome Route Duration Dose Dizziness Foreign Zanaflex PS Elan Pharma Other International Ltd ORAL

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

PTReport Source Product Role Manufacturer Outcome Route Duration Dose Hospitalization -Bradycardia Health Zanaflex PS Elan Pharma Initial or Prolonged Condition Aggravated Professional International Ltd ORAL 4 MG DAILY,

Hypertonia

PER ORAL

Muscle Spasms Ditropan C
Diazepam C
Lipitor C
Aspirin C

Aspirin C
Prilosec C
Restoril C

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Freedom Of Information (FOI) Report

ORAL

ORAL

ORAL

Date:12/11/00ISR Number: 3626570-9Report Type:Expedited (15-DaCompany Report #ZANA030701 (1)

Gender: Female Age: I/FU:F

Outcome PΤ Report Source Product Role Manufacturer Route Duration Dose

Death Jaundice Health Zanaflex PS Elan Pharma

Professional International Ltd

12 MG DAILY,

Dose

2 PER ORAL MON

Date:12/22/00ISR Number: 3636567-OReport Type:Expedited (15-DaCompany Report #ZANA000694 (0)

Age:45 YR Gender: Female I/FU:I

Duration

Report Source Role Manufacturer Outcome PΤ Product Route

Duration Dose

Zanaflex Elan Pharma Hypertension Foreign PS Other

Oedema Peripheral International Ltd Health

24 MG DAILY

Professional

ORAL

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

Role Manufacturer Outcome PTReport Source Product Route

Disability Depressed Level Of Foreign Zanaflex PS Elan Pharma

Consciousness

Health International Ltd 4 MG DAILY

Hypotension Professional ORAL

Methylprednisolone С Effexor

Thyroxine I 125 С

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

PT Report Source Product Role Manufacturer Outcome

Route Dose Duration

			Tizanidine Valoron "Goedecke" (Tilidine Hydrochloride)	SS SS		
Date:12/26/00ISR Numb Age: Gender:Fe	er: 3637973-0Report Type:Exp male I/FU:I	pedited (15-DaCompany Ro	eport #PHNU2000DE01850			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Congenital Anomaly	Abortion Spontaneous	Foreign	Voltaren	PS	Novartis	
Other	Accidental Exposure	Health			Pharmaceuticals Corp	
	Foetal Disorder	Professional	Sirdalud (Sanofi			
		Other	Winthrop) (Ti			
			Zanidine	~~		
			Hydrochloride)	SS		
			Valoron "Goedecke"(Tilidine			
			Hydrochloride)	SS		
			ily at ocition tac,	טט		

Voltaren

Sirdalud (Sanofi

Winthrop) (Ti Zanidine

Hydrochloride,

Novartis

Pharmaceuticals Corp

PS

Foreign

Professional

Health

Other

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Congenital Anomaly

Other

Abortion Spontaneous

Accidental Exposure

Multiple Congenital

Abnormalities

Freedom Of Information (FOI) Report

Date:01/03/01ISR Number: 3641287-2Report Type:Expedited (15-DaCompany Report #ZANA000742 (0)

PRN)

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Dther	Cardiac Arrest	Foreign	Zanaflex	PS	Elan Pharma	
Julier	Cardiac Arrest	Health	Zanariex	PS	International Ltd	ORAL
2 MG DAILY		D C ' 1				
DRAL		Professional				
			Senna	С		
			Aspirin	C		
			Tamsulosin Co-Danthramer	C C		
			CO Dancinamer	C		
	r: 3641648-1Report Type:Exped:	ited (15-DaCompany Re	eport #001-0945-M0000196			
Age:40 YR Gender:Fem	ale I/FU:F					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration		_		_		
Hospitalization -	Arthralgia	Consumer	Neurontin	PS	Parke Davis	0011
Initial or Prolonged 900 MG(300 MG	Asthenia				Pharmaceuticals Ltd	ORAL
Other	Blood Potassium Decreased					
FID):2400MG(8						
OOMG	Carpal Tunnel Syndrome					
701-10	Cholelithiasis					
FID):2100MG(7						
20	Cholestasis					
OOMG	Decreased Activity		Baclofen	SS		ORAL
30 MG PER	Decreased Activity		Bacioleii	ಎಎ		ORAL
70 110 1 211	Dental Caries					
DRAL						
1600 250	Depression		Ms Contin	SS		
L600 MG	Difficulty In Walking		Propulsid	CC		
	Dry Mouth		Methadone	SS SS		
2500 MG			110 0110 00110	22		
	Fall		Percocet	SS		
L OR 2 (Q 4 H						
	Fatigue					

		Galibladder Pain	Zanailex	SS
8 MG PER ORAL		Headache	Zoloft	SS
200 MG PER		nedadone	201010	
		Hypoaesthesia		
ORAL		** (1)	** 1 1.7 .1.1 .1.1	
100 MG PER		Hypothyroidism	Hydrochlorothiazide	SS
100 110 1210		Joint Dislocation		
ORAL				
0000 MG DED		Lethargy	Veetids	SS
2000 MG PER		Liver Function Test		
ORAL 1	WK	liver runction lest		
		Abnormal	Synthroid	SS
		Lymphadenopathy	Oxy Ir (Oxycodone	
0 10 DATE:		Malnutrition	Hydrochloride)	SS
8-10 DAILY		Movement Disorder	Lasix	SS
80 MG		PIOVEMENT DISOLUCI	TGSIV	טט
-		Nervous System Disorder	Ritalin	SS
80 MG				
00 1100		Oedema Peripheral	K-Dur	SS
20 MCG		Osteoporosis	Compania	CC
		Ovarian Cyst	Seroquel Ketamine	SS 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		**	Dankaranakh la	aa
200 MG		Vomiting	Dextromethorphan	SS
ZUU I'IG		Weight Decreased	Nadolol	SS
		Weight Increased	Tegaderm	SS
Date:01/11/01ISR N Age:74 YR Gender		: 3646580-5Report Type:Expedited (15-DaCompany Reported I/FU:I	rt #2001010006	
Outcome		PT		
Hospitalization -		Akathisia		
Initial or Prolong	ed	Anorexia		

Valium

Zanaflex

SS

SS

ORAL

ORAL

ORAL

ORAL

Gallbladder Disorder

Gallbladder Pain

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80 MG

Freedom Of Information (FOI) Report

Zanaflex

PS

Elan Pharma

SEE IMAGE				Tizanidine Hcl	SS		ORAL
3 MG/D, PO PO				Etizolam	SS		ORAL
				Etilefrine Pravastatin Sodium Azulene Sulfonate Sodium/L-Glutamine Haloperidol Tiapride Hcl	C C C C		
Date:01/22/0 Age:	01ISR Number Gender:Fema	r: 3652795-2Report Type:Exp ale I/FU:F	pedited (15-DaCompany Re	eport #ZANA000723 (0)			
	Gender:Fema		pedited (15-DaCompany Re Report Source	eport #ZANA000723 (0) Product	Role	Manufacturer	Route
Age:		ale I/FU:F	Report Source		Role	Manufacturer Elan Pharma	Route
Age: Outcome Dose Other	Gender:Fema	ale I/FU:F		Product			Route ORAL
Age: Outcome Dose	Gender:Fema	ale I/FU:F PT Ammonia Increased	Report Source Foreign	Product		Elan Pharma	
Age: Outcome Dose Other 8 MG DAILY ORAL	Gender: Fema	PT Ammonia Increased Blood Urea Increased Hypertension Nephritis Interstitial Oliguria	Report Source Foreign Health Professional	Product		Elan Pharma	
Age: Outcome Dose Other 8 MG DAILY ORAL Date:02/01/0	Gender:Fema Duration Olisk Number	PT Ammonia Increased Blood Urea Increased Hypertension Nephritis Interstitial Oliguria	Report Source Foreign Health Professional	Product Zanaflex	PS	Elan Pharma	

Consumer

Anxiety

Coagulopathy

Other

Verapamil С Triamterene/Hydrochl orothiazide С Propranolol С Esterifield Estrogens С Baclofen С Clonazepam С Donnatal С Aspirin С ORAL

ORAL

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

2MG DAILY

ORAL

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Freedom Of Information (FOI) Report

Trazodone

Dilantin

Dulcolax

C

С

ORAL

Date:02/01/01ISR Number: 3659385-6Report Type:Periodic Company Report #ZANA000704 (0)

Age:71 YR Gender:Male I/FU:I

ORAL

Outcome PTReport Source Product Role Manufacturer Route Duration Dose

Other Hypotension Health Zanaflex PS Elan Pharma

Syncope Professional International Ltd

ORAL ORAL

Date: 02/01/01ISR Number: 3659386-8Report Type: Periodic Company Report #ZANA000705 (0)

Gender: Female I/FU:I Age:

Role Manufacturer PTReport Source Product Outcome Route

Dose Duration

Other Dry Mouth Consumer Zanaflex PS Elan Pharma

Sedation International Ltd

2-8 MG DAILY

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

Outcome PTReport Source Product Role Manufacturer Route

Dose Duration

Hyperhidrosis Other 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

PTRole Manufacturer

Outcome Report Source Product Route Duration Dose

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	Zanaflex	PS	Elan Pharma	0D 7 T
12 MG DAILY			Professional			International Ltd	ORAL
IZ MG DVIDI							
ORAL							
1				Zyrtec	С		
				Atenolol	C		
				Premarin	С		
				Fiorinal	C		
1				Oxycontin	С		
1				Tylenol#3	С		
Date:02/01/	01ISR Number	r: 3659390-XReport Type:Period	dic Company Re	eport #ZANA000715 (0)			
	Gender:Male						
1							
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Laboratory Test Abnormal	Health	Zanaflex	PS	Elan Pharma	2D 7 T
0 MC DATES			Professional			International Ltd	ORAL
2 MG DAILY							
1							

ORAL

Vioxx C Oxycontin С Percocet С

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Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659391-1Report Type:Periodic Company Report #ZANA000718 (0) Gender: Female Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Consumer Laboratory Test Abnormal Zanaflex PS Elan Pharma Other Health International Ltd ORAL 12-16 MG Professional DAILY ORAL Plexeril C Date:02/01/01ISR Number: 3659392-3Report Type:Periodic Company Report #ZANA000719 (0) Gender: I/FU:I Age: Role Manufacturer PTReport Source Product Outcome Route Duration Dose Other Laboratory Test Abnormal Health Zanaflex PS Elan Pharma Professional International Ltd ORAL ORAL Date:02/01/01ISR Number: 3659393-5Report Type:Periodic Company Report #ZANA000683 (0) Gender:Male Age:47 YR I/FU:I Role Manufacturer PTReport Source Product Outcome Route Dose Duration Other Hypertonia Consumer Zanaflex PS Elan Pharma International Ltd Muscle Spasms ORAL 2 MG DAILY ORAL Company Report #ZANA000684 (0) Date:02/01/01ISR Number: 3659394-7Report Type:Periodic Age: Gender: I/FU:I Role Manufacturer

Report Source

Representative

Company

Product

Zanaflex

PS

Elan Pharma

International Ltd

Route

ORAL

Outcome

2 MG DAILY

Dose

Other

PT

Pain

Duration

ORAL

Date:02/01/01ISR Number: 3659395-9Report Type:Periodic

Pruritus

Age:56 YR Gender:Female I/FU:I

Report Source Product Role Manufacturer Route Outcome PT

Company Report #ZANA000685 (0)

ORAL

Duration Dose Health Zanaflex Elan Pharma Other Diarrhoea PS

Professional International Ltd

Premarin С

Date:02/01/01ISR Number: 3659396-OReport Type:Periodic Company Report #ZANA000686 (0)

Age:63 YR Gender:Male I/FU:I

Role Manufacturer Outcome PTReport Source Product Route Dose Duration

Hyperhidrosis Consumer Zanaflex PS Elan Pharma Other

Pain

International Ltd ORAL

32 MG DAILY

ORAL

Sedation Paxil С

> Claritin-D 24 Hour С Prilosec С

Celebrex С

Hydroxyzine С

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Freedom Of Information (FOI) Report

ORAL

Date:02/01/01ISR Number: 3659397-2Report Type:Periodic Company Report #ZANA000687 (0)

Age:57 YR Gender: Female I/FU:I

Outcome	December	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Facial Palsy Sedation	Consumer Health	Zanaflex	PS	Elan Pharma International Ltd	ORAL
ORAL		Speech Disorder	Professional	Norvasc	С		
		Stupor		Estrogen Supplement Aciphex Zovirax	С С С		
				Vioxx	C		
Date:02/01/ Age:	01ISR Number Gender:Fema	r: 3659398-4Report Type:Fale I/FU:I	Periodic Company Re	port #ZANA000688 (0)			

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration

Other Dizziness Consumer Zanaflex PS Elan Pharma

International Ltd

Dry Mouth

ORAL

Date:02/01/01ISR Number: 3659399-6Report Type:Periodic Company Report #ZANA000689 (0)

Age: Gender: Female I/FU:I

Outcome PTReport Source Product Role Manufacturer Route Dose Duration

Cardiovascular Disorder Other 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 PΤ Report Source Product Role Manufacturer Route Dose Duration

Other Abdominal Pain Consumer Zanaflex PS Elan Pharma

Anorexia International Ltd ORAL

6-12 MG DAILY

Outcome

Celebrex С Diuretic

Product

Role Manufacturer

Route

ORAL

ORAL

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

PT

Dose Duration Other Accident Health Zanaflex PS Elan Pharma

Report Source

Clonic Convulsion Professional International Ltd

4 MG DAILY

Distributor Hypertonia ORAL

SS ORAL Luvox

200 MG DAILY

ORAL Anafranil С

Ambien С Tylox С Prempro С

Neurontin

Date:02/01/01ISR Number: 3659402-3Report Type:Periodic Company Report #ZANA000692(0)

Gender:Male I/FU:I Age:

PTReport Source Product Role Manufacturer Outcome Route Duration

Dose

Laboratory Test Abnormal Health Zanaflex Elan Pharma Other PS

Professional International Ltd

ORAL

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Freedom Of Information (FOI) Report

C

С

ORAL

ORAL

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 Zanaflex PS Elan Pharma

Professional 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

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

Norvasc Paxil

Premarin

Dose Duration

Other Accident Health Zanaflex PS Elan Pharma

Hallucination Professional International Ltd

4 MG DAILY

Hypotension

ORAL

Date:02/01/01ISR Number: 3659406-OReport Type:Periodic Company Report #ZANA000672 (0)

Age: Gender: I/FU:I

DOSE	Duracion						
Other		Hallucination	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
ORAL							
	01ISR Number Gender:Fema	: 3659407-2Report Type:Periodi le I/FU:I	c Company Repor	rt #ZANA000673 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Asthenia Dizziness	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL
6-8MG DILY		Nausea				incernacional 200	Oldin
ORAL				Oral Contraceptives	С		
	01ISR Number Gender:Fema	: 3659408-4Report Type:Periodi le I/FU:I	c Company Repor	rt #ZANA000674 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other ORAL	- 1	Muscle Spasms Pain	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL
ORAL				Dantrium	С		
1							

Report Source

Product

Role Manufacturer

Route

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Outcome

Dose

PT

Duration

Freedom Of Information (FOI) Report

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
ose ther	Duration	Blood Creatinine Increased	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
MG DAILY			1101055101101			incernacional lea	01412
)RAL		Blood Urea Increased					
		Hyperkalaemia					
		r: 3659410-2Report Type:Peri	odic Company R	eport #ZANA000676 (0)		
Age:35 YR	Gender:Male	e I/FU:I					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Blood Creatinine Increased		Zanaflex	PS	Elan Pharma International Ltd	ORAL
2 MG DAILY		Blood Urea Increased					
ORAL							ļ
		Urinary Tract Infection		Hydrocodone	С		
		r: 3659411-4Report Type:Peri	odic Company R	eport #ZANA000678 (0)	ı		
Age:	Gender:Fema	ale I/FU:I					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Pain Paraesthesia	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
12MG DAILY		Paraesthesia	PIOLESSIONAI			international bu	URAL
ODAI		Sedation					
ORAL		Tremor					

Report Source

Product

Role Manufacturer

Route

Age:

Dose

Outcome

Gender:Male

Duration

PT

I/FU:I

Other		Testicular Disorder	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
4 MG DAILY							
ORAL							
	lISR Number: Gender:Male	: 3659413-8Report Type:Peric	odic Company R	eport #ZANA000648 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Daracion	Depressed Level Of Consciousness	Consumer	Zanaflex	PS	Elan Pharma International Ltd	
4 MG DAILY		Dyspnoea Hallucination Sedation		Vioxx	С		
Date:02/01/0 Age:36 YR		: 3659414-XReport Type:Perio	odic Company R	eport #ZANA000650 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Syncope	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
12 MG DAILY							
ORAL				Methadone	С		

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Freedom Of Information (FOI) Report

International Ltd

C

ORAL

Date:02/01/01ISR Number: 3659415-1Report Type:Periodic Company Report #ZANA000655 (0) Gender: Female I/FU:I Age: Report Source Role Manufacturer Outcome PTProduct Route Duration Dose Dry Mouth Consumer Zanaflex PS Elan Pharma Other Health 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 Report Source Role Manufacturer Outcome PTProduct Route Duration Dose Hallucination Health Zanaflex Elan Pharma PS Other Professional International Ltd ORAL ORAL Date:02/01/01ISR Number: 3659417-5Report Type:Periodic Company Report #ZANA000658 (0) Gender: Female Age: I/FU:I Report Source Role Manufacturer Outcome РΤ Product Route Dose Duration Abnormal Dreams Health Zanaflex Elan Pharma PS Professional International Ltd Dry Mouth ORAL ORAL Sedation Date:02/01/01ISR Number: 3659418-7Report Type:Periodic Company Report #ZANA000659 (0) Age:44 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Accident Consumer Zanaflex PS Elan Pharma

Avonex

Muscle Spasms

Sedation

4 MG DAILY

ORAL

Tylenol Pm С Ditropan С Vitamin Supplement С

Date:02/01/01ISR Number: 3659419-9Report Type:Periodic Gender: Female

I/FU:I

Outcome PT

Dose Duration

Other

Clonic Convulsion

Health Professional

Report Source

Product

Elan Pharma PS

Role Manufacturer

International Ltd ORAL

6 MG DAILY

Age:50 YR

ORAL

Ambien С Tylox С Luvox С Clomipramine С

Company Report #ZANA000661 (0)

Zanaflex

Company Report #ZANA000660 (0)

Date:02/01/01ISR Number: 3659420-5Report Type:Periodic

Age:40 YR Gender:Male I/FU:I

Duration

PT

Report Source

Product

Role Manufacturer

Route

Route

Hiccups Health Elan Pharma Other Zanaflex PS

Professional

International Ltd ORAL

4 MG DAILY

ORAL

Outcome

Dose

Prednisone

С

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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 Report Source Role Manufacturer PTProduct Route

Dose Duration

Other Alopecia Health Zanaflex PS Elan Pharma

Visual Field Defect Professional International Ltd

ORAL

2 MG DAILY

Duragesic Patch С Actiq C Ativan С

Fiorinal C ORAL

ORAL

ORAL

Date:02/01/01ISR Number: 3659422-9Report Type:Periodic Company Report #ZANA000665 (0)

Age:21 YR Gender:Male I/FU:I

Report Source Role Manufacturer Outcome PTProduct Route

Dose Duration

Sedation Elan Pharma Other Consumer Zanaflex PS

International Ltd

16 MG DAILY

ORAL

Oxybutynin С Contac

Zoloft

С

Date:02/01/01ISR Number: 3659443-6Report Type:Periodic Company Report #ZANA000579 (0)

Age:18 YR Gender: Female I/FU:I

PTReport Source Role Manufacturer Outcome Product Route

Duration Dose

Other Alopecia Health Zanaflex PS Elan Pharma

Professional International Ltd

8 MG DAILY

ORAL

	1ISR Number Gender:Male	: 3659444-8Report Type:Periodi	LC Com	mpany Report	#ZANA000580 (0)			
Age.	Gender · Mare	1/FU·1						
Outcome Dose	Duration	PT	Report Sour	rce	Product	Role	Manufacturer	Route
Other	<i>D</i> 4.1 4	Laboratory Test Abnormal	Health Professiona	al	Zanaflex	PS	Elan Pharma International Ltd	ORAL
ORAL					3 6			
					Baclofen Wellbutrin	C		
	1ISR Number Gender:Femal	: 3659445-XReport Type:Periodi le I/FU:I	ic Com	mpany Report	#ZANA000581 (0)			
Age ·	Gender • r ema.	1/ 1/ 1/ 1						
Outcome Dose	Duration	PT	Report Sour	rce	Product	Role	Manufacturer	Route
Other		Hypersensitivity	Consumer		Zanaflex	PS	Elan Pharma International Ltd	ORAL
20 MG DAILY								ļ
ORAL								
OKALI					Hyzaar	С		
					Prilosec	С		
					Soma	С		
	1ISR Number Gender:Fema	: 3659446-1Report Type:Periodi le I/FU:I	LC Com	mpany Report	#ZANA000582 (0)			
Outcome Dose	Duration	PT	Report Sour	rce	Product	Role	Manufacturer	Route
Other	Duracron	Akathisia	Health Professiona	al	Zanaflex	PS	Elan Pharma International Ltd	ORAL
20 MG DAILY			11010001	31			111001111101101101111111111111111111111	C1111
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Freedom Of Information (FOI) Report

ORAL

ORAL

ORAL

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

Arthritis International Ltd

8 MG DAILY

O MG DAILLI

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 Zanaflex PS Elan Pharma

Myasthenic Syndrome Professional International Ltd

36 MG DAILY

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

6 MG DAILY

ORAL

Date:02/01/01ISR Number: 3659450-3Report Type:Periodic Company Report #ZANA000588 (0) Age:

Gender:Female I/FU:I

Report Source Role Manufacturer Outcome Product PTRoute Duration Dose Diarrhoea Consumer Zanaflex PS Elan Pharma Other International Ltd ORAL

2 MG DAILY

ORAL

Diovan	C
Calcium	С
Aspirin	С
Acidophilus Tablets	C
Clonazepam	С
Estradiol	C
Pravachol	C
Albuterol	C
Azmacort	C
Serevent	С
Alpha Interferon	
Shots	С
B12 Shots	С
Multivitamins	С
Vitamin C	С
Vitamin E	С
Imodium	С
Compazine	C
Lomotil	C

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Freedom Of Information (FOI) Report

Zanaflex (Tizanidine

ORAL

ORAL

Date:02/01/01ISR Number: 3659451-5Report Type:Periodic Company Report #ZANA000592 (0)

Age:57 YR Gender: Female I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration

Other Abnormal Dreams Health Zanaflex PS Elan Pharma

Drug Interaction Professional International Ltd

4 MG DAILY

ORAL

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

Report Source Role Manufacturer PTProduct Route Outcome

Duration Dose

Elan Pharma Other Anorexia Consumer Zanaflex PS

Asthenia International Ltd

Consumer

Dry Mouth

Myasthenic Syndrome

Urinary Retention

Date:02/01/01ISR Number: 3659453-9Report Type:Periodic Company Report #ZANA000595(0)

Gender:Male Age:42 YR I/FU:I

Role Manufacturer Report Source Product Route

Outcome PΤ

Dose Duration

Other

Hydrochloride) ORAL PS

16 MG DAILY

PRN ORAL

Ms Contin С Hydromorphone С

Klonopin

Date:02/01/01ISR Number: 3659454-0Report Type:Periodic Company Report #ZANA000596(0)

Age: Gender:Male I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Hypoglycaemia	Consumer Health	Zanaflex	PS	Elan Pharma International Ltd	ORAL
16 MG DAILY			Professional				
ORAL				Glyburide Glucose	C C		
	lisk Number Gender:Fema	: 3659455-2Report Type:Periodi le I/FU:I	.c Company Repor	rt #ZANA000597(0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Hallucination	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL
12 MG DAILY							
ORAL				Vioxx Neurontin	C C		
Date:02/01/0 Age:11 YR		: 3659456-4Report Type:Periodi I/FU:I	.c Company Repor	rt #ZANA000598(0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Asthenia Malaise	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL
ORAL		Sedation					
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I							

Freedom Of Information (FOI) Report

ORAL

ORAL

Date:02/01/01ISR Number: 3659457-6Report Type:Periodic Company Report #ZANA000599(0)

Age:73 YR Gender: Female I/FU:I

Outcome PTReport Source Product Role Manufacturer Route Dose Duration

Other Asthenia Consumer Zanaflex PS Elan Pharma

International Ltd

Cough 4 MG DAILY

Dyspnoea

Headache

Date: 02/01/01ISR Number: 3659458-8Report Type: Periodic Company Report #ZANA000602(0)

Age:47 YR Gender: Female I/FU:I

Role Manufacturer PTReport Source Product Outcome Route Dose Duration

Muscle Twitching Other Health Zanaflex PS Elan Pharma

Professional International Ltd 6 MG DAILY

ORAL

ORAL

Baclofen C С Prempro

Date:02/01/01ISR Number: 3659459-XReport Type:Periodic Company Report #ZANA000603(0)

Gender:Male Age:61 YR I/FU:I

Role Manufacturer Outcome PTReport Source Product Route Dose Duration

Sedation Health Zanaflex PS Elan Pharma Other

Professional International Ltd ORAL ORAL

C Avonex

Baclofen С Valium

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	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
8 MG DAILY		Pneumonia	1101000101101				01412
ORAL		PileuiioiiIa					
01412				Alprazolam	С		
				Imipramine	С		
				Procyclidine	С		
Date:02/01/0	lisk Number	: 3659461-8Report Type:Period	lic Company Repo	rt #ZANA000612(0)			
	Gender:Fema						
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Tongue Oedema	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL
ORAL				_			
				Soma	C		
				Lodine Vitamin E	C C		
		: 3659462-XReport Type:Period	dic Company Repo	rt #ZANA000613(0)			
Age:55 YR	Gender:Fema	le I/FU:I					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Sedation	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
ORAL				Premarin	С		
22-Aug-2005 Page: 86	12:09 PM						
l.							

Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659487-4Report Type:Periodic Company Report #ZANA000573(0) Gender: Female I/FU:I Age: Report Source Role Manufacturer Outcome PTProduct Route Dose Duration Elan Pharma Hospitalization -Hypotension Company Zanaflex PS Initial or Prolonged Representative 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							

0	MG	DATL

ORAL	

Haldol Prevacid С Norflex С Paxil С Colace Restoril С Dulcolax С Benadryl С Ativan

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	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL
		ocaciia reripiierar				IIICCIIIACIOIIAI ECA	014111

Valium

12 MG DAILY Paraesthesia

ORAL

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	С

Product

Neurontin

Role Manufacturer

C

Route

Date:02/01/01ISR Number: 3659491-6Report Type:Periodic Company Report #ZANA000567(0)

Weight Increased

Age:41 YR Gender:Female I/FU:I

PT

Dose	Duration		-				
Other		Dizziness Hallucination	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
UNKNOWN ORA	L						
		Insomnia		Vioxx	SS		ORAL
25 MG DAILY	,						
		Nausea					
ORAL							

Report Source

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Outcome

Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3659493-XReport Type:Periodic Company Report #ZANA000571 (0)

Gender: Female Age: I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Duration Dose

Other Alopecia Health Zanaflex PS Elan Pharma

Professional International Ltd

ORAL

ORAL

ORAL

ORAL

ORAL

Date:02/01/01ISR Number: 3659494-1Report Type:Periodic Company Report #ZANA000572 (0)

Gender: Female Age: I/FU:I

Outcome РΤ Report Source Product Role Manufacturer Route

Dose Duration

Hypotension Health Zanaflex Elan Pharma Other PS

Professional International Ltd

8 MG DAILY

ORAL

ORAL

ORAL

Date:02/01/01ISR Number: 3659495-3Report Type:Periodic Company Report #ZANA000575 (0)

Age:37 YR Gender: Female I/FU:I

Report Source Role Manufacturer РΤ Product Route Outcome

Duration Dose

Laboratory Test Abnormal Health Elan Pharma Other Zanaflex PS

Professional International Ltd

Flexeril C

Date:02/01/01ISR Number: 3659497-7Report Type:Periodic Company Report #ZANA000576 (0)

Gender: Male I/FU:I Age:

Outcome PTReport Source Product Role Manufacturer Route Duration Dose

Other Laboratory Test Abnormal Health Zanaflex PS Elan Pharma

Professional International Ltd

Melatonin C Date:02/01/01ISR Number: 3659498-9Report Type:Periodic Company Report #ZANA000577 (0)

Age:48 YR Gender:Male I/FU:I

Outcome PTReport Source Product Role Manufacturer Route Dose Duration

ORAL

ORAL

Delusion Health Zanaflex Elan Pharma Other PS

Hallucination Professional International Ltd

Mirapex С Elavil С

Prilosec С Propulsid

Date:02/01/01ISR Number: 3659499-OReport Type:Periodic Company Report #ZANA000578 (0)

Gender: Female I/FU:I Age:

Report Source Product Role Manufacturer Outcome PTRoute

Dose Duration Sedation Health Zanaflex PS Elan Pharma Other

Professional International Ltd ORAL

2 MG DAILY

ORAL

ORAL

Date:02/01/01ISR Number: 3659530-2Report Type:Periodic Company Report #ZANA000633 (0)

Age:43 YR Gender:Male I/FU:I

PTReport Source Product Role Manufacturer Outcome Route Duration Dose

Liver Function Test Zanaflex Elan Pharma Consumer PS

Other

Abnormal International Ltd

24 MG DAILY

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Freedom Of Information (FOI) Report

Nortriptyline

Celexa

C

ORAL

ORAL

Date:02/01/ Age:	01ISR Number Gender:Fema	:: 3659531-4Report Type:Perio	odic Company R	eport #ZANA000636 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Dizziness Emotional Disorder	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL
ORAL		Hyperhidrosis Myalgia		Clonazepam Diovan	C C		
Date:02/01/ Age:	01ISR Number Gender:Fema	:: 3659533-8Report Type:Perio	odic Company R	eport #ZANA000637 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Daracion	Arthralgia Muscle Spasms	Consumer	Zanaflex	PS	Elan Pharma International Ltd	
6 MG DAILY ORAL		Nausea					
		Tremor		Avonex Vicodin Soma	C C		
	01ISR Number Gender:Fema	r: 3659535-1Report Type:Perio	odic Company R	eport #ZANA000640 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Alopecia	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
12 MG DAILY			TIOTOBBIONAL			incernational lea	Oldin

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 Zanaflex PS Elan Pharma

Dizziness Professional International Ltd

ORAL

ORAL

12 MG DAILY

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

Dizziness International Ltd

12 MG DAILY

Hallucination

ORAL

Baclofen C
Prilosec C

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Freedom Of Information (FOI) Report

)1ISR Number Gender:Male	: 3659539-9Report Type:Pe	riodic Company Re	eport #ZANA000643 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	241401011	Dizziness Hallucination	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
10 MG DAILY		Nausea					
ORAL				Vioxx	С		
Date:02/01/0 Age:82 YR		: 3659540-5Report Type:Pe le I/FU:I	riodic Company Re	eport #ZANA000644 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Daracion	Urinary Retention	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
6 MG DAILY							
LORAL				Methadone	С		
				Celexia	C		
				Atenolol Prinivil	C C		
				Topamax	C		
				Neurontin	С		
Date:02/01/0 Age:36 YR		: 3659542-9Report Type:Pe ! I/FU:I	riodic Company Re	eport #ZANA000645 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Amnesia Sedation	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
12 MG DAILY							
ORAL				Methadone	SS		
30 MG Q 6H							
				Ibuprofen Viagra	C C		

Potassium Chloride (Kcl) С Spironolactone С

Date:02/01/01ISR Number: 3659543-OReport Type:Periodic

Gender:Male I/FU:I Age:

PT

Report Source

Role Manufacturer Product

Company Report #ZANA000647 (0)

Route

Dose Duration Other

Sedation

Health

Elan Pharma Zanaflex PS

Sexual Dysfunction Professional

2 MG DAILY

International Ltd ORAL

ORAL

ORAL

Outcome

Pamelor С

Date:02/01/01ISR Number: 3659556-9Report Type:Periodic Company Report #ZANA000720 (0)

Age:77 YR Gender:Female I/FU:I

Report Source Role Manufacturer Outcome PTProduct Route

Duration Dose

Dizziness Zanaflex Elan Pharma Other Consumer PS

International Ltd

4 MG DAILY

ORAL

Vioxx С

Premarin С

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Freedom Of Information (FOI) Report

Date:02/01/ Age:	01ISR Number Gender:Fema	r: 3659557-0Report Type:Periodi ale I/FU:I	c Company Repor	rt #ZANA000721 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	2 01 01 2 2 2 2	Sedation Sexual Dysfunction	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
4 MG DAILY		0011441 = 1 = = = = = = = = = = = = = = =					C
ORAL				Celexa	С		,
				Buspar	C		,
I				Darvocet-N100	C		,
				Pepcid Ac	C		,
				Premarin	C		,
				Progesterone	С		
Date:02/01/ Age:17 YR Outcome Dose Other	01ISR Number Gender:Fema Duration	r: 3659558-2Report Type:Periodi ale I/FU:F PT Malaise	ic Company Repor Report Source Health	rt #ZANA000559 (1) Product Zanaflex	Role PS	Manufacturer Elan Pharma	Route
ORAL			Professional			International Ltd	ORAL
	01ISR Number Gender:Fema	r: 3659559-4Report Type:Periodi ale I/FU:F	ic Company Repor	rt #ZANA000560 (1)			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Hyperacusis	Health	Zanaflex	PS	Elan Pharma	ŗ
Orner		нурегасия:s Visual Disturbance	неаттп Professional	Zanariex	Pb	International Ltd	ORAL
ORAL		VISual Disturbance	FIOLESSIONAL			Internacional Loa	OIUIL
	01ISR Number Gender:Male	r: 3659560-0Report Type:Periodi e I/FU:I	ic Company Repor	rt #ZANA000615 (0)			

Report Source

Consumer

Product

Zanaflex

Role Manufacturer

Elan Pharma

PS

Route

PT

Myasthenic Syndrome

Duration

Outcome

Dose

Other

C

ORAL

ORAL

Date:02/01/	/Ulisa Number:	3659561-2Report Type:Periodic	Company Report #ZANA000617 (0)
Age:38 YR	Gender:Female	e 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

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Dysphagia Gait Disturbance	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL
8 MC DATIV		date bibearbanee				International Lea	Ordin

8 MG DAILY

Sedation

ORAL

Oxyconti N Vioxx Pamelar

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Freedom Of Information (FOI) Report

Prempro	С
Prevacid	С
Ritalin	С
Calcium Supplement	С
Multivitamin	С
Vitamin B Complex	С
Glucosamine	C

ORAL

ORAL

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 Health Zanaflex PS Elan Pharma

Abnormal Professional International Ltd

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 Consumer Zanaflex PS Elan Pharma

Vasodilatation International Ltd

Loracet

C

С

С

8 TABS DAILY,

O TIME DITTEL

ORAL

Ambien Elavil

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 Health Zanaflex PS Elan Pharma

other british rest hearth bandres is brain market

Abnormal Professional International Ltd ORAL

ORAL

Age: Gender: Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Drug Ineffective Consumer Zanaflex PS Elan Pharma Other

Company Report #ZANA000623 (0)

Product

International Ltd

Role Manufacturer

ORAL

Route

4 MG DAILY

ORAL

Date:02/01/01ISR Number: 3659567-3Report Type:Periodic Company Report #ZANA000624 (0)

Age: Gender:Female I/FU:I

PT

Dose Duration
Other Asthenia Health Zanaflex PS Elan Pharma
Confusional State Professional International Ltd ORAL

3 MG DAILY

Emotional Disorder

Date:02/01/01ISR Number: 3659566-1Report Type:Periodic

ORAL

Outcome

Euphoric MoodDayproCSpeech DisorderEffexorCXanaxC

Report Source

22-Aug-2005 12:09 PM

Freedom Of Information (FOI) Report

Methylphenidate

Date:02/01/01ISR Number: 3659568-5Report Type:Periodic Company Report #ZANA000625 (0) Age: Gender: I/FU:I Outcome PTReport 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 С Neurontin С Celebrex С Pamelor C Date: 02/01/01ISR Number: 3659569-7Report Type: Periodic Company Report #ZANA000630 (0) Age:36 YR Gender: Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Other Insomnia Consumer Zanaflex PS Elan Pharma International Ltd Myalgia 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 PTRole Manufacturer Outcome Report Source Product Route Duration Dose Other Coma Foreign Zanaflex PS Elan Pharma Convulsion Health International Ltd ORAL 8 MG DAILY Hemiparesis Professional ORAL Hypotension Etidronate Disodium C Hypoxia Fucidin С Paracetamol С Imodium С Heparin С Lansoprazole C

Baclofen

С

Date:02/15/01ISR Number: 3666462-2Report Type:Expedited (15-DaCompany Report #ZANA000726 (0)

Age:57 YR Gender:Male I/FU:I

Outcome PT

Duration Dose

Disability

Disability

Report Source

Professional

Product

Role Manufacturer

Route

Foreign Health

Zanaflaex

(Tizanidine

Hydrochloride)

ORAL

6 MG DAILY

ORAL

Omeprazole Lactulose

С

PS

Date:02/21/01ISR Number: 3669332-9Report Type:Expedited (15-DaCompany Report #ZANA000727 (0)

Age: 37 YR Gender: Male I/FU:I

Outcome

Hospitalization -Drooling

Initial or Prolonged Drug Interaction

Drug Withdrawal Syndrome

Eye Disorder

Heart Rate Increased

Hypertension

22-Aug-2005 12:09 PM

Freedom Of Information (FOI) Report

Dose		Pain					
Dose		Paraesthesia	Report Source	Product	Role	Manufacturer	Route
	Duration						
		Sedation	Health	Zanaflex	PS	Elan Pharma	
l		Vomiting	Professional			International Ltd	ORAL
8-12 MG DAIL	Y						
ORAL							
				Prednisone	C		
				Sulfasalazine	C		ľ
				Vioxx	C		ľ
				Prilosec	C		ľ
				Prozac	C		ľ
i				Enbrel	C		
				Betoptic	C		Ī
				Lorcet	C		ľ
Date:02/26/0 Age:71 MON Outcome Dose Life-Threate 8MG Q6H PO	Gender:Male Duration	: 3670049-5Report Type:Dir E I/FU:I PT Bradycardia	rect Company Re Report Source	Product Zanaflex 8 Mg Q6h	Role PS	Manufacturer	Route ORAL
~		Hypotension					
		:: 3672108-XReport Type:Exp ale I/FU:I	pedited (15-DaCompany Re	port #ZANA000728 (0)			
Age:	lisk Number Gender:Fema	ale I/FU:I					
Age: Outcome	Gender:Fema		pedited (15-DaCompany Re Report Source	eport #ZANA000728 (0) Product	Role	Manufacturer	Route
Age: Outcome Dose		ale I/FU:I PT	Report Source	Product			Route
Age: Outcome	Gender:Fema	ale I/FU:I PT Hepatic Necrosis	Report Source Health		Role PS	Elan Pharma	
Age: Outcome Dose	Gender:Fema	ale I/FU:I PT	Report Source	Product			Route ORAL

Date:03/06/01ISR Number: 3674623-1Report Type:Direct Company Report # Age:46 YR Gender: I/FU:I

Hypoaesthesia

Dose	Duracion					
Required		Adrenal Insufficiency		Tizanidine		
Intervention	to	Bradycardia		(Zanaflex)	PS	ORAL
24 MG PO						•
Prevent Perma		Decreased Appetite		Synthroid	C	,
Impairment/Da	amage	Hypotension		Fosamax	C	,
i		Hypothermia		Depakote	C	,
		Hypothyroidism		Colace	C	7
1		Lethargy		Tegretol	C	7
1				Vasotec	C	7
1				Oscal	C	7
i				Loestrin	C	,
1				Mvi	C	,
1				Senokot	C	•
	lISR Number: Gender:Male	: 3680753-0Report Type:Direct I/FU:I	Company Report	t #		
				_	_	
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalizati Initial or Pr	ion -	Blood Pressure Decreased Bradycardia		Zanaflex	PS	

Product

Role Manufacturer

Route

Report Source

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Outcome

Dose

PT

Heart Rate Decreased

Hypotension

Duration

Freedom Of Information (FOI) Report

ORAL

Date:03/14/01ISR Number: 3682360-2Report Type:Expedited (15-DaCompany Report #ZANA000729 (0) Gender:Male Age:41 YR I/FU:I

Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration

Hospitalization -Drug Withdrawal Foreign Zanaflex PS Elan Pharma

Initial or Prolonged Convulsions Health International Ltd

12 MG DAILY

Professional ORAL

Analgesics Other (Unspecified) C

Date:03/15/01ISR Number: 3682206-2Report Type:Expedited (15-DaCompany Report #ZANA000730 (0)

Age: 22 MON Gender: Female I/FU:I

Report Source Role Manufacturer Outcome РΤ Product Route

Dose Duration

Hyperpyrexia Health Elan Pharma Life-Threatening Zanaflex PS

ORAL

Tachycardia Professional International Ltd Hospitalization -

2 MG ORAL

Initial or Prolonged Rocephin C Erythromycin C Glycopyrrolate С

Toradol

Date:03/19/01ISR Number: 3684687-7Report Type:Expedited (15-DaCompany Report #ZANA000732(0)

Gender: Female Age: I/FU:I

PТ Role Manufacturer Outcome Report Source Product Route

Duration Dose

Hospitalization -Rhabdomyolysis Zanaflex Health PS Elan Pharma

Initial or Prolonged Professional International Ltd ORAL ORAL

Date:03/19/01ISR Number: 3684688-9Report Type:Expedited (15-DaCompany Report #ZANA000731(0)

Age: Gender: Female I/FU:I

РΤ Report Source Product Role Manufacturer Route Outcome Dose Duration

Hospitalization -Hypotension Zanaflex PS Elan Pharma Company

				Antihypertensive	С		
	lISR Number Gender:Male	: 3705738-7Report Type:Periodi	c Company Repor	t #WAES 01011445			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route	
	Daracion	Sedation Syncope	Health Professional	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL
25 MG/BID/PO				Tab Zanaflex Unk Acetaminophen (+) Hydrocodone	SS C		
		: 3689727-7Report Type:Expedit	ed (15-DaCompany Repor	t #ZANA000734 (0)			
Age: G	Gender:Male	I/FU:I					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death Hospitalizati ORAL		Respiratory Distress	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
Initial or Pr	colonged			Unspecified Narcotic	C		

Representative

International Ltd

ORAL

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Initial or Prolonged 4 MG DAILY

ORAL

Shock

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
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Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Life-Threatening	Dece de conserval à s	Health	Zanaflex	Da	Elan Pharma	
Hospitalization -	Bradycardia Hypotension	Professional	Zanariex	PS	International Ltd	ORAL
L2 MG DAILY	пуросензтон	FIOLESSIONAL			incernacional ded	OKAL
Initial or Prolonged						
ORAL						
			Luvox	С		
			Prevacid	С		
			Fioricet	С		
	er: 3706283-5Report Type:E:	xpedited (15-DaCompany Re	eport #PHH02000DE01410			
Age:58 YR Gender:Mal	le I/FU:F					
Age:58 YR Gender:Mal Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Outcome		Report Source	Product	Role	Manufacturer	Route
Outcome Dose Duration Hospitalization -		Report Source Foreign	Product Sandoglobulin Or	Role	Manufacturer	Route
Outcome Dose Duration	PT	_		Role	Manufacturer	Route
Outcome Dose Duration Hospitalization -	PT Aphasia	Foreign	Sandoglobulin Or	Role	Manufacturer	Route
Outcome Dose Duration Hospitalization -	PT Aphasia	Foreign Study Health	Sandoglobulin Or Placebo (Placebo		Manufacturer	Route
Outcome Dose Duration Hospitalization - Initial or Prolonged INTRAVENOUS QMO,	PT Aphasia	Foreign Study	Sandoglobulin Or Placebo (Placebo		Manufacturer	Route
Outcome Dose Duration Hospitalization - Initial or Prolonged INTRAVENOUS QMO,	PT Aphasia	Foreign Study Health Professional	Sandoglobulin Or Placebo (Placebo Placebo)	PS	Manufacturer	Route
Outcome Dose Duration Hospitalization - Initial or Prolonged	PT Aphasia	Foreign Study Health	Sandoglobulin Or Placebo (Placebo Placebo) Baclofen (Baclofen)		Manufacturer	Route
Outcome Dose Duration Hospitalization - Initial or Prolonged INTRAVENOUS QMO,	PT Aphasia	Foreign Study Health Professional	Sandoglobulin Or Placebo (Placebo Placebo) Baclofen (Baclofen) Ds-103-282	PS	Manufacturer	Route
Outcome Dose Duration Hospitalization - Initial or Prolonged INTRAVENOUS QMO,	PT Aphasia	Foreign Study Health Professional	Sandoglobulin Or Placebo (Placebo Placebo) Baclofen (Baclofen) Ds-103-282 (Tizanidine	PS SS	Manufacturer	Route
Outcome Dose Duration Hospitalization - Initial or Prolonged INTRAVENOUS QMO,	PT Aphasia	Foreign Study Health Professional	Sandoglobulin Or Placebo (Placebo Placebo) Baclofen (Baclofen) Ds-103-282 (Tizanidine Hydrochloride)	PS	Manufacturer	Route
Outcome Dose Duration Hospitalization - Initial or Prolonged INTRAVENOUS QMO,	PT Aphasia	Foreign Study Health Professional	Sandoglobulin Or Placebo (Placebo Placebo) Baclofen (Baclofen) Ds-103-282 (Tizanidine Hydrochloride) Orfiril (Valproate	PS SS SS	Manufacturer	Route
Outcome Dose Duration Hospitalization - Initial or Prolonged INTRAVENOUS QMO,	PT Aphasia	Foreign Study Health Professional	Sandoglobulin Or Placebo (Placebo Placebo) Baclofen (Baclofen) Ds-103-282 (Tizanidine Hydrochloride) Orfiril (Valproate Sodium)	PS SS	Manufacturer	Route
Outcome Dose Duration Hospitalization - Initial or Prolonged INTRAVENOUS QMO,	PT Aphasia	Foreign Study Health Professional	Sandoglobulin Or Placebo (Placebo Placebo) Baclofen (Baclofen) Ds-103-282 (Tizanidine Hydrochloride) Orfiril (Valproate	PS SS SS	Manufacturer	Route

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						
Hospitaliz	ation -	Blood Pressure Decreased		Zanaflex / 2 Mg /			
Initial or	Prolonged	Dysarthria		Athena	PS	Athena	ORAL

6 MG 1 DOSE

Feeling Abnormal

Heart Rate Decreased

Tonque Oedema

Norvasc С С Evista Synthroid С Vioxx С

Date:04/05/01ISR Number: 3700145-5Report Type:Direct

Age:67 YR Gender:Male Company Report #

I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalizat:	ion -	Bradycardia		Tizanidine	PS		
_							

8 MG PO TID

Hypotension Initial or Prolonged

PTA

Mental Impairment Fluoxetine С

Lansoprazole С Oxycodone С

Date:04/10/01ISR Number: 3702337-8Report Type:Expedited (15-DaCompany Report #ZANA000758 (0)

Age:65 YR Gender:Female I/FU:I

Outcome PT

Alanine Aminotransferase Hospitalization -

Initial or Prolonged

Increased Aspartate

Aminotransferase

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Freedom Of Information (FOI) Report

		Bradycardia Dysarthria Feeling Abnormal	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	3					
		Hypotension Speech Disorder	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
6 MG ORAL		_					
		Tongue Oedema		Norvasc	C		
				Evista Synthroid	C C		
Date:04/13/0	lisk Number	: 3704774-4Report Type:	Direct Company Re	port #			
	Gender:Fema						
Outcome Dose	Duration	PT	Report Source	Product		Manufacturer	Route
2 MG 3 TIMES		Liver Disorder		Zanaflex 4mg Athena	PS	Athena	ORAL
ORAL							
				Estrogen	C		
				Artane	C		
				Neurontin Mvi	C C		
				Calcium	C		
				Ibuprofen	C		
Date:05/10/0 Age:61 YR (Expedited (15-DaCompany Re	port #TCI2000A02663			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat 15 MG (15 MG		Angina Pectoris	Study	Actos	PS		ORAL
Initial or Part Initial or Part In 1 D)		Back Pain	Health				
5 MG		Cardiomegaly	Professional	Simvastatin	SS		ORAL
		Chest Pain		Mecobalamin	SS		ORAL
1 TAB		Malaise		Tizanidine			
		Palpitations		Hydrochloride	SS		ORAL
1 TAB		<u> </u>		<u> </u>			

Increased

Date:05/17/011SR Numbe Age:54 YR Gender:Fem	er: 3724580-4Report Type:Direc male I/FU:I	ct Company Re	port #			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 4 MG PO TID /	Bradycardia		Zanaflex	PS		ORAL
Initial or Prolonged SINCE BACK	Hypotension					
	Syncope					
SURGERY			Prilosec Zoloft Baycol Vit E Calcium Vioxx Oxycotin	0 0 0 0 0 0		
Date:05/21/01ISR Numbe Age: Gender:Mal	er: 3726541-8Report Type:Exped le I/FU:I	lited (15-DaCompany Re	eport #ZANA000785 (0)			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 18 MG DAILY	Orthostatic Hypotension Rebound Hypertension		Zanaflex	PS	Elan Pharma International Ltd	ORAL
ORAL	Syncope					
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2.5 MG

0.6 MG

 ${\tt Glibenclamide}$

Basen (Voglibose)

SS

SS

ORAL

ORAL

Freedom Of Information (FOI) Report

С

Zestril

Lasix

Date:05/23/01ISR Number:						
Age:60 YR Gender:Male	: 3727129-5Report Type:Expedi I/FU:I	ted (15-DaCompany Repor	t #260011			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 1014 DAY	Anaemia		Panaldine	PS	Roche	
Initial or Prolonged			Ternelin Itrizole	SS SS		
Date:05/25/01ISR Number: Age:60 YR Gender:Male	: 3729311-XReport Type:Expedi I/FU:I	ted (15-DaCompany Repor	t #260011			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 100 MG DAILY	Anaemia	Foreign	Ticlid	PS	Syntex (Usa) Inc Llc	ORAL
Initial or Prolonged		Health Professional	Ternelin (Tizanidine Hydrochloride)	SS		ORAL
ORAL ORAL		Other	Itrizole (Itraconazole)	SS		ORAL
	: 3733084-4Report Type:Expedi le I/FU:F	ted (15-DaCompany Repor	t #2000011288US			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Arthralgia Dysphagia D, IV	Consumer Other	Solu-Medrol	PS	Pharmacia And Upjohn Co	
	Haemorrhagic Stroke Hemiparesis		Solu-Medrol Regime #2	SS		
INTRAVENOUS 80 MG,Ç INTRAVENOUS 60 MG,Ç	Hypertension		Sol-Medrol Regime #3	SS		
	בען, וע Injection Site Pain		Sol-Medrol Regimen			

			Hydrochloride)	С		
Date:06/05/01ISR Numbe: Age:45 YR Gender:Fema	r: 3734012-8Report Type:Ex ale I/FU:I	pedited (15-DaCompany Re	eport #WAES 01058223			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged Other 25 MG/DAILY	Asthenia Drug Interaction Fatigue	Foreign Other	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL
PO 5 DA	Oedema Peripheral Y Sinus Bradycardia		Tab Tizanidine	SS		ORAL
4 MG/DAILY PO 5 DA						
Date:06/08/01ISR Numbe: Age:54 YR Gender:Fema	r: 3736257-XReport Type:Ex ale I/FU:I	pedited (15-DaCompany Re	eport #ZANA000794 (0)			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 8 MG DAILY	Bradycardia Hypotension	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL

#4

Prednisone

Zanaflex (Tizanidine

Cardizem

Oxycontin

Prilosec

SS

С

С

С

Speech Disorder

Liver Function Test

Rebound Hypertension

Abnormal

Tendonitis

40 MG,QD,IV

INTRAVENOUS

ORAL

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Freedom Of Information (FOI) Report

Company Report #2000-09-1047

Azulfidine C

	der:Male	I/FU:I	company repo	110 #2000 05 1047			
Outcome Dose Du	ration	PT	Report Source	Product	Role	Manufacturer	Route
		Drug Interaction Skin Disorder	Consumer	Claritin	PS	Schering Corp Sub Schering Plough Corp	ORAL
10 MG/QD ORAL				Zanaflex (Tizanidine			
4-8 MG/PRN				Hcl) Tablets	SS		ORAL
ORAL							
25 MG/TID				Dantrium	SS		
10 MG/TID				Procardia	SS		
1/2-2 TSP/BID				Docusate Sodium	SS		ORAL
ORAL							
00.150/077				Senokot Baclofen	SS 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:06/12/01IS Age:71 YR Gen			e:Expedited (15-DaCompany Repo	ort #PHBS2001JP05015			
Outcome Dose Du	ration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization Initial or Prol 40 MG/DAY,		Dermatitis Exfoliativ Rash Pruritic	re Foreign Health	Diovan	PS	Novartis Pharmaceuticals Corp	ORAL
ORAL		Toxic Epidermal	Professional				

Date:06/11/01ISR Number: 3737262-XReport Type:Periodic

	Hydrochloride, Tizanidine Hydrochloride)	SS	ORAL
3 MG/DAY,	-		
ORAL			
	Proheparum (Cysteine, Choline Bitartrate, Liver Hydrolysate,		
	Inositol)	SS	ORAL
3 DF/DAY,ORAL	Diagonam (Diagonam)	C.C.	ODAT
6 MG/DAY,	Diazepam (Diazepam)	SS	ORAL
ORAL			
	Cimetidine (Cimetidine)	SS	ORAL
600 MG/DAY,	(Cimetiaine)	55	ORAL
ORAL			
	Solon (Sofalcone) Digestive Enzymes (No Ingredients/Substanc	С	
	es) Propacall (Ticlopidine	С	
	Hydrochloride)	C	

Ternelin (Tizanidine

Other

Date:06/12/01ISR Number: 3738806-4Report Type:Expedited (15-DaCompany Report #WAES 01058223

Age:45 YR Gender:Female I/FU:F

Necrolysis

Outcome Hospitalization -Initial or Prolonged

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Freedom Of Information (FOI) Report

Other

Duration

Anaemia

Dose

Hospitalization -

100 MG DAILY

Duration	PT	Report Source	Product	Role	Manufacturer	Route
Duracion	Asthenia Drug Interaction Fatigue	Foreign Other	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL
5 DAY			Tah Tizanidine	SS		ORAL
5 DAY			Tab Tizaniuine	טט		ONAL
		ed (15-DaCompany Repor	t #ZANA000795 (0)			
Duration	PT	Report Source	Product	Role	Manufacturer	Route
Duracion	Neuropathy Peripheral	Foreign Health	Zanaflex	PS	Elan Pharma	ORAL
					Illuctifiactoriat new	OKAL
		Professional				
		ed (15-DaCompany Repor	rt #260011			
Demotion	PT	Report Source	Product	Role	Manufacturer	Route
	Anaemia		Panaldine	PS	Roche	
rolonged			Ternelin	SS		
			ltrizoie	SS		
		ed (15-DaCompany Repor	rt #260011			
	PT	Report Source	Product	Role	Manufacturer	Route
1 ()	5 DAY 1ISR Number Gender:Male Duration 1ISR Number Gender:Male Duration ion -	Duration Asthenia Drug Interaction Fatigue 5 DAY Oedema Peripheral 5 DAY Sinus Bradycardia 1ISR Number: 3741501-9Report Type:Expedit Gender:Male I/FU:I PT Duration Neuropathy Peripheral 1ISR Number: 3742324-7Report Type:Expedit Gender:Male I/FU:F PT Duration ion - Anaemia rolonged 1ISR Number: 3745870-5Report Type:Expedit Gender:Male I/FU:F	Duration Asthenia Drug Interaction Fatigue 5 DAY Oedema Peripheral 5 DAY Sinus Bradycardia 1ISR Number: 3741501-9Report Type:Expedited (15-DaCompany Report Gender:Male PT Report Source Neuropathy Peripheral Foreign Health Professional 1ISR Number: 3742324-7Report Type:Expedited (15-DaCompany Report Gender:Male I/FU:F PT Report Source Professional 1ISR Number: 3742324-7Report Type:Expedited (15-DaCompany Report Duration ion - Anaemia rolonged	Duration	Asthenia Poreign Vioxx PS Partigue DAY Ocdema Peripheral Sinus Bradycardia IISR Number: 3741501-9Report Type:Expedited (15-DaCompany Report #ZANA000795 (0) PT Report Source Product Role Neuropathy Peripheral Foreign Zanaflex PS PS Poreign Zanaflex PS PT Report Type:Expedited (15-DaCompany Report #260011 Role Type:Expedited Ro	Buration

Foreign

Ticlid

Syntex (Usa) Inc Llc ORAL

PS

Other 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) Gender: Female I/FU:I Age: Role Manufacturer Product Outcome PTReport Source Route Duration Dose Hospitalization -Hepatitis Health Elan Pharma Zanaflex PS Professional Initial or Prolonged 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 Report Source Role Manufacturer Outcome PTProduct Route Duration Dose Hospitalization -Abdominal Pain Upper Tizanidine PS 4 MG QID Initial or Prolonged Chromaturia Hepatotoxicity Jaundice Lethargy Necrosis 22-Aug-2005 12:09 PM Page: 100

Health

Professional

Ternelin (Tizanidine

Initial or Prolonged

ORAL

Freedom Of Information (FOI) Report

Date:07/10/01ISR Number: 3756280-9Report Type:Expedited (15-DaCompany Report #ZANA000775 (1)

Age:30 YR Gender:Male I/FU:F

Tremor

Outcome	5	PT	Report Source	Product	Role	Manufacturer	Route
Dose Death Hospitalizat 4-28 MG DAIL	Y	Acute Respiratory Distress Syndrome	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
Initial or P ORAL	rolonged	Bradycardia					
		Culture Urine Positive Hyperglycaemia Hypotension Intentional Misuse Pneumonia Pulmonary Oedema Pyrexia Respiratory Arrest Respiratory Depression Respiratory Distress Sedation Sepsis Staphylococcal Infection		Baclofen Ambien Temazepam	C C C		
	1ISR Number Gender:Fema	c: 3756281-0Report Type:Expedi ale I/FU:I	ted (15-DaCompany Repo	rt #ZANA000788 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	241401011	Asthenia Bradycardia	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL

16 MG DAILY

Dizziness ORAL

> Dry Mouth Celebrex C Fatigue Pamelor Headache Darvocet-N С

Heart Rate Decreased Hypertension Hypoaesthesia Hypotension Lethargy Sedation Skin Warm

Vision Blurred

Neuropathy Peripheral

Urinary Incontinence

Oedema

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 Other	Duration	Arthralgia Back Pain	Consumer	Zanaflex	PS	Elan Pharma International Ltd	ORAL
24 MG DAILY							
		Bronchospasm					
ORAL							
		Cognitive Disorder		Duragesic	C		
		Dermatitis		Celebrex	С		
		Diplopia Neck Pain		Morphine	С		

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Freedom Of Information (FOI) Report

Imipramine

Lactulose

Baclofen

Senna

С

С

С

)1ISR Number Gender:Male	: 3760960-9Report Type:Exp e I/FU:I	edited (15-DaCompany Re	eport #ZANA000815 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Disability		Peripheral Ischaemia	Foreign Health	Zanaflex	PS	Elan Pharma International Ltd	ORAL
16 MG DAILY			Professional				
ORAL			Professional				
O.G.				Co-Proxamol Acetylsalicylic Acid Lactulose	C C		
)1ISR Number Gender:Fema	c: 3762665-7Report Type:Exp ale I/FU:I	edited (15-DaCompany Re	eport #ZANA000818 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Daracion	Autoimmune Disorder Condition Aggravated	Health Professional	Zanaflex	PS	Elan Pharma International Ltd	ORAL
ORAL		D' 1		D.1.	a		
		Diabetes Mellitus Hallucination		Ditropan Prozac	C C		
		Hypertonia		Baclofen	C		
		Pyrexia		Betaseron	C		
		- 1		Synthroid	C		
				Insulin	С		
)1ISR Number Gender:Fema	r: 3766155-7Report Type:Exp ale I/FU:I	edited (15-DaCompany Re	eport #ZANA000821 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or E 36 MG DAILY	cion -	Liver Function Test Abnormal	Foreign Health	Zanaflex	PS	Elan Pharma International Ltd	ORAL
ORAL		Malaise	Professional				
V-11111					_		

Prednisolone С Arachis Oil С

Date:08/06/01ISR Number: 3772111-5Report Type:Expedited (15-DaCompany Report #ZANA000823 (0)

Age:49 YR Gender: Female I/FU:I

PTReport Source Product Role Manufacturer Route Outcome Duration Dose Health Zanaflex Elan Pharma Other Anxiety PS Professional International Ltd Dizziness ORAL

56 MG DAILY

Drug Dependence

ORAL

Drug Withdrawal Syndrome Premarin С Vicodin С Fall Feeling Jittery Dilaudid С

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 -Blood Pressure Decreased

Initial or Prolonged Bradycardia

Heart Rate Decreased

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Freedom Of Information (FOI) Report

Hypothermia

Ι	Duration		Report Source	Product	Role	Manufacturer	Route
	Duracion		Foreign Health	Zanaflex	PS	Elan Pharma International Ltd	ORAL
DAILY			Professional				
ı				Clonazepam	С		
				Epilim	С		
				Baclofen	С		
	lISR Number Gender:Male	: 3777130-0Report Type:Expedit	ced (15-DaCompany Repor	t #PHBS2001JP05015			
ome I	Duration	PT	Report Source	Product	Role	Manufacturer	Route
-Threateni italizatio G/DAY,	ning	Toxic Epidermal Necrolysis	Foreign Health	Diovan	PS	Novartis Pharmaceuticals Corp	ORAL
ial or Pro	rolonged		Professional				
				Proheparum (Cysteine, Choline Bitartrate, Liver Hydrolysate,			
/DAY,				Inositol)	SS		ORAL
ı				Diazepam (Diazepam)	SS		ORAL
/DAY,				2-43-2F (-		32 = .
				Cimetidine	~~		~ ~ ~ T
MG/DAY,				(Cimetiaine)	55		ORAL
				Solon (Sofalcon) Digestive Enzymes (No Ingredients/Substanc	SS		
MG/DAY,				(Cimetidine) Solon (Sofalcon) Digestive Enzymes (No	SS		

3			es)	SS		ORAL
DOSAGES/DAY,						
ORAL			Harnal (Tamsulosin			
0.2 MG/DAY,			Harnal (Tamsulosin Hydrochloride)	SS		ORAL
ORAL						
6			Eviprostat	SS		ORAL
DOSAGES/DAY,O						
RAL			Ternelin (Tizanidine Hydrochloride, Tizanidine	_		
3 MG/DAY,			Hydrochloride)	SS		ORAL
ORAL			Propacall (Ticlopidine Hydrochloride)	С		
Date:08/15/01ISR Number Age:76 YR Gender:Fema		Type:Expedited (15-DaCompany Repo	ort #ZANA000828 (0)			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Convulsion	Foreign Health	Zanaflex	PS	Elan Pharma International Ltd	ORAL
12 MG DAILY		Professional				
ORAL			Prolopa Selegiline	C C		
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Freedom Of Information (FOI) Report

Cimetidine

Levothyroxine C

Dose Duration Disability Difficulty In Walking Consumer Zanaflex PS Elan Pharmaceuticals Consumer Disability Difficulty In Walking Consumer Zanaflex PS Elan Pharmaceuticals Consumer 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 RDose Duration Other Muscle Spasms Zanaflex 2mg PS 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 RDose Duration Life-Threatening Toxic Epidermal Foreign Diovan PS Novartis Pharmaceuticals Corp Company Initial or Prolonged Professional ORAL Other Proheparum(Cysteine,				port #ZANA000830 (0)	ted (15-DaCompany Re	:: 3779082-6Report Type:Expedate I/FU:I	1ISR Number: Gender:Femal	
Disability Difficulty In Walking Consumer Zanaflex PS Elan Pharmaceuticals Consumer PS Mypotonia Report Source Product Role Manufacturer Role Dose Duration Other PT Report Type:Expedited (15-DaCompany Report #PHBS2001JP05015 Age:71 YR Gender:Male I/FU:F Outcome PT Report Source Product Role Manufacturer Role Manufacturer PS	Route	Manufacturer	Role	Product	Report Source	PT		
ORAL Date:08/17/01ISR Number: 3778997-2Report Type:Direct	ORAL	Elan Pharmaceuticals	PS	Zanaflex	Consumer	Difficulty In Walking		Disability
Age:53 YR Gender:Female I/FU:T Outcome PT Report Source Product Role Manufacturer R 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 R Dose Duration Life-Threatening Toxic Epidermal Foreign Diovan PS Novartis Hospitalization - Necrolysis Health Pharmaceuticals Corp C 40 MG/DAY, Initial or Prolonged ORAL Other Proheparum(Cysteine,						Hypotonia		ORAL
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 R Dose Duration Life-Threatening Toxic Epidermal Foreign Diovan PS Novartis Hospitalization - Necrolysis Health Pharmaceuticals Corp C 40 MG/DAY, Initial or Prolonged Professional ORAL Other Proheparum(Cysteine,				port #	Company Re			
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 R Dose Duration Life-Threatening Toxic Epidermal Foreign Diovan PS Novartis Hospitalization - Necrolysis Health Pharmaceuticals Corp C 40 MG/DAY, Initial or Prolonged Professional ORAL Other Proheparum(Cysteine,	Route	Manufacturer	Role	Product	Report Source	PT		
Age:71 YR Gender:Male I/FU:F Outcome PT Report Source Product Role Manufacturer R Dose Duration Life-Threatening Toxic Epidermal Foreign Diovan PS Novartis Hospitalization - Necrolysis Health Pharmaceuticals Corp C 40 MG/DAY, Initial or Prolonged Professional ORAL Other Proheparum(Cysteine,			PS	Zanaflex 2mg		Muscle Spasms		Other
Dose Duration Life-Threatening Toxic Epidermal Foreign Diovan PS Novartis Hospitalization - Necrolysis Health Pharmaceuticals Corp C 40 MG/DAY, Initial or Prolonged Professional ORAL Other Proheparum(Cysteine,				port #PHBS2001JP05015	ted (15-DaCompany Re			
Life-Threatening Toxic Epidermal Foreign Diovan PS Novartis Hospitalization - Necrolysis Health Pharmaceuticals Corp C 40 MG/DAY, Initial or Prolonged Professional ORAL Other Proheparum(Cysteine,	Route	Manufacturer	Role	Product	Report Source	PT		
Initial or Prolonged Professional ORAL Other Proheparum(Cysteine,	ORAL		PS	Diovan			ning	Life-Threate Hospitalizat
Other Proheparum(Cysteine,					Professional		rolonged	
Choline Bitartrate, Liver Hydrolysate,				Choline Bitartrate, Liver Hydrolysate,	Other			
3 DF/DAY,ORAL	ORAL			·			L	3 DF/DAY,ORA
Diazepam (Diazepam) SS C 6 MG/DAY,	ORAL		SS	Diazepam (Diazepam)				6 MG/DAY,

ORAL

600 MG/DAY,	(Cimetidine)	SS	ORAL
ORAL 3	Solon(Sofalcone) Digestive Enzymes(No Ingredients/Substanc es)	SS	ORAL
DOSAGES/DAY,			
ORAL	Eviprostat(Chimaphil a Umbellata, Populus Tremuloides, Sodium Taurocholate, Pulsatilla	SS	ORAL
6			
DOSAGES/DAY,			
ORAL 3 MG/DAY,	Ternelin(Tizanidine Hydrochloride, Tizanidine Hydrocholoride)	SS	ORAL
ORAL	Harnal (Tamsulosin Hydrochloride)	C	
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Freedom Of Information (FOI) Report

Cipro

	SR Number: nder:Male	: 3780457-XReport Type:Direct I/FU:I		Company Report	t#				
Outcome		PT	Report	Source	Product		Role	Manufacturer	Route
Dose D Other	uration	Blood Pressure Decreased			Zanaflex 4 (Sandoz)	Mg	PS	Sandoz	ORAL
2 MG PO. 4 MG					(Dallacz)		- 5	2411402	01112
PO 8 HRS		Fatigue							
		Heart Rate Decreased							
LATER		Respiratory Rate Decreased Sedation			Cardiozem Vasotec Hydrodiuril	L	C C C		
Date:08/22/01I Age:43 YR Ge Outcome		: 3781638-1Report Type:Direct le I/FU:I	Report	Company Report	t # Product		Role	Manufacturer	Route
Dose D	uration		repor s	Dource				Hallatacalet	nouce
Life-Threateni 1 TAB TAKEN	ng	Dysphagia			Zanaflex 4	4 Mg	PS		
		Sedation							
AT BEDTIME					Estrace		С		
Date:08/22/01I Age:79 YR Ge		: 3781932-4Report Type:Direct le I/FU:I		Company Report	t #				
Outcome Dose D	uration	PT	Report	Source	Product		Role	Manufacturer	Route
Hospitalizatio 4 MG DAILY PO		Hepatitis			Zanaflex		PS		ORAL
Initial or Pro	longed				Glucophage Glucotrol X Neurontin	Xl	C C C		

Date:08/31/01ISR Number: 3786636-XReport Type:Direct Company Report # Age:53 YR Gender:Female I/FU:I

Nitroglycerin O	C
Premarin	C
Lopressor	С
Endocet	C
Aciphex	C
Baclofen	C
Paxil	C
Levothroid	C
Lorazepam	C
Methadone Hcl	C
y Report #ZANA000835 (0)	
	Premarin Lopressor Endocet Aciphex Baclofen Paxil Levothroid Lorazepam Methadone Hcl

Product

Product

Zanaflex (Tizanidine

Hydrochloride)

Zanaflex 4 Mg

Role Manufacturer

Role Manufacturer

PS

PS

Route

ORAL

Route

ORAL

Report Source

Report Source

Other

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Hospitalization -

Initial or Prolonged

Outcome

Outcome

Dose

ORAL

4 MG PO Q 8H

Dose

PT

PT

Delirium

Confusional State

Duration

Liver Function Test

Duration

Freedom Of Information (FOI) Report

Role Manufacturer

Route

Product

Date:09/17/01ISR Number: 3794327-4Report Type:Expedited (15-DaCompany Report #ZANA000834 (0)

Age:58 YR Gender:Female I/FU:I

Duration

PT

Outcome

Dose

ORAL

Hospitalization -	Asthenia	Health	Zanaflex (Tizanidine		
Initial or Prolonged 4 MG DAILY	Hyperhidrosis	Professional	Hydrochloride)	PS	ORAL
Other ORAL	Hypotension				
	Pallor		Sporanox	С	
	Syncope		Protonix	С	
			Estratest	C	
			Vioxx	C	
			Synthroid	C	
			Ditropan	C	
Age:42 YR Gender:Mal Outcome Dose Duration Hospitalization -	PT Alanine Aminotransferase	Report Source	Product Zanaflex (Tizanidine	Role Manufacturer	Route
Initial or Prolonged 24 MG DAILY	Increased	Professional	Hydrochloride)	PS	ORAL
	Bradycardia				
ORAL					
	Drug Withdrawal Syndrome		Novantrone	C	
	Nausea		Baclofen	C	
	Orthostatic Hypotension				
	Rebound Hypertension				
	Sedation				
	Tremor				

Report Source

Date:09/21/01ISR Number: 3797301-7Report Type:Expedited (15-DaCompany Report #ZANA000843 (0) Age:73 YR Gender:Male I/FU:I

Vomiting

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Life-Threaten	ning	Blood Pressure Systolic	Literature	Zanaflex (Tizanidine			
Hospitalizati	lon -	Increased	Health	Hydrochloride)	PS		ORAL

Initial or Prolonged	Clonic Convulsion	Professional	Selegiline	С
	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	С

Date:10/05/01ISR Number: 3806714-6Report Type:Expedited (15-DaCompany Report #ZANA000851(0)

Age:59 YR Gender:Female I/FU:I

PT

Dose D	Duration					
Hospitalizatio 8 MG DAILY	on -	Atrial Fibrillation	Consumer	Zanaflex	PS	ORAL
Initial or Pro ORAL	olonged	Hypertension				
Other		Speech Disorder		Synthroid	C	
		Transient Ischaemic		Glucophage	C	
		Attack		Estradiol	C	
				Propoxyphene	C	

Product

Zestril

Role Manufacturer

C

Route

Report Source

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Outcome

Freedom Of Information (FOI) Report

Atenolol C

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Required Intervention to Prevent Permanent Impairment/Damage 500 MG, 1 I 1	Drug Interaction Hypotension Sedation	Foreign Health Professional Other	Depakine (Depakene) (Sodium Valproate/ Valproic Acid) (Sodium	PS		ORAL
D, PER ORAL			Tizanidine Hydrochloride Paracetamil	SS		ORAL
2 MG, 1 IN 1						
D, PER ORAL			Paracetamol	С		
Date:10/12/01ISR Numbe: Age:51 YR Gender:Mal	er: 3810672-8Report Type:Exped e I/FU:I	ited (15-DaCompany Re	eport #001-0945-M0101183			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 300 MG PER	Amnesia Blood Pressure Increased	Consumer	Neurontin (Gabapentin)	PS		ORAL
Other ORAL	Dry Mouth					
	Dysarthria Dysuria		Vioxx (Rofecoxib) Zanaflex	SS		
	Fatigue Miosis Nausea		(Tizanidine)	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 I	Duration						
Other		Fall	Health	Zanaflex (Tizanidine			
		Hypotension	Professional	Hydrochloride)	PS		ORAL
4 MG DAILY							
		Rib Fracture					
ORAL							
				Antihypertensive			
i				Medication	C		
Date:10/17/01I	ISR Number	: 3810616-9Report Type:Expedi	ted (15-DaCompany Repo	rt #ZANA000862 (0)			
Age:61 YR Ge	ender:Male	I/FU:I					
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
	Duration						
Hospitalizatio		Stevens-Johnson Syndrome	Health	Sirdalud (Tizanidine			
Initial or Pro	olonged		Professional	Hydrochloride)	PS		ORAL
ORAL							
			Distributor	Ponstan (Mefenamic			
				Acid)	SS		ORAL
1000 MG DAILY							
ORAL							
				Atorvastatin	C		
				Pradif	C		

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Freedom Of Information (FOI) Report

PS

ORAL

ORAL

ORAL

Date:10/17/01ISR Number: 3810617-OReport Type:Expedited (15-DaCompany Report #ZANA000853 (0)

Gender: Female I/FU:I Age:

Role Manufacturer Outcome PΤ Report Source Product Route

Dose Duration

Other Drug Dependence Health Zanaflex (Tizanidine

Hypertension Professional Hydrochloride)

17 TABS DAILY

Hypotension

ORAL

Date:10/17/01ISR Number: 3810857-OReport Type:Expedited (15-DaCompany Report #ZANA000857 (0)

Age:45 YR Gender: Female I/FU:I

PΤ Report Source Product Role Manufacturer Outcome Route

Duration Dose

Hospitalization -Drug Interaction Foreign Sirdalud (Tizanidine

Initial or Prolonged Fatigue Health Hydrochloride) PS

4 MG DAILY

Oedema Peripheral Professional Other

ORAL

Distributor Vioxx (Rofecoxib) Sinus Bradycardia SS

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

PТ Role Manufacturer Outcome Report Source Product Route

Duration Dose

Complications Of Maternal Celebrex(Celecoxib)C Disability Foreign

Exposure To Therapeutic Other ORAL apsule PS

200 MG, TID,

Drugs 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,	valium (Diazepam)	33
SUBCUTANEOUS			
		Morphine	C
		Tramadol	C
		Paracetamol	C
		Tetrazepam	С
	Jumber: 3811501-9Report Type:Expedited (15-DaCompany Report Female I/FU:I	rt #WAES 00050132	

Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other PO	Duration	Blood Pressure Decreased	- Health	Tab Vioxx	PS	ORAL
		Drug Interaction Dysphagia Hallucination Psychotic Disorder Tachycardia	Professional Other	Zanaflex	SS	

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				

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Freedom Of Information (FOI) Report

Neurontin(Gabapentin

SS

ORAL

Date:10/22/01ISR Number: 3812487-3Report Type:Expedited (15-DaCompany Report #ZANA000865 (0)

Exposure To Therapeutic

Drugs

Sequence	Outcome Oose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
DRAL Date:10/24/01ISR Number: 3814605-XReport Type:Expedited (15-DaCompany Report #ZANA000861 (0) Age:36 YR Gender:Female I/FU:I Dutcome Disability Abdominal Pain Diarrhoea Professional Hydrochloride) FS ORAL ORAL ORAL Gastrointestinal Disorder Nightmare Neuromtin C Neuromtin	Required Intervention		Joint Dislocation	2	· ·	PS		ORAL
Date:10/24/01ISR Number: 3814605-XReport Type:Expedited (15-DaCompany Report #ZANA000861 (0) Age:36 YR Gender:Female I/FU:I Outcome Dose Duration Disability Abdominal Pain Health Zanaflex (Tizanidine Professional Hydrochloride) Precling Hot And Cold ORAL Gastrointestinal Disorder Nightmare Sleep Talking Number: 3820271-XReport Type:Periodic Company Report #2001073793US Age:30 YR Gender:Female I/FU:I Outcome Dose Duration Fer Report Source Product Role Manufacturer Route Pamelor C Sagic C C Company Report #2001073793US Age:30 YR Gender:Female I/FU:I Outcome Dose Duration Complications Of Maternal Consumer Celebrex PS ORAL		anent		Professional				
Date:10/24/01ISR Number: 3814605-XReport Type:Expedited (15-DaCompany Report #ZANA000861 (0) Age:36 YR Gender:Female I/FU:I Outcome Duration Disability Abdominal Pain Health Zanaflex (Tizanidine Professional Hydrochloride) 2 MG DAILY Feeling Hot And Cold ORAL Gastrointestinal Disorder Nightmare Sleep Talking Seep Talking 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 Dose Duration C Maternal Consumer Celebrex PS ORAL	-							
Outcome PT Report Source Product Role Manufacturer Route Dose Duration Disability Abdominal Pain Diarrhoea Professional Hydrochloride) PS ORAL 2 MG DAILY Feeling Hot And Cold ORAL Gastrointestinal Disorder Nightmare Sleep Talking Eagle CLozol CPTilosec CLoestrin 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 Dose Duration Complications Of Maternal Consumer Celebrex PS ORAL	Impairment/D	amage						
Dose Duration Disability				ited (15-DaCompany Re	eport #ZANA000861 (0)			
Disability Abdominal Pain Diarrhoea Professional Health Zanaflex (Tizanidine Hydrochloride) PS ORAL 2 MG DAILY Feeling Hot And Cold ORAL Gastrointestinal Disorder Neurontin C Neurontin C Sleep Talking Maxalt C Esgic C Lozol C Prilosec C Lozol C Prilosec C Lozol C Prilosec C Lozol C C Noestrin 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 Dose Duration Complications Of Maternal Consumer Celebrex PS ORAL			PT	Report Source	Product	Role	Manufacturer	Route
Diarrhoea Professional Hydrochloride) PS ORAL MG DAILY Feeling Hot And Cold ORAL Gastrointestinal Disorder Nightmare Sleep Talking Date:10/31/01ISR Number: 3820271-XReport Type:Periodic Company Report #2001073793US Age:30 YR Gender:Female I/FU:I Outcome Dose Duration Complications Of Maternal Consumer Celebrex PS ORAL		Duration	-1.1.		- 63 (-1 131			
Feeling Hot And Cold ORAL Gastrointestinal Disorder Pamelor C Nightmare Neurontin C Sleep Talking Maxalt C Esgic C Lozol C Prilosec 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 Consumer Celebrex PS ORAL	Disability				· · · · · · · · · · · · · · · · · · ·	DC		$\bigcap D \Lambda T$
Feeling Hot And Cold ORAL 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 Dose Duration Complications Of Maternal Consumer Celebrex PS ORAL	2 MG DATLY		Diarriioea	PIOLESSIONAL	hydrochroride)	PS		URAL
Gastrointestinal Disorder Pamelor C Nightmare Neurontin C Sleep Talking Maxalt C Esgic C Lozol 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 Duration Complications Of Maternal Consumer Celebrex PS ORAL			Feeling Hot And Cold					
Nightmare 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 Dutcome Duration Complications Of Maternal Consumer Celebrex PS ORAL	ORAL							
Sleep Talking Maxalt Esgic Lozol C Prilosec C Loestrin Fe 1.5/30 C Date:10/31/01ISR Number: 3820271-XReport Type:Periodic Age:30 YR Gender:Female I/FU:I Company Report #2001073793US Age:30 YR Gender:Female Outcome PT Report Source Product Role Manufacturer Route Dose Duration Complications Of Maternal Consumer Celebrex PS ORAL								
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 Dutcome PT Report Source Product Role Manufacturer Route Dose Duration Complications Of Maternal Consumer Celebrex PS ORAL								
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 Dutcome PT Report Source Product Role Manufacturer Route Dose Duration Complications Of Maternal Consumer Celebrex PS ORAL			Sleep Talking					
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 Consumer Celebrex PS ORAL					_			
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 Consumer Celebrex PS ORAL								
Age:30 YR Gender:Female I/FU:I Outcome PT Report Source Product Role Manufacturer Route Dose Duration Complications Of Maternal Consumer Celebrex PS ORAL								
Dose Duration Complications Of Maternal Consumer Celebrex PS ORAL				dic Company Re	eport #2001073793US			
Complications Of Maternal Consumer Celebrex PS ORAL		Duration	PT	Report Source	Product	Role	Manufacturer	Route
200 MG, QD,		uration	Complications Of Maternal	Consumer	Celebrex	PS		ORAL

750 MG, BID,

ORAL

Elavil (Amitriptyline

Hydrochloride)

SS

SS

Zanaflex (Tizanidine

Hydrochloride) 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 Hospitalization -

PTCrying

Initial or Prolonged Depressed Level Of Consciousness

Drug Interaction Electrocardiogram

Abnormal

Encephalopathy

Heart Rate Increased

Hypertension Hypotension Joint Stiffness

Pallor

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Freedom Of Information (FOI) Report

	Sedacion					
Duration		Report Source	Product	Role	Manufacturer	Route
Duration		Literature	Lisinopril	PS		
		Health Professional	Lisinopril Tizanidine	SS SS		
			Valium Clonazepam Valproic Acid	C C		
		ed (15-DaCompany Repor	t #ZANA000870 (0)			
Duration	PT	Report Source	Product	Role	Manufacturer	Route
Duracion	Cerebrovascular Accident	Foreign Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
		Professional				
			Aspirin Co-Amilofruse Glibenclamide	C C		
		Company Repor	t #			
Dunahi an	PT	Report Source	Product	Role	Manufacturer	Route
Duration	Erectile Dysfunction		Zanaflex Prevacid	PS C		
		ed (15-DaCompany Repor	t #ZANA000875 (0)			
December 1	PT	Report Source	Product	Role	Manufacturer	Route
puration	Condition Aggravated	Consumer	Zanaflex (Tizanidine			
	Gender:Fema Duration 1ISR Number Gender:Male Duration 1ISR Number	Duration 1ISR Number: 3821962-7Report Type:Expedit Gender:Female I/FU:I PT Duration Cerebrovascular Accident 1ISR Number: 3823151-9Report Type:Direct Gender:Male I/FU:I PT Duration Erectile Dysfunction 1ISR Number: 3824881-5Report Type:Expedit Gender:Male I/FU:I PT Duration	Duration Report Source	Duration Report Source Report Source Literature Lisinopril Realth Professional Tizanidine Valium Clonazepam Valproic Acid 1ISR Number: 3821962-7Report Type:Expedited (15-DaCompany Report #ZANA000870 (0)) PT Puration PT Report Source Product Report Source Product Aspirin Co-Amilofruse Glibenclamide 1/FU:1 PT PT PUration PT Report Source Product Aspirin Co-Amilofruse Glibenclamide 1/FU:1 PT Report Source Product Aspirin Co-Amilofruse Glibenclamide 1/FU:1 Report Source Product Aspirin Co-Amilofruse Glibenclamide 1/FU:1 Report Source Product Aspirin Co-Amilofruse Glibenclamide 1/FU:1 Report Source Product Product	Report Source Product Role Literature Lisinopril PS Health Professional Lisinopril SS Report Source Clonazepam Colonazepam	Duration Duration

Sedation

		Lipitor	C	
r: 3832724-9Report Type:Exped	ited (15-DaCompany Re	eport #001-0945-M0101183		
PT	Report Source	Product	Role Manufacturer	Route
Amnesia	Consumer	Neurontin		
Blood Pressure Increased	Health	(Gabapentin)	PS	ORAL
Depressed Level Of	Professional			
Consciousness Dry Mouth		Vioxx (Rofecoxib) Zanaflex	SS	
Dysarthria Dysuria Fatigue Gait Disturbance Lethargy Miosis Nausea Sedation		(Tizanidine)	SS	
	PT Amnesia Blood Pressure Increased Depressed Level Of Consciousness Dry Mouth Dysarthria Dysuria Fatigue Gait Disturbance Lethargy Miosis Nausea	PT Report Source Amnesia Consumer Blood Pressure Increased Health Depressed Level Of Professional Consciousness Dry Mouth Dysarthria Dysuria Fatigue Gait Disturbance Lethargy Miosis Nausea	Lipitor T: 3832724-9Report Type:Expedited (15-DaCompany Report #001-0945-M0101183 I/FU:F PT Report Source Product Amnesia Consumer Neurontin (Gabapentin) Depressed Level Of Professional Consciousness Vioxx (Rofecoxib) Dry Mouth Zanaflex (Tizanidine) Dysarthria Dysarthria (Tizanidine) Pysuria Fatigue Gait Disturbance Lethargy Miosis Nausea	Lipitor C r: 3832724-9Report Type:Expedited (15-DaCompany Report #001-0945-M0101183 and I/FU:F PT Report Source Product Role Manufacturer Amnesia Consumer Neurontin (Gabapentin) PS Depressed Level Of Professional Consciousness Vioxx (Rofecoxib) SS Dry Mouth Zanaflex (Tizanidine) SS Dysuria Fatigue Gait Disturbance Lethargy Miosis Nausea

Hydrochloride)

Toprol Xl

Babypyrin

PS

С

С

ORAL

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Other

ORAL

4 MG DAILY

Difficulty In Walking

Dyspnoea

Pain

Muscle Spasms

Freedom Of Information (FOI) Report

С

Neurontin

Date:12/12/01ISR Number: 3839471-8Report Type:Expedited (15-DaCompany Report #ZANA000880 (0)

	IISR Number Gender:Fema	: 38394/1-8Report Type:Exp le I/FU:I	eartea (15-DaCompany Re	±POLC #ZWWAAAAAA (A)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P 2 MG DAILY		Flushing Headache	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
ORAL		Migraine					
ORAL		Rebound Hypertension Tremor		Theophylline Xr (Theophylline) Albuterol	SS		
				(Salbutamol) Celebrex	SS C		
				"Steroid Spinal Injections"	С		
Outcome Dose	Gender:Male	PT	Report Source	Product		Manufacturer	Route
Dose Other 500 MG DAILY	ose Duration ther	Bradycardia	Foreign	Ciprofloxacin	PS		
		Hypotension Hypotonia	Health Professional Other	Tizanidine	SS		
	lISR Number Gender:Fema	: 3840878-3Report Type:Exp	edited (15-DaCompany Re	eport #ZANA000885 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Electrocardiogram Qt Prolonged	Foreign Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
4 MG DAILY		Syncope	Professional				
ORAL		-		Prozac	С		
				Vioxx	C		

Date:12/20/01ISR Number: 3843372-9Report Type:Expedited (15-DaCompany Report #HQ9319810DEC2001

Age:75 YR Gender:Male I/FU:I

Fatigue

Hallucination, Visual

Outcome	D +	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat: Initial or P: Disability Other 8 MG 1 X PER		Bradycardia Coma Hypotension	Foreign Health Professional Other	Cordarone (Amiodarone, Tablet) Sirdalud (Tizanidine Hydrochloride,)	PS SS		ORAL
1 DAY	1 DAY			Tramal-Slow Release (Tramadol Hydrochloride)	SS		ORAL
	lISR Number Gender:Male	: 3844568-2Report Type:Expedit I/FU:I	ted (15-DaCompany Repor	t #ZANA000891(0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Disability 16 MG DAILY	242402011	Confusional State Disturbance In Attention	Foreign Health	Zanaflex (Tizanidne Hydrochloride)	PS		ORAL

Professional

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ORAL

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 - ORAL	Hepatic Failure	Professional	Hydrochloride)	PS	ORAL
Initial or Prolonged	Loss Of Consciousness		Lipitor		
	Renal Failure Acute		(Atorvastatin)	SS	ORAL
ORAL					
	Respiratory Failure		Atenolol	C	
	Rhabdomyolysis		Toradol	C	
			Lidoderm Patch	С	

Date:12/26/01ISR Number: 3845205-3Report Type:Expedited (15-DaCompany Report #ZANA000892 (0)

Age:46 YR Gender:Female I/FU:I

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
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

ORAL

riger 51 Tit Geriaer man	1/10-1				
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Hospitalization -	Amnesia	Consumer	Neurontin		
Initial or Prolonged 300 MG	Blood Pressure Increased	Health	(Gabapentin)	PS	ORAL
Disability	Confusional State	Professional			
(ONCE), PER					
Other	Difficulty In Walking				

		Dysuria				
PER ORAL		Fatigue		Zanaflex		
		Gait Disturbance		(Tizanidine)	SS	ORAL
2 MG (ONCE),				,		
		Hemiparesis				
PER ORAL						
		Lethargy Loss Of Consciousness Memory Impairment Mental Status Changes Miosis Nausea Photophobia Somnolence Speech Disorder		(Clopidogrel)	C	
	lISR Number Gender:	: 3864582-0Report Type:Peri I/FU:I	odic Company Re	eport #WAES 01112908		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration		7.1			
25 MG/ PO		Asthenia	Health	Tab Vioxx	PS	ORAL
		Drug Interaction	Professional	Ultram	SS	
		Fatigue	Company	Zanaflex	SS	
			Representative	Neurontin	SS	

Vioxx (Rofecoxib)

SS

ORAL

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Dysarthria

50 MG (ONCE),

Freedom Of Information (FOI) Report

SS

Date:12/28/01ISR Number: 3845935-3Report Type:Direct Company Report #CTU 157992 Gender: Male Age: I/FU:I Report Source Role Manufacturer Outcome PTProduct Route Dose Duration Disability Nystagmus Tizanidine(2 Mg) Required Vertigo (Athena Intervention to Neurosciences Inc) Athena Neurosciences PS ORAL 2 MG QHS ORAL Prevent Permanent Amitriptyline С Sertraline Impairment/Damage С Gabapentin С Methadone Date:12/31/01ISR Number: 3846940-3Report Type:Expedited (15-DaCompany Report #EMADSS2001007513 Age:75 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Accidental Overdose Tramadol Foreign Initial or Prolonged Bradycardia Health Hydrochloride PS ORAL 100 MG, 3 IN Professional Coma 1 DAY(S), Drug Interaction ORAL Sirdalud (Tizanidine Hypotension Spinal Fracture Hydrochloride) SS 16-OCT-2001 HE WAS FIRST GIVEN Cordarone (Amiodarone Hydrochloride) ORAL

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

Date:01/07/02ISR Number: 3849534-9Report Type:Expedited (15-DaCompany Report #200111032BNE

ORAL

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration				

	Hypotonia Muscular Weakness		in column one		
Date:01/08/02ISR Number Age:34 YR Gender:Male	r: 3849864-0Report Type:Exped	lited (15-DaCompany Re	eport #PHBS2001JP11095		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged	Aspartate Aminotransferase	Foreign Health	Lamisil (Terbinafine Hydrochloride)		
Disability 125 MG/D,	Increased	Professional	Tablet	PS	ORAL
ORAL	Blood Creatine	Other			
	Phosphokinase Increased Blood Lactate		Lornoxicam(Lornoxica m)	SS	ORAL
4 MG/D, ORAL 10 DAY	Y Dehydrogenase Increased Malaise		Ternelin (Tizanidine Hydrochloride, Tizanidine		
1 MG/D, ORAL 10 DAY	Y		Hydrochloride)	SS	ORAL
			Mucosta (Rebamipide)	С	

Ciprofloxacin

Tizanidine

Oxybutynin

Mitozantrone

PS

SS

С

С

ORAL

ORAL

Foreign

Health

Other

Professional

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Life-Threatening

6 MG QID ORAL 4

500 MG BID Other

ORAL

Asthenia

YR

Bradycardia

Potentiation

Hypotension

Drug Interaction

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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 Hospitalizat		Hypotension		Zanaflex (4mg)	PS		
4MG 2 TAB PO Initial or P TID							
TID				Celebrex	С		
				Naproxen	C		
				Prilosec	С		
				Orphenadrine	С		
				Synthroid	С		
				Triam/Hctz	C		
				Atenolol	C		
				Lotrel	С		
Date:01/09/(Age:44 YR	02ISR Numbe Gender:Male		ype:Expedited (15-DaCompany Repo	ort #ZANA000873 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route

Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Alanine Aminotransferase Increased	Foreign Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
24 MG DAILY ORAL		Aspartate	Professional				
OKAL		Aminotransferase		Oxybutynin	С		

Aminotransferase
Increased
Blood Bilirubin Increased
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 PTReport 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 С Neurontin С Hypertension Hypotension Voltaren С Hypovolaemia Vioxx С

Date:01/17/02ISR Number: 3854196-OReport 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

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Freedom Of Information (FOI) Report

Malaise

Dose	Duration		Report Source	Product	Role	Manufacturer	Route
	Duracion		Health Professional	Ciflox (Ciprofloxacin)	PS		ORAL
1000 MG DAILY	Y			(01,1011010111)	- 0		01111
ORAL			Other				
				Sirdalud (Tizanidine Hydrochloride)	SS		ORAL
SEE IMAGE				Lioresal (Baclofen)	CC		ODAT
SEE IMAGE				Lioresal (Bacloien)	SS		ORAL
				Myolastan (Tetrazepam)	SS		ORAL
75 MG DAILY				(Teerazepani)	DD		OKAL
ORAL							
				Voltarene	C		
				Zyloric	С		
				Verospiron	С		
				Pantozol	C		
				L!Snesium	C		
				Melperon	C C		
				Zocor	C		
	2ISR Number Gender:Male	: 3854822-6Report Type:Expe	edited (15-DaCompany Re	eport #ZANA000896 (0)			
Age:38 YR (Outcome	Gender:Male		edited (15-DaCompany Re Report Source	eport #ZANA000896 (0) Product	Role	Manufacturer	Route
Age:38 YR (Outcome Dose	Gender:Male Duration	I/FU:I	Report Source	Product	Role	Manufacturer	Route
Age:38 YR (Outcome Dose	Gender:Male Duration	I/FU:I PT Bradycardia	Report Source Foreign	Product Zanaflex (Tizanidine		Manufacturer	
Age:38 YR (Outcome Dose Life-Threater	Gender:Male Duration	I/FU:I	Report Source	Product	Role	Manufacturer	Route ORAL
Age:38 YR (Outcome Oose Life-Threater	Gender:Male Duration	I/FU:I PT Bradycardia Drug Effect Increased	Report Source Foreign Health	Product Zanaflex (Tizanidine		Manufacturer	
Age:38 YR (Outcome Dose Life-Threater 24 MG DAILY	Gender:Male Duration	I/FU:I PT Bradycardia	Report Source Foreign	Product Zanaflex (Tizanidine		Manufacturer	
Age:38 YR (Outcome Dose Life-Threater 24 MG DAILY	Gender:Male Duration	I/FU:I PT Bradycardia Drug Effect Increased Drug Interaction	Report Source Foreign Health	Product Zanaflex (Tizanidine Hydrochloride)		Manufacturer	
Age:38 YR (Dutcome Dose Life-Threater 24 MG DAILY	Gender:Male Duration	I/FU:I PT Bradycardia Drug Effect Increased	Report Source Foreign Health	Product Zanaflex (Tizanidine Hydrochloride) Ciproxin		Manufacturer	
Age:38 YR (Dutcome Dose Life-Threater 24 MG DAILY DRAL	Gender:Male Duration	I/FU:I PT Bradycardia Drug Effect Increased Drug Interaction Hypotension	Report Source Foreign Health	Product Zanaflex (Tizanidine Hydrochloride)	PS	Manufacturer	ORAL
Age:38 YR (Gender:Male Duration	I/FU:I PT Bradycardia Drug Effect Increased Drug Interaction Hypotension	Report Source Foreign Health	Product Zanaflex (Tizanidine Hydrochloride) Ciproxin (Ciprofloxacin)	PS SS	Manufacturer	ORAL
Age:38 YR (Outcome Dose Life-Threater 24 MG DAILY ORAL	Gender:Male Duration	I/FU:I PT Bradycardia Drug Effect Increased Drug Interaction Hypotension	Report Source Foreign Health	Product Zanaflex (Tizanidine Hydrochloride) Ciproxin	PS	Manufacturer	ORAL

Date:01/17/02ISR Number: 3855884-2Report Type:Expedited (15-DaCompany Report #ZANA000897 (0)

Age:79 YR Gender:Female I/FU:I

Outcome	December 1	PT	Report Source	Product	Role	Manufacturer	Route
Dose Life-Threater	Duration	Hypotension	Foreign	Zanaflex (Tizanidine			
nile illeacei	11119	Sepsis	Health	Hydrochloride)	PS		ORAL
6 MG DAILY		26,212		11, 41 0011101 140,			01412
			Professional				
ORAL							
				Enoxaparin Sodium	C		
				Frusemide	C C		
				Atenolol	C		
	2ISR Number Gender:Male	: 3860390-5Report Type:Expedit	ced (15-DaCompany Repor	rt #PHRM2002FR00519			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	D 1					
Hospitalizati Initial or Pr		Bradypnoea Drug Interaction	Foreign Health	Lioresal(Baclofen)Ta blet	PS		ORAL
30 MG DAILY,	oronged	Drug Interaction	nearch	biec	PS		ORAL
50 NG DILLLI,		Hypotension	Professional				
ORAL		71					
		Hypotonia	Other	Sirdalud(Tizanidine			
		Malaise		Hydrochloride)	SS		ORAL
12 MG DAILY,							
ODAT		Skin Infection					
ORAL				Myolastan(Tetrazepam			
)	SS		ORAL
75 MG PER				1	55		OIGIL
DAY, ORAL							
DIII, OKAL							

Ciflox(Ciprofloxacin

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Freedom Of Information (FOI) Report

1 G DAILY

ORAL

Neurontin

Oxycontin

)Tablet

Voltarene Lp (Diclofenac Sodium) C

SS

C

C

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - INTRAVENOUS 40.00	Bradycardia MG	Foreign	Feldene Capsules	PS	
Initial or Prolonged FOTAL; DAILY;	Confusional State	Health			
INTRAVENOUS	Drug Abuser	Professional			
2200.00 MG	Drug Interaction		Gabapentin	SS	ORAL
TOTAL; ORAL	Drug Level Increased				
12.00 MG	Dysarthria		Tizanidine	SS	ORAL
TOTAL; ORAL	Dysphagia				
	Hallucination Hypertension		Seropram Voltaren	C C	
	Hypotension Hypovolaemia		Vioxx	C	
Date:02/04/02ISR Number Age:47 YR Gender:Fema	:: 3865091-5Report Type:Expedit le I/FU:I	ed (15-DaCompany Repor	t #ZANA000901 (0)		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Death Duracion	Hyperpyrexia	Health	Zanaflex (Tizanidine		

Date:02/06/02ISR Number: 3865672-9Report Type:Expedited (15-DaCompany Report #ZANA000902 (0) Age:41 YR Gender: Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Disability Dysphemia Health Zanaflex (Tizandine Professional Hydrochloride) ORAL PS 6 MG ORAL Vioxx С Date:02/07/02ISR Number: 3867637-XReport Type:Expedited (15-DaCompany Report #PHBS2001JP11095 Age:34 YR Gender:Male I/FU:F Report Source Role Manufacturer Outcome PTProduct Route Duration Dose Hospitalization -Lamisil (Terbinafine Aspartate Foreign Initial or Prolonged Health Aminotransferase Hydrochloride) Disability Professional Tablet ORAL Increased PS 125 MG/D, Blood Creatine Other

ORAL

т

10

Phosphokinase Increased Lornoxicam
Blood Lactate (Lornoxicam)

DAY

Dehydrogenase Increased Ternelin (Tizanidine

Malaise Hydrochloride,

Tizanidine Hydrochloride)

Hydrochloride) Unknown

1 MG/D, ORAL 10 DAY
Mucosta (Rebamipide) C

SS

SS

ORAL

ORAL

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4 MG/D, ORAL

Freedom Of Information (FOI) Report

Voltarene Lp

(Diclofenac Sodium) C

Date:02/08/02ISR Number: 3866916-XReport Type:Direct Company Report #CTU 161325

Age:56 YR Gender:Female I/FU:I

1 G DAILY

Age:56 YR Gender:Fem	ale I/FU:I				
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration			- 63		
Life-Threatening 4 MG 3X A	Bladder Pain		Zanaflex 4 Mg	PS	ORAL
Required DAY ORAL	Blood Cholesterol				
Intervention to	Increased				
Prevent Permanent	Blood Triglycerides				
Impairment/Damage	Increased				
	Dysuria				
	Hepatomegaly				
Date:02/08/02ISR Numbe Age:24 YR Gender:Mal	r: 3867329-7Report Type:Exp e I/FU:F	pedited (15-DaCompany Re	eport #PHRM2002FR00519		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Hospitalization -	Bradycardia	Foreign	Lioresal (Baclofen)		
Initial or Prolonged 30 MG DAILY,	Drug Interaction	Health	Tablet	PS	ORAL
	Hypotension	Professional			
ORAL					
	Hypotonia Malaise	Other	Sirdalud (Tizanidine Hydrochloride)		
			Unknown	SS	ORAL
12 MG DAILY,					
ORAL					
			Myolastan	~~	0.7.7
75 MG PER			(Tetrazepam)	SS	ORAL
DAY, ORAL					
			Ciflox		
			(Ciprofloxacin)		
			Tablet	SS	

on Hypersensitivity	Health Professional	Zanaflex (Tizanidine		
	TICICODICIAL	Hydrochloride)	PS	ORAL
		ny di deni di lac /		Oldin
		Vicodin	С	
		Keflex	С	
		Ortho-Novum	С	
		Diazepam	С	
		Percocet	С	
		Ibuprofen	С	
	nber: 3868898-3Report Type:I	mber: 3868898-3Report Type:Expedited (15-DaCompany Re	Keflex Ortho-Novum Diazepam Percocet	Keflex C Ortho-Novum C Diazepam C Percocet C Ibuprofen C

Date:02/08/02ISR Number: 3868545-OReport Type:Expedited (15-DaCompany Report #ZANA000910 (0)

I/FU:I Gender: Female Age:

Report Source Product Outcome PTRole Manufacturer Route Dose Duration Drug Withdrawal Syndrome Zanaflex (Tizanidine Other Health Overdose Hydrochloride) Professional PS ORAL

ORAL

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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 -	n Bradycardia	Foreign	Neurontin		
Initial or Prolonged 2200 MG		Health	(Gabapentin)	PS	ORAL
	Drug Abuser	Professional			
(DAILY), PER					
	Drug Interaction				
ORAL	Drug Level Above		(Piroxicam)	SS	
INTRAMUSCULAR 40 N			(PIIOXICAIII)	55	
	Therapeutic				
INTRAMUSCULAR	-				
	Dysarthria		(Tizanidine		
10 MG DED	Dysphagia		Hydrochloride)	SS	ORAL
12 MG, PER	Hallucination				
ORAL	natiucinacion				
	Hypertension		(Citalopram		
	Hypotension		Hydrobromide)	SS	ORAL
PER ORAL				_	
	Hypovolaemia		(Diclofenac Sodium)	C	
			(Rofecoxib)	С	
Date:02/21/02ISR Numb	oer: 3872735-0Report Type:D	irect Company Re	eport #CTU 162008		

Role Manufacturer Outcome Report Source Product Route Dose Duration Dizziness Zanaflex (4mg) PS ORAL

Hospitalization -

4MG PO QID

Age: 45 YR Gender: Female

Electrocardiogram Qt

I/FU:I

Initial or Prolonged

PT

Prolonged

Date:02/22/02ISR Number: 3875053-XReport Type:Expedited (15-DaCompany Report #ZANA000914 (0) Age:60 YR Gender:Female I/FU:I

Outcome PTReport Source Product Role Manufacturer Route Dose Duration Life-Threatening

Ammonia Increased Health Zanaflex (Tizanidine

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Other	Drug Interaction Fatigue	Consumer Other	Cipro (Ciprofloxacin Hydrochloride)	PS	ORAL
500 MG BID;	-		-		
ORAL	Speech Disorder				
			Zanaflex (Tizanidine Hydrochloride)	SS	ORAL
4 MG DAILY;			•		
ORAL					
			Fibercon	C	
			Vit C	C	
			Multivitamin	C	
			Mevacor	C	
			Tylenol	С	

Professional

Hydrochloride)

Ascriptin

Lopressor

Norvasc

PS

С

С

С

ORAL

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Hospitalization - 4 - 6 MG

DAILY ORAL

Initial or Prolonged

Hallucination, Visual

Hepatitis

Hyperglycaemia

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Freedom Of Information (FOI) Report

Role Manufacturer

Route

Product

Citalopram

Voltaren

Vioxx

SS

С

С

Date:02/28/02ISR Number: 3889406-7Report Type:Periodic Company Report #001-0945-M0100756

Outcome

TOTAL: ORAL

20.00 MG

TOTAL

PT

Hallucination

Hypertension

Hypotension

Hypovolaemia

Medication Error

Age:59 YR Gender: Male I/FU:I

· ·		nepore bource	1100000	nore nanaracearer	nouce
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				
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration			- 11		
Hospitalization -	Bradycardia	Foreign	Feldene Capsules	PS	
	00 MG	1.1			
Initial or Prolonged	Confusional State	Health			
TOTAL:DAILY:I					
	Drug Interaction	Professional			
NTRAMUSCULAR					
2200.00 MG	Drug Level Above		Gabapentin	SS	ORAL
	_		Gabapentin	SS	ORAL
TOTAL:ORAL	Drug Level Above Therapeutic		Gabapentin	SS	ORAL
	Therapeutic		-		
	_		Gabapentin Tizanidine	SS	ORAL
12.00 MG	Therapeutic Dysarthria		-		
12.00 MG	Therapeutic		-		-

Report Source

Date:03/05/02ISR Number: 3877686-3Report Type:Expedited (15-DaCompany Report #WAES 0202CAN00128

Urinary Tract Infection

Ventricular Tachycardia

Age:57 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Paralysis	Health Professional	Vioxx Tizanidine	PS		ORAL
9 WK				Hydrochloride	SS		ORAL
y Wit				Tolterodine Tartrate	С	Merck & Co., Inc	ORAL
	02ISR Number Gender:Male	: 3881712-5Report Type:Exped: I/FU:I	ited (15-DaCompany Re	eport #ZANA000918 (0)			
			ited (15-DaCompany Re Report Source	eport #ZANA000918 (0) Product	Role	Manufacturer	Route
Age: Outcome	Gender:Male	I/FU:I			Role	Manufacturer	Route
Age: Outcome Dose	Gender:Male Duration ening tion -	I/FU:I	Report Source	Product	Role	Manufacturer	Route ORAL

Baclofen

Gabapentin

Methadone

C

C

C

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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
-----------	-------------	--------

Age:35 YR Gender:Male	I/FU:I				
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged 32 MG DAILY	Bradycardia	Foreign Health	Zanaflex (Tizanidine Hydrochloride)	PS	ORAL
01 110 21121		Professional			
ORAL				_	
			Interferon Fluoxetine Baclofen	C C	
			Baciolen	С	
Age:57 YR Gender:Male	I/FU:I PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Other	Paralysis	Foreign	Tab Vioxx		
25 MG/DAILY		Other	(Rofecoxib)	PS	ORAL
PO					
			Tizanidine Hydrochloride	SS	ORAL
			nyarochrorrae	55	URAL
8 MG/DAILY PO					
8 MG/DAILY PO			Tolterodine Tartrate	С	
8 MG/DAILY PO			Tolterodine Tartrate	C	

Age: Gender:Female I/FU:I

PT

Outcome

Duration Dose Hallucination, Auditory Health Other Zanaflex (Tizanidine Professional Hydrochloride) PS ORAL ORAL Percocet С

Product

Role Manufacturer

Route

Report Source

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
	uration						
Hospitalization		Asthenia	Foreign	Tab Vioxx			
Initial or Prol 25 MG/DAILY	longed	Drug Interaction	Other	(Rofecoxib)	PS		ORAL
Other		Fatigue					
PO	5 D	PAY					
		Oedema Peripheral		Tab Tizanidine	SS		ORAL
4 MG/DAILY	5 D	PAY					
		Sinus Bradycardia					
		per: 3887412-XReport Type:E	Expedited (15-DaCompany R	eport #ZANA000930 (0)			
Age:30 YR Ger	nder:Fe	emale I/FU:I					
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
	uration						
Hospitalization		Asthenia	Consumer	Zanaflex (Tizanidine			
Initial or Prol ORAL	longed	Bacteraemia		Hydrochloride)	PS		ORAL
		Cough		Low-Ogestrel	C		
		Headache		Steroid Epidural	C		
		Infection		Ibuprofen	C		
		Inflammation					
		Influenza Like Illness					
		Malaise					
		Nausea					
		Pain					
		Procedural Complication	1				
		Pyrexia					
		Urinary Tract Infection	n				
20 7 2005 16	0.00 DW	Urinary Tract Infection Vomiting	ı				

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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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat Initial or P ORAL	ion -	Crying Headache	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
		Influenza Like Illness Malaise Nausea Pain Urinary Tract Infection Vomiting		Low -Ogestrel Steroid Epidural	C C		
	2ISR Number Gender:	: 3890402-4Report Type:Direct I/FU:I	Company Repor	rt #USP 54808			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Durati	Duracion	Medication Error		Zanaflex Gabitril	PS SS	Athena Cephalon	
	2ISR Number Gender:Fema	: 3902957-1Report Type:Expedit le I/FU:I	ced (15-DaCompany Repor	rt #ZANA000939 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Drug Withdrawal Syndrome	Health	Zanafley (Tizanidine			· ·

Other Drug Withdrawal Syndrome Health Zanaflex (Tizanidine Rebound Hypertension Professional Hydrochloride) PS ORAL

Baclofen

С

16 MG DAILY

ORAL

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

ORAL				~	
			Vicodin Keflex	C	
			Ortho-Novum	C C	
			OP LIIO-NOV uiii	C	
Date:04/22/02ISR Numbe Age:58 YR Gender:Fem	er: 3904511-4Report Type:Dire	ect Company Re	eport #CTU 166324		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Other	Confusional State		Zanaflex	PS	
TWICE/DAY				-	
	Depression		Atenolol	C	
	Disorientation		Neurontin	С	l
			Lorazepam	С	
			Pravachol	C	
			Aciphex	С	
Date:04/22/02ISR Numbe Age:81 YR Gender:Mal	er: 3905326-3Report Type:Expe e I/FU:I	edited (15-DaCompany Re	eport #200210184BNE		
Outcome	PT	Report Source			

Foreign

Health

Professional

Hydrochloride)

PS

ORAL

Other

Other

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Lymphoma

Skin Disorder

8 MG DAILY

Freedom Of Information (FOI) Report

Professional Other

Dogo	Duration			Product	Role	Manufacturer	Route
Dose 30 MG DAILY	Duracion			Nifedipine	PS		ORAL
ORAL							
				Betaxolol Allopurinol	SS SS		
100 MG DAILY				Simvastatin	SS		
10 MG DAILY				Enalapril	SS		
20 MG DAILY							-
150 MG DAILY				Nizatidine	SS		
				Aspirin (Acetylsalicylic Acid)	SS		
75 MG DAILY							
				Paracetamol Tizanidine	SS SS		
2 MG DAILY				Prazosin	SS		
500 UG TID				114200111			
	2ISR Number: Gender:Male	: 3907853-1Report Type:Expedit I/FU:I	ed (15-DaCompany Report	t #ZANA000941 (0)			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other		Lymphoma Skin Disorder	Foreign Health Professional	Zanaflex (Tizanidine	5.0		077T
2 MG DAILY			Professional	Hydrochloride)	PS	•	ORAL
ORAL							
	ODUMII			Betaxolol (Betaxolol)	SS		
OPHTHALMIC	ОРНТН			Allopurinol (Allopurinol)	SS		
100 MG DAILY				Simvastatin			

10 MG DAILY			(Simvastatin)	SS	
10 MG DAILI			Enalapril (Enalapril)	SS	
20 MG DAILY			Nifedipine		
			(Nifedipine)	SS	
30 MG DAILY			Nizatidine		
			(Nizatidine)	SS	
150 MG DAILY					
			Aspirin (Acetylsalicylic		
I			Acid)	SS	
75 MG DAILY			Paracetamol		
			(Paracetamol)	SS	
2 PRN					
			Prazosin (Prazosin)	SS	
500 MCG DAILY			(114200111)		
Date:04/25/02ISR Number Age: Gender:Male	r: 3907899-3Report Type:Ex = I/FU:I	spedited (15-DaCompany Re	eport #ZANA000940 (0)		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization -	Acute Psychosis	Health	Zanaflex (Tizanidine		I
Initial or Prolonged 36 MG DAILY	Agitation	Professional	Hydrochloride)	PS	ORAL
	Arthralgia				
ORAL	Confusional State		Baclofen	3	
	Confusional State Fall		Baclofen Oxycontin	C C	I
	Hallucination		ON CONCIN	C	

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Insomnia

Vomiting

Urinary Tract Infection

Freedom Of Information (FOI) Report

Date:04/25/02ISR Number: 3907906-8Report Type:Expedited (15-DaCompany Report #ZANA000942 (0)

(DAILY)

Age: Gender: Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Urinary Tract Infection Health Zanaflex (Tizanidine Initial or Prolonged Professional Hydrochloride) PS ORAL 6 MG DAILY ORAL Baclofen С Oxycontin Date:04/26/02ISR Number: 3908302-XReport Type:Expedited (15-DaCompany Report #200200069 Gender:Male I/FU:I Age: PTReport Source Role Manufacturer Outcome Product Route Dose Duration Prazosin (Prazosin) Other Lymphoma Foreign PS 1.5 MG (TID) Health Nifedipine(Nifedipin Professional e) SS 30 MG (DAILY) Other Allopurinol SS 100 MG (DAILY) Simvastatin SS 10 MG (DAILY) Enalapril SS 20 MG (DAILY) Betaxolol SS OPHTHALMIC (BID) OPHTHALMIC Acetylsalicylic Acid SS 75 MG (DAILY) Paracetamol SS Tizanidine SS 2 MG (DAILY) Nizatidine SS 150 MG

Date:04/30/02ISR Number: 3910374-3Report Type:Expedited (15-DaCompany Report #PHBS2002JP04033 Age:63 YR Gender:Female I/FU:F

	1/10-1				
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization -	Erythema	Foreign	Diovan (Valsartan)		
Initial or Prolonged 40 MG, QD,	Erythema Multiforme	Health	Tablet	PS	ORAL
40 MG, QD,	Face Oedema	Professional			
ORAL	race dedella	Professionar			
	Pruritus	Other	Osteluc (Etodolac)	SS	ORAL
100 MG, TID,					
ORAL					
			Mecobamide		
			(Mecobalamin)	SS	ORAL
500 UG, TID,					
ORAL					
			Ternelin (Tizanidine	<u>e</u>	

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 Dose	Durati	on	PT	Report Source	Product	Role	Manufacturer	Route
Death	Duraci	OII	Abdominal Distension Abdominal Pain	Study Health	Actos Tablets 30 (Pioglitazone			
00			Hepatic Neoplasm	Professional	(Flogificazone Hydrochloride)	PS		ORAL
30 MG	582	DAY	Malignant		Dihydroergocristine			
PER ORAL	4	YR	Hepatic Steatosis		Mesilate	SS		ORAL
PER ORAL	4	IK			Zaltoprofen	SS		ORAL
PER ORAL	946	DAY						
					Glibenclamide	SS		ORAL
3.5 MG /								
1.25 MG	337	DAY				99		0077
1.5 GM PER					Teprenone	SS		ORAL
ORAL	946	DAY						

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Freedom Of Information (FOI) Report

Cipro (Ciprofloxacin

			Tizanidine			
PER ORAL 673 DAY	7		Hydrochloride	SS		ORAL
PER ORAL 0/3 DAI	•		Ticlopidine			
			Hydrochloride	С		
			Dihydroergocristine Mesilate	С		
			Zaltoprofen	C		
			Tizanidine			
			Hydrochloride	C		
			Teprenone Glibenclamide	C C		
			off Deliotamitae	C		
Date:05/13/02ISR Number Age: Gender:Fema	r: 3915665-8Report Type:Expedit ale I/FU:I	ted (15-DaCompany Repor	rt #ZANA000954 (0)			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Blood Pressure Decreased	Health Professional	Zanaflex (Tizanidine	DC		ORAL
8 MG DAILY	Bradycardia	Professional	Hydrochloride)	PS		UKAL
0 1.0 2	Dizziness					
ORAL			~ .11.1	~		
	Hallucination Heart Rate Increased		Synthroid Tylenol	C C		
	Hypotension		TYTCHOT	C		
	r: 3916451-5Report Type:Direct	Company Repor	rt #CTU 167997			
Age:48 YR Gender:Fema	ale I/FU:I					
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Hypersensitivity		Zanaflex	PS		
Initial or Prolonged			Baclofen	SS		
Date:05/14/02ISR Number Age:53 YR Gender:Male	c: 3916935-XReport Type:Expedit	ted (15-DaCompany Repor	rt #200211271BWH			
Age.55 ik Gender.Male	: 1/FU-F					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dawa D+:						

Consumer

Dose

Other

Duration

Drug Interaction

ORAL		Speech Disorder	FIOLESSIONAL			
ORAL			Other	Zanaflex (Tizanidine		
				Hydrochloride)	SS	ORAL
4 MG DAILY						
ORAL					~	
				Fibercon	C	
				Vit C	C	
				Multivitamin	C	
I				Mevacor	C	
I				Clonazepam	C	
				Tylenol	С	
i						
D 105/17/	0070D N	. 20107F1 1D	1': 1 /15 D-G D	. "77777000055 (0)		
		: 3918751-1Report Type:Expe	edited (15-DaCompany kep	ort #ZANAUUU955 (U)		
Age:	Gender:Fema	ale I/FU:I				
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration		_			
Other		Dry Mouth	Consumer	Zanaflex (Tizanidine		
		Feeling Abnormal	-	Hydrochloride)	PS	ORAL
24 MG DAILY						
		Hallucination, Visual				
ORAL		110111011111111111111111111111111111111				
OTULE				1'	a	F
		Hypoaesthesia		Valiim	(
i		Hypoaesthesia		Valium Talwin	C	
1		Hypoaesthesia		Talwin	C	
		Hypoaesthesia				
22 7112-2005	12.00 DM	Hypoaesthesia		Talwin	C	
22-Aug-2005	12:09 PM	Hypoaesthesia		Talwin	C	
22-Aug-2005 Page: 124	12:09 PM	Hypoaesthesia		Talwin	C	
	12:09 PM	Hypoaesthesia		Talwin	C	

Hydrochloride)

PS

ORAL

Health

Professional

Fatigue

Speech Disorder

500 MG BID

Freedom Of Information (FOI) Report

Maxipime (Cefepime)

Targocid(Teicoplanin

Date:05/22/02ISR Number: 3920186-2Report Type:Direct Company Report #USP 54846

Prolonged

Pancytopenia

Age:33 YR	Gender: Fema	ale I/FU:I	Company in	5,010 11010			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Medication Error		Zanaflex (Tizanidine Hydrochloride) Anaflex (Salsalate)	PS SS	Athena Neurosciences	
Date:05/22/(Age:69 YR		r: 3921212-7Report Type:Expe ale I/FU:I	dited (15-DaCompany Re	eport #ZANA000956 (0)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or F 4 MG DAILY		Atrioventricular Block First Degree	Consumer Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
		Bradycardia	Professional				
ORAL		Disorientation		Neurontin	С		
		Dry Mouth		Alloprin	C		
		Gait Disturbance		Dyazide	C		
		Heart Rate Increased		Asa	C		
		Hypotension		Vitamin Nos	C		
				Calcium	С		
				Vioxx	С		
	02ISR Number Gender:Male	: 3924560-XReport Type:Expe	dited (15-DaCompany Re	eport #EMADSS2002003182			
Outgomo		PT	Report Source	Product	Dolo	Manufacturer	Doute
Outcome Dose	Duration	PI	Report Source	Product	KOTE	Manuracturer	Route
Disability	Daracion	Agranulocytosis	Foreign	Sporanox			
-		Back Pain	Health	(Unspecified)			
		Bacterial Infection	Professional	(Itraconazole)	PS		ORAL
800 MG,							
		Blood Culture Positive					
DAYS(S), ORA	AL	Drug Interaction		Sidalud (Tizanidine)	CC		
		Drug Interaction Drug Level Increased		Mst (Morphine	SS		
		Electrocardiogram Qt		MSt (Morphine Sulfate)	С		
l		Ercerocardrogram Qe		Surface)	~		

Pyrexia)	С
Tooth Infection	Flagyl	
	(Metronidazole)	C
	Neupogene	
	(Filgrastim)	C
	Liquemine (Heparin	
	Sodium)	C
	Antra (Omeprazole)	C
	Frangulae-Rudolac	C

Report Source

Date:05/28/02ISR Number: 3925259-6Report Type:Expedited (15-DaCompany Report #ZANA000959 (0)

Age:50 YR Gender:Female I/FU:I

PT

Dose	Duration					
Other		Convulsion	Health	Zanaflex (Tizanidine		
			Professional	Hydrochloride)	PS	ORAL
2 MG DAILY						
ORAL						
				Vioxx	C	
				Dilantin	C	
				Prempro	C	

Product

Role Manufacturer

Route

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Outcome

Freedom Of Information (FOI) Report

e

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 -	Contusion	Health	Zanaflex (Tizanidine			
Initial or Prolonged 12 MG DAILY	Fall	Professional	Hydrochloride)	PS		ORAL
Other	Hypersomnia					
ORAL						
	Psychotic Disorder		Prednisone	C		
	Rib Fracture		Neurontin	C		
	Somnolence		Lopid	С		

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 Dur	ation					
Hospitalization	- Amnesia	Health	Zanaflex (Tizanidine	<u> </u>		
Initial or Prolo	nged Catatonia	Professional	Hydrochloride)	PS		ORAL
2 TABS ORAL						
	Communication Disor	rder	Catapres	C		
	Dehydration		Hydrochlorothiazide	C		
	Eating Disorder					

Date:06/04/02ISR Number: 3929345-6Report Type:Expedited (15-DaCompany Report #ZANA000966 (0)

Mental Status Changes

Gender:Female Age:41 YR I/FU:I

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

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	Hypen (Etodolac,		
Hospitalization -	Cardiac Failure	Professional	Unspec)	PS	ORAL
400MG DAILY 9 DAY					
Initial or Prolonged	Pneumonitis	Other	Tizanidine		
	Respiratory Distress		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)	С	
			Furosemide		
			(Furosemide)	С	
			Spironolactone		
			SPILOHOCCOHC		

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Freedom Of Information (FOI) Report

Product

(Spironolactone) C Misoprostol С (Misoprostol)

Role Manufacturer

Route

Date:06/17/02ISR Number: 3935718-8Report Type:Expedited (15-DaCompany Report #ZANA000959 (1)

Age:50 YR Gender: Female I/FU:F

PT

Dose Duration Convulsion Health Zanaflex (Tizanidine Other Professional Hydrochloride) PS ORAL

Report Source

2 MG DAILY

Outcome

ORAL

C Vioxx Dilantin С Prempro

Date:06/18/02ISR Number: 3935263-XReport Type:Direct Company Report #CTU 170348

Age: Gender: Female I/FU:I

PΤ Report Source Role Manufacturer Outcome Product Route Duration Dose

Life-Threatening Liver Function Test Zanaflex 4mg Athena

Abnormal Neuro PS Athena Neuro ORAL

1-2MG DAY

ORAL

Accolate С Tolectin C Loestrin С

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 PΤ Report Source Product Role Manufacturer Route Dose Duration

Other Blood Glucose Increased Health Zonegran

Vision Blurred Professional (Zonisamide) PS ORAL

200 MG DAILY

Zanailex	
(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

Role Manufacturer

Route

Product

Date:06/20/02ISR Number: 3937398-4Report Type:Expedited (15-DaCompany Report #ZANA000971 (0)

Age:35 YR Gender:Female I/FU:I

PT

Dose	Duration					
Hospitalizati Initial or Pr		Bradycardia Drug Interaction	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS	ORAL
12 MG DAILY	orongea	prag interaction	riorespionar	ny ar confer fac /		OTUIL
ORAL			Company			
			Representative	Birth Control Pills		
				(Oral Contraceptive		
				Nos)	SS	

Report Source

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Outcome

Freedom Of Information (FOI) Report

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or I 12 MG DAILY Other	tion -	Aspiration Condition Aggravated Drug Ineffective	Consumer	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
ORAL		Dysphagia Eating Disorder Jaw Disorder Muscle Spasticity Weight Decreased		Baclofen	С		
Date:06/21/(Age:	02ISR Number Gender:	:: 3937202-4Report Type:Direct I/FU:I	Company Repo	rt #CTU 170714			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Back Pain Blood Pressure Increased Ear Infection Fatigue Gastrooesophageal Reflux Disease Sinusitis Tinnitus Visual Acuity Reduced Weight Increased		Zanaflex Vioxx	PS SS		
Date:06/24/(Age:	02ISR Number Gender:Fema	:: 3937897-5Report Type:Direct ale I/FU:I	Company Repo	rt #CTU 170793			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
	ening	Hallucination		Zanaflex 4mg			

Hospitalization -Liver Function Test Novartis PS Novartis 1-2 TABS Initial or Prolonged Abnormal Required Nausea Intervention to Tachycardia

Prevent Permanent Tinnitus Impairment/Damage

Vision Blurred

Date:06/24/02ISR Number: 3937899-9Report Type:Direct

Age:

Gender:Female

I/FU:I

Outcome	PT	Report Source	Product	Role Manufacturer	Route
---------	----	---------------	---------	-------------------	-------

Company Report #CTU 170794

Duration Dose

Zanaflex 4mg PS Other Fear

2-3 TABS

Hallucination

Date:06/27/02ISR Number: 3978979-1Report Type:Periodic Company Report #WAES 0204USA02209

Gender:Male I/FU:I Age:

Report Source Role Manufacturer Outcome PTProduct Route

Dose Duration

Hallucination Health Tab Vioxx PS ORAL

ΡO

Professional Somnolence Zanaflex SS

Company

Representative

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Freedom Of Information (FOI) Report

SS

Date:06/28/02ISR Number: 3941537-9Report Type:Direct Company Report #CTU 171244

Age:39 YR Gender: Female I/FU:I

Role Manufacturer Outcome PTReport Source Product 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

РΤ Role Manufacturer Report Source Product Outcome Route

Dose Duration

Hospitalization -Health Anaemia Novantrone Strength Professional PS

Initial or Prolonged Infection Unknown

Q 3 MO

Liver Function Test Acetaminophen SS Abnormal Tizanidine SS

Amantadine С Surgery Oxybutynin C

Baclofen 4-Aminopyridine С Fluoxetine

Date:07/09/02ISR Number: 3945469-1Report Type:Direct Company Report #CTU 171933

Age:57 YR Gender: Female I/FU:I

PTReport Source Role Manufacturer Outcome Product Route

Duration Dose

Hospitalization -Zanaflex ORAL Anxiety PS

2 TABS PO QHS

Initial or Prolonged Hallucination

SINGLE DOSE

Insomnia Epidural Steroid

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
Dose	Duration					
Other	Lympl	homa	Foreign	Prazosin(Prazosin)	PS	
1.5 MG(TID)						
				Nifedipine(Nifedipin	00	
30 MG(DAILY)			Professional	e)	SS	
30 MG(DAILI)				Allopurinol	SS	
100 MG					DD	
(DAILY)						
				Simvastatin	SS	
10 MG (DAILY)					
00 MO(DATIV)				Enalapril	SS	
20 MG(DAILY)				Betaxolol	SS	
OPHTHALMIC	UNK(BID),			Becaxoloi	טט	
011111111111	01111(222),					
OPHTHALMIC						
				Acetylsalicylic Acid	SS	
75 MG(DAILY)				_		
				Paracetamol	SS	
2 MG (DAILY)				Tizanidine	SS	
Z MG (DAILI)				Nizatidine	SS	
150 MG(DAILY)			Nizacianic	טט	
	,					
		4308-4Report Type:Expedite	ed (15-DaCompany Report	t #ZANA000984 (0)		
Age:47 YR (Gender:Female	I/FU:I				
Outgomo	PT					
Outcome						

Route

Hospitalization -Dialysis Initial or Prolonged Hypotension

Loss Of Consciousness Nephritis Allergic

Rash

Renal Failure

Sepsis

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Freedom Of Information (FOI) Report

Vasculitis

Dose Duration		Report Source	Product	Role	Manufacturer	Route
Dose Duration		Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
10 MG DAILY		PIOLESSIONAL	nyarochioriae,	ro		UAAU
ORAL						
			Hydrochlorothiazide (Hydrochlorothiazide			
25 MG DAILY)	SS		ORAL
ORAL						
OKALI			Desyrel	C		
			Oxycontin Celexa	C C		
Date:08/09/02ISR Number Age:48 YR Gender:Fema	r: 3961479-2Report Type:Expeditale I/FU:I	ted (15-DaCompany Repor	rt #ZONI000844 (0)			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 400 MG DAILY	Blood Pressure Increased Orthostatic Hypotension	Consumer	Zonegran (Zonisamide)	PS		ORAL
	Tachycardia					
ORAL	Urinary Retention		Zanaflex (Tizanidine Hydrochloride)	SS		ORAL
ORAL						OICAL
4			Overgontin	\sim		
			Oxycontin	С		
Date:08/14/02ISR Number Age:65 YR Gender:Male	r: 3963199-7Report Type:Expedit	ted (15-DaCompany Repoi		C		
		ted (15-DaCompany Repor Report Source			Manufacturer	Route

					Carbamazepine Docusate Baclofen Ipratropium Aspirin Paracetamol	0 0 0 0		
Date:08/15/ Age:53 YR	02ISR Number Gender:Male	: 3962334-4Report Type:Direct I/FU:I		Company Repor	rt #CTU 174198			
Outcome		PT	Report	Source	Product	Role	Manufacturer	Route
Dose	Duration				a' (a' 51 '			
Other		Drug Interaction Fatigue			Cipro (Ciprofloxacin Hydrochloride)	PS		ORAL
500MG BID								
		Speech Disorder						
ORAL					- 63 (-1 13)			
					Zanaflex (Tizanidine Hydrochloride)	SS		ORAL
4MG DAILY					nydrochioride)	aa		ORAL
ORAL								
					Fibercon	С		
					Vit C	С		
					Multivitamin	C		

Senna

Quinine

Mevacor

С

С

С

Professional

Myocardial Infarction

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ORAL

Freedom Of Information (FOI) Report

PS

ORAL

Date: 08/19/02ISR Number: 3963437-OReport Type: Direct Company Report #CTU 174417

Age: Gender: I/FU:I

Duration

Outcome PTReport Source Product Role Manufacturer Route

Pharmaceutical Product

Zanoflex 2mg (Bd) Complaint Generic And Brand

Name PS

SS Tiziainidine (Gen)

Date:08/21/02ISR Number: 3965831-0Report Type:Expedited (15-DaCompany Report #ZANA000986 (0)

Age:50 YR Gender: Female I/FU:I

Role Manufacturer РΤ Report Source Product Outcome Route

Dose Duration

Zanaflex (Tizanidine Hospitalization -Orthostatic Hypotension Health

Initial or Prolonged Professional Hydrochloride) ORAL Syncope PS

8 MG DAILY

Dose

ORAL

Effexor C Fiorinal C

Evista Desyrel C

Date:08/21/02ISR Number: 3965879-6Report Type:Expedited (15-DaCompany Report #ZANA000987 (0)

Age: Gender: Male I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration

Convulsion Zanaflex (Tizanidine Other Consumer

Hydrochloride)

16 MG DAILY

ORAL

Date: 08/21/02ISR Number: 3966130-3Report Type: Expedited (15-DaCompany Report #ZANA000988 (0)

Gender: Female I/FU:I Age:

PT Report Source Product Role Manufacturer Route Outcome Dose Duration

Date:08/23/02ISR Numbe Age:76 YR Gender:Fen	er: 3967355-3Report Type:Expedit male I/FU:I	ed (15-DaCompany Repor	t #ZANA000989 (0)			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						ļ
Hospitalization -	Anaemia	Health	Zanaflex (Tizanidine			ľ
Initial or Prolonged 12 MG DAILY	Arrhythmia	Professional	Hydrochloride)	PS		ORAL
1	Gastric Ulcer Haemorrhage					ļ
ORAL	-					ļ
1	Pain		Duragesic Patch	С		ļ
1	Torsade De Pointes		Metoprolol	C		ļ
	Ulcer Haemorrhage Ventricular Tachycardia		Darvocet-N	C		
Date:08/27/02ISR Numbe Age: Gender:	er: 3967782-4Report Type:Direct I/FU:I	Company Report	t #CTU 175180			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duracion	Anaphylactic Shock Pharmaceutical Product		Zanaflex 2mg (Bd) Tizanidine (Gen)	PS SS		

Zanaflex (Tizanidine

PS

ORAL

Hydrochloride)

Health

Professional

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Other

ORAL

Cardiomyopathy

Complaint

Cerebrovascular Accident

Freedom Of Information (FOI) Report

Date:09/03/02ISR Number: 3970040-5Report Type:Direct Company Report #CTU 175545

Age: Gender:Female I/FU:I

Duration	PT	Report Source	Product	Role	Manufacturer	Route
Duracion	Drug Effect Decreased Mobility Decreased		Trizantadine 4 Mg Holt	PS	Holt	ORAL
	-					
	Complaint					
		ited (15-DaCompany Re	port #2001076005CH			
0011201		December Courses	Desa dinak	Dele	Marrie English	Doubo
Duration	БД	Report Source	Product	коте	Manuiacturer	Route
	Complications Of Maternal	Foreign	Celebrex (Celecoxib)	20		00.11
	Exposure To Therapeutic	Study	Capsule	PS		ORAL
	Drugs	Health				
	Pregnancy	Professional	Doxycycline			
	11031111101	Other	(Doxycycline)	SS		
			Cirdalud (Tizanidina			
			Hydrochloride)	SS		
				SS		
1 TM.T			Valium (Diazepam)	SS		
± ±1N∪ ,	,					
			arlada	a		
			-			
•	2ISR Number Gender: Duration	Duration Drug Effect Decreased Mobility Decreased Pharmaceutical Product Complaint 2ISR Number: 3971368-5Report Type:Exped: Gender: I/FU:F PT Duration Complications Of Maternal Exposure To Therapeutic Drugs Pregnancy 1 INJ,	Duration Drug Effect Decreased Mobility Decreased Pharmaceutical Product Complaint 2ISR Number: 3971368-5Report Type:Expedited (15-DaCompany Regender: I/FU:F PT Report Source Duration Complications Of Maternal Foreign Exposure To Therapeutic Study Drugs Health Pregnancy Professional Other	Duration Drug Effect Decreased Mobility Decreased Mobility Decreased Holt	Duration Drug Effect Decreased Mobility Decreased Mobility Decreased Mobility Decreased Product	Duration Pug Effect Decreased Mobility Decreased Mobility Decreased Pharmaceutical Product Complaint PT Report Source Product Complications Of Maternal Expeditor Exposure To Therapeutic Drugs Health Pregnancy Pregnancy Pregnancy Professional Other Other Noroxin (Norfloxacin) SS Valium (Diazepam) C C C C C C C C C C C C C C C C C C C

Date:09/09/02ISR Number: 3974562-2Report Type:Direct

Age:45 YR Gender:Female I/FU:I

Paracetamol Tetrazepam С

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Durat			7	D.C.		
Disability 1 1/2 TAB	Abdominal Pain		Zanaflex 4mg	PS		
Required	Liver Function Test					
DAILY						
Intervention to	Abnormal		Phenobarbital	C		
Prevent Permanent	Malaise		Synthroid	C C		
Impairment/Damage	Nausea		Zyrtec	C		
Date:09/10/02ISR N Age:51 YR Gender	Tumber: 3974113-2Report Type: Female I/FU:I	pe:Direct Company Re	eport #CTU 176038			
			_	_	_	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Durat Hospitalization -	.ion Asthenia		Tizanidine			
Initial or Prolong			(Zanaflex)	PS		
2MG 1ST X 3			, ,	-		
	Dizziness					
WEEKS; 4MG	_					
NOL	Dry Mouth					
NOM	Dysarthria		Zantac	С		
	Paraesthesia		Vioxx	C		
			Estrogen	C		
Date:09/13/02ISR N Age:53 YR Gender		e:Expedited (15-DaCompany Re	eport #MK200209-0108-1			
Outcome Dose Durat	PT	Report Source	Product	Role	Manufacturer	Route
Dose Durat	Movement Disorder	Foreign Study	Anafranil Capsules 100 Depakene R	PS SS		
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Freedom Of Information (FOI) Report

Ternelin	SS
Lochol	SS

Date:09/16/02ISR Number: 3975911-1Report Type:Expedited (15-DaCompany Report #USA-2002-0002143

Date:09/20/02ISR Number: 3977881-9Report Type:Direct

I/FU:I

Gender:

Age:

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Hospitalization -	Drug Interaction	Health	Oxyir Capsules 5 Mg		
Initial or Prolonged	Neuroleptic Malignant	Professional	(Oxycodone		
	Syndrome		Hydrochloride) Ir		
	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			100200		01412
110, 01111			Remeron		
			(Mirtazapine) Tablet	SS	ORAL
MG, ORAL			(Hill salapine) Tables		01412
110, 0141			Effexor (Venlafaxine		
			Hydrochloride)		
			Tablet	SS	ORAL
MG, ORAL			Tables		Oldin
MG, OKAL			Gabitril (Tiagabine		
			Hydrochloride)		
			Tablet	SS	ORAL
MG, ORAL			IGDIEC	55	UKAL
MG, ORAL					

Outcome PT Report Source Product Role Manufacturer Route
Dose Duration

Company Report #USP 055217

Tizanidine Hydrochloride

Nizatidine

PS Par SS

С

C

Mylan

Date:09/20/02ISR Number: 3979356-XReport Type:Expedited (15-DaCompany Report #ZANA001010 (0)

Gender:Female Age:37 YR I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitaliza	ation -	Chills	Health	Zanaflex (Tizanidine			
Initial or	Prolonged	Hepatitis	Professional	Hvdrochloride)	PS		ORAL

24-32 MG

Influenza Like Illness

DAILY; ORAL

Relafen С Nausea Prothrombin Time Cipro Prolonged Tylenol

Serum Ferritin Increased

Tremor

Urinary Tract Infection

Vomiting

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Freedom Of Information (FOI) Report

PS

PS

ORAL

ORAL

Date:09/24/02ISR Number: 3981881-2Report Type:Expedited (15-DaCompany Report #ZANA001013 (0)

Gender: Female Age: I/FU:I

Outcome PΤ Report Source Product Role Manufacturer Route

Dose Duration

Hospitalization -Cardiac Disorder Health Zanaflex (Tizanidine

Initial or Prolonged Coma Professional Hydrochloride)

ORAL

Rhabdomyolysis Company

Representative

Date:09/25/02ISR Number: 3980226-1Report Type:Direct Company Report #CTU 177090

Age:60 YR Gender: Female I/FU:I

Report Source Product Role Manufacturer Outcome PΤ Route

Dose Duration

Zanaflex Dizziness PS Required

4MG OD OR BID

С Intervention to Hypotension Amitryptiline

Prevent Permanent Neurontin C

Impairment/Damage Bumex C Lisonopril

Date:09/27/02ISR Number: 3984292-9Report Type:Expedited (15-DaCompany Report #PHBS2002JP04033

Age:63 YR Gender:Female I/FU:F

Outcome PΤ Report Source Product Role Manufacturer Route

Dose Duration

Hospitalization -Erythema Multiforme Foreign Diovan (Valsartan)

Initial or Prolonged Face Oedema Health Tablet

40 MG, QD,

Pruritus Professional

ORAL

Other Ternelin (Tizanidine

Hydrochloride,

Tizanidine Hydrochloride)

Unknown

SS ORAL

0.5 MG, TID,

ORAL Osteluc (Etodolac) SS ORAL

100 MG, TID,

Mecobamide (Mecobalamin)

Product

SS

Role Manufacturer

ORAL

Route

500 UG, TID,

ORAL

Date:11/01/02ISR Number: 4005575-2Report Type:Expedited (15-DaCompany Report #2002AP03571

Age:47 YR Gender: I/FU:I

PTReport Source Product Role Manufacturer Outcome Route Duration Dose Intentional Misuse Literature Metoprolol Death PS Suicide Attempt Health Salicylate SS Professional Tizanidine SS

Date:11/12/02ISR Number: 4011639-XReport Type:Expedited (15-DaCompany Report #ZANA001033 (0)

Gender: Female I/FU:I Age:

PT

Duration Dose Hospitalization -Bradycardia Health Zanaflex (Tizanidine Initial or Prolonged Hypotension Professional Hydrochloride) PS ORAL ORAL Myocardial Infarction Neurontin С Required Intervention to Syncope

Report Source

Prevent Permanent

Impairment/Damage

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Outcome

Freedom Of Information (FOI) Report

Baclofen

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	С		
			Darvocet-N	C		
Date:11/14/02ISR Number	r: 4012577-9Report Type:Expedit	ted (15-DaCompany Repor	rt #ZANA001028 (1)			
Age:50 YR Gender:Fema			, ,			
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						
1 *						

Date:11/15/02ISR Number: 4011395-5Report Type:Direct Company Report #CTU 181034

Difficulty In Walking

Motor Dysfunction

Hypotension

Somnolence Stupor

Age:50 YR	Gender:Fem	ale I/FU:I				
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Life-Threat	tening	Anger		Zanaflex 4g	PS	ORAL
4MG TID ORA	ĄL					
Hospitaliza	ation -	Blood Glucose Decrease	ed			

Initial or Prolonged Chest Pain Flushing Hallucinations, Mixed Incoherent Insomnia Memory Impairment Mental Status Changes Nausea Nightmare Palpitations Psychotic Disorder

Vomiting

Urinary Incontinence

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	<u> </u>	Product	Role	Manufacturer	Route
Dose	Duration							
Required		Blood Pressure Decreased			Tizanidine 4 Mg			
Intervention	to	Hypertension			Tablets	PS		
8 MG 3 TIMES	i							
Prevent Perm	anent							
DAILY								
<pre>Impairment/D</pre>	amage				Clonidine 0.1 Mg			
					Tablets	SS	•	
0.1 MG - 2								
1								
DOSES								
1					Paxil	C		

Remeron

С

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Freedom Of Information (FOI) Report

rethindrone)

PS

ORAL

Colace	С
Metamucil	С
Intrathecal Pump	
(Clonidine Baclofen	
Morphene)	С
Neurontin	С
Lipitor	С

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 Dur	ration						
Required		Blood Pressure Decreased		Tizanidine 4mg			
Intervention to		Hypertension		Tablets	PS		•
8MG 3 TIMES							•
Prevent Permanen	nt						, , , , , , , , , , , , , , , , , , ,
DAILY							, , , , , , , , , , , , , , , , , , ,
Impairment/Damag	ge			Clonidine 0.1mg			•
				Tablets	SS		, , , , , , , , , , , , , , , , , , ,
0.1MG -2							
DOSES							
				Paxil	C		•
				Colace	C		•
				Metamucil	C		•
				Neurontin	C		
				Lipitor	С		
				Clonidine	С		
				Baclotch	С		
				Morphine	C		

Date:11/21/02ISR Number: 4016887-OReport Type:Expedited (15-DaCompany Report #NSADSS2002042283

Age: 37 YR Gender: Female I/FU: I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Dura	tion					
Life-Threatening	Bradycardia	Health	Ortho-Novum			
Hospitalization -	Drug Interaction	Professional	7/7/7(Tablet)			
Initial or Prolon	ged Hypotension		(Ethinylestradiol/N	10		

1 TABLET,

DAILY, ORAL				Zanaflex (Tizanidine			
8 MG, 1 IN 1	1				SS		ORAL
DAILY, ORAL							
				Vioxx (Rofecoxib) Darvocet-N	C		
					С		
	02ISR Number Gender:Fema	: 4013851-2Report Type:Expedite le I/FU:I	ed (15-DaCompany Report	: #WAES 0211USA01696			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Disability	Daracion	Somnolence		Vioxx	PS	Merck & Co., Inc	ORAL

[Composition Unspecified]

Zanaflex

SS

SS

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Freedom Of Information (FOI) Report

Zanaflex (Tizanidine

PS

ORAL

Hydrochloride)

Date:11/26/02ISR Number: 4017976-7Report Type:Expedited (15-DaCompany Report #12115150 Age:47 YR Gender: I/FU:I

Biliary Tract Disorder

Cholangitis Acute

Eosinophilia

Age. 47 YR Gender:	1/10.1					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Death ORAL	Completed Suicide	Literature	Metoprolol Tartrate	PS		ORAL
Other	Overdose	Health Professional	Salicylate (Salicylate Salts)	SS		ORAL
ORAL			- Tizanidine			
ORAL			(Tizanidine Hcl)	SS		ORAL
Date:11/26/02ISR Numbe Age:49 YR Gender:Fem	er: 4018026-9Report Type:Exp male I/FU:I	pedited (15-DaCompany Re	eport #ZANA001039			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 12 MG DAILY	Bradycardia Hypotension	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
ORAL	Loss Of Consciousness					
ORAL	Memory Impairment		Estrace (Estradiol Valerate)	SS		ORAL
1 MG DAILY						
ORAL			D1 '1	a		
			Plaquenil Vioxx Prozac	C C C		
Date:11/26/02ISR Numbe Age:44 YR Gender:Mal	er: 4018108-1Report Type:Exp le I/FU:I	pedited (15-DaCompany Re	eport #ZANA001037			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Daracion .						

Literature

Professional

Health

ORAL

Hospitalization -

16 MG DAILY

Initial or Prolonged

Hepatic	Congestion
Hepatic	Failure
Hepatic	Fibrosis
Hepatic	Haemorrhage
Hepatic	Steatosis
Hepatoce	ellular Damage

Oxycodone

Product

C

Role Manufacturer

Route

Date:11/29/02ISR Number: 4018276-1Report Type:Expedited (15-DaCompany Report #ZANA001043 Age:47 YR Gender: I/FU:I

Dose	Duration					
Death		Completed Suicide	Literature	Zanaflex (Tizanidine		
			Health	Hydrochloride)	PS	ORAL
ORAL						
			Professional	Metoprolol		
				(Metoprolol)	SS	ORAL
ORAL						
				Salicylate	C	

Report Source

Date:11/29/02ISR Number: 4018348-1Report Type:Expedited (15-DaCompany Report #ZANA001042

Age:43 YR Gender: I/FU:I

PT

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Daracion	Cardio-Respiratory Arrest Completed Suicide	Literature Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
ORAL		-		_			

Professional

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Outcome

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 PTReport Source Product Role Manufacturer Route

Duration Dose

Tardive Dyskinesia Zanaflex PS Required

SEE

Intervention to DESCRIPTION

Prevent Permanent Impairment/Damage

Date:12/04/02ISR Number: 4022020-1Report Type:Expedited (15-DaCompany Report #ZANA001045

Gender: Female I/FU:I Age:

Role Manufacturer Report Source Outcome PTProduct Route

Duration Dose

Other Ankle Fracture Health Zanaflex (Tizanidine Dizziness Professional Hydrochloride) PS ORAL

2 MG DAILY

Fall Company

ORAL

Middle Insomnia Representative

Age:38 YR Gender: Female I/FU:I

Outcome PΤ Report Source Product Role Manufacturer Route

Company Report #CTU 182319

Dose Duration

Tizanidine 4 Mg Teva PS Other Drug Effect Decreased Teva

3 PILLS EVERY

Pharmaceutical Product

Date:12/09/02ISR Number: 4020891-6Report Type:Direct

NIGHT

Complaint

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

PTReport Source Product Role Manufacturer Outcome Route Duration Dose

Hospitalization -Bradycardia Health Estrace Tabs 1 Mg Apothecon ORAL PS

	Hypotension Loss Of Consciousness Memory Impairment		Vioxx Prozac Zanaflex	C	ORAL
Date:12/18/02ISR N Age:20 YR Gender	umber: 4029340-5Report Type:Exp :Male I/FU:I	pedited (15-DaCompany R	eport #ZANA001049		
Outcome Dose Durat:	PT	Report Source	Product	Role Manufacturer	Route
Other	Tardive Dyskinesia	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS	ORAL
24 MG DAILY		1101000101101	in alcomotac,		Oldin
ORAL			Milk Of Magnesia Ducolax Lacri-Lube	C C C	
	umber: 4029343-0Report Type:Exp :Female	pedited (15-DaCompany R	eport #ZANA001013		
Outcome Dose Durat:	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonge ORAL	Cardiac Disorder	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS	ORAL
	Drug Interaction Nervous System Disorder Respiratory Disorder Rhabdomyolysis				
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Professional

Plaquenil

Vioxx

C C

Initial or Prolonged

Drug Interaction

Hypotension

Freedom Of Information (FOI) Report

Depakote

Prometrium

Vitamins Nos

C C

C

Effexor

Botox

Date:12/19/02ISR Number: 4030130-8Report Type:Expedited (15-DaCompany Report #ZANA001045

ORAL

Aspartate

Increased

Headache

Convulsion

Aminotransferase

Age:54 YR Gender:Fem	r: 4030130-8Report Type:Exped ale	ited (15-DaCompany Re	port #ZANAUU1U45			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Ankle Fracture Dizziness Postural	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
6 MG DAILY Required	Fall					
ORAL Intervention to	Middle Insomnia		Klonopin	С		
Prevent Permanent Impairment/Damage			Celexa Estrogen	C C		
Date:12/24/02ISR Numbe: Age:46 YR Gender:Fem	r: 4033743-2Report Type:Exped ale I/FU:I	ited (15-DaCompany Re	port #ZANA001052			
Age. 40 IK Gender Felli						
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Convulsion	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
12 MG DAILY						
ORAL						
			Effexor Depakote	C C		
			Vitamins Nos	C		
Date:12/24/02ISR Numbe Age:46 YR Gender:Fem	r: 4033769-9Report Type:Exped ale I/FU:I	ited (15-DaCompany Re	port #ZANA001051			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Agitation Alanine Aminotransferase	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
12 MG DAILY	manific Aminochansterase	TIOTOSSIOHAI	ing dr ochror rde /	ıυ		OKAL
	Increased					

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 -	Aphasia	Foreign	Sandoglobulin Or			
Initial or Prolonged	Disease Recurrence Epilepsy Grand Mal Convulsion	Health Professional Other	Placebo (Placebo Placebo) (Sandoglobulin Or			
	Multiple Sclerosis		Placebo)	PS		
INTRAVENOUS QMO,	_					
	Relapse					
INTRAVENOUS						
	Postictal State		Baclofen (Baclofen)			
	Pyrexia		Capsule	SS		
			Ds 103-282			
			(Tizanidine			
			Hydrochloride)			
			Capsule	SS		
			Neuromet			
			(Oxiracetam)	C		
			Orfiril (Valproate			
			Sodium)	С		

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Freedom Of Information (FOI) Report

Imigran

Imigran

SS

SS

ORAL

ORAL

Date:01/03/03ISR Number: 4039017-8Report Type:Expedited (15-DaCompany Report #ZANA001053

Age:55 YR	Gender:Fema	le I/	'FU:I
-----------	-------------	-------	-------

3	·					
Outcome Dose Dura	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolong	Blood Pressure Increase	ed Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
	Lethargy Medication Error Neuroleptic Malignant Syndrome		Cozaar Lisinopril Lopressor	C C C		
	Number: 4039033-6Report Type:I r:Female I/FU:I	Expedited (15-DaCompany Ro	eport #ZANA001054			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Dura Death	Death Death	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
4 MG DAILY		Company				
ORAL		Representative	Opioids (Unspecified)	С		
	Number: 4041180-XReport Type:I r:Female I/FU:F	Expedited (15-DaCompany Ro	eport #2002AP04402			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Dura Hospitalization - 2.5 MG DAILY	tion Autoimmune Hepatitis	Foreign	Zomig	PS		ORAL

Health

Professional

Required 50 MG DAILY Intervention to

Initial or Prolonged

ΡO

Other

PO

Tension Headache

Prevent Permanent 50 MG DAILY

Impairment/Damage

00 110 211121					
PO			Mi mai at an		ORAL
60 MG DAILY			Migristene	С	ORAL
PO					
Date:01/23/03ISR Numbe Age:44 YR Gender:Fen	er: 4046403-9Report Type:Exp nale I/FU:F	pedited (15-DaCompany Re	eport #2002AP04402		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - 2.5 MG DAILY	Autoimmune Hepatitis	Foreign	Zomig	PS	ORAL
Initial or Prolonged PO	Cholelithiasis	Health			
Required 50 MG DAILY	Chronic Hepatitis	Professional	Imigran	SS	ORAL
Intervention to PO	Hepatitis	Other			
Prevent Permanent 50 MG DAILY	Tension Headache		Imigran	SS	ORAL
Impairment/Damage PO					
60 MG DAILY			Migristene	SS	ORAL
PO					
60 MG DAILY			Arofuto	SS	ORAL
PO			Ternelin	SS	ORAL
3 MG DAILY PO			1611161111	55	OKAL

Ternelin

Arofuto

SS

SS

ORAL

ORAL

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3 MG DAILY PO

60 MG DAILY

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					
Hospitaliz	ation -	Dry Mouth		Tizanidine	PS	
8 MG TID						
Initial or	Prolonged	Hypotension		Simvastatin	С	
Required				Metformin Hcl	С	
Interventi	on to			Atenolol	С	
Prevent Pe	rmanent			Glipizide	С	
Impairment	/Damage			Lisinopril	С	
				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 Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged UNK ORAL	Blood Pressure Increased Cerebral Infarction	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS	ORAL
	Convulsion Escherichia Infection Hallucination Lethargy Medication Error Nervous System Disorder Pneumonia Klebsiella Sinus Tachycardia Status Epilepticus		Cozaar Lisinopril Lopressor	C C C	

Date:01/28/03ISR Number: 4049768-7Report Type:Expedited (15-DaCompany Report #ZANA001033

Urinary Tract Infection

Vasculitis

Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Life-Threatening Bradycardia Health Zanaflex (Tizanidine

	. 4040554 05	11. 1 (15.5.0			
Age: 37 YR Gender: Fem	er: 4049774-2Report Type:Expenale I/FU:F	dited (15-Dacompany Ro	eport #ZANAUUIUIU		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Hospitalization -	Hepatitis	Health	Zanaflex (Tizanidine		
Initial or Prolonged	Influenza Like Illness	Professional	Hydrochloride)	PS	ORAL
24-32 MG					
	Serum Ferritin Increased				
DAILY ORAL					
	Transferrin Abnormal		Relafen	С	

Hydrochloride)

Neurontin

Climara

Cipro

Tylenol

Klonopin

PS

С

С

С

С

С

ORAL

Professional

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Hospitalization -

Intervention to

Prevent Permanent

Impairment/Damage

Initial or Prolonged

32 MG DAILY

ORAL Required Cardiac Arrest

Myocardial Infarction

Ventricular Fibrillation

Urinary Tract Infection

Hypotension

Syncope

Freedom Of Information (FOI) Report

PS

PS

PS

ORAL

ORAL

ORAL

Date:01/29/03ISR Number: 4050764-4Report Type:Periodic Company Report #ZANA000920

Gender: Male Age: I/FU:I

Outcome PTReport Source Product Role Manufacturer Route

Dose Duration

Hospitalization -Hypotension Consumer Zanaflex (Tizanidine

Initial or Prolonged Hydrochloride)

4 MG DAILY

ORAL

Date:01/29/03ISR Number: 4050765-6Report Type:Periodic Company Report #ZANA000948

Age: Gender: Male I/FU:I

Report Source Role Manufacturer Outcome PTProduct Route

Duration Dose

Hospitalization -Hypotension Health Zanaflex (Tizanidine

Initial or Prolonged Professional Hydrochloride)

2 MG DAILY

ORAL Vicodin C

Date:01/29/03ISR Number: 4050769-3Report Type:Periodic Company Report #ZANA000981

Gender: Female I/FU:I Age:

Outcome PTReport Source Product Role Manufacturer Route

Dose Duration

Other Alanine Aminotransferase Consumer Zanaflex (Tizanidine Increased Hydrochloride)

ORAL

Birth Control Pills

Date:02/03/03ISR Number: 4051426-XReport Type:Expedited (15-DaCompany Report #2002AP04402

Age:44 YR Gender: Female I/FU:F

Outcome PTReport Source Product Role Manufacturer Route

Dose Duration

Hospitalization -Autoimmune Hepatitis Foreign PS ORAL Zomiq

2.5 MG DAILY

Initial or Prolonged PO	Cholelithiasis	Health			
Required 50 MG DAILY	Chronic Hepatitis	Professional	Imigran	SS	ORAL
Intervention to PO	Hepatitis	Other			
Prevent Permanent 50 MG DAILY Impairment/Damage PO			Imigran	SS	ORAL
60 MG DAILY			Migristene	SS	ORAL
PO			Arofuto	SS	ORAL
60 MG DAILY			ALOLUCO	55	Olvan
PO 3 MG DAILY PO			Ternelin	SS	ORAL
Date:02/03/03ISR Number Age:44 YR Gender:Male	r: 4052066-9Report Type:Per: e I/FU:I	iodic Company R	Report #A0373546A		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Life-Threatening Required 25 MG ORAL	Chest Discomfort Chest Pain	Health Professional	Lamictal (Lamotrigine)	PS	ORAL
Intervention to Prevent Permanent Impairment/Damage	Skin Discolouration Swelling Face Swollen Tongue		Tizanidine Hydrochloride (Tizanidine		ł
ORAL	Urticaria		Hydrochloride)	SS	ORAL
	Wheezing		Pirbuterol Acetate Tramadol	С	I
			Hydrochloride Fluticasone+Salmeter	С	
			ol Salbutamol Sulphate	C C	
22-Aug-2005 12:09 DM					1

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Freedom Of Information (FOI) Report

PS

ORAL

Date:02/04/03ISR Number: 4052829-XReport Type:Expedited (15-DaCompany Report #ZANA001057

Gender: Female Age: I/FU:I

Outcome PTReport Source Product Role Manufacturer Route Dose Duration

Life-Threatening Coma Health Zanaflex (Tizanidine

Hospitalization -Professional Hydrochloride) Pancreatitis

ORAL

Initial or Prolonged

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

Role Manufacturer PTReport Source Product Outcome Route Dose Duration

Completed Suicide Tizanidine Literature PS Death

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 PTReport Source Product Role Manufacturer Route Dose Duration

Death Completed Suicide Literature Tizanidine PS

UNKNOWN UNKNOWN

Intentional Misuse Health Metoprolol С

Professional Salicylate С Other

Date:02/11/03ISR Number: 4056957-4Report Type:Expedited (15-DaCompany Report #DEU-2003-0000272 Age:65 YR Gender:Female I/FU:I

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Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Depression Hyperhidrosis Insomnia	Foreign Health Professional Other	Oxycodone Hydrochloride Cr Tablets (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL
20 MG, DAILY	,						
ORAL				Cosaar (Losartan	99		0011
50 MG, DAILY	,			Potassium)	SS		ORAL
ORAL							
				Sirdalud (Tizanidine Hydrochloride)	SS		ORAL
8 MG, DAILY,							
ORAL				The same that a			
				Fluoxetine (Fluoxetine)	SS		ORAL
20 MG, DAILY	,						
ORAL				Pantozol(Pantoprazol			
				e Sodium)	SS		ORAL
20 MG, DAILY	,						
ORAL							
				Diclofenac (Diclofenac)	С		

Freedom Of Information (FOI) Report

Tegaserod (Zelnorm)

PS

Samples

Date: 02/19/03ISR Number: 4059873-7Report Type: Expedited (15-DaCompany Report #2003-02-0499

	3ISR Numb Gender:Fe		ł059873-7Report Type:Expe I/FU:I	edited (15-DaCompany Re	port #2003-02-0499			
Outcome Dose	Duration			Report Source	Product	Role	Manufacturer	Route
Death			naphylactic Shock	Foreign Health Professional	Diprospan (Betamethasone Sodium Phosphate/Dipropiona			
1 ML					te) Injectable	PS		
8 MG BID	2 I	DAY			Lornoxicam (Chlorotenoxipam)	SS		
O MG BID	2 1	JAI			Milgamma (Pyridoxine/Benfotia mine)	SS		
2 ML QD	3 I	DAY			•			
4 MG TID	10 I	DAY			Sirdalud	SS		
400 MG BID		DAY			Trental	SS		
	3ISR Numk Gender:Fe		1067688-9Report Type:Expe I/FU:F	edited (15-DaCompany Re	port #ZANA001057			
Outcome		PΊ	[Report Source	Product	Role	Manufacturer	Route
Dose Life-Threate Hospitalizat ORAL		Ch	nolelithiasis oma	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
Initial or P	rolonged	Pa	ancreatitis					
Date:03/18/0 Age:22 YR			1075176-9Report Type:Dire	ect Company Re	port #CTU 188897			
Outcome Dose	Duration	PT 1	·	Report Source	Product	Role	Manufacturer	Route

(SAMPLES)

UNKNOWN

Life-Threatening

Electrocardiogram Qt

Prolonged

Syncope

UNKNOWN

			Prn	SS	ORAL
4 MG PO TID					
PRN					
			Valium	C	
			Xanax	C	
			Prozac	C	
			Nodete	C	
			Zanatlex	C	
			Albuterol	С	
Date:03/18/03ISR Numbe Age:35 YR Gender:Mal Outcome Dose Duration Hospitalization - Initial or Prolonged	r: 4078191-4Report Type:Expe I/FU:I PT Drug Dependence	pedited (15-DaCompany R Report Source Foreign Literature Health	eport #PHBS2003JP02453 Product Tizanidine Hydrochloride (Tizanidine	Role Manufacturer	Route
		Professional	Hydrochloride)	PS	ORAL
3 MG/DAY,			1		
		Other			
ORAL					
			Carbamazepine(Carbam azepine) Unknown	SS	ORAL
400 MG/DAY,			,		
ORAL					

Tizanidine (Ranatlex) 4 Mg Tid

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Freedom Of Information (FOI) Report

Zofran

Tizanide

Glaxo Welcome

Eon

PS

SS

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 Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged Other	Hepatic Failure Multiple Sclerosis TANEOUS	Consumer Health Professional	Betaseron (Interferon Beta - 1b)Injection	PS		
			Zanaflex(Tizanidine Hydrochloride)	SS		
Date:03/19/03ISR Number Age:59 YR Gender:Male	c: 4076379-XReport Type:Direct	Company Repo	rt #CTU 189056			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 4MG QD ORAL	Bradycardia Dehydration		Tizanidine -Zanaflex-	PS		ORAL
50 QD ORAL	Dizziness		Atenolol	SS		ORAL
10MG QD ORAL	Drug Interaction		Lexapro	SS		ORAL
	Hypotension Lethargy Renal Failure		Diovan Norvasc Vioxx Aspirin Hydrochlorothiazide Temazepam	C C C C C		
Date:03/20/03ISR Number Age: Gender:Fema	r: 4078196-3Report Type:Directale I/FU:I	Company Repo	rt #USP 55504			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route

Date:03/20/03ISR Number: 4080622-OReport Type:Expedited (15-DaCompany Report #USA-2002-0001447

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

Other

Medication Error

Somnolence

Outcome

Hospitalization -

Initial or Prolonged

Accident

PT

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

Hypernidrosi Hypertonia Insomnia

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Dose	Duration	Liver Disorder Migraine Muscle Contractions Involuntary Muscle Twitching Oedema Peripheral	Report Source Consumer Health Professional	Product Oxycontin Tablets (Oxycodone Hydrochloride) Cr	Role	Manufacturer	Route
		Palpitations	Other	Tablet	PS		ORAL
40 MG, BID,		Pancreatitis					
ORAL		Fancieatitis					
		Pyrexia Skin Discolouration Speech Disorder		Zanaflex (Tizanidine Hydrochloride) Tablet	SS		ORAL
12 MG, TID,				2.00-2.2			
ORAL		Syncope					
ORAL		Tremor Vision Blurred Visual Disturbance		Depakote(Valproate Semisodium) Tablet Motrin Tablet Demerol (Pethidine Hydrochloride) Injectable Phenergan"Wyeth-Ayer st" (Promethazine Hydrochloride) Injectable Elavil (Amitriptyline Hydrochloride) Tablet Xanax (Aprazolam) Prednisone (Prednisone) Tablet Zyprexa (Olanzapine) Tablet	C C C C C C C		
				Skelaxin (Metaxalone) Tablet Robaxin (Methocarbamol) Tablet Bactrium Ds(Sulfamethoxazole, Trimethoprim) Tablet Vicodin Tablet Neurontin (Gabapentin) Tablet	C C C C C		

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Reglan Tablet	С
Stadol Ns	
(Butorphanol	
Tartrate) Spray	C
Doxepin (Doxepin)	
Tablet	C
Thorazine	
(Chlorpromazine	
Hydrochloride)	
Tablet	C
Flexeril	
(Ciclobenzaprine	
Hydrochloride)	
Tablet	C
Orphenadrine	
(Orphenadrine)	
Tablet	С

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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Loss Of Consciousness	Foreign Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
8 MG DAILY				,			
ORAL			Professional				
			Other	Thyroxine Premarin Codeine	С С С		
	3ISR Number Gender:Fema	r: 4088558-6Report Type:Expe ale I/FU:F	edited (15-DaCompany Re	eport #JP-SHR-03-002988			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Haemolytic Anaemia	Foreign Health Professional	Betaferon (Interferon Beta-1b) Injection	PS			
SUBCUTANEOUS	4 MIU,	EVERY	0.1	-			
2 D,			Other				
SUBCUTANEOUS							
				Zantac (Ranitidine Hydrochloride)			
300 MG, ORAL				Tablet	SS		ORAL
300 1137 01411				Mucosta (Rebamipide) Tablet	99		
300 MG, ORAL				Ternelin (Tizanidine Hydrochloride)	SS		ORAL
2 MG, ORAL				Tablet	SS		ORAL
				Prednisolone Voltaren "Ciba-Geigy"	С		
				(Diclofenac Sodium) Tegretol	С		
				(Carbamazepine) Takepron	С		

(Lansoprazole) C Solu-Medrol

С

(Methylprednisolone
Sodium Succinate)

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

ORAL

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 - Drug Dependence Foreign
Initial or Prolonged Literature

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Freedom Of Information (FOI) Report

Daga	Dunahi an		Health Professional Other	Product	Role	Manufacturer	Route
Dose	Duration			Tizanidine Hydrochloride (Tizanidine			
3 MG/DAY,				Hydrochloride)	PS		ORAL
ORAL							
				Carbamazepine(Carbam azepine)	SS		ORAL
SEE IMAGE							
	3ISR Number Gender:Male	: 4090503-4Report Type:Expedit	ed (15-DaCompany Repor	t #PHBS2003JP02453			
Outcome	Description	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat Initial or F		Drug Dependence	Foreign Literature Health Professional	Tizanidine Hydrochloride (Tizanidine Hydrochloride)Unknow			
3 MG/DAY,			Other	n	PS		ORAL
ORAL							
				Caqrbamazepine (Carbamazepine)Unkno wn	SS		ORAL
500 MG/DAY,				WII	ಎಎ		UKAL
ORAL							
	3ISR Number Gender:Fema	r: 4097287-4Report Type:Directale I/FU:I	Company Repor	rt #CTU 191425			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Nausea		Xanaflex	PS		

25 MG (2 Q 8

H)

Pharmaceutical Product

Complaint

Nervousness

Date:04/22/03ISR Number: 4097289-8Report Type:Direct

Company Report #CTU 191426

Product

Diasera L

Alfarol

Role Manufacturer

С

С

Route

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

Outcome

Muscle Spasms

PRN PRN

Pharmaceutical Product

PT

Complaint

Date:04/24/03ISR Number: 4102202-OReport Type:Expedited (15-DaCompany Report #200310010BYL

Age:68 YR Gender:Female I/FU:I

Duration Dose Hospitalization -Erythema Multiforme Foreign Bayaspirin Initial or Prolonged Health (Acetylsalicylic Professional Acid) ORAL PS ORAL Other Celgotin S (Nicergoline) SS ORAL ORAL Enchinin (Tizanidine Hydrochloride) SS ORAL ORAL

Report Source

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Freedom Of Information (FOI) Report

C

Inderal

Norvasc

Date:04/24/03ISR Numbe Age:14 YR Gender:Mal	r: 4102658-3Report Type:Expede	dited (15-DaCompany Re	eport #ZANA001068		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Hospitalization - Initial or Prolonged ORAL	Clonic Convulsion Condition Aggravated	Literature Health	Zanaflex (Tizanidine Hydrochloride)	PS	ORAL
INTRATRACHEAL INTHC	Dyspnoea	Professional	Baclofen (Baclofen)	SS	
	Hyperpyrexia Mechanical Complication Of Implant Medical Device Complication Muscle Spasms Respiratory Rate Increased r: 4104230-8Report Type:Expec	dited (15-DaCompany Re	Lorazepam Clonazepam eport #PHBS2003JP02453	C C	
Age:35 YR Gender:Mal					
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged	Drug Dependence	Foreign Literature Health Professional	Tizanidine Hydrochloride (Tizanidine Hydrochloride)	PS	ORAL
3 MG/DAY,		rioressionar	ny droenror rae /		Oldin
•		Other			
ORAL			Carbamazepine		
			(Carbamazepine)	SS	ORAL

Date:04/30/03ISR Number: 4104792-OReport Type:Expedited (15-DaCompany Report #200310010BYL Age:68 YR Gender:Female I/FU:F

SEE IMAGE

Dose Duration Tospitalization - Tnitial or Prolonged	Erythema Multiforme	Foreign				
		Foroign	_ ' '			
nitial or Prolonged			Bayaspirin			
	Nasopharyngitis	Health	(Acetylsalicylic			
		Professional	Acid)	PS		ORAL
PRAL						
		Other	Celgotin S			
			(Nicergoline)	SS		ORAL
RAL						
			Enchinin (Tizanidine			
			Hydrochloride)	SS		ORAL
RAL						
			Diasera	C		
			Alfarol	C		
			Inderal	С		
			Norvasc	С		
age:45 YR Gender:Mal Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Hyperbilirubinaemia	Health	Zonegran			
		Professional	(Zonisamide)	PS		ORAL
PRAL						
			Zanaflex (Tizanidine			
			Hydrochloride)	SS		ORAL
.2 MG DAILY						
RAL				_		
			Elavil	C		
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<u> </u>						
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Product

Darvocet	(
Phrenilin	(

Role Manufacturer

Route

Date: 05/02/03ISR Number: 4106520-1Report Type: Expedited (15-DaCompany Report #ZANA001075

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

Outcome

ORAL

PT

Dose	Duration					
Other		Cerebrovascular Accident	Consumer	Zanaflex (Tizanidine		
				Hydrochloride)	PS	ORAL

Report Source

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 Hospitalization - SEE IMAGE	Alanine Aminotransferase Increased	Foreign Health	Tegretol(Carbamazepi ne)Tablet	PS		ORAL
Initial or Prolonged	Blood Alkaline Phosphatase Increased Gamma-Glutamyltransferase Increased Hepatic Function Abnormal Hypogammaglobulinaemia Immunodeficiency Pneumonia Productive Cough Pyrexia Rash Generalised Upper Respiratory Tract Infection	Professional Other	Ternelin(Tizanidine Hydrochloride) Gaster(Famotidine) Predonine Selbex (Teprenone) Rize (Clotiazepam)	SS SS C C		

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							
Hospitalizat:	ion -	Carpal Tunnel	Syndrome	Consumer	Neurontin			

Initial or Prolonged 400 MG	Cognitive Deterioration	Health	(Gabapentin)	PS
Other (DAILY), ORAL	Condition Aggravated	Professional		
(2::22 / / 0:22	Confusional State Disturbance In Attention Drug Interaction Encephalopathy		Anxiolytics Tizanidine Hydrochloride (Tizanidine	SS
	2		Hydrochloride) Tramadol Hydrochloride (Tramadol	SS
			Hydrochloride) Alprazolam	SS
			(Alpazolam) Oxycodone Hydrochloride (Oxycodone	С
			Hydrochloride) Hypnotics And	С
			Sedatives	С

ORAL

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Freedom Of Information (FOI) Report

Betaseron

Corticosteroid Nos

Fosamax

С

C

Date:05/05/03ISR Number: 4105660-OReport Type:Direct Company Report #CTU 192289

Age:37 YR Gender:Female I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 25 MG (2 Q	Duration	Nausea		Xanaflex	PS		
8H)		Nervousness					
,		Pharmaceutical Product Complaint					
	03ISR Number Gender:Male	:: 4108799-9Report Type:Expedit	ted (15-DaCompany Repor	st #ZANA001077			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duracion	Cardiotoxicity Ejection Fraction	Literature Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
ORAL		Decreased	Professional	Mitoxantrone (Mitoxantrone) Amantadine Indocin Corticosteroid Nos	SS C C		
	03ISR Number Gender:Fema	r: 4108801-4Report Type:Expeditale I/FU:I	ted (15-DaCompany Repor	ct #ZANA001078			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Cardiotoxicity	Literature Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
ORAL			Professional	Mitoxantrone			
12.5 MG/M2				(Mitoxantrone)	SS		

Date:05/13/0	03ISR Number:	4108166-8Report	Type:Expedited	(15-DaCompany Re	eport	#CH-BRISTOL-MYERS	SQUIBB	COMPANY-12119780	
700.43 VD	Candar · Famala	T/FII:F							

Report Source

Product

Duraclon (Clonidine Hydrochloride)

SS

Role Manufacturer

Route

PT

Outcome

900 MCG DAILY

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INTHC

Dose Duration						
Other	Abortion Induced	Health Professional	Selipran	PS	Bristol-Myers Squibb	
YR	Complications Of Maternal	Professional			Company	ORAL
	Exposure To Therapeutic		Seropram	SS		ORAL
YR	Drugs		Sirdalud	SS		ORAL
2 WK	DI 435		Bildalad	DD		Oldin
7 DAY	Maternal Drugs Affecting		Ponstan	SS		ORAL
7 DAY	Foetus		Brufen	SS		ORAL
7 DAY						
	Pregnancy					
	er: 4111600-0Report Type:Exped	ited (15-DaCompany R	eport #OXYS000009			
Age:42 YR Gender:Mal	e I/FU:I					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Condition Aggravated	Literature	Roxicodone	D.C.		0011
Initial or Prolonged 30 ML MONTHLY	Eosinophilia	Health	(Oxycodone Hcl)	PS		ORAL
30 HH 1101111111	Pleural Effusion	Professional				
ORAL						
			Zanaflex (Tizanidine Hydrochloride)	SS		ORAL
4 MG Q 8 HR			Hydrochroride;	55		UKAL
ORAL						

С

C C

С

Morphine

Fentanyl

Morphine

Bupivacaine

			Morphine Sulfate Gabapentin Fluoxetine Baclofen	0 0 0		
Date:05/13/03ISR Number Age:42 YR Gender:Male	r: 4111637-1Report Type:Expede	dited (15-DaCompany Re	eport #CLON000028			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged INTRATHECAL 900 MG	Breath Sounds Decreased Diarrhoea CG DAILY	Literature Health	Duraclon (Clonidine Hydrochloride)	PS		
INTHC	Muscle Spasms	Professional				
2 MG Q 8 HR	Nausea Pleural Effusion		Zanaflex (Tizanidine Hydrochloride)	SS		ORAL
ORAL	Vomiting					
			Morphine Bupivacaine Fentanyl	C C C		
Date:05/13/03ISR Number Age:42 YR Gender:Male	r: 4111638-3Report Type:Expece	dited (15-DaCompany Re	eport #ZANA001079			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 2MG Q 8 HR	Breath Sounds Decreased Condition Aggravated	Literature Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
ORAL	Diarrhoea	Professional				
	Muscle Spasms Nausea		Duraclon (Clonidine Hydrochloride)	SS		
INTRATHECAL 900 MG	CG DAILY Pleural Effusion					
INTHC						

Bupivacaine C Fentanyl Patch С

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 Other 8MG QID	Duration	Condition Aggravated		Tizanidine (Generic)	PS		
~		Drug Ineffective		Ambien	С		
		Headache		Prevacid	С		
		Loss Of Consciousness		Oxycontin	С		
		Pancreatic Disorder		Xanax	С		
		Pharmaceutical Product		Advair	С		
		Complaint		Imitrex	С		
				Tylox	С		
				02	С		

Date:05/15/03ISR Number: 4113569-1Report Type:Direct

Age: Gender:Female I/FU:I

Outcome PT

Condition Aggravated Other Drug Ineffective

Headache

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Company Report #CTU 193144

Freedom Of Information (FOI) Report

Xanaflex

PS

		Loss Of Consciousness Pancreatic Disorder Pharmaceutical Product	Donort Course	Product	Dolo	Manufacturer	Doute
Dose	Duration	Pharmaceutical Product	Report Source	Product	Role	Manufacturer	Route
DOSC	Daracion	Complaint		Tizanidine (Generic)			
		-		Eon Lab	PS	Eon Lab	
8 MG QID							
				Ambien	C		
				Prevacid	C		
				Oxycontin	С		
				Xanax	C		
				Advair	C		
				Imitrex	C		
				Tylox	C		
				02	С		
Outcome	Gender:Fema	ale I/FU:I PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration			0 (0') 1			
Disability		Abortion Induced	Foreign	Seropram (Citalopram	D.C.		
20 MG QD PO		Arthralgia	Other	Hybrobromide)	PS		
ZU MG QD PO		Complications Of Maternal		Selipran			
		Exposure To Therapeutic		(Pravastatin Sodium)	SS		
		Drugs		Sirdalud (Tizanidine	22		
		Drug Exposure During		Hydrochloride)	SS		
2 MG QD PO		5 1		,			
		Pregnancy		Ponstan (Mefenamic			
		Limb Injury		Acid)	SS		
500 MG QD P	0						
		Maternal Drugs Affecting Foetus		Brufen (Ibuprofen)	SS		
	03ISR Number Gender:Fema	r: 4117342-XReport Type:Direct ale I/FU:I	Company Repo	ort #CTU 194045			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration				11010		
				61			

Other

25 MG (2 Q

Nausea

Necrosis

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 - Abdominal Discomfort

Initial or Prolonged Anticonvulsant Drug Level

Other Increased

Asthenia

Cervical Vertebral

Fracture

Chest Discomfort

Convulsion Deafness

Deafness Neurosensory

Dental Plaque

Difficulty In Walking

Dizziness Dysstasia

Feeling Abnormal Hypoaesthesia

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Dose	Duration	Injury Joint Stiffness Muscle Spasms	Report Source	Product	Role Manufacturer	Route
DOSE	Duracion	Paralysis Road Traffic Accident	Consumer Health	Neurontin (Gabapentin)	DC.	ODAT
UNKNOWN				(Gabapentin)	PS	ORAL
(UNKNOWN),		Somnolence	Professional			
ORAL		Spinal Cord Injury				
		Tinnitus Tooth Discolouration		Dilantin Kapseals (Phenytoin Sodium)	SS	ORAL
UNKNOWN		Tooth Disorder				
(UNKNOWN),		Visual Acuity Reduced				
ORAL				Zoloft	SS	ORAL
UNKNOWN						
(UNKNOWN),						
ORAL				Lamotrigine		
UNKNOWN	UNKNOWI	N		(Lamotrigine)	SS	
(UNKNOWN),						
UNKNOWN						
				Topiramate (Topiramate)	SS	
UNKNOWN	UNKNOWI	N				
(UNKNOWN),						
UNKNOWN				Tizanidine		
				Hydrochloride (Tizanidine		
UNKNOWN				Hydrochloride)	SS	ORAL
(UNKNOWN),						
ORAL						

Cefuroxime Axetil	С
Fluoxetine	
Hydrochloride	C
Citalopram	
Hydrobromide	C
Levetiracetam	C
Lactulose	С
Lorazepam	C

Role Manufacturer

PS

Route

ORAL

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

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

Dose Duration

PT

Other Alopecia Consumer Zanaflex (Tizanidine

Product

Blood Cholesterol Hydrochloride)
4 MG BID ORAL

Increased Lortab C

Blood Pressure Increased Cerebrovascular Accident

Report Source

Headache Nausea Vomiting

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Outcome

Date:06/12/03ISR Number: 4129145-OReport Type:Expedited (15-DaCompany Report #USA-2002-0001447 Age:38 YR Gender:Female I/FU:F

Age. 30 IR Gender Fello	ale 1/ro·r					
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Abdominal Pain	Consumer	Oxycontin			
Initial or Prolonged	Alanine Aminotransferase	Health	(Oxycodone			
	Increased	Professional	Hydrochloride) Cr	PS		ORAL
40 MG, BID,			-			
	Anorexia	Other				
ORAL						
	Anxiety		Zanaflex (Tizanidine			
	Arthralgia		Hydrochloride)	SS		ORAL
12 MG, TID,						
	Aspartate					
ORAL						
	Aminotransferase		Depakote (Valproate			
	Increased		Semisodium)	C		
	Asthenia		Motrin Tablet	C		
	Back Pain		Demerol (Pethidine			
	Bile Duct Obstruction		Hydrochloride)			
	Chest Pain		Injectable	C		
	Chills		Phenergan			
	Coagulopathy		(Promethazine			
	Condition Aggravated		Hydrochloride)			
	Coordination Abnormal		Injectable	C	Wyeth-Ayerst	
	Cushingoid		Elavil			
	Dehydration		(Amitriptyline			
	Disorientation		Hydrochloride)			
	Dizziness Postural		Tablet	C		
	Drug Withdrawal Syndrome		Xanax			
	Duodenal Ulcer		(Alprazolam)	C		
	Dysphemia		Prednisone			
	Dyspnoea		(Prednisone) Tablet	С		
	Emotional Distress		Zyprexa			
	Fatigue		(Olanzapine) Tablet	С		
	Fear		Skelaxin			
	Feeling Cold		(Metaxalone) Tablet	С		
	Hallucination		Robaxin			
	Hepatotoxicity		(Methocarbamol)			
	Hyperhidrosis		Tablet	C		
	Insomnia		Bactrium Ds			
	Loss Of Consciousness		(Sulfamethoxazole,			
	Migraine		Trimethoprim) Tablet			
	Muscle Spasms		Vicodin Tablet	C		
	Muscle Twitching		Neurontin			
ı	Nausea		(Gabapentin) Tablet	C		

Neck Pain	Reglan Tablet	С
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

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Prednisone

Date:06/17/03ISR Number: 4130541-6Report Type:Direct Company Report #CTU 195994

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

Hyperhidrosis

Age 15 IK Gender Fell	1/10-1					
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Muscle Spasms Pharmaceutical Product		Tizanidine Hcl 4 Mg Teva Brand	PS	Teva	
1/2 TAB AT	Complaint					
BEDTIME						
	Tremor					
Date:06/17/03ISR Numbe Age:38 YR Gender:Fem	er: 4131733-2Report Type:Expe	dited (15-DaCompany R	eport #USA-2002-001447			
Outcome	PT	Report Source	Product	Pole	Manufacturer	Route
Dose Duration	11	Report Bource	Troduct	ROIC	Manaraccarci	Rouce
Hospitalization - 40 MG, BID,	Anorexia	Consumer	Oxycontin Tablets Cr	PS		ORAL
Initial or Prolonged ORAL	Anxiety	Health				
	Arthralgia Bile Duct Obstruction	Professional Other	Zanaflex (Tizanidine			
	Chest Pain Chills		Hydrochloride) Tablet	SS		ORAL
12 MG, TID,	0		10.0 10 0	22		01412
	Condition Aggravated					
ORAL			D 1 / /77 3 /			
	Confusional State Coordination Abnormal		Depakote (Valproate Semisodium)	С		
	Cushingoid		Motrin	C		
	Dehydration		Demerol (Pethidine			
	Disorientation		Hydrochoride)			
	Dizziness Postural		Injectable	C		
	Drug Withdrawal Syndrome		Phenergan "Wyeth			
	Duodenal Ulcer		Ayerst"			
	Dyspnoea Emotional Distress		(Promethazine Hydrochloride)			
	Fear		Injectable	С	Wyeth Ayerst	
	Feeling Of Body		Elavil	Ü		
	Temperature Change		(Amitriptyline			
	Hallucination		Hydrochloride)			
	Hepatitis		Tablet	С		
	Hepatotoxicity		Xanax (Alprazolam)	С		

Insomnia	(Prednisone) Tablet	С			
Intervertebral Disc	Zyprexa (Olanzapine)				
Disorder	Tablet				
Irritability	Skelaxin				
Migraine	(Metaxalone) Tablet	C			
Muscle Contractions	Robaxin				
Involuntary	(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	С			

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Product

Flexeril		
(Cyclobenzaprine		
Hydrochloride)		
Tablet	С	
Orphenadrine		
(Orphenadrine)	С	
Butalbital,		
Acetaminophen &		
Caffeine		
(Butalbital)	C	
Zithromax		
(Azithromycin)	С	Pfizer

Role Manufacturer

Route

Date:06/24/03ISR Number: 4135851-4Report Type:Expedited (15-DaCompany Report #S03-USA-02601-01

Age:49 YR Gender:Female I/FU:I

PT

Outcome

Dose Dur	ation				
Life-Threatening	Bradycardia	Health	Lexapro		
Hospitalization 10 MG QD PO	- Electrocardiogram Qt	Professional	(Escitalopram)	PS	ORAL
Initial or Prolo	nged Prolonged		Zanaflex (Tizanidine		
	Torsade De Pointes		Hydrochloride)	SS	
			Zanaflex (Tizanidine		
1			Hydrochloride)	SS	

Report Source

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

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Dose	Duration	Involuntary Muscle Spasms Nausea Nervousness	Report Source	Product	Role	Manufacturer	Route
	241401011	Oedema Peripheral Pain Palpitations Pancreatitis	Consumer Health Professional Other	Oxycontin Tablets(Oxycodone Hydrochloride) Cr Tablet	PS		ORAL
40 MG, BID,							
ORAL		Pyrexia					
		Road Traffic Accident Sensory Disturbance Skin Discolouration		Zanaflex(Tizandine Hydrochloride) Tablet	SS		ORAL
12 MG, TID,							
ORAL		Syncope					
		Tremor Vision Blurred Vomiting		Depakote (Valproate Semisodium) Tablet Motrin Tablet	C C		
				Demerol (Pethidine Hydrochloride) Injectable Phenergan	С		
				"Wyeth-Ayerst" (Promethazine Hydrochloride)			
				Injectablet Elavil (Amitriptyline	С		
				Hydrochlride) Tablet Xanax (Alprazolam) Prednisone	C		
				(Prednisone) Tablet Zyprexa (Lanzapine) Tablet	C C		
				Skelanxin (Metaxalone) Tablet Robaxin	С		
				(Methocarbamol) Tablet Bactrium Ds	С		
				(Sulfamethoxazole, Trimethoprim) Tablet Vicodin Tablet	C C		
				Neurontin (Gabapentin) Tablet	С		

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Reglan Tablet	С
Stadol Ns	
(Butorphanol	
Tartrate) Spray	C
Doxepin (Doxepin)	
Tablet	C
Thorazine	
(Chlorpromazine	
Hydrochloride)	
Tabelt	C
Flexeril	
(Cyclobenzaprine	
Hydrochloride)	
Tablet	C
Orphenadrine	
(Orphenadrine)	С
Butalbital,	
Acetaminophen &	

Caffeine

Freedom Of Information (FOI) Report

(Butalbital)

Product

Zithromax "Pfizer"

(Azithromycin) C

С

Role Manufacturer

Route

Date:06/26/03ISR Number: 4136019-8Report Type:Expedited (15-DaCompany Report #WAES 0306CHE00020

Age:29 YR Gender:Female I/FU:I

PT

Dose Duration						
Hospitalization -	Bradycardia	Health	Vioxx	PS	Merck & Co., Inc	ORAL
6 DAY Initial or Prolonged		Professional	Tramadol Hydrochloride	SS		ORAL
6 DAY			Tizanidine Hydrochloride	SS		ORAL

Report Source

Date:07/01/03ISR Number: 4140379-1Report Type:Expedited (15-DaCompany Report #USA-2002-0001447

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

Outcome F

Outcome

6

DAY

Hospitalization - Abdominal Pain

Initial or Prolonged 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

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Vision	Blurred
Vomitir	ng

Daga	Duna ki ara	Vision Blurred Vomiting	Report Source
Dose	Duration		Consumer Health Professional Other
40 MG, BID, ORAL			Offici
12 MG, TID,			

Report Source	Product	Role	Manufacturer	Route
Consumer Health Professional Other	Oxycontin Tablets(Oxycodone Hydrochloride) Cr Tablets	PS		ORAL
	Zanaflex (Tizanidine Hydrochloride) Tablet	SS		ORAL
	Depakote (Valproate Semisodium)Tablet Motrin Tablet Demerol (Pethidine	C C		
	Hydrochloride) Injectable Phenergan "Wyeth-Ayerst" (Promethazine Hydrochloride)Inject	С		
	able Elavil (Amitriptyline	С		
	Hydrochloride)Tablet Xanax (Alprazolam) Prednisone	C C		
	(Prednisone)Tablet Zyprexa	С		
	(Olanzapine)Tablet Skelaxin (Metaxalone) Tablet	C		
	Robaxin (Methocarbamol)			
	Tablet Bactrium Ds (Sulfamethoxazole,	С		
	Trimethoprim) Tablet	C		
	Vicodin Tablet Neurontin	C		

(Gabapentin) Tablet C

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Reglan Tablet	С
Stadol Ns	
(Butorphanol	
Tartrate) Spray	C
Doxepin (Doxepin)	
Tablet	С
Thorazine	
(Chlorpromazine	
Hydrochloride)	
Tablet	С
Flexeril	
(Cyclobenzaprine	
Hydrochloride)	
Tablet	С
Orphenadrine	
(Orphenadrine)	С
Butalbital,	
Acetaminophen &	
Caffeine	

(Butalbital)	С
Zithromax "Pfizer"	
(Azithromycin)	С
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-Threate	ening	Bradycardia	Health	Zanaflex (Tizanidine			
Hospitalizat	tion -	Electrocardiogram	Professional	Hydrochloride)	PS		
Initial or E	Prolonged	Abnormal	Other	Lexapro			
Required	_	Electrocardiogram Qt		(Escitalopram)	SS		ORAL
10 MG OD ORA	ΔΤ,						

10 MG QD ORAL

Intervention to Corrected Interval

Prevent Permanent Prolonged

Impairment/Damage Electrocardiogram Qt

Prolonged

Torsade De Pointes

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 - Anxiety
Initial or Prolonged 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

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Dose	Duration	Palpitations Pancreatitis Paraesthesia	Report Source	Product	Role	Manufacturer	Route
Dose	Duracion	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		Zanaflex(Tizanidine Hydrochloride)			
12 MG, TID,		Vision Blurred		Tablet	SS		ORAL
ORAL				Depaire to (Malayeeta			
				Depakote (Valproate Semisodium) Motrin Demerol (Pethidine	C C		
				Hydrochloride) Phenergan	С		
				Wyeth-Ayerst (Promethazine Hydrochloride)	С		
				Elavil (Amitriptyline Hydrochloride)	С		
				<pre>Xanax (Alprazolam) Prednisone (Prednisone)</pre>	C C		
				Zyprexa (Olanzapine) Skelaxin	C		
				(Metaxalone) Robaxin (Methocarbamol)	C C		
				Bactrium Ds (Sulfamethoxazole,	C		
				Trimethoprim) Vicodin Neurontin	C C		
				(Gabapentin) Reglan Stadol Ns	C C		
				(Butorphanol Tartrate)	С		

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Doxepin (Doxepin)	С
Thorazine	
(Chlorpromazine	
Hydrochloride)	С
Flexeril	
(Cyclobenzaprine	
Hydrochloride)	C
Orphenadrine	
(Orphenadrine)	С
Butalbital,	
Acetaminophen &	
Caffeine	
(Butalbital)	C
Zithromax Pfizer	
(Azithromycin)	C
Promethazine	
(Promethazine)	C
Cipro (Ciprofloxacin	
Hydrochloride)	С

Freedom Of Information (FOI) Report

Product

Zydone C
Triamterene (Triamterene) C

Role Manufacturer

Route

Date:07/16/03ISR Number: 4150486-5Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20030701841

Age:29 YR Gender:Female I/FU:I

PT

Dose Durati	ion				
Hospitalization -	Bradycardia	Foreign	Tramal (Tramadol		
Initial or Prolonge 20 GTT, ORAL	ed Drug Interaction	Health	Hydrochloride)	PS	ORAL
		Professional	Vioxx (Rofecoxib)	SS	ORAL
50 MG, ORAL					
			Sirdalud (Tizanidine		
			Hydrochloride)	SS	ORAL

Report Source

6 MG, 1 IN 1

DAY, ORAL

Outcome

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 - And

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

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		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,			Orner	IADIEC	ro		LAAU
ORAL				a 63 /=' '-'			
				Zanaflex(Tizanidine Hydrochloride)Tablet	SS		ORAL
12 MG, TID,				, ar ociiror rue / rabret	SO		OIVALI
ORAL				Noncogen (Noncogen)	a		
				Naprosyn (Naproxen) Depakote (Valproate	С		
				Semisodium) Tablet	С		
				Motrin Tablet	С		
				Demeron (Pethidine			
I				Hydrochloride)	C		
1				Injectable Phenergan	С		
				"Wyeth-Ayerst"			
I				(Promethazine			
				Hydrochloride)Inject			
				able	С		
				Elavil (Amitriptyline			
				(Amitriptyline Hydrochloride)	С		
				Xanax (Alprazolam)	C		
				Prednisone			
I				(Prednisone)Tablet	C		
I				Zyprexa	a		
I				(Olanzaprine)Tablet Skelaxin	С		
I				(Metaxalone)Tablet	С		
				Robaxin	-		
				(Methocarbamol)			
				Tablet	С		
				Bactrium Ds			
				(Sulfamethoxazole, Trimethoprim)Tablet	С		
				Vicodin Tablet	C		
				Neurontin			
				(Gabapentin) Tablet	С		

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Reglan Tablet	С
Stadol Ns	
(Butorphanol	
Tartrate)Spray	C
Doxepin (Doxepin)	
Tablet	C
Thorazine	
(Chlorpromazine	
Hydrochloride)	
Tablet	С
Flexeril	
(Cyclobenzaprine	
Hydrochloride)	
Tablet	С
Orphenadrin	
(Orphenadrine)	С
Butalbital,	
Acetaminophen &	
Caffeine -	

(Butalbital)	С
Zithromax "Pfizer"	
(Azithromycin)	C
Promethazine	
(Promethazine)	C
Cipro (Ciprofloxacin	
Hydrochloride)	C
Zydone	C
Triamterene	
(Triamterene)	C

Role Manufacturer

Route

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-Threater	ning	Blood Pressure Decreased		Vioxx	PS	Merck & Co., Inc	ORAL
1 DAY							
Hospitalizat:	ion -	Bradycardia		Zanaflex	SS		
Initial or Pa	rolonged	Chest Pain		Premarin	С		
		Difficulty In Walking		Lidocaine	С		
		Dyspnoea		Alprazolam	С		
		Myocardial Infarction					

Date:07/22/03ISR Number: 4154620-2Report Type:Expedited (15-DaCompany Report #ZANA001087

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

Gender:Male

PT

Outcome

Age:

Intervention to Prevent Permanent Impairment/Damage

Dose	Duration					
Other		Ectopic Pregnancy	Consumer	Zanaflex (Tizanidi	.ne	
Required				Hydrochloride)	PS	ORAL
ORAL						

Product

Report Source

Date:07/28/03ISR Number: 4158211-9Report Type:Expedited (15-DaCompany Report #001-0945-950345

Outcome PT Report Source Product Role Manufacturer Route
Dose Duration

Hospitalization - Abasia Consumer Neurontin

I/FU:F

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)	С	
1			•		

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Freedom Of Information (FOI) Report

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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threate Hospitalizat 40 MG DAILY	ening tion -	Acidosis Acute Respiratory Failure	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
Initial or E	Prolonged	Anuria					
		Blood Urine Cardiac Disorder		Toradol (Ketorolac) Lipitor	SS		
1		Coma		(Atorvastatin)	SS		ļ
1		Crepitations		Betapace (Sotalol)	С		ļ
1		Depressed Level Of		Lasix (Furosemide)	С		ļ
1		Consciousness		Potassium			ļ
1		Dialysis		(Potassium)	C		ļ
1		Drug Screen Positive		Synthroid			ļ
1		Hyperkalaemia		(Levothyroxine)	C		!
1		Hypotension		Proventil Inhaler			I
1		Hypothermia		(Salbutamol)	C		
1		Intentional Misuse		Phenergan			
1		Nervous System Disorder		(Promethazine)	C		
1		Pneumonia Aspiration					
1		Respiratory Rate					
1		Decreased					
A .		Rhabdomyolysis					
1		Suicide Attempt					
1							

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							

Date:08/07/03ISR Number: 4165028-8Report Type:Direct Company Report #CTU 199561

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

Outcome PTReport Source Product Role Manufacturer Route Dose Duration Zanaflex PS

Abnormal Behaviour Conversion Disorder

Crying

Euphoric Mood Excitability

Fall

Feeling Abnormal Feeling Of Despair

Formication Headache

Loss Of Consciousness Self-Injurious Ideation

Vertigo

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Other

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 Required 10 MG DAILY	Duration	Drug Interaction	Foreign	Zestril	PS	ORAL
Intervention PO	to	Hypotension	Health			
Prevent Perma 2 MG DAILY PO			Professional	Sirdalud	SS	ORAL
Impairment/Da	amage		Other	Senokot Magnesium Oxide	C C	
				Amikin	C	
				Trandate	С	
				Nimotop	С	
				Well-Well	C	
				Glycerol	C	
				Mucosolvan	C	
				Clincin	С	
				Ofloxacin	C	
Date: 08/20/0	RISR Number	r: 4173184-NReport Type:Eype	edited (15-DaCompany Re	enort #7ANA001090		

Date:08/20/03ISR Number: 4173184-0Report Type:Expedited (15-DaCompany Report #ZANA001090

Gender:Female I/FU:I Age:

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalizat		Anaphylactic Reaction		Zanaflex (Tizanidine			
Initial or P	rolonged		Professional	Hydrochloride)	PS		ORAL
ORAL							

Date:08/21/03ISR Number: 4173426-1Report Type:Direct Company Report #CTU 200454

Gender: Female I/FU:I Age:

Role Manufacturer Outcome PTReport Source Product Route Duration Dose

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

Outcome PTReport Source Product Role Manufacturer Route

Duration Dose

Drug Ineffective Tizanidine (Generic Other Infection Zanaflex) 4 Mg Q6 PS ORAL

4 MG Q 6 PO

Pharmaceutical Product

Complaint

Date:09/05/03ISR Number: 4181550-2Report Type:Direct Company Report #CTU 201346

Gender:Female Age:57 YR I/FU:I

Report Source Role Manufacturer Outcome PTProduct Route Duration Dose

Drug Ineffective Tizanidine (Generic Other

Zanaflex) 4mg Q 6 Infection

Pharmaceutical Product Hrs PS ORAL

4MG Q 6 HRS

Complaint

PΟ

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Freedom Of Information (FOI) Report

Hydrocodone /Apap

Product

Role Manufacturer

PS

Route

ORAL

Date:09/08/03ISR Number: 4185781-7Report Type:Expedited (15-DaCompany Report #ZANA001092

Age:32 YR Gender:Female I/FU:I

PT

Dose Duration

Hospitalization - Intentional Misuse Health Zanaflex (Tizanidine

Initial or Prolonged Loss Of Consciousness Professional Hydrochloride) PS ORAL

Report Source

4 MG ORAL

Respiratory Rate Decreased

Medication Error

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

Outcome

Other

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

365 DAY

Outcome PT Report Source Product Role Manufacturer Route

Dose Duration

Hospitalization - Renal Failure Acute Health Bextra (Valdecoxib)

Initial or Prolonged Professional Tablet

10 MG, BID;

Glucophage

(Metformin

Hydrochloride) SS ORAL 500 MG, BID;

Joo no, bib.

ORAL

ORAL Valium (Diazepam) SS ORAL

UNK, UNK;

ORAL

		Baclofen (Baclofen)	SS	
UNKNOWN	UNK, UNK, UNK	Diama (Malaastan)		
UNKNOWN	UNK, UNK, UNK	Diovan (Valsartan)	SS	
		Zanaflex (Tizanidine		
UNK, UNK;		Hydrochloride)	SS	ORAL
ORAL				
		Hydrocodone (Hydrocodone)	SS	
UNKNOWN	UNK, UNK, UNK	Niacin (Nicotinic Acid)	SS	ORAL
250 MG, QD;		ACIU)		OKALI
ORAL				
		Vasotec (Enalapril Maleate)	SS	ORAL
10 UNK, UNK;		Maleace	55	OKAL
ORAL				
		Potassium Chloride	99	ODAT
8 UNK, BID;		(Potassium Chloride)	SS	ORAL
ORAL				
		Tolterodine		
		L-Tartrate Ultram (Tramadol	C	
		Hydrochloride)	С	
		Protonix (Pyritinol)	C	
		Lasix	C	
		Norvasc (Amlodipine Besilate)	С	

Lortab

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Freedom Of Information (FOI) Report

Date:09/24/03ISR Number: 4193327-2Report Type:Expedited (15-DaCompany Report #WAES 0309ITA00012

Gender:Female Age:76 YR I/FU:F

	Report Source	Product	Role	Manufacturer	Route
ion Face Oedema	Health	Vioxx	PS		ORAL
Tongue Oedema Urticaria	Professional	Tizanidine Hydrochloride	SS		ORAL
		_			
		Cozaar	С	Merck & Co., Inc	ORAL
:Unknown I/FU:I	e:Expedited (15-DaCompany Re Report Source	eport #US-JNJFOC-200309046 Product		Manufacturer	Route
Overdose	Literature Health	Tylox (Oxycodone/ Acetaminophen)	20		0.7.7
	Professional	Capsules	PS		ORAL
	Distributor	Oxycodone(Oxycodone) Tizanidine	SS		
_	Urticaria Number: 4199610-9Report Typ r:Unknown I/FU:I PT	Urticaria Number: 4199610-9Report Type:Expedited (15-DaCompany Rec:Unknown I/FU:I PT Report Source tion Overdose Literature Health	Urticaria Hydrochloride Cozaar Number: 4199610-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-200309046 c:Unknown I/FU:I PT Report Source Product cion Overdose Literature Tylox (Oxycodone/ Health Acetaminophen)	Urticaria Hydrochloride SS Cozaar C Number: 4199610-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030904656 S:Unknown I/FU:I PT Report Source Product Role Cion Overdose Literature Tylox (Oxycodone/ Health Acetaminophen)	Urticaria Hydrochloride SS Cozaar C Merck & Co., Inc Number: 4199610-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030904656 r:Unknown I/FU:I PT Report Source Product Role Manufacturer rion Overdose Literature Tylox (Oxycodone/ Health Acetaminophen)

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Rebound Hypertension	Consumer	Zanaflex (Tizanidine			
		Somnolence		Hydrochloride)	PS		ORAL
10 MG DAILY							
		Tremor					
ORAL							
				Vioxx (Rofecoxib)	С		
				Vicodin			

	-
icodin	
Paracetamol)	C
icodin	
Paracetamol)	C

Date:10/06/03ISR Number: 4204989-5Report Type:Expedited (15-DaCompany Report #ZANA001097

Age: Gender: Female I/FU:I

Outcome PTReport Source Product Role Manufacturer Route

PS

SS

SS

ORAL

Dose Duration

Hospitalization -Hallucinations, Mixed Health Zanaflex (Tizanidine

Initial or Prolonged Professional Hydrochloride)

8 MG DAILY

ORAL Ambien (Zolpidem) С

Date:10/10/03ISR Number: 4208761-1Report Type:Expedited (15-DaCompany Report #2003110069

Gender: Female Age:38 YR I/FU:I

Role Manufacturer Outcome PTReport Source Product Route Duration Dose

Other Bladder Spasm Health Neurontin

Complex Regional Pain Professional (Gabapentin) PS ORAL

300 MG (TID),

Syndrome

ORAL

Zonisamide Condition Aggravated

Feeling Abnormal (Zonisamide)

Laboratory Test Abnormal Ropinirole

Medication Error Hydrochloride

Vaginitis Bacterial (Ropinirole

White Blood Cell Count Hydrochloride) Decreased

Tizanidine

Hydrochloride (Tizanidine

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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		Generalised Oedema		Zanaflex 2mg	PS	ORAL
2MG-16MG Q	HS					
Intervention	n to					
ORAL						
Prevent Per	manent					

Date:10/16/03ISR Number: 4210563-7Report Type:Direct Company Report #CTU 203921

Age: 9 YR Gender: Male I/FU:I

Impairment/Damage

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Pharmaceutical Product		Tizanidine 2 Mg	PS		

2 MG BID

Complaint Baclofen 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 - Acute Respiratory Failure

Initial or Prolonged Anuria

Blood Creatine Phosphokinase Blood Urine Cardiac Disorder

Coma

Crackles Lung Depressed Level Of

Consciousness

Dyspnoea

Haemodynamic Instability

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D	D	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				ny ar contor rac ,	10		Oldin
ORAL		Rhabdomyolysis					
ORALI		Suicide Attempt Urine Abnormality		Toradol (Ketorolac) Lipitor	SS		
				(Atorvastatin)	SS		
				Betapace (Sotalol)	C		
				Lasix (Furosemide)	С		
				Potassium			
				(Potassium)	С		
				Synthroid	~		
				(Levothyroxine) Proventil Inhaler	С		
				Proventil Inhaler (Salbutamol)	С		
				(Salbutamol) Phenergan	C		
				(Promethazine)	С		
)3ISR Number Gender:Male	: 4216029-2Report Type:Exped	lited (15-DaCompany Re	eport #US-JNJFOC-200309046	556		
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration		10010 000100	1104400	11010	Manaractarer	1.00.00
Death	20222	Alcohol Use	Literature	Tylox			
1		Blood Bicarbonate	Health	(Oxycodone/Acetamino			
		Decreased	Professional	phen) Capsules	PS		ORAL
ORAL							
		Blood Creatine	Distributor	Oxycodone			
1		Pl: 1: 1 ' = 1		/ 0 1)	~~		

Phosphokinase Increased (Oxycodone) SS Blood Creatine Tizanidine Phosphokinase Mb (Tizanidine) SS Ethanol (Ethanol) Increased SS Blood Ph Decreased Corticosteroid Blood Potassium Increased (Corticosteroids) SS Blood Pressure Systolic Increased Body Temperature Increased Cardio-Respiratory Arrest

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

Report Source Role Manufacturer Outcome PTProduct Route Dose Duration

Hospitalization -Intentional Misuse Zanaflex PS

Initial or Prolonged

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Freedom Of Information (FOI) Report

Zanaflex (Tizanidine

PS

Hydrochloride)

Dose

Other

12 TO 24 MG

Duration

Angioneurotic Oedema

Hypersensitivity

Date:10/22/03ISR Numbe Age:40 YR Gender:Fem	er: 4217003-2Report Type:Expenale I/FU:I	dited (15-DaCompany Re	eport #KII-2003-0002484			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
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			
40 MG, ORAL			Sulfate) Cr Tablet	SS		ORAL
			Zanaflex (Tizanidine Hydrochloride)	SS		ORAL
SEE TEXT,						
Date:10/27/03ISR Numbe Age:48 YR Gender:	er: 4221012-7Report Type:Expe I/FU:I	dited (15-DaCompany Re	eport #ZANA001103			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Completed Suicide Multiple Drug Overdose	Literature Health Professional	Zanaflex (Tizanidine Hydrochloride) Propoxyphene/Acetami onophen	PS		
			(Dextropropoxyphene) Venlafaxine	SS		
			(Venlafaxine)	SS		
Date:10/30/03ISR Numbe Age:37 YR Gender:Fem	r: 4223831-XReport Type:Expe	dited (15-DaCompany Re	eport #ZANA001106			
	nale I/FU:I					
Outcome	nale I/FU:I PT	Report Source	Product	Role	Manufacturer	Route

Health

Professional

Complaint

Date:10/30/03ISR Number: 4223835-7Report Type:Expedited (15-DaCompany Report #ZANA001105

Age:50 YR Gender: Male I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration

Other Drug Withdrawal Syndrome Health Zanaflex (Tizanidine

Medication Error Professional Hydrochloride) PS ORAL

48 MG DAILY

ORAL Baclofen (Baclofen)

Date:10/30/03ISR Number: 4223838-2Report Type:Expedited (15-DaCompany Report #ZANA001104

Age:56 YR Gender: Female I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Duration Dose

Health Zanaflex (Tizanidine

Hospitalization -Blood Pressure Increased

Initial or Prolonged Myocardial Infarction Professional Hydrochloride) PS ORAL

2-5 MG DAILY

ORAL

Vioxx (Rofecoxib) С

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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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threate		Bradycardia	Health	Lexapro			
Hospitalizat	_	Electrocardiogram Qt	Professional	(Escitalopram)	PS		ORAL
Initial or Prolonged	Prolonged Torsade De Pointes		Zanaflex (Tizanidine Hydrochloride) Zanaflex (Tizanidine	SS			
				Hydrochloride)	SS		
)3ISR Number Gender:	: 4224110-7Report Type:Expe I/FU:I	edited (15-DaCompany Re	eport #OXYT000102			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Death	Literature Health	Roxicodone	PS		
		Multiple Drug Overdose	Professional	(Oxycodone Hcl) Zanaflex (Tizanidine	PS		
				Hydrochloride)	SS		
				Acetaminophen/Oxycod one			
				(Acetaminophen/Oxyco			
				done)	SS		
)3ISR Number Gender:Fema	r: 4224269-1Report Type:Expe ale I/FU:I	edited (15-DaCompany Re	eport #KII-2003-0003787			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route

Dose Duration

Oxycontin Tablets Other Medication Error Health Respiratory Rate Professional (Oxycodone

Hydrochloride) Cr Increased Tablet

SEE IMAGE DAY

Zaroxolyn

(Metolazone) SS ORAL 7.5 MG, SEE

PS

ORAL

TEXT, ORAL

	Lipitor		
10 MG, SEE	(Atorvastatin)	SS	ORAL
TEXT, ORAL	Slow-Mag (Magnesium		
SEE TEXT,	Chloride Anhydrous)	SS	ORAL
ORAL			
25 MG, SEE	Aldactone (Spironolactone)	SS	ORAL
TEXT, ORAL			
TEAT, ORAL	Oscal (Calcium Carbonate)	SS	ORAL
500 MG, SEE	Carbonate)	55	URAL
TEXT, ORAL	Cleocin (Clindamycin		
150	Hydrochloride)	SS	ORAL
150 MG, SEE			
TEXT, ORAL	K-Dur (Potassium		
20 MEQ, SEE	Chloride)	SS	ORAL
TEXT, ORAL			
	Zanaflex (Tizanidine Hydrochloride)	SS	ORAL
4 MG, SEE			01412
TEXT, ORAL	Lasix (Furosemide)	SS	ORAL
160 MG, SEE	Lasix (Fullosemide)		OKAL
TEXT, ORAL	Atarax (Hydroxyzine		
22-Aug-2005 12:09 Page: 173	Acarax (hydroxy21he		

Freedom O	f Information (FOI) Re	port	
	Hydrochloride)	SS	ORAL
	Skelaxin (Metaxalone)	SS	ORAL
	Premarin (Estrogens Conjugated)	SS	ORAL
	Prozac (Fluoxetine Hydrochloride)	SS	ORAL
	Zantac (Ranitidine Hydrochloride)	SS	ORAL
	Colace (Docusate Sodium)	SS	ORAL
	Dilantin (Phenytoin Sodium)	SS	
	Valium (Diazepam)	SS	
	Cardizem (Diltiazem Hydrochloride)	SS	
	Antivert (Meclozine Hydrochloride, Nicotinic Acid)	SS	
	Niferex (Polysaccharide-Iron Complex)	SS	
	Lovenox (Heparin-Fraction,		

25 MG, SEE

TEXT, ORAL

400 MG, SEE

TEXT, ORAL

1.25 MG, SEE

TEXT, ORAL

10 MG, SEE

TEXT, ORAL

150 MG, SEE

TEXT, ORAL

100 MG, SEE

100 MG 1 DAY

1

DAY

5 MG 1 DAY

300 MG 1 DAY

20 MG 1 DAY

150 MG 1 DAY

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

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Freedom Of Information (FOI) Report

Dose	Duration	Pupil Fixed Respiratory Rate Decreased	Report Source	Product	Role M	anufacturer	Route
DOSE	Duracion	Respiratory Rate Increased	Health Professional Other	Oxycontin Cr Methadone (Methadone) Trazodone(Trazodone) Gabapentin(Gabapenti	PS SS SS		
400 MG				n)	SS		
200 MG				Quetiapine(Quetiapin e)	SS		
20 MG				Citalopram(Citalopra m)	SS		
				Clonazepam (Clonazepam)	SS		
1 MG				Zanaflex(Tizanidine Hydrochloride)	SS		ORAL
4 MG, ORAL				Bupropion(Amfebutamo ne)	SS		
150 MG				Cyclobenazprine(Cycl			
10 MG				obenzaprine) Amitriptyline(Amitri	SS		
50 MG				<pre>ptyline) Estalopram()</pre>	SS		
				istatopram()			
Date:11/04/0 Age:	31SR Number Gender:	: 4227704-8Report Type:Direct I/FU:I	Company Report	t #CTU 205236			
Outcome Dose	Duration	PT	Report Source	Product		anufacturer	Route
2 TID		Drug Ineffective		Zanaflex 4mg	PS		
		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 Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 4 MG BID PO	Abnormal Behaviour		Zanaflex	PS	ORAL
1 1.6 212 16	Confusional State		Aciphex	С	
	Crying		Trazodone	C	
	Feeling Abnormal		Paxil	С	
	Paranoia		Zyprexa	C	
	Urinary Tract Infection		Atenolol	C	
			Ms Contin	C	
			Neurontin	C	
Age:65 YR Gender:Ma Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - 75 MG QD,	Alanine Aminotransferase	Foreign	Clopidogrel Sulfate	PS	ORAL
Initial or Prolonged ORAL	Increased	Health			
	Aspartate	Professional	Stilnox - (Zolpidem)	SS	ORAL
10 MG QD,	-		-		
	Aminotransferase	Other			
ORAL					
	Increased		Phenhydan -		
	Stevens-Johnson Syndrome			99	
	Scevens-Common Syndrome		(Phenytoin)	SS	ORAL
300 MG QD,	Toxic Epidermal		(Phenytoin)	SS	ORAL

Ritrovil -

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Necrolysis

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ORAL

					(Lonazepam)	SS		
INTRAVENOUS	0.	.5 MG,	1		(Honazepa,			
INTRAVENOUS								1
NOS	1	DAY			- ' ' (Glabaram)	3.3		
20 MG QD,					Frisium - (Clobazam)	SS		ORAL
ORAL	2	DAY			.			
05					Clont - (Metronidazole)	SS		ORAL
500 MG QD,	_							
ORAL	9	DAY			Klacid			
500 MG QD,					-(Clarithromycin)	SS		ORAL
ORAL	9	DAY						
					Pantozol - (Pantoprazole			
40 MG QD,					Sodium)	SS		ORAL
ORAL	9	DAY						
					Sirdalud - (Tizanidine			
					Hydrochloride)- Unknown	SS		ORAL
4 MG QD ORAL					Metronidazole	C		0141_
					Clarithromycin	С		
					Pantoprazole	С		
			: 4232803-OReport Type:Direct I/FU:I	Company Report	c #CTU 205667			
Outcome Dose	Durati		PT	Report Source	Product	Role	Manufacturer	Route
ANY	Durac		Blood Pressure Decreased		Zanaflex	PS		
ANY			Loss Of Consciousness					
1								, , , , , , , , , , , , , , , , , , ,

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						
Hospitalizati	lon -	Hepatic Failure	Foreign	Unspecified			ļ
Initial or Pr	rolonged	Hepatic Necrosis	Literature	Paracetamol Product			
Required		Hepatic Steatosis	Other	(Paracetamol)	PS		ORAL
35 G PO							ļ
Intervention	to	Nausea		Tizanidine	SS		ORAL
PO							
Prevent Perma	anent	Overdose		Alcohol	SS		
Impairment/Da	amage	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 -	Drug Screen Positive	Study	Morphine			
Initial or Prolonged	Hyperhidrosis	Health	Sulfate(Similar To			
Other	Hyperpyrexia	Professional	Nda 19-516)(Morphine			
	Medication Error	Other	Sulfate) Unknown	PS		
	Multiple Drug Overdose		Soma (Carisoprodol)	SS		
	Sinus Tachycardia		Valium(Diazepam)	SS		
	Somnolence		Ace Inhibitor Nos()	SS		
	White Blood Cell Count		Antihistamine()	SS		
			Nortriptyline(Nortri			ļ
			ptyline)	SS		
			Biguandes()	SS		
			Anticonvulsant()	SS		
			Ssri()	SS		

Acetaminophen(Parace

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Hydrochloride)

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

SS

Date:11/14/03ISR Number: 4235450-XReport Type:Direct Company Report #CTU 206114

I/FU:I

Gender: Female Age:

Outcome PTReport 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

Company Report #CTU 206352 Date:11/18/03ISR Number: 4237313-2Report Type:Direct

Gender: Female Age: I/FU:I

Role Manufacturer PTReport Source Product Outcome 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 PTReport 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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Deafness		Diovan	PS	Novartis Sector: Pharma	ORAL
				Ternelin	SS		ORAL
				Gasmotin	C		ORAL
				Norvasc	· ·		01412
				/Den/	С		
Age:38 YR Outcome	Gender:Fema	ale I/FU:F PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Bladder Spasm	Health	Neurontin			
		Feeling Abnormal	Professional	(Gabapentin)	PS		ORAL
300 MG (TID)	,						
0077		Nervousness					
ORAL		Vaginitis Bacterial		Zonisamide			
		White Blood Cell Count		(Zonisamide)	SS		
		Decreased		Ropinirole	مم		
		Decreased		Hydrochloride			
				(Ropinirole			
1				(MODILLITE OTC			

Hydrochloride)

SS

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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)	С
Ascorbic Acid	
(Ascorbic Acid)	C C
Zinc (Zinc)	C
Chromium (Chromium)	C
Policosanol	
(Policosanol)	C
Lactobacillus	
Acidophilus	
(Lactobacillus	
Acidophilus)	C

C

С

Aspirin

Clarinex

Hctz

Date:12/02/03ISR Number: 4244848-5Report Type:Direct Company Report #CTU 207204

Muscle Spasms

Movement Disorder

Muscular Weakness

Age:	Gender:Fema	ile I/FU:I				
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Other		Abnormal Dreams Chest Discomfort		Tizanidine Hcl (Zanaflex)	PS	
2 MG Q HS,				(Zanarien)		
		Convulsion				
TAPERED UP	TO					
		Depression				
8 MG/ SEE	B5 6 MON	I				
		Dizziness		Lipitor	C	
		Eye Pain		Vioxx	C	
i		Hyperhidrosis		Toprol Xl	С	

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

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Prevent Permanent Impairment/Damage

Nausea

Tachycardia

Vomiting

Respiratory Arrest

Troponin Increased

impairment, bama	50						
Dose Du:	ıration	PT	Report Source	Product	Role	Manufacturer	Route
ose bu		Dialysis Hepatic Necrosis	Foreign Literature	Unspecified Paracetamol Product	D.G.		CD II
35 G PO		Hepatic Steatosis	Other	(Paracetamol)	PS		ORAL
		Nausea		Tizanidine	SS		ORAL
PO		Overdose Suicide Attempt Vomiting		Alcohol	SS		
	SR Number: nder:Male	: 4254974-2Report Type:Expedite	ed (15-DaCompany Repor	t #PERC20030095			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Du: Death PO	ıration	Alcohol Use	Literature	Percocet	PS	Endo	ORAL
Life-Threatenin	g	Blood Creatine	Health	Oxycodone	SS		ORAL
Hospitalization PO	. –	Phosphokinase Increased	Professional	Tizanidine	SS		ORAL
Initial or Prole	onged	Blood Creatine		Ethanol	SS		ORAL
ONCE INJ		Phosphokinase Mb		Corticosteroid	SS		
		Increased Blood Potassium Increased Blood Pressure Systolic Increased Body Temperature Increased Cardiac Arrest Coma Diabetes Insipidus Hypotension Muscle Rigidity					

Date:12/17/03ISR Number: 4254987-OReport 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-Threate	ening	Drug Interaction	Health	Zanaflex (Tizanidine			
Other		Haemolysis	Professional	Hydrochloride)	PS		ORAL
36 MG ORAL							
1				Baclofen (Baclofen)	SS		
ı				Neurontin			
ı				(Gabapentin)	С		
A				Ditropan			
ı				(Oxybutynin)	С		
A				Prednisone			
<i>A</i>				(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

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Freedom Of Information (FOI) Report

Role Manufacturer

Route

Product

Representative Other

Duration

Dose

		Oxycontin Tablets (Oxycodone Hydrochloride)	PS		
		Reglan (Metoclopramide)	SS		
		(11000010F141400)	22		
		Lexapro (Citalopram)	SS		
		Percocet (Paracetamol, Oxycodone Hydrochloride)	SS		
		Zantac (Ranitidine	aa		
		Hydrochioride)	SS		
		Zanaflex (Tizanidine Hydrochloride) Flagyl	SS		
		(Metronidazole)	SS		
: 4271088-6Report Type:Period le I/FU:I	ic Company Rep	port #KII-2003-0004072			
PT	Report Source	Product	Role	Manufacturer	Route
Bradycardia Hypertension	Health Professional	Oxycontin Tablets (Oxycodone	DC		ORAL
Multiple blug Overdose			PS		ORAL
			SS		ORAL
	le I/FU:I PT Bradycardia	le I/FU:I PT Report Source Bradycardia Health Hypertension Professional	(Oxycodone Hydrochloride) Reglan (Metoclopramide) Lexapro (Citalopram) Percocet (Paracetamol, Oxycodone Hydrochloride) Zantac (Ranitidine Hydrochloride) Zantac (Ranitidine Hydrochloride) Zanaflex (Tizanidine Hydrochloride) Flagyl (Metronidazole) : 4271088-6Report Type:Periodic Company Report #KII-2003-0004072 le I/FU:I PT Report Source Product Bradycardia Health Oxycontin Tablets Hypertension Professional (Oxycodone	(Oxycodone Hydrochloride) PS Reglan (Metoclopramide) SS Lexapro (Citalopram) SS Percocet (Paracetamol, Oxycodone Hydrochloride) SS Zantac (Ranitidine Hydrochloride) SS Zantac (Ranitidine Hydrochloride) SS Zanaflex (Tizanidine Hydrochloride) SS Flagyl (Metronidazole) SS : 4271088-6Report Type:Periodic Company Report #KII-2003-0004072 le I/FU:I PT Report Source Product Role Bradycardia Health Oxycontin Tablets Hypertension Professional (Oxycodone Hydrochloride) PS Tizanidine	(Oxycodone Hydrochloride) PS Reglan (Metoclopramide) SS Lexapro (Citalopram) SS Percocet (Paracetamol, Oxycodone Hydrochloride) SS Zantac (Ranitidine Hydrochloride) SS Zantac (Ranitidine Hydrochloride) SS Zanaflex (Tizanidine Hydrochloride) SS Flagyl (Metronidazole) SS : 4271088-6Report Type:Periodic Company Report #KII-2003-0004072 le I/FU:I PT Report Source Product Role Manufacturer Bradycardia Health Oxycontin Tablets (Oxycodone Hydrochloride) PS Tizanidine

Flexeril

Zanaflex 16 Mg Po

ORAL

ORAL

ORAL

Date:12/17/03ISR Number: 4271091-6Report Type:Periodic Company Report #KII-2003-0003784

Age:50 YR Gender:Male I/FU:I

Report Source Role Manufacturer Outcome PTProduct Route

Dose Duration

Multiple Drug Overdose Health Hospitalization -Oxycontin Tablets Professional (Oxycodone

Initial or Prolonged

Other Hydrochloride) PS

SEE TEXT

(Cyclobenzaprine Hydrochloride) SS

SEE TEXT

Tizanidine (Tizandine) SS

SEE TEXT

Date:12/22/03ISR Number: 4256059-8Report Type:Direct Company Report #CTU 208553

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

Report Source Role Manufacturer Outcome PTProduct Route

Duration Dose

Disability Asthenia

Dysarthria Bid PS

16 MG PO BID

Swollen Tonque

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Freedom Of Information (FOI) Report

Date:12/22/03ISR Number: 4256944-7Report Type:Direct Company Report #CTU 208592

Gender: Female Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Disability Activities Of Daily Tizanidine (Athema Living Impaired Neurosuane) PS Athena Neuroscience Other 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 Role Manufacturer Outcome PTReport Source Product Route Dose Duration Cipro (Ciprofloxacin Life-Threatening Apnoea Foreign Health Hydrochloride) Other Blood Pressure Decreased PS ORAL 500 MG, BID, Blood Pressure Increased Professional ORAL Other Tizanidine Coma SS SEE IMAGE Dehydration Fucidine C Heart Rate Decreased Altace C С Heart Rate Increased Metoprolol Hypoventilation Hydrochlorothiazide C Pallor Zanaflex С Respiratory Depression Ramipril С Clindamycin

Date:12/29/03ISR Number: 4261566-8Report Type:Expedited (15-DaCompany Report #FI-JNJFOC-20031204242 Age: Gender:Male I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
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

Duration

Diabetes Insipidus

PT

Health

Zanaflex (Tizanidine

Product

Professional

Report Source

Hydrochloride)

PS

Role Manufacturer

ORAL

Route

2 MG DAILY

ORAL

Other

Dose

Other

Copaxone

(Glatiramer) С

Date:12/30/03ISR Number: 4262511-1Report Type:Expedited (15-DaCompany Report #ZANA001117

Age:72 YR Gender:Male I/FU:I

Outcome

PT

Bradycardia

Fatigue

Oxygen Saturation

Decreased

Palpitations

Report Source

Foreign

Health

Professional

Company

Representative

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Freedom Of Information (FOI) Report

Role Manufacturer

Route

Product

(Prednisone)

С

Other

Dose	Duration					
Dose	Duracion			Zanaflex (Tizanidine		
				Hydrochloride)	PS	ORAL
2 MG DAILY						
ORAL						
				Atenolol (Atenolol) Aspirine (Acetylsalicylic	С	
				Acid) Nifedipine	С	
				(Nifedipine) Simvastatin	С	
				(Simvastatin) Aspirine (Acetylsalicylic	С	
				(Acetyisalicylic Acid)	С	
				Methocarbamol	C	
I				(Methocarbamol)	C	
	4ISR Number Gender:Male	r: 4263784-1Report Type:Exped e I/FU:F	lited (15-DaCompany Re	port #ZANA001112		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration		-			I
Life-Threate	ning	Glucose-6-Phosphate	Health	Zanaflex (Tizanidine		
Other 36 MG ORAL		Dehydrogenase Deficiency	Professional	Hydrochloride)	PS	ORAL
		Haemolysis Refusal Of Treatment By		Baclofen (Baclofen) Neurontin	SS	
		Patient		(Gabapentin) Ditropan	С	
				(Oxybutynin) Predenisone	С	

Date:01/07/04ISR Number: 4267039-0Report Type:Expedited (15-DaCompany Report #ZANA001119

Age:32 YR Gender:Male I/FU:I

90 MG DAILY						
		Infection				
ORAL						
I		Constipation				
1		Faecal Incontinence				
		Myelitis Transverse				
		Paraesthesia				
		Urinary Incontinence				
Date: 01/07/04	TCR Number	: 4267041-9Report Type:Exp	edited (15-DaCompany Re	200rt #7ANA001118		
	ender:Male		edited (13-Dacompany Re	SPOIC #ZANAUUIIIO		
Age · JZ II	CHACI THAIC	1/10-1				
Outcome		PT	Report Source	Product	Role Manufacturer	Route
	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						
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Report Source

Literature

Professional

Health

Product

Zanaflex (Tizanidine

Ms Contin (Morphine) SS

Hydrochloride)

Role Manufacturer

PS

Route

ORAL

Outcome

Dose

Other

PT

Asthenia

Acinetobacter Infection

Catheter Related

Duration

Freedom Of Information (FOI) Report

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 Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening	Alanine Aminotransferase	Health	Panaldine	PS	Roche	ORAL
Hospitalization -	Increased	Professional	Euglucon	SS	Roche	ORAL
Initial or Prolonged	Aspartate		Basen	SS		ORAL
	Aminotransferase		Ternelin	SS		ORAL
	Increased		Adalat L	С		ORAL
	Hepatic Function Abnormal		Takepron	С		ORAL
	Lymphocyte Stimulation		Cardenalin	С		ORAL
	Test Positive		Caltan	С		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-Threater	ning	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 Overdose	Literature Health	Zanaflex (Tizanidine 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

	Hypotension	Literature	Zanaflex (Tizanidine			
Other	Overdose	Health	Hydrochloride)	PS		ORAL
28 MG ORAL						·
		Professional				
Date:01/26/04ISR Num Age:51 YR Gender:M	ber: 4278949-2Report Type:Exped	ited (15-DaCompany Re	eport #JP-ROCHE-353443			
	1/10-1					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duratio	n	_				
Life-Threatening	Dialysis	Health	Panaldine	PS	Roche	ORAL
Life-Threatening Hospitalization -	Dialysis Hepatic Enzyme Increased	Health Professional	Panaldine Euglucon	PS SS	Roche Roche	ORAL ORAL
_	Hepatic Enzyme Increased					
Hospitalization -	Hepatic Enzyme Increased		Euglucon	SS		ORAL
Hospitalization -	Hepatic Enzyme Increased Hepatic Function Abnormal		Euglucon Basen	SS SS		ORAL ORAL
Hospitalization -	Hepatic Enzyme Increased Hepatic Function Abnormal Lymphocyte Stimulation		Euglucon Basen Ternelin	SS SS SS		ORAL ORAL ORAL
Hospitalization -	Hepatic Enzyme Increased Hepatic Function Abnormal Lymphocyte Stimulation Test Positive		Euglucon Basen Ternelin Adalat L	SS SS SS C		ORAL ORAL ORAL ORAL

Report Source

Product

Role Manufacturer

Route

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Outcome

Dose

PT

Duration

Freedom Of Information (FOI) Report

Calcium Carbonate

Date:01/26/04ISR Number: 4278992-3Report Type:Expedited (15-DaCompany Report #WAES 0306CHE00020 Age:29 YR Gender:Female I/FU:F

Outcome Dose I	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization Mospitalization		Bradycardia	Health	Vioxx	PS	Merck & Co., Inc	ORAL
Initial or Pro	olonged		Professional	Tizanidine Hydrochloride	SS		ORAL
6 DAY				Tramadol			
6 DAY				Hydrochloride	SS		ORAL
	ISR Number ender:Male	r: 4280390-3Report Type:Exped	ited (15-DaCompany Re	eport #200322722GDDC			
	Mar∙Mare						
Outcome Dose I	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threateni		Alanine Aminotransferase	Foreign	Glibenclamide			
Hospitalizatio		Increased	Health	(Euglucon) Tablets	PS		ORAL
Initial or Pro	olonged 28 WK	Aspartate	Professional				
		Aminotransferase Increased	Other	Ticlopidine Hydrochloride			
200 MG/DAY PO	11 WK	Blood Alkaline		(Panaldine)	SS		ORAL
		Phosphatase Increased		Voglibose (Basen)	SS		ORAL
PO	28 WK	Blood Bilirubin Increased		Tizanidine			
		Dialysis		Hydrochloride			
	10	Hepatic Function Abnormal		(Ternelin)	SS		ORAL
PO	19 WK	Lymphocyte Stimulation		Nifedipine (Adalat			
		Test Positive		L)	С		
		Pneumonia		Lansoprazole			
				(Takepron)	C		
				Doxazosin Mesilate	_		
i				(Cardenalin)	C		

Date:01/27/04ISR Number: 4280642-7Report Type:Expedited (15-DaCompany Report #ZONI001246 Age:60 YR

Gender:Male I/FU:F

Outcome PTReport Source Product Role Manufacturer Route Dose Duration

Life-Threatening Carotid Artery Stenosis Health Zonegran

Hospitalization -Cerebrovascular Accident Professional (Zonisamide) PS

200 MG DAILY Initial or Prolonged Palpitations

ORAL

Zanaflex (Tizanidine

Hydrochloride) SS ORAL

2 MG DAILY

Vioxx (Rofecoxib) С Nexium (Esomeprazole Magnesium) С

Skelaxin (Metaxalone) С Ultracet (Tramadol

ORAL

Hydrochloride/Acetam inophen) С

Ketoprofen (Ketoprofen) С

Date:01/28/04ISR Number: 4280419-2Report Type:Direct Company Report #CTU 210961

Gender:Male I/FU:I Age:

PTOutcome

Irritability

Pharmaceutical Product

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Freedom Of Information (FOI) Report

Complaint

Dose Duration		Report Source	Product	Role	Manufacturer	Route
Dose Duración	1		Generic Zanaflex	PS		ORAL
6 MG PO QID						
Date:01/28/04ISR Numk Age:41 YR Gender:Fe	oer: 4281937-3Report Type:Exped	lited (15-DaCompany Ro	eport #ZANA001121			
Outcome Dose Duration	PT n	Report Source	Product	Role	Manufacturer	Route
Life-Threatening Required 16 MG/DAY	Apnoea Cellulitis	Foreign Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
Intervention to ORAL	Coma	Professional				
Prevent Permanent Impairment/Damage	Dehydration Hypotension Pallor Respiratory Arrest		Ramipril (Ramipril) Metoprolol (Metoprolol) Fucidine (Fusidate	C C		
	Urinary Tract Infection		Sodium) Clindamycin	С		
7	4001000 FD 4 F 4 F	11: 1 /15 D G	(Clindamycin)	С		
Date:01/28/04ISR Numb Age:41 YR Gender:Fe	oer: 4281939-7Report Type:Expedemale I/FU:I	lited (15-Dacompany Re	eport #ZANAUUIIZZ			
Outcome Dose Duratior	PT a	Report Source	Product	Role	Manufacturer	Route
Life-Threatening Hospitalization - 16 MG/DAY	Apnoea Blood Pressure Increased	Foreign Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
Initial or Prolonged ORAL	Bradycardia	Professional				
	Coma Pallor		Ramipril (Ramipril) Metoprolol	С		
			(Metoprolol) Fucidin (Fusidic	С		
			Acid) Clindamycin	С		
			(Clindamycin)	С		

Date:01/29/04ISR Number: 4283003-XReport Type:Expedited (15-DaCompany Report #ZANA001126

Age:54 YR Gender:Male I/FU:I

PT	Report Source	Product	Role	Manufacturer	Route
Hyperreflexia Labile Blood Pressure	Literature Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
	Professional	Baclofen (Baclofen0 Senna Concentrate	С		
		(Senna Concentrate) Gabapentin	С		
		(Gabapentin) Calcium Carbonate	C		
		(Calcium Carbonate) Glyburide	C		
		(Glibenclamide) Fluoxetine	C		
		(Fluoxetine) Lovastatin	C		
		(Lovastatin) Aspirin "Bayer"	С		
		(Acetylsalicylic Acid) Ascorbic Acid	С		
	Hyperreflexia	Hyperreflexia Literature Labile Blood Pressure Health	Hyperreflexia Labile Blood Pressure Professional Baclofen (Baclofen0 Senna Concentrate (Senna Concentrate) Gabapentin (Gabapentin) Calcium Carbonate (Calcium Carbonate) Glyburide (Glibenclamide) Fluoxetine (Fluoxetine) Lovastatin (Lovastatin) Aspirin "Bayer" (Acetylsalicylic Acid)	Hyperreflexia Literature Labile Blood Pressure Professional 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	Hyperreflexia Labile Blood Pressure Professional 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

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Freedom Of Information (FOI) Report

Vioxx

Zanaflex

Ultracet

(Ascorbic Acid) Multi-Vitamins (Multi-Vitamins)

C

C

PS

SS

С

Merck & Co., Inc

ORAL

Age:48 YR Gender: Female I/FU:I Role Manufacturer PTReport Source Product Outcome Route Duration Dose Convulsion Health Zanaflex (Tizanidine Other Professional Hydrochloride) Drug Interaction PS ORAL ORAL Dyskinesia Other Gabitril (Tiagabine) SS ORAL 12 MG QD ORAL Extrapyramidal Disorder Klonopin (Clonazepam) С Date:01/30/04ISR Number: 4283016-8Report Type:Expedited (15-DaCompany Report #WAES 0401USA01663 Age: Gender: Male I/FU:I Role Manufacturer Outcome PΤ Report Source Product Route Duration Dose

Date:01/30/0	04ISR Number:	4289028-2Report	Type:Periodic	Company	Report	#ZANA001044	
7 1 7 TD	Canalana Bamala	т / птт • п					

Date:01/29/04ISR Number: 4283074-0Report Type:Expedited (15-DaCompany Report #ZANA001127

Age:27 YR Gender: Female I/FU:F

Dizziness

Dry Mouth

Hyperhidrosis

Hypotension Somnolence Speech Disorder Vision Blurred

Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Liver Function Test Health Zanaplex (Tizanidine

Abnormal Professional Hydrochloride)

PS ORAL 8 MG DAILY

Hospitalization -

DAY

1

Initial or Prolonged

ORAL Neurontin 22-Aug-2005 12:09 PM Page: 186

(Gabapentin)	С
Albuterol	
(Salbutamol)	C
Ativan (Lorazepam)	С
Senokot (Senna)	C
Diastat (Pectin)	C
Robitussin	
(Guaifenesin)	С
Synthroid	
(Levothyroxine	
Sodium)	С
Vitamin C (Ascorbic	!
Acid)	C
Magnesium (Magnesiu	ιm
Oxide)	C
Keppra	
(Levetiracetam)	С
Dulcolax (Bisacodyl	.) C

Freedom Of Information (FOI) Report

Calcium Carbonate

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 D Life-Threateni 1200 MG PO	urati ng	on	Alcohol Use		Paroxetine	PS		ORAL
Hospitalizatio	n -		Intentional Misuse					
Initial or Pro	longe	d	Suicide Attempt		Zanaflex Rum	SS SS		
Date:02/04/04I Age:51 YR Ge			: 4286811-4Report Type:Expedi I/FU:F	ted (15-DaCompany Repo	rt #200322722GDDC			
Outcome Dose D	urati	on	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threateni Hospitalizatio 0.625 MG QD	_		Alanine Aminotransferase Increased	Foreign Health	Glibenclamide (Euglucon) Tablets	PS		ORAL
Initial or Pro	longe 199		Aspartate	Professional				
			Aminotransferase Increased Hepatic Function Abnormal	Other	Ticlopidine Hydrochloride (Panaldine)	SS		ORAL
200 MG/DAY PO	78	DAY	Lymphocyte Stimulation		Voglibose (Basen)	SS		ORAL
PO	199	DAY	Test Positive Pneumonia		Tizanidine Hydrochloride (Ternelin)	g g		ORAL
PO	138	DAY				SS		ORAL
					Nifedipine (Adalat L) Lansoprazole	С		
					(Takepron) Doxazosin Mesilate	С		
					(Cardenalin)	С		

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-Threater	ning	Asthenia	Health	Zonegran			
Hospitalizati 200 MG DAILY	lon -	Balance Disorder	Professional	(Zonisamide)	PS		ORAL
Initial or Pr ORAL	Initial or Prolonged ORAL	Carotid Artery Stenosis	Company				
		Cerebrovascular Accident Coordination Abnormal	Representative	Zanaflex (Tizanidine 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)	С		
i							

Date:02/17/04ISR Number: 4299044-2Report Type:Expedited (15-DaCompany Report #ZANA001129

Age:61 YR Gender:Female I/FU:I

Outcome Death

Myocardial Infarction

Rash

Urticaria

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Freedom Of Information (FOI) Report

Ventricular Fibrillation

Outcome

Dose

Other

PT

Blood Pressure Increased

Duration

		Vencilcular Fibrillacion					
	D		Report Source	Product	Role	Manufacturer	Route
Dose	Duration		Foreign	Zanaflex (Tizanidine			
			Health	Hydrochloride)	PS		ORAL
4 MG DAILY				-			
0037			Professional				
ORAL			Distributor	Vancocyn			
			DISCIIDACOI	(Vancomycin)	С		
				Flagyl	C		
				(Metronidazole)	С		
				Tylenol			
				(Acetaminophen)	С		
				Neurontin			
				(Gabapentin)	C		
				Ativan (Lorazepam)	C		
				Valium (Diazepam)	С		
				Diovol (Magnesium	a		
				Hydroxide)	C C		
				Lovenox (Enoxaparin)	C		
Date:02/24/0 Age:37 YR		: 4303810-4Report Type:Direct le I/FU:I	Company Repor	t #CTU 213047			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration				_		
Required 4 MG 1-1 1/2		Dyspepsia		Tizanidine	PS		
Intervention Q4-6 HR	to	Nausea					
Prevent Perm	anent	Pharmaceutical Product					
Impairment/D		Complaint					
		Rash					
	4ISR Number Gender:Male	: 4304359-5Report Type:Expedit	ed (15-DaCompany Repor	t #ZANA001130			

Report Source

Consumer

Product

Zanaflex (Tizanidine

Role Manufacturer

Route

Accupril (Quinapril Convulsion Hydrochloride) Dizziness С Vioxx (Rofecoxib) Dyspepsia С **Epistaxis** Zocor (Simvastatin) Feeling Abnormal Hyperacusis Hypoaesthesia Loss Of Consciousness Nasal Dryness Paraesthesia Rhinorrhoea Date:02/25/04ISR Number: 4304819-7Report Type:Direct Company Report #CTU 213181 Gender:Female Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Asthenia Tizanidine 52mg PS ORAL 1/2 PO BID Fatigue AND 1 PO QHS Feeling Abnormal

Chest Pain

Pharmaceutical Product

Complaint

Coma

18 MG DAILY

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ORAL

Hydrochloride)

PS

Freedom Of Information (FOI) Report

Neurontin

/Unk/(Gabapentin)

SS

ORAL

Date:03/02/04ISR Number: 4310883-1Report Type:Direct Company Report #CTU 213607

Gender: Female Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Asthenia Tizanidine 2mg PS ORAL 1/2 PO BID Fatique 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 Report Source Role Manufacturer Outcome РΤ Product Route Duration Dose Drug Ineffective Other Zanaflex 4 Mg 1 -Bid Ndc -59075-0594-15 Dysuria 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 Gender: Female Age:43 YR I/FU:I Role Manufacturer Outcome PΤ Report Source Product Route Dose Duration Alanine Aminotransferase Health Other Betaseron Increased Professional (Interferon Beta-1b) Injection, 250ug Aspartate PS 8 MIU, EVERY SUBCUTANEOUS Aminotransferase 2D, Increased SUBCUTANEOUS Blood Bilirubin Increased Zanaflex (Tizanidine Hydrochloride) SS ORAL

ORAL

Product

Product

PS

PS

С

Role Manufacturer

Role Manufacturer

ORAL

Route

ORAL

Route

ORAL

Date: 03/17/04ISR Number: 4320171-5Report Type: Expedited (15-DaCompany Report #ZANA001142

Age:48 YR Gender:Male I/FU:I

Duration Dose

Other

Blood Pressure Increased

Cognitive Disorder

Hypoaesthesia Oral

ORAL

Outcome

6 MG DAILY

PT

Somnolence

Other

Foreign

Consumer

Report Source

Flotac (Diclofenac) С

Sirdalud (Tizanidine

Hydrochloride)

Enalapril Dexamethasone С

Sirdalud (Tizanidine

Hydrochloride)

Date: 03/17/04ISR Number: 4320172-7Report Type: Expedited (15-DaCompany Report #ZANA001143

Age:47 YR Gender: Female I/FU:I

Outcome

Duration Dose

Life-Threatening

PT

Dry Mouth

Bradycardia

Hypotension

Professional

Foreign Health

Other

Report Source

Estalis (Norethisterone)

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2 MG DAILY

Freedom Of Information (FOI) Report

Magnesium Oxide

Date:03/17/04ISR Number: 4320215-OReport Type:Expedited (15-DaCompany Report #ZANA001134 Age: Gender: I/FU:I

RECTAL

Outcome Dose Death						
	Duration	PT	Report Source	Product	Role Manufacturer	Route
Deach	Duracion	Bronchopneumonia	Foreign Health	Zanaflex (Tizanidine Hydrochloride)	PS	ORAL
4 MG DAILY				7		
ORAL			Professional			
			Other	Hypromellose (Hypromellose)	С	
				Perindopril (Perindopril)	С	
				Paracetamol		
			(Paracetamol)	C		
				Lactulose (Lactulose)	С	
Outcome Dose Hospitalizat	Duration	PT	Report Source	Product	Role Manufacturer	
Initial or I		Hepatic Function Abnormal Pruritus	Foreign Health	Ternalin (Tizanidine Hydrochloride)	PS PS	Route ORAL
Initial or I 3 MG DAILY				Ternalin (Tizanidine		
Initial or I 3 MG DAILY		Pruritus	Health	Ternalin (Tizanidine Hydrochloride) Loxonin (Loxoprofen	PS	ORAL
Initial or I 3 MG DAILY ORAL	Prolonged	Pruritus	Health Professional	Ternalin (Tizanidine Hydrochloride)		
Initial or I 3 MG DAILY ORAL	Prolonged	Pruritus	Health Professional	Ternalin (Tizanidine Hydrochloride) Loxonin (Loxoprofen Sodium)	PS	ORAL
Initial or I 3 MG DAILY DRAL 180 MG DAILY	Prolonged	Pruritus	Health Professional	Ternalin (Tizanidine Hydrochloride) Loxonin (Loxoprofen	PS	ORAL
Initial or I	Prolonged	Pruritus	Health Professional	Ternalin (Tizanidine Hydrochloride) Loxonin (Loxoprofen Sodium)	PS	ORAL

2 G DAILY			(Magnesium Oxide)	SS	ORAL
ORAL					
12 MG ONCE			Pursennid (Senna)	SS	
			Juvela (Tocopheryl Nicotinate)	SS	ORAL
600 MG DAILY			NICOCINACC /	55	OKAL
ORAL					
TOPICAL TOPICA	AL		Mohrus	SS	
			Xylocaine (Lidocaine Hydrochloride)	С	
Date:03/17/04ISR Number Age:24 YR Gender:Male	c: 4320217-4Report Type:Expe	edited (15-DaCompany Re	eport #ZANA001136		
		Develope Course	D	D. J	D 2004 0
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged 12 MG DAILY	Bradycardia Drug Interaction	Foreign Health	Sirdalud (Tizanidine Hydrochloride)	PS	ORAL
	Hypotension	Professional			
ORAL	Hypotonia	Other	Lioresal (Baclofen)	SS	ORAL
30 MG DAILY	Malaise				
ORAL	Skin Infection		Myolastan		
75 MG DAILY	5.1.1 .2		(Tetrazepam)	SS	ORAL
ORAL			Ciflox		
1 G DAILY			(Ciprofloxacin)	SS	
I G DAILI			Voltarene Lp (Diclofenac Sodium)	С	
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1					

(Magnesium Oxide)

SS

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	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Amnesia Aptyalism	Foreign Health	Sirdalud (Tizanidine Hydrochloride)	PS	ORAL	
4 MG DAILY		Dizziness Postural	Professional				
ORAL							
			Other	Rytmonorm (Propafenone			
				Hydrochloride) Norvasc (Amlodipine	С		
				Besilate) Ticlopidine (Ticlopidine	С		
				Hydrochloride) Losartan (Losartan	С		
				Potassium) Hydrochlorothiazide (Hydrochlorothiazide	С		
)	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 Life-Thr		uration ng	Hepatic Function Abnormal		Tegretol	PS	Novartis Sector:	
Hospital	lizatio	n –	Hypogammaglobulinaemia		10910001	10		ORAL
200 mg,	BID	36000MIN						,
Initial	or Pro	_	Immune System Disorder Pneumonia		Tegretol	SS	Novartis Sector: Pharma	ORAL
200 mg,	TID	5760 MIN						1
_ · · · · · · · · · · · · · · · · · · ·			Productive Cough		Tegretol	SS	Novartis Sector:	,
1			Pyrexia				Pharma	ORAL
200 mg,	QID	25920MIN						ļ
1			Rash Generalised		Tegretol	SS	Novartis Sector:	,
1			Upper Respiratory Tract				Pharma	ļ
200 mg,	TID	60480MIN						ļ
			Infection		Tegretol		Novartis Sector: Pharma	ORAL
200 mg,	BID	40320MIN						

15 mg/day			11000		OTTIL
150 mg/day			Selbex	С	ORAL
			Rize	С	ORAL
5 mg/day					
Date:03/19/04ISR Number Age:73 YR Gender:Fema	r: 4322313-4Report Type:Exp ale I/FU:I	edited (15-DaCompany Re	eport #ZANA001144		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization -	Anaemia	Foreign	Sirdalud (Tizanidine		
Initial or Prolonged 8 MG DAILY	Gastritis	Health	Hydrochloride)	PS	ORAL
		Professional			
ORAL					
		Other	Oxaprozin		
1200 MG DAILY			(Oxaprozin)	SS	ORAL
ORAL					
Date:03/19/04ISR Numbe: Age:60 YR Gender:Fema	r: 4322314-6Report Type:Exp ale I/FU:I	edited (15-DaCompany Re	eport #ZANA001146		
Outcome Hospitalization -	PT Condition Aggravated	Report Source			
nospicalizacion -	Condition Aggravated	Foreign			

Health

Professional

UNKNOWN

UNKNOWN

Initial or Prolonged

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Other

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Hepatitis B

Treatment Noncompliance

Gaster

Ternelin

Predonine

SS

SS

С

Freedom Of Information (FOI) Report

Other

Other

Dose	Duration			Product	Role	Manufacturer	Route
3 MG DAILY	Duracion			Ternalin (Tizanidine Hydrochloride)	PS		ORAL
ORAL							
ORAL				Takepron (Lansoprazole) Methotrexate	С		
				(Methotrexate) Foliamin (Folic	С		
				Acid) Predonine	С		
				(Prednisolone) Flucam (Ampiroxicam) Cytotec	C C		
				(Misoprostol) Depas (Etizolam) Biofermin R	C C		
				(Streptococcus Faecalis) Selbex (Teprenone)	C C		
				Berizym (Enzymes Nos) Gasmotin	C C		
				Alinamin F (Fursultiamine) Cerekinon	С		
				(Trimebutine Maleate)	С		
Date:03/19/0 Age:45 YR	04ISR Number Gender:Fema	:: 4322349-3Report Type:Ex ale I/FU:I	spedited (15-DaCompany Re	eport #ZANA001141			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	_	Hallucination Murder	Foreign Literature	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL
ORAL		Restlessness Suicidal Ideation	Health Professional				

Date:03/19/04ISR Number: 4322350-XReport Type:Expedited (15-DaCompany Report #ZANA001145

Age:34 YR Gender:Male I/FU:I

PT

Dose	Duration					
Hospitalizat:	ion -	Aspartate	Foreign	Ternalin (Tizanidine		
Initial or Pr 1 MG DAILY	rolonged	Aminotransferase	Health	Hydrochloride)	PS	ORAL
		Increased	Professional			
ORAL						
		Blood Creatine Phosphokinase Increased	Other	Lamisil (Terbinafine Hydrochloride)	SS	ORAL
125 GM DAILY		-		-		
		Blood Lactate				
ORAL						
		Dehydrogenase Increased Malaise		Lornoxicam (Lornoxicam)	SS	ORAL
4 MG DAILY						
ORAL						
				Mucosta (Rebamipide)	C	

Product

Role Manufacturer

Route

Report Source

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Outcome

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

PT	Report Source	Product	Role	Manufacturer	Route
	_				
Drug Interaction	Health	Hydrochloride)	PS		ORAL
Hypotension	Professional				
Hypotonia	Other	Lioresal (Baclofen)	SS		ORAL
Malaise					
		Myolastan			
		(Tetrazepam)	SS		ORAL
		(Ciprofloxacin)	SS		
		Diclofenac Sodium)	С		
: 4327874-7Report Type:Expedit	ted (15-DaCompany Repor	ct #ZANA001156			
:: 4327874-7Report Type:Expeditale I/FU:I	ted (15-DaCompany Repor	rt #ZANA001156			
	Bradycardia Drug Interaction Hypotension Hypotonia	Bradycardia Foreign Drug Interaction Health Hypotension Professional Hypotonia Other	Bradycardia Foreign Sirdalud (Tizanidine Drug Interaction Health Hydrochloride) Hypotension Professional Hypotonia Other Lioresal (Baclofen) Malaise Myolastan	Bradycardia Drug Interaction Health Sirdalud (Tizanidine Hydrochloride) PS Hypotension Professional Hypotonia Other Lioresal (Baclofen) SS Malaise SS Ciflox (Ciprofloxacin) SS Voltaren Lp	Bradycardia Drug Interaction Health Sirdalud (Tizanidine Hydrochloride) PS Hypotension Professional Hypotonia Other Lioresal (Baclofen) SS Malaise Ciflox (Ciprofloxacin) SS Voltaren Lp

Dose Duration Drug Withdrawal Syndrome Foreign Sirdalud (Tizanidine Death Hospitalization -Hepatitis A Health Hydrochloride) PS Initial or Prolonged Pancreatitis Acute Professional Saroten Other (Amitriptyline Hydrochloride) С 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

Hospitalization - Initial or Prolonged 8 MG A DAT	Bradycardia	Foreign Health	Zanaflex (Tizanidine Hydrochloride)	PS	ORAL
Other ORAL		Professional			
			Digoxin (Digoxin)	SS	
125 MCGS			Morphine (Morphine) Fluoxetine	C	
			(Fluoxetine) Simvastatin	С	
			(Simvastatin)	C	1
1			Ramipril (Ramipril)	C	ľ
			Warfarin (Warfarin) Gabapentin	С	
			(Gabapentin)	С	
Date:03/25/04ISR Numbe Age: Gender:Fem	er: 4327928-5Report Type:Exped: male I/FU:I	ited (15-DaCompany Re	eport #2004017487		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Other	Drug Withdrawal Syndrome Dyspnoea	Health Professional	Zoloft (Sertraline) Tizanidine	PS	

Product

Hydrochloride

Hydrochloride)

(Acetylsalicylic

Acetylsalicylic Acid

SS

(Tizanidine

Role Manufacturer

Route

Report Source

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Outcome

Dose

PΤ

Fatigue

Pain Somnolence

Nerve Injury

Myoclonic Epilepsy

Duration

Freedom Of Information (FOI) Report

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-Threate	ening	Angioneurotic Oedema	Health	Trileptal		
		Pharyngeal Oedema	Professional	(Oxcarbazepine)		
		Tongue Oedema	Company	Suspension	PS	ORAL
7 ML, Q12H,						
			Representative			
ORAL						

ORAL

Zanaflex (Lic.
Athena) (Tizanidine
Hydrochloride,
Tizanidine
Hydrochloride) SS

2, QHS

Klonopin C

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	Sirdalud (Tizanide			
			Health	Hydrochloride)	PS		ORAL
6 MG DAILY							

Profess

Professional

Other

Date:03/29/04ISR Number: 4329926-4Report Type:Expedited (15-DaCompany Report #ZANA001157

Age:29 YR Gender:Female I/FU:I

Outcome

PT

Alanine Aminotransferase

Hospitalization -Initial or Prolonged

Life-Threatening

Increased Aspartate

Aminotransferase

Increased Blood Alkaline

Phosphatase Increased Gamma-Glutamyltransferase

Increased

Hepatic Function Abnormal

Hypoaesthesia

Hypogammaglobulinaemia

Immunodeficiency Multiple Sclerosis

Pneumonia

Rash Generalised

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Freedom Of Information (FOI) Report

		Upper Respiratory Tract Infection					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration		Foreign Health Professional	Ternalin (Tizanidine Hydrochloride) Tegretol	PS		
400 MG DAIL	.V		Other	(Carbamazepine)	SS		
400 MG DAIL	11			Predonine (Prednisolone) Selbex (Teprenone) Rize (Clotiazepam)	С С С		
Date:04/01/ Age:47 YR	04ISR Number Gender:Fema	: 4331667-4Report Type:Direc	t Company Ro	eport #CTU 215739			
Outcome	D	PT	Report Source	Product	Role	Manufacturer	Route
Dose Required 4 MG PO TID	Duration	Deafness Bilateral		Zanaflex 4 Mg Tid	PS		ORAL
Interventic Prevent Per Impairment/	manent Damage	Deafness Neurosensory Tinnitus : 4333989-XReport Type:Exped	ited (15-DaCompany R	Prednisone Synthroid Premarin Nexium Lipitor Topomax Fluoxetine Toprol Xl Wellbutrin Flexeril Duragesic	0 0 0 0 0 0 0 0 0		
Date:04/02/ Age:70 YR	Gender:Fema		ited (15-DaCompany Ro	eport #ZANAUUII58			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 6 MG DAILY		Bradycardia Hypotension	Foreign Health	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL
ORAL		Nausea	Professional				

Date:04/08/04ISR Number: 4336984-XReport Type:Expedited (15-DaCompany Report #US-SHR-04-021606

Potassium (Potassium)

SS

ORAL

Age:43 YR Gender:Female I/FU:F Outcome Report Source Product Role Manufacturer PTRoute Dose Duration Alanine Aminotransferase Health Other Betaseron Increased Professional (Interferon Beta-1b) Aspartate Injection, 250ug PS SUBCUTANEOUS 8 MIU, EVERY Aminotransferase 2D, Increased SUBCUTANEOUS Blood Bilirubin Increased Zanaflex (Tizanidine Liver Function Test Hydrochloride) SS ORAL ORAL Abnormal Neurontin /Unk/ (Gabapentin) SS ORAL ORAL

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ORAL

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Freedom Of Information (FOI) Report

OTHER

PS

Date:04/12/04ISR Number: 4337502-2Report Type:Direct Company Report #CTU 216446

Gender: Female Age: I/FU:I

Outcome PTReport Source Product Role Manufacturer Route

Duration Dose

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

РΤ Role Manufacturer Report Source Product Outcome Route

Dose Duration

Abdominal Pain Sirdalud (Tizanidine Foreign Other ORAL

Hydrochloride) Body Temperature Consumer PS

2 DF/DAY ORAL

Other Vioxx (Rofecoxib) Increased SS ORAL 25 MG/DAY

Dermatitis Bullous

ORAL

OTHER

Exanthem Rash Macular

Date: 04/13/04ISR Number: 4342443-0Report Type: Expedited (15-DaCompany Report #ZANA001162

Gender:Female Age:11 YR I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration

Hospitalization -Foreign Sirdalud (Tizanidine Apathy

Initial or Prolonged Medication Error Hydrochloride) Health

4MG

Somnolence Professional

ONCE/SINGLE

Other

Date:04/15/04ISR Number: 4342039-0Report Type:Expedited (15-DaCompany Report #2004017487

Age: Gender: Female I/FU:F

PT	Report Source	Product	Role	Manufacturer
Aphasia Convulsion Drug Withdrawal Syndrome Dyskinesia	Health Professional	Zoloft (Sertraline) Tizanidine Hydrochloride (Tizanidine	PS	
Dyspnoea Fatigue Hypoaesthesia		Hydrochloride) Acetylsalicylic Acid (Acetylsalicyklic	SS	
Muscle Rigidity Myotonia Nerve Injury Paraesthesia		Acid) Other Respiratory System Products	С	
Paraesthesia Paralysis Procedural Complication		(Other Respiratory System Products) Omeprazole	С	
Respiratory Rate Increased Somnolence		(Omeprazole) Amlodipine Besilate (Amlodipine	С	
		Besilate)	C	
		Digoxin (Digoxin) Trazodone	С	
		(Trazodone) Oxycodone Hydrochloride (Oxycodone	С	
		Hydrochloride)	C	
		Diazepam (Diazepam) Furosemide	С	
		(Furosemide)	C	

Route

Outcome

Duration

Dose

Other

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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

J	·					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization -	Embolia Cutis	Consumer	Vistaril (Im)			
Initial or Prolonged	Medicamentosa	00112001	(Hydroxyzine			
Disability	Gait Disturbance		Hydrochloride)	PS		
Other	Injection Site Irritation		Neurontin			
	Injection Site Pain		(Gabapentin)	SS		ORAL
300 MG, ORAL	3		,			-
	Medication Error		Pethidine			
	Muscle Spasms		Hydrochloride			
	Necrosis		(Pethidine			
			Hydrochloride)	SS		ORAL
ORAL			-			
			Oxycodone			
			Hydrochloride			
			(Oxycodone			
			Hydrochloride)	SS		ORAL
20 MG			•			
(UNKNOWN),						
ORAL						
			Tizanidine			
			Hydrochloride			
			(Tizanidine			
			Hydrochloride)	SS		ORAL
2 MG			,			
(UNKNOWN),						
ORAL						
Data:04/26/04ICD Number	· 4240247 ODenort Time:Eirodi	tod (15 DaCompany Da	2225 #7ANA001162			

Date:04/26/04ISR Number: 4349347-8Report Type:Expedited (15-DaCompany Report #ZANA001163 Age:14 YR Gender:Male I/FU:I

gevil in deliaer hare 1/10°

4							
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose I	Duration						
Hospitalizatio	on -	Drug Screen Positive	Foreign	Ternelin (Tizanidine			
Initial or Pro	olonged	Medication Error	Health	Hydrochloride)	PS		ORAL
ORAL							

Somnolence Professional Rohypnol

Depas (Etizolam)

Benzalin

(Nitrazepam)

Solanax (Alprazolam) C

SS

C

C

ORAL

ORAL

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Date:05/04/04ISR Number: 4355103-7Report Type:Expedited (15-DaCompany Report #200410240BYL Age: 75 YR Gender: Male I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Jaundice	Foreign Health	Bayaspirin (Acetylsalicylic			
ORAL			Professional	Acid)	PS		ORAL
Oldan			Other	Nitorol R (Isosorbide			
				Dinitrate)	SS		ORAL
ORAL				Spelear (Fudosteine)	SS		ORAL
ORAL				Oatolua (Etodoloa)	CC		OD X T
ORAL				Osteluc (Etodolac)	SS		ORAL
				Ternelin (Tizanidine Hydrochloride)	SS		ORAL
ORAL				Mucosta	С		
				Empynase P	C		
				Resplen	C		

Freedom Of Information (FOI) Report

Date:05/05/04ISR Number: 4355461-3Report Type:Expedited (15-DaCompany Report #ZANA001244

Age:52 YR Gender:Female I/FU:I

Age:52 YR	Gender:Fema	lle I/FU:I					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Daracron	Hepatitis Toxic	Foreign Other	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL
12 MG/D ORAL	1		Oction	n, ar sometime,	15		Oldin
				Homeopathic Preparation (Unspecified) (Homeopathic Preparation	С		
	4ISR Number Gender:Male	: 4355931-8Report Type:Expedi	ted (15-DaCompany Rep	port #ZANA001216			
Age TO TR	ochaci marc	1,1011					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death Hospitalizat 0.6 MG DAILY		Blood Uric Acid Increased Bronchitis	Foreign Health	Ternelin (Tizanidine Hydrochloride)	PS		ORAL
Initial or P ORAL		Cardio-Respiratory Arrest	Professional				
		Dehydration Insomnia	Other	Hyserenin (Valproate Sodium)	С		
		Musculoskeletal Stiffness Pyrexia		Depas (Etizolam) Theodur	С		
		White Blood Cell Count Increased		(Theophylline)	С		
Date:05/12/0	4TSR Number	: 4358565-4Report Type:Expedi	ted (15-DaCompany Rer	port #71N1001156			
	Gender:Fema		.cca (13 Dacompany Rep	OLC TAMMOOTIO			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route

Drug Withdrawal Syndrome Sirdalud (Tizanidine Death Foreign Hydrochloride) Hospitalization -Hepatitis A Health PSORAL ORAL Initial or Prolonged Pancreatitis Acute Professional Saroten (Amitriptyline Other Hydrochloride) C Seroxat "Novo

Nordisk" (Paroxetine Hydrochloride)

Date: 05/17/04ISR Number: 4361416-5Report Type: Expedited (15-DaCompany Report #ZANA001286

Age:29 YR Gender:Female I/FU:I

PTReport Source Product Role Manufacturer Route Outcome

Duration Dose

Zanaflex (Tizanidine Other Rash Maculo-Papular Foreign ORAL

Viral Rash Health

Hydrochloride) PS

8 MG DAILY

Professional ORAL

Other Paracetamol

(Paracetamol) С Citalopram

(Citalopram) С

Date: 05/17/04ISR Number: 4362226-5Report Type: Expedited (15-DaCompany Report #ZANA001290

Age:74 YR Gender:Male I/FU:I

Outcome Report Source PT

Jaundice Other Foreign

Laboratory Test Abnormal Health

Professional

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Freedom Of Information (FOI) Report

Product

Role Manufacturer

Route

Other

Dose	Duration					
				Ternelin (Tizanidine		
				Hydrochloride)	PS	ORAL
2 MG DAILY						
ORAL						
				Mucosta (Rebamipide)	C	
				Osteluc (Etodolac)	C	
				Nitrendipine	_	
				(Nitrendipine)	C	
				Bayaspirina (Acetylsalicylic		
				(Acetyisalicylic Acid)	С	
				Resplen (Eprazinone	C	
				Hydrochloride)	С	
				Empynase (Pronase)	C	
				Spelear (Fudosteine)	C	
		: 4363007-9Report Type:Expe	dited (15-DaCompany Re	port #ZANA001309		
Age:32 YR	Gender:Fema	ile I/FU:I				
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Other		Confusional State	Foreign	Sirdalud (Tizanidine		
0 4 MG/DAT		Coordination Abnormal	Health	Hydrochloride)	PS	ORAL
2-4 MG/DAY		Disorientation	Professional			
ORAL		Disorientation	Professional			
OKAL						
40-80 MG/DAY		Drug Interaction	Other	Entumin (Clotiapine)	SS	ORAL
		Drug Interaction	Other	Entumin (Clotiapine)	SS	ORAL
ORAL		Drug Interaction Gait Disturbance	Other	Entumin (Clotiapine)	SS	ORAL
			Other	Entumin (Clotiapine)	SS	ORAL
			Other	Entumin (Clotiapine) Lorazepam	SS	ORAL
			Other		SS	ORAL
4.5 MG/DAY			Other	Lorazepam		
4.5 MG/DAY			Other	Lorazepam		
			Other	Lorazepam		
ORAL			Other	Lorazepam (Lorazepam)		
ORAL			Other	Lorazepam (Lorazepam) Seroquel (Quetiapine	SS	ORAL
4.5 MG/DAY ORAL 50-700 MG/DA			Other	Lorazepam (Lorazepam) Seroquel (Quetiapine	SS	ORAL

	(Levomepromazine)	SS	ORAL
50 MG, QD			

Nozinan

Sodium)

Orfiril (Valproate

SS

1000 MG/DAY

ORAL

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			
Hospitalization - 1.2 MG DAILY	Anuria	Health	Hydrochloride)	PS		ORAL
Initial or Prolonged ORAL	Blood Uric Acid Increased	Professional				
1	Bronchitis	Other	Hyserenin (Valproate			
1	Cardio-Respiratory Arrest		Sodium)	С		
1	Dehydration		Depas (Etizolam)	С		
1	Insomnia		Theodur			
	Musculoskeletal Stiffness Ocular Hyperaemia		(Theophylline) Phenobal	С		
1	Oculogyration		(Phenobarbital)	С		
1	Pyrexia		Gabalon (Baclofen)	C		
1	White Blood Cell Count		Meptin (Procaterol			ļ
1	Increased		Hydrochloride)	С		ļ
1			Mucodyne			1
1			(Carbocisteine)	С		ļ
			Tricloryl (Triclofos			ļ

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Freedom Of Information (FOI) Report

Product

Sodium) C Racol (Racol) C

Role Manufacturer

Route

Date:05/18/04ISR Number: 4363009-2Report Type:Expedited (15-DaCompany Report #ZANA001306 Age:83 YR Gender:Male I/FU:I

Dose	Duration		-			
Hospitalizati		Arthralgia	Foreign	Sirdalud (Tizanidine		
Initial or Pr 2 MG/D ORAL	colonged	Bacteria Urine Identified	Health	Hydrochloride)	PS	ORAL
		Diarrhoea	Professional	Trasicor (Oxprenolol		
		Drug Interaction	Other	Hydrochloride)	SS	ORAL
20 MG/D ORAL						
		Pyelocaliectasis		Alzodone (Butizide)	SS	ORAL
27.5 MG, QW3						
		Renal Failure Acute				
ORAL						
000 MG/D 0D31				Celebrex (Celecoxib)	SS	ORAL
200 MG/D ORAL	1			View (Defectib)	SS	ORAL
ORAL				Vioxx (Rofecoxib)	55	ORAL
ORAL				Becozyme Forte		
				(Pyridoxine)	С	
				Bioflorin	C	
				(Lactobacillus		
				Acidophilus)	C	
i						

Report Source

Date:05/20/04ISR Number: 4365769-3Report Type:Expedited (15-DaCompany Report #ZANA001307 Age: Gender:Female I/FU:I

PT

Outcome

Outcome		PT	Report Source	Product	Ro⊥e	Manufacturer	Route
Dose	Duration						
Hospitaliz	ation -	Pneumonia Aspiration	Foreign	Zanaflex (Tizanidine			
Initial or	Prolonged		Consumer	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

Date:05/21/ Age:	04ISR Number: Gender:	: 4363044-4Report Type:Direct I/FU:I	Company Re	eport #USP 56478			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Daracron	Medication Error		Gabitril	PS	Cephalon	
TABLET				Tizanidin	SS		
TABLET							
Date:05/21/ Age:74 YR Outcome Dose	04ISR Number: Gender:Femal	: 4363810-5Report Type:Expedit le I/FU:I PT	ed (15-DaCompany Re	eport #ZANA001296 Product	Role	Manufacturer	Route
Hospitaliza		Hepatic Fibrosis	Foreign	Sirdalud (Tizanidine			
Initial or : 6 MG DAILY	Prolonged	Hepatocellular Damage	Health	Hydrochloride)	PS		ORAL
ORAL		Liver Function Test	Professional				
		Abnormal	Other	Panacod (Codeine Phosphate) Prednisone	С		
				(Prednisone) Miacalcic	С		
				(Calcitonin, Salmon)	С		

Gabitril

Tizanidine

PS

SS

Cephalon

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Medication Error

TABLET

TABLET

Freedom Of Information (FOI) Report

Date: 05/26/04ISR Number: 4366388-5Report Type: Direct Company Report #CTU 219597

Gender: Female Age: I/FU:I

Outcome PTReport Source Product Role Manufacturer Route

Duration Dose

Other Pharmaceutical Product Zanaflex (Generic

> Complaint PS Only)

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 РΤ Report Source Product Role Manufacturer Route

Dose Duration

Tizanidine PS Required Nausea

4 MG 1 - 1

Pharmaceutical Product Intervention to

1/2 Q 4-6 H

Prevent Permanent Complaint

PRN SPASMS

ORAL

Impairment/Damage 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 PTReport Source Product Role Manufacturer Route

Dose Duration

Hospitalization -Delusion Health Zanaflex (Tizanidine

Initial or Prolonged Hallucination Professional Hydrochloride) PS

4 MG DAILY

Requip (Ropinirole) Sinemet (Levodopa) Mirapex (Pramipexole

Dihydrochloride0 C ORAL

Date: 05/27/04ISR Number: 4370131-3Report Type: Expedited (15-DaCompany Report #ZANA001279

Age:77 YR Gender: Female I/FU:I

6 MG DAILY						
	Aspartate	Professional				
ORAL	Aminotransferase Increased Blood Lactate Dehydrogenase Increased Hepatic Function Abnormal	Other	Halfdigoxin-Ky (Digoxin) Warfarin (Warfarin) Tenormin (Atenolol)	C C C		
Date:06/03/04ISR Numbe Age:53 YR Gender:Fem	r: 4373335-9Report Type:Expediale I/FU:I	ted (15-DaCompany Rep	port #ZANA001311			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization -	Confusional State	Consumer	Zanaflex (Tizanidine			
Initial or Prolonged 8 MG DAILY	Dry Mouth	Consumer	Hydrochloride)	PS		ORAL
0 110 211221	Dysarthria					
ORAL	-					
	Facial Palsy					
Age:18 YR Gender:Fem		dic Company Rep	port #FROV000184			
Outcome	PT Dysarthria Mental Impairment					
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Report Source

Foreign

Health

Product

Ternelin (Tizanidine

Hydrochloride)

Role Manufacturer

PS

Route

ORAL

Outcome

6 MG DAILY

Dose

Other

PΤ

Increased

Alanine Aminotransferase

Duration

Freedom Of Information (FOI) Report

Somnolence

Dose	Duration		Report	Source	Product	Role	Manufacturer	Route
Dose	Duracion		Consume	er	Frova (Frovatriptan Succinate)	PS		ORAL
2.5 MG ORAL					Zanaflex (Tizanidine			
					Hydrochloride)	SS		ORAL
16MG DAILY								
ORAL								
					Wellbutrin Xl (Wellbutrin Xl) Coreg (Carvedilol)	C C		
	4ISR Number Gender:Fema	:: 4399761-XReport Type:Period: ale I/FU:I	ic	Company Repor	t #FROV000185			
Outcome	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Dose	Duration	Dysarthria	Consume	er	Frova (Frovatriptan			
		Mental Impairment			Succinate)	PS		ORAL
2.5 MG ORAL		Somnolence			Zanaflex (Tizanidine			
		Bonaro Terrec			Hydrochloride)	SS		ORAL
16 MG ORAL					Wellbutrin Xl			
					(Wellbutrin XI) Coreg (Carvedilol)	C C		
					corey (carvearior)	C		
	4ISR Number Gender:Fema	:: 4378813-4Report Type:Expeditale I/FU:F	ted (15-I	DaCompany Repor	t #ZANA001286			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
	Daracion	Rash Maculo-Papular Viral Rash	Foreigr Health		Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
8 MG DAILY					-			
ORAL			Profess	sional				
					Paracetamol			

Citalopram (Citalopram)

Date:06/14/04ISR Number: 4379978-OReport 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	n Abdominal Distension	Foreign	Ternelin (Tizanidine			
Hospitalization - 1.2 MG DAILY	Anuria	Health	Hydrochloride)	PS		ORAL
Initial or Prolonged ORAL	Blood Uric Acid Increased	Professional				
	Bronchitis	Other	Hyserenin (Valproate			
	Cardio-Respiratory Arrest		Sodium)	C		
	Cardiovascular Disorder		Depas (Etizolam)	C		
	Dehydration		Theodur			
	General Physical		(Theophylline)	C		
	Condition Abnormal		Phenobal			
	Insomnia		(Phenobarbital)	C		
	Musculoskeletal Stiffness		Gabalon (Baclofen)	C		
	Ocular Hyperaemia		Meptin (Procaterol			
	Oculogyration		Hydrochloride)	C		
			Mucodyne			
			(Carbocisteine)	C		
			Tricloryl (Triclofos			
			Sodium)	C		
			Racol (Racol)	C		

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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

Age. 36 IR Gender.	1/ F U • 1					
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization -	Dehydration	Foreign	Zanaflex (Tizanidine			
Initial or Prolonged 2 MG DAILY	Fatigue	Health	Hydrochloride)	PS		ORAL
	Liver Function Test	Professional				
ORAL						
	Abnormal Somnolence		Baclofen (Baclofen) Oxybutynin	С		
			(Oxybutynin) Carbamazepine	С		
			(Carbamazepine) Pyridoxine	С		
			(Pyridoxine) Isoniazid	С		
			(Isoniazid)	С		
			Ascorbic Acid	a		
			(Ascorbic Acid) Warfarin (Warfarin)	C C		
			Zinc Sulphate (Zinc	C		
			Sulphate)	С		
Date:06/15/04ISR Number Age:28 YR Gender:Fema	r: 4381932-XReport Type:Expedi ale I/FU:I	ted (15-DaCompany Repo	rt #ZANA001314			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Blood Pressure Decreased	Foreign	Sirdalud (Tizanidine			
	Dizziness	Consumer	Hydrochloride)	PS		ORAL
2 MG DAILY						
	Jaundice	Other				
ORAL	Tachycardia					

Date:06/15/04ISR Number: 4382207-5Report Type:Expedited (15-DaCompany Report #ZANA001313 Age: Gender:Male I/FU:I

A							ļ
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalizati	.on -	Abnormal Dreams	Consumer	Zanaflex (Tizanidine			

Hydrochloride) Orthostatic Hypotension С Respiratory Disorder Tachycardia Date:06/16/04ISR Number: 4380826-3Report Type:Expedited (15-DaCompany Report #ZANA001317 Age:52 YR Gender: Female I/FU:I PTReport Source Product Role Manufacturer Outcome Route Duration Dose Alpha 1 Foetoprotein Foreign Sirdalud (Tizanidine Other Increased Health Hydrochloride) PS ORAL 12 MG DAILY Professional Hepatitis ORAL Serum Ferritin Increased Other Mercurius Solution (Mercurous Nitrate) C Date:06/16/04ISR Number: 4381375-9Report Type:Expedited (15-DaCompany Report #ZONI001444

Hydrochloride)

Evoxac (Cevimeline

PS

ORAL

Health

Professional

Age:55 YR Gender:Male I/FU:I

Outcome PT

Agitation Other

Asthenia

Heart Rate Irregular

Nasal Dryness

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Initial or Prolonged

ORAL

Freedom Of Information (FOI) Report

Aspirine

Blopress

Acid)

(Acetylsalicylic

С

		Confusional State Disturbance In Attention Dry Mouth	Report Source	Product	Role	Manufacturer	Route
Dose :	Duration	Dysgeusia	Consumer	Zonegran			
		Dysphasia		(Zonisamide)	PS		ORAL
200 MG DAILY							
ORAL		Irritability					
		Memory Impairment Mental Impairment Pruritus		Zanaflex (Tizanidine Hydrochloride) Clonidine	SS		
		Somnolence Vision Blurred		(Clonidine) Avinza (Morphine	С		
				Sulafte)	С		
				Provigil (Modafinil) Melatonin	С		
				(Melatonin)	С		
				Androgel			
		r: 4383593-2Report Type:Exp	pedited (15-DaCompany Re	(Testosterone Gel) eport #ZANA001318	С		
Age:77 YR G Outcome	Gender:Fema		pedited (15-DaCompany Re Report Source			Manufacturer	Route
Age:77 YR G Outcome Dose	Gender:Fema	ale I/FU:I PT	Report Source	eport #ZANA001318 Product		Manufacturer	Route
Age:77 YR G Outcome Dose Hospitalizati Initial or Pr	Gender:Fema Duration ion -	ale I/FU:I		eport #ZANA001318		Manufacturer	Route ORAL
Age:77 YR G Outcome Dose Hospitalizati Initial or Pr 18 MG DAILY	Gender:Fema Duration ion -	ale I/FU:I PT Drug Interaction	Report Source Foreign	eport #ZANA001318 Product Sirdalud (Tizanidine	Role	Manufacturer	
Age:77 YR G Outcome Dose Hospitalizati Initial or Pr 18 MG DAILY	Gender:Fema Duration ion -	ale I/FU:I PT Drug Interaction	Report Source Foreign Health Professional	eport #ZANA001318 Product Sirdalud (Tizanidine Hydrochloride)	Role	Manufacturer	
Age:77 YR G Outcome Dose Hospitalizati Initial or Pr 18 MG DAILY	Gender:Fema Duration ion -	ale I/FU:I PT Drug Interaction	Report Source Foreign Health	eport #ZANA001318 Product Sirdalud (Tizanidine	Role	Manufacturer	
Age:77 YR G Outcome Dose Hospitalizati Initial or Pr 18 MG DAILY	Gender:Fema Duration ion -	ale I/FU:I PT Drug Interaction	Report Source Foreign Health Professional	Product Sirdalud (Tizanidine Hydrochloride) Noroxin (Norfloxacin) Lioresal (Baclofen)	Role PS	Manufacturer	
Age:77 YR G Outcome Dose Hospitalizati Initial or Pr 18 MG DAILY	Gender:Fema Duration ion -	ale I/FU:I PT Drug Interaction	Report Source Foreign Health Professional	Product Sirdalud (Tizanidine Hydrochloride) Noroxin (Norfloxacin)	Role PS	Manufacturer	
Age:77 YR G Outcome Dose Hospitalizati Initial or Pr 18 MG DAILY	Gender:Fema Duration ion -	ale I/FU:I PT Drug Interaction	Report Source Foreign Health Professional	Product Sirdalud (Tizanidine Hydrochloride) Noroxin (Norfloxacin) Lioresal (Baclofen) Daonil (Glibenclamide) Metformin	Role PS SS C	Manufacturer	
Age:77 YR G Outcome Dose Hospitalizati Initial or Pr 18 MG DAILY	Gender:Fema Duration ion -	ale I/FU:I PT Drug Interaction	Report Source Foreign Health Professional	eport #ZANA001318 Product Sirdalud (Tizanidine Hydrochloride) Noroxin (Norfloxacin) Lioresal (Baclofen) Daonil (Glibenclamide) Metformin (Metformin)	Role PS SS C	Manufacturer	
Age:77 YR G Outcome Dose Hospitalizati Initial or Pr 18 MG DAILY	Gender:Fema Duration ion -	ale I/FU:I PT Drug Interaction	Report Source Foreign Health Professional	Product Sirdalud (Tizanidine Hydrochloride) Noroxin (Norfloxacin) Lioresal (Baclofen) Daonil (Glibenclamide) Metformin (Metformin) Spasmo-Urgenin N	Role PS SS C C	Manufacturer	
Age:77 YR G	Gender:Fema Duration ion -	ale I/FU:I PT Drug Interaction	Report Source Foreign Health Professional	eport #ZANA001318 Product Sirdalud (Tizanidine Hydrochloride) Noroxin (Norfloxacin) Lioresal (Baclofen) Daonil (Glibenclamide) Metformin (Metformin)	Role PS SS C	Manufacturer	

(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

Agitation Asthenia

Confusional State

Disturbance In Attention

Dry Mouth
Dysgeusia
Hyperaesthesia
Irritability
Memory Impairment

Pruritus Somnolence

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Other

Freedom Of Information (FOI) Report

Speech Disorder Vision Blurred

Dose	Duration		Report Source	Product	Role	Manufacturer	Route
DOSE	Duracion		Consumer	Zanaflex (Tizanidine			
				Hydrochloride)	PS		ORAL
100 MG ORAL				_			
				Zonegran	aa		OD 7 I
200 MG ORAL				(Zonisamide)	SS		ORAL
200 MG ORAL				Clonidine			
				(Clonidine)	С		
				Provigil (Modafinil)	C		
				Melatonin			
				(Melatonin)	С		
				Avinza (Morphine			
				Sulfate)	C		
				Androgel			
				(Testosterone)	С		
Age: Outcome							
Dose		PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat	Duration				Role	Manufacturer	Route
	ion -	Abnormal Dreams	Consumer	Zanaflex (Tizanidine		Manufacturer	
ORAL					Role	Manufacturer	Route ORAL
ORAL	ion -	Abnormal Dreams	Consumer	Zanaflex (Tizanidine		Manufacturer	
ORAL	ion -	Abnormal Dreams Blood Pressure	Consumer Health	Zanaflex (Tizanidine Hydrochloride)		Manufacturer	
ORAL	ion -	Abnormal Dreams Blood Pressure Orthostatic Decreased Dehydration Nasal Dryness	Consumer Health	Zanaflex (Tizanidine Hydrochloride) Evoxac (Cevimeline Hydrochloride) Bentyl	PS	Manufacturer	
ORAL	ion -	Abnormal Dreams Blood Pressure Orthostatic Decreased Dehydration Nasal Dryness Pulse Abnormal	Consumer Health	Zanaflex (Tizanidine Hydrochloride) Evoxac (Cevimeline Hydrochloride) Bentyl (Dicycloverine)	PS	Manufacturer	
ORAL	ion -	Abnormal Dreams Blood Pressure Orthostatic Decreased Dehydration Nasal Dryness Pulse Abnormal Respiration Abnormal	Consumer Health	Zanaflex (Tizanidine Hydrochloride) Evoxac (Cevimeline Hydrochloride) Bentyl (Dicycloverine) Synthroid	PS C C	Manufacturer	
ORAL	ion -	Abnormal Dreams Blood Pressure Orthostatic Decreased Dehydration Nasal Dryness Pulse Abnormal	Consumer Health	Zanaflex (Tizanidine Hydrochloride) Evoxac (Cevimeline Hydrochloride) Bentyl (Dicycloverine) Synthroid (Levothyroxine)	PS C	Manufacturer	
ORAL	ion -	Abnormal Dreams Blood Pressure Orthostatic Decreased Dehydration Nasal Dryness Pulse Abnormal Respiration Abnormal	Consumer Health	Zanaflex (Tizanidine Hydrochloride) Evoxac (Cevimeline Hydrochloride) Bentyl (Dicycloverine) Synthroid (Levothyroxine) Extex Pse	PS C C	Manufacturer	
ORAL	ion -	Abnormal Dreams Blood Pressure Orthostatic Decreased Dehydration Nasal Dryness Pulse Abnormal Respiration Abnormal	Consumer Health	Zanaflex (Tizanidine Hydrochloride) Evoxac (Cevimeline Hydrochloride) Bentyl (Dicycloverine) Synthroid (Levothyroxine) Extex Pse (Guaifenesin)	PS C C	Manufacturer	
ORAL	ion -	Abnormal Dreams Blood Pressure Orthostatic Decreased Dehydration Nasal Dryness Pulse Abnormal Respiration Abnormal	Consumer Health	Zanaflex (Tizanidine Hydrochloride) Evoxac (Cevimeline Hydrochloride) Bentyl (Dicycloverine) Synthroid (Levothyroxine) Extex Pse (Guaifenesin) Prevacid	PS C C C	Manufacturer	
ORAL	ion -	Abnormal Dreams Blood Pressure Orthostatic Decreased Dehydration Nasal Dryness Pulse Abnormal Respiration Abnormal	Consumer Health	Zanaflex (Tizanidine Hydrochloride) Evoxac (Cevimeline Hydrochloride) Bentyl (Dicycloverine) Synthroid (Levothyroxine) Extex Pse (Guaifenesin) Prevacid (Lansoprazole)	PS C C	Manufacturer	
ORAL	ion -	Abnormal Dreams Blood Pressure Orthostatic Decreased Dehydration Nasal Dryness Pulse Abnormal Respiration Abnormal	Consumer Health	Zanaflex (Tizanidine Hydrochloride) Evoxac (Cevimeline Hydrochloride) Bentyl (Dicycloverine) Synthroid (Levothyroxine) Extex Pse (Guaifenesin) Prevacid	PS C C C	Manufacturer	

Date:06/29/04ISR Number: 4388210-3Report Type:Direct Age:

I/FU:I Gender:Female

Company Report #CTU 221765

Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Other		Condition Aggravated		Tizanidine	PS	
		Pharmaceutical Product		Ambien	С	
		Complaint		Nexium	С	
		Unevaluable Event		Xanax	С	
				Oxycontin	С	
				Tylox	С	
				Advair	С	
				Valiium	С	

Date:07/07/04ISR Number: 4394843-OReport Type:Expedited (15-DaCompany Report #ZANA001321

Age:37 YR Gender:Female I/FU:I

Outcome PT Other Amm

Amnesia Crying

Feeling Cold Lethargy Sedation

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Freedom Of Information (FOI) Report

Zinc Sulphate (Zinc

C

Sulphate)

Self-Medication Somnolence

	Bollinotence					
Dose Dur	ation	Report Source	Product	Role	Manufacturer	Route
Dose Dur	ation	Foreign	Sirdalud (Tizanidine			
		Other	Hydrochloride)	PS		ORAL
2 DF/D; ORAL						
			Bromazepam	C		
			Cipramil (Citalopram	a		
			Hydrobromide) Omeprazle	C C		
			Cipramil (Citalopram	_		
			Hydrobromide)	C		
Age:38 YR Gend Outcome	-	Report Source Foreign Health	eport #ZANA001315 Product Zanaflex (Tizanidine Hydrochloride)	Role	Manufacturer	Route ORAL
2 MG DAILY						
ORAL	Liver Function Test	Professional				
ORAL	Abnormal		Baclofen (Baclofen)	С		
	Somnolence		Oxybutynin	C		
	_ _ _		(Oxybutynin)	С		
			Carbamazepine			
			(Carbamazepine)	C		
			Pyridoxine			
			(Pyridoxine) Isoniazid	С		
			(Isoniazid)	С		
			Ascorbic Acid	-		
			(Ascorbic Acid)	C		
			Warfarin (Warfarin)	C		

Date:07/07/04ISR Number: 4395287-8Report Type:Expedited (15-DaCompany Report #ZANA001320

Age:84 YR Gender:Female I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Daracion	Disease Progression Hyperhidrosis	Foreign Health	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL
4 MG BID ORA	A L	Pneumonia Vomiting	Professional Other	,			
	04ISR Number: Gender:Femal	: 4398016-7Report Type:Direct le I/FU:I	Company Repor	rt #CTU 222670			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
4 MG 1 TID	Durucion	Pharmaceutical Product Complaint		Zanaflex 4 Mg 1 Tid	PS		
	04ISR Number: Gender:Male	: 4398090-8Report Type:Direct I/FU:I	Company Repor	rt #CTU 222795			
Outcome Life-Threate Hospitalizat Initial or E	tion -						
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Freedom Of Information (FOI) Report

Product

Role Manufacturer

Route

PT	Report Source	Product	ROIE	Manuracturer	Route
Acute Myocardial		Zanaflex	PS		
Infarction Angina Unstable					
: 4399990-5Report Type:Expedi	ited (15-DaCompany Re	port #ZANA001322			
PT	Report Source	Product	Role	Manufacturer	Route
C-Reactive Protein Increased	Foreign Literature	Ternelin (Tizanidine Hydrochloride)	PS		ORAL
Erythema Multiforme Hepatic Function Abnormal	Health Professional	Tegretol (Carbamazepine)	SS		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		
: 4406699-8Report Type:Expedi	ited (15-DaCompany Re	port #ZANA001323			
PT	Report Source	Product	Role	Manufacturer	Route
Visual Disturbance	Foreign Health	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL
	Professional				
	Acute Myocardial Infarction Angina Unstable : 4399990-5Report Type:Expedication Infarction PT C-Reactive Protein Increased Erythema Multiforme Hepatic Function Abnormal 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 : 4406699-8Report Type:Expedication Type:Expedication Type:Expedication Increased	Acute Myocardial Infarction Angina Unstable : 4399990-5Report Type:Expedited (15-DaCompany Reference of I/FU:I PT Report Source C-Reactive Protein Increased Erythema Multiforme Erythema Multiforme Health Hepatic Function Abnormal 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 : 4406699-8Report Type:Expedited (15-DaCompany Reference) I/FU:I PT Report Source Visual Disturbance Foreign	Acute Myocardial Infarction Angina Unstable : 4399990-5Report Type:Expedited (15-DaCompany Report #ZANA001322	Acute Myocardial Zanaflex PS Infarction Angina Unstable : 4399990-5Report Type:Expedited (15-DaCompany Report #ZANA001322	Acute Myocardial Infarction Angina Unstable : 4399990-5Report Type:Expedited (15-DaCompany Report #ZANA001322

Report Source

Required

Intervention to

Prevent Permanent

PT

Date:07/16/04ISR Number: 4406642-1Report Type:Expedited (15-DaCompany Report #DRON00204002327

Age:50 YR Gender:Female I/FU:F

Outcome	D	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 2.5 MG BID,	Duration	Circulatory Collapse	Foreign	Marinol (Dronabinol)	PS		ORAL
PO		Confusional State	Study				
		Somnolence Speech Disorder	Health Professional	Amitripytline (Amitriptyline)	SS		ORAL
200 MG DAILY			Other				
PO				Baclofen (Baclofen)	SS		ORAL
70 MG DAILY				bactoren (bactoren)	DD		OKAL
PO							
				Tizanidine (Tizanidine)	SS		ORAL
32 MG DAILY							

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Freedom Of Information (FOI) Report

ORAL

ORAL

Date:07/20/04ISR Number: 4405375-5Report Type:Expedited (15-DaCompany Report #ZANA001314

Age:28 YR Gender: Female I/FU:F

Outcome PTReport Source Product Role Manufacturer Route Duration Dose

Other Blood Pressure Decreased Foreign

Sirdalud (Tizanidine Dizziness Hydrochloride) PS Consumer

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

Role Manufacturer PTReport Source Product Outcome Route Duration Dose

36 mg/d

Haemoglobin Decreased Baclofen Life-Threatening Health PS Novartis Sector:

Haemolysis Professional Other Pharma

Zanaflex \$E1 SS

Neurontin C

UNKNOWN

Ditropan C UNKNOWN

Date: 07/29/04ISR Number: 4412075-4Report Type: Direct Company Report #CTU 223860

Gender: Female Age: I/FU:I

PΤ Report Source Role Manufacturer Outcome Product Route

Duration Dose

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

tcome	PT	Report Source	Product	Role	Manufacturer	Route
se Duration		-				
fe-Threatening	Dyspnoea	Foreign	Sirdalud (Tizanidine			
	Sensation Of Foreign Body	Health	Hydrochloride)	PS		ORAL
MG DAILY		- 6 1 3				
n T		Professional				
AL		Other	Panadol			
		Other	(Paracetamol)	SS		ORAL
O MG DAILY			(raraccamer)	DD		Oldin
AL						
			Mercilon	_		
			(Desogestrel)	С		
			Beklometasone			
			Dipropionate			
			(Beclometasone Dipropionate)	C		
			Dipropionate)	С		
tcome fe-Threatening spitalization - itial or Prolonged	PT Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Alkaline Phosphatase Increased Gamma-Glutamyltransferase Increased Hepatic Function Abnormal					
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Freedom Of Information (FOI) Report

Baclofen (Baclofen)

Ditropan (Oxybutynin

Hydrochloride)

Neurontin (Gabapentin) SS

С

С

		Hypogammaglobulinaemia					
		Multiple Sclerosis	. <u>.</u>			•	
Dose	Duration	Myotonia	Report Source	Product	Role	Manufacturer	Route
	Daracion	Pneumonia Productive Cough		Tegretol	PS	Novartis Sector: Pharma	ORAL
200 mg, BID	36000MIN	Pyrexia		Tegretol	SS	Novartis Sector:	
200 mg, TID	5760 MIN	Rash Generalised				Pharma	ORAL
200 mg, 11D	3/00 MIIN	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	ODAI
200 mg, BID	40320MIN					Pnarma	ORAL
UNKNOWN				Gaster	SS		
				Ternelin	SS		
UNKNOWN				Predonine	С		ORAL
15 mg/day				G 31	a		
150 mg/day				Selbex	С		ORAL
				Rize	С		ORAL
5 mg/day							
	4ISR Number: Gender:Male	: 4422425-0Report Type:Expedi I/FU:I	ted (15-DaCompany Repor	rt #PHBS2004US09673			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Life-Threate	Duration	Glucose-6-Phosphate	Ecroian	Zanaflow CEl			
Llie-IIIreace	aing	Dehydrogenase Deficiency	Foreign Health	Zanaflex \$E1 (Tizanidine			
36 MG/D		Haemoglobin Decreased	Professional	Hydrochloride)	PS		ORAL
1							

Other

Haemolysis

Date:08/06/04ISR Number: 4416952-XReport Type:Expedited (15-DaCompany Report #PHBS2003JP01063

Age:29 YR Gender:Female I/FU:F

Outgomo		PT	Deposit Course	Drodugt	Dolo	Manufacturer	Doute
Outcome Dose	Duration	P.T.	Report Source	Product	Role	Manuracturer	Route
Life-Threaten Hospitalizati	ning	Eosinophilia Erythema		Tegretol	PS	Novartis Sector: Pharma	ORAL
200 mg, BID	36000MIN	-					ŀ
Initial or Pr		Hepatic Function Abnormal Hypogammaglobulinaemia		Tegretol	SS	Novartis Sector: Pharma	ORAL
200 mg, TID	5760 MIN						
		Lung Infiltration Pneumonia		Tegretol	SS	Novartis Sector: Pharma	ORAL
200 mg, QID	25920MIN						ŀ
		Productive Cough Pyrexia		Tegretol	SS	Novartis Sector: Pharma	
200 mg, TID	60480MIN	-					ŀ
İ		Rales		Tegretol	SS	Novartis Sector:	ŀ
İ		Rash Generalised				Pharma	ORAL
200 mg, BID	40320MIN						ŀ
		Skin Exfoliation		Gaster	SS		ŀ
UNKNOWN		There are Données tours Though		W a 1 d m	aa		ŀ
UNKNOWN		Upper Respiratory Tract		Ternelin	SS		I
UNKINOMIN		Infection		Predonine	С		ORAL
15 mg/day					C		01111
5, 1				Selbex	С		ORAL
150 mg/day							
İ				Rize	С		ORAL

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

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5 mg/day

Freedom Of Information (FOI) Report

(Hydrocodone)

		Angina Unstable Back Pain Chest Pain	Report Source	Product	Polo	Manufacturer	Route
Dose	Duration	CHEST PAIN	κεροις σοσίσε	Product	KOTE	Malluracturer	πυαιε
r		Condition Aggravated	Health	Zanaflex (Tizanidine			
' ***		Coronary Artery Disease	Professional	Hydrochloride)	PS		ORAL
4 MG DAILY		Muscle Spasms					
ORAL		Plabete Spasine					
		Nerve Compression Pain Pain In Jaw Treatment Noncompliance		Vicodin (Paracetamol) Accupril (Quinapril) Zoloft (Sertraline) Klonopin	C C C		
				(Clonazepam)	С		
Age:69 YR Outcome Dose Hospitaliza	Duration	ale I/FU:I PT Amnesia	Report Source	Product Zanaflex (Tizanidine	Role	Manufacturer	Route
Initial or 4 MG ORAL		Angiopathy	Professional	Hydrochloride)	PS		ORAL
Other		Blood Creatine Phosphokinase Increased Carotid Artery Stenosis Confusional State Encephalopathy Mental Status Changes Overdose Sleep Disorder Urinary Tract Infection	Other	Copaxone (Glatiramer Acetate)	SS		
		: 4432541-5Report Type:Expec	dited (15-DaCompany Re	eport #ZANA001332			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitaliza		Depression	Literature	Zanaflex (Tizanidine			
Initial or		General Physical Health	Health	Hydrochloride)	PS		
Other		Deterioration	Professional	Hydrocodone	a		

Hip Fracture

Orthostatic Hypotension	Acetaminophen	
	(Paracetamol)	С
	Carbamazepine	
	(Carbamazepine)	С
	Aspirin	
	(Acetylsalicylic	
	Acid)	С
	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

PT

Dose Duratio	n				
Life-Threatening	Drug Screen Positive	Foreign	Zanaflex (Tizanidine		
Hospitalization - 32 MG DAILY	Respiratory Depression	Health	Hydrochloride)	PS	ORAL
Initial or Prolonged ORAL	Urinary Tract Infection	Professional			
			Methadone		
			(Methadone)	SS	

Product

Role Manufacturer

Route

Report Source

50 MG DAILY

Outcome

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Freedom Of Information (FOI) Report

(Carbamazepine)

Rivotril	
(Clonazepam)	С
Coumadin (Warfarin)	C
Vioxx (Rofecoxib)	C
Neurontin	
(Gabapentin)	C
Baclofen (Baclofen)	C
Bactrim	
(Sulfamethoxazole)	C
Phencyclidine	
(Phencyclidine)	С

Date: 08/23/04ISR Number: 4432954-1Report Type: Expedited (15-DaCompany Report #ZANA001333

Age:71 YR Gender:Female I/FU:I

Outcome Dose Du	ıration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Enitial or Prolonged Hospital ORAL	Hospitalisation	Foreign Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	
O MG OKAL			Professional Other	Baclofen (Baclofen) Ranitidine	С		
				(Ranitidine) Paracetamol	С		
				(Paracetamol) Atorvastatin	С		
				(Atorvastatin) Oxybutynin	С		
				(Oxybutynin) Amitriptyline	C		
				(Amitriptyline)	С		
				Warfarin (Warfarin)	C		
				Zopiclone (Zopiclone) Carbamazepine	С		

Date:08/23/04ISR Number: 4432955-3Report Type:Expedited (15-DaCompany Report #ZANA001157

Age:29 YR Gender:Female I/FU:I

Outcome Life-Threatening

Alanine Aminotransferase

Hospitalization -

Increased

Initial or Prolonged

Aspartate

 ${\tt Aminotransferase}$

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

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Freedom Of Information (FOI) Report

		Skin Exfoliation Upper Respiratory Tract			_		
Dose	Duration	Infection	Report Source	Product	Role	Manufacturer	Route
DOSE	Duracion	Upper Respiratory Tract Inflammation	Foreign Literature Health	Ternelin (Tizanidine Hydrochloride) Tegretol	PS		
400 MG DATE			Professional	(Carbamazepine)	SS		ORAL
400 MG DAIL	ıΥ		Other				
ORAL			Ocher				
				Gaster (Famotidine) Predonine	SS		
				(Prednisolone)	C		
				Selbex (Teprenone)	C		
				Rize (Clotiazepam)	C		
m-+00/22/	/OATCD Number	. 4422000 OD Throat Erro of	1' - 3 /15 Da Componer De				
Age:69 YR	/04ISR Number Gender:Fema			eport #ZANA001328			
Age:69 YR Outcome	Gender:Fema		dited (15-DaCompany Re Report Source		Role	Manufacturer	Route
Age:69 YR Outcome Dose	Gender:Fema	ale I/FU:I	Report Source	eport #ZANA001328 Product	Role	Manufacturer	Route
Age:69 YR Outcome Dose Hospitaliza	Gender:Fema Duration ation -	ale I/FU:I		eport #ZANA001328 Product Zanaflex (Tizanidine	Role	Manufacturer	Route ORAL
Age:69 YR Outcome Dose	Gender:Fema Duration ation -	ale I/FU:I PT Amnesia	Report Source Health	eport #ZANA001328 Product		Manufacturer	
Age:69 YR Outcome Dose Hospitaliza Initial or	Gender:Fema Duration ation -	ale I/FU:I PT Amnesia	Report Source Health	eport #ZANA001328 Product Zanaflex (Tizanidine		Manufacturer	
Age:69 YR Outcome Dose Hospitaliza Initial or 4 MG ORAL	Gender:Fema Duration ation - Prolonged	PT Amnesia Blood Creatine Phosphokinase Increased	Report Source Health Professional	eport #ZANA001328 Product Zanaflex (Tizanidine Hydrochloride) Copaxone (Glatiramer	PS	Manufacturer	
Age:69 YR Outcome Dose Hospitaliza Initial or 4 MG ORAL Other	Gender:Fema Duration ation - Prolonged US 20 MG	PT Amnesia Blood Creatine Phosphokinase Increased Carotid Artery Stenosis DAILY,	Report Source Health Professional	eport #ZANA001328 Product Zanaflex (Tizanidine Hydrochloride) Copaxone (Glatiramer	PS	Manufacturer	
Age:69 YR Outcome Dose Hospitaliza Initial or 4 MG ORAL Other SUBCUTANEOU	Gender:Fema Duration ation - Prolonged US 20 MG	PT Amnesia Blood Creatine Phosphokinase Increased Carotid Artery Stenosis DAILY,	Report Source Health Professional	eport #ZANA001328 Product Zanaflex (Tizanidine Hydrochloride) Copaxone (Glatiramer	PS	Manufacturer	
Age:69 YR Outcome Dose Hospitaliza Initial or 4 MG ORAL Other SUBCUTANEOU	Gender:Fema Duration ation - Prolonged US 20 MG	PT Amnesia Blood Creatine Phosphokinase Increased Carotid Artery Stenosis DAILY, Confusional State Delirium	Report Source Health Professional	Product Zanaflex (Tizanidine Hydrochloride) Copaxone (Glatiramer Acetate)	PS SS	Manufacturer	ORAL
Age:69 YR Outcome Dose Hospitaliza Initial or 4 MG ORAL Other SUBCUTANEOU	Gender:Fema Duration ation - Prolonged US 20 MG	PT Amnesia Blood Creatine Phosphokinase Increased Carotid Artery Stenosis DAILY, Confusional State	Report Source Health Professional	Product Zanaflex (Tizanidine Hydrochloride) Copaxone (Glatiramer Acetate)	PS SS	Manufacturer	ORAL

Date:08/25/04ISR Number: 4433560-5Report Type:Direct

Overdose

Mental Status Changes

Urinary Tract Infection

Pain In Extremity

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

Company Report #CTU 225635

Initial or Prolonged	Myocardial In	farction				
Other	Pain					
Required	Thrombosis					
Intervention to						
Prevent Permanent						
Impairment/Damage						
Date:09/01/04ISR Number Age:79 YR Gender:Male		oort Type:Expedited (15-	DaCompany Report #Zi	NA001338		
Age:79 YR Gender:Male Outcome				ANA001338 duct Role	Manufacturer R	Route
Age:79 YR Gender:Male Outcome Dose Duration	I/FU:I	Report	Source Prod	duct Role	Manufacturer R	Route
Age:79 YR Gender:Male Outcome	I/FU:I	Report Foreig	Source Prod	duct Role dalud (Tizanidine		
Age:79 YR Gender:Male Outcome Dose Duration	I/FU:I	Report	Source Prod	duct Role		Route ORAL
Age:79 YR Gender:Male Outcome Dose Duration Life-Threatening	I/FU:I	Report Foreig	Source Prod n Siro Hydr	duct Role dalud (Tizanidine		

Other

Report Source

Product

Zanaflex 4 Mg

Brufen (Ibuprofen)

Role Manufacturer

PS

Route

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Outcome

Life-Threatening

1 TWICE DAILY Hospitalization -

Dose

PT

Discomfort

Loss Of Consciousness

Duration

Freedom Of Information (FOI) Report

Phenelzine

SS

Date:09/01/04ISR Number: 4443131-2Report Type:Expedited (15-DaCompany Report #ZANA001323

UNKNOWN

Date:09/01/ Age:40 YR	04ISR Number Gender:Male	r: 4443131-2Report Type:Exped e I/FU:F	ited (15-DaCompany Re	eport #ZANA001323			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Visual Disturbance	Foreign Health	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL
8 MG DAILY			Professional	•			
ORAL			Other				
Date:09/02/ Age:	04ISR Number Gender:Male	:: 4441090-XReport Type:Direc	t Company Re	eport #CTU 226225			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Disability	Duracion	Drug Ineffective Pharmaceutical Product		Zanaflex 8 Mg Tid - Qid	PS		
8 MG TID -		Complaint		Q1d	15		
QID		Complaine		_			
				Ultracet	С		
	04ISR Number Gender:Fema	r: 4440511-6Report Type:Exped ale I/FU:I	ited (15-DaCompany Re	eport #PHBS2004US11398			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Depressed Level Of Consciousness	Health Professional	Baclofen	PS	Novartis Sector: Pharma	
UNKNOWN			TTOTESSTORAL			THATMA	
		Dizziness Tachycardia		Tizanidine Hydrochloride	SS		
UNKNOWN				Nortriptyline			
UNKNOWN				Hydrochloride	SS		
UNKNOWN				Gabapentin	SS		
				-1 7 1			

UNKNOWN			Olanzapine	55	
Date:09/03/04ISR Number Age:33 YR Gender:Fema	: 4444842-5Report Type:Expeditle I/FU:I	dited (15-DaCompany Re	eport #2004PK01436		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Required 700 MG DAILY	Confusional State	Foreign	Seroquel	PS	ORAL
Intervention to	Coordination Abnormal	Health			
Prevent Permanent 4 MG DAILY PO	Drug Interaction	Professional	Sirdalud	SS	ORAL
Impairment/Damage 80 MG DAILY		Other	Entumin	SS	ORAL
PO			Orfiril	SS	ORAL
1 G DAILY PO					-
4.5 MG DAILY			Lorazepam	SS	ORAL
PO					
Date:09/03/04ISR Number Age:65 YR Gender:Male	:: 4445304-1Report Type:Expec	dited (15-DaCompany Re	eport #ZANA001342		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged 3 MG ORAL	Blood Pressure Systolic Decreased	Foreign Health	Ternelin (Tizanidine Hydrochloride)	PS	ORAL
	Heart Rate Decreased	Professional Other	Loxonin (Loxoprofen Sodium)	SS	ORAL
180 MG 300 MG ORAL			Mucosta(Rebamipide)	SS	ORAL

UNKNOWN

UNKNOWN

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Ketorolac

Bethanechol

Olanzapine

SS

SS

SS

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 - 8 DAY	Alanine Aminotransferase	Health	Vioxx	PS	Merck & Co., Inc	ORAL
Initial or Prolonged	Increased Aspartate	Professional	Diclofenac Sodium Tizanidine	SS		ORAL
	Aminotransferase		Hydrochloride	SS		ORAL
3 DAY						
	Increased Blood Alkaline Phosphatase Increased Bradycardia Gamma-Glutamyltransferase Increased		Herbs (Unspecified)	С		ORAL

Date:09/14/04ISR Number: 4448421-5Report Type:Expedited (15-DaCompany Report #PHBS2004CH11775

Age:60 YR Gender:Female I/FU:

Age:60 YR Gender:Fen	male I/FU:I					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Alanine Aminotransferase		Voltaren	PS	Novartis Sector:	
Initial or Prolonged	Increased				Pharma	
UNKNOWN	4320 MIN					
Other	Aspartate		Sirdalud	SS		
UNKNOWN 6 mg/	/day 4320 MIN					
	Aminotransferase		Vioxx	SS		
UNKNOWN	4320 MIN					
	Increased		Herbal Extracts Nos	SS		
	Blood Alkaline					
	Phosphatase Increased					
	Bradycardia					
	Chest Discomfort					
	Diarrhoea					
	Drug Interaction					
	Dyspnoea					
	Fibrin D Dimer Increased					
	Gamma-Glutamyltransferase	9				
	Increased					
	Haemangioma Of Liver					
	Hepatic Enzyme Increased					
	Hepatic Lesion					
	Hyperhidrosis					
4						

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

PT

Dose Duration					
Hospitalization -	Biopsy Skin Abnormal	Foreign	Ternelin (Tizanidine		
Initial or Prolonged	C-Reactive Protein	Literature	Hydrochloride)	PS	ORAL
ORAL					
	Increased	Health	Tegretol		
	Eosinophilia	Professional	(Carbamazepine)	SS	ORAL
ORAL	_				
	Erythema Multiforme	Other	Loxonin (Loxoprofen		
	Hepatic Function Abnormal		Sodium)	C	
	Human Herpes Virus 6		Prednisolone	С	
	Serology Positive				
	Hypersensitivity				
	Leukocytosis				
	Lymphocyte Stimulation				
	Test Positive				
i	Purpura				

Product

Role Manufacturer

Route

Report Source

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Outcome

Freedom Of Information (FOI) Report

Hydrochloride)

(Fluvoxamine)

Wypax (Lorazepam)

Amoxan (Amoxapine)

Depromel

PS

С

С

С

ORAL

Date:09/14/04ISR Number: 4450216-3Report Type:Expedited (15-DaCompany Report #ZANA001290 Age:74 YR Gender:Male I/FU:F

Outcome	D	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	False Positive Laboratory Result	Foreign Health	Ternelin (Tizanidine Hydrochloride)	PS		ORAL
2 MG DAILY		1.02 0.10	11001011	, a 00 01 01 01			01412
		Hepatitis Cholestatic	Professional				
ORAL							
		Laboratory Test Abnormal	Other	Mucosta (Rebamipide)	SS		
		Lymphocyte Stimulation Test Positive		Osteluc (Etodolac) Nitrendipine	C C		
		Urticaria		Bayaspirina	C		
		or or our ra		(Acetylsalicylic			
				Acid)	C		
				Resplen (Eprazinone			
				Hydrochloride)	C		
				Empynase (Pronase)	C		
				Spelear (Fudosteine) Nitorol (Isosorbide	С		
				Dinitrate)	С		
				Difficulty (C		
Date:09/14/	04TSR Number	c: 4450218-7Report Type:Exped	ited (15-DaCompany Re	eport #ZANA001344			
Age:	Gender: Male		(======================================				
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Blood Pressure Decreased	Foreign	Ternelin (Tizanidine			

Date:09/15/04ISR Number: 4452325-1Report Type:Expedited (15-DaCompany Report #ZANA001309 Age:32 YR Gender:Female I/FU:F

Dehydration

ORAL

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Confusional State	Foreign	Sirdalud (Tizanidine			

Health

Other

Professional

	Coordination Abnormal	Health	Hydrochloride)	PS	ORAL
2-4 MG/DAY		D 6 1 1			
ORAL	Depressive Delusion	Professional			
40.00 MG/DAY	Disease Recurrence	Other	Entumin (Clotiapine)	SS	ORAL
40-80 MG/DAY	Disorientation				
ORAL	Diborremederon				
	Drug Interaction Gait Disturbance		Lorazepam (Lorazepam)	SS	ORAL
4.5 MG/DAY	-1 -1				
ORAL	Sleep Disorder				
			Seroquel (Quetiapine	9.9	0777
100 - 700			Fumarate)	SS	ORAL
MG/DAY ORAL					
			Nozinan (Levomepromazine)	SS	ORAL
50 MG DAILY			(Developromazine)		Oranz
ORAL					
			Orfiril (Valproate Sodium)	aa	ORAL
1000 MG/DAY			Soatum)	SS	ORAL
ORAL					
Date:09/15/04ISR Numbe Age:53 YR Gender:Fer	er: 4452379-2Report Type:Ex male I/FU:I	pedited (15-DaCompany R	eport #ZANA001345		
Outcome Hospitalization -	PT Hepatitis Acute	Report Source Foreign			
- 1.1.1		1.1			

Initial or Prolonged

Foreign Health

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Freedom Of Information (FOI) Report

Professional Other

Dose	Duration			Product	Role	Manufacturer	Route
3	Duracion			Ternelin (Tizanidine Hydrochloride)	PS		ORAL
TABLETS/DAY,							
ORAL 3				Cerocral (Ifenprodil Tartrate)	SS		ORAL
TABLETS/DAY,							
ORAL				Methycobal (Mecobalamin)	С		
Date:09/17/04 Age:33 YR (xpedited (15-DaCompany Re	port #DSA_24963_2004			
Outcome Dose	Duration	PT					
Other 4.5 MG Q DAY		FI	Report Source	Product	Role	Manufacturer	Route
		Confusional State	Report Source Foreign	Product Temesta	Role PS	Manufacturer	Route ORAL
						Manufacturer	
PO		Confusional State	Foreign			Manufacturer	
		Confusional State Coordination Abnormal	Foreign Health	Temesta	PS	Manufacturer	ORAL
PO 700 MG Q DAY		Confusional State Coordination Abnormal	Foreign Health Professional	Temesta	PS	Manufacturer	ORAL
PO 700 MG Q DAY PO		Confusional State Coordination Abnormal	Foreign Health Professional	Temesta Seroquel	PS SS	Manufacturer	ORAL
PO 700 MG Q DAY PO 4 MG Q DAY PO		Confusional State Coordination Abnormal	Foreign Health Professional	Temesta Seroquel Sirdalud	PS SS	Manufacturer	ORAL ORAL

Date:09/23/04ISR Number: 4460500-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040903505 Age:21 YR Gender:Female I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death Hospitalizati Initial or Pi Other 300 MG, 1 IN	ion - rolonged	Aggression Aspiration Drug Interaction Potentiation	Literature Health Professional	Cyclobenzaprine (Cyclobenzaprine Hydrochloride) Unknown	PS		ORAL
300 110, 1 111		Drug Screen Positive					
1 DAY, ORAL		_					
		Drug Toxicity Lung Disorder		Acetaminophen/Tramad ol (Tramadol/Apap)	SS		
30 G/3 G							
		Multiple Drug Overdose Sedation		Amitriptyline (Amitriptyline)	SS		ORAL
700 MG, 1 IN							
		Self-Medication					
1 DAY, ORAL		Suicide Attempt		Tizanidine			
		Vomiting		(Tizanidine)	SS		ORAL
120 MG, 1 IN							
1 DAY, ORAL							
				Rofecoxib	9.0		20.7.1
750 MG, 1 IN				(Rofecoxib)	SS		ORAL
1 DAY, ORAL							
				Omeprazole			
300 MG, 1 IN				(Omeprazole)	SS		ORAL

Date:09/24/04ISR Number: 4457840-2Report Type:Expedited (15-DaCompany Report #US-MERCK-0409USA01708 Gender:Female Age:21 YR I/FU:I

Outcome Death Hospitalization -Initial or Prolonged

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1 DAY, ORAL

Freedom Of Information (FOI) Report

Other

Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
DORE	Duracion	Aggression Aspiration Completed Suicide Depressed Level Of	Health Professional	Vioxx Acetaminophen And Tramadol Hydrochloride	PS SS	Merck & Co., Inc	ORAL
UNKNOWN		Depressed Level OI		нуагосптоттае	55		
		Consciousness Drug Toxicity		Elavil Tizanidine	SS		ORAL
		Intentional Misuse Vomiting		Hydrochloride Flexeril Omeprazole	SS SS		ORAL ORAL ORAL
Date:09/24/0	4TSR Number	: 4462090-XReport Type:Direct	Company Rend	ort #CTU 228006			
	Gender: Male		company respe	510 HC10 220000			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 2 MG BID	Muscle Spasticity		Tizanidine 2mg	PS			
	Z MO BID	Pharmaceutical Product Complaint Retching Vomiting		Baclofen	С		
Date:09/28/0 Age:71 YR		:: 4462613-0Report Type:Expedi ale I/FU:I	ted (15-DaCompany Repo	ort #200412698GDS			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Foreign Health	Ciproxine (Ciprofloxacin)	PS		ORAL
ORAL		Bradycardia	Professional				
20 MG, BID,		Electrocardiogram Qt	Other	Propanolol	SS		ORAL
ORAL		Prolonged			_		
4 MG, TOTAL		Hypotension		Tizanidine	SS		ORAL
4							

Outcome

Aspirin C
Irbesartan C
Simvastatin C
Oxazepam C
Dextran Sulfate C
Tramadol C

Promac (Polaprezinc) C

Product

Role Manufacturer

Route

Date:09/30/04ISR Number: 4465441-5Report Type:Expedited (15-DaCompany Report #ZANA001349

Age:54 YR Gender:Female I/FU:I

PT

Dogo	D +		-			
Dose Other	Duration	Blood Pressure Systolic Increased	Foreign Health	Ternelin (Tizanidine Hydrochloride)	PS	ORAL
3 TABLETS						
		Epilepsy	Professional			
DAILY ORAL						
i			Other	Luvox (Fluvoxamine		
i				Maleate)	C	
i				Myslee (Zolpidem		
i				Tartrate)	C	
i				Gasmotin (Mosapride		
1				Citrate)	С	

Report Source

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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 Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Cardiac Enzymes Increased Cardiac Failure	Foreign Health	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL
ORAL		Professional Other				
Date:09/30/04ISR Numb Age:81 YR Gender:Fe	er: 4465453-1Report Type:Exped male I/FU:I	ited (15-DaCompany R	eport #ZANA001347			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Alanine Aminotransferase	Foreign	Ternelin (Tizanidine			
Initial or Prolonged 3 MG DAILY	Increased	Health	Hydrochloride)	PS		ORAL
ORAL	Aspartate	Professional				
30 MG DAILY	Aminotransferase	Other	Ketas (Ibudilast)	SS		ORAL
30 110 211121	Increased					
ORAL						
	Blood Alkaline		Gasmotin (Mosapride			
	Phosphatase Increased		Citrate)	SS		ORAL
15 MG DAILY						
OD A F	Blood Lactate					
ORAL	Dehydrogenase Increased Gamma-Glutamyltransferase Increased Hypoaesthesia Liver Disorder		Chinese Medication	С		

Date:10/04/04ISR Number: 4467946-XReport Type:Expedited (15-DaCompany Report #200412698GDS

Therapy Non-Responder

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

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Freedom Of Information (FOI) Report

Dogo Di	uration		Report Source	Product	Role	Manufacturer	Route
Dose Du	uration		Foreign Health	Ciproxine (Ciprofloxacin)	PS		ORAL
500 MG, BID,				(
0			Professional				
ORAL			Other	Inderal (Propranolol	a a		0071
20 MG, BID,				Hydrochloride)	SS		ORAL
ORAL							
				Sirdalud (Tizanidine			
				Hydrochloride)	SS		ORAL
4 MG, TOTAL							
DAILY, ORAL							
,				Aspirin Cardio	С		
				Coaprovel	C		
				Simcora	C		
				Quilinorm	C		
				Surmontil	C		
				Seresta	C		
				Neurontin	C		
				Celebrex	C		
				Tramal	C		
				Phlebodril N	С		
	SR Number: nder:Femal	4469462-8Report Type:Expedite e I/FU:I	ed (15-DaCompany Repor	t #ZANA001350			
Outcome Dose Du	uration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization		Blood Creatinine	Foreign	Sirdalud (Tizanidine			
Initial or Prol		Increased	Health	Hydrochloride)	PS		ORAL
4 MG DAILY				nyaroenrorrae)	10		Oldin
ORAL		Delirium	Professional				
OKAL		Electrocardiogram Qrs	Other	Inderal (Propranolol			
40		Complex Prolonged		Hydrochloride)	SS		ORAL
40 MG DAILY		m1					
ORAL		Electrocardiogram Qt					

Tremor

Urinary Tract Infection

1000 MG DAILY

Prolonged	Ciproxin	
Electrocardiogram	(Ciprofloxacin)	SS
Paralanian tian	7	
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)	С
Pyrexia	Quilonorm (Lithium	
Sinus Arrest	Acetate)	С
Sinus Bradycardia	Surmontil	
Somnolence	(Trimipramine	
Therapeutic Agent	Maleate)	С
Toxicity	Neurontin	_
Tremor	(Gabapentin)	С
Urine Abnormality	Celebrex (Celecoxib)	C
ornic marrey	Cipralex	_
	(Escitalopram)	C
	-	C
	Lithium (Lithium)	C

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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 6 MG DAILY	Alanine Aminotransferase Increased	Foreign Health	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL
Other	Aspartate	Professional				
ORAL	Aminotransferase Increased Blood Alkaline Phosphatase Increased Bradycardia 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	Other	Voltaren (Diclofenac Sodium) Vioxx (Rofecoxib) Herbal Extracrs Nos (Herbal Extracts Nos)	SS SS		

Date	: T ()/06/0	141SR	. Numbe	r:	4470653-0Report	Type:Direct	Company	Report	#C.I.O	228942
					_						

Age:46 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Other		Pharmaceutical Product		Zanaflex		
		Complaint		(Tizanidine)	PS	
4 MG FOR QJS 6	6 MON					
				Flexent	С	
				Clonazepam	С	
				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 Durati Death 700 MG DAILY;	on Abnormal Chest Sound	Literature	Elavil	PS	ORAL
Hospitalization - PO	Aggression	Health			
Initial or Prolonge 750 MG DAILY;	d Aspiration	Professional	Vioxx	SS	ORAL
Required PO	Completed Suicide				
Intervention to 300 MG DAILY;	Depressed Level Of		Flexeril	SS	ORAL
Prevent Permanent PO	Consciousness				
<pre>Impairment/Damage 30 G</pre>	Drug Toxicity		Acetaminophen	SS	
3G	Intentional Misuse Sedation		Tramadol Hydrochloride	SS	
39	Vomiting		Tizanidine Hydrochloride	SS	ORAL
120 MG DAILY;			-		
PO			Omeprazole	SS	ORAL
300 MG DAILY;			Omeprazore		ORAL

PO

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Freedom Of Information (FOI) Report

Date:10/07/04ISR Number: 4471850-OReport Type:Expedited (15-DaCompany Report #ZANA001353

Liver Disorder

ORAL

Age:41 YR Gender:Fema	ale I/FU:I					
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Bradycardia Nausea	Foreign Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
16 MG DAILY			, « « « »			01111
ORAL	Orthostatic Hypotension	Professional				
	Vomiting	Other	Avonex (Interferon)	С		
	Weight Decreased		Sandostatin (Octreotide)	С		
Date:10/12/04ISR Number Age:72 YR Gender:Fema	r: 4475626-XReport Type:Exped. ale I/FU:F	ited (15-DaCompany Re	port #ST-2004-008072			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration	-	-				
Hospitalization - 20 MG QD PO	Anorexia	Foreign	Olmetec	PS		ORAL
Initial or Prolonged 80 MG QD PO	Dizziness	Health	Diovan	SS	Novartis	ORAL
7 F MG BTD DO	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 Norvasc	C C		
Date:10/12/04ISR Number Age:18 YR Gender:Male	r: 4475637-4Report Type:Exped. e I/FU:I	ited (15-DaCompany Re	port #ZANA001352			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration		-				
Other	Agitation	Foreign	Zanaflex (Tizanidine			_
1 MG DATIV	Hepatic Enzyme Increased	Other	Hydrochloride)	PS		ORAL
1 MG DAILY						

Pyrexia	Baclofen (Baclofen)	С
Rash Erythematous	Heparin (Heparin)	С
	Risperidone	
	(Risperidone)	С

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 -	Aggression	Study	Morphine Sulfate			
Initial or Prolonged	Agitation	Health	(Morphine Sulfate)	PS		
Other	Alkalosis	Professional	Other Hypnotics And			
	Areflexia	Other	Sedatives ()	SS		
	Back Pain		Muscle Relaxants ()	SS		
	Blood Ph Decreased		Tizanidine			
	Coma		(Tizanidine)	SS		
	Headache		Cyclobenzaprine			
	Muscle Twitching		(Cyclobenzaprine)	SS		
	Myocardial Infarction		Benzodiazepine			
	Neck Pain		Derivatives ()	SS		
	Pericarditis		Amitriptyline			
	Pneumonia Aspiration		(Amitriptyline)	SS		
	Pyrexia					
	Restlessness					

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Viral Infection

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	(Doxepin)	PS		
			Professional	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

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration

Tizanidine PS Nausea

Required

4 MG 1 - 1

Intervention to

Rash

1/2 Q 6 H

Stomach Discomfort Prevent Permanent

Impairment/Damage

Date:10/14/04ISR Number: 4475455-7Report Type:Direct Company Report #CTU 229593

Gender: Female I/FU:I Age:

PTReport Source Role Manufacturer Outcome Product Route

Duration Dose

Tizanidine Other Condition Aggravated PS

CHANGE TO

Muscle Spasms

ZANAFLEX BMN

[LIFETIME]

Age: Gender:Male I/FU:I Report Source Role Manufacturer Outcome PTProduct Route Dose Duration Drug Ineffective Tizanidine 4 Mg PS 4 MG DAILY Therapeutic Response Unexpected With Drug Substitution

Company Report #CTU 239853

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

Consciousness

Hallucination

Hallucination, Visual

Nightmare

Date:10/14/04ISR Number: 4678669-6Report Type:Direct

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NIGHTLY

Freedom Of Information (FOI) Report

Date:10/20/04ISR Number: 4482108-8Report Type:Expedited (15-DaCompany Report #ACO_0006_2004

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

1							
Outcome Dose Du	ıration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization 3 TAB QDAY PO		Hepatitis Acute	Foreign	Ternelin	PS		ORAL
Initial or Prol TAB QDAY PO	.onged	Malaise	Health	Cerocral	SS		ORAL
J 111D QD111 1 0			Professional	Methycobal	С		
Date:10/20/04TS	SR Number:	: 4483459-3Report Type:Expedite	ed (15-DaCompany Repor	+ #ACO 0007-2004			
Age:74 YR Gen			ca (13 bacompany nepot.	C πACO_0007 2001			
Outcome Dose Du	ıration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization 2 MG QDAY PO	ι –	Myocardial Infarction	Health	Sirdalud	PS		ORAL
Initial or Prol	.onged		Professional				
Date:10/21/04IS Age:71 YR Gen		: 4486099-5Report Type:Expedite	ed (15-DaCompany Report	t #HQWYE706312OCT04			
1	ider · r eilla.	1/10-1					

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Blood Creatinine	Health	Inderal (Propranolol			
Hospitalization -	Increased	Professional	Hydrochloride,			
Initial or Prolonged	Bradycardia	Other	Tablet)	PS		ORAL
40 MG 1X PER						
Other	Drug Interaction					
1 DAY ORAL 7 DAY						
	Electrocardiogram Qt		Ciproxin			
	Prolonged		(Ciprofloxacin,)	SS		ORAL
1 G 1X PER 1						
	Hypotension					

DAY DAY

Sirdalud - Slow Loss Of Consciousness

Sinus Arrest Release (Tizanidine

Hydrochloride,)

4 MG 1X PER 1

DAY ORAL

Aspirin "Bayer"

SS

ORAL

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С
C
С
C
C
C
C
C
C
С

Freedom Of Information (FOI) Report

Oxycodone

SS

ORAL

Date:10/22/04ISR Number: 4484597-1Report Type:Expedited (15-DaCompany Report #2004AL000677 Age:30 YR Gender: I/FU:I

ΡO

Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Death	Duracion	Completed Suicide Multiple Drug Overdose	Literature	Tizanidine Hydrochloride Tablets, 2 Mg And 4			
PO				Mg (Purepac)	PS	Purepac	ORAL
PO				Valproic Acid	SS		ORAL
	4ISR Number Gender:	r: 4484598-3Report Type:Exped	dited (15-DaCompany Re	eport #2004AL000709			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Duration	Completed Suicide Multiple Drug Overdose	Literature	Tizanidine Hydrochloride Tablets, 2 Mg And 4			
PO				Mg (Purepac)	PS	Purepac	ORAL
PO				Paroxetine	SS		ORAL
	4ISR Number Gender:	: 4484604-6Report Type:Exped	dited (15-DaCompany Re	eport #2004AL000683			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Death	Duration	Completed Suicide Multiple Drug Overdose	Literature	Tizanidine Hydrochloride Tablets, 2 Mg And 4 Mg (Purepac)	PS	Purepac	ORAL
PO						- 41 0540	
PO				Doxepin	SS		ORAL

Date:10/26/04ISR Number: 4486575-5Report Type:Direct Company Report #CTU 230473 Age:94 YR

Gender:Female I/FU:I

Outcome PTReport 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

Report Source Product Role Manufacturer PTRoute Outcome

Dose Duration

Hospitalization -Ternelin Overdose Foreign PS

Somnolence

Initial or Prolonged Health

Professional

Other

Date:10/27/04ISR Number: 4489642-5Report Type:Expedited (15-DaCompany Report #FLUV00304003016

Age:67 YR Gender: Female I/FU:F

Report Source Role Manufacturer Outcome PTProduct Route

Dose Duration

Foreign Depromel 25

Dizziness Postural Other

Drug Interaction Health (Fluvoxamine ORAL PS

Professional Dysstasia Maleate)

50 MILLIGRAM

Fall Other

(S) BID ORAL

Muscular Weakness Ternelin (Tizanidine

Orthostatic Hypotension Hydrochloride) ORAL SS

1 MILLIGRAM

(S) TID ORAL

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Freedom Of Information (FOI) Report

Product

Meilax (Ethyl	
Loflazepate)	С
Dogmatyl (Sulpiride)	С
Lendormin	
(Brotizolam)	C
Gosha-Jinki-Gan	
(Gosha-Jinki-Gan)	С

Role Manufacturer

Route

Date:10/28/04ISR Number: 4490060-4Report Type:Expedited (15-DaCompany Report #2004082345

Age: Gender:Female I/FU:I

PT

Outcome

Dose	Duration				
Other		Cutaneous Lupus	Consumer	Neurontin	
		Erythematosus		(Gabapentin)	PS
		Fibromyalgia		Zoloft (Sertraline)	SS
		Rheumatoid Arthritis		Methotrexate	
		Sjogren'S Syndrome		(Methotrexate)	SS
				Infliximab	
				(Infliximab)	SS
				Hydroxychloroquine	
				Phosphate	
				(Hydroxychloroquine	
				Phosphate)	SS
				Tizanidine	
				Hydrochloride	
				(Tizanidine	
				Hydrochloride)	SS
				Morphine Sulfate	
				(Morphine Sulfate)	С

Report Source

Date:11/02/04ISR Number: 4491034-XReport Type:Expedited (15-DaCompany Report #US-MERCK-0409USA01708 Age:21 YR Gender:Female I/FU:F

Role Manufacturer Outcome PTReport Source Product Route Dose Duration Aggression Vioxx Death PS Merck & Co., Inc ORAL Aspiration Hospitalization -Flexeril SS ORAL Acetaminophen And Initial or Prolonged Completed Suicide

Other	Depressed Level Of	Tramadol		
	Consciousness	Hydrochloride	SS	
UNKNOWN				
	Drug Toxicity	Omeprazole	SS	ORAL

Date:11/03/ Age:30 YR	/04ISR Number Gender:	r: 4494900-4Report Type:Expe I/FU:I	dited (15-DaCompany R	eport #ACO_0009_2004		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Death	Duracion	Completed Suicide Multiple Drug Overdose	Literature Health	Tizanidine Hydrochloride	PS	
DE						

Professional

Elavil Tizanidine

Hydrochloride

Valproic Acid

SS

SS

SS

ORAL

ORAL

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Intentional Misuse

Vomiting

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DF

Freedom Of Information (FOI) Report

Copegus

Topamax

Flomax

Zanaflex

Roche

SS

SS

SS

С

ORAL

ORAL

ORAL

Date:11/03/04ISR Number: 4495377-5Report Type:Expedited (15-DaCompany Report #ACO_0011_2004

Age:39 YR Gender: I/FU:I

SUBCUTANEOUS

Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Death	Duración	Completed Suicide Intentional Misuse	Literature Health Professional	Tizanidine Hydrochloride Paroxetine	PS SS	
Date:11/03, Age:43 YR	/04ISR Number Gender:	r: 4495383-OReport Type:Ex I/FU:I	spedited (15-DaCompany Re	eport #ACO_0010_2004		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Death	Duración	Completed Suicide Intentional Misuse	Literature Health Professional	Tizanidine Hydrochloride Oxycodone Doxepin	PS SS SS	
Date:11/05, Age:	/04ISR Numbe: Gender:	r: 4493790-3Report Type:Ex I/FU:I	spedited (15-DaCompany Re	eport #US-ABBOTT-04P-1	63-0279307-00	
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Death	Duracion	Completed Suicide		Valproic Acid Tizanidine	PS SS	ORAL ORAL
Date:11/08, Age:54 YR	/04ISR Number Gender:Fema	r: 4495564-6Report Type:Ex ale I/FU:F	spedited (15-DaCompany Re	eport #US-ROCHE-384009		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Disability	Daracion	Vertigo		Pegasys	PS Roche	

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 -	Areflexia		Prinivil	PS	Merck & Co., Inc	ORAL
Initial or Prolonged	Cerebral Haemorrhage		Tizanidine			
	Cerebrovascular Accident		Hydrochloride	SS		
UNKNOWN				a		
UNKNOWN	Coma		Amlodipine Besylate	С		
ONKNOWN	Corneal Reflex Decreased		Ofloxacin	С		
UNKNOWN	cornear herrex beereabea		Olionacin	C		
	Decerebration		Biofermin	С		
UNKNOWN						
	Depressed Level Of		Theophylline	C		
UNKNOWN						
TINIZATOLIA	Consciousness		Nimodipine	С		
UNKNOWN	Drug Interaction		Labetalol			
	Hypertension		Hydrochloride	С		
UNKNOWN	117 PC1 CC1151011		nyaroenroriae	C		
	Hypotension					
	Movement Disorder					
	Muscle Rigidity					
	Opisthotonus					
	Respiratory Failure					

Sepsis

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Freedom Of Information (FOI) Report

Vioxx

Tizanidine Hydrochloride PS

SS

Merck & Co., Inc

ORAL

ORAL

Date:11/11/04ISR Number: 4499275-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908829

Duration

Abdominal Pain

Pyrexia

Dermatitis Bullous

Dose Other

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Durati Death OROPHARINGEAL	on Aggression		Ultracet	PS	
	Aspiration		Cyclobenzaprine	SS	
OROPHARINGEAL					
OROPHARINGEAL	Completed Suicide		Amitriptyline	SS	
	Depressed Level Of Consciousness Drug Toxicity Intentional Misuse Lung Crepitation Sedation Vomiting		Tizanidine Rofecoxib Omeprazole	SS SS SS	
Date:11/12/04ISR Nu					
Age:47 YR Gender:	Male I/FU:I		eport #ACO_0013_2004	Dala Manufartuur	Davita
Age:47 YR Gender: Outcome	Male I/FU:I	rpedited (15-DaCompany Ro Report Source	eport #ACO_0013_2004 Product	Role Manufacturer	Route
Age:47 YR Gender: Outcome Dose Durati Disability	Male I/FU:I			Role Manufacturer	Route ORAL
Age:47 YR Gender: Outcome Dose Durati Disability	Male I/FU:I PT on	Report Source	Product		
Age:47 YR Gender: Outcome	Male I/FU:I PT on Dry Mouth	Report Source Foreign	Product Zanaflex	PS	
Age:47 YR Gender: Outcome Dose Durati Disability 2 MG QDAY PO	PT On Dry Mouth Fatigue Headache Insomnia Muscle Spasms Nightmare Somnolence mber: 4500819-2Report Type:Ex	Report Source Foreign Health Professional Other	Product Zanaflex Ibuprofen Cialis	PS C C	

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

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Freedom Of Information (FOI) Report

		Hypotension Miosis Overdose	Report Source	Product	Role	Manufacturer	Route
Dose I	Duration		1				
30 TAB ONCE		Respiratory Depression	Literature	Tizanidine	PS		ORAL
PO			Health				
			Professional				
	ISR Number ender:Fema	r: 4504993-3Report Type:Exped	ited (15-DaCompany Re	port #ACO_0014_2004			
Outcome Dose I	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threateni 2000 MG QDAY	ing	Anxiety	Foreign	Tizandine	PS		ORAL
Hospitalizatio PO	on -	Convulsion	Literature				
Initial or Pro 12 MG QDAY PO		Delirium	Health	Tizanidine	SS		ORAL
7500 MG QDAY		Drug Withdrawal Syndrome	Professional	Zolpidem	SS		ORAL
7500 MG QDA1		Hypotonia	Other				
PO		Medication Error		Zolpidem	SS		ORAL
DF QDAY PO		Medication Error		zoipidelli	مم		URAL
100 MG ODAY		Muscle Spasms		Xylometazoline	SS		
100 MG QDAY		Paraesthesia		Xylometazoline	SS		
DF QDAY		Treatment Noncompliance					
		c: 4503821-XReport Type:Exped	ited (15-DaCompany Re	port #CH-MERCK-0411CHE	:00026		
Age:83 YR Ge	ender:Male	e I/FU:I					
Outcome Dose I	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizatio		Diarrhoea	Health	Vioxx	PS	Merck & Co., Inc	ORAL

Professional

Celecoxib

SS

ORAL

21

44

DAY

DAY

Initial or Prolonged Drug Interaction

6 YR			1		-
O IR			Ascorbic Acid And Vitamin B		
			(Unspecified)	C	
UNKNOWN			(011220011100)		
			Enterococcus Faecium		
			(As Drug)	C	
UNKNOWN					
I					
	r: 4506997-3Report Type:Exped	ited (15-DaCompany Re	eport #2004-BP-11398YA		
Age:41 YR Gender:Mal	e I/FU:I				
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration	PI	Report Source	Product	ROIE Manuracturer	Route
Hospitalization -	Alanine Aminotransferase	Foreign	Harnal		
Initial or Prolonged	Increased	Health	(Tamsulosin)	PS	ORAL
0.2 MG PO			·		
	Aspartate	Professional	Dantrium (Dantrolene		
	Aminotransferase	Other	Sodium)	SS	ORAL
25 MG PO	7		- '		
	Increased Blood Bilirubin Increased		Lioresal (Dantrolene Sodium)	SS	ORAL
5 MG PO	BIOOD BIIIIUDIN INCLEASED		Soaruii)	55	UKAL
J MG 10	Blood Lactate		Ternelin (Tizanidine		
	Dehydrogenase Increased		Hydrochloride)	SS	ORAL
1 MG PO	<u>-</u>		-		
	Gamma-Glutamyltransferase		Vitamedin		
	Increased		(Benfotiamine/B6/B12		
	Hepatic Function Abnormal)	C	ORAL
			Diazepam (Diazepam)	C	

Buthiazide

Tizanidine Hydrochloride

Oxprenolol Hydrochloride SS

SS

SS

ORAL

ORAL

ORAL

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6

44

MON

DAY

Renal Failure Acute

Freedom Of Information (FOI) Report

Date:11/18/04ISR Number: 4507134-1Report Type:Expedited (15-DaCompany Report #B0349830A Age:39 VR Gender:Unknown T/FU:T

Age:81 YR Gender:Female

I/FU:I

Outcome Dose Duration						
Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Completed Suicide Drug Level	Literature Health Professional	Proxetine Hydrochloride Tablet-Controlled Release (Generic) (Paroxetine	D.C.		ODAT
ORAL			(Paroxetine	PS		ORAL
JRAL			Tizanidine (Formulation			
			Unknown) (Tizanidine)	SS		ORAL
ORAL			(Tizaniuine)	۵۵		ORAL
Age:34 YR Gender:Mal	r: 4512376-5Report Type:Exped e I/FU:I PT	ited (15-DaCompany Re	eport #ACO_0018_2004 Product	Role	Manufacturer	Route
Age:34 YR Gender:Male Outcome Dose Duration Other	e I/FU:I			Role PS	Manufacturer	Route ORAL
Age:34 YR Gender:Male Outcome Dose Duration Other 3 MG QDAY PO	e I/FU:I	Report Source	Product		Manufacturer	
Age:34 YR Gender:Male Outcome Dose Duration Other	PT Blood Pressure Decreased Blood Pressure Systolic	Report Source Foreign Health	Product Ternelin	PS	Manufacturer	ORAL
Age:34 YR Gender:Male Outcome Dose Duration Other 3 MG QDAY PO 150 MG QDAY	PT Blood Pressure Decreased	Report Source Foreign	Product Ternelin	PS	Manufacturer	ORAL
Age:34 YR Gender:Male Outcome Dose Duration Other 3 MG QDAY PO	PT Blood Pressure Decreased Blood Pressure Systolic Increased	Report Source Foreign Health Professional	Product Ternelin Fluvoxamine Maleate	PS SS	Manufacturer	ORAL
Age:34 YR Gender:Male Outcome Dose Duration Other 3 MG QDAY PO	PT Blood Pressure Decreased Blood Pressure Systolic Increased Dehydration	Report Source Foreign Health	Product Ternelin Fluvoxamine Maleate Lorazepam	PS SS	Manufacturer	ORAL
Age:34 YR Gender:Male Outcome Dose Duration Other 3 MG QDAY PO 150 MG QDAY	PT Blood Pressure Decreased Blood Pressure Systolic Increased Dehydration Dialysis	Report Source Foreign Health Professional	Product Ternelin Fluvoxamine Maleate Lorazepam Amoxan	PS SS C	Manufacturer	ORAL
Age:34 YR Gender:Male Outcome Dose Duration Other 3 MG QDAY PO	PT Blood Pressure Decreased Blood Pressure Systolic Increased Dehydration Dialysis Dialysis Disequilibrium	Report Source Foreign Health Professional	Product Ternelin Fluvoxamine Maleate Lorazepam Amoxan Allopurinol	PS SS	Manufacturer	ORAL
Age:34 YR Gender:Male Outcome Dose Duration Other 3 MG QDAY PO 150 MG QDAY	PT Blood Pressure Decreased Blood Pressure Systolic Increased Dehydration Dialysis Dialysis Disequilibrium Syndrome	Report Source Foreign Health Professional	Product Ternelin Fluvoxamine Maleate Lorazepam Amoxan Allopurinol Lansoprazole	PS SS C C C	Manufacturer	ORAL
Age:34 YR Gender:Male Outcome Dose Duration Other 3 MG QDAY PO	PT Blood Pressure Decreased Blood Pressure Systolic Increased Dehydration Dialysis Dialysis Disequilibrium	Report Source Foreign Health Professional	Product Ternelin Fluvoxamine Maleate Lorazepam Amoxan Allopurinol	PS SS C C C	Manufacturer	ORAL

Outcome PT Report Source Product Role Manufacturer Route

Dose Duration

Hospitalization - Alanine Aminotransferase Foreign Ternelin PS ORAL

2 MG QDAY PO

	Gamma-Glutamyltransfera Increased Hypoaesthesia Limb Discomfort Liver Disorder	se			
Date:11/24/04ISR Numk Age:47 YR Gender:Fe Outcome	ber: 4514139-3Report Type:E emale I/FU:F	Expedited (15-DaCompany Re	eport #2003AP02691 Product	Role Manufacturer	Route
Dose Duration		report source	Product	Roie Manuracturer	Route
Required 10 MG DAILY	Drug Interaction	Foreign	Zestril	PS	ORAL
Intervention to PO	Hypotension	Literature			
Prevent Permanent 2 MG DAILY PO		Health	Sirdalud	SS	ORAL
Impairment/Damage		Professional Other	Senokot Magnesium Oxide Amikin	С С С	

Ketas

Gasmotin

Trandate

Chinese Medicine

SS

SS

С

С

ORAL

ORAL

Health

Other

Professional

Initial or Prolonged

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30 MG QDAY PO

15 MG QDAY PO

Increased

Aspartate

Increased Blood Alkaline

Aminotransferase

Blood Lactate

Phosphatase Increased

Dehydrogenase Increased

Freedom Of Information (FOI) Report

Nimotop	C
Well-Well	С
Glycerol	С
Mucosolvan	C
Clincin	С
Ofloxacin	С
Amlodipine	С
Nimodipine	С
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 - 2 MG ONCE PO	Blood Pressure Decreased	Foreign	Tizanidine	PS	ORAL
Initial or Prolonged	Depressed Level Of Consciousness	Health Professional Other	Labetalol Amlodipine Nimodipine Lisinopril	C C C	

Date:12/14/04ISR Number: 4528889-6Report Type:Expedited (15-DaCompany Report #HQWYE762806DEC04

Age:17 YR Gender:Female I/FU:I

	PT	Report Source	Product	Role	Manufacturer	Route
Duration						
on -	Serotonin Syndrome	Health	Tazobac			
olonged		Professional	(Piperacillin/Tazoba			
		Other	ctam Injection)	PS		
	on -	Duration on - Serotonin Syndrome	Duration on - Serotonin Syndrome Health olonged Professional	Duration on - Serotonin Syndrome Health Tazobac olonged Professional (Piperacillin/Tazoba	Duration on - Serotonin Syndrome Health Tazobac olonged Professional (Piperacillin/Tazoba	Duration on - Serotonin Syndrome Health Tazobac olonged Professional (Piperacillin/Tazoba

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 (Gentamicin Sulfate)

30 MG 2X PER

DRIP

1 DAY			
	Nexium		
	(Esomeprazole)	SS	
40 MG DAILY			
	Sirdalud (Tizanidine		
	Hydrochloride)	SS	ORAL
3 MG DAILY			
	Tramal (Tramadol		
50 Mg 444 DDD	Hydrochloride)	SS	
50 MG 4X PER			
1 DAY			
	Bactrim		
	(Sulfamethoxazole/Tr		
	imethoprim)	SS	
	Zoloft (Sertraline		
	Hydrochloride)	SS	ORAL
50 MG			
	Neurontin		
	(Gabapentin)	C	
	Rivotril		
	(Clonazepam)	C	
	Fraxiparin		
	(Heparin-Fraction,		
	Calcium Salt)	C	
	Benerva (Thiamine		
	Hydrochloride)	C	

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С

Temesta (Lorazepam)

Becozyme Forte (Biotin/Calcium Pantothenate/Cyanoco

Freedom Of Information (FOI) Report

Product

balamin/Nicotinamide	
/Pyridoxine/	С
Mst (Morphine	
Sulfate)	С
Dafalgan	
(Paracetamol)	С

Role Manufacturer

Route

Date:12/14/04ISR Number: 4529397-9Report Type:Expedited (15-DaCompany Report #2004PK02050

Age:17 YR Gender:Female I/FU:I

PT

Outcome

oaccome			Report boarde	110000	HOIC HAHALACCALCE	nouce
	uration					
Required		Agitation	Foreign	Nexium	PS	
40 MG DAILY						
Intervention to	0	Asthenia	Health	Tramal	SS	ORAL
200 MG DAILY						
Prevent Permane	ent	Coordination Abnormal	Professional			
PO						
Impairment/Dama	age	Dysaesthesia	Other	Sirdalud	SS	ORAL
8 MG DAILY PO						
		Hyperaesthesia		Zoloft	SS	
		Motor Dysfunction		Brufen	SS	ORAL
1200 MG DAILY						
		Pain In Extremity				
PO						
		Postoperative Infection		Tazobac	SS	
INTRAVENOUS	13.5 G					
		Pseudomonas Infection				
IV						
		Pyrexia		Gentamicine	SS	
INTRAVENOUS	160 MG	DAILY				
		Sedation				
IV						
		Serotonin Syndrome		Neurontin	С	
		Skin Necrosis		Rivotril	С	
		Somnolence		Mst	С	
		Tremor		Dafalgan	С	
				Temesta	С	
				Bactrim	С	
				Fraxiparin	С	
				Benerva	С	
				Becozyme Forte	C	

Report Source

Date:12/16/04ISR Number: 4531909-6Report Type:Expedited (15-DaCompany Report #2004-BP-12563BP Age:56 YR

Gender:Female I/FU:I

Outcome PTReport Source Product Role Manufacturer Route

Dose Duration

Hospitalization -Chromaturia Health Mirapex Tablets Initial or Prolonged Diarrhoea Professional (Pramipexole

Jaundice Dihydrochloride)

PO (THERAPY

Nausea

DATES: ABOUT

Vomiting

ONE YEAR AGO

- NR)

Metformin (Metformin) SS Estrogen SS Zanaflex (Tizanidine Hydrochloride) SS

PS

ORAL

Rebif (Interferon

SS Beta)

Date:12/20/04ISR Number: 4536994-3Report Type:Expedited (15-DaCompany Report #2004104140

Gender: Female Age: I/FU:I

Outcome PT

Agitation Asthenia

Coordination Abnormal

Diarrhoea Dysaesthesia

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Other

Freedom Of Information (FOI) Report

Dose	Duration	Hyperaesthesia Myoclonus Neuralgia	Report Source	Product	Role	Manufacturer	Route
(50 MG), OR <i>i</i>	ΛΤ	Pain	Foreign	Zoloft (Sertraline)	PS		ORAL
(50 MG), ORF	¥Ш	Postoperative Infection Pseudomonas Infection	Health Professional	Gentamicin (Gentamicin)	SS		
INTRAVENOUS	INTRA	VENOUS					
		Serotonin Syndrome		Pip/Tazo			
		Somnolence		(Piperacillin			
		Tremor		Sodium, Tazobactam Sodium)	SS		
				Ibuprofen	ಎಎ		
				(Ibuprofen)	SS		
				Tizanidine	55		
				Hydrochloride			
				(Tizanidine			
				Hydrochloride)	SS		
				Tramadol			
				Hydrochloride			
				(Tramadol Hydrochloride)	SS		
				Doxorubicin	55		
				(Doxorubicin)	С		
				Esomeprazole			
				(Esomeprazole)	С		
				Gabapentin			
				(Gabapentin)	С		
				Clonazepam	~		
				(Clonazepam) Morphine Sulfate	С		
				(Morphine Sulfate)	С		
				Paracetamol	C		
				(Paracetamol)	С		
				Lorazepam			
				(Lorazepam)	C		
				Bactrim			
				(Sulfamethoxazole,	_		
				Trimethoprim)	С		
				Heparin-Fraction, Calcium Salt			
				(Heparin-Fraction,			
				Calcium Salt)	С		
				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

		loute
Literat	Oxycodone Hcl Tabets PS	
Health	Doxepine SS	
Profess	nal Tizanidine SS	
Multiple Drug Overdose Health Professiona	. · · · · · · · · · · · · · · · · · · ·	

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Freedom Of Information (FOI) Report

Role Manufacturer

PS

Route

ORAL

ORAL

Date:12/22/04ISR Number: 4538886-2Report Type:Expedited (15-DaCompany Report #ACO_0030_2004

Age:64 YR Gender:Female I/FU:I

Heal onsciousness Prof b Fracture lReport Type:Expedited (1 U:F Repo minotransferase Fore Heal Prof	lth Z fessional 15-DaCompany Report ort Source F eign H	Zanaflex #2004-BP-11398YA Product Harnal	PS	Manufacturer	Route
onsciousness Prof b Fracture lReport Type:Expedited (1 U:F Repo minotransferase Fore Heal Prof	fessional 15-DaCompany Report ort Source F eign H	#2004-BP-11398YA Product Harnal	Role	Manufacturer	Route
b Fracture 1Report Type:Expedited (1 U:F Repo minotransferase Fore Heal Prof	15-DaCompany Report ort Source F eign H	Product Harnal		Manufacturer	
U:F Repo minotransferase Fore Heal Prof	ort Source F eign H	Product Harnal		Manufacturer	
minotransferase Fore Heal Prof	eign E lth	Harnal		Manufacturer	
Heal Prof	lth		PS		
Heal Prof	lth		PS		
Prof		(Tamsulosin)	PS		
	7				ORAL
		Dantrium			
sferase Othe		(Dantrolene			
	Ş	Sodium)	SS		ORAL
	_				
	-				
	•	•	CC		ORAL
lase Increased	1.	nydrochioride)	55		OKAL
tamvltransferase					
2 3 3 3 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4					
	7	Vitamedin			
order	((Benfotiamine/B6/B12			
))	C		
	Γ	Diazepam (Diazepam)	C		
.1	irubin Increased tate nase Increased tamyltransferase order	irubin Increased tate nase Increased tamyltransferase order 2Report Type:Expedited (15-DaCompany Report	irubin Increased tate (Tizanidine nase Increased Hydrochloride) tamyltransferase Vitamedin (Benfotiamine/B6/B12) Diazepam (Diazepam) 2Report Type:Expedited (15-DaCompany Report #ACO_0018_2004	<pre>irubin Increased tate nase Increased tamyltransferase Vitamedin order (Benfotiamine/B6/B12) C Diazepam (Diazepam) C 2Report Type:Expedited (15-DaCompany Report #ACO_0018_2004</pre>	irubin Increased tate (Tizanidine nase Increased Hydrochloride) SS tamyltransferase Vitamedin (Benfotiamine/B6/B12) C Diazepam (Diazepam) C 2Report Type:Expedited (15-DaCompany Report #ACO_0018_2004

Report Source

Foreign

Health

Product

Ternelin

Fluovoxamine Maleate SS

150 MG QDAY

Duration

PT

Balance Disorder

Blood Pressure Decreased

Outcome

3 MG QDAY PO

Dose

Other

Dehydration

Dizziness Nausea Somnolence Other

Professional

Lorazepam C
Amoxan C
Allopurinol C

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

Role Manufacturer Report Source Product Outcome PTRoute Duration Dose Tizanidine Hospitalization -Blood Pressure Decreased Foreign PS ORAL 2 MG ONCE PO Initial or Prolonged Depressed Level Of Health Labetalol С Consciousness Amlodipine Professional С Other Nimodipine С Lisinopril С

Date:12/27/04ISR Number: 4541346-6Report Type:Expedited (15-DaCompany Report #ACO_0006_2004

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

Outcome Hospitalization -Initial or Prolonged PT Hepatitis Acute Report Source Foreign Health

Professional

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Freedom Of Information (FOI) Report

Role Manufacturer

PS

Route

ORAL

Other

Dose Duration			Product	Role Manufacturer	Route
			Ternelin	PS	ORAL
3 TAB QDAY PO			Cerocral	SS	ORAL
3 TAB QDAY PO					01412
			Methycobal	С	
Date:12/27/04ISR Numbe Age: Gender:Fem		Expedited (15-DaCompany Re	eport #ACO_0008_2004		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization -	Overdose	Foreign	Ternelin	PS	
Initial or Prolonged	Somnolence	Health Professional			
ı		Other			
Date:12/27/04ISR Numbe Age:47 YR Gender:Mal Outcome Dose Duration		Expedited (15-DaCompany Re Report Source	eport #ACO_0013_2004 Product	Role Manufacturer	Route
Disability	Dry Mouth	Foreign	- 61		Route
2 MG QDAY PO			Zanaflex	PS	ORAL
	Fatigue	Health	Ibuprofen	С	
	Fatigue Headache Insomnia Muscle Spasms	Health Professional	Ibuprofen	С	
	Fatigue Headache Insomnia Muscle Spasms Nightmare	Health Professional	Ibuprofen	С	
	Fatigue Headache Insomnia Muscle Spasms	Health Professional	Ibuprofen	С	
2 MG QDAY PO	Fatigue Headache Insomnia Muscle Spasms Nightmare Somnolence	Health Professional	Ibuprofen Cialis	С	

Report Source

Foreign

Outcome

Life-Threatening

2000 MG QDAY

Dose

PT

Abnormal Behaviour

Duration

Product

Tizanidine

Hospitalization -	Anxiety	Literature			
PO					
Initial or Prolonged 12 MG ODAY PO	Convulsion	Health	Tizanidine	SS	ORAL
Required 7500 MG QDAY	Delirium	Professional	Zolpidem	SS	ORAL
Intervention to PO	Drug Withdrawal Syndrome	Other			
Prevent Permanent DF QDAY PO	Hypotonia		Zolpidem	SS	ORAL
Impairment/Damage 100 MG QDAY	Muscle Spasms		Xylometazoline	SS	
DF QDAY	Paraesthesia		Xylometazoline	SS	
Dr. Apvi	Social Avoidant Behaviour Treatment Noncompliance				

Date:12/27/04ISR Number: 4541358-2Report Type:Expedited (15-DaCompany Report #ACO_0017_2004

Gender:Female Age:81 YR I/FU:I

Outcome PT

Hospitalization -Alanine Aminotransferase

Initial or Prolonged Increased Aspartate

Aminotransferase

Increased Blood Alkaline

Phosphatase Increased

Blood Lactate

Dehydrogenase Increased

Discomfort

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Freedom Of Information (FOI) Report

Dose D	uration	Hypoaesthesia	Report Source	Product	Role	Manufacturer	Route
	diacion	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	С		
Date:12/27/04I Age:30 YR Ge		: 4542153-0Report Type:Expedi le I/FU:I	ted (15-DaCompany Repo	rt #ACO_0016_2004			
Outcome Dose D	uration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threateni 30 TAB ONCE		Blood Pressure Increased	Literature	Tizanidine	PS		ORAL
PO		Depressed Level Of	Health				
		Consciousness Drug Ineffective Heart Rate Decreased Hypotension Intentional Misuse Miosis Respiratory Depression Treatment Noncompliance	Professional				
Date:12/27/04I Age:46 YR Ge		: 4542155-4Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	rt #ACO_0015_2004			
Outcome Dose D	uration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threateni 360 MG ONCE		Blood Pressure Decreased	Literature	Tizanidine	PS		ORAL
		Coma	Health				
PO		Drug Ineffective Heart Rate Decreased Miosis Overdose	Professional				

Gamma-Glutamyltransferase

Increased

Date:12/27/04ISR Number: 4542157-8Report Type:Expedited (15-DaCompany Report #ACO_0007_2004

Multiple Drug Overdose

Age:74 YR Gender:Female I/FU:I

Outcome	D	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat 2 MG DAILY F		Cardiac Enzymes Increased	Health	Sirdalud	PS		ORAL
Initial or F	Prolonged	Myocardial Infarction	Professional				
)4ISR Number Gender:	: 4542249-3Report Type:Expedit	ced (15-DaCompany Repor	t #ACO_0011_2004			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Duracion	Completed Suicide Overdose	Literature Health Professional	Tizanidine Hydrochloride Paroxetine	PS SS		
	04ISR Number Gender:	: 4542417-0Report Type:Expedit	ced (15-DaCompany Repor	t #ACO_0009_2004			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death		Completed Suicide	Literature	Tizanidine			

Hydrochloride

Valproic Acid

PS

SS

Health

Professional

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DF

DF

Freedom Of Information (FOI) Report

C

Date:12/27/04ISR Number: 4542420-OReport Type:Expedited (15-DaCompany Report #ACO_0010_2004

Age:43 YR Gender: I/FU:I

Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Death	Duracion	Completed Suicide Multiple Drug Overdose	Literature Health Professional	Tizanidine Hydrochloride Oxycodone Doxepin	PS SS SS		
	04ISR Number Gender:Fema	r: 4542433-9Report Type:Expe ale I/FU:I	dited (15-DaCompany Re	eport #2004AP000937			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Chest Pain Depressed Level Of Consciousness	Consumer	Tizanidine Hydrochloride Tablets	PS		ORAL
8 MG; EVERY		Collectoubliess		Tablets	15		OKAL
D311 (D3 T111)	_	Dizziness					
DAY (DAILY)	,	Dizziness Postural					
ORAL							
		Dysstasia		Donnatal Extentabs	С		

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

Overdose

Complaint Sedation

Pharmaceutical Product

150

Decreased milligram(s)

Drug Interaction Zopiclone

UNKNOWN Daily dose:

	Dry Mouth				
unknown	Heart Rate Decr	reased	Flunitrazepam	С	
UNKNOWN	Daily dose:	casca	r rannor and param	C	
unknown				-	
UNKNOWN	Daily dose:		Candesartan	С	
unknown			Fomotidino		
UNKNOWN	Daily dose:		Famotidine	С	
unknown			Carbamazanina		
UNKNOWN	Daily dose:		Carbamazepine	С	
unknown			Bezafibrate	С	
UNKNOWN	Daily dose:		Bezaribrace	C	
unknown					
UNKNOWN	Daily dose:		Ticlopidine	С	
unknown			- 121.22.2	~	
UNKNOWN	Daily dose:		Benidipine	С	
unknown			Tizanidine	-	
UNKNOWN	Daily dose: 3		Tizanidine	I	1
milligram(s)					
	R Number: 4544292-7Repor der:Female I/FU:I	t Type:Expedited (15-DaCompany Re	eport #ACO_0034_2004		
Outcome	PT	Report Source	Product	Role Manufacturer	Route

01 Dose Duration Other Aphasia Foreign Sirdalud - Slow Health ORAL Drug Interaction Release PS 6 MG DAILY PO Epilepsy Professional Sirdalud SS ORAL

> Other Zocor "Merck" SS Merck

80 MG QDAY PO

ORAL

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4 MG DAILY PO

Freedom Of Information (FOI) Report

Product

Role Manufacturer

Route

Zocor "Merck" SS ORAL Merck 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

PT

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - 3 MG QDAY PO	Body Temperature	Foreign	Tizanidine	PS	ORAL
Initial or Prolonged 150 MG QDAY	Decreased	Literature	Fluvoxamine	SS	
	Dry Mouth	Health	Zopiclone	С	
	Enuresis	Professional	Flunitrazepam	С	
	Heart Rate Decreased	Other	Benidipine	C	
			Candesartan	С	
			Ticlopidine	С	
			Famotidine	C	
			Bezafibrate	С	
			Carbamazepine	С	

Date:12/31/04ISR Number: 4542792-7Report Type:Expedited (15-DaCompany Report #PHBS2004JP16522

Age: 27 YR Gender: Female I/FU:F

Outcome

Dose	Duration						
Hospitalizati	on -	Alanine Aminotransferase	Health	Voltaren	PS	Novartis Sector:	
Initial or Pr	colonged	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	С		ORAL
1000 ug/day							

Report Source

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 PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Pyrexia Health Tazobac Initial or Prolonged Serotonin Syndrome Professional (Piperacillin/Tazoba Other ctam, Injection) PS 4.5 G 3X PER INTRAVENOUS 1 DAY INTRAVENOUS DAY Brufen (Ibuprofen) ORAL SS 400 MG 3X PER 1 DAY ORAL Garamycin (Gentamicin Sulfate) SS INTRAVENOUS DRIP 30 MG 2X PER 1 DAY INTRAVENOUS DRIP Nexium (Esomeprazole) SS 40 MG DAILY Sirdalud (Tizanidine Hydrochloride) SS ORAL 3 MG DAILY ORAL Tramal (Tramadol Hydrochloride) ORAL SS 50 MG 4X PER 1 DAY ORAL

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Zoloft (Sertraline

Freedom Of Information (FOI) Report

Hydrochloride)

Product

50 MG ORAL

Neurontin (Gabapentin) С Rivortil (Clonazepam) C Mst (Morphine Sulfate) С Dafalgan (Paracetamol) С Bactrim (Sulfamethoxazole/Tr imethoprim) С Fraxiparin (Heparin-Fraction, Calcium Salt) С Benerva (Thiamine Hydrochloride) С Becozyme Forte (Biotin/Calcium Pantothenate/Cyanoco balamin/Nicotinamide /Pyridoxine/Riboflav C Temesta (Lorazepam)

SS

Role Manufacturer

ORAL

Route

Date:01/10/05ISR Number: 4551309-2Report Type:Expedited (15-DaCompany Report #ACO_0037_2004

Age: 27 YR Gender: Female I/FU: I

Outcome

PΤ

D + 2		noporo source	110000	11010 11011010000101	110000
Duration	Drug Interaction	Foreign	Ternelin	PS	ORAL
	Respiratory Disorder	Health	Ternelin	SS	ORAL
	Serotonin Syndrome	Professional	Paxil	SS	ORAL
	Therapy Non-Responder Tremor	Other			
	Duration	Drug Interaction Respiratory Disorder Serotonin Syndrome Therapy Non-Responder	Duration Drug Interaction Respiratory Disorder Health Serotonin Syndrome Professional Therapy Non-Responder Other	Duration Drug Interaction Foreign Ternelin Respiratory Disorder Health Ternelin Serotonin Syndrome Professional Paxil Therapy Non-Responder Other	Duration Drug Interaction Foreign Ternelin PS Respiratory Disorder Health Ternelin SS Serotonin Syndrome Professional Paxil SS Therapy Non-Responder Other

Report Source

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

1,101

Outcome PT Report Source Product Role Manufacturer Route

Dose Duration

Other Nephrolithiasis Tizanidine PS

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

Ct/

Stomach Discomfort

22-Aug-2005 12:09 PM

Freedom Of Information (FOI) Report

Temgesic

(Buprenorphine)

Aspirin Cardio

C

Date:01/24/05ISR Number: 4563646-6Report Type:Expedited (15-DaCompany Report #ACO_0036_2004

Age:27 YR Gender:Fema	ale I/FU:I	.rcca (13 Dacompany R	CPOIC #ACO_0030_2004		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - 3 MG QDAY PO	Alanine Aminotransferase	Foreign	Ternelin	PS	ORAL
Initial or Prolonged 75 MG QDAY PO	Increased	Health	Voltaren	SS	ORAL
300 MG QDAY	Aspartate	Professional	Mucosta	SS	ORAL
PO	Aminotransferase	Other			
	Increased Back Pain Liver Disorder Lymphocyte Stimulation Test Positive		Mecobalamin	C	
Date:01/25/05ISR Number Age:67 YR Gender:Male	r: 4563233-XReport Type:Exped e I/FU:I PT	dited (15-DaCompany Ro Report Source	eport #CH-2005-000910 Product	Role Manufacturer	Route
Dose Duration Hospitalization -	Delirium	Foreign	Sotalol (Sotalol	ROTC TAMELACCALCE	1.000
Initial or Prolonged	Hallucination, Auditory	Health Professional	Hydrochloride) Tablet	PS	ORAL
80 MG,		Other	Tablet	F3	OKAL
2X/DAY, ORAL		Ocher	Sirdalud (Tizanidine		
4 MG, 1X/DAY,			Hydrochloride)	SS	ORAL
ORAL					
			Transtec Tts (Buprenorphine) Torem (Torasemide) Plavix (Clopidogrel Sulfate) Dafalgan	C C C	
			Zestril (Lisinopril)	C	

(Acetylsalicylic Acid)

С

Date:01/26/05ISR Number: 4566551-4Report Type:Direct Company Report #CTU 238193

Age: Gender:Male I/FU:I

PTReport Source Product Role Manufacturer Outcome Route

Duration Dose

Tizanidine Other Muscle Spasms 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

Hospitalization -Cerebral Haemorrhage Initial or Prolonged Cerebral Ventricle

Dilatation

Cerebrovascular Accident

Coma

Decerebration Drug Interaction Hypertension Hypotension

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Freedom Of Information (FOI) Report

Dose	Duration	Jaw Disorder Opisthotonus Pain	Report Source	Product	Role Manufacturer	Route
2020	Daracron	Respiratory Failure	Foreign	Tizanidine	PS	ORAL
2 MG ONCE P	0					
10 MG QDAY	DO		Literature	Lisinopril	SS	ORAL
IO MG QDAI	PO		Health	Labetalol	С	
			Professional	Amlodipine	C	
			Other	Nimodipine	C	
	05ISR Number Gender:Fema	: 4601995-3Report Type:Perio	dic Company Re	eport #ACO_0029_2004 Product	Role Manufacturer	Route
Dose	Duration	PI	Report Source	Product	Role Manufacturer	Route
Hospitalization - H MG TID PO 1 YR	Alanine Aminotransferase		Zanaflex	PS	ORAL	
Initial or	nitial or Prolonged	Increased		Aminopyridine	С	
		Aspartate		Rebif	С	
		Aminotransferase		Mirapex	C	
		Increased Blood Bilirubin Increased Chromaturia Jaundice Nausea Vomiting		Estrogen	C	
	05ISR Number Gender:Fema	: 4601997-7Report Type:Perio	dic Company Re	eport #ACO_0019_2004		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitaliza DF	tion -	Accidental Overdose	Consumer	Zanaflex	PS	
Initial or DF	Prolonged	Coma		Baclofen	SS	
5.7		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 Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization -	Cerebral Infarction	Foreign	Sirdalud	PS	ORAL
Initial or Prolonged Disability	Condition Aggravated Hypotension Memory Impairment	Health Professional Other	Ciproxin	SS	

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 Other	Duration	Convulsion	Foreign	Ternelin	PS	ORAL
DF QDAY PO		Convarsion	roreign	rernerm	PS	ORAL
		Disease Recurrence	Health	Ternelin	SS	ORAL
DF QDAY PO		Drug Interaction	Professional	Paxil	SS	ORAL
35 MG QDAY P	0	Dyspnoea	Other	Lexotan	SS	
DF						

Epilepsy

Hyperventilation

Myoclonus

Oxygen Saturation

Decreased

Serotonin Syndrome Therapy Non-Responder

Tremor

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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 Dose Duratio	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - DF	Depressed Level Of	Literature	Zanaflex	PS	
Initial or Prolonged DF PO	d Consciousness	Health	Lisinopril	SS	ORAL
	Heart Rate Increased Hypotension Musculoskeletal Stiffness Pallor Somnolence	Professional	Valproic Acid Valium Clonazepam	C C C	

Date:02/08/05ISR Number: 4576909-5Report Type:Expedited (15-DaCompany Report #05-02-0156

Age: 48 YR Gender: Female I/FU:I

PT	Report Source	Product	Role Manufacturer	Route
Depressed Level Of	Foreign	Lisinopril Tablets	PS	ORAL
Consciousness	Literature	Tizanidine	SS	
Drug Interaction Hypotension		Nimopidine	C C	
	Depressed Level Of Consciousness Drug Interaction	Depressed Level Of Foreign Consciousness Literature Drug Interaction	Depressed Level Of Foreign Lisinopril Tablets Consciousness Literature Tizanidine Drug Interaction Amlodipine	Depressed Level Of Foreign Lisinopril Tablets PS Consciousness Literature Tizanidine SS Drug Interaction Amlodipine C Hypotension C

Date:02/08/05ISR Number: 4579159-1Report Type:Direct Company Report #CTU 239730

Age: 28 YR Gender: Female I/FU:I

ORAL

Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Other		Blood Pressure Decreased		Zanaflex	PS	ORAL
1/2 AT NIG	HT					
		Heart Date Degraaged				

Heart Rate Decreased

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

Hospitalization -	Hallucination, Auditory	Foreign	Sirdalud	PS	ORAL
4 MG QDAY PO Initial or Prolonged 160 MG QDAY		Health	Sotalex	SS	ORAL
100 Mg QDA1		Professional			
PO					
		Other	Buprenorphine	C	
			Torem	C	
			Plavix	C	
			Dafalgan	С	
			Zestril	C	
			Temgesic "Essex		
			Pharma"	C	
			Aspirin Compound	С	
Date:02/09/05ISR Number Age:51 YR Gender:Fema	r: 4578634-3Report Type:Direct	Company Repo	rt #CTU 239962		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization -	Jaundice		Tizanidine	PS	
Initial or Prolonged	Myalgia		Zolpidem	С	
Required	Nausea		Venlafaxine	C	
Intervention to	Vomiting		Propanolol	C	
Prevent Permanent			Levothyroxine	C	
Impairment/Damage			Ropinirole	С	

Report Source

Product

Loratidine

C

Role Manufacturer

Route

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Outcome

Dose

PT

Duration

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

PT	Report Source	Product	Role Manufacturer	Route
Dissociative Disorder	Foreign	Zomig	PS	ORAL
Drug Abuser	Health	Sirdalud	SS	ORAL
Intentional Misuse	Professional	Diflucan	SS	ORAL
Somnolence Stupor Tachycardia	Other	Benzodiazepines	SS	
er: 4579912-4Report Type:Expe	dited (15-DaCompany R	eport #2004AI.000677		
	Dissociative Disorder Drug Abuser Intentional Misuse Somnolence Stupor Tachycardia	Dissociative Disorder Foreign Drug Abuser Health Intentional Misuse Professional Somnolence Other Stupor Tachycardia	Dissociative Disorder Foreign Zomig Drug Abuser Health Sirdalud Intentional Misuse Professional Diflucan Somnolence Other Benzodiazepines Stupor Tachycardia	Dissociative Disorder Foreign Zomig PS Drug Abuser Health Sirdalud SS Intentional Misuse Professional Diflucan SS Somnolence Other Benzodiazepines SS Stupor

Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration	ı					
Death	Bradycardia	Literature	Tizanidine			
Hospitalization -	Cardio-Respiratory Arrest	Health	Hydrochloride			
Initial or Prolonged	Coma	Professional	Tablets, 4 Mg			
1	Completed Suicide		(Purepac)	PS	Purepac	ORAL
PO						
1	Haemodialysis		Valproic Acid	SS		ORAL
PO						
1	Hypotension					
1	Intentional Misuse					

Date:02/16/05ISR Number: 4589351-8Report Type:Expedited (15-DaCompany Report #ACO_0128_2005

Mental Status Changes

Age: 39 YR Gender: Female I/FU:I

Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Hospitalizati 20 MG QDAY PO		Confusional State	Foreign	Sirdalud	PS	ORAL
Initial or Pr	rolonged	Gait Disturbance	Health	Oxaprozin	C	
		Vertigo	Professional Other	Kenacort	С	

Date:02/22/05ISR Number: 4591094-1Report Type:Direct Company Report #CTU 241023

Age:47 YR Gender:Female I/FU:I

Heart Rate Increased

Muscle Contracture

Somnolence

Stupor

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 4MG AND 8MG	Duracion	Drug Effect Decreased		Tizanidine	PS	Apo Ti-4	ORAL
		Dry Mouth					
BID ORAL							
		Fatigue Muscle Spasticity Pharmaceutical Product Complaint		Copaxone Prevacid Wellbutrin Sr Femhrt Tizanidine	C C C C		
Age:	5ISR Number Gender:Fema						
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P ORAL		Dissociative Disorder Drug Abuser	Foreign Health	Diflucan Tablets (Fluconazole)	PS		ORAL

Tizanidine

(Tizanidine Hydrochloride)

Zolmitriptan

Hydrochloride

SS

ORAL

Professional

16 MG (4 MG,

1 IN 1

D),ORAL

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Freedom Of Information (FOI) Report

(Zolmitriptan)

SS

ORAL

MG, 1 IN 1					
D), ORAL			Benzodiazepine Derivatives (Benzodiazepine Derivatives)	SS	
Date:02/23/05ISR Number Age:51 YR Gender:Fema	r: 4595107-2Report Type:Expe ale I/FU:F	edited (15-DaCompany Re	eport #JP-SHR-03-002988		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Other	Haemolytic Anaemia Leukopenia Neutropenia	Foreign Study Health	Betaferon (Interferon Beta-1b) Injection	PS	
SUBCUTANEOUS SEE I	Relapsing-Remitting Multiple Sclerosis	Professional Other	Ternelin (Tizanidine Hydrochloride)		ODAL
2 MG, 1X/DAY,	Therapy Non-Responder		Tablet	SS	ORAL
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	J.G.I.D.
			Solu-Medrol (Methylprednisolone Sodium Succinate)	C	

10 MG (2.5

Glyceol (Glycerol,	
Fructose)	С
Predonine	С
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 Dur Life-Threatening PO ONCE QID	Duration ning	Chest Pain		Tizanidine 4mg	PS	ORAL
		Dyspnoea		Tizanidine 4mg	SS	
		Feeling Abnormal		Klonopin	C	
		Syncope		Neurontin	C	
				Soma	C	
				Lortabs	C	

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Freedom Of Information (FOI) Report

Zomig C

Date: 03/03/	USISR Number:	4599864-UReport	Type:Expedited	(15-DaCompany	Report	#ACO_0130_2005	
Age:23 YR	Gender:Female	e I/FU:I					

Outcome PTReport Source Product Role Manufacturer Route Dose Duration Conversion Disorder Sirdalud Hospitalization -Foreign PS ORAL 16 MG QD PO Initial or Prolonged Dissociative Disorder Health Diflucan SS ORAL 1 TAB QDAY PO Professional Drug Abuser Zomig ORAL SS 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 I	Duration						
Required		Drug Interaction	Foreign	Lisinopril	PS	Watson Laboratories	ORAL
10 MG, DAILY,							
Intervention t	to	Potentiation	Literature				
ORAL							
Prevent Perman	nent	Hypotension	Health	Tizanidine			
Impairment/Dar	mage	Idiosyncratic Drug	Professional	(Tizanidine)	SS		
2 MG, SINGLE							
		Reaction	Other	Amlodipine			
				(Amlodipine)	C		
				Nimodipine			
				(Nimodipine)	C		
				Labetalol			
				(Labetalol)	C		
				Ofloxacin			
				(Ofloxacin)	C		
				Theophylline	С		
				Biofermin			
				(Lactobacillus			
				Acidophilus,			

Bacillus Subtilis, Streptococcus

Product

Role Manufacturer

Route

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 Other PO	Duration	Lymphocyte Stimulation	Foreign	Ternelin	PS	ORAL
		Test Positive Toxic Skin Eruption Urticaria	Health Professional Other	Peon Marzulene S	SS SS	

Date:03/09/05ISR Number: 4602775-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908829

Age:21 YR Gender:Female I/FU:I

PT

Dose	Duration				
Death	Compl	leted Suicide	Health	Ultracet	PS
OROPHARINGEA	L 30g/3 g				
Hospitalizat:	ion -		Professional	Cyclobenzaprine	SS
Initial or Pa	rolonged			Amitriptyline	SS
OROPHARINGEA	L				
				Tizanidine	SS
				Rofecoxib	SS
				Omeprazole	SS

Report Source

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Outcome

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 - 0.2 MG (NR)	Alanine Aminotransferase	Foreign	Harnal (Tamsulosin)	PS		ORAL
Initial or Prolonged PO	Increased	Health				
Other	Aspartate Aminotransferase	Professional	Dantrium (Dantrolene Sodium) (Nr)	SS		ORAL
25 MG (NR) PO						
	Increased Blood Bilirubin Increased		Lioresal (Dantrolene Sodium) (Nr)	SS		ORAL
6 DF (NR) PO						
	Blood Lactate Dehydrogenase Increased		Ternelin (Tizanidine Hydrochloride) (Nr)	SS		ORAL
1 MG TID (NR,						
	Gamma-Glutamyltransferase					
TID) PO	_					
	Increased		Vitamedin			
	Liver Disorder Lymphocyte Stimulation		(Benfotiamine/B6/B12) (Nr)	С		
	Test Positive		Diazepam (Diazepam)	C		
	Malaise		(Nr)	С		
	r: 4611182-OReport Type:Direct	Company Repor	t #CTU 243250			
Age: Gender:Fema	ale I/FU:I					
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dobe Daracion	Drug Ineffective		Zanaflex - Generic			
	Pharmaceutical Product		Form	PS		
2 MG						
	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	111001101011011 11120020		(201020-0000)	22	01412
	Rhabdomyolysis		Tizanidine		
	Suicide Attempt		Hydrochloride		
	Vomiting		(Tizanidine		
	Vollitering		Hydrochloride)	SS	ORAL
ORAL			Hydrochroride)	33	ORAL
ORAL			Zonialono		
			Zopiclone	99	ODAT
			(Zopiclone)	SS	ORAL

ORAL

Other

Date:03/17/05ISR Number: 4611206-OReport Type:Expedited (15-DaCompany Report #US-MERCK-0409USA01708

Age:21 YR Gender:Female I/FU:F

Outcome PT Death Ago

Aggression Aspiration

Hospitalization -Initial or Prolonged

Completed Suicide
Depressed Level Of
Consciousness
Drug Interaction
Drug Screen Positive

Drug Toxicity

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Freedom Of Information (FOI) Report

-Tizanidine-

PS

		Foreign Body Aspiration Intentional Misuse						
		Lung Crepitation	Report S	ource	Product	Role	Manufacturer	Route
Dose	Duration	T			***	D.C.	Marie C. Co. Trop	0D 7 T
		Lung Disorder Sedation			Vioxx Flexeril	PS SS	Merck & Co., Inc	ORAL
		Sedation Self-Medication			Ultracet	SS		ORAL
UNKNOWN		Sell-Medication			Ultracet	۵۵		I
OTATAOMIA		Vomiting			Omeprazole	SS		ORAL
		VOIIITETIIG			Elavil	SS		ORAL
					Tizanidine	טט		OIVALI
					Hydrochloride	SS		ORAL
					nyaroemorrae	55		01412
Date:03/17/0!	SISR Number	: 4611425-3Report Type:Expedit	ted (15-Da	Company Report	t #PHBS2004JP16522			
	Gender: Fema		()	JOHN 1111/1	9 112-3-2-2-3-3-3-3-3-3-3-3-3-3-3-3-3-3-3-			
Outcome		PT	Report S	ource	Product	Role	Manufacturer	Route
Dose	Duration							ļ
Hospitalizati		Alanine Aminotransferase			Voltaren	PS	Novartis Sector:	ļ
Initial or Pi	_	Increased					Pharma	ORAL
75 mg/day	43200MIN							ľ
i		Aspartate			Ternelin	SS		ORAL
3 mg/day	43200MIN							ļ
i		Aminotransferase			Mucosta	SS		ORAL
300 mg/day	43200MIN							ļ
1		Increased			Mecobalamin	С		ORAL
1000 ug/day								
1		Back Pain						
i		Condition Aggravated						
		Gamma-Glutamyltransferase						
1		Increased						
1		Liver Disorder						
1		Lymphocyte Stimulation						
		Test Positive						
	_							
		: 4619026-8Report Type:Direct	(Company Report	t #CTU 243514			
Age: (Gender:	I/FU:I						
Outcome		PT	Report S	ource	Product	Role	Manufacturer	Route
Dose	Duration							
1		Blood Pressure Systolic			Sirdalud			

Decreased

Dizziness

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

ZANAFLEX 2MG

Complaint

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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 PTReport Source Product Role Manufacturer Route

Dose Duration

Hospitalization -Delirium Tizanidine Hcl PS ORAL

4MG 1 TID

Initial or Prolonged Drug Withdrawal Syndrome

PRN ORAL

Overdose

Psychotic Disorder

Date:03/24/05ISR Number: 4617527-XReport Type:Expedited (15-DaCompany Report #PHBS2005BE04067

Age: 47 YR Gender: Female I/FU:I

Role Manufacturer Outcome PTReport Source Product Route

Dose Duration

Lamisil Other Drug Abuser PS Novartis Sector:

> Medication Error Pharma

6 x 56 UNKNOWN

tablets = 336

Sirdalud SS

8 packages

tablets

of 100

Sirdalud 4 mg

92160MIN tablets Sirdalud SS

UNKNOWN 32 packages

of 100

tablets 106 DAY

Methadone SS

UNKNOWN 10 x 60

tablets = 600

Sirdalud 4 mg

tablets Serenase SS UNKNOWN 3×50

tablets

tablets = 150

Temgesic SS 50 DF, UNKNOWN

ONCE/SINGLE

Ranitidine SS 9 x 28 or 56 UNKNOWN

tablets Amoxycillin SS

500 mg, UNKNOWN

ONCE/SINGLE Brufen SS

UNKNOWN 400 mg,

ONCE/SINGLE Ciproxine SS

 3×20 UNKNOWN

tablets = 60

Age: 47 YR Gender: Male I/FU:F

Date: 03/24/05ISR Number: 4620084-5Report Type: Expedited (15-DaCompany Report #2005040174

Outcome PTHospitalization -Abdominal Pain

Initial or Prolonged Acute Prerenal Failure

Other Aphagia

Blood Chloride Decreased

Blood Pressure Systolic Increased

Blood Sodium Decreased

Dehydration Haemodialysis

Hepatic Function Abnormal

Intentional Misuse Rhabdomyolysis Suicide Attempt

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tablets

Freedom Of Information (FOI) Report

Vomiting

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
DOBC	Datacion	Foreign Literature	Halcion (Triazolam)	PS		ORAL
0.25 MG (0.2	5		(11101010)			01412
MG,) ORAL		Health				
2,,		Professional	Lorazepam (Lorazepam)			
1 MG (1 MG,			(Lorazepam)	SS		ORAL
QD), ORAL						
			Phenobarbital (Phenobarbital)	SS		ORAL
ORAL			Zopiclone			
ORAL			(Zopiclone)	SS		ORAL
			Vegetamin(Chlorproma zine Hydrochloride, Phenobarbital,			
ORAL			Promethazine Hydrochloride)	SS		ORAL
OKAL			Tizanidine Hydrochloride (Tizanidine			
ORAL			Hydrochloride)	SS		ORAL
			Flunitrazepam (Flunitrazepam)	С		ORAL
2 MG (2 MG,			· • • • • • • • • • • • • • • • • • • •			
QD), ORAL						
			All Other Therapeutic Products (All Other Therapeutic Products)	С		
			FI OUUCLS /	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

Hospitalization -

Initial or Prolonged

-1 1

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

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Freedom Of Information (FOI) Report

Role Manufacturer

Route

Product

Somnolence Suicide Attempt

Vomiting

Dose	Duration	-			
		Foreign	Ternelin	PS	ORAL
20 MG ONCE P		Health	Rohypnol	SS	ORAL
46 MG ONCE P	0	Professional	Halcion	SS	ORAL
2.5 MG ONCE		Other			
PO					
20 MG ONCE P	20		Wypax	SS	ORAL
			Slowheim	SS	ORAL
75 MG ONCE P	0		Vegetamin A	SS	ORAL
600 MG ONCE			vegetamin n		01412
1					

Report Source

Date:04/01/05ISR Number: 4628375-9Report Type:Expedited (15-DaCompany Report #ACO_0133_2005 Gender:Female I/FU:I

Age:46 YR

ΡO

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					ļ
Hospitalization -	Amnesia	Health	Zanaflex	PS	ORAL
4 MG PO					,
Initial or Prolonged	Confusional State	Professional	Trazodone		ļ
1	Depression		Hydrochloride	SS	ORAL
100 MG PO					ļ
1	Insomnia		Dilaudid	SS	ļ
1	Lethargy		Xanax	SS	
1	Muscular Weakness		Quinapril	SS	
1			Valium	SS	
A					

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	Ro⊥e	Manufacturer	Route
Dose	Duration						
Other		Drug Abuser		Lamisil	PS	Novartis Sector:	

SS

SS

SS

SS

SS

SS

6 x 56

tablets = 336

Sirdalud 4 mg

tablets

UNKNOWN

8 packages

of 100

tablets UNKNOWN

of 100

Sirdalud 4 mg

tablets

UNKNOWN tablets = 600

tablets

UNKNOWN

tablets

UNKNOWN ONCE/SINGLE

UNKNOWN

tablets UNKNOWN

ONCE/SINGLE

UNKNOWN ONCE/SINGLE

UNKNOWN 3×20

32 packages

106 DAY

 3×50

tablets = 150

10 x 60

92160MIN

50 DF,

9 x 28 or 56

400 mg,

Sirdalud

500 mg,

Sirdalud

Methadone

Serenase

Temgesic

Ranitidine

Brufen

Ciproxine

Amoxycillin SS

SS

SS

tablets = 60

tablets

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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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitaliza Initial or I	tion -	Condition Aggravated Dyskinesia Muscle Spasms Speech Disorder	Foreign Consumer Other	Zanaflex Inhaler	PS C		
Date:04/07/0 Age:	05ISR Number Gender:	: 4708207-0Report Type:Direct I/FU:I	Company Repor	t #USP 57197			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Duracion	Drug Dispensing Error		Gabitril	PS	Cephalon	
TABLET TABLET		Medication Error		Zanaflex	SS		
)5ISR Number Gender:Male	: 4633338-3Report Type:Expedit	ed (15-DaCompany Repor	t #ACO-0127_2005			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other PO	Duracion	Generalised Erythema	Foreign	Ternelin	PS		ORAL
		Lymphocyte Stimulation Test Positive Pigmentation Disorder Rash Toxic Skin Eruption	Health Professional Other	Peon Marzulene S Dan Rich Over-The - Counter Antitussives (Nos)	SS SS SS		

Date:04/12/05ISR Number: 4633339-5Report Type:Expedited (15-DaCompany Report #ACO_0036_2004 Age: 27 YR Gender: Female I/FU:F

Urticaria

Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Hospitalization -		Alanine Aminotransferase	Foreign	Ternelin	PS	ORAL
3 MG QDAY PO						

		I I I I I I I I I I I I I I I I I I I	OCIICI			
PO						
		Increased		Mecobalamin	С	
		Back Pain				
		Gamma-Glutamyltransferase				
		Abnormal				
		Liver Disorder				
		Lymphocyte Stimulation				
		Test Positive				
5 04/14	/05=65 3- 1	4626004 777	11. 1 (15.5.0			
		: 4636804-XReport Type:Expe	dited (15-DaCompany Re	eport #ACO_0137_2005		
Age:64 YR	Gender:Male	e I/FU:I				
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration		-			
Disability		Confusional State	Foreign	Sirdalud	PS	
2 		Dyspnoea	Health	2 == 3.3.= 3.3.		
		Loss Of Consciousness	Professional			
		Loss Of Consciousness Quadriparesis				
		Loss Of Consciousness	Professional			

Voltaren

Mucosta

SS

SS

ORAL

ORAL

Health

Other

Professional

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Initial or Prolonged

75 MG QDAY PO

300 MG QDAY

Increased

Aspartate

Aminotransferase

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

Age:47 YR	Gender:Fema	le	I/FU:I					
Outcome	D	PT		Report Source	Product	Role	Manufacturer	Route
Dose Other 4 MG PO	Duration	Drug	Abuser	Foreign	Zanaflex	PS		ORAL
				Health Professional	Lamisil Methadone	SS 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								
400 MG PO					Brufen Abbott	SS		ORAL
500 MG PO					Ciproxine	SS		ORAL
Date:04/14/0 Age:40 YR			5822-1Report Type:Expedite	ed (15-DaCompany Report	t #DSA_26193_2005			
Outcome Dose	Duration	PT		Report Source	Product	Role	Manufacturer	Route
Hospitalizat 20 MG ONCE P	ion -	Abdom	ninal Pain	Foreign	Wypax	PS		ORAL
Initial or P 2.5 MG ONCE	rolonged	Blood	d Potassium Increased	Health	Halicion	SS		ORAL
PO		Blood	d Pressure Systolic	Professional				
PO		Incre	ased	Other	Rohypnol	SS		ORAL

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - 20 MG ONCE PO	Abdominal Pain	Foreign	Wypax	PS	ORAL
Initial or Prolonged 2.5 MG ONCE	Blood Potassium Increased	Health	Halicion	SS	ORAL
PO	Blood Pressure Systolic	Professional			
	Increased	Other	Rohypnol	SS	ORAL
DF ONCE PO	Body Temperature		Ternelin	SS	ORAL
20 MG ONCE PO 600 MG ONCE	Decreased		Vegetamin A	SS	ORAL
PO	Depression				
75 MG ONCE PO	Dry Skin		Slowheim	SS	ORAL

DF UNK PO					
	Haemodialysis		Rohypnol	SS	ORAL
DF UNK PO	Hepatic Function Abnormal		Ternelin	SS	ORAL
DF UNK PO					
DF UNK PO	Intentional Misuse		Vegetamin A	SS	ORAL
DI ONICIO	Oedema Peripheral		Slowheim	SS	ORAL
DF UNK PO	Renal Failure Acute Rhabdomyolysis Suicide Attempt				
Date:04/21/05ISR Number Age:43 YR Gender:Fema	:: 4643078-2Report Type:Expedite I/FU:F	dited (15-DaCompany Re	eport #ACO_0135_2005		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - 4 MG Q6HR PO	Back Pain	Foreign	Tizanidine	PS	ORAL
Initial or Prolonged	Dyskinesia Muscle Spasms Speech Disorder Torticollis	Consumer Other	Inhaler (Name Unknown)	C	
Date:04/21/05ISR Number Age:53 YR Gender:Male	: 4643080-0Report Type:Expect	dited (15-DaCompany Re	eport #ACO_0141_2005		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Other DF	Chest Pain	Foreign	Ternelin	PS	
D.	Peripheral Coldness	Health Professional Other			
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Wypax

Halcion

SS

SS

ORAL

ORAL

Glasgow Coma Scale

Abnormal

DF UNK PO

DF UNK PO

Freedom Of Information (FOI) Report

SS

Date:04/28/05ISR Number: 4649741-1Report Type:Direct Company Report #CTU 247336

Age: Gender: Male I/FU:I

Outcome PΤ Report Source Product Role Manufacturer Route

Dose Duration

Hospitalization -Swelling Face Zanaflex 4 Mg PS

Initial or Prolonged

Date:05/02/05ISR Number: 4651569-3Report Type:Expedited (15-DaCompany Report #2005061462

Gender: Female Age: I/FU:I

Outcome PTReport Source Product Role Manufacturer Route

Dose Duration

ORAL Other Asthenia Consumer Bextra (Valdecoxib) PS

20 MG (20 MG,

Blister

1 IN 1 D),

ORAL

Celebrex (Celecoxib) SS Crying ORAL

(1 IN 1 D),

ORAL

Drug Ineffective

Emotional Distress Tizanidine Exostosis Hydrochloride

(Tizanidine Fear Hydrochloride) Herpes Simplex

Inadequate Analgesia Intervertebral Disc

Disorder

Chondropathy

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 РΤ Report Source Product Role Manufacturer Route

Dose Duration

Hospitalization -Blood Sodium Decreased Study Oxycodone

Initial or Prolonged Electrocardiogram Qt Other Hydrochloride

Other	Corrected Interval	(Similar To Nda		
	Prolonged	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

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

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ORAL

Freedom Of Information (FOI) Report

		Muscular Weakness Somnolence					
		Tongue Disorder	Report Source	Product	Role	Manufacturer	Route
Dose	Duration		The second second	Girana lana			
			Foreign Health	Cipralex (Escitalopram)	PS		ORAL
10 MG QD PO				(
			Professional	Sirdalud (Tizanidine Hydrochloride)	aa		
			Other	нуdrochioride) Felden (Piroxicam)	SS C		
				Ponstan (Mefenamic	J		
				Acid)	C		
				Xefo (Lornoxicam)	С		
	5ISR Number Gender:Fema	: 4656778-5Report Type:Expedile I/FU:I	dited (15-DaCompany Re	eport #2005PK00757			
1190-20 110	deliael i ella						
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Required	Duracion	Convulsion	Foreign	Nolvadex			
Intervention 20 MG DAILY	to	Sleep Disorder	Health	Astrazeneca	PS	Astrazeneca	ORAL
Prevent Perm PO	anent		Professional				
Impairment/D 100 MG DAILY			Other	Tramal	SS		ORAL
PO				Sirdalud	SS		ORAL
2 MG DAILY P	0			Silvalu	טט		OKAL
	5ISR Number Gender:Fema	: 4658145-7Report Type:Expedite I/FU:F	dited (15-DaCompany Re	eport #2005061462			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 20 MG (20 MG	Duration	Activities Of Daily	Consumer	Bextra (Valdecoxib)	PS		ORAL
1 IN 1 D),	•	Living Impaired					
		Crying					

ORAL

Exostosis

ORAL Fatigue

Herpes Simplex Intervertebral Disc

Disorder

Memory Impairment

Oral Mucosal Blistering

Pain Pruritus Rash Pruritic Scar

Scar

Skin Disorder Skin Reaction Somnolence Stress Tizanidine Hydrochloride (Tizanidine Hydrochloride)

SS

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 - Anaemia

Initial or Prolonged Balance Disorder Blindness Transient

Blood Pressure Increased

Bradycardia Cardiomegaly Carotid Bruit

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Freedom Of Information (FOI) Report

Felden

			Dizziness					
			Drug Interaction	Report Source	Product	Role	Manufacturer	Route
Dose	Duration							
2 770 00777 00	22 -		Electrocardiogram Poor	Foreign	Tizanidine	PS		ORAL
3 MG QDAY PO	33 I	DAY	R-Wave Progression	Literature	Ticlopidine	SS		ORAL
100 MG TID PO)		R-Wave Progression	Literature	ιτοτοβιατιίε	ಎಎ		UKAL
			Electrocardiogram St-T Change Glycosylated Haemoglobin Increased Pulse Absent Reflexes Abnormal Sinus Arrhythmia Sinus Bradycardia Ventricular Hypertrophy	Health Professional Other				
Age:56 YR (Gender:Fe	emal	4660036-2Report Type:Expedie I/FU:F	ted (15-DaCompany Repor Report Source	rt #US-2004-BP-12563BP Product	Role	Manufacturer	Route
Dose	Duration	n	Character to the control of		Mirror Malalaka	Da	D T	
Hospitalizat: Initial or P			Chromaturia Diarrhoea Jaundice		Mirapex Tablets	PS	B.I. Pharmaceuticals, Inc. /Ridgefield	ORAL
			Nausea		Metformin	SS	/RIdgelleld	OKAL
			Vomiting		Estrogen	SS		
					Zanaflex Rebif	SS SS		
	5ISR Numl Gender:Fe		4663254-2Report Type:Expedi- e I/FU:I	ted (15-DaCompany Repor	rt #ACO_0144_2005			
Outcome Dose	Duration		PT	Report Source	Product	Role	Manufacturer	Route
Other 4 TAB QDAY PO			Burning Sensation	Foreign	Sirdalud	PS		ORAL
			Dizziness	Health	Cipralex	SS		ORAL
10 MG NIGHTLY	Y		Dyspnoea	Professional				
PO								
				_ •				

Other

Coronary Artery Stenosis

Muscular Weakness

Somnolence Ponstan С Sudden Onset Of Sleep Xefo С

Tongue Disorder

Date:05/16/05ISR Number: 4664015-OReport Type:Direct Company Report #CTU 248634

Gender: Female I/FU:I Age:

Report Source Role Manufacturer Outcome PTProduct Route

Duration Dose

> 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

Hospitalization -Anaphylactic Shock

Initial or Prolonged Blood Pressure Decreased

Confusional State

Erythema

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Freedom Of Information (FOI) Report

Vomiting

INTRATHECAL

0.1 MCG/HR

Dose	Duration		Report Source	Product	Role	Manufacturer	Route
Dose	Duracion			Voltaren Sr	PS	Novartis Sector: Pharma	ORAL
75 mg/day							-
2 mg/day				Ternelin	SS		ORAL
2 DF/day				Mucosta	SS		ORAL
z bi / ddy							
Date:06/02/(Age:	05ISR Number Gender:Fema	: 4679968-4Report Type:Expedit le I/FU:I	ed (15-DaCompany Repor	t #PHFR2005GB01965			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threate Hospitalizat 40 mg, QD	ening	Blood Creatinine Increased		Baclofen	PS	Novartis Sector: Pharma	ORAL
Initial or I 36mg/day	Prolonged	Drug Level Increased		Tizanidine	SS		ORAL
Other		Epilepsy		Gabapentin	SS		
UNKNOWN	400 mg	, BID Glasgow Coma Scale		Bendrofluazide	С		ORAL
2.5mg/day		Classow coma scale		Demarorrade	C		014111
		Abnormal					
		Hallucination					
		Loss Of Consciousness					
		Overdose					
		Renal Failure Acute					
		Urinary Tract Infection					
Date:06/02/(Age:48 YR	05ISR Number Gender:Fema	: 4681511-0Report Type:Expedit le I/FU:I	ed (15-DaCompany Repor	t #ZICO001221			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat		Anaemia	Health	Prialt (Ziconotide			
Initial or I		Anxiety	Professional	Intrathecal			
		Blood Albumin Decreased	1 1 0 1 0 0 0 1 0 1 1 0 1	Infusion)	PS		
TATION A INTERIOR T	0 1 1/0	C /IID					

INTRATHECAL

Phosphokinase Increased Blood Creatine Phosphokinase Mb Increased Dyspnoea Headache Pulmonary Oedema

Blood Creatine

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Zanaflex	
(Tizanidine)	SS
Neurontin	
(Gabapentin)	С
Restoril (Temazepam)	C
Wellbutrin	_
(Amfebutamone	
Hydrochloride)	C
Dilaudid	Ü
(Hydromorphone	
Hydrochloride)	C
Oxybutryn	
(Oxybutryn)	С
Protonix(Pantoprazol	
e)	С
Zoloft (Sertraline	
Hydrochloride)	С
Procrit	
(Erythropoeitin)	C
Hydrochlorothiazid	
(Hydrochlorothiazide	
)	C
Levaquin	
(Levofloxacin)	С

Freedom Of Information (FOI) Report

Product

Role Manufacturer

PS

Route

Date:06/02/05ISR Number: 4682499-9Report Type:Direct Company Report #CTU 250170

Gender: Female Age:57 YR I/FU:I

Outcome PTReport Source Product Role Manufacturer Route Duration Dose Drug Effect Decreased Tizanidine 4 Mg PS

3 PER DAY; 1

Dry Mouth

3 TIMES PER

Headache

Outcome

DAY

Insomnia

PT

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

D.... + 1 ---

Dose	Duration					
Hospitalizat	cion -	Bradycardia	Vioxx	PS	Merck & Co., Inc	ORAL
8 DAY						
Initial or F	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)	С		ORAL

Report Source

Date:06/09/05ISR Number: 4688149-XReport Type:Expedited (15-DaCompany Report #430015M05USA

Age:41 YR Gender:Female I/FU:I

Outcome PTReport Source Product Role Manufacturer Route

Dose Duration

Hospitalization -Idiopathic Health Novantrone Initial or Prolonged Thrombocytopenic Purpura Professional (Mitoxantrone

Hydrochloride)

25 MG/M2, 3

IN 1 MONTHS

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Effexor (Venlafazine	
Hydrochloride)	SS
Zanaflfex	
(Tizanidine	
Hydrochloride)	SS
Neurontin	
(Gabapentin)	C C
Provigil (Modafinil)	С
Inderal (Propranolol	
Hydrochoride)	С
Clonazepam	
(Clonazepam)	C C
Naprilan (Enalapril)	C
Ambien (Zolipen	
(Enalapril)	C
Imitrex (Sumatriptan	
Succinate)	С
Urocholine (All	
Other	
Non-Therapeutic	
Products)	С
Trileptal	
(Oxycarbazepine)	С

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
-----------	---------------	--------

Blood Creatine Phosphokinase Mb

Blood Lactate

Blood Glucose Increased Blood Iron Decreased

Dehydrogenase Increased

Increased

Age: 40 IK Gender: Fell	1/10:1				
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Other DF PO	Depression	Health	Zanaflex	PS	ORAL
	Paranoia	Professional	Effexor-Xr	SS	ORAL
37.5 MG ONCE					
20					
			Lexapro	С	
			Duragesic	С	
			Zonegran	C	
			Clonidine	C	
			Ultram	С	
Age:48 YR Gender:Fem Outcome Dose Duration Hospitalization - DF PO	PT Alanine Aminotransferase	Report Source Health	Product Tizanidine	Role Manufacturer	Route ORAL
Initial or Prolonged INTRATHORACIC DF I	Increased T	Professional	Prialt/Ziconotide	SS	
	Anaemia		Neurontin	C	
	Anxiety		Restoril	C	
	Aspartate				
	Aminotransferase				
	Increased				
	Band Neutrophil				
	Percentage Decreased				
	Blood Alkaline				
	Phosphatase Increased				
	Blood Calcium Decreased				
	Blood Creatine				
	Phosphokinase Increased				
	THOSPHORTHASE THETEASED				

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

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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

Outgomo	PT	Bonort Course	Product	Dolo	Manufacturer	Bout o
Outcome Dose Duration	L1	Report Source	Product	коте	manuracturer	Route
Hospitalization -	Idiopathic	Health	Novantrone			
Initial or Prolonged	Thrombocytopenic Purpura	Professional	(Mitoxantrone			
			Hydrochloride,			
			Injection)	PS		
25 MG/M2						
EVERY 3						
MONTHS						
			Effexor (Venlafaxine			
			Hydrochloride,			
			Tablet)	SS		
			Zanaflex (Tizanidine	aa		
			Hydrochloride,) Neurontin	SS		
			(Gabapentin)	С		
			Inderal (Propranolol	C		
			Hydrochloride)	С		
			Clonazepam	Ü		
			(Clonazepam)	С		
			Naprilene (Enalapril			
			Maleate)	С		
			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 Du Hospitalization 3 MG DAILY PO	uration n -	Anaemia	Foreign	Tizanidine Hcl	PS	ORAL
Initial or Prol	longed	Areflexia Balance Disorder Blindness Transient	Literature Health Professional	Ticlopidine Hcl	С	

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

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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-Threat	ening	Abdominal Pain Uppe	er	Voltaren	PS	Novartis Sector:	
Hospitaliza	ation -	Alanine Aminotransf	Terase			Pharma	
UNKNOWN	50 mg/	d 4320 MIN					
Initial or	Prolonged	Increased		Sirdalud	SS		ORAL
6 mg/day	4320 MIN	Ī					
Other		Aspartate		Vioxx	SS		
UNKNOWN	25 mg/	d 4320 MIN					
		Aminotransferase		Herbal Extracts Nos	SS		
		Increased					
		Brain Natriuretic F	Peptide				
		Increased					
		Chest Discomfort					
		Chest Pain					
		Diarrhoea					
		Drug Interaction					
		Dyspnoea					
		Fibrin D Dimer Incr					
		Gamma-Glutamyltrans	sferase				
		Increased					
		Haemangioma Of Live					
		Hepatic Enzyme Incr	reased				
		Hepatic Lesion					
		Hepatotoxicity					
		Hyperhidrosis					
		Nausea					
		Pleural Effusion					
		Pulmonary Hypertens	sion				
		Right Ventricular F	Failure				
		Sinus Bradycardia					
1		Vomiting					
		-					

Date:06/16/05ISR Number: 4693790-4Report Type:Expedited (15-DaCompany Report #ACO_0166_2005

Age:62 YR Gender:Female I/FU:I

	P.I.	Report Source	Product	Role Manufacturer	Route
Duration					
on -	Exanthem	Foreign	Ternelin	PS	ORAL
		** 1.1	** 1.		0037
olongea	Hypotension	Health	Voltaren	SS	ORAL
	n -	ouration on - Exanthem	ouration on - Exanthem Foreign	ouration on - Exanthem Foreign Ternelin	ouration on - Exanthem Foreign Ternelin PS

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 -Acute Right Ventricular

Initial or Prolonged Failure

Alanine Aminotransferase

Intervention to Increased Prevent Permanent Angiopathy Impairment/Damage Aspartate

Aminotransferase

Increased

Blood Pressure Systolic

Increased Bradycardia Drug Interaction

Gamma-Glutamyltransferase

Increased

Haemangioma Of Liver

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Required

Freedom Of Information (FOI) Report

			Hepatic Cyst Liver Function Test Abnormal	Report Source	Product	Role	Manufacturer	Route
Dose	Durati	on	Pulmonary Hypertension	Foreign	Sirdalud	PS		ORAL
VAR QDAY PO	3	DAY		10101911	bildalaa	10		014111
25 MG QDAY PO	^		Tachycardia	Literature	Vioxx	SS		ORAL
23 MG QDAI PO	J		Ventricular Extrasystoles	Health Professional Other	Voltaren Phytotherapeutics	C C		
	5ISR Nu Gender:		: 4697993-4Report Type:Expedi I/FU:F	ted (15-DaCompany Repo	rt #2005084736			
Outcome	Durati	on	PT	Report Source	Product	Role	Manufacturer	Route
Dose Disability 50 MG (50 MG)		Abasia	Foreign	Serlain (Sertraline)	PS		ORAL	
1 IN 1 D),			Drug Interaction	Health				
I IN I D),			Feeling Abnormal	Professional				
ORAL ORAL					Sirdalud (Tizanidine Hydrochloride)	SS		ORAL
	5ISR Nu Gender:		: 4699425-9Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	rt #ACO_0170_2005			
Outcome Dose	Durati	on	PT	Report Source	Product	Role	Manufacturer	Route
Other 20 DF ONCE PO		OII	Blood Pressure Systolic	Foreign	Ternelin	PS		ORAL
			Decreased Intentional Misuse Overdose Somnolence	Health Professional Other	Alcohol	SS		

Date:06/22/05ISR Number: 4699426-0Report Type:Expedited (15-DaCompany Report #ACO_0171_2005 Age:8 MON Gender: I/FU:I

32 MG ONCE PO					
Initial or Prolonged	Child Bradycardia Depressed Level Of Consciousness	Other			
Date:06/22/05ISR Numbe Age: Gender:Fem	er: 4699427-2Report Type:Expediale I/FU:I	dited (15-DaCompany Ro	eport #ACO_0169_2005		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - 36 MG PO	Epilepsy	Foreign	Zanaflex	PS	ORAL
Initial or Prolonged 800 MG PO	Glasgow Coma Scale	Health	Gabapentin	SS	ORAL
40 MG PO	Abnormal	Professional	Baclofen	SS	ORAL
	Hallucination Intentional Misuse Loss Of Consciousness Overdose Renal Failure Acute Urinary Tract Infection	Other	Ciprofloxacin Bendrofluazide	C C	

Report Source

Foreign

Product

Sirdalud

Role Manufacturer

PS

Route

ORAL

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Outcome

Hospitalization -

Dose

PT

Accidental Drug Intake By

Duration

Freedom Of Information (FOI) Report

SS

SS

Tegretol

Tegretol

Pharma

Pharma

Novartis Sector:

Novartis Sector:

ORAL

ORAL

Date:06/27/05ISR Number: 4701637-2Report Type:Expedited (15-DaCompany Report #2005084736 Age:53 YR Gender:Male I/FU:F

Hypogammaglobulinaemia

Immunodeficiency

Myotonia

Lung Infiltration

200 mg, TID

200 mg, QID

5760 MIN

25920MIN

Age.53 ik Gender Male	e 1/FU·F					
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Disability 50 MG (50 MG,	Abasia	Foreign	Serlain (Sertraline)	PS		ORAL
1 IN 1 D),	Depression	Health				
ORAL	Drug Interaction	Professional				
	Feeling Abnormal		Sirdalud (Tizanidine Hydrochloride)	SS		ORAL
ORAL						
Date:06/29/05ISR Numbe: Age:24 YR Gender:Male	r: 4702901-3Report Type:Expedi e I/FU:I	ted (15-DaCompany Repo:	rt #US-JNJFOC-200506061	116		
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Intentional Misuse		Flexeril	PS		
Initial or Prolonged	Loss Of Consciousness		Zanaflex	SS		
			Klonopin No-Doz	SS SS		
			No-Doz	SS		
			Lexapro	C		
			Depakote	С		
Date:06/29/05ISR Numbe Age:29 YR Gender:Fema	r: 4702997-9Report Type:Expedi ale I/FU:F	ted (15-DaCompany Repo:	rt #PHBS2003JP01063			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening Hospitalization - 200 mg, BID 36000MI	Eosinophilia Generalised Erythema N		Tegretol	PS	Novartis Sector: Pharma	ORAL
Initial or Prolonged	Hepatic Function Abnormal		Tegretol	SS	Novartis Sector:	22.5

J.		Productive Cough Pyrexia		Tegretol	SS	Novartis Sector: Pharma	ORAL
200 mg, BID	40320MIN	Palas		Conton	aa		
UNKNOWN		Rales		Gaster	SS		
		Rash Generalised		Ternelin	SS		
UNKNOWN		Skin Exfoliation		Predonine	С		ORAL
15 mg/day		SKIII EXIOTIACION		rredonine	C		ORAL
150 / 1		Upper Respiratory Tract		Selbex	С		ORAL
150 mg/day		Infection		Rize	С		ORAL
5 mg/day					J		01412
		Upper Respiratory Tract Inflammation					
Date:07/05/05 Age:61 YR G		: 4708794-2Report Type:Expedi I/FU:I	ted (15-DaCompany Repor	t #ACO_0172_2005			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Lethargy	Foreign	Zanaflex	PS		ORAL
2 MG TID PO		Lechargy	roreign	Zanariex	PS		UKAL
		Myalgia	Health	Zanaflex	SS		ORAL
2 MG QWK PO			Professional	Evening Primrose	С		
			Other	Vitamin C	C		
				Ibuprfen	C		
				Imipramine	C		

Pharma

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Pneumonia

60480MIN

200 mg, TID

Freedom Of Information (FOI) Report

Date:07/07/05ISR Number: 4708246-XReport Type:Expedited (15-DaCompany Report #PHBS2003JP01063

Age:29 YR Gender:Fema	ale I/FU:F					
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Life-Threatening Hospitalization - 200 mg, BID 36000MIN	Eosinophilia Generalised Erythema		Tegretol	PS	Novartis Sector: Pharma	ORAL
Initial or Prolonged	Hepatic Function Abnormal Hypogammaglobulinaemia		Tegretol	SS	Novartis Sector: Pharma	ORAL
200 mg, TID 5760 MIN	N Lung Infiltration Pneumonia		Tegretol	SS	Novartis Sector: Pharma	ORAL
200 mg, QID 25920MIN	N Productive Cough Pyrexia		Tegretol	SS	Novartis Sector: Pharma	
200 mg, TID 60480MIN			Tegretol	SS	Novartis Sector: Pharma	ORAL
200 mg, BID 40320MIN			Gaster	SS	Pilariia	OIVE
UNKNOWN UNKNOWN	Infection		Ternelin	SS		
15 mg/day			Predonine	C		ORAL
150 mg/day			Selbex Rize	C C		ORAL
5 mg/day						
Date:07/07/05ISR Number Age: Gender:Male	r: 4709528-8Report Type:Expedit e I/FU:I	ted (15-DaCompany Repor	t #ACO_0173_2005			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - DF PO	Drug Screen Positive		Zanaflex	PS		ORAL
Initial or Drolongod	Foolings Of Worthlosenoss		Vlonopin	CC		\bigcirc D7T

Age:	Gender:Male	I/FU:I				
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Hospitaliza	tion -	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	

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 - 2 MG QDAY PO	Erythema	Health	Ternelin	PS	ORAL
Initial or Prolonged 75 MG QDAY PO	Exanthem	Professional	Voltaren	SS	ORAL
	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 Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 2 MG QDAY PO		Difficulty In Walking	Foreign	Tizanidine	PS	ORAL
~		Dizziness	Health	Propranol	C	
		Dry Mouth Feeling Abnormal	Professional Other	Losartan Potassium W/Hydrochlorothiazid		
		Speech Disorder		е	C	
				Euthyrox	C	

Date:07/13/05ISR Number: 4715469-2Report Type:Expedited (15-DaCompany Report #KII-2005-0017347

Gender:Female Age:41 YR I/FU:I

Outcome Hospitalization -Initial or Prolonged

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Freedom Of Information (FOI) Report

Marzulene

Other

Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duracion	Intentional Misuse Multiple Drug Overdose	Study Health	Morphine Sulfate (Morphine Sulfate)	PS		ORAL
SEE TEXT,				, , ,			-
ORAL		Oxygen Saturation	Professional				
OKAL		Decreased Polysubstance Abuse	Other	Tizanidine (Tizanidine)	SS		ORAL
SEE TEXT,		Respiratory Rate		(TIZATICITE)	55		Olum
ORAL		Respiratory Rate					
SEE TEXT,		Decreased		Diazepam (Diazepam)	SS		ORAL
ORAL		Respiratory Rate					
		Increased Sinus Tachycardia		Clonazepam (Clonazepam)	SS		ORAL
SEE TEXT,		-		- ·			
ORAL		Somnolence					
RESPIRATORY				Marijuana (Cannabis)	SS		
,							
(INHALATION)	INHALA	ATION					
Date:07/19/0 Age:83 YR		r: 4718975-XReport Type:Expedit ale I/FU:I	ced (15-DaCompany Repor	t #ACO_0175_2005			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death 1 MG QDAY; P		Body Temperature	Foreign	Ternelin	PS		ORAL
Hospitalizat 50 MG QDAY;		Decreased	Health	Solantal	SS		ORAL

Date:07/20/05ISR Number: 4718400-9Report Type:Expedited (15-DaCompany Report #CH-MERCK-0409CHE00009

Professional

Other

Age:60 YR Gender:Female I/FU:F

Drug Interaction

Myocardial Infarction

Initial or Prolonged

Dose	Duration	PT	Report Source	Product	Role	Manufacturer		Route
Hospitalizati 8 DAY		Abdominal Discomfort		Vioxx	PS	Merck & Co., In	С	ORAL
Initial or Pr	colonged	Abdominal Pain Acute Right Ventricular		Tizanidine Hydrochloride	SS			ORAL
1 DAY								
		Failure Bradycardia		Tizanidine Hydrochloride	SS			ORAL
1 DAY		Diarrhoea		Tizanidine				
1 DAY		Hepatic Cyst		Hydrochloride	SS			ORAL
I DAI		Hepatic Enzyme Increased Hyperhidrosis Nausea		Diclofenac Sodium Herbs (Unspecified)	SS C			ORAL ORAL
		Pulmonary Hypertension Sinus Bradycardia Vomiting						
Age:50 YR G	5ISR Number Gender:Male				Role	Manufacturer		Route
Age:50 YR G Outcome			ited (15-DaCompany Rep Report Source	ort #S05-CAN-02441-01 Product	Role	Manufacturer		Route
Age:50 YR G Outcome	Gender:Male	I/FU:I			Role	Manufacturer		Route
Age:50 YR G Outcome Dose	Gender:Male	I/FU:I PT Aggression Drug Withdrawal Syndrome	Report Source Foreign Health	Product Citalopram (Hydrobromide)	PS	Manufacturer		Route
Age:50 YR G Outcome Dose Other	Gender:Male	I/FU:I PT Aggression Drug Withdrawal Syndrome Personality Change	Report Source Foreign Health Professional	Product Citalopram (Hydrobromide) Marijuana (Cannabis)	PS SS	Manufacturer		Route
Age:50 YR G Outcome Dose Other 40 MG QD	Gender:Male	I/FU:I PT Aggression Drug Withdrawal Syndrome	Report Source Foreign Health	Product Citalopram (Hydrobromide)	PS	Manufacturer		Route
Age:50 YR G Outcome Dose Other 40 MG QD UNKNOWN	Gender:Male	I/FU:I PT Aggression Drug Withdrawal Syndrome Personality Change	Report Source Foreign Health Professional	Product Citalopram (Hydrobromide) Marijuana (Cannabis)	PS SS	Manufacturer		Route

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Freedom Of Information (FOI) Report

РΟ

Coma

Intentional Misuse

Date:07/29/0 Age:61 YR		: 4733536-4Report Type:Exped le I/FU:F	ited (15-DaCompany Re	eport #ZANA001129		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Death 4 MG QDAY PO		Myocardial Infarction	Foreign	Zanaflex	PS	ORAL
4 MG QDAY PO		Rash	Health	Zanaflex	SS	ORAL
		Respiratory Tract	Professional	Zanaflex	SS	ORAL
0.01 MG TID	38 DAY	Infection	Other			
		Ventricular Fibrillation		Vancocyn Flagyl Tylenol Neurontin Ativan Valium Diovol Lovenox	C C C C C C	
	5ISR Number Gender:Fema	: 4733326-2Report Type:Direc le I/FU:I	t Company Re	eport #CTU 254997		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
4 MG PO BID	Daracton	Drug Ineffective Pharmaceutical Product Complaint		Zanaflex	PS	ORAL
	5ISR Number Gender:	: 4736410-2Report Type:Exped I/FU:F	lited (15-DaCompany Re	eport #ACO_0170_2005		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalizat 20 TAB ONCE		Blood Pressure Systolic	Foreign	Ternelin	PS	ORAL
Initial or P	rolonged	Decreased	Health			

Professional

Other

Alcohol

SS

Intentional Self-Injury Overdose

Somnolence

Chest Pain

Date: 08/02/05ISR Number: 4736412-6Report Type: Expedited (15-DaCompany Report #ACO_0141_2005

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

Dose

Duration

Other

DF

Outcome

PT

Hypoaesthesia

Peripheral Coldness

I/FU:I

Health

Foreign

Report Source

Professional

Other

Date:08/03/05ISR Number: 4735833-5Report Type:Direct

Gender:Male Age:

Outcome

PT

Duration

Dose Other

4MG TID

Pharmaceutical Product

Complaint Vomiting

Report Source

Company Report #CTU 255403

Product Zanaflex

Product

Ternelin

Baclofen

Artane

С C

PS

PS

Role Manufacturer

Role Manufacturer

Route

Route

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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 Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death Hospitalization - Initial or Prolonged UNKNOWN	Abnormal Chest Sound Aggression Aspiration		Vioxx Flexeril Ultracet	PS SS SS	Merck & Co., Inc	ORAL ORAL
Other	Completed Suicide Depressed Level Of Consciousness Drug Interaction Drug Screen Positive Drug Toxicity Intentional Misuse Lung Crepitation Lung Disorder Sedation Self-Medication Vomiting		Omeprazole Elavil Tizanidine Hydrochloride	SS SS SS		ORAL ORAL

Date:08/16/05ISR Number: 4746208-7Report Type:Expedited (15-DaCompany Report #CH-MERCK-0409CHE00009

Age:60 YR Gender:Female I/FU:F

Dyspnoea

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration	on					
Hospitalization - 8 DAY	Abdominal Pain		Vioxx	PS	Merck & Co., Inc	ORAL
Initial or Prolonged	Alanine Aminotransferase		Tizanidine			
_	Increased		Hydrochloride	SS		ORAL
1 DAY						
	Aspartate		Tizanidine			
	Aminotransferase		Hydrochloride	SS		ORAL
1 DAY						
	Increased		Tizanidine			
	Back Pain		Hydrochloride	SS		ORAL
1 DAY						
	Blood Alkaline		Diclofenac Sodium	SS		ORAL
	Phosphatase Increased		Herbs (Unspecified)	С		ORAL
	Bradycardia					
	Chest Discomfort					
	Diarrhoea					
	Drug Interaction					

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 P

Other Abdominal Discomfort

Gastrointestinal

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Freedom Of Information (FOI) Report

Product

Ambien

Role Manufacturer

PS

Route

ORAL

Haemorrhage

Duration

Dose

UNK						
UNK			Plavix	SS		ORAL
UNK			Carafate	SS		ORAL
UNK			Metoclopramide	SS		ORAL
			Darvocet	SS		ORAL
UNK			Mycelex	SS		
UNKNOWN U	NK		Promethazine	SS		ORAL
UNK			Lasix	SS		ORAL
UNK			Tizanidine	SS		ORAL
UNK						
	:Female I/FU:I	:Expedited (15-DaCompany Rep				
Outcome Dose Durat	PT ion	Report Source	Product	Role	Manufacturer	Route
Other	Abdominal Discomfort Gastrointestinal		Lasix	PS	Aventis Pharmaceuticals Inc.	ORAL
dose: UNKNOWN			Ambien	SS	That made at 10 at 11 at	ORAL
dose: UNKNOWN	Haemorrhage					
dose: UNKNOWN			Plavix	SS		ORAL
dose: UNKNOWN			Carafate	SS		ORAL
dose: UNKNOWN			Metoclopramide	SS		ORAL
dose: UNKNOWN						
ICOSE • UNKNOWN			Darvocet-N	SS		ORAL
			Darvocet-N Mycelex	SS SS		ORAL
dose: UNKNOWN						ORAL
			Mycelex	SS		

Report Source

Role Manufacturer

ORAL

Route

dose: UNKNOWN

Outcome

Date:08/19/05ISR Number: 4749387-OReport Type:Expedited (15-DaCompany Report #CH-MERCK-0409CHE00009

Age:60 YR Gender:Female I/FU:F

PT

Dose	Duration					
Hospi	italization -	Bradycardia	Vioxx	PS	Merck & Co., Inc	ORAL
8	DAY					
Initi	ial or Prolonged	Hepatic Enzyme Increased	Tizanidine			
i			Hydrochloride	SS		ORAL
1	DAY					
i			Tizanidine			
i			Hydrochloride	SS		ORAL
1	DAY					
			Tizanidine			
ı			Hydrochloride	SS		ORAL
1	DAY					
			Diclofenac Sodium	SS		ORAL
			Herbs (Unspecified)	С		ORAL

Product

Report Source

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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

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