



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Center for Drug Evaluation and Research
Office of Regulatory Policy
Division of Information Disclosure Policy
5600 Fishers Lane, HFD-13
Rockville, Maryland 20857

August 25, 2005

In Response Refer to File: F05-8456

ProCon.Org
ATTN: Jeffrey Yablan
100 Wilshire Blvd., 3rd Floor
Santa Monica, CA 90401

Dear Mr. Yablan,

This is in response to your letter of 6/24/05, in which you requested adverse events associated with the use of Compazine. Your request was received in the Center for Drug Evaluation and Research on 6/28/05.

Please find the enclosed data which summarizes reports of events to the above mentioned drug(s). This data contains only reports of adverse events which have been entered into the computerized filing system maintained by the Office of Drug Safety. This AERS report may include duplicate reports (e.g., more than one report for the same adverse event).

Charges of \$74.00 (Search \$19.00, Review \$, Reproduction \$, Computer time \$55.00) will be included in a monthly invoice. **DO NOT SEND ANY PAYMENT UNTIL YOU RECEIVE AN INVOICE.**

If there are any problems with this response, please notify us in writing of your specific problem(s). Please reference the above file number.

This concludes the response from the Center for Drug Evaluation and Research.

Sincerely,

Harold D. Stepper

Paralegal Specialist
Office of Regulatory Policy
Division of Information Disclosure Policy, HFD-13

Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

**Selections for: PHENOTHIAZINE
 COMPАЗINE**

From: 01-NOV-1997 To: Present

Disclaimer: The information contained in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of adverse drug reactions.

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 11/13/97	ISRN Number: 3005939-X	Report Type: Direct	Company Report#:	Age: 61 YR	Gender: Male	I/FU: 1
Outcome: Disability	PT: Hallucination		Report Source: Health Professional	Route: INTRAVENOUS	Dose: 10 MG- 15 MG Q 4 H PRN IV	Duration:
			Product: Compazine	Manufacturer: Sfb	Role: PS	
Date: 11/17/97	ISRN Number: 3013936-3	Report Type: Direct	Company Report#:	Age: 36 YR	Gender: Male	I/FU: 1
Outcome:	PT: Dyskinesia		Report Source: Compazine	Route: INTRAVENOUS	Dose: 10MG IV PRN ; PRN USE	Duration:
			Product: Compazine	Manufacturer:	Role: PS	
Date: 11/24/97	ISRN Number: 3005391-4	Report Type: Direct	Company Report#:	Age: 22 YR	Gender: Female	I/FU: 1
Outcome: Hospitalization - Initial or Prolonged	PT: Dystonia		Report Source: Compazine	Route:	Dose:	Duration:
			Product: Compazine	Manufacturer:	Role: PS	
Date: 11/25/97	ISRN Number: 3006153-4	Report Type: Direct	Company Report#:	Age: 34 YR	Gender: Male	I/FU: 1
Outcome: Hospitalization - Initial or Prolonged	PT: No Adverse Drug Effect		Report Source:	Route:	Dose: 25 MG X 1 SUPPOSITORY	Duration:
			Product: Compazine	Manufacturer: Smithkline Beecham	Role: PS	
Date: 11/26/97	ISRN Number: 3003406-0	Report Type: Expedited (15-Day)	Company Report#: 97027200-1	Age: 43 YR	Gender: Female	I/FU: 1
Outcome: Other	PT: Abortion Spontaneous Anxiety Muscle Rigidity Tardive Dyskinesia Vaginal Haemorrhage		Report Source: Consumer	Route: ORAL	Dose: 5MG 2 DAILY ORAL 10MG 2 DAILY ORAL	Duration: 2 DAY 2 DAY
			Product: Compazine	Manufacturer: Smithkline Beecham	Role: PS	
			Product: Compazine	Manufacturer: Smithkline Beecham	Role: SS	
Date: 12/01/97	ISRN Number: 3006473-3	Report Type: Direct	Company Report#:	Age:	Gender: Female	I/FU: 1
Outcome: Hospitalization - Initial or Prolonged	PT: Hypoaesthesia Hypoaesthesia Oral		Report Source:	Route: INTRAVENOUS DRIP	Dose: 25MG/ LITER OF D5LR 125CC PER HOUR	Duration:
			Product: Compazine	Manufacturer: Smithkline Baccham	Role: PS	
			Product: Compazine	Manufacturer: Smithkline Beecham	Role: PS	
			Product: Dsr1		Role: C	

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 12/02/97	ISR Number: 3007011-1	Report Type: Direct	Company Report#:	Age:	Gender: Female	I/FU: I
Outcome Other	PT Speech Disorder Tongue Oedema		Report Source Compazine	Route INTRAVENOUS	Dose 5 MG	Duration
Date: 12/03/97	ISR Number: 3007287-0	Report Type: Direct	Company Report#:	Age: 29 YR	Gender: Female	I/FU: I
Outcome Hospitalization - Initial or Prolonged	PT Dyskinesia Dystonia Muscle Twitching Vision Blurred		Report Source Compazine Questran Levsin	Route	Dose	Duration
Date: 12/22/97	ISR Number: 3012612-0	Report Type: Expedited (15-Day)	Company Report#: D/97/04078/LEX	Age: 33 YR	Gender: Female	I/FU: I
Outcome Life-Threatening Hospitalization - Initial or Prolonged	PT Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Urea Increased Hepatic Failure Lipid Metabolism Disorder Prothrombin Level Increased		Report Source Health Professional	Route ORAL OCCLUSIVE DRESSING ORAL	Dose 100MG 2MG	Duration
Date: 01/07/98	ISR Number: 3016113-5	Report Type: Expedited (15-Day)	Company Report#: 8-97307-001D	Age: 31 YR	Gender: Female	I/FU: I
Outcome Hospitalization - Initial or Prolonged Other	PT Caiatonia Diplopia Oculogyration Overdose Tachycardia Vision Blurred		Report Source Health Professional	Route INTRAVENOUS INTRAVENOUS INTRAVENOUS	Dose 75 MG DAILY INCREASED TO 100 MG DAILY 50 MG "SEVERAL DOSE OF COMAPZINE" IM	Duration 8 WK
Date: 02/03/98	ISR Number: 3028919-7	Report Type: Direct	Company Report#:	Age: 32 YR	Gender: Female	I/FU: I
Outcome Hospitalization - Initial or Prolonged	PT Feeling Jittery		Report Source Compazine Atenolol Demerol	Route	Dose INJ	Duration

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 02/06/98	ISR Number: 3028479-0	Report Type: Direct	Company Report#:	Age:	Gender: Female	I/FU: 1
Outcome Hospitalization - Initial or Prolonged	PT Hyperhidrosis Pain In Jaw	Report Source	Product Compazine Leucovorin Fluorouracil	Role PS C C	Manufacturer	Dose 10MG PO Duration
Date: 02/17/98	ISR Number: 3031003-X	Report Type: Expedited (15-Day)	Company Report#: D/98/00338/LEX	Age: 49 YR	Gender: Male	I/FU: F
Outcome Death Other	PT Cachexia Renal Cell Carcinoma Stage Unspecified	Report Source Health Professional	Product Leponex Tavor Fluanxol Taxilan Eunerpan N/A N/A	Role PS SS SS SS SS C C	Manufacturer	Dose 750 MG 3 MG 25 MG 200 MG 100 MG Duration 10 YR 10 YR 10 YR
Date: 02/26/98	ISR Number: 3039785-8	Report Type: Direct	Company Report#:	Age: 14 YR	Gender: Female	I/FU: 1
Outcome Other	PT Nightmare	Report Source Health Professional	Product Compazine Skelaxin	Role PS SS	Manufacturer	Dose 10 MG PO Q 6 400 MG Q 4 HRS WHILE AWAKE Duration
Date: 03/24/98	ISR Number: 3068923-6	Report Type: Expedited (15-Day)	Company Report#: 1998006925-1	Age: 40 YR	Gender: Female	I/FU: 1
Outcome Life-Threatening	PT Bruxism Heart Rate Increased Hyperhidrosis Muscle Contractions Involuntary Muscle Rigidity Pharyngeal Oedema Post-Traumatic Stress Disorder Tremor Trismus Urinary Incontinence	Report Source Consumer	Product Compazine Prozac Versed	Role PS C C	Manufacturer Smithkline Beecham	Dose INTRA VENOUS Duration INTRA VENOUS
Date: 03/27/98	ISR Number: 3060685-1	Report Type: Expedited (15-Day)	Company Report#: 8-97176-006S	Age: 1 DY	Gender: Female	I/FU: F
Outcome Death Hospitalization - Initial or Prolonged Congenital Anomaly	PT Calcinosis Chromosome Abnormality Cleft Palate Congenital Anomaly Facial Dysmorphism Fallot'S Tetralogy Hemihypertrophy Infant	Report Source	Product			

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Multiple Congenital Abnormalities	<u>Report Source</u> Consumer Other	<u>Product</u> Pondimin / Phentermine	<u>Role</u> PS	<u>Manufacturer</u>	<u>Route</u> TRANSPLACENTAL TRANSPLACENTAL L L	<u>Dose</u> L	<u>Duration</u> TRANSPLACENTAL TRANSPLACENTAL L L
Oesophageal Atresia		Phentermine	SS				
Ovarian Atrophy		Compazine	SS				3 WK
Prophy/laxis		Progestin	SS				

Date: 03/31/98 **ISR Number:** 3062095-X **Report Type:** Direct **Company Report#:** **Age:** **Gender:** **I/FU:** I

<u>Outcome</u>	<u>PT</u> Extrapyramidal Disorder	<u>Report Source</u>	<u>Product</u> Compazine	<u>Role</u> PS	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>

Date: 04/07/98 **ISR Number:** 3071823-9 **Report Type:** Direct **Company Report#:** **Age:** **Gender:** Female **I/FU:** I

<u>Outcome</u>	<u>PT</u> Condition Aggravated Confusional State Depressed Level Of Consciousness Disorientation Memory Impairment	<u>Report Source</u>	<u>Product</u> Compazine Phentoin Busulfan Morphine Sulfate	<u>Role</u> PS C C C	<u>Manufacturer</u>	<u>Route</u> INTRAVENOUS	<u>Dose</u> 10MG IV Q6 DEGREES	<u>Duration</u>
Other								

Date: 04/15/98 **ISR Number:** 3071712-X **Report Type:** Direct **Company Report#:** **Age:** 43 YR **Gender:** Female **I/FU:** I

<u>Outcome</u>	<u>PT</u> Asthemia Dizziness Hypertension Vision Blurred	<u>Report Source</u>	<u>Product</u> Compazine Levaguin Mesalamine Deltason Zolof	<u>Role</u> PS C C C C	<u>Manufacturer</u>	<u>Route</u> ORAL	<u>Dose</u> 10 MG PO Q DEGREES	<u>Duration</u>
Other								

Date: 04/20/98 **ISR Number:** 3065264-8 **Report Type:** Expedited (15-Day) **Company Report#:** JAGER-38649 **Age:** 29 YR **Gender:** Male **I/FU:** I

<u>Outcome</u>	<u>PT</u> Aspiration Blood Creatine Phosphokinase Increased Somnolence Suicide Attempt Tachycardia	<u>Report Source</u> Foreign Health Professional	<u>Product</u> Risperdal Biperiden Taxilan Neogama Deprilept	<u>Role</u> PS SS SS SS SS	<u>Manufacturer</u> Janssen	<u>Route</u> ORAL ORAL ORAL PO	<u>Dose</u> ORAL ORAL ORAL PO	<u>Duration</u>
Other								

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 04/20/98 ISR Number: 3066560-0 Report Type: Expedited (15-Day) Company Report#: JAGER-38649

<u>Outcome</u> Other	<u>PT</u> Aspiration Blood Creatine Phosphokinase Increased Somnolence Suicide Attempt Tachycardia	<u>Report Source</u> Foreign Health Professional	<u>Product</u> Risperidal Bisperiden Taxilan Neogama Deprilept	<u>Role</u> PS SS SS SS SS	<u>Manufacturer</u>	<u>Route</u> ORAL ORAL ORAL ORAL ORAL	<u>Dose</u> ORAL ORAL ORAL ORAL ORAL	<u>Duration</u>	<u>Gender: Male</u>	<u>Age: 29 YR</u>	<u>I/FU: 1</u>
-------------------------	--	---	---	---	---------------------	--	---	-----------------	---------------------	-------------------	----------------

Date: 04/27/98 ISR Number: 3068966-2 Report Type: Expedited (15-Day) Company Report#: AM98030051

<u>Outcome</u> Hospitalization - Initial or Prolonged Other	<u>PT</u> Blood Glucose Increased Cholelithiasis Dysphagia Flushing Hepatic Function Abnormal Hepatic Steatosis Increased Viscosity Of Bronchial Secretion Mucosal Inflammation Nausea Retching Vomiting	<u>Report Source</u> Study Health Professional	<u>Product</u> Ethyol Compazine Carboplatin Injectable Ethyol/Placebo Soluble Powder Radiation Therapy Kytril Injectable Prilosec Reflux Morphine Sulfate Alka-Seltzer Pm	<u>Role</u> PS SS SS SS C C C C C C	<u>Manufacturer</u>	<u>Route</u> INTRAVENOUS INTRAVENOUS INTRAVENOUS INTRAVENOUS	<u>Dose</u> 660 MG INTRAVENOUS 25 MG PRN RECTAL 155 MG INTRAVENOUS 440 MG INTRAVENOUS	<u>Duration</u>	<u>Gender: Male</u>	<u>Age: 44 YR</u>	<u>I/FU: F</u>
--	--	---	---	---	---------------------	--	---	-----------------	---------------------	-------------------	----------------

Date: 04/29/98 ISR Number: 3078822-1 Report Type: Direct

<u>Outcome</u>	<u>PT</u> Diabetic Ketoacidosis Nausea Torticollis Vomiting	<u>Report Source</u>	<u>Product</u> Compazine	<u>Role</u> PS	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>	<u>Gender:</u>	<u>Age:</u>	<u>I/FU: 1</u>
----------------	---	----------------------	-----------------------------	-------------------	---------------------	--------------	-------------	-----------------	----------------	-------------	----------------

Date: 05/04/98 ISR Number: 3164291-X Report Type: Periodic

<u>Outcome</u> Life-Threatening	<u>PT</u> Catatonia Muscle Spasms	<u>Report Source</u> Consumer Health Professional	<u>Product</u> Compazine Percocet (Acetaminophen And Oxycodone Hydrochloride)	<u>Role</u> PS C	<u>Manufacturer</u> Smithkline Beecham	<u>Route</u> RECTAL	<u>Dose</u> 25 MILLIGRAMS 1.0 DAILY RECTAL	<u>Duration</u> 1 DAY	<u>Gender: Female</u>	<u>Age: 15 YR</u>	<u>I/FU: 1</u>
------------------------------------	---	--	--	------------------------	---	------------------------	---	--------------------------	-----------------------	-------------------	----------------

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Gait Disturbance Mental Disorder Nausea Overdose Pain Sedation Thinking Abnormal	<u>Report Source</u>	<u>Product</u> Percocet Ms Contin Compazine	<u>Role</u> PS SS SS	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u> 1-2 TABLETS EVERY 4 HOURS 90 MG PO BID TWICE A DAY 10 MG TWICE A DAY	<u>Duration</u>
Date: 08/10/98 ISR Number: 3114888-8 Report Type: Expedited (15-Day) Company Report#: 1998019891-1							
Outcome Hospitalization - Initial or Prolonged	<u>Report Source</u> Consumer	<u>Product</u> Compazine	<u>Role</u> PS	<u>Manufacturer</u> Smithkline Beecham	<u>Route</u> INTRAVENOUS	<u>Dose</u> 10 MILLIGRAMS 1.0 DAILY INTRAVENOUS	<u>Duration</u> 1 DAY
Date: 08/31/98 ISR Number: 3124173-6 Report Type: Expedited (15-Day) Company Report#: JAUSA-29522							
Outcome Death	<u>Report Source</u> Consumer	<u>Product</u> Duragesic Demerol Nubain Vistaril Phenergan Compazine Synthroid	<u>Role</u> PS SS SS SS SS SS C	<u>Manufacturer</u> Janssen	<u>Route</u> TRANSDERMAL	<u>Dose</u> 50 MCG/HR TRANSDERMAL	<u>Duration</u>
Date: 09/08/98 ISR Number: 3126987-5 Report Type: Expedited (15-Day) Company Report#: 8-98181-018A							
Outcome Life-Threatening Hospitalization - Initial or Prolonged Disability Required Intervention to Prevent Permanent Impairment/Damage	<u>Report Source</u> Health Professional	<u>Product</u> Phenergan Compazine Compazine	<u>Role</u> PS SS C	<u>Manufacturer</u>	<u>Route</u> INTRAMUSCULAR RECTAL	<u>Dose</u> ONE 8 MG DOSE I.M.; INJECTION ONE 2.5 MG DOSE RECTAL; SUPPOSITORY	<u>Duration</u>
Date: 09/17/98 ISR Number: 3131735-9 Report Type: Expedited (15-Day) Company Report#: 980266							
Outcome Death Hospitalization - Initial or Prolonged	<u>Report Source</u> Health Professional	<u>Product</u> Ms Contin Ct Daltmane (Flurazepam) Vicodin (Hydrocodone/Aceta minophen)	<u>Role</u> PS SS SS	<u>Manufacturer</u>	<u>Route</u> ORAL ORAL ORAL	<u>Dose</u> PO PO PO	<u>Duration</u>

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

<p>Date: 10/26/98 ISR Number: 3147707-4 Report Type: Expedited (15-Day) Company Report#: B042005 Age: 49 YR Gender: Female I/FU: 1</p>									
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>	
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Coma Depression Laboratory Test Abnormal Lactic Acidosis Renal Impairment Sedation Shock Suicide Attempt	Foreign Health Professional	Glucophage Carbamate Benzodiazepines Phenothiazine Glucor Zolof Terican Equamil Laroxyl Valium	PS SS SS SS C C C C C C C		ORAL	ORAL		
<p>Date: 11/16/98 ISR Number: 3158246-9 Report Type: Expedited (15-Day) Company Report#: TIC980001 Age: 39 YR Gender: Female I/FU: 1</p>									
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>	
Hospitalization - Initial or Prolonged Other	Tardive Dyskinesia	Health Professional	Tigan Compazine Fluoxetine Hcl	PS SS C		ORAL ORAL	250MG QD PO 10MG QD PO		
<p>Date: 12/09/98 ISR Number: 3169827-0 Report Type: Direct Company Report#: Age: Gender: I/FU: 1</p>									
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>	
Hospitalization - Initial or Prolonged Other	Muscle Rigidity	Health Professional	Compazine	PS		INTRAVENOUS	10 MG IV X 1		
<p>Date: 12/21/98 ISR Number: 3172546-8 Report Type: Direct Company Report#: Age: 35 YR Gender: Female I/FU: 1</p>									
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>	
Life-Threatening	Bradycardia Chest Pain Hypotension	Health Professional	Compazine	PS		INTRAVENOUS	10 MG IV X 1		
<p>Date: 01/07/99 ISR Number: 3178220-6 Report Type: Expedited (15-Day) Company Report#: 1998031062-1 Age: 59 YR Gender: Male I/FU: 1</p>									
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>	
Death	Cardiac Arrest Coma Hepatic Steatosis Medication Error	Health Professional	Compazine Lorazepam Benzodiazepine	PS C C		INTRAVENOUS	25 MILLIGRAMS INTRAVENOUS		
<p>Date: 02/04/99 ISR Number: 3192022-6 Report Type: Expedited (15-Day) Company Report#: 1999002265-1 Age: 30 YR Gender: Male I/FU: 1</p>									
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>	
Hospitalization - Initial or Prolonged Disability	Gangrene Medication Error Skin Discolouration	Health Professional	Compazine	PS	Smithkline Beecham				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date: 02/05/99 ISR Number: 3199375-3 Report Type: Periodic Company Report#: FLUV002980073									
<u>Outcome</u> Other	<u>PT</u> Clonic Convulsion Hypertonia Muscle Rigidity Nausea Tremor Trismus	<u>Report Source</u> Health Professional	<u>Product</u> Lavox Compazine (Prochlorperazine Edisylate)	<u>Role</u> PS SS	<u>Manufacturer</u>	<u>Route</u> ORAL ORAL	<u>Dose</u> 100 MG, PER ORAL 10 MG, PER ORAL	<u>Gender:</u> Female	<u>IFU:</u> I
Date: 02/19/99 ISR Number: 3202225-X Report Type: Direct Company Report#:									
<u>Outcome</u> Hospitalization - Initial or Prolonged	<u>PT</u> Dystonia Overdose	<u>Report Source</u>	<u>Product</u> Compazine Lomotil	<u>Role</u> PS C	<u>Manufacturer</u> Skb Pharm	<u>Route</u> ORAL	<u>Dose</u> 10MG Q6H PRN PO	<u>Gender:</u> Female	<u>IFU:</u> I
Date: 02/22/99 ISR Number: 3205270-3 Report Type: Expedited (15-Day) Company Report#: 1999003881-1									
<u>Outcome</u> Hospitalization - Initial or Prolonged	<u>PT</u> Asthenia Feeling Jittery Tremor	<u>Report Source</u> Health Professional	<u>Product</u> Compazine Smithkline Beecham	<u>Role</u> PS	<u>Manufacturer</u> Smithkline Beecham	<u>Route</u> INTRAVENOUS	<u>Dose</u> 5 MILLIGRAMS INTRAVENOUS	<u>Gender:</u> Female	<u>IFU:</u> I
Date: 02/25/99 ISR Number: 3207919-8 Report Type: Direct Company Report#:									
<u>Outcome</u> Hospitalization - Initial or Prolonged	<u>PT</u> Dystonia Muscle Rigidity Poisoning Deliberate	<u>Report Source</u> Health Professional	<u>Product</u> Carborator Fluid Haldol Phenothiazine	<u>Role</u> PS SS SS	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Gender:</u> Male	<u>IFU:</u> I
Date: 03/01/99 ISR Number: 3208269-6 Report Type: Direct Company Report#: 52065									
<u>Outcome</u> Other	<u>PT</u> No Adverse Drug Effect	<u>Report Source</u>	<u>Product</u> Compazine (Prochlorperazine) Neosynephrine 10% (Phenylephrine Hcl)	<u>Role</u> PS SS	<u>Manufacturer</u> Elkins-Sinn Amer Regent Lab	<u>Route</u>	<u>Dose</u> INJECTABLE INJECTABLE	<u>Gender:</u>	<u>IFU:</u> I
Date: 03/08/99 ISR Number: 3214084-X Report Type: Direct Company Report#:									
<u>Outcome</u>	<u>PT</u> Dyspnoea Feeling Abnormal Oculogyration Tremor	<u>Report Source</u>	<u>Product</u> Compazine	<u>Role</u> PS	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u> 10MG	<u>Gender:</u>	<u>IFU:</u> I

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 03/08/99	ISRN Number: 3214564-7	Report Type: Periodic	Company Report#: 99-10-276-1	Age: 34 YR	Gender: Female	IFU: I
Outcome Hospitalization - Initial or Prolonged	PT Chest Pain Dyspnoea Eye Disorder Joint Stiffness	Report Source Other	Product Compazine Tablets	Route ORAL	Dose 10 MG SINGLE PO	Duration
				Role PS	Manufacturer	
Date: 03/10/99	ISRN Number: 3219763-6	Report Type: Periodic	Company Report#: USA000022	Age: 70 YR	Gender: Male	IFU: I
Outcome Hospitalization - Initial or Prolonged	PT Agitation Drug Dependence Hallucination Nervousness Psychomotor Hyperactivity	Report Source Consumer Other	Product Vicodin Compazine Zoloft Nifedipine	Route	Dose	Duration
				Role PS SS C C	Manufacturer	
Date: 03/16/99	ISRN Number: 3221728-5	Report Type: Expedited (15-Day)	Company Report#: 1998031062-1	Age: 59 YR	Gender: Male	IFU: F
Outcome Death Other	PT Alcohol Withdrawal Syndrome Anoxia Apnoea Cardio-Respiratory Arrest Coma Convulsion Cyanosis Encephalopathy Medication Error Metabolic Disorder Nervous System Disorder Obstructive Airways Disorder Oxygen Saturation Decreased	Report Source Health Professional	Product Compazine Lorazepam Librium (Chlordiazepoxide Hcl) Zoloft (Sertraline) Verapamil Altace (Ramipril) Antibiotics (Nos) Morphine Sulfate	Route INTRAVENOUS	Dose 25 MILLIGRAMS INTRAVENOUS	Duration
				Role PS C C C C C C	Manufacturer	
Date: 03/18/99	ISRN Number: 3223519-8	Report Type: Direct	Company Report#:	Age: 91 YR	Gender: Female	IFU: I
Outcome Hospitalization - Initial or Prolonged	PT Depressed Level Of Consciousness Drug Level Above Therapeutic Encephalopathy Mental Impairment Urinary Incontinence	Report Source Health Professional	Product Phenothiazine	Route	Dose	Duration
				Role PS	Manufacturer	
Date: 03/22/99	ISRN Number: 3312152-5	Report Type: Periodic	Company Report#: USA007193	Age: 31 YR	Gender: Female	IFU: I
Outcome	PT Aphasia Asthenia					

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Blood Pressure Increased
Cold Sweat
Drooling
Feeling Hot
Headache
Insomnia
Nausea
Sedation
Tinnitus

Report Source
Consumer

Product
Meridia
Compazine
Iron
Vitamin

Role
PS
SS
C
C

Manufacturer

Route
ORAL
INTRAVENOUS

Dose
15 MG OD PO
10 MG IV

Duration

Date: 03/25/99 **ISR Number:** 3226360-5 **Report Type:** Direct **Company Report#:** **Age:** 61 YR **Gender:** Female **IFU:** I

Outcome
Hospitalization -
Initial or Prolonged
Required
Intervention to
Prevent Permanent
Impairment/Damage

PT
Dystonia

Report Source

Product
Compazine

Role
PS

Manufacturer
Srb Pharm

Route
INTRAMUSCULAR

Dose
Q8H IM

Duration

Date: 03/29/99 **ISR Number:** 3228437-7 **Report Type:** Direct **Company Report#:** **Age:** 69 YR **Gender:** Male **IFU:** I

Outcome
Hospitalization -
Initial or Prolonged

PT
Difficulty In Walking
Lethargy
Nausea
Oedema Peripheral

Report Source

Product
Compazine 10mg Po
Procrbazine

Role
PS
C

Manufacturer

Route
ORAL

Dose
10MG PO

Duration

Date: 04/16/99 **ISR Number:** 3240566-0 **Report Type:** Direct **Company Report#:** **Age:** 61 YR **Gender:** Male **IFU:** I

Outcome
Required
Intervention to
Prevent Permanent
Impairment/Damage

PT
Hypotension
Oedema Peripheral
Oxygen Saturation
Decreased
Tachycardia

Report Source

Product
Demerol
Compazine 100mg Po Q
6h
Zithrimix->Rouphine
Atenolol
Hydrea
Refles
Glucotrol

Role
PS
SS
C
C
C
C

Manufacturer

Route
ORAL
ORAL

Dose
25MG PO
100MG PO Q 6H

Duration

Date: 04/16/99 **ISR Number:** 3241730-7 **Report Type:** Expedited (15-Day) **Company Report#:** 1999008016-1 **Age:** **Gender:** Female **IFU:** I

Outcome
Hospitalization -
Initial or Prolonged

PT
Ill-Defined Disorder

Report Source
Consumer

Product
Compazine

Role
PS

Manufacturer
Smithkline Beecham

Route
ORAL

Dose
15 MILLIGRAMS

Duration

Date: 04/21/99 **ISR Number:** 3244475-2 **Report Type:** Expedited (15-Day) **Company Report#:** R039060 **Age:** **Gender:** Female **IFU:** I

Outcome
Hospitalization -
Initial or Prolonged

PT
Asthenia
Confusional State

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Coordination Abnormal	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hypoesthesia	Study	Taxol Inj	PS		INTRAVENOUS	IV	1 DAY
Hypotension	Health	Paraplatin Inj	SS		INTRAVENOUS	IV	1 DAY
Oesophageal Candidiasis	Professional	Navelbine	SS		INTRAVENOUS	IV	1 DAY
Po2 Decreased		Amiodarone	SS				
Respiratory Distress		Halcion	SS				
Sepsis		Compazine	SS				
White Blood Cell Count Decreased							

Date: 04/27/99 **ISR Number:** 3251696-1 **Report Type:** Periodic **Company Report#:** 1998020443-1 **Age:** 74 YR **Gender:** Female **I/FU:** 1

Outcome Life-Threatening Hospitalization - Initial or Prolonged	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
	Health Professional	Compazine Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	10 MG INTRAVENOUS	1 DAY

Date: 04/27/99 **ISR Number:** 3251699-7 **Report Type:** Periodic **Company Report#:** 1998027240-1 **Age:** 25 YR **Gender:** Male **I/FU:** 1

Outcome Hospitalization - Initial or Prolonged	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
	Consumer	Compazine Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	1 DAILY INTRAVENOUS	1 DAY

Date: 04/27/99 **ISR Number:** 3251710-3 **Report Type:** Periodic **Company Report#:** 1998027460-1 **Age:** 39 YR **Gender:** Female **I/FU:** 1

Outcome Hospitalization - Initial or Prolonged	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
	Health Professional	Compazine Prozac Tigan	PS C C	Smithkline Beecham	ORAL	10 MG ORAL	1 DAY

Date: 05/04/99 **ISR Number:** 3252803-7 **Report Type:** Direct **Company Report#:** **Age:** 23 YR **Gender:** Female **I/FU:** 1

Outcome Dyskinesia Dystonia Jaw Disorder Tongue Disorder	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
	Health Professional	Compazine Roche	PS	Roche	INTRAMUSCULAR IM		

Date: 05/04/99 **ISR Number:** 3253295-4 **Report Type:** Expedited (15-Day) **Company Report#:** 1999068016-1 **Age:** **Gender:** Female **I/FU:** F

Outcome Hospitalization - Initial or Prolonged	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
	Consumer	Compazine Smithkline Beecham	PS	Smithkline Beecham	ORAL	15 MILLIGRAMS ORAL	

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 06/04/99		ISRN: 3276396-3	Report Type: Expedited (15-Day)	Company Report#: 9921836	Age: 60 YR	Gender: Female	I/FU: I
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Disability Required Intervention to Prevent Permanent Impairment/Damage	Condition Aggravated Decreased Appetite Fatigue Headache Nausea	Consumer	Marax Tablets Compazine Proventil Inhaler Lipitor Capoten Hydrochlorothiazide	PS SS C C C C		ORAL	2.00 TOTAL: BID: ORAL
Date: 06/15/99		ISRN: 3284148-3	Report Type: Direct	Company Report#:	Age: 22 YR	Gender: Female	I/FU: I
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Dystonia Tardive Dyskinesia	Health Professional	Metoclopramide Compazine	PS SS		INTRAVENOUS INTRAVENOUS	10 MG IV Q6H PRN 10 MG IV Q6H PRN
Date: 06/21/99		ISRN: 3286449-1	Report Type: Direct	Company Report#:	Age:	Gender:	I/FU: I
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Agitation Dystonia		Compazine	Compazine	PS			
Date: 06/23/99		ISRN: 3289984-5	Report Type: Expedited (15-Day)	Company Report#: 9921836	Age: 60 YR	Gender: Female	I/FU: F
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Disability Required Intervention to Prevent Permanent Impairment/Damage	Abnormal Behaviour Decreased Appetite Drug Dependence Fatigue Headache Nausea	Consumer Health Professional	Marax Tablets Compazine Proventil Inhaler Lipitor Capoten Hydrochlorothiazide	PS SS C C C C		ORAL	2.00 TOTAL: BID: ORAL
Date: 06/29/99		ISRN: 3294465-9	Report Type: Direct	Company Report#:	Age: 50 YR	Gender: Female	I/FU: I
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Death Life-Threatening Hospitalization - Initial or Prolonged	Asthma Atrial Fibrillation Atrial Flutter Cardiac Disorder Chest Pain Dyspnoea Ejection Fraction Abnormal Hypotension Myocardial Infarction Phaeochromocytoma Pulmonary Oedema						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Renal Failure Acute Rhabdomyolysis	<u>Report Source</u> Health Professional	<u>Product</u> Compazine Toradol	<u>Role</u> PS C	<u>Manufacturer</u>	<u>Route</u> INTRAMUSCULAR	<u>Dose</u> 5MG IM	<u>Duration</u>
Date: 07/16/99 ISR Number: 3305686-0 Report Type: Expedited (15-Day) Company Report#: 1999016121-2							
<u>Outcome</u> Other	<u>Report Source</u> Health Professional	<u>Product</u> Compazine Beecham	<u>Role</u> PS	<u>Manufacturer</u> Smithkline Beecham	<u>Route</u> TRANSPACENTAL	<u>Dose</u> TRANSPACENTAL	<u>Duration</u> TRANSPACENTAL
PT Complications Of Maternal Exposure To Therapeutic Drugs Foetal Growth Retardation							
Date: 07/19/99 ISR Number: 3306382-6 Report Type: Expedited (15-Day) Company Report#: 1999016121-2							
<u>Outcome</u> Other	<u>Report Source</u> Health Professional	<u>Product</u> Compazine Beecham	<u>Role</u> PS	<u>Manufacturer</u>	<u>Route</u> TRANSPACENTAL	<u>Dose</u> TRANSPACENTAL	<u>Duration</u> TRANSPACENTAL
PT Complications Of Maternal Exposure To Therapeutic Drugs Foetal Growth Retardation							
Date: 07/27/99 ISR Number: 3311639-9 Report Type: Expedited (15-Day) Company Report#: 1999016121-2							
<u>Outcome</u> Congenital Anomaly	<u>Report Source</u> Health Professional	<u>Product</u> Compazine Smithkline Beecham	<u>Role</u> PS	<u>Manufacturer</u> Smithkline Beecham	<u>Route</u> TRANSPACENTAL	<u>Dose</u> 25 MILLIGRAMS 6.0 DAILY	<u>Duration</u> TRANSPACENTAL
PT Complications Of Maternal Exposure To Therapeutic Drugs Facial Dysmorphism Finger Deformity Foetal Growth Retardation Gynaecomastia Hirsutism Oligohydramnios Penis Disorder Small For Dates Baby							
Date: 08/13/99 ISR Number: 3324393-1 Report Type: Direct Company Report#: 1999016121-2							
<u>Outcome</u> Other	<u>Report Source</u> Health Professional	<u>Product</u> Compazine (Prochlorperazine)	<u>Role</u> PS	<u>Manufacturer</u>	<u>Route</u> RECTAL	<u>Dose</u> 25 MG SUPPOSITORY	<u>Duration</u>
PT Dyskinesia Extrapyramidal Disorder Muscle Rigidity Muscle Spasms Musculoskeletal Stiffness Pain In Jaw							

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 08/18/99		ISRN Number: 3327500-X	Report Type: Direct	Age: 53 YR	Gender: Male	I/FU: 1
Outcome	PT	Report Source	Product	Role	Manufacturer	Dose
	Medication Error		Vistaril (Hydroxyzine Pamoate) Compazine (Prochlorperazine)	PS SS	Pfizer Smithkline Beecham	
Company Report#:						
Date: 08/24/99		ISRN Number: 3333686-3	Report Type: Expedited (15-Day)	Age: 60 YR	Gender: Male	I/FU: 1
Outcome	PT	Report Source	Product	Role	Manufacturer	Dose
Death Life-Threatening Required Intervention to Prevent Permanent Impairment/Damage	Convulsion Foreign Body Aspiration Reflexes Abnormal	Foreign Health Professional	Haldol (2 Mg/Ml) Drops (Haloperidol) Taxilan (Perazine) Remergil (Mirtazapine) Valiquid (Diazepam)	PS SS SS SS		4 MG, 3 IN 1 DAY(S), ORAL 100 MG, 3 IN 1 DAY(S) 30 MG, 1 IN 1 DAY(S), ORAL 3.3 MG, 2 IN 1 DAY(S), ORAL
Company Report#:						
Date: 09/07/99		ISRN Number: 3341792-2	Report Type: Direct	Age: 22 YR	Gender: Female	I/FU: 1
Outcome	PT	Report Source	Product	Role	Manufacturer	Dose
Life-Threatening Hospitalization - Initial or Prolonged Other	Muscle Spasms Muscle Twitching Trismus	Health Professional	Compazine Supp Folic Acid Prenatal Vit Lamictal	PS C C C		PRN 25MG 1 DAY
Company Report#:						
Date: 09/07/99		ISRN Number: 3341795-8	Report Type: Direct	Age: 24 YR	Gender: Female	I/FU: 1
Outcome	PT	Report Source	Product	Role	Manufacturer	Dose
Life-Threatening Hospitalization - Initial or Prolonged Other	Dysarthria Dystonia Jaw Disorder Tongue Disorder	Health Professional	Compazine 5mg Naprosyn Pepcid	PS C C		PO Q4-6 HR PRN 2 DAY
Company Report#:						
Date: 09/15/99		ISRN Number: 3348335-8	Report Type: Expedited (15-Day)	Age: 43 YR	Gender: Female	I/FU: 1
Outcome	PT	Report Source	Product	Role	Manufacturer	Dose
Death	Aspiration Brain Damage Cardio-Respiratory Arrest Coordination Abnormal Dysarthria Extrapyramidal Disorder Feeling Abnormal Medication Error Muscle Twitching	Consumer Health Professional Other	Oxycontin Cr Tablets .80mg (Oxycodone Hydrochloride) Compazine (Prochlorperazine) Morphine Sulfate	PS SS C		80 MG BID PO IV

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 09/23/99		ISRN: 3355773-6	Report Type: Direct	Company Report#:	Age: 36 YR	Gender: Female	I/FU: 1
Outcome: Hospitalization - Initial or Prolonged	PT: Agitation Movement Disorder Musculoskeletal Stiffness Parkinsonian Gait	Report Source:	Product: Compazine (Prochlorperazine)	Role: PS	Manufacturer: Elkins-Si	Dose: 10MG IV 4-6HRS PRN	Duration: INTRA VENOUS
Date: 09/27/99		ISRN: 3358781-4	Report Type: Direct	Company Report#:	Age: 47 YR	Gender: Male	I/FU: 1
Outcome: Life-Threatening Hospitalization - Initial or Prolonged	PT: Electrocardiogram Qt Prolonged Ventricular Tachycardia	Report Source:	Product: Phenothiazine	Role: PS	Manufacturer:	Dose:	Duration:
Date: 09/30/99		ISRN: 3361261-3	Report Type: Direct	Company Report#:	Age: 52 YR	Gender: Female	I/FU: 1
Outcome: Other	PT: Rash Erythematous Rash Papular	Report Source: Health Professional	Product: Neupogen 359mcg Amgen	Role: PS	Manufacturer: Amgen	Dose: 359MCG QD IVPB OVER30 MINUTES	Duration: 2 DAY
Date: 10/05/99		ISRN: 3365057-8	Report Type: Expedited (15-Day)	Company Report#: 1999025849-1	Age:	Gender: Female	I/FU: 1
Outcome: Hospitalization - Initial or Prolonged Disability Other Required Intervention to Prevent Permanent Impairment/Damage	PT: Aphasia Decubitus Ulcer Deep Vein Thrombosis Demyelination Diarrhoea Faecal Incontinence Frequent Bowel Movements Hypersensitivity Hypertonia Nausea Neurogenic Bladder Oedema Genital Pyrexia Tracheostomy Urinary Incontinence	Report Source: Consumer	Product: Compazine Smithkline Beecham Dilaudid (Hydromorphone Hydrochloride) Zovirax (Aciclovir) Zinc Sulfate Oscal (Calcium) Bactrim Ds (Sulfamethoxazole/Tr imethoprim) Prednisone Multiple Vitamin W/O Minerals Heparin Prilosec (Omeprazole) Baclofen Neurontin (Gabapentin) Neurontin (Gabapentin) Vitamin E	Role: PS C C C C C C C C C C C C C C C	Manufacturer: Smithkline Beecham	Dose:	Duration:

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

FK506 (Tacrolimus) C
 Prednisone C
 Lasix (Furosemide) C
 Colace (Docusate Sodium) C
 Trazadone C

Date: 02/02/00 **ISR Number:** 3450190-2 **Report Type:** Direct **Company Report#:** **Age:** **Gender:** Female **IFU:** I
Outcome: Hospitalization - Initial or Prolonged Other **PT:** Respiratory Arrest **Report Source:** **Product:** Morphine Pca **Role:** PS **Manufacturer:** **Dose:** 1.5MG PCA QID 10MG IV 1330-1900 **Route:** INTRAVENOUS **Duration:**

Date: 02/09/00 **ISR Number:** 3455539-2 **Report Type:** Expedited (15-Day) **Company Report#:** 00P-062-0086630-00 (0) **Age:** 53 YR **Gender:** Male **IFU:** I

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Post Procedural Complication	Foreign Health Professional	Tranxilium (Tranxene) (Clorazepate Dipotassium)	PS		INTRAVENOUS	50 MG, 1 IN 1 D,	INTRAVENOUS
	Stevens-Johnson Syndrome		Doxycycline	SS		INTRAVENOUS	200 MG, 1 IN 1 D,	INTRAVENOUS
			Phenobarbital	SS		INTRAVENOUS	40 MG, 1 IN 1 D,	INTRAVENOUS
			Isopromethazine Hydrochloride	SS		INTRAVENOUS	50 MG, 1 IN 1 D,	INTRAVENOUS
			Heparin-Fraction, Sodium Salt	SS		INTRAVENOUS	500 MG, 1 IN 1 D,	INTRAVENOUS
			Acetylsalicylate Lysine	SS		SUBCUTANEOUS	20MG, 1 IN 1 S,	SUBCUTANEOUS
			Pethidine Hydrochloride	C		INTRAVENOUS	50 MG, 1 IN 1 D,	INTRAVENOUS
			Triflupromazine Aqua Ad Inj	C				
			Metronidazole (Metronidazole) Haes-Steril (Sodium, Hydroxyethylcellulose)	C				
			Suxamethonium Chloride (Suxamethonium Chloride)	C				
			Alcuronium Chloride	C				

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

(Alcuronium Chloride)	C
Fentanyl (Fentanyl Thiopental Sodium)	C
(Thiopental Sodium) Droperidol	C
(Droperidol) Enflurane	C
(Enflurane) Belladonna Alkaloids	C
(Belladonna Alkaloids) Furosemide	C
(Furosemide) Tramadol	C
Hydrochloride (Tramadol Hydrochloride)	C
Acetylcysteine (Acetylcysteine) Ranitidine	C
Hydrochloride (Ranitidine Hydrochloride)	C
Ake 1100 Mit Glucose (Glycerophosphate Sodium, Glucose Monohydrate, Amino Acids Nos,	C
Tutofusin (Vitamins Nos, Amino Acids Nos, Electrolytes Nos)	C
Sodium Chloride (Sodium Chloride) Dimetindene Maleate	C
(Dimetindene Maleate) Calcium Gluconate	C
(Calcium Gluconate)	C

Date: 02/15/00 ISR Number: 3458107-1 Report Type: Expedited (15-Day) Company Report#: HQ1878311OCT1999

Age: 24 YR Gender: Female I/FU: F

PT
 Amblyopia
 Asthenia
 Choreoathetosis
 Condition Aggravated
 Coordination Abnormal
 Copper Metabolism Disorder
 Decubitus Ulcer
 Deep Vein Thrombosis
 Delirium
 Demyelination
 Diarrhoea
 Dystonia
 Enlarged Clitoris
 Faecal Incontinence
 Fall

Outcome
 Hospitalization - Initial or Prolonged Disability

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Hallucination
 Head Injury
 Hypersensitivity
 Hypertonia
 Mental Impairment
 Muscle Twitching
 Nausea
 Neurogenic Bladder
 Pyrexia
 Rhonchi
 Sedation
 Speech Disorder
 Tremor
 Urinary Incontinence

Report Source
 Consumer

Product
 Reglan Injection
 Compazine
 Ativan Unspecified
 Colace
 Heparin
 Lasix
 Prednisone
 Tacrolimus
 Trazodone
 Tylenol

Manufacturer

Route

Dose

Duration

Date: 02/22/00 ISR Number: 3461923-2 Report Type: Direct

Company Report#:

Age: 39 YR Gender: Female I/FU: 1

Outcome
 Life-Threatening

PT
 Agitation
 Anaphylactic Shock
 Chest Discomfort
 Hyperhidrosis
 Hypertension
 Hypoxia
 Throat Tightness

Report Source

Product
 Compazine 10 Mg
 Ginko Biloba

Manufacturer

Role
 PS
 C

Route
 INTRAMUSCULAR

Dose
 IM 10MG X 1

Duration

Date: 02/22/00 ISR Number: 3461245-0 Report Type: Expedited (15-Day) Company Report#: 200003963-2

Age: 18 YR Gender: I/FU: 1

Outcome
 Congenital Anomaly

PT
 Complications Of Maternal Exposure To Therapeutic Drugs
 Congenital Anomaly

Report Source
 Health Professional

Product
 Compazine Smithkline Beecham

Manufacturer
 Smithkline Beecham

Role
 PS

Route
 TRANSPLACENTAL/TRANSPLACENTARY

Dose

Duration

Date: 02/24/00 ISR Number: 3461956-7 Report Type: Direct

Company Report#:

Age: 46 YR Gender: Male I/FU: 1

Outcome
 Required Intervention to Prevent Permanent Impairment/Damage

PT
 Exophthalmos
 Eye Movement Disorder
 Trismus

Report Source

Product
 Compazine Injection

Manufacturer

Role
 PS

Route

Dose

Duration

Date: 02/29/00 ISR Number: 3466434-7 Report Type: Direct

Company Report#:

Age: 29 YR Gender: Male I/FU: 1

Outcome
 Anaphylactic Reaction

PT
 Anaphylactic Reaction

Report Source

Product
 Motrin
 Compazine

Manufacturer

Role
 PS
 SS

Route

Dose
 BEFORE ADMIT

Duration

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 03/07/00 ISR Number: 3471110-0 Report Type: Expedited (15-Day) Company Report#: HQ1017610FEB2000

Outcome Congenital Anomaly	PT Cognitive Disorder Complications Of Maternal Exposure To Therapeutic Drugs Congenital Hip Deformity Developmental Delay Emotional Disorder Genitalia External Ambiguous Mild Mental Retardation Renal Dysplasia Renal Failure Chronic Urinary Tract Malformation	Report Source Health Professional	Product Robaxin Tablet Compazine	Role PS SS	Manufacturer	Route ORAL INTRAVENOUS	Dose 1 GRAM ORAL 10 MG, INTRAVENOUS	Gender: Female	Age:	IFU: F
--------------------------------------	--	--	---	-------------------------	---------------------	-------------------------------------	---	-----------------------	-------------	---------------

Date: 03/16/00 ISR Number: 3477611-3 Report Type: Expedited (15-Day) Company Report#: 2000003963-2

Outcome Congenital Anomaly	PT Cognitive Disorder Complications Of Maternal Exposure To Therapeutic Drugs Congenital Cleft Hand Developmental Delay Genitalia External Ambiguous Mental Retardation Severity Unspecified Renal Dysplasia Renal Failure Chronic Urinary Tract Malformation	Report Source Health Professional	Product Compazine Smithkline Beecham Robaxin (Metocarbamol)	Role PS C	Manufacturer Smithkline Beecham	Route TRANSPLACENTAL	Dose	Gender: Female	Age:	IFU: F
--------------------------------------	--	--	--	------------------------	---	--------------------------------	-------------	-----------------------	-------------	---------------

Date: 05/01/00 ISR Number: 3494716-1 Report Type: Expedited (15-Day) Company Report#: 2000003963-2

Outcome Congenital Anomaly	PT Cognitive Disorder Complications Of Maternal Exposure To Therapeutic Drugs Congenital Hip Deformity Dementia Developmental Delay Emotional Disorder Genitalia External Ambiguous Mild Mental Retardation Renal Dysplasia Renal Failure Chronic Urinary Tract Malformation	Report Source Health Professional	Product Compazine Smithkline Beecham Robaxin (Methocarbamol) Morphine Sulfate	Role PS C C	Manufacturer Smithkline Beecham	Route TRANSPLACENTAL:TRANSPLACENTA RY	Dose	Gender: Female	Age:	IFU: F
--------------------------------------	--	--	---	-----------------------------	---	--	-------------	-----------------------	-------------	---------------

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date: 05/02/00 ISR Number: 3500132-6 Report Type: Periodic Company Report#: 1999008314-1

Age: 32 YR Gender: Female IFU: I

Outcome	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Health Professional	Compazine	PS	Smithkline Beecham	INTRAVENOUS	10 MILLIGRAMS 1.0 DAILY	INTRAVENOUS 1 DAY
		Domperidone	C				
		Pepcid (Famotidine)	C				
		Nepirocaps	C				
		Prednisone	C				
		Cyclosporin	C				
		Tums (Calcium Carbonate)	C				
		Insulin [Nos]	C				

Date: 05/12/00 ISR Number: 3499817-X Report Type: Expedited (15-Day) Company Report#: JRFUSA2000000555

Age: 81 YR Gender: Female IFU: F

Outcome	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Consumer Health Professional	Propulsid	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	ORAL	
Hospitalization - Initial or Prolonged		Compazine	SS				
Other		(Prochlorperazine Edisylate)					
Required Intervention to Prevent Permanent Impairment/Damage		Levaquin	C				
		(Unspecified) (Levofloxacin)	C				
		Aciphex	C				
		(Rabeprazole)	C				
		Mycelx	C				
		(Clotrimazole)	C				
		Digoxin (Digoxin) Nitro Spray	C				
		(Isosorbide Dinitrate)	C				
		Morphine (Morphine) Reglan	C				
		(Metoclopramide) Benadryl	C				
		(Diphenhydramine Hydrochloride)	C				

Date: 05/15/00 ISR Number: 3499939-3 Report Type: Direct

Age: Gender: Male IFU: I

Outcome	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Health Professional	Compazine	PS		ORAL	15MG PO PRN	
		Compazine	PS		ORAL		
		Akathisia	PT				
		Tardive Dyskinesia					

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 05/16/00	ISRN: 3500776-1	Report Type: Direct	Company Report#:	Age: 21 YR	Gender: Female	I/FU: 1
Outcome: Hospitalization - Initial or Prolonged	PT: Headache Musculoskeletal Stiffness Parkinson'S Disease Tardive Dyskinesia	Report Source:	Product: Compazine (I V) 10 Mg Depakote	Role: PS C	Dose: Q6-8HR	Duration: 2 DAY
Date: 05/30/00	ISRN: 3508924-5	Report Type: Expedited (15-Day)	Company Report#: 2000015131-1	Age: 16 YR	Gender: Male	I/FU: 1
Outcome: Death Other	PT: Arrhythmia Cardiac Arrest	Report Source: Consumer Health Professional	Product: Compazine	Role: PS	Dose: 10 MILLIGRAMS INTRAVENOUS	Duration:
Date: 06/02/00	ISRN: 3508097-8	Report Type: Expedited (15-Day)	Company Report#: JACGER20000000725	Age: 34 YR	Gender: Female	I/FU: 1
Outcome:	PT: Sedation Suicide Attempt	Report Source: Foreign Health Professional	Product: Haldol Taxilan (Perazine) Atosil (Isopromethazine Hydrochloride) Tavor (Lorazepam) Diazepam (Diazepam)	Role: PS SS SS SS SS	Dose: 7 MG, 1 IN 1 TIME(S), ORAL 300 MG, 1 IN 1 TIME(S), ORAL 200 MG, 1 IN 1 TIME(S), ORAL 200 MG, 1 IN 1 TIME(S), ORAL 20 MG, 1 IN 1 TIME(S), ORAL	Duration:
Date: 06/15/00	ISRN: 3513876-7	Report Type: Direct	Company Report#:	Age: 37 YR	Gender: Male	I/FU: 1
Outcome: Other	PT: Dystonia Restlessness	Report Source:	Product: Compazine	Role: PS	Dose: 10MG & UP	Duration:
Date: 06/19/00	ISRN: 3515105-7	Report Type: Direct	Company Report#: USP 52065	Age:	Gender:	I/FU: 1
Outcome:	PT: Medication Error	Report Source:	Product: Compazine (Prochlorperazine) Neosynephrine 10% (Phenylephrine Hcl)	Role: PS SS	Dose:	Duration:

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Paroxetine)
C
Lorazepam
C
(Lorazepam)

Date: 08/01/00 ISR Number: 3538298-4 Report Type: Expedited (15-Day) Company Report#: 2000022436-1 Age: 30 YR Gender: Female I/FU: I

Outcome: Hospitalization - Initial or Prolonged
PT: Migraine
Report Source: Health Professional
Product: Compazine
Role: PS
Manufacturer: Smithkline Beecham Pharmaceuticals
Route:
Dose:
Duration:
Imetrex (Sumatriptan Succinate)
SS
Pethidine
SS
Hydrochloride

Date: 08/10/00 ISR Number: 3548715-1 Report Type: Expedited (15-Day) Company Report#: 2000015131-1 Age: 16 YR Gender: Male I/FU: F

Outcome: Death
PT: Arrhythmia
Cardiac Arrest
Report Source: Consumer Health Professional
Product: Compazine
Role: PS
Manufacturer: Smithkline Beecham Pharmaceuticals
Route: INTRAVENOUS
Dose: 10 MILLIGRAMS
Duration: INTRAVENOUS

Date: 08/16/00 ISR Number: 3551575-6 Report Type: Expedited (15-Day) Company Report#: JRFUSA2000005925 Age: 48 YR Gender: Female I/FU: I

Outcome: Hospitalization - Initial or Prolonged
PT: Anxiety
Cerebrovascular Accident
Hypoesthesia
Palpitations
Tic
Report Source: Consumer
Product: Propulsid
Role: PS
Manufacturer: Janssen Research Fdn Div Johnson And Johnson
Route: ORAL
Dose: 3 IN 1 DAY (S), ORAL
Duration:
Promethazine (Promethazine)
SS
Compazine
SS
(Prochlorperazine Edisylate)
C
Pancrease
C
Fiorinal
C
Xanax
C
Prevacid
C
Hyoscyamine
C
Lomotil
C

Date: 08/17/00 ISR Number: 3554641-4 Report Type: Expedited (15-Day) Company Report#: 2000022436-1 Age: 25 YR Gender: Female I/FU: F

Outcome: Life-Threatening Hospitalization - Initial or Prolonged
PT: Anaphylactic Shock
Migraine
Report Source: Health Professional
Product: Compazine
Role: PS
Manufacturer: Smithkline Beecham Pharmaceuticals
Route:
Dose:
Duration:
Imetrex (Sumatriptan Succinate)
SS
Pethidine
SS
Hydrochloride

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 08/18/00 ISR Number: 3553801-6 Report Type: Expedited (15-Day) Company Report#: JRFUSA2000004376

Age: 29 YR Gender: Female IFU: F

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Death	Abdominal Pain Asthma Bronchitis Condition Aggravated Decreased Appetite Dehydration Dyspepsia Feeling Abnormal Livedo Reticularis Pulse Absent Respiratory Arrest Sedation Vomiting Weight Decreased	Propulsid	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	10 MG, 4 IN 1 DAY (S), ORAL		
		Biaxin (Clarithromycin)	SS		UNKNOWN	500 MG, 2 IN 1 DAY (S), UNKNOWN		
		Naproxen (Naproxen)	SS		UNKNOWN	550 MG UNKNOWN		
		Compazine (Prochlorperazine Edisylate)	SS		INTRAMUSCULAR	10 MG, 1 IN 1 TIME (S), IM		
		Klonopin (Clonazepam)	C					
		Prilosec (Omeprazole)	C					
		Bella Alk/Pb (Belladonna Alkaloids)	C					
		Mylicon (Dimeticone, Activated)	C					
		Donnatal (Donnatal)	C					
		Demerol (Pethidine Hydrochloride)	C					
		Versed (Midazolam Hydrochloride)	C					
		Pepcid (Famotidine)	C					
		Primatene Mist (Epinephrine)	C					
		Paxil (Paroxetine Hydrochloride)	C					
		Simethicone (Dimeticone, Activated)	C					
		Duravent (Totolin)	C					
		Diloram (Diloran)	C					
		Contraceptive (Oral Contraceptive Nos)	C					

Date: 08/23/00 ISR Number: 3556211-0 Report Type: Direct

Age: 36 YR Gender: Female IFU: I

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Required Intervention to Prevent Permanent Impairment/Damage	Bruxism Convulsion Hypersensitivity Movement Disorder Neck Pain Tooth Injury	Compazine Skin Cap Paxil	PS SS C		ORAL TOPICAL	1 D 3 X ORAL DAILY OFF SHELF TOPICAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date: 09/11/00	ISRN: 3570161-5	Report Type: Expedited (15-Day)	Company Report#: 2000022436-1	Age: 25 YR	Gender: Female	I/FU: F
Outcome: Life-Threatening Hospitalization - Initial or Prolonged	PT: Anaphylactoid Reaction Dysphonia Migraine Vocal Cord Disorder	Report Source: Health Professional	Product: Compazine Imtrex(Sumatriptan Succinate) Pethidine Hydrochloride	Role: PS SS SS	Manufacturer: Smithkline Beecham Pharmaceuticals	Route:
				Dose:	Duration:	
Date: 09/29/00	ISRN: 3584438-0	Report Type: Expedited (15-Day)	Company Report#: 2000028038-1	Age:	Gender: Female	I/FU: I
Outcome: Death	PT: Death	Report Source: Consumer	Product: Compazine Morphine Sulfate	Role: PS C	Manufacturer: Smithkline Beecham Pharmaceuticals	Route:
				Dose: 10 MILLIGRAMS 4.0 DAILY	Duration:	
Date: 09/29/00	ISRN: 3584652-4	Report Type: Expedited (15-Day)	Company Report#: 2000028596-1	Age: 21 YR	Gender:	I/FU: I
Outcome: Death	PT: Death	Report Source: Health Professional	Product: Compazine	Role: PS	Manufacturer: Smithkline Beecham Pharmaceuticals	Route: INTRAVENOUS INTRAVENOUS
				Dose:	Duration:	
Date: 10/02/00	ISRN: 3584842-0	Report Type: Direct	Company Report#:	Age: 50 YR	Gender: Female	I/FU: I
Outcome:	PT: Tardive Dyskinesia	Report Source:	Product: Compazine Smith Kline & French	Role: PS	Manufacturer: Smith Kline & French	Route: ORAL
				Dose: ONE TAB PRN ORAL	Duration:	
Date: 10/05/00	ISRN: 3588920-1	Report Type: Direct	Company Report#:	Age:	Gender: Female	I/FU: I
Outcome: Other	PT: Dystonia	Report Source:	Product: Compazine 10 Mg Tab	Role: PS	Manufacturer:	Route: ORAL
				Dose: 10 MG AS NEEDED ORAL	Duration:	
Date: 10/10/00	ISRN: 3591829-0	Report Type: Expedited (15-Day)	Company Report#: JRFUSA2000007886	Age: 47 YR	Gender: Female	I/FU: I
Outcome: Hospitalization - Initial or Prolonged	PT: Atrial Fibrillation Tachycardia	Report Source: Consumer	Product: Propulsid Compazine Prochlorperazine Edisylate) Lanoxin (Digoxin) Synthroid (Levothyroxine Sodium)	Role: PS SS C C	Manufacturer: Janssen Research Fdn Div Johnson And Johnson	Route: ORAL
				Dose: 10 MG, 1 IN 1 DAY(S) ORAL PRN	Duration:	

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Corgard (Nadolol) C
 Antivert (Ancover) C
 Valium (Diazepam) C

Date: 10/16/00 ISR Number: 3595964-2 Report Type: Expedited (15-Day) Company Report#: JRFUSA2000006335 Age: 48 YR Gender: Male I/FU: F

Outcome	PT
Hospitalization -	Abdominal Pain
Initial or Prolonged	Abnormal Behaviour
Disability	Aggression
Other	Angina Pectoris
Required	Anhedonia
Intervention to	Anxiety
Prevent Permanent	Arachnoiditis
Impairment/Damage	Asthma
	Back Pain
	Bronchitis, Acute
	Cardiac Disorder
	Cardiomegaly
	Cervical Spinal Stenosis
	Chest Pain
	Condition Aggravated
	Constipation
	Coronary Artery Disease
	Cough
	Decreased Appetite
	Depression
	Diarrhoea
	Dizziness
	Dry Mouth
	Dyspnoea
	Echocardiogram Abnormal
	Ejection Fraction
	Abnormal
	Electrocardiogram
	Abnormal
	Electrocardiogram Qt
	Prolonged
	Emotional Disorder
	Fall
	Fibrosis
	Gastric Ulcer
	Gastroesophageal Reflux
	Disease
	Haematochezia
	Hallucination
	Headache
	Hyperhidrosis
	Hypoesthesia
	Hypotension
	Influenza Like Illness
	Injury
	Insomnia
	Joint Swelling
	Malaise
	Mental Disorder
	Mitral Valve Incompetence
	Mononeuropathy
	Muscle Spasms

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Myalgia	Health Professional	Propulsid	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	20 MG, 4 IN 1 DAY(S), ORAL	
Mycardial Infarction		Pamelor (Nortriptyline Hydrochloride)	SS		ORAL	75 MG, 1 IN 1 DAY(S), ORAL	
Nasal Congestion		Promethazine	SS		ORAL	50 MG, 4 IN 1 DAILY, ORAL	
Nausea		Mellari (Thioridazine Hydrochloride)	SS				
Neck Pain		Compazine (Prochlorperazine Edisylate)	SS				
Nervous System Disorder		Neurontin (Gabapentin)	SS			600 MG, 2 IN 1 DAILY	
Nervousness		Biaxin (Clarithromycin)	SS			500 MG, 2 IN 1 DAILY	
Nuclear Magnetic Resonance Imaging Abnormal		Elavil (Amitriptyline Hydrochloride)	SS				
Pain		Prilosec	C				
Pain In Extremity		Paxil (Paroxetine Hydrochloride)	C				
Palpitations		Prozac (Fluoxetine Hydrochloride)	C				
Pancreatitis		Nitroglycerin (Nitroglycerin Comp. /Net)	C				
Pharyngitis		Vicodin	C				
Pharyngolaryngeal Pain		Procordia	C				
Polydipsia		(Nifedipine)	C				
Polyp		Valium (Diazepam)	C				
Polyuria		Prevacid	C				
Pruritus		(Lansoprazole)	C				
Pyrexia		Reglan	C				
Rash Erythematous		(Metoclopramide)	C				
Rash Papular		Baclofen	C				
Rectal Haemorrhage		Vistari (Hydroxyzine Embonate)	C				
Renal Colic		Vitamins	C				
Rhinitis		Darvocet	C				
Road Traffic Accident		Parafon (Parafon Forte)	C				
Sinus Tachycardia		Flexeril	C				
Spinal Osteoarthritis		(Cyclobenzaprine Hydrochloride)	C				
Suicidal Ideation		Isocet (Axotal (Old Form))	C				
Swelling		Trazodone	C				
Tachycardia		Amoxil (Amoxicillin)	C				
Tricuspid Valve Incompetence		Metoprolol	C				
Ultrasound Scan Abnormal							
Urinary Retention							
Urinary Tract Infection							
Ventricular Extrasystoles							
Ventricular Fibrillation							
Vision Blurred							
Vomiting							
Weight Decreased							

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Carbamazepine C
 Talacen (Fortagesic) C
 Nifrex-150 Forte C
 Celexa (Citalopram Hydrobromide) C
 Medrol Dose Pack (Methylprednisolone) C
 Lactulose C
 Atarax (Hydroxyzine Hydrochloride) C
 Limbitrol C
 Baclofen C
 Remeron C
 (Mirtazapine) C
 Ms Contin (Morphine Sulfate) C
 Oxycodone (Oxycodone Hydrochloride) C
 Hemorrhoidal Suppository (Unspecified) C
 Midrin (Midrid) C
 Zithromax (Azithromycin) C
 Viokase (Pancrelipase) C
 Lorazepam C

Date: 10/17/00 ISR Number: 3597606-7 Report Type: Expedited (15-Day) Company Report#: 2000012661-1

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

Outcome Death Hospitalization - Initial or Prolonged	PT Cardio-Respiratory Arrest Gram Stain Positive Overdose	Report Source Health Professional	Product Compazine	Role PS	Manufacturer Smithkline Beecham Pharmaceuticals	Route	Dose	Duration
---	---	--	-----------------------------	-------------------	---	--------------	-------------	-----------------

Date: 10/18/00 ISR Number: 3597600-8 Report Type: Expedited (15-Day) Company Report#: JRFUSA2000006148

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

Outcome Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	PT Abdominal Pain Acute Sinusitis Anhedonia Anxiety Arthralgia Arthropathy Asthenia Bacillus Infection Back Pain Bacterial Infection Bradycardia Bronchitis Bursitis Cardiac Disorder Chills Clonic Convulsion Compression Fracture Condition Aggravated Confusional State	Report Source Health Professional	Product Compazine	Role PS	Manufacturer Smithkline Beecham Pharmaceuticals	Route	Dose	Duration
---	--	--	-----------------------------	-------------------	---	--------------	-------------	-----------------

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Health Professional	Propulsid	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	SEE IMAGE	
Health Professional	Phenergan	SS		ORAL	UNK; 25MG PRN	
Health Professional	Compazine	SS		RECTAL	ORAL 10 MG, PRN, RECTAL	
Health Professional	Seldane D	C				
Health Professional	Vistaryl	C				
Health Professional	Minoxidil	C				
Health Professional	Vasotec	C				
Health Professional	Normodyne	C				
Health Professional	Mevacor	C				
Health Professional	Nephrocaps	C				
Health Professional	Phoslo	C				
Health Professional	Prozac	C				
Health Professional	Claritin	C				
Health Professional	Betoptic	C				
Health Professional	Felodipine	C				
Health Professional	Fosinopril	C				
Health Professional	Vitamin B Complex	C				
Health Professional	Floxin	C				

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Bradycardia	Literature	Compazine	PS	Smithkline Beecham Pharmaceuticals	INTRAVENOUS	10 MILLIGRAMS	
Other	Dizziness	Health Professional	Quinidine	C		INTRAVENOUS	INTRAVENOUS	
Other	Electrocardiogram Abnormal	Health Professional	Clarithromycin	C				
Other	Electrocardiogram Qr Prolonged	Health Professional						
Other	Hypokalaemia	Health Professional						
Other	Syncope	Health Professional						
Other	Torsade De Pointes	Health Professional						

Date: 10/30/00 ISR Number: 3604175-3 Report Type: Expedited (15-Day) Company Report#: 2000030688-1 Age: 47 YR Gender: Male I/FU: 1

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 10/31/00 **ISR Number:** 3605061-5 **Report Type:** Expedited (15-Day) **Company Report#:** 2000031277-1 **Age:** 47 YR **Gender:** Female **I/FU:** 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Atrial Fibrillation Tachycardia	Consumer	Compazine	PS	Smithkline Beecham Pharmaceuticals			
			Propulsid (Cisapride)	SS	Janssen Pharmaceutica	ORAL	10 MILLIGRAMS 1.0 DAILY	ORAL
			Synthroid (Levothyroxine Sodium)	C				
			Corgard (Nadolol)	C				
			Antivert (Ancovert)	C				
			Valium (Diazepam)	C				

Date: 11/09/00 **ISR Number:** 3608939-1 **Report Type:** Direct **Company Report#:** **Age:** 55 YR **Gender:** Female **I/FU:** 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Other	Eyelid Function Disorder Facial Palsy Mastication Disorder		Adriamycin	PS		INTRAVENOUS	117 MG IV Q 21 DAYS	
			Cytosin	SS		INTRAVENOUS	1170 MG IVPB Q 21 DAYS	
			Zofran 32 Mg	SS			32 MG	
			Decadron 10/Mg	SS			10 MG	
			Anzemet 100 Mg Po	SS		ORAL	100 MG PO	
			Compazine 10 Mg Po	SS		ORAL	10 MG PO	
			Neupogen 480 Mcg Sq	SS		SUBCUTANEOUS	480 MCG SQ	
			Effexor 75 Mg 1 Tab Daily	SS			75 MG 1 TAB DAILY	
			Zantac 150 Mg Bid Prn	SS			150 MG BID PRN	
			Kytril 1 Mg	SS			1 MG	
			Decadron 5 Mg	SS			5 MG	

Date: 11/09/00 **ISR Number:** 3610385-1 **Report Type:** Expedited (15-Day) **Company Report#:** JRFUSA2000006335 **Age:** 48 YR **Gender:** Male **I/FU:** F

<u>Outcome</u>	<u>PT</u>
Hospitalization - Initial or Prolonged	Abdominal Pain
Disability	Abnormal Behaviour
Other	Abnormal Dreams
Required	Angina Pectoris
Intervention to Prevent Permanent Impairment/Damage	Anhedonia
	Anxiety
	Arachnoiditis
	Asthenia
	Back Pain
	Bladder Disorder
	Bronchitis
	Bronchitis Acute
	Cardiac Disorder
	Cardiomegaly
	Cervical Spinal Stenosis
	Chest Pain

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Colonic Polyp
Condition Aggravated
Constipation
Coronary Artery Disease
Cough
Decreased Appetite
Depression
Diarrhoea
Dizziness
Dry Mouth
Dyspnoea
Echocardiogram Abnormal
Ejection Fraction
Abnormal
Electrocardiogram
Abnormal
Electrocardiogram Qt
Prolonged
Emotional Disorder
Fall
Fibrosis
Gait Disturbance
Gastric Ulcer
Gastroesophageal Reflux
Disease
Haematochezia
Hallucination
Hyperhidrosis
Hypoesthesia
Hypotension
Influenza Like Illness
Injury
Insomnia
Joint Swelling
Malaise
Mental Disorder
Migraine
Mitral Valve Incompetence
Mononeuropathy
Muscle Spasms
Myalgia
Myocardial Infarction
Nasal Congestion
Nausea
Neck Pain
Nervous System Disorder
Nervousness
Nuclear Magnetic
Resonance Imaging
Abnormal
Pain
Pain In Extremity
Palpitations
Pancreatitis
Pharyngitis
Pharyngolaryngeal Pain
Polydipsia
Polyuria
Pruritus
Pyrexia
Rash Erythematous

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Rectal Haemorrhage	Health Professional	Propulsid	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	SEE IMAGE	
Renal Colic		Pamelor (Nortriptyline Hydrochloride)	SS		ORAL	75 MG, 1 IN 1 DAY(S), ORAL	
Rhinitis		Promethazine (Promethazine)	SS		ORAL	50 MG, 4 IN 1 DAILY, ORAL	
Road Traffic Accident		Mellariil (Thioridazine Hydrochloride)	SS				
Sinus Tachycardia		Compazine (Prochlorperazine Edisylate)	SS				
Spinal Osteoarthritis		Neurontin (Gabapentin)	SS				
Suicidal Ideation		Biaxin (Clarithromycin)	SS			600 MG, 2 IN 1 DAILY	
Swelling		Elavil (Amitriptyline Hydrochloride)	SS			500 MG, 2 IN 1 DAILY	
Syncope		Prilosec (Omeprazole)	C				
Tricuspid Valve		Faxil (Paroxetine Hydrochloride)	C				
Incompetence		Prozac (Fluoxetine Hydrochloride)	C				
Urinary Tract Infection		Nitroglycerin (Nitroglycerin Comp. /Net)	C				
Ventricular Extrasystoles		Procardin (Vicodin (Vicodin))	C				
Ventricular Fibrillation		(Nifedipine)	C				
Vision Blurred		Valium (Diazepam)	C				
Vomiting		Prevacid (Lansoprazole)	C				
Weight Decreased		Reglan (Metoclopramide)	C				
		Baclofen (Baclofen)	C				
		Vistaril (Hydroxyzine Embonate)	C				
		Vitamins (Vitamins)	C				
		Darvocet (Darvocet)	C				
		Parafon (Parafon Forte)	C				
		Flexeril (Cyclobenzaprine Hydrochloride)	C				
		Isocet (Axotal (Old Form))	C				
		Trazodone	C				
		Amoxil (Amoxicillin)	C				

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Metoprolol C
 (Metoprolol)
 Carbamazepine C
 (Carbamazepine)
 Talacen (Fortagesic) C
 Nifrex-150 Forte C
 (Unspecified)
 Celexa (Citalopram C
 Hydrobromide)
 Lorazepam C
 (Lorazepam)
 Medrol Dose Pack C
 (Methylprednisolone)
 Lactulose C
 (Lactulose)
 Atarax (Hydroxyzine C
 Hydrochloride)
 Limbitrol C
 (Limbital)
 Baclofen (Baclofen) C
 Remeron C
 (Mirtazapine)
 Ms Contin (Morphine C
 Sulfate)
 Oxycodone (Oxycodone C
 Hydrochloride)
 Hemorrhoidal C
 Suppository C
 (Unspecified)
 Midrin (Midrid) C
 Zithromax C
 (Azithromycin)
 Viokase C
 (Pancrelipase)

Date: 11/09/00 ISR Number: 3610386-3 Report Type: Expedited (15-Day) Company Report#: JRFUSA20000000500

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

PT
 Outcome
 Hospitalization -
 Initial or Prolonged
 Akinesia
 Aortic Valve Incompetence
 Aphasia
 Arterial Disorder
 Asthenia
 Atrioventricular Block
 First Degree
 Blood Carbon Monoxide
 Increased
 Bundle Branch Block
 Carboxyhaemoglobin
 Cardiac Disorder
 Cardiomegaly
 Carotid Artery Stenosis
 Cerebrovascular Accident
 Confusional State
 Convulsion
 Dyspnoea
 Echocardiogram Abnormal
 Ejection Fraction
 Abnormal

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Consumer Health Professional	Propulsid	PS	Janssen Research And Div Johnson And Johnson	ORAL	20 MG, 3 IN 1 DAY(S), ORAL	
Gait Disturbance	Compazine (Prochlorperazine Edisylate)	SS		INTRAVENOUS	IV	
Headache	Cardizem (Diltiazem Hydrochloride)	C				
Hypertension	Ibuprofen (Ibuprofen)	C				
Hypoxia	Septira (Bactrim)	C				
Loss Of Consciousness	Klonopin (Clonazepam)	C				
Mitral Valve Disease	Vicodin (Vicodin)	C				
Mitral Valve Incompetence	Vioxx (Rofecoxib)	C				
Nausea	Vicoprofen (Vicoprofen)	C				
Pco2 Increased	Aspirin (Acetylsalicylic Acid)	C				
Po2 Decreased	Albuterol (Salbutamol)	C				
Respiratory Acidosis	Atrovent (Ipratropium Bromide)	C				
Rhinitis	Vancenase	C				
Sinus Bradycardia	(Beclometasone Dipropionate)	C				
Transient Ischaemic Attack	Habitrol (Nicotine)	C				
Ventricular Extrasystoles	Caapres (Clonidine)	C				
Vomiting	Demerol (Pethidine Hydrochloride)	C				

Date: 11/13/00 ISR Number: 3610817-9 Report Type: Expedited (15-Day) Company Report#: JRFUSA2000006148 Age: 47 YR Gender: Male I/FU: F

Outcome
 Hospitalization - Initial or Prolonged Required
 Intervention to Prevent Permanent Impairment/Damage
 PT
 Abdominal Pain
 Acute Sinusitis
 Anhedonia
 Anxiety
 Arthralgia
 Arthropathy
 Asthenia
 Bacillus Infection
 Blood Phosphorus Increased
 Bradycardia
 Bronchitis
 Bursa Removal
 Cardiac Disorder
 Chills
 Clonic Convulsion Condition Aggravated
 Confusional State
 Diarrhoea

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Health Professional	Propulsid	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	1)10MG, 4/1D, PO; 2)10MG, 3/1D, PO; 3)20MG, 3/1D, PO; 4)10MG,	
	Phenergan (Promethazine Hydrochloride)	SS		ORAL	1) UNKNOWN; 2) 25 MG, PRN, ORAL	
	Compazine (Prochlorperazine Edisylate)	SS		RECTAL	10 MG, PRN, RECTAL	
	Seldane D (Seldane D)	C				
	Vistari (Hydroxyzine Embonate)	C				
	Minoxidil (Minoxidil)	C				
	Vasotec (Enalapril Maleate)	C				
	Normodyne (Labetalol Hydrochloride)	C				
	Mevacor (Lovastatin)	C				
	Neprocaps (Nephrocaps)	C				
	Phosto (Calcium Acetate)	C				
	Prozac (Fluoxetine Hydrochloride)	C				
	Clartan (Loratadine)	C				
	Betoptic (Betaxolol Hydrochloride)	C				
	Felodipine (Felodipine)	C				
	Fosinopril (Fosinopril)	C				
	Vitamin B Complex (B-Komplex "Lectiva")	C				
	Floxin (Ofloxacin)	C				

Difficulty In Walking
Dizziness
Duodenal Ulcer
Duodenitis
Dyspnoea
Emotional Disorder
Emotional Distress
Fear
Fear Of Disease
Feelings Of Worthlessness
Flatulence
Gastric Ulcer
Gastritis Erosive
Haematoctrit Decreased
Headache
Heart Rate Irregular
Hiatus Hernia
Hyperreflexia
Hypokalaemia
Hypovolaemia
Hypoxia
Injury
Insomnia
Lymphadenopathy
Medication Error
Mental Disorder
Myelopathy
Nasal Congestion
Nausea
Neck Pain
Osteolysis
Pain
Pain In Extremity
Peritonitis
Pyrexia
Respiratory Disorder
Rhinitis
Serratia Sepsis
Sinusitis
Spinal Compression
Fracture
Tooth Abscess
Ventricular Fibrillation
Vomiting

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Impairment/Damage

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Activated Partial Thromboplastin Time Prolonged	Consumer Health Professional	Propulsid	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	ORAL	
Anaemia		Compazine (Prochlorperazine Edisylate)	SS				
Angina Unstable		Levaquin (Levofloxacin)	C				
Atrial Flutter		Aciphex (Rabeprazole)	C				
Blood Creatine Phosphokinase Increased		Mycelex (Clotrimazole)	C				
Cardiac Failure		Digoxin	C				
Congestive Cardiomegaly		Nitro Spray (Isosorbide Dinitrate)	C				
Chest Pain		Morphine	C				
Drug Ineffective		Reglan (Metoclopramide)	C				
Dyspnoea		Benadryl (Diphenhydramine Hydrochloride)	C				
Electrocardiogram Abnormal							
Electrocardiogram Segment Depression							
Haematocrit Decreased							
Haemoglobin Increased							
Heart Rate Increased							
Hypokalaemia							
Hyponatraemia							
Leukopenia							
Lung Infiltration							
Myocardial Ischaemia							
Pancytopenia							
Pneumonia							
Prothrombin Time Prolonged							
Tachycardia							
Thrombocytopenia							

Date: 11/13/00 ISR Number: 3611226-9 Report Type: Periodic Company Report#: FLUV00299001047

Age: 26 YR Gender: Female I/FU: 1

Outcome	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Consumer	Luvox	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	
Anxiety		Compazine (Prochlorperazine Edisylate)	SS				
Drug Interaction		Augementin Oral (Amoxicillin/Clavulanic Acid)	C				
Emotional Disorder		Decongestant (Decongestant)	C				
Vasodilatation							

Date: 11/15/00 ISR Number: 3611395-0 Report Type: Direct

Age: 25 YR Gender: Female I/FU: 1

Outcome	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other							
Insomnia							
Movement Disorder							
Muscle Spasms							
Neck Pain							

25-Aug-2005 09:42 AM

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Mental Disorder	Neuronitin	PS	Parke Davis Pharmaceuticals Ltd		1200 MG (DAILY), UNKNOWN	
Mitral Valve Incompetence	Propulsid (Cisapride)	SS		ORAL	30 MG (DAILY), PER ORAL, 40 MG (DAILY), PER ORAL	
Muscle Spasms	Pamelor (Nortriptyline Hydrochloride)	SS		ORAL	75 MG (DAILY), PER ORAL	
Myalgia	(Promethazine)	SS		ORAL	200 MG (DAILY), PER ORAL	
Myocardial Ischaemia	Mellariil (Thioridazine Hydrochloride)	SS				
Neck Pain	Compazine (Prochlorperazine Edisylate)	SS				
Neuropathy Peripheral	Biaxin (Clarithromycin)	SS				
Pancreatic Carcinoma	Elavil (Amitriptyline Hydrochloride)	SS				
Pharyngitis	Prilosec (Omeprazole)	C				
Polydipsia	Paxil (Paroxetine Hydrochloride)	C				
Polyuria	Prozac (Fluoxetine Hydrochloride)	C				
Rash Papular	Vicodin (Paracetamol, Hydrocodone Bitartrate)	C				
Rectal Haemorrhage	Procordia (Nifedipine)	C				
Renal Colic	Valium (Diazepam)	C				
Rhinitis	Prevacid (Lansoprazole)	C				
Road Traffic Accident	Reglan (Metoclopramide)	C				
Suicidal Ideation	(Baclofen)	C				
Suicide Attempt	Vistaril (Hydroxyzine Embonate)	C				
Syncope	Vitamins (Vitamins Nos)	C				
Tachycardia	Nitroglycerin (Phenobarbital, Atropine Methonitrate, Glyceyl Trinitrate,	C				
Tricuspid Valve						
Incompetence						
Ultrasound Scan Abnormal						
Urinary Retention						
Urinary Tract Infection						
Ventricular Extrasystoles						
Ventricular Fibrillation						
Vision Blurred						
Vomiting						
Weight Decreased						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Darvocet	
(Paracetamol,	
Dextropropoxyphene)	C
Parafon Forte	
(Chlorzoxazone,	
Paracetamol)	C
Flexeril	
(Cyclobenzaprine	
Hydrochloride)	C
Isocet (Caffeine,	
Butalbital,	
Paracetamol)	C
(Trazodone)	C
Amoxil (Amoxicillin)	C
(Metoprolol)	C
(Carbamazepine)	C
Talacen	
(Paracetamol,	
Pentazocine	
Hydrochloride)	C
Niferex-150 Forte	
(Vitamins Nos,	
Minerals Nos)	C
Celexa (Citalopram	
Hydrobromide)	C
(Lorazepam)	C
Medrol Dose Pak	
(Methylprednisolone)	C
(Lactulose)	C
Atarax (Hydroxyzine	
Hydrochloride)	C
Limbitrol	
(Chlordiazepoxide,	
Amitriptyline	
Hydrochloride)	C
Remeron	
(Mirtazapine)	C
Ms Contin (Morphine	
Sulfate)	C
Oxycontin (Oxycodone	
Hydrochloride)	C
Hemorrhoidal	
Suppository	
Unspecified	
Midrin (Paracetamol,	
Dichloralphenazone,	
Isometheptene)	C
Zithromax	
(Azithromycin)	C
Viokase	
(Pancrelipase)	C

Date: 12/01/00 ISR Number: 3621320-4 Report Type: Expedited (15-Day) Company Report#: 001-0945-M00001245

Age: 48 YR Gender: Male

I/FU: F

Outcome
 Life-Threatening
 Hospitalization -
 Initial or Prolonged
 Disability

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Other

PT
Anhedonia
Anxiety
Arrhythmia
Asthenia
Back Pain
Bronchitis
Cardiac Disorder
Cardiomegaly
Chest Pain
Condition Aggravated
Cough
Dizziness
Drug Abuser
Dyspnoea
Electrocardiogram Qt
Corrected Interval
Prolonged
Electrocardiogram Qt
Prolonged
Emotional Disorder
Emotional Distress
Fall
Fear Of Disease
Fibrosis
Headache
Heart Rate Irregular
Hyperhidrosis
Hypoesthesia
Injury
Joint Swelling
Left Ventricular Failure
Malaise
Mental Disorder
Mitral Valve Incompetence
Myalgia
Nasal Congestion
Nausea
Neck Pain
Nuclear Magnetic
Resonance Imaging
Abnormal
Pain
Pancreatic Carcinoma
Pancreatitis
Pharyngitis
Pharyngolaryngeal Pain
Polydipsia
Polyuria
Pyrexia
Rash Erythematous
Renal Colic
Rhinitis
Road Traffic Accident
Sinus Tachycardia
Spinal Osteoarthritis
Suicide Attempt
Syncope
Tricuspid Valve

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Incompetence
Urinary Retention
Urinary Tract Infection
Ventricular Fibrillation
Vomiting

<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
	Neurontin	PS	Parke Davis Pharmaceuticals Ltd		1200 MG (DAILY)	
	Propulsid	SS		ORAL	30 MG (DAILY), PER ORAL (SEE IMAGE)	
	Promethazine	SS		ORAL	200 MG (DAILY), PER ORAL	
	Pamelor	SS		ORAL	75 MG (DAILY), PER ORAL	
	Mellaril	SS			1000 MG (DAILY)	
	Biaxin	SS				
	Elavil	SS				
	Compazine	SS				
	Prilosec	C				
	Trazodone	C				
	Isocet	C				
	Flexeril	C				
	Parafon Forte	C				
	Darvocet	C				
	Nitroglycerin	C				
	Vitamins	C				
	Vistaril	C				
	Baclofen	C				
	Zithromax	C				
	Midrin	C				
	Hemorrhoidal	C				
	Suppository	C				
	Unspecified	C				
	Oxycontin	C				
	Ms Contin	C				
	Remeron	C				
	Limbitrol	C				
	Atarax	C				
	Laculose	C				
	Viokase	C				
	Medrol Dose Pak	C				
	Lorazepam	C				
	Celexa	C				
	Niferex-150 Forte	C				
	Talacen	C				
	Carbamazepine	C				
	Metoprolol	C				
	Amoxil	C				
	Vicodin	C				
	Procardia	C				
	Valium	C				
	Reglan	C				
	Prevacid	C				
	Paxil	C				
	Prozac	C				

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 12/22/00 **ISR Number:** 3638956-8 **Report Type:** Expedited (15-Day) **Company Report#:** JRFUSA2000005072

Age: **Gender:** Female **I/FU:** F

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Life-Threatening Disability	Anhedonia Anxiety Arrhythmia Cardiac Arrest Electrocardiogram Qt Prolonged Emotional Disorder Renal Failure Ventricular Fibrillation Ventricular Tachycardia		Propulsid	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	ORAL	
			Propulsid	SS		ORAL	ORAL	
			Diflucan	SS		ORAL	ORAL	
			Biaxin	SS		ORAL	ORAL	
			Hismanal	SS		ORAL	ORAL	
			Compazine	SS		ORAL	ORAL	
			Vasotec	C		ORAL	ORAL	
			Triamterene / Hctz	C				
			Levsin	C				
			Zantac	C				
			Ferrous Sulfate	C				
			Hydrocodone W/ Apap	C				
			Forosemide	C				
			Tagamet	C				
			Vaseretic	C				
			Potassium Chloride	C				
			Cyproheptadine	C				
			Cataflam	C				
			Nitroglycerin	C				
			Procardia	C				
			Vasotec	C				
			Amoxicillin	C				
			Prilosec	C				
			Premarin	C				
			Prempro	C				
			Megace	C				
			Methyldopa	C				
			Ranitidine	C				
			Tylenol With Codeine	C				
			Lotrisone	C				
			Cephalexin	C				
			Imodium	C				
			Tetracycline	C				
			Cardizem	C				

Date: 12/26/00 **ISR Number:** 3638955-5 **Report Type:** Expedited (15-Day) **Company Report#:** 2000033074-1

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

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Drug Interaction Dysphagia Joint Dislocation Movement Disorder Muscle Rigidity Neck Pain Speech Disorder Tongue Oedema Trismus Vision Blurred	Consumer Health Professional	Compazine	PS	Smithkline Beecham Pharmaceuticals	RECTAL	25 MILLIGRAMS 1.0 DAILY	1 DAY
			Prozac	SS		ORAL	20 MILLIGRAMS 1.0 DAILY	
			Vioxx (Rofexocib)	C				
			Vicodin (Acetaminophen With Hydrocodone Bitartrate)	C				
			Claritin (Loratadine)	C				
			Malic Acid Florenif	C				

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

(Fludrocortisone
Acetate)
C
Amoxicillin
C

Date: 12/28/00 ISR Number: 3640467-X Report Type: Periodic Company Report#: 2000USA00976 Age: Gender: Female I/FU: 1

Outcome
Hospitalization -
Initial or Prolonged

PT
Drug Effect Decreased
Migraine

Report Source
Health
Professional

Product
Demerol
Imitrex "Glaxo"
Compazine

Role
PS
SS
SS

Manufacturer
Sanofi Synthelabo
Inc

Route

Dose

Duration

Date: 01/02/01 ISR Number: 3653205-1 Report Type: Periodic Company Report#: JRFUSA2000007290 Age: 13 YR Gender: Female I/FU: 1

Outcome

PT
Cardiac Murrur
Migraine

Report Source
Consumer

Product
Propulsid
Compazine
(Prochlorperazine
Edisylate)

Role
PS
SS

Manufacturer
Janssen Research Fdn
Div Johnson And
Johnson

Route
ORAL
INTRAMUSCULAR IM

Dose
4 IN 1
DAY(S) ORAL

Duration

Date: 01/02/01 ISR Number: 3653212-9 Report Type: Periodic Company Report#: JRFUSA2000007317 Age: 41 YR Gender: Female I/FU: 1

Outcome

PT
Arrhythmia
Hypotension
Tachycardia

Report Source
Consumer

Product
Propulsid
Compazine
(Prochlorperazine
Edisylate)
Amitriptyline
(Amitriptyline)
Erythromycin(Erythro
mycin)
Thorazine
(Chlorpromazine
Hydrochloride)
Levothroid
(Levothyroxine
Sodium)
Reglan
(Metoclopramide)
Pepcid (Famotidine)
Atrovent
(Ipratropium
Bromide)
Tenormin (Atenolol)

Role
PS
SS
SS
SS
SS
C
C
C
C
C

Manufacturer
Janssen Research Fdn
Div Johnson And
Johnson

Route
ORAL

Dose
20 MG 2 IN 1
DAY (S) ORAL
PRN

Duration

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Triamterene)
Hyoscyamine Sulfate
Enalapril Maleate

Date: 01/22/01 ISR Number: 3652910-0 Report Type: Expedited (15-Day) Company Report#: 2001000046-1 Age: 4 YR Gender: Female I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Decreased Activity Decreased Appetite Extrapyramidal Disorder Eye Rolling Headache Heart Rate Increased Ketonuria Lethargy Musculoskeletal Stiffness Nasopharyngitis Pyelonephritis Respiratory Rate Increased Tremor Vomiting White Blood Cell Count Increased	Literature Health Professional	Compazine Acetaminophen Ibuprofen	PS C C	Smithkline Beecham Pharmaceuticals			

Date: 01/29/01 ISR Number: 3656857-5 Report Type: Expedited (15-Day) Company Report#: 2001001047-1 Age: 8 YR Gender: Male I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Dystonia Lethargy Mood Altered	Health Professional	Compazine Compazine	PS SS	Smithkline Beecham Pharmaceuticals	ORAL INTRAMUSCULAR	5 MILLIGRAMS 1.0 AS NEEDED ORAL 5 MILLIGRAMS 1.0 DAILY INTRAMUSCULAR	3 DAY DAY DAY

Date: 02/15/01 ISR Number: 3665973-3 Report Type: Direct Company Report#: Age: 32 YR Gender: Male I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Spasms Tic		Compazine	PS				

Date: 02/22/01 ISR Number: 3669624-3 Report Type: Expedited (15-Day) Company Report#: 2001003889-1 Age: 25 YR Gender: Female I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypersensitivity Skin Ulcer	Consumer	Compazine Avonex (Interferon Beta-1a) Biogen Avonex (Interferon Beta-1a) Biogen	PS SS SS	Smithkline Beecham Pharmaceuticals Biogen Biogen	INTRAMUSCULAR INTRAMUSCULAR	30 MICROGRAMS 1.0 WEEKLY INTRAMUSCULAR	YR YR

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

INTRAMUSCULAR

Date: 03/02/01 ISR Number: 3672902-5 Report Type: Expedited (15-Day) Company Report#: 2001004880-1

Outcome Life-Threatening
PT Dyskinesia
 Required Intervention to Prevent Permanent Impairment/Damage
Report Source Consumer
Product Compazine
Role PS
Manufacturer Smithkline Beecham Pharmaceuticals
Route RECTAL
Dose 20 MILLIGRAMS
Duration 2 DAY
Gender: Female
Age:
IFU: I

Date: 03/02/01 ISR Number: 3672941-4 Report Type: Expedited (15-Day) Company Report#: 2001004880-1

Outcome Life-Threatening
PT Dyskinesia
 Required Intervention to Prevent Permanent Impairment/Damage
Report Source Consumer
Product Compazine
Role PS
Manufacturer Smithkline Beecham Pharmaceuticals
Route RECTAL
Dose 20 MILLIGRAMS
Duration 2 DAY
Gender: Female
Age:
IFU: I

Date: 03/30/01 ISR Number: 3706272-0 Report Type: Expedited (15-Day) Company Report#: 198026D8

Outcome Other
PT Dizziness
 Intention Tremor
 Parkinson'S Disease
Report Source Foreign Study Health Professional
Product Peg-Intron (Peginterferon Alfa-2b) Soluble Powder
 Cisapride
 Sinogan
 Kliogest For
 Chomacteric
 Estrogen Nos
 Thyroxin
 Triazolam
 Lansoprazole
Role PS
 SS
 SS
 C
 C
 C
 C
Manufacturer
Route SUBCUTANEOUS
 ORAL
Dose 6-2MCG/KG/WK*
 SUBCUTANEOUS
 ORAL
 DAILY
Duration 8
MON
Age: 59 YR
Gender: Female
IFU: I

Date: 04/03/01 ISR Number: 3696137-5 Report Type: Expedited (15-Day) Company Report#: 2001003889-1

Outcome Hospitalization - Initial or Prolonged
PT Asthenia
 Cerebrovascular Accident
 Drug Hypersensitivity
 Multiple Sclerosis
 Skin Ulcer
Report Source Consumer
Product Compazine
 Avonex (Interferon Beta-1a) Biogen
 Avonex (Interferon Beta-1a) Biogen
Role PS
 SS
 SS
Manufacturer Smithkline Beecham Pharmaceuticals
Route INTRAMUSCULAR
 INTRAMUSCULAR
 INTRAMUSCULAR
Dose 30 MICROGRAMS
 1.0 WEEKLY
 INTRAMUSCULAR
 30 MICROGRAMS
 1.0 WEEKLY
 INTRAMUSCULAR
Duration
YR
YR
YR
Age: 25 YR
Gender: Female
IFU: F

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 04/05/01	ISR Number: 3690985-1	Report Type: Direct	Company Report#:	Age: 62 YR	Gender: Female	I/F/U: 1
Outcome Required Intervention to Prevent Permanent Impairment/Damage	PT Respiratory Distress	Report Source Compazine 10 Mgm Pm	Product Compazine 10 Mgm Pm	Role PS	Manufacturer Smithkline Beecham Pharmaceuticals	Route ORAL Dose 10 MGM PO Q 6 H PRN Duration
Date: 04/10/01	ISR Number: 3702512-2	Report Type: Expedited (15-Day)	Company Report#: 2001001020-2	Age: 10 YR	Gender: Female	I/F/U: 1
Outcome Hospitalization - Initial or Prolonged Other	PT Convulsion Dystonia	Report Source Health Professional	Product Amoxil Compazine (Prochlorperazine)	Role PS SS	Manufacturer Smithkline Beecham Pharmaceuticals	Route ORAL ORAL Dose 250 MILLIGRAMS 3.0 DAILY ORAL Duration DAY DAY
Date: 04/10/01	ISR Number: 3702517-1	Report Type: Expedited (15-Day)	Company Report#: 2001001047-1	Age: 6 YR	Gender: Male	I/F/U: F
Outcome Hospitalization - Initial or Prolonged Other	PT Dystonia Lethargy Vomiting	Report Source Health Professional	Product Compazine Phenergan (Promethazine Hcl)	Role PS C	Manufacturer Smithkline Beecham Pharmaceuticals	Route ORAL Dose SEE IMAGE Duration 3 DAY
Date: 04/23/01	ISR Number: 3709147-6	Report Type: Expedited (15-Day)	Company Report#: 2001003889-1	Age: 25 YR	Gender: Female	I/F/U: F
Outcome Hospitalization - Initial or Prolonged	PT Asthma Cerebrovascular Accident Dystonia Hypersensitivity Multiple Sclerosis Skin Ulcer	Report Source Consumer Health Professional	Product Compazine Avonex (Interferon Beta-1a) Biogen	Role PS SS	Manufacturer Smithkline Beecham Pharmaceuticals	Route INTRAMUSCULAR Dose 30 MICROGRAMS 1.0 WEEKLY INTRAMUSCULAR Duration YR
Date: 04/30/01	ISR Number: 3714057-4	Report Type: Expedited (15-Day)	Company Report#: 2001004880-1	Age: 26 YR	Gender: Female	I/F/U: F
Outcome Life-Threatening Required Intervention to Prevent Permanent Impairment/Damage	PT Dyspnoea Muscle Spasms Respiratory Distress Tongue Paralysis Trismus	Report Source Consumer	Product Compazine	Role PS	Manufacturer Smithkline Beecham Pharmaceuticals	Route RECTAL Dose RECTAL Duration 2 DAY
Date: 05/03/01	ISR Number: 3717671-5	Report Type: Periodic	Company Report#: 2001001861-1	Age: 10 YR	Gender:	I/F/U: 1
Outcome Other	PT Dystonia Medication Error					

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Overdose

Report Source
Health Professional

Product
Compazine

Role
PS

Manufacturer
Smithkline Beecham Pharmaceuticals

Route
INTRAVENOUS

Dose
20 MILLIGRAMS
IV

Duration
30 HR

Date: 05/03/01 **ISR Number:** 3717673-9 **Report Type:** Periodic **Company Report#:** 2000006660-1 **Age:** 2 YR **Gender:** Female **I/FU:** F

Outcome
Disability
Other

PT
Accidental Overdose
Anuria
Coma
Gait Disturbance
Lethargy
Loss Of Consciousness
Oral Intake Reduced
Skin Discolouration
Speech Disorder
Tardive Dyskinesia

Report Source
Consumer

Product
Compazine

Role
PS

Manufacturer
Smithkline Beecham Pharmaceuticals

Route
INTRAMUSCULAR

Dose
12 MICROLITER
INTRAMUSCULAR

Duration
DAY

Date: 05/03/01 **ISR Number:** 3717677-6 **Report Type:** Periodic **Company Report#:** 1999033579-1 **Age:** 45 YR **Gender:** Female **I/FU:** I

Outcome
Disability

PT
Blepharospasm
Dystonia
Influenza Like Illness
Tardive Dyskinesia

Report Source
Consumer
Health Professional

Product
Compazine
Klonopin(Clonazepam)
Prozac(Fluoxetine)
Hel)
Darvocet
(Propoxyphene/Acetam
inophen)

Role
PS
C
C
C

Manufacturer
Smithkline Beecham
Pharmaceuticals

Route
ORAL

Dose
1.0 AS NEEDED
ORAL

Date: 05/03/01 **ISR Number:** 3717680-6 **Report Type:** Periodic **Company Report#:** 2001001020-1 **Age:** 10 YR **Gender:** Female **I/FU:** I

Outcome
Hospitalization -
Initial or Prolonged
Other

PT
Accidental Overdose
Convulsion
Dystonia

Report Source
Health Professional

Product
Compazine
Amoxicillin
Compazine

Role
PS
SS
SS

Manufacturer
Smithkline Beecham
Pharmaceuticals

Route
ORAL
ORAL
INTRAMUSCULAR

Dose
10 MILLIGRAM
1.0 AS NEEDED
ORAL
250
MILLIGRAMS
3.0 DAILY
ORAL
10 MILLIGRAMS
1.0 DAILY
INTRAMUSCULAR

Duration
3 DAY
DAY

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 05/29/01 ISR Number: 3729704-0 Report Type: Expedited (15-Day) Company Report#: 2001004880-1

Outcome Life-Threatening Required Intervention to Prevent Permanent Impairment/Damage	PT Dystonia	Report Source Consumer Health Professional	Product Compazine Birth Control Pills (Nos)	Role PS C	Manufacturer Smithkline Beecham Pharmaceuticals	Route RECTAL RECTAL	Dose RECTAL	Duration 2 DAY	Age: 26 YR	Gender: Female	I/FU: F
---	-----------------------	--	---	----------------------------	--	--------------------------------------	---------------------------	------------------------------	-------------------	-----------------------	----------------

Date: 05/30/01 ISR Number: 3730887-7 Report Type: Direct

Outcome Other	PT Muscle Contractions Involuntary	Report Source	Product Compazine (10mg) (Spansule) Metomidazole Endocet(Oxycodone) Ortho-Cyclen Ibuprofen	Role PS C C C C	Manufacturer	Route ORAL	Dose 10MG ORAL EVERY 12HRS	Duration	Age:	Gender: Female	I/FU: I
-------------------------	---	----------------------	---	---	---------------------	----------------------	---	-----------------	-------------	-----------------------	----------------

Date: 06/01/01 ISR Number: 3732261-6 Report Type: Expedited (15-Day) Company Report#: 2012615

Outcome Death	PT Atherosclerosis Cardiac Disorder Cardiomegaly Coronary Artery Disease Hiv Infection Cdc Group Iv Subgroup C1 Hypertension	Report Source Health Professional Other	Product Oxycodone Hydrochloride (Similar To Nda 20-553) Amitriptyline Trimethoprim Nicotine Phenothiazine Fluconazole Promethazine Ethanol Nortriptyline Valproic Acid	Role PS SS SS SS SS SS SS SS SS SS	Manufacturer Purdue Pharm L.P.	Route	Dose	Duration	Age: 33 YR	Gender: Male	I/FU: I
-------------------------	--	---	--	---	--	--------------	-------------	-----------------	-------------------	---------------------	----------------

Date: 06/07/01 ISR Number: 3735942-3 Report Type: Expedited (15-Day) Company Report#: 10861672

Outcome Other	PT Electrocardiogram Qt Corrected Interval Prolonged Ventricular Tachycardia	Report Source Health Professional	Product Tequin Compazine (Prochlorperazine)	Role PS SS	Manufacturer Bristol Myers Squibb Co Pharmaceutical Research Institute	Route	Dose	Duration	Age:	Gender:	I/FU: I
-------------------------	---	--	---	-----------------------------	--	--------------	-------------	-----------------	-------------	----------------	----------------

Date: 06/11/01 ISR Number: 3738203-1 Report Type: Expedited (15-Day) Company Report#: 10866382

Outcome Other	PT Drug Interaction Ventricular Extrasystoles Ventricular Tachycardia	Report Source Health Professional	Product Tequin Compazine	Role PS	Manufacturer Bristol Myers Squibb Co Pharmaceutical Research Institute	Route INTRAVENOUS	Dose IV	Duration	Age:	Gender:	I/FU: I
-------------------------	---	--	---	-------------------	--	-----------------------------	-------------------	-----------------	-------------	----------------	----------------

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

(Prochlorperazine) SS

IV

Date: 06/20/01 **ISRN Number:** 3743558-8 **Report Type:** Expedited (15-Day) **Company Report#:** 10866382

Age: **Gender:** **I/FU:** F

Outcome
Other
PT
Drug Interaction
Electrocardiogram Qt
Corrected Interval
Prolonged
Ventricular Extrasystoles
Ventricular Tachycardia

Report Source
Health
Professional

Product
Tequin

Compazine(Prochlorperazine)

Role
PS

SS

Manufacturer
Bristol Myers Squibb
Co Pharmaceutical
Research Institute

Route
INTRAVENOUS

Dose
IV

Duration

Date: 06/20/01 **ISRN Number:** 3743561-8 **Report Type:** Expedited (15-Day) **Company Report#:** 10861672

Age: **Gender:** **I/FU:** F

Outcome
Other
PT
Electrocardiogram Qt
Corrected Interval
Prolonged
Ventricular Tachycardia

Report Source
Health
Professional

Product
Tequin

Compazine(Prochlorperazine)

Role
PS

SS

Manufacturer
Bristol Myers Squibb
Co Pharmaceutical
Research Institute

Route

Dose

Duration

Date: 06/26/01 **ISRN Number:** 3750583-X **Report Type:** Expedited (15-Day) **Company Report#:** 200104852-1

Age: 27 YR **Gender:** Female **I/FU:** 1

Outcome
Required
Intervention to
Prevent Permanent
Impairment/Damage
PT
Aphasia
Dystonia
Eye Rolling
Facial Palsy
Muscle Spasms
Tongue Oedema
Tongue Spasm
Vaginal Haemorrhage

Report Source
Health
Professional

Product
Compazine

Role
PS

Manufacturer
Smithkline Beecham
Pharmaceuticals

Route

Dose
4.0 DAILY
RECTAL

Duration
2 DAY

Date: 06/29/01 **ISRN Number:** 3750255-1 **Report Type:** Direct **Company Report#:**

Age: 11 YR **Gender:** Male **I/FU:** 1

Outcome
Hospitalization -
Initial or Prolonged
PT
Extrapyramidal Disorder

Report Source

Product
Compazine

Role
PS

Manufacturer

Route

Dose
SUPPOSITORY X
1

Duration

Date: 07/18/01 **ISRN Number:** 3760140-7 **Report Type:** Direct **Company Report#:**

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

Outcome
PT
Paraesthesia

Report Source

Product
Compazine
Celexa
Morphine
Peppid

Role
PS
C
C
C

Manufacturer

Route
INTRAMUSCULAR

Dose
10 MG IM Q6H

Duration

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date: 07/19/01 **ISR Number:** 3761109-9 **Report Type:** Direct **Company Report#:** **Age:** 32 YR **Gender:** Female **I/FU:** 1

Outcome Other	PT Dehydration Hyperemesis Gravidarum Malaise Sleep Disorder Vision Blurred	Report Source	Product Compazine 25mg Suppositories Generic-Don T Know Atropine 1% Ophthalmic Soln Prenatal Vits	Role	Manufacturer	Route	Dose	Duration
				PS SS C		SUBLINGUAL SUBLINGUAL C	RECTAL QD PRN SUBLINGUAL BID-TID	

Date: 07/19/01 **ISR Number:** 3762090-9 **Report Type:** Expedited (15-Day) **Company Report#:** EM2001-0702 **Age:** 53 YR **Gender:** Male **I/FU:** 1

Outcome Life-Threatening Other	PT Dyspnoea Dystonia	Report Source Health Professional	Product Proleukin; Chiron Corporation(Aldesleu kin) Injection Compazine (Prochlorperazine Edisylate) Proleukin; Chiron Corporation	Role	Manufacturer	Route	Dose	Duration
				PS SS SS C	Chiron Corporation Chiron Corporation	INTRA VENOUS BOLUS	14 DOSES 720,000 IU/KG IV BOLUS	

Date: 07/20/01 **ISR Number:** 3762461-0 **Report Type:** Expedited (15-Day) **Company Report#:** 2001016877-1 **Age:** 25 YR **Gender:** Male **I/FU:** 1

Outcome Other Required Intervention to Prevent Permanent Impairment/Damage	PT Anxiety Blood Pressure Increased Delusion	Report Source Consumer	Product Compazine	Role	Manufacturer	Route	Dose	Duration
				PS	Smithkline Beecham Pharmaceuticals			

Date: 07/23/01 **ISR Number:** 3763761-0 **Report Type:** Expedited (15-Day) **Company Report#:** NSADSS2001018471 **Age:** **Gender:** F **I/FU:** F

Outcome Other	PT Leukopenia	Report Source Foreign Health Professional	Product Risperdal Phenothiazine (Phenothiazine)	Role	Manufacturer	Route	Dose	Duration
				PS SS	Janssen Research Fdn	ORAL	MG, ORAL	

Date: 07/23/01 **ISR Number:** 3763781-6 **Report Type:** Expedited (15-Day) **Company Report#:** 2013413 **Age:** 45 YR **Gender:** Female **I/FU:** 1

Outcome Death	PT Completed Suicide Coronary Artery Disease Injury Lung Disorder Toxicologic Test Abnormal	Report Source Health Professional Other	Product Oxycontin Acetaminophen Meprobamate Carisoprodol Phenothiazine Diltiazem Hcl Caffeine Anhydride Promethazine Hcl	Role	Manufacturer	Route	Dose	Duration
				PS SS SS SS SS SS SS SS SS	Purdue Pharma Lp	ORAL	PO	

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Percocet SS Endo Labs

Date: 08/20/01 **ISR Number:** 3780312-5 **Report Type:** Direct **Company Report#:** **Age:** 29 YR **Gender:** Male **I/FU:** 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Intervention to Prevent Permanent Impairment/Damage	Dyskinesia Joint Sprain Muscle Spasms Muscle Strain Muscular Weakness Musculoskeletal Stiffness		Compazine - Prochlorperazine 5 & 10 Mg	PS				

Date: 09/05/01 **ISR Number:** 3788675-1 **Report Type:** Expedited (15-Day) **Company Report#:** 2001019086-1 **Age:** 35 YR **Gender:** Female **I/FU:** 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Other Intervention to Prevent Permanent Impairment/Damage	Bruixism Dysphagia Dystonia Infection Neck Pain Tooth Disorder Tooth Loss	Consumer Health Professional	Compazine	PS	Smithkline Beecham		25 MILLIGRAMS	2 DAY

Date: 09/14/01 **ISR Number:** 3793890-7 **Report Type:** Expedited (15-Day) **Company Report#:** 2001-05-0082 **Age:** 28 YR **Gender:** Female **I/FU:** F

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Other	Abscess Breast Disorder Drug Abuser Hirsutism Hypertrophy Breast Mastication Disorder Overdose Scar Suicidal Ideation Suicide Attempt Tooth Injury	Foreign Consumer Health Professional Other	Trilafon (Perphenazine) Lergigan Sobril Rotipinol Mallorol Buronil Disipal Mimifon Dimetikon "Aco"	PS SS SS SS C C C C		ORAL	SEE IMAGE SEE IMAGE SEE IMAGE	

Date: 09/14/01 **ISR Number:** 3794253-0 **Report Type:** Expedited (15-Day) **Company Report#:** 2001004880-1 **Age:** 26 YR **Gender:** Female **I/FU:** F

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Life-Threatening Intervention to Prevent Permanent Impairment/Damage	Dyskinesia Dyspnoea Dystonia Trismus	Consumer Health Professional	Compazine Smithkline Beecham Birth Control Pills	PS C	Smithkline Beecham	RECTAL	25 MILLIGRAMS RECTAL	2 DAY

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 09/21/01	ISRN Number: 3796992-4	Report Type: Direct	Company Report#:	Age: 87 YR	Gender: Male	I/FU: 1
Outcome Other	PT Rash Erythematous Rash Generalised Rash Papular Rash Pruritic	Report Source	Product Gleevec Compazine Temazepam Levothyroxine Propoxyphene/Acetaminophen	Role PS SS C C C	Manufacturer	Route ORAL ORAL
					Dose 400MG PO DAILY 10MG PO Q8H PRN	Duration
Date: 09/25/01	ISRN Number: 3798122-1	Report Type: Direct	Company Report#:	Age: 77 YR	Gender: Male	I/FU: 1
Outcome Required Intervention to Prevent Permanent Impairment/Damage	PT Bronchospasm	Report Source	Product Compazine	Role PS	Manufacturer	Route
						Dose
						Duration
Date: 10/01/01	ISRN Number: 3802434-2	Report Type: Expedited (15-Day)	Company Report#: 2001013944-2	Age: 17 YR	Gender: Female	I/FU: 1
Outcome Other	PT Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Dystonia Full Blood Count Abnormal Hepatitis A Hepatomegaly Jaundice Nausea Pyrexia Vomiting	Report Source Health Professional	Product Compazine Smithkline Beecham Engerix-B Smithkline Beecham Engerix-B Smithkline Beecham	Role PS SS SS	Manufacturer Smithkline Beecham Smithkline Beecham Smithkline Beecham	Route
						Dose 1.0 DAILY 1.0 DAILY
						Duration 1 DAY 1 DAY
Date: 10/03/01	ISRN Number: 3804465-5	Report Type: Expedited (15-Day)	Company Report#: 2001019086-1	Age: 35 YR	Gender: Female	I/FU: F
Outcome Other Required Intervention to Prevent Permanent Impairment/Damage	PT Bite Other Dysphagia Dystonia Fracture Hypersensitivity Infection Neck Pain Pain Spinal Osteoarthritis Tooth Disorder Tooth Loss	Report Source Consumer Health Professional	Product Compazine Smithkline Beecham	Role PS	Manufacturer Smithkline Beecham	Route
						Dose 25 MILLIGRAMS
						Duration 2 DAY

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 10/16/01		ISR Number: 3809832-1	Report Type: Direct	Company Report#:		Age: 61 YR	Gender: Male	I/FU: 1
<u>Outcome</u>	<u>PT</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>	
Death Hospitalization - Initial or Prolonged	Abdominal Pain Cardiac Arrest Chest Pain Convulsion Nausea Vomiting	Compazine (1v-5 Mg) Gi Cocktail (Mylanta/Lidocaine)	PS SS			BUPRENEX/PAIN		
Date: 10/24/01		ISR Number: 3815060-6	Report Type: Expedited (15-Day)	Company Report#: 2001019086-1		Age: 35 YR	Gender: Female	I/FU: F
<u>Outcome</u>	<u>PT</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>	
Other Required Intervention to Prevent Permanent Impairment/Damage	Dystonia Hypersensitivity Infection Neck Pain Pain Tooth Injury Tooth Loss	Compazine Smithkline Beecham	PS	Smithkline Beecham		25 MILLIGRAMS	2 DAY	
Date: 10/29/01		ISR Number: 3817027-0	Report Type: Direct	Company Report#:		Age: 28 YR	Gender: Male	I/FU: 1
<u>Outcome</u>	<u>PT</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>	
Required Intervention to Prevent Permanent Impairment/Damage	Blood Pressure Abnormal Chest Pain Dyspnoea Dystonia Feeling Abnormal Tremor	Compazine Antibiotic	PS C		ORAL	ORAL		
Date: 10/29/01		ISR Number: 3817029-4	Report Type: Direct	Company Report#:		Age:	Gender: Female	I/FU: 1
<u>Outcome</u>	<u>PT</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>	
Hospitalization - Initial or Prolonged Other	Dyspnoea Dystonia Jaw Disorder Oculogyration Opisthotonus Tooth Disorder Torticollis Trismus Vision Blurred	Compazine 10 Mg Smithkline Benadryl	PS C	Smithkline	ORAL	10 MG ONCE ORAL		
Date: 11/13/01		ISR Number: 3823867-4	Report Type: Direct	Company Report#:		Age:	Gender: Female	I/FU: 1
<u>Outcome</u>	<u>PT</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>	
Disability	Abnormal Behaviour Anxiety Skin Discolouration Sleep Disorder	Compazine Wellbutrin	PS C		INTRAVENOUS	1 X INTRAVENOUS		

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 11/14/01 **ISR Number:** 3825126-2 **Report Type:** Expedited (15-Day) **Company Report#:** 2001013944-2 **Age:** 17 YR **Gender:** Female **I/FU:** F

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Other	Arthralgia Asthenia Decreased Appetite Dystonia Fatigue Hepatomegaly Myalgia Nausea Pyrexia Vomiting Weight Increased	Health Professional	Compazine Smithkline Beecham Engerix-B Smithkline Beecham Toprol XI (Metoprolol)	PS SS C	Smithkline Beecham Smithkline Beecham		1.0 DAILY	1 DAY

Date: 11/20/01 **ISR Number:** 3826283-4 **Report Type:** Expedited (15-Day) **Company Report#:** A0159171A **Age:** 48 YR **Gender:** Female **I/FU:** F

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Other	Chest Pain Circulatory Collapse Convulsion Dizziness Drug Interaction Ecchymosis Face Oedema Fall Head Injury Muscle Spasms Nausea Paralysis Sedation Tremor		Wellbutrin Phenothiazine Atenolol Lipitor Methotrexate Folic Acid Ambien Ativan Zantac	PS SS C C C C C C C	Glaxo Wellcome	ORAL INTRAVENOUS	100MG Twice per day	2 MON

Date: 11/26/01 **ISR Number:** 3829350-4 **Report Type:** Direct **Company Report#:** **Age:** 21 YR **Gender:** Female **I/FU:** I

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Other	Coordination Abnormal Dyskinesia Feeling Drunk Lid Lag Sedation		Compazine 5mg Trazodone 50mg	PS SS		ORAL ORAL	10MG Q8H ORAL 50MG QD AT HS ORAL	

Date: 12/06/01 **ISR Number:** 3836468-9 **Report Type:** Direct **Company Report#:** **Age:** 28 YR **Gender:** Female **I/FU:** I

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Other	Speech Disorder Tongue Oedema Trismus		Compazine Supp Flonase	PS C			1 DOSE	

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 12/17/01		ISR Number: 3839954-0	Report Type: Direct	Company Report#:	Age: 63 YR	Gender: Female	I/FU: 1
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
	Tremor		Compazine	PS			10MG, 4-6 HOURS PRN
			Taxol	SS			175MG/M2 (280MG)
			Carboplatin	SS			AUC 5(483MG)
			Gemcitabine	SS			800MG/M2 (1280MG)
			Percocet	C			
			Zofran	C			
Date: 12/18/01 ISR Number: 3841915-2 Report Type: Expedited (15-Day) Company Report#: 2015062							
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Death	Asphyxia	Health Professional	Oxycodone	PS		ORAL	PO
	Drowning	Other	Hydrochloride (Similar To Nda 20-553)	SS		ORAL	PO
	Drug Dependence		Carisoprodol	SS		ORAL	PO
	Excitation		Acetaminophen	SS		ORAL	PO
	Pulmonary Oedema		Phenothiazine	SS		ORAL	PO
	Toxicologic Test Abnormal		Caffeine	SS		ORAL	PO
			Methamphetamine	SS		ORAL	PO
			Amphetamine	SS		ORAL	PO
Date: 01/08/02 ISR Number: 3850068-6 Report Type: Direct Company Report#:							
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Other	Medication Error		Methotrexate	PS	Mylan		
			Compazine(Prochlorperazine)	SS	Mylan		
Date: 01/29/02 ISR Number: 3862668-8 Report Type: Expedited (15-Day) Company Report#: 2002000698-1							
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Hospitalization - Initial or Prolonged Other	Brain Damage Convulsion Dyskinesia	Consumer	Compazine	PS	Glaxosmithkline	INTRAVENOUS	1.0 AS NEEDED INTRAVENOUS 3 YR
Date: 01/30/02 ISR Number: 3861588-2 Report Type: Direct Company Report#: CTU 160469							
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Required Intervention to Prevent Permanent Impairment/Damage	Choking Pharyngeal Oedema		Compazine	PS		ORAL	10MG PO QH

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 02/11/02	ISR Number: 3867461-8	Report Type: Direct	Company Report#: CTU 161381	Age:	Gender: Female	I/FU: 1
Outcome: Other	PT: Hypersensitivity	Report Source:	Product: Compazine	Role: PS	Manufacturer:	Dose: 10 MG Q 4-6 HRS PRN
Date: 02/13/02	ISR Number: 3869592-5	Report Type: Periodic	Company Report#: 2012334	Age: 49 YR	Gender: Male	I/FU: 1
Outcome: Death	PT: Overdose	Report Source: Health Professional Other	Product: Oxycodone Hydrochloride (Similar To Nda 20-553) Secobarbital Phenobarbital Cocaine Dextromethorphan Phenothiazine	Role: PS SS SS SS SS SS	Manufacturer:	Dose:
Date: 02/13/02	ISR Number: 3871042-X	Report Type: Periodic	Company Report#: 2012355	Age: 19 YR	Gender: Male	I/FU: 1
Outcome: Death	PT: Accidental Overdose	Report Source: Health Professional Other	Product: Oxycodone Hydrochloride Diphenhydramine Cocaine Phenothiazine Nicotine Acetaminophen Promethazine	Role: PS SS SS SS SS SS SS	Manufacturer:	Dose:
Date: 02/28/02	ISR Number: 3877991-0	Report Type: Expedited (15-Day)	Company Report#: A0359205A	Age: 69 YR	Gender: Female	I/FU: 1
Outcome: Death Required Intervention to Prevent Permanent Impairment/Damage	PT: Heart Rate Decreased Pulse Absent	Report Source: Consumer	Product: Compazine Injection (Prochlorperazine)	Role: PS	Manufacturer:	Dose: 5 MG SINGLE DOSE/ INTRAVENOUS
Date: 03/01/02	ISR Number: 3878405-7	Report Type: Expedited (15-Day)	Company Report#: USA-2002-0000113	Age: 36 YR	Gender: Female	I/FU: 1
Outcome: Death	PT: Angiopathy Aspiration Completed Suicide Drug Level Above Therapeutic Drug Screen Positive Inflammation Lung Disorder Nervous System Disorder Obesity	Report Source: Consumer	Product: Salbutamol Sulphate	Role: C	Manufacturer:	Dose: 5 MG SINGLE DOSE/ INTRAVENOUS

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 04/02/02	ISR Number: 3894220-2	Report Type: Expedited (15-Day)	Company Report#: A0348824A	Age: 27 YR	Gender: Female	I/FU: F
Outcome Required Intervention to Prevent Permanent Impairment/Damage	PT Aphasia Dystonia Tongue Oedema Tongue Spasm Vaginal Haemorrhage	Report Source Health Professional	Product Compazine Suppository (Prochlorperazine)	Role PS	Manufacturer	Route RECTAL
					Dose FOUR TIMES PER DAY/PER RE	Duration
Date: 04/03/02	ISR Number: 3894929-0	Report Type: Direct	Company Report#: CTU 164902	Age: 42 YR	Gender: Male	I/FU: I
Outcome Other	PT Dystonia	Report Source	Product Compazine	Role PS	Manufacturer	Route INTRAVENOUS
					Dose 10MG IVP SLOW	Duration
Date: 04/08/02	ISR Number: 3898191-4	Report Type: Direct	Company Report#: CTU 165155	Age: 42 YR	Gender: Male	I/FU: I
Outcome Other	PT Dystonia	Report Source	Product Compazine	Role PS	Manufacturer	Route INTRAVENOUS
					Dose 10MG IVP SLOW	Duration
Date: 04/22/02	ISR Number: 3904819-2	Report Type: Expedited (15-Day)	Company Report#: A0348824A	Age: 27 YR	Gender: Female	I/FU: F
Outcome Required Intervention to Prevent Permanent Impairment/Damage	PT Anaphylactic Shock Aphasia Cerebrovascular Accident Complication Of Pregnancy Complications Of Maternal Exposure To Therapeutic Drugs Dystonia Maternal Drugs Affecting Foetus Muscle Spasms Tongue Oedema Tongue Spasm Vacuum Extractor Delivery Vaginal Haemorrhage	Report Source Health Professional	Product Compazine Suppository (Prochlorperazine)	Role PS	Manufacturer	Route RECTAL
					Dose FOUR TIMES PER DAY/PER RE	Duration
Date: 04/23/02	ISR Number: 3905235-X	Report Type: Direct	Company Report#: CTU 166442	Age: 75 YR	Gender: Female	I/FU: I
Outcome Disability	PT Malaise Tremor	Report Source	Product Hexalen 350mg Compazine 5mg Norgesic Primarin	Role PS SS C C	Manufacturer	Route
					Dose 7 A DAY X 8D 5 A DAY X 5 D THEN OFF X 2WK	Duration

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 04/26/02	ISRN Number: 3908079-8	Report Type: Expedited (15-Day)	Company Report#: A0357376A	Age: 48 YR	Gender: Male	I/FU: F
Outcome: Hospitalization - Initial or Prolonged Other	PT: Brain Damage Convulsion Dyskinesia	Report Source: Consumer	Product: Compazine Ampule (Prochlorperazine)	Route: INTRAVENOUS	Dose: INTRAVENOUS	Duration: 3 YR
		Role: PS	Manufacturer:			
Date: 05/15/02	ISRN Number: 3917031-8	Report Type: Direct	Company Report#: CTU 168096	Age: 29 YR	Gender: Female	I/FU: I
Outcome: Disability Other	PT: Clonic Convulsion Diaphragmatic Disorder Dyskinesia Dysphagia Dystonia Muscle Spasms Muscle Twitching Nervous System Disorder Paraesthesia Retching Tardive Dyskinesia	Report Source:	Product: Compazine Phenergan Demerol Phenergan/Compazine Ultram Versed	Route: INTRAVENOUS INTRAVENOUS DRIP	Dose: 25 MG EVERY 6 INTRAVENOUS 25 MG EVERY 6 INTRAVENOUS DRIP	Duration:
		Role: PS SS C C C C	Manufacturer:			
Date: 05/22/02	ISRN Number: 3921230-9	Report Type: Direct	Company Report#: CTU 168620	Age: 13 YR	Gender: Female	I/FU: I
Outcome:	PT: Feeling Abnormal Joint Dislocation Joint Stiffness Torticollis Tremor	Report Source:	Product: Compazine Meclizine Nasocort Doxycycline Compazine Zithromax	Route:	Dose:	Duration:
		Role: PS SS C C C C	Manufacturer:			
Date: 05/22/02	ISRN Number: 3921878-1	Report Type: Expedited (15-Day)	Company Report#: 02P-062-0193121-00	Age: 40 YR	Gender: Female	I/FU: I
Outcome: Required Intervention to Prevent Permanent Impairment/Damage	PT: Agranulocytosis Asthma Night Sweats Pharyngolaryngeal Pain	Report Source: Foreign Health Professional	Product: Akineton (Biperiden) (Biperiden) Perazine Haloperidol Venlafaxine Hydrochloride	Route: ORAL ORAL ORAL ORAL	Dose: 2 MG, 2 IN 1 D, PER ORAL SEE IMAGE 15 MG, 1 IN 1 D, PER ORAL 150 MG, 1 IN 1 D, PER ORAL	Duration:
		Role: PS SS SS SS	Manufacturer:			
Date: 06/13/02	ISRN Number: 3934060-9	Report Type: Expedited (15-Day)	Company Report#: D0038615A	Age: 20 YR	Gender: Female	I/FU: I
Outcome: Hospitalization - Initial or Prolonged	PT: Intentional Misuse Somnolence	Report Source: Foreign Health Professional	Product: Paxil Tablet (Paroxetine Hydrochloride)	Route: ORAL	Dose: 600 MG / SINGLE DOSE/ORAL	Duration:
		Role: PS	Manufacturer:			

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Compazine/Prochlorperazine Edisylate 10mg
 Toradol/Ketorolac Tromethamine 60mg

<u>Outcome</u>	<u>Date:</u> 07/16/02	<u>ISR Number:</u> 3949304-7	<u>Report Type:</u> Direct	<u>Company Report#:</u> CTU 172400	<u>Age:</u> 16 YR	<u>Gender:</u> Female	<u>I/FU:</u> 1
<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Apnoea		Demerol/Meperidine Hydrochloride 50mg	PS		INTRAMUSCULAR	50MG X 1 IM -030	
Brain Death		Phenergan/Promethazine Hydrochloride 50mg	SS		INTRAMUSCULAR	50MG X 1 IM -030	
Isatrogenic Injury		Compazine/Prochlorperazine ?Dosulate 10mg	SS		INTRAVENOUS	10MG X 1 IV 042	
Respiratory Depression		Toradol/Ketorolac Tromethamine 60mg	SS		INTRAVENOUS	60MG X 1 X IV 042	

Date: 08/16/02 ISR Number: 3964477-8 Report Type: Expedited (15-Day) Company Report#: NSADSS2002025900

<u>Outcome</u>	<u>Date:</u> 08/16/02	<u>ISR Number:</u> 3964477-8	<u>Report Type:</u> Expedited (15-Day)	<u>Company Report#:</u> NSADSS2002025900	<u>Age:</u> 80 YR	<u>Gender:</u> Female	<u>I/FU:</u> 1
<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Consumer	Fentanyl(50 Mcg/Hr Patch) (Fentanyl)	PS		TRANSDERMAL	25 MCG/H, 1 IN 72 HOUR(S), TRANSD	
Atherosclerosis		Propulsid(10 Mg Tablet) (Cisapride)	SS		ORAL	10 MG, 3 IN 1 DAILY, ORAL	
Cardiac Failure		Compazine (Prochlorperazine Edisylate)	SS		INTRAVENOUS	1 TIME(S), IV	
Congestive		Zantac (Ranitidine Hydrochloride)	C				
Cardiomegaly		Alprazolam (Alprazolam)	C				
Carotid Artery Stenosis		Aldactone (Spironolactone)	C				
Confusional State							
Dehydration							
Depressed Level Of Consciousness							
Drug Withdrawal Syndrome							
Hypertension							
Iron Deficiency Anaemia							
Metabolic Encephalopathy							
Mitral Valve Incompetence							
Nausea							
Somnolence							
Tricuspid Valve Incompetence							

Date: 08/19/02 ISR Number: 3965343-4 Report Type: Expedited (15-Day) Company Report#: EM1987-0071

<u>Outcome</u>	<u>Date:</u> 08/19/02	<u>ISR Number:</u> 3965343-4	<u>Report Type:</u> Expedited (15-Day)	<u>Company Report#:</u> EM1987-0071	<u>Age:</u> 48 YR	<u>Gender:</u> Male	<u>I/FU:</u> 1
<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Death	Study	Proleukin; Chiron	PS		INTRAVENOUS	5 MU/M2, TIW, IV; SEE IMAGE	
Life-Threatening Hospitalization - Initial or Prolonged	Literature Health Professional	Corporation (Aldesleukin) Injection					
Hypotension		Interferon Beta(Interferon					
Nasopharyngeal Disorder							
Pemphigus							
Pyrexia							
Sepsis							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration	
Hospitalization - Initial or Prolonged	Eosinophilia Pleural Infection	Foreign Health Professional Other	Beta)	SS		INTRAVENOUS	5 MU, MW, TTW, IV	5 DAY	
			Indocin(Indometacin)	SS					
			Compazine (Prochlorperazine Edisylate)	SS					5 DAY
			Demerol (Pethidine Hydrochloride)	SS					5 DAY
Date: 09/11/02 ISR Number: 3974283-6 Report Type: Expedited (15-Day) Company Report#: S02-GER-01891-01 Age: 48 YR Gender: Male I/FU: I									
Hospitalization - Initial or Prolonged			Cipramil (Citalopram Hydrobromide)	PS		ORAL	10 MG QD PO		
			Taxilan (Perazine)	SS		ORAL	200 MG QD PO		
			Atosil (Isopromethazine Hydrochloride)	SS		ORAL	50 MG QD PO		
Date: 09/11/02 ISR Number: 3974547-6 Report Type: Expedited (15-Day) Company Report#: 2002122476DE Age: 55 YR Gender: Female I/FU: I									
Death	Gastroenteritis Graft Versus Host Disease	Foreign Health Professional Other	Medrate Soluble 40/125/500/1000 (Methylprednisolone) Powder, Sterile	PS		INTRAVENOUS	IV		
			Alprostadiil Upjohn (Alprostadiil) Solution, Sterile, 500ug/MI	SS	Upjohn	INTRAVENOUS	IV		
Hospitalization - Initial or Prolonged			Farmitrexat (Methotrexate) Solution Sterile	SS		INTRAVENOUS	IV		
			Theo-Dur (Theophylline) Capsule	SS		INTRAVENOUS	400 MG, QD, IV		
			Neupogen (Filgrastim)	SS		INTRAVENOUS	700 UG, QD, IV		
			Furosemide (Furosemide)	SS		INTRAVENOUS	IV		
			Metamizole Sodium (Metamizole Sodium) Ofloxacin (Ofloxacin)	SS		INTRAVENOUS	IV		
			Ofloxacin (Ofloxacin)	SS		INTRAVENOUS	400 MG, QD, IV		
			Bromazepam (Bromazepam)	SS		ORAL	ORAL		
			Nystatin (Nystatin) Amphoteracin B (Amphotericin B) Morphine Hydrochloride (Morphine Hydrochloride) (Acetylcysteine (Acetylcysteine)	SS SS SS SS		ORAL ORAL QD, IV IV			
				SS		INTRAVENOUS	IV		
				SS		INTRAVENOUS	QD, IV		

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Omeprazole	SS	INTRAVENOUS	40 MG, QD, IV
(Omeprazole)			
Ceftazidime	SS	INTRAVENOUS	QD, IV
(Ceftazidime)			
Teicoplanin	SS	INTRAVENOUS	400 MG, QD, IV
(Teicoplanin)			
Tobramycin	SS	INTRAVENOUS	IV
(Tobramycin)			
Albumin Normal Human Serum (Albumin Normal Human Serum)	SS	INTRAVENOUS	IV
Insulin Human (Insulin Human)	SS	INTRAVENOUS	SINGLE, IV
Erythromycin (Erythromycin)	SS	INTRAVENOUS	QD, IV
Cilastatin Sodium w/Imipenem (Cilastatin Sodium, Imipenem)	SS	INTRAVENOUS	QD, IV
Isopromethazine Hydrochloride (Isopromethazine Hydrochloride)	SS	INTRAVENOUS	QD, IV
Doxycycline (Doxycycline)	SS	INTRAVENOUS	SEE IMAGE
Plasma Protein Fraction (Human)	SS	INTRAVENOUS	SINGLE, IV
Fraction (Human)			
Dexpanthenol (Dexpanthenol)	SS	RESPIRATORY (INHALATION)	RESPIRATORY
Ganciclovir Sodium (Ganciclovir Sodium)	SS	INTRAVENOUS	QD, IV
Salbutamol (Salbutamol)	SS	RESPIRATORY (INHALATION)	QD, RESPIRATORY
Lorazepam (Lorazepam)	SS	INTRAVENOUS	1 MG, IV
Vancomycin (Vancomycin)	SS	INTRAVENOUS	1 G, IV
Norepinephrine Hydrochloride (Norepinephrine Hydrochloride)	SS	INTRAVENOUS	SINGLE, IV
Ipratropium Bromide (Ipratropium Bromide)	SS	RESPIRATORY (INHALATION)	RESPIRATORY
Propofol (Propofol)	SS	INTRAVENOUS	IV
Sufentanil Citrate (Sufentanil Citrate)	SS	INTRAVENOUS	IV

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 09/11/02 ISR Number: 3974634-2 Report Type: Expedited (15-Day) Company Report#: A04200200319

Age: 51 YR Gender: Male I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Delirium Hallucination, Visual		Health Professional	Sitilnox (Zolpidem)Tablet 10 Mg Atosil (Isopromethazine Hydrochloride) Metoprolol Enalapril Diursan(Hydrochlorot iazide + Amiloride)	PS SS C C C		ORAL ORAL	10 MG ONCE 200 MG, ORAL	2 DAY

Date: 09/17/02 ISR Number: 3978440-4 Report Type: Expedited (15-Day) Company Report#: B0279790A

Age: 39 YR Gender: I I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Misuse	Literature Health Professional	Compazine (Formulation Unknown) (Prochlorperazine) Peglidine Hydrochloride (Formulation Unknown) (Meperidine Hydrochloride) Amitriptyline (Formulation Unknown) (Amitriptyline)	PS SS SS				

Date: 09/24/02 ISR Number: 3980291-1 Report Type: Expedited (15-Day) Company Report#: A214356

Age: 67 YR Gender: Female I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Attention Deficit/Hyperactivity Disorder Drug Interaction Drug Toxicity Extrapyramidal Disorder Lower Limb Fracture Medication Error Suicide Attempt Tachycardia	Foreign Health Professional	Zoloft (Sertraline) Unspecified Antidepressant Medication (Antidepressants) Phenothiazine (Phenothiazine) All Other Therapeutic Products	PS SS SS C		ORAL	ORAL	

Date: 10/15/02 ISR Number: 3993977-X Report Type: Direct

Age: 43 YR Gender: Female I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other Required Intervention to Prevent Permanent Impairment/Damage	Asthenia Dizziness Postural Fatigue Oligodipsia		L-Asparaginase Iv Compazine Po Allopurinol Allegra D Bactrim Ds	PS SS C C C		INTRAVENOUS ORAL	1700 UNITS DAY 18-29 IV 10 MG PO	

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 10/23/02 ISR Number: 3999554-9 Report Type: Expedited (15-Day) Company Report#: B0282420A Age: 37 YR Gender: Unknown I/FU: 1

<u>Outcome</u> Death	<u>PT</u> Completed Suicide Intentional Misuse	<u>Report Source</u> Literature Health Professional	<u>Product</u> Compazine (Formulation Unknown) (Prochlorperazine) Methadone Hydrochloride (Formulation Unknown) (Methadone Hydrochloride)	<u>Role</u> PS SS	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
-------------------------	--	--	--	-----------------------------	---------------------	--------------	-------------	-----------------

Date: 10/28/02 ISR Number: 3999520-3 Report Type: Direct Company Report#: CTU 179740 Age: 39 YR Gender: I/FU: 1

<u>Outcome</u> Hospitalization - Initial or Prolonged	<u>PT</u> Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Alkaline Phosphatase Increased Blood Bilirubin Increased	<u>Report Source</u>	<u>Product</u> Compazine 10 Mg Famvir 250 Mg	<u>Role</u> PS SS	<u>Manufacturer</u>	<u>Route</u> ORAL ORAL	<u>Dose</u> 10 Q 6 HR PO 250 MG PO	<u>Duration</u>
---	--	----------------------	--	-------------------------	---------------------	------------------------------	--	-----------------

Date: 11/19/02 ISR Number: 4012820-6 Report Type: Direct Company Report#: CTU 181330 Age: 16 YR Gender: Female I/FU: 1

<u>Outcome</u> Other	<u>PT</u> Dystonia	<u>Report Source</u>	<u>Product</u> Compazine 10mg Po Q6h Pm (Prochlorperazine Utd)	<u>Role</u> PS	<u>Manufacturer</u>	<u>Route</u> ORAL	<u>Dose</u> 10MG PO Q6H	<u>Duration</u>
-------------------------	-----------------------	----------------------	--	-------------------	---------------------	----------------------	----------------------------	-----------------

Date: 11/26/02 ISR Number: 4018654-0 Report Type: Expedited (15-Day) Company Report#: 325793 Age: 30 YR Gender: Male I/FU: 1

<u>Outcome</u> Death	<u>PT</u> Decreased Activity Deep Vein Thrombosis Depression Pulmonary Embolism Sedation	<u>Report Source</u> Foreign Study Health Professional	<u>Product</u> Diazepam (Diazepam) Haldol (Haloperidol) Taxilan (Perazine) Akineton (Biperiden Hydrochloride)	<u>Role</u> PS SS SS C	<u>Manufacturer</u>	<u>Route</u> ORAL ORAL ORAL ORAL	<u>Dose</u> 2.5 MG DAILY ORAL 5 MG DAILY ORAL 400 MG DAILY ORAL	<u>Duration</u>
-------------------------	---	--	--	------------------------------------	---------------------	--	---	-----------------

Date: 12/17/02 ISR Number: 4026079-7 Report Type: Direct Company Report#: CTU 182858 Age: 77 YR Gender: Female I/FU: 1

<u>Outcome</u> Hospitalization - Initial or Prolonged	<u>PT</u> Alanine Aminotransferase Abnormal Aspartate Aminotransferase Abnormal Blood Alkaline	<u>Report Type: Direct</u>	<u>Company Report#: CTU 182858</u>
---	---	----------------------------	------------------------------------

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Phosphatase Abnormal
Chest Pain
Nausea

Report Source
Compazine Supp 25mg

Role
PS

Route

Dose
RECTAL 25MG 1
DOSE

Duration

Date: 01/21/03 ISR Number: 4046906-7 Report Type: Expedited (15-Day) Company Report#: 2002-07-2525 Age: 53 YR Gender: Female I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia Anxiety Depression Extrapyramidal Disorder Fatigue Influenza Like Illness Insomnia Psychomotor Retardation Weight Decreased	Health Professional Company Representative	Peg-Intron (Peginterferon Alfa-2b) Injectable Powder Rebetol (Ribavirin) Capsules Compazine Ativan Paxil Trazodone Xanax	PS SS SS SS SS SS SS SS		SUBCUTANEOUS ORAL UNKNOWN UNKNOWN UNKNOWN UNKNOWN	SEE IMAGE 1200 MG QD ORAL UNKNOWN UNKNOWN UNKNOWN UNKNOWN	

Date: 01/21/03 ISR Number: 4047077-3 Report Type: Expedited (15-Day) Company Report#: 2002-07-2525 Age: 53 YR Gender: Female I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia Anxiety Depression Extrapyramidal Disorder Fatigue Influenza Like Illness Insomnia Psychomotor Retardation Weight Decreased	Health Professional Company Representative	Peg-Intron (Peginterferon Alfa-2b) Rebetol Powder Compazine Ativan Paxil Trazodone Xanax	PS SS SS SS SS SS SS SS		SUBCUTANEOUS ORAL	SEE IMAGE 1200 MG QD ORAL	

Date: 01/22/03 ISR Number: 4044442-5 Report Type: Expedited (15-Day) Company Report#: A0392065A Age: F Gender: Female I/FU: F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Twitching Opisthotonus Overdose Speech Disorder		Compazine	PS	Glaxo Wellcome	ORAL		

Date: 02/06/03 ISR Number: 4055671-9 Report Type: Expedited (15-Day) Company Report#: USA-2003-0004785 Age: 54 YR Gender: Female I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Coordination Abnormal Fall Fatigue Neuropathy Peripheral Tremor	Study Health Professional Other	Ms Contin Tablets (Morphine Sulfate) Cr Tablet Msir Capsules (Morphine Sulfate) Ir Capsule	PS SS		ORAL	ORAL	37 DAY 37 DAY

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Epo 906i36441+	SS	REGIMEN #1	37	DAY
Solinf) Solution		REGIMEN #1	37	DAY
Compazine				
(Prochlorperazine				
Edisylate)	SS			
Depakote (Valproate				
Semisodium)	SS			
Bactrim				
(Sulfamethoxazole,				
Trimethoprim)	C			
Imodium	C			
Lactulose	C			
Albuterol				
(Salbutamol)	C			
Glucophag (Metformin				
Hydrochloride)	C			
Lamictal				
(Lamotrigine)	C			
Ibuprofen	C			

Date: 02/12/03 ISR Number: 4054815-2 Report Type: Expedited (15-Day) Company Report#: US-GLAXOSMITHKLINE-A0395206A

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration	IFU: I
Other	Asthenia		Compazine	PS	Glaxosmithkline	RECTAL	25MG Single dose	1 DAY	
	Blood Pressure								
	Fluctuation								
	Dysarthria								
	Loss Of Consciousness								
	Memory Impairment								
	Somnolence								

Date: 03/04/03 ISR Number: 4070406-1 Report Type: Expedited (15-Day) Company Report#: B0293115A

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration	IFU: I
Other	Cyanosis	Foreign Literature Health Professional	Compazine (Formulation Unknown)	PS		INTRAMUSCULAR	12.5 MG / PER DAY / INTRAMUSCULAR		
	Dyspnoea								
	Dystonia								
	Stridor								

Date: 03/05/03 ISR Number: 4066291-4 Report Type: Expedited (15-Day) Company Report#: JP-GLAXOSMITHKLINE-B0293076A

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration	IFU: I
Hospitalization - Initial or Prolonged	Dyspnoea	Health Professional	Paxil	PS	Glaxosmithkline	ORAL	30MG per day		
Other	Joint Stiffness		Fluvoxamine Maleate	SS		ORAL	200MG per day		
	Speech Disorder		Risperidone	SS		ORAL	2MG per day		
			Phenothiazine	SS		ORAL			
			Over Counter Cold Remedy	SS		ORAL			

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 03/19/03 ISR Number: 4078709-1 Report Type: Expedited (15-Day) Company Report#: EMADSS2003002149

Age: 42 YR Gender: Male I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Contusion Convulsion Drug Dependence Drug Interaction Drug Level Increased Electrocardiogram Q Prolonged Haematoma	Foreign Health Professional	Haldol (Unspecified) (Haloperidol) Stangyl (Trimipramine Malcate) Taxilan (Perazine)	PS SS SS		ORAL ORAL ORAL	SEE IMAGE 100 MG, DAILY, ORAL 300 MG, DAILY, ORAL	
			Dominal (Prothipendyl Hydrochloride)	SS		ORAL	80 MG, DAILY, ORAL	
			Fevarin (Fluvoxamine Malcate) Nexium (Esomeprazole Magnesium) Vitamin B1 (Thiamine Hydrochloride) Carbamazepine (Carbamazepine)	SS C C C		ORAL	SEE IMAGE	

Date: 04/25/03 ISR Number: 4097629-X Report Type: Direct Company Report#: USP 51502

Age: Gender: I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Compazine (Prochlorperazine Maleate) Tablet Compazine (Prochlorperazine Edisylate)	PS SS	Smithkline Beecham Smithkline Beecham			INJECTABLE

Date: 04/25/03 ISR Number: 4097696-3 Report Type: Direct Company Report#: USP 51534

Age: 62 YR Gender: Female I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation Medication Error		Compazine (Prochlorperazine) Metamucil (Psyllium)	PS SS	Smithklinebeecham		VIAL 10 MG VIAL 2 ML SEE IMAGE	

Date: 04/25/03 ISR Number: 4097747-6 Report Type: Direct Company Report#: USP 51570

Age: 75 YR Gender: Male I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Compazine	PS	Skb		VIAL	

Date: 04/25/03 ISR Number: 4103003-X Report Type: Expedited (15-Day) Company Report#: 2003AP01598

Age: 53 YR Gender: Male I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Disease Recurrence Ileus Paralytic Psychomotor Hyperactivity							

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Restlessness

<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Foreign	Seroquel	PS		ORAL	25 MG TID PO	
Study	Seroquel	SS		ORAL	50 MG TID PO	
Health	Seroquel	SS		ORAL	100 MG TID PO	
Professional	Levotamin	SS		ORAL	85 MG DAILY	
Other	Levotamin	SS		ORAL	200 MG DAILY	
	Tasmolin	C				
	Depakene	C				
	Vegetamin	C				
	Benzalin	C				
	Lendormin	C				
	Forsenid	C				
	Laxoberon	C				

Date: 05/01/03 **ISR Number:** 4101750-7 **Report Type:** Expedited (15-Day) **Company Report#:** JP-GLAXOSMITHKLINE-B0293076A **Age:** 17 YR **Gender:** Female **I/FU:** F

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization -	Dyspnoea	Health	Paxil	PS	Glaxosmithkline	ORAL	30MG per day	
Initial or Prolonged	Jaw Disorder	Professional	Fluvoxamine Maleate	SS		ORAL	200MG per day	
Other	Muscle Rigidity		Risperidone	SS		ORAL	2MG per day	
	Speech Disorder		Phenothiazine	SS		ORAL		
			Over Counter Cold Remedy	SS		ORAL		1 DAY

Date: 05/06/03 **ISR Number:** 4119047-8 **Report Type:** Periodic **Company Report#:** A0369558A **Age:** 56 YR **Gender:** Female **I/FU:** I

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Other	Grand Mal Convulsion	Consumer	Compazine Injection (Prochlorperazine)	PS			SINGLE DOSE/ OTHER	
	Skin Discolouration							
	Swollen Tongue							

Date: 05/06/03 **ISR Number:** 4119049-1 **Report Type:** Periodic **Company Report#:** A0376095A **Age:** **Gender:** Male **I/FU:** I

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization -	Extrapyramidal Disorder	Health	Compazine Injection (Prochlorperazine)	PS		INTRAMUSCULAR	5 MG/PER DAY/ INTRAMUSCULAR	DAY
Initial or Prolonged	Tardive Dyskinesia	Professional						

Date: 05/06/03 **ISR Number:** 4119052-1 **Report Type:** Periodic **Company Report#:** A0377060A **Age:** 25 YR **Gender:** Female **I/FU:** I

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Required Intervention to Prevent Permanent Impairment/Damage	Dystonia	Health	Compazine Injection (Prochlorperazine)	PS		INTRAVENOUS	INTRAVENOUS	
		Professional	Compazine					
			Suppository (Prochlorperazine)	SS		RECTAL	PER RECTUM	
			Percocet	C				
			Hydrocodone	C				
			Necon	C				

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 05/12/03 ISR Number: 4112024-2 Report Type: Direct Company Report#: USP 51607 Age: 80 YR Gender: Female I/FU: 1

Outcome
Other
PT
Medication Error
Report Source
Heparin Sodium
Compazine Injection
Role
PS
SS
Manufacturer
Abbott
Skb
Route
INTRAVENOUS
Dose
INJECTABLE
250 ML IV BAG
INJECTABLE 2
ML VIAL
Duration

Date: 05/27/03 ISR Number: 4117927-0 Report Type: Expedited (15-Day) Company Report#: DEWYE137120MAY03 Age: 51 YR Gender: Male I/FU: 1

Outcome
Hospitalization -
Initial or Prolonged
PT
Blood Creatine
Phosphokinase Increased
Overdose
Somnolence
Report Source
Foreign
Health
Professional
Product
Tavor (Lorazepam,
Tablet, 0)
Aurorix
Euphyllong
(Moclobemide, 0)
(Theophylline, 0)
Ibuprofen
(Ibuprofen, 0)
Katadolon
(Flupirtine Maleate,
0)
Oxycodone
(Oxycodone, 0)
Seroquel (Quetiapine
Fumarate, 0)
Taxilan (Perazine,
0)
Role
PS
SS
SS
SS
SS
SS
SS
SS
SS
SS
Manufacturer
Route
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
Dose
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
Duration
1 DAY
1 DAY
1 DAY
1 DAY
1 DAY
1 DAY
1 DAY
1 DAY
1 DAY
1 DAY

Date: 05/30/03 ISR Number: 4121296-X Report Type: Expedited (15-Day) Company Report#: DSA_60319_2003 Age: 45 YR Gender: Female I/FU: 1

Outcome
Other
PT
Cerebrovascular Accident
Report Source
Health
Professional
Company
Representative
Product
Dhc-45
Reglan
Compazine
Role
PS
SS
SS
Manufacturer
Route
Dose
Duration

Date: 06/04/03 ISR Number: 4123933-2 Report Type: Expedited (15-Day) Company Report#: 03P-056-0219648-00 Age: 56 YR Gender: Female I/FU: 1

Outcome
Hospitalization -
Initial or Prolonged
PT
Anorexia
Bradyphrenia
Conduction Disorder
Dehydration
Diarrhoea
Electrocardiogram Qt
Prolonged
General Physical Health
Deterioration
Hypersomnia
Hyperthyroidism
Hypokalaemia
Limb Injury
Loss Of Consciousness
Malaise
Report Source
Product
Role
Manufacturer
Route
Dose
Duration

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Renal Disorder
Syncope
Weight Decreased

<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Foreign Health Professional	Isopine Sr (Verapamil)	PS		ORAL	120 MG, 2 IN 1 D, PER ORAL	
	L-Thyroxin	SS		ORAL	200 MCG, 1 IN 1 D, PER ORAL	
	Fluoxetine	SS		ORAL	20 MG, 2 IN 1 D, PER ORAL	
	Alimemazine	SS		ORAL	25 MG, PER ORAL	
	Sodium Divalproate	SS		ORAL	2 DOSAGES FORMS, 2 IN 1 D, PER ORAL	
	Hexaquine	SS		ORAL	2 DOSAGES FORM, 3 IN 1 D, PER ORAL	
	Prazepam	C				
	Zopiclone	C				
	Endotelon	C				
	Omeprazole	C				
	Potassium	C				
	Estrogens	C				
	Panadine Co	C				
	Mebeverine	C				
	Phloroglucinol	C				
	Metronidazole	C				

Date: 06/04/03 ISR Number: 4124213-1 Report Type: Expedited (15-Day) Company Report#: B0300214A

Age: 16 YR Gender: I I/FU: I

Outcome
Death

<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Cardio-Respiratory Arrest Completed Suicide	Literature Health Professional	Compazine (Formulation Unknown) (Prochlorperazine)	PS				

Date: 06/11/03 ISR Number: 4126388-7 Report Type: Expedited (15-Day) Company Report#: US-GLAXOSMITHKLINE-A0411046A

Age: Gender: Female I/FU: F

Outcome
Other

PT
Complications Of Maternal Exposure To Therapeutic Drugs
Hypersensitivity
Tongue Disorder
Trismus

<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
	Thorazine	PS	Glaxosmithkline	ORAL		2 WK
	Compazine	SS	Glaxosmithkline	ORAL		6 WK
	Codeme	C				
	Valium	C				

Date: 06/11/03 ISR Number: 4126389-9 Report Type: Expedited (15-Day) Company Report#: US-GLAXOSMITHKLINE-A0411046B

Age: 18 MON Gender: Male I/FU: F

Outcome
Other

PT
Aphasia
Drug Exposure During Pregnancy
Hypokinesia
Inability To Crawl

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Lisencephaly	Thorazine	PS	Glaxosmithkline			2 WK
Respiratory Disorder	Compazine	SS	Glaxosmithkline			6 WK
Visual Disturbance	Codeine	C				
	Valium	C				
	Zofran	C	Glaxosmithkline			
	Phenergan	C	Glaxosmithkline			
	Reglan	C	Glaxosmithkline			
	Ativan	C				
	Ambien	C				
	Benadryl	C	Glaxosmithkline			

Date: 06/20/03 **ISR Number:** 4132967-3 **Report Type:** Direct **Company Report#:** CTU 196289E **Age:** 47 YR **Gender:** Male **I/FU:** 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Diabetes Mellitus		Peg-Intron	PS		SUBCUTANEOUS		
Other	Encephalopathy		(Peginterferon Alfa-2b) Injectable Powder	SS		SUBCUTANEOUS		
	Parkinson'S Disease		Compazine	SS		ORAL		
			Rebrol (Ibavirin) Capsules			ORAL		

Date: 06/20/03 **ISR Number:** 4134155-3 **Report Type:** Direct **Company Report#:** CTU 196314 **Age:** 15 YR **Gender:** Male **I/FU:** 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Intervention to Prevent Permanent Impairment/Damage	Dystonia		Compazine	PS			25 RS X 2	

Date: 06/23/03 **ISR Number:** 4134599-X **Report Type:** Expedited (15-Day) **Company Report#:** 03P-062-0221394-00 **Age:** 39 YR **Gender:** Female **I/FU:** 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Agitation	Foreign Health Professional	Kiaacid	PS		ORAL	2500 MG, ONCE, PER ORAL	
	Hyperventilation		Filmtablet(Biaxin) (Clarithromycin)					
	Psychotic Disorder		Isopromethazine	SS		ORAL	PER ORAL	
	Somnolence		Hydrochloride	SS		ORAL	PER ORAL	
	Suicide Attempt		Dominal 80	SS		ORAL	40 MG, ONCE, PER ORAL	
	Vomiting		Lorazepam	SS		ORAL	11340 MG, ONCE, PER ORAL	
			Phenobarbital	SS		ORAL	1395 MG, ONCE, PER ORAL	
			Dormicum	SS		ORAL	ONCE, PER ORAL	
			Diazepam	SS		ORAL	1250 MG, ONCE, PER ORAL	

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Nervous System Disorder
Schizoaffective Disorder
Tic

Report Source
Foreign

Product
Anafranil 25mg
Capsules 100
Leponex
Quilonum Slow
Release
Haldol
Taxilan

Role

PS
SS
SS
SS
SS

Route

Dose
225MG

Duration

Date: 08/04/03 ISR Number: 4161138-X Report Type: Direct Company Report#: USP 55988

Age: Gender: I/F/U: I

Outcome
PT Medication Error

Report Source

Product
Ipratropium Bromide
Inhalation Sol
Nephron Pharm Corp;
Deylabs

Role

PS

Route

Dose

Duration

Nephron Pharm Corp;
Deylabs

Manufacturer

Albuterol Sulf.
Inhalation Sol Dey
Labs Napa, Ca;
Alpharma

SS

Route

Dose

Duration

Dey Labs Napa, Ca;
Alpharma

Manufacturer

Refresh Ophthalmic
Allergan, Inc,
Irvine, Ca

SS

Route

Dose

Duration

Allergan, Inc,
Irvine, Ca

Manufacturer

Acetaminophen Rectal
Suppose 325mg. G&W
Labs, Plainfield, Nj

SS

Route

Dose

Duration

G&W Labs,
Plainfield, Nj

Manufacturer

Pilocar
(Pilocarpine) Ophth.
Solution 4% Ciba
Vision, Duluth, Ga

SS

Route

Dose

Duration

Ciba Vision, Duluth,
Ga

Manufacturer

Diovan Tablets 80mg
Novartis

SS

Route

Dose

Duration

Novartis

Manufacturer

Bactroban Nasal Oint
1 Gm Glaxo/Smith,
Research Triangle
Park, Nc

SS

Route

Dose

Duration

Glaxo/Smith,
Research Triangle
Park, Nc

Manufacturer

Sodium Chloride
Inhalation Solution
10 Ml Ballard
Medical Products

SS

Route

Dose

Duration

Ballard Medical
Products

Manufacturer

Depakote Tab 500mg
Abbott Labs

SS

Route

Dose

Duration

Abbott Labs

Manufacturer

Dilantin Caps 100 Mg
Parke-Davis
Compazine Rectal

SS

Route

Dose

Duration

Parke-Davis

Manufacturer

Suppositories 5mg
Smith-Kline Beecham
Xopenex Sepracor

SS
SS

Route

Dose

Duration

Smith-Kline Beecham
Sepracor

Manufacturer

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 08/15/03	ISRN: 4169510-9	Report Type: Direct	Company Report#: USP 50817	Age: 95 YR	Gender: Male	I/FU: 1
Outcome: Other	PT: Medication Error	Report Source:	Product: Restoril Compazine	Role: PS SS	Manufacturer: Sandoz Smithkline Beecham	Dose: CAPSULE Duration:
Date: 09/04/03	ISRN: 4181140-1	Report Type: Direct	Company Report#: USP 042232	Age:	Gender:	I/FU: 1
Outcome: Other	PT: Medication Error	Report Source:	Product: Compazine Combid	Role: PS SS	Manufacturer: Smith Kline Beecham Smith Kline Beecham	Dose: ENTORIC TABS Duration:
Date: 09/11/03	ISRN: 4189422-4	Report Type: Expedited (15-Day)	Company Report#: 2003UW11044	Age: 54 YR	Gender: Female	I/FU: 1
Outcome: Death	PT: Cardiomegaly Deep Vein Thrombosis Diverticulum Intestinal Drug Screen Positive Echymosis Liver Disorder Post Procedural Complication Pulmonary Embolism Renal Disorder Spleen Disorder Ventricular Hypertrophy	Report Source: Health Professional	Product: Mepivacaine Acetaminophen Phenothiazine Metabolites Ephedrine Pseudoephedrine Benzodiazepine	Role: PS SS SS SS SS SS	Manufacturer:	Dose: Duration:
Date: 09/25/03	ISRN: 4200308-9	Report Type: Expedited (15-Day)	Company Report#: MK200211-0154-3	Age: 31 YR	Gender: Male	I/FU: F
Outcome: Hospitalization - Initial or Prolonged	PT: Serotonin Syndrome	Report Source: Foreign Literature	Product: Anafranil (Clomipramine Hydrochloride) Levotomin Amoxapine Seniran Rohypnol Solatex	Role: PS SS C C C C	Manufacturer:	Dose: 25 MG Duration:
Date: 10/27/03	ISRN: 4219531-2	Report Type: Direct	Company Report#: CTU 204615	Age: 76 YR	Gender: Female	I/FU: 1
Outcome: Hospitalization - Initial or Prolonged	PT: Anxiety Restlessness	Report Source:	Product: Metoclopramide Compazine Synthroid Duragesic Coumadin Lorazepam Compazine (Prochlorperazine)	Role: PS SS C C C C C	Manufacturer:	Dose: ORAL Duration: 1 DAY

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 10/28/03 ISR Number: 4233108-4 Report Type: Periodic Company Report#: WAES 0307USA03048

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Spasms Nuchal Rigidity	Health Professional Company Representative	Cap Emend Compazine Anzemet Decadron Tablets Cisplatin Etoposide	PS SS SS C C C		ORAL ORAL	125 MG/1X/PO PO	

Date: 11/03/03 ISR Number: 4226617-5 Report Type: Expedited (15-Day) Company Report#: 03P-087-0238185-00

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Fall Haemodialysis Renal Failure Acute Rhabdomyolysis	Foreign Health Professional	Akineton (Biperiden) (Biperiden) Risperidone Haloperidol Phenothiazine Amanitadine Hydrochloride Flunitrazepam Dantrolene Sodium	PS SS SS SS SS SS SS SS C		ORAL ORAL ORAL ORAL ORAL ORAL	PER ORAL PER ORAL PER ORAL PER ORAL PER ORAL PER ORAL	

Date: 11/25/03 ISR Number: 4242317-X Report Type: Expedited (15-Day) Company Report#: B0312991A

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension Ascites Breath Sounds Decreased Cardiac Murmur Cholestasis Hepatic Failure Hepatic Fibrosis Inflammation Oedema Peripheral Pleural Effusion Pruritus	Literature Health Professional	Compazine (Formulation Unknown) Sirolimus(Prochlorpe razine) Sirolimus Tacrolimus Prednisone Ranitidine Hydrochloride Co-Trimoxazole Multivitamin Frusemide Spironolactone Insulin Lorazepam Calcium Carbonate	PS C C C C C C C C C C C C				27 MON

Date: 11/26/03 ISR Number: 4243968-9 Report Type: Expedited (15-Day) Company Report#: 2003-DE-05938GD

Age: 64 YR Gender: Female I/FU: I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Multiple Drug Overdose	Foreign Literature	Paracetamol (Paracetamol) Codeine (Codeine) Tricyclic Antidepressants (Antidepressants) Phenothiazine Alkaloid	PS SS SS SS SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date: 12/12/03 ISR Number: 4250917-6 Report Type: Expedited (15-Day) Company Report#: US-GLAXOSMITHKLINE-A0442575A Age: 70 YR Gender: Female I/F/U: 1

Outcome
Hospitalization - Initial or Prolonged

PT
Dehydration
Fatigue
Nausea
Vomiting

Report Source
Zofran
Compazine

Product
Zofran
Compazine

Role
PS
SS

Manufacturer
Glaxosmithkline
Glaxosmithkline

Route
UNKNOWN
UNKNOWN

Dose

Duration

Date: 12/17/03 ISR Number: 4270891-6 Report Type: Periodic Company Report#: USA-2002-0000387 Age: 23 YR Gender: Male I/F/U: 1

Outcome
Death

PT
Accidental Overdose
Respiratory Depression

Report Source
Consumer
Health
Professional
Other

Product
Oxycontin Tablets
(Oxycodone Hydrochloride)
Ethanol (Ethanol)
Diazepam (Diazepam)
Cannabis (Cannabis)
Phenothiazine
(Phenothiazine)
Caffeine (Caffeine)
Lidocaine
(Lidocaine)

Role
PS
SS
SS
SS
SS
SS
SS

Manufacturer

Route
INTRAVENOUS

Dose
UNK MG UNK
INTRAVENOUS

Duration

Date: 12/22/03 ISR Number: 4256895-8 Report Type: Direct Company Report#: CTU 208582 Age: Gender: Female I/F/U: 1

Outcome
Hospitalization - Initial or Prolonged

PT
Pharmaceutical Product
Complaint
Torticollis

Report Source

Product
Mg
Benadryl

Role
PS
C

Manufacturer
Mylan

Route

Dose
TID/PPW

Duration

Date: 12/29/03 ISR Number: 4261069-0 Report Type: Expedited (15-Day) Company Report#: DSA_23642_2003 Age: 44 YR Gender: Female I/F/U: F

Outcome
Hospitalization - Initial or Prolonged

PT
Bowel Sounds Abnormal
Diarrhoea
Hypotension
Intentional Misuse
Somnolence

Report Source
Foreign
Health
Professional
Other

Product
Tavor
Taxilan

Role
PS
SS

Manufacturer

Route
ORAL
ORAL

Dose
20 MG ONCE PO
6000 MG ONCE
PO

Duration

Date: 01/28/04 ISR Number: 4286904-1 Report Type: Expedited (15-Day) Company Report#: KI-2003-0006918 Age: 56 YR Gender: Female I/F/U: 1

Outcome
Death

PT
Breast Cancer Metastatic
Metastases To Spine
Nervous System Disorder

Report Source
Health
Professional
Company
Representative

Product
Ms Contin Tablets
(Morphine Sulfate)
C- Tablet
Msir Capsules
(Morphine Sulfate)
Ir Capsule
Compazine
(Prochlorperazine Edisylate)
Ativan (Lorazepam)

Role
PS
SS
SS
SS

Manufacturer

Route

Dose
30 MG, Q12H
30 MG, Q2-4H

Duration

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 02/03/04 **ISR Number:** 4289644-8 **Report Type:** Periodic **Company Report#: 200311879BWH** **Age:** 63 YR **Gender:** Female **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema Flushing Hypersensitivity Throat Tightness Tremor Urticaria	Consumer Company Representative	Avelox (Moxifloxacin Hydrochloride) Darvocet N 100 Compazine (Prochlorperazine Edisylate)	PS SS SS		ORAL ORAL	400 MG, QD, ORAL ORAL	

Date: 02/04/04 **ISR Number:** 4286917-X **Report Type:** Expedited (15-Day) **Company Report#: US-JNIFOC-20040105212** **Age:** 38 YR **Gender:** Female **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Spontaneous Complications Of Maternal Exposure To Therapeutic Drugs Intra-Uterine Death Maternal Drugs Affecting Foetus Pregnancy	Study Health Professional	Infliximab (Infliximab Recombinant) Lyophilized Powder Mesalamine (Mesalazine) Asacol Azathioprine; Imuran (Azathioprine) Levbid (Hyoscyamine Sulfate) Prevacid (Lansoprazole) Gaviscon (Gaviscon) Phenergan (Promethazine Hydrochloride) Bentyl (Dicycloverine Hydrochloride) Compazine (Prochlorperazine Edisylate) Ativan (Lorazepam) Klonopin (Clonazepam) Narcotic Analgesics (Analgesics) Other Crohn'S Therapy (Nos) (All Other Therapeutic Products)	PS SS SS SS SS SS SS SS SS SS SS SS SS SS SS SS SS SS C C		INTRAVENOUS	5 MG/KG, INTRAVENOUS	

Date: 02/26/04 **ISR Number:** 4305267-6 **Report Type:** Periodic **Company Report#: US-BRISTOL-MYERS SQUIBB COMPANY-12110375** **Age:** 77 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Agitation Back Pain Dyskinesia Muscle Spasms Neurotoxicity		Taxol	PS	Bristol-Myers Squibb Company	INTRAVENOUS	Cycle 2: 13-Nov-02, 2 mg in 100 ml saline Cycle 1: 05-Nov-02	

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Combivent	SS			
Compazine	SS			
Carboplatin	C		Bristol-Myers Squibb Company	INTRAVENOUS
Flovent	C			
Isordil	C			
Tylenol	C			
Zofran	C			
Benadryl	C			
Pepcid	C			
Dexamethasone	C			INTRAVENOUS
Vistaril	C			ORAL

Pre-med for cycle 2

Date: 02/27/04 ISR Number: 4308855-6 Report Type: Expedited (15-Day) Company Report#: MK200402-0235-1 Age: 23 YR Gender: Male I/FU: 1

Outcome
Hospitalization - Initial or Prolonged

PT
Cardiac Arrest
Loss Of Consciousness
Pancreatic Pseudocyst
Pancreatitis Acute

<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Anafranil Capsules	PS				
Melleril	SS				
Lexotan	SS				
Pyrethia	SS				
Vegetamin A	SS				
Hirnamin	SS				
Isonyral	SS				
Halcion	SS				
Ritalin	SS				

Date: 03/01/04 ISR Number: 4309658-9 Report Type: Expedited (15-Day) Company Report#: KIL-2003-0007244 Age: 36 YR Gender: Female I/FU: 1

Outcome
Hospitalization - Initial or Prolonged
Other

PT
Bradycardia
Depressed Level Of Consciousness
Depressed Mood
Dysarthria
Hyperhidrosis
Hypertension
Intentional Misuse
Multiple Drug Overdose
Orthostatic Hypotension
Po2 Abnormal
Sedation
Somnolence

<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Morphine Sulfate	PS		ORAL	ORAL	
Clonidine	SS		ORAL	ORAL	
Hydrocodone	SS		ORAL	ORAL	
W/Acetaminophen	SS		ORAL	ORAL	
W/Oxycodone	SS		ORAL	ORAL	
Acetaminophen	SS		ORAL	ORAL	
W/Codeine	SS		ORAL	ORAL	
Tramadol	SS		ORAL	ORAL	
Progesterone	SS		ORAL	ORAL	
Furosemide	SS		ORAL	ORAL	
Naprosyn (Naproxen)	SS		ORAL	ORAL	
Acetylsalicylic Acid	SS		ORAL	ORAL	
Indomethacin	SS		ORAL	ORAL	
Phenergan	SS		ORAL	ORAL	
"Specia" (Promethazine Hydrochloride)	SS	Specia	ORAL	ORAL	
Folic Acid	SS		ORAL	ORAL	
Phenothiazine	SS		ORAL	ORAL	
Trazodone	SS		ORAL	ORAL	
Ibuprofen	SS		ORAL	ORAL	
Benzodiazepines	C		ORAL	ORAL	
Drivatives	C		ORAL	ORAL	
Nasal Spray	C		ORAL	ORAL	
Ssri	C		ORAL	ORAL	
Corticosteroid Nos	C		ORAL	ORAL	
Antibiotics	C		ORAL	ORAL	

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 03/10/04 **ISR Number:** 4315837-7 **Report Type:** Expedited (15-Day) **Company Report#:** MK200402-0235-2 **Age:** 23 YR **Gender:** Male **I/FU:** F

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Cardiac Arrest Cardiac Fibrillation Hypothermia Loss Of Consciousness Mydriasis Oedematous Pancreatitis Overdose Pancreatic Pseudocyst Pancreatitis Acute Pupil Fixed Suicide Attempt	Foreign Health Professional Other	Anafranil Capsules Mellril Lexotan Pyrethia Vegetamin A Hirnamin Isomytal Halcion Ritalin	PS SS SS SS SS SS SS SS			ONE TIME DOSE ONE TIME DOSE ONE TIME DOSE ONE TIME DOSE ONE TIME DOSE ONE TIME DOSE ONE TIME DOSE ONE TIME DOSE	

Date: 03/15/04 **ISR Number:** 4318224-0 **Report Type:** Expedited (15-Day) **Company Report#:** 2004-113527-NL **Age:** 45 YR **Gender:** Male **I/FU:** I

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Lactate Dehydrogenase Increased Drug Level Increased Gamma-Glutamyltransferase Increased	Health Professional	Mirtazapine Perazine Lorazepam Sertraline Hydrochloride	PS SS SS C		ORAL ORAL ORAL	SEE IMAGE 100 MG, ORAL SEE IMAGE	13 W/KY 3 DAY

Date: 03/30/04 **ISR Number:** 4331959-9 **Report Type:** Expedited (15-Day) **Company Report#:** B0326031A **Age:** **Gender:** Male **I/FU:** I

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Congenital Anomaly	Anomaly Of External Ear Congenital Apnoea Asthma Body Height Below Normal Bradycardia Neonatal Cervical Spinal Stenosis Chondrodystrophy Congenital Musculoskeletal Anomaly Congenital Nose Malformation Finger Hypoplasia Hyperreflexia Maternal Drugs Affecting Foetus Micrognathia Movement Disorder Multiple Congenital Abnormalities Neonatal Respiratory Distress Syndrome Premature Baby	Literature Health Professional	Zofran (Formulation Unknown) Hydrochloride Zantac (Formulation Unknown) (Ranitidine Hydrochloride) Compazine (Formulation Unknown) (Prochlorperazine) Diphenhydramine Hydrochloride (Formulation Unknown) (Diphenhydramine) Metoclopramide Hcl (Formulation Unknown) (Metoclopramide Hcl)	PS SS SS SS		TRANSPLACENTAL TRANSPLACENTAL TRANSPLACENTAL TRANSPLACENTAL TRANSPLACENTAL TRANSPLACENTAL TRANSPLACENTAL TRANSPLACENTAL		

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Emgel (Formulation Unknown) (Erythromycin)	SS	TRANSPLACENTAL/TRANSPLACENTARY
Simethicone (Formulation Unknown) (Simethicone)	SS	TRANSPLACENTAL/TRANSPLACENTARY
Promethazine Hcl (Formulation Unknown) (Promethazine Hcl)	SS	TRANSPLACENTAL/TRANSPLACENTARY
Iron Supplements (Formulation Unknown) (Iron Supplements)	SS	TRANSPLACENTAL/TRANSPLACENTARY

Date: 03/31/04 ISR Number: 4327683-9 Report Type: Periodic Company Report#: US-GLAXOSMITHKLINE-A0402035A Age: 11 YR Gender: Female I/FU: F

<u>Outcome</u>	<u>PT</u> Chest Discomfort Dry Mouth Sedation	<u>Report Source</u>	<u>Product</u> Compazine	<u>Role</u> PS	<u>Manufacturer</u> Glaxosmithkline	<u>Route</u> INTRAMUSCULAR	<u>Dose</u>	<u>Duration</u>
----------------	--	----------------------	-----------------------------	-------------------	--	-------------------------------	-------------	-----------------

Date: 03/31/04 ISR Number: 4327685-2 Report Type: Periodic Company Report#: US-GLAXOSMITHKLINE-A0398843A Age: Gender: Female I/FU: I

<u>Outcome</u>	<u>PT</u> Anal Discomfort	<u>Report Source</u>	<u>Product</u> Compazine	<u>Role</u> PS	<u>Manufacturer</u> Glaxosmithkline	<u>Route</u> RECTAL	<u>Dose</u> 25MG	<u>Duration</u> Unknown
----------------	------------------------------	----------------------	-----------------------------	-------------------	--	------------------------	---------------------	----------------------------

Date: 03/31/04 ISR Number: 4327686-4 Report Type: Periodic Company Report#: US-GLAXOSMITHKLINE-A0420530A Age: 46 YR Gender: Male I/FU: I

<u>Outcome</u>	<u>PT</u> Dysphoria Tinnitus	<u>Report Source</u>	<u>Product</u> Compazine	<u>Role</u> PS	<u>Manufacturer</u> Glaxosmithkline	<u>Route</u> ORAL	<u>Dose</u> 5MG	<u>Duration</u> Four times per day
			Wellbutrin	SS	Glaxosmithkline	ORAL		1 YR
			Vicodin	C		ORAL		WK
			Lexapro	C		ORAL		
			Unspecified Medication	C				

Date: 03/31/04 ISR Number: 4327687-6 Report Type: Periodic Company Report#: US-GLAXOSMITHKLINE-A0423731A Age: YR Gender: Male I/FU: I

<u>Outcome</u>	<u>PT</u> Coordination Abnormal	<u>Report Source</u>	<u>Product</u> Compazine	<u>Role</u> PS	<u>Manufacturer</u> Glaxosmithkline	<u>Route</u> UNKNOWN	<u>Dose</u>	<u>Duration</u>
----------------	------------------------------------	----------------------	-----------------------------	-------------------	--	-------------------------	-------------	-----------------

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

<u>Date:</u> 03/31/04	<u>ISR Number:</u> 4327688-8	<u>Report Type:</u> Periodic	<u>Company Report#:</u> US-GLAXOSMITHKLIN-A0424772A	<u>Age:</u>	<u>Gender:</u> Male	<u>I/FU:</u> F
<u>Outcome</u>	PT Agitation Anxiety		<u>Report Source</u>	<u>Product</u> Compazine	<u>Role</u> PS	<u>Manufacturer</u> Glaxosmithkline
				<u>Route</u> UNKNOWN	<u>Dose</u>	<u>Duration</u>
<u>Date:</u> 03/31/04	<u>ISR Number:</u> 4327689-X	<u>Report Type:</u> Periodic	<u>Company Report#:</u> US-GLAXOSMITHKLIN-A0431570A	<u>Age:</u> 73 YR	<u>Gender:</u> Female	<u>I/FU:</u> I
<u>Outcome</u>	PT Hypersensitivity		<u>Report Source</u>	<u>Product</u> Compazine	<u>Role</u> PS	<u>Manufacturer</u> Glaxosmithkline
				<u>Route</u> UNKNOWN	<u>Dose</u>	<u>Duration</u>
<u>Date:</u> 03/31/04	<u>ISR Number:</u> 4327690-6	<u>Report Type:</u> Periodic	<u>Company Report#:</u> US-GLAXOSMITHKLIN-A0440424A	<u>Age:</u>	<u>Gender:</u> Male	<u>I/FU:</u> F
<u>Outcome</u>	PT Dizziness		<u>Report Source</u>	<u>Product</u> Compazine	<u>Role</u> PS	<u>Manufacturer</u> Glaxosmithkline
				<u>Route</u> UNKNOWN	<u>Dose</u>	<u>Duration</u>
<u>Date:</u> 03/31/04	<u>ISR Number:</u> 4327691-8	<u>Report Type:</u> Periodic	<u>Company Report#:</u> US-GLAXOSMITHKLIN-A0442578A	<u>Age:</u>	<u>Gender:</u> Female	<u>I/FU:</u> I
<u>Outcome</u>	PT Adverse Event Drug Ineffective		<u>Report Source</u>	<u>Product</u> Compazine Zofran	<u>Role</u> PS C	<u>Manufacturer</u> Glaxosmithkline Glaxosmithkline
				<u>Route</u> UNKNOWN	<u>Dose</u>	<u>Duration</u>
<u>Date:</u> 03/31/04	<u>ISR Number:</u> 4327692-X	<u>Report Type:</u> Periodic	<u>Company Report#:</u> US-GLAXOSMITHKLIN-A0442582A	<u>Age:</u>	<u>Gender:</u> Female	<u>I/FU:</u> F
<u>Outcome</u>	PT Ill-Defined Disorder		<u>Report Source</u>	<u>Product</u> Compazine	<u>Role</u> PS	<u>Manufacturer</u> Glaxosmithkline
				<u>Route</u> UNKNOWN	<u>Dose</u>	<u>Duration</u>
<u>Date:</u> 04/01/04	<u>ISR Number:</u> 4332339-2	<u>Report Type:</u> Expedited (15-Day)	<u>Company Report#:</u> DSA_24021_2004	<u>Age:</u> 28 YR	<u>Gender:</u> Male	<u>I/FU:</u> F
<u>Outcome</u>	PT Hospitalization - Initial or Prolonged		<u>Report Source</u>	<u>Product</u> Tavor	<u>Role</u> PS	<u>Manufacturer</u>
				<u>Foreign Health Professional Other</u>		
				<u>Atosil</u>	SS	
				<u>Promethazine</u>	SS	
				<u>Tramadol/or</u>	SS	
				<u>Neurocil</u>	SS	
				<u>Neurocil Drops</u>	SS	
				<u>Alcohol</u>	SS	
				<u>100 MG ONCE</u>		
				<u>PO</u>		
				<u>300 MG ONCE</u>		
				<u>PO</u>		
				<u>160 MG ONCE</u>		
				<u>PO</u>		
				<u>100 MG ONCE</u>		
				<u>PO</u>		
				<u>100 MG ONCE</u>		
				<u>PO</u>		
				<u>100 MG ONCE</u>		
				<u>PO</u>		
<u>Date:</u> 04/02/04	<u>ISR Number:</u> 4333934-7	<u>Report Type:</u> Expedited (15-Day)	<u>Company Report#:</u> KII-2004-0008915	<u>Age:</u> 49 YR	<u>Gender:</u> Female	<u>I/FU:</u> I
<u>Outcome</u>	PT Agitation Alanine Aminotransferase					
<u>Other</u>						

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Increased	Study	Oxycontin	PS				
Aspartate	Health	Tablets(Oxycodone Hydrochloride) Cr					
Aminotransferase	Professional	Tablet					
Increased	Other	Compazine					
Aspiration		(Prochlorperazine Edisylate)	SS				
Blood Alkaline		Warfarin (Warfarin)	SS				
Phosphatase Increased		Hypnotics And Sedatives	SS				
Blood Bicarbonate							
Decreased							
Blood Chloride Decreased							
Blood Creatinine							
Increased							
Blood Glucose Increased							
Blood Sodium Decreased							
Blood Urea Increased							
Depressed Level Of							
Consciousness							
Electrocardiogram St-T							
Change							
Fluid Overload							
Haematocrit Decreased							
Haemoglobin Decreased							
International Normalised							
Ratio Increased							
Melaena							
Mental Status Changes							
Multiple Drug Overdose							
Platelet Count Decreased							
Prothrombin Time							
Prolonged							
Respiration Abnormal							
Respiratory Rate							
Decreased							
Troponin T Increased							
White Blood Cell Count							
Increased							

Date: 04/22/04 ISR Number: 4347996-4 Report Type: Expedited (15-Day) Company Report#: KII-2004-0009590

Age: 40 YR Gender: Female I/FU: 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Acidosis	Study	Morphine Sulfate (Similar To Nda 19-516)(Morphine Sulfate) Unknown	PS				
Other	Aspiration	Health	Phenothiazine					
	Blood Pressure Increased	Professional	(Phenothiazine)	SS				
	Body Temperature	Other	Antipsychotics (Benzodiazepine Derivatives()	SS				
	Decreased							
	Depressed Level Of							
	Consciousness							
	Heart Rate Increased							
	Multiple Drug Overdose							
	Pneumonia							
	Pupillary Reflex Impaired							
	Rhonchi							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date: 05/04/04 ISR Number: 4352632-7 Report Type: Expedited (15-Day) Company Report#: PHEH2004US04593

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Death	Medication Error Movement Disorder Sudden Death		Ritalin	PS	Novartis Sector: Pharma		20 mg, BID 200 mg, QHS	I/FU: 1
			Clozapine	SS			50 mg, QD (50mg QAM) 1 mg, TID	
			Compazine	SS				
			Percocet	SS				
			Paxil	C				
			Ativan	C				

Date: 05/04/04 ISR Number: 4352724-2 Report Type: Expedited (15-Day) Company Report#: 04-03-0377

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Death	Death		Compazine	PS	Glaxosmithkline	ORAL	200MG At night	
			Clozapine	SS			20MG Twice per day	
			Ritalin	SS				
			Percocet	SS				
			Paxil Cr	C				
			Ativan	C	Glaxosmithkline	ORAL ORAL	1MG Three times per day	

Date: 05/06/04 ISR Number: 4356509-2 Report Type: Expedited (15-Day) Company Report#: 2004210967FR

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Life-Threatening	Cardio-Respiratory Arrest Coma Drug Interaction Musculoskeletal Stiffness Oxygen Saturation Decreased Pupillary Disorder Trismus	Foreign Health Professional Other	Xanax (Alprazolam) Tablet Mepronizine (Meprbamate, Aceprometazine) Theralene (Alimemazine Tartrate) Skenan (Morphine Sulfate) Seropram (Citalopram Hydrobromide)	PS SS SS SS SS SS			40 MG/DAY, IV SEE IMAGE	

Date: 05/27/04 ISR Number: 4369412-9 Report Type: Expedited (15-Day) Company Report#: KII-2004-0010500

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Aggression Agitation Alcohol Withdrawal Syndrome Confusional State Drug Screen Positive False Positive Laboratory Result Hallucination Heart Rate Increased Mydriasis							

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Pyrexia
Restlessness

<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Study	Oxycontin Tablets					
Health Professional	(Oxycodone Hydrochloride) Cr	PS		ORAL	ORAL	
Other	Tablet					
	Cyclobenzaprine (Cyclobenzaprine)	SS		ORAL	ORAL	
	Phenothiazine (Phenothiazine)	SS				
	Marijuana (Cannabis)	SS				

Date: 06/02/04 **ISR Number:** 4371997-3 **Report Type:** Expedited (15-Day) **Company Report#:** B033187A **Age:** 36 YR **Gender:** Female **I/F/U:** I

<u>Outcome Required</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Intervention to Prevent Permanent Impairment/Damage	Aphonia Dystonia Laryngeal Disorder	Literature Health Professional	Compazine (Prochlorperazine)	PS			10 MG / FOUR TIMES PER DAY	24 HR

Date: 06/21/04 **ISR Number:** 4396327-2 **Report Type:** Periodic **Company Report#:** USA-2003-0010945 **Age:** 43 YR **Gender:** Female **I/F/U:** I

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Death	Intentional Misuse Multiple Drug Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride) Citalopram (Citalopram) Promethazine (Promethazine) Alprazolam (Alprazolam) Lorazepam (Lorazepam) Doxepin (Doxepin) Methadone (Methadone) Phenothiazine (Phenothiazine) Acetaminophen (Paracetamol) Nicotine (Nicotine)	PS SS SS SS SS SS SS SS SS SS SS				

Date: 06/21/04 **ISR Number:** 4399081-3 **Report Type:** Periodic **Company Report#:** 2012355 **Age:** 19 YR **Gender:** Male **I/F/U:** F

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Death Other	Accidental Overdose Drug Abuser	Consumer Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) Oxycodone Hydrochloride Diphenhydramine					

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

(Diphenhydramine)
Cocaine (Cocaine)
Phenothiazine
(Phenothiazine)
Nicotine (Nicotine)
Acetaminophen
(Paracetamol)
Promethazine
(Promethazine)

Date: 07/02/04 **ISR Number:** 4392948-1 **Report Type:** Expedited (15-Day) **Company Report#:** 04P-062-0260467-00 **Age:** 60 YR **Gender:** Female **I/FU:** F

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Coma	Foreign Health Professional	Akineton (Biperiden)	PS		ORAL	PER ORAL	
	Disturbance In Attention		(Biperiden)	SS		ORAL	PER ORAL	
	Somnolence		Mirtazapine	SS		ORAL	PER ORAL	
	Suicide Attempt		Lorazepam	SS		ORAL	PER ORAL	
			Risperidone	SS		ORAL	PER ORAL	
			Zop 7.5	SS		ORAL	PER ORAL	
			Isopromethazine	SS		ORAL	PER ORAL	
			Hydrochloride	SS		ORAL	PER ORAL	
			Dominal	SS		ORAL	PER ORAL	
			Flunitrazepam	SS		ORAL	PER ORAL	

Date: 07/13/04 **ISR Number:** 4398114-8 **Report Type:** Expedited (15-Day) **Company Report#:** DSA_24531_2004 **Age:** 32 YR **Gender:** Female **I/FU:** I

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Agitation	Foreign Health Professional Other	Tavor	PS		ORAL	50 MG ONCE PO	
	Blood Creatine		Atosil	SS		ORAL	1000 MG ONCE	
	Phosphokinase Increased		Geodon	SS		ORAL	240 MG ONCE	
	Blood Lactate			SS		ORAL	PO	
	Dehydrogenase Increased			SS		ORAL	100 MG ONCE	
	C-Reactive Protein Increased		Melperone	SS		ORAL	PO	
	Disorientation							
	Intentional Misuse							
	Somnolence							
	Suicide Attempt							
	Tachycardia							

Date: 07/21/04 **ISR Number:** 4407424-7 **Report Type:** Expedited (15-Day) **Company Report#:** 2004046354 **Age:** **Gender:** Male **I/FU:** I

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome	Foreign Health Professional	Zeldox (Capsules) (Ziprasidone)	PS		ORAL	80 MG (1 IN 1 D)	
			Perazine (Perazine)	SS				
			Fluphenazine (Fluphenazine)	SS				

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 07/23/04 ISR Number: 4409430-5 Report Type: Expedited (15-Day) Company Report#: K200401050
Outcome: Other
PT: Agitation, Confusional State, Dystonia, Hallucination
Report Source: Foreign Health Professional, Other
Product: Kemadrin (Procyclidine) Tablet, 5mg, Compazine (Prochlorperazine Edisylate)
Role: PS, SS
Manufacturer:
Duration:
Age: 54 YR Gender: Female I/FU: 1

Date: 07/29/04 ISR Number: 4443772-2 Report Type: Periodic Company Report#: USA-2004-0014421
Outcome: Death
PT: Accidental Overdose
Report Source: Health Professional, Other
Product: Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate)
Role: PS, SS, SS, SS, SS, SS, SS, SS, SS, SS, SS, SS, SS, SS, SS, SS, SS
Manufacturer:
Duration:
Age: 30 YR Gender: Female I/FU: 1

Date: 08/09/04 ISR Number: 4420810-4 Report Type: Periodic Company Report#: US-GLAXOSMITHKLINE-A0430899A
Outcome: Diarrhoea, Fall, Nausea, Pollakiuria
PT: Diarrhoea, Fall, Nausea, Pollakiuria
Report Source:
Product: Paxil, Paxil, Compazine Effxor, Buspar, Aspirin
Role: PS, SS, SS, C, C, C
Manufacturer: Glaxosmithkline, Glaxosmithkline, Glaxosmithkline, Glaxosmithkline
Route: ORAL, ORAL, UNKNOWN
Dose: 12.5MG Per day, 10MG Per day, 75MG Twice per day, 5MG Three times per day, 81MG Per day
Duration: 3, 3
Age: 81 YR Gender: Male I/FU: 1

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 08/26/04	ISR Number: 4435565-7	Report Type: Expedited (15-Day)	Company Report#: 2004046354	Age: 72 YR	Gender: Male	I/FU: F
Outcome: Hospitalization - Initial or Prolonged	PT: Blood Creatine Phosphokinase Increased Chills Extrapyramidal Disorder Fall Neuroleptic Malignant Syndrome Somnolence	Report Source: Foreign Health Professional	Product: Zeldox (Capsules) (Ziprasidone) Perazine (Perazine) Fluphenazine (Fluphenazine)	Role: PS SS SS	Manufacturer:	Duration: 80 MG (1 IN 1 D) 400 (200) 3 MG (3 MG)
Date: 09/01/04	ISR Number: 4439512-3	Report Type: Direct	Company Report#: CTU 226021	Age:	Gender: Female	I/FU: I
Outcome: Hospitalization - Initial or Prolonged	PT: Dyskinesia Sensation Of Heaviness Tongue Disorder	Report Source: Product Compazine	Product: Compazine	Role: PS	Manufacturer:	Duration: [2 DAYS PRIOR TO ADMISSION]
Date: 10/27/04	ISR Number: 4491081-8	Report Type: Expedited (15-Day)	Company Report#: DSA_25016_2004	Age: 35 YR	Gender: Female	I/FU: F
Outcome: Hospitalization - Initial or Prolonged	PT: Fatigue Intentional Misuse Tachycardia	Report Source: Foreign Health Professional Other	Product: Tavor Champagne Taxilan	Role: PS SS SS	Manufacturer:	Duration: 0.75 BOTTLE ONCE PO 750 MG ONCE PO
Date: 11/15/04	ISR Number: 4503678-7	Report Type: Expedited (15-Day)	Company Report#: 2004-121637-NL	Age: 62 YR	Gender: Female	I/FU: F
Outcome: Life-Threatening Hospitalization - Initial or Prolonged	PT: Coma Epilepsy Hyponatraemia Lung Disorder	Report Source: Foreign Health Professional	Product: Mirtazapine Cyamemazine Loprazolam Mesilate	Role: PS SS C	Manufacturer:	Duration: 15 MG/30MG ORAL 75 MG ORAL 1 WK 2 DAY
Date: 11/30/04	ISR Number: 4518162-4	Report Type: Expedited (15-Day)	Company Report#: A01200405843	Age: 48 YR	Gender: Male	I/FU: I
Outcome: Death Hospitalization - Initial or Prolonged	PT: Abdominal Distension Cardiac Arrest Circulatory Collapse Colon Cancer Dehydration Diarrhoea Haemoglobin Decreased Hyponatraemia Hypotension Metastases To Peritoneum Nausea Pitting Oedema Pleural Effusion Pneumonia Aspiration					

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Pneumonitis
Pulse Absent
Signet-Ring Cell
Carcinoma
Tachycardia
Vomiting

<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Health Professional	Ambien	PS				
	Ativan - Lorazepam - Dose : Ni	SS				
	Compazine - Prochlorperazine	SS				
	Edisylate - Dose: Ni	SS				
	Oxycodone - Dose : Ni	SS				
	Oxycontin - Oxycodone	SS				
	Hydrochloride - Dose: Ni	C				
	Loperamide	C				
	Ondansetron	C				
	Hydrochloride	C				
	5-Fluorouracil	C				
	Leucovorin	C				
	Flavopiridol	C				
	Pantoprazole Sodium	C				

Date: 01/18/05 **ISR Number:** 4554751-9 **Report Type:** Expedited (15-Day) **Company Report#:** 04US08831

<u>Outcome</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Other	Health Professional	Compazine	PS	Glaxosmithkline	UNKNOWN		

Date: 01/18/05 **ISR Number:** 4556497-X **Report Type:** Expedited (15-Day) **Company Report#:** 2005-01-0367

<u>Outcome</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Other	Health Professional	Intron A (Interferon Alfa-2b Recombinant) Injectable	PS		INTRAVENOUS	44 MU 5XWK; INTRAVENOUS	
		Wellbutrin (Bupropion)	SS		ORAL	300 MG BID; ORAL	
		Allopurinol	SS		ORAL	100 MG HS; ORAL	
		Clonazepam	SS		ORAL	0.5 MG QHS; ORAL	
		Trazodone	SS		ORAL	50 MG QHS; ORAL	
		Zocor	SS		ORAL	10 MG QD; ORAL	
		Remeron	SS		ORAL	45 MG HS; ORAL	
		Multivitamins Glucosamine Compazine	SS SS SS		ORAL ORAL ORAL	PRN; ORAL PRN; ORAL 10 MG PRN; ORAL	

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 01/19/05 ISR Number: 4555851-X Report Type: Expedited (15-Day) Company Report#: PHEH2004US04593

Age: 72 YR Gender: Female I/FU: F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser Movement Disorder Overdose Sudden Death		Ritalin	PS	Novartis Sector: Pharma		20 mg, BID 200 mg, QHS	
			Clozapine	SS			50 mg, QD (50mg QAM)	
			Compazine	SS			1 mg, TID	
			Percocet	C				
			Paxil	C				
			Ativan	C				

Date: 01/24/05 ISR Number: 4559761-3 Report Type: Expedited (15-Day) Company Report#: US-MERCK-0501USA02727

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asithenia Confusional State Decreased Appetite Dehydration Drug Interaction Lethargy Nausea		Zocor Intron A	PS SS	Merck & Co., Inc	ORAL INTRAVENOUS DRIP		37 DAY
			Wellbutrin	SS		ORAL		
			Allopurinol	SS		ORAL		
			Clonazepam	SS		ORAL		
			Trazodone	SS		ORAL		
			Hydrochloride	SS		ORAL		
			Remeron	SS		ORAL		
			Vitamins	SS		ORAL		
			(Unspecified)	SS		ORAL		
			Glucosamine	SS		ORAL		
			Compazine	SS		ORAL		

Date: 01/27/05 ISR Number: 4562807-X Report Type: Expedited (15-Day) Company Report#: US-GLAXOSMITHKLINE-A054275A

Age: Gender: Female I/FU: F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Facial Palsy		Compazine Synthroid Sectral Sinequan Chlorpheniramine	PS C C C C	Glaxosmithkline Glaxosmithkline Glaxosmithkline Glaxosmithkline Glaxosmithkline			

Date: 01/28/05 ISR Number: 4563370-X Report Type: Periodic

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abdominal Pain Drug Interaction Ear Congestion Insomnia Nausea Pharyngolaryngeal Pain Tinnitus Tremor Vomiting White Blood Cell Count Decreased		Wellbutrin Percocet Decadron Kytril Compazine Ativan Benadryl	PS SS SS SS SS SS SS	Glaxosmithkline Glaxosmithkline Glaxosmithkline Glaxosmithkline Glaxosmithkline Glaxosmithkline Glaxosmithkline	ORAL UNKNOWN UNKNOWN UNKNOWN UNKNOWN	100MG Twice per day	12 YR

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 01/31/05 **ISR Number:** 4569930-4 **Report Type:** Expedited (15-Day) **Company Report#:** 2005-124455-NL **Age:** 61 YR **Gender:** Male **I/FU:** 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Other	Asthma	Health Professional	Remeron /Net/ Intron A	PS	Schering-Plough"	ORAL	45 MG QD	ORAL
	Confusional State			SS		INTRAVENOUS	44 MIU	INTRAVENOUS
	Decreased Appetite			SS		ORAL	300 MG BID	(NOS)
	Dehydration			SS		ORAL	100 MG QD	ORAL
	Depression			SS		ORAL	0.5 MG QD	ORAL
	Drug Interaction			SS		ORAL	50 MG QD	ORAL
	Lethargy			SS		ORAL	10 MG QD	ORAL
	Malignant Melanoma Stage Iii			SS		ORAL	DF PRN	ORAL
	Nausea			SS		ORAL	10 MG PRN	ORAL
	Oral Intake Reduced							

Date: 02/17/05 **ISR Number:** 4586856-0 **Report Type:** Direct **Company Report#:** CTU 240697 **Age:** 13 YR **Gender:** Male **I/FU:** 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Contraindication To Medical Treatment		Compazine	PS		INTRAVENOUS	10 MG	EVERY 6 HOURS
Intervention to Prevent Permanent Impairment/Damage	Convulsion			C				INTRAVENOUS
	Drooling			C				
	Dystonia							
	Medication Error							
	Speech Disorder							
	Tongue Disorder							

Date: 02/24/05 **ISR Number:** 4595589-6 **Report Type:** Expedited (15-Day) **Company Report#:** KII-2005-0015250 **Age:** 38 YR **Gender:** Female **I/FU:** 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Coma	Study Health Professional	Morphine Sulfate (Similar To Nda-19-516)	PS				
Other	Miosis	Other	(Morphine Sulfate)	SS				
	Pneumonia		Tramadol (Tramadol)	SS				
	Pupillary Reflex Impaired		Ephedrine/Pseudoephedrine ()	SS				
			Diphenhydramine (Diphenhydramine)	SS				
			Phenothiazine (Phenothiazine)	SS				
			Ranitidine (Ranitidine)	SS				
			Dextromethorphan (Dextromethorphan)	C				

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date	ISRN	ISRN	Report Type	Direct	Company Report#	CTU	Age	YR	Gender	Female	I/FU	I
Outcome	Required	Intervention to	Prevent Permanent	Impairment/Damage	Report Source	Product	Role	Manufacturer	Route	Dose	Duration	
02/28/05	4597555-3	4597555-3	Expedited (15-Day)	Direct	241393	CTU	27	YR	Female		I/FU: 1	
PT	Bruixism				Compazine (Generic)	PS			Q 6 HRS PRN			
	Dysarthria				Lexapro	C						
	Dystonia				Orthoevra Patch	C						
03/01/05	4594187-8	4594187-8	Expedited (15-Day)		2005003330		48	YR	Female		I/FU: F	
PT	Drug Abuser				Rohypnol	PS			ORAL			
	Somnolence				Taxilan	SS			ORAL			
					Glaxosmithkline	SS			ORAL			
									ORAL			
03/07/05	4602705-6	4602705-6	Expedited (15-Day)		163-20785-05020473		22	YR	Female		I/FU: 1	
PT	Blood Human Chorionic				Thalomid	PS			ORAL			
	Gonadotropin Increased				(Thalidomide) (50							
	Nausea				Miligram, Capsules)							
	Pregnancy Test Urine				Compazine							
	Positive				(Prochlorperazine							
					Edisylate)							
03/11/05	4608215-4	4608215-4	Expedited (15-Day)		2003PK00386		60	YR	Female		I/FU: 1	
PT	Delirium				Seroquel	PS			ORAL			
	Disorientation											
	Drug Interaction				Seroquel Zeneca	SS			ORAL			
	Feeling Abnormal											
	Restlessness				Taxilan	SS						
	Sensation Of Pressure				Akineton Retard	SS						
					Tranxilium	C						
					Tavor	C						
03/11/05	4609060-6	4609060-6	Expedited (15-Day)		K11-2005-0015423		45	YR	Male		I/FU: 1	
PT	Acute Respiratory				Oxycodone	PS			ORAL			
	Distress Syndrome				Hydrochloride							
	Agitation				(Similar To Nda							
	Blood Glucose Increased				20-553)(Oxycodone							
	Body Temperature				Hydrochloride)							
	Decreased				Loperamide							
	Bowel Sounds Abnormal				(Loperamide)							
	Coma				Valproic Acid							
	Hypotension				(Valproic Acid)							
	Mitosis				Acetaminophen							
	Overdose				W/Hydrocodone							
	Respiratory Depression				Bitartrate(Paracetam							

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

ol, Hydrocodone									
Bitartrate)	SS	ORAL	ORAL						
Antiretroviral	SS	ORAL	ORAL						
Aciclovir									
(Aciclovir)	SS	ORAL	ORAL						
Other									
Anti-Asthmatics For									
Systemic Use	SS	ORAL	ORAL						
Antifungals For									
Systemic Use	SS	ORAL	ORAL						
Trazodone									
(Trazodone)	SS	ORAL	ORAL						
Antibiotics	SS	ORAL	ORAL						
Antihistamines For									
Systemic Use	SS	ORAL	ORAL						
Salicylates(Salicyla									
tes)	SS	ORAL	ORAL						
Phenothiazine									
(Phenothiazine)	SS	ORAL	ORAL						
Dhea(Prasterone)	SS	ORAL	ORAL						
Proton Pump									
Inhibitor	SS	ORAL	ORAL						
Methyphenidate									
(Methyphenidate)	SS	ORAL	ORAL						
Multivitamins And									
Iron	SS	ORAL	ORAL						
Acetylsalicylic Acid									
(Acetylsalicylic									
Acid)	SS	ORAL	ORAL						

Date: 03/15/05 **IS**R Number: 4608829-1 **Report Type:** Expedited (15-Day) **Company Report#:** US-GLAXOSMITHKLINE-A0549282A **Age:** **Gender:** Female **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Facial Palsy Muscle Contractions Involuntary Muscle Contracture		Compazine	PS	Glaxosmithkline	UNKNOWN		

Date: 03/16/05 **IS**R Number: 4610101-0 **Report Type:** Periodic **Company Report#:** US-GLAXOSMITHKLINE-A0536597A **Age:** 16 YR **Gender:** Female **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion		Compazine Vicodin	PS C	Glaxosmithkline	RECTAL		1 DAY

Date: 03/16/05 **IS**R Number: 4610105-8 **Report Type:** Periodic **Company Report#:** US-GLAXOSMITHKLINE-A0503858A **Age:** 35 YR **Gender:** Female **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dyspnoea Swollen Tongue		Compazine Taxol Carboplatin	PS C C	Glaxosmithkline	ORAL	10MG Six times per day	3 DAY

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 03/16/05	ISR Number: 4610106-X	Report Type: Periodic	Company Report#: US-GLAXOSMITHKLINE-A0504921A	Age:	Gender: Female	I/FU: 1
Outcome	PT Agitation Tremor		Report Source	Product Compazine Zofran	Role PS SS	Manufacturer Glaxosmithkline Glaxosmithkline
				Route UNKNOWN ORAL	Dose 8MG Variable dose 8MG Variable dose	Duration
Date: 03/16/05	ISR Number: 4610107-1	Report Type: Periodic	Company Report#: US-GLAXOSMITHKLINE-A0506937A	Age:	Gender: Male	I/FU: 1
Outcome	PT Akathisia		Report Source	Product Compazine Tenormin Prinivil Dyazide Prevacid Metadate Cd Xanax	Role PS C C C C C C	Manufacturer Glaxosmithkline Glaxosmithkline Glaxosmithkline
				Route ORAL	Dose 10MG Four times per day	Duration 1 WK
Date: 03/16/05	ISR Number: 4610108-3	Report Type: Periodic	Company Report#: US-GLAXOSMITHKLINE-A0518591A	Age: 57 YR	Gender: Male	I/FU: 1
Outcome	PT Drug Ineffective		Report Source	Product Compazine Chemotherapy	Role PS C	Manufacturer Glaxosmithkline
				Route UNKNOWN UNKNOWN	Dose	Duration
Date: 03/16/05	ISR Number: 4610109-5	Report Type: Periodic	Company Report#: US-GLAXOSMITHKLINE-A0520392A	Age:	Gender: Female	I/FU: 1
Outcome	PT Nightmare		Report Source	Product Compazine	Role PS	Manufacturer Glaxosmithkline
				Route UNKNOWN	Dose	Duration 0 DAY
Date: 03/16/05	ISR Number: 4610110-1	Report Type: Periodic	Company Report#: US-GLAXOSMITHKLINE-A0537918A	Age: 16 YR	Gender: Female	I/FU: 1
Outcome	PT Dizziness Drug Toxicity Fatigue Headache Muscle Spasms		Report Source	Product Compazine Lexapro Multivitamin	Role PS SS C	Manufacturer Glaxosmithkline Glaxosmithkline
				Route ORAL	Dose	Duration
Date: 03/16/05	ISR Number: 4610114-9	Report Type: Periodic	Company Report#: 04US08775	Age:	Gender: Male	I/FU: 1
Outcome	PT Drug Ineffective		Report Source	Product Compazine	Role PS	Manufacturer Glaxosmithkline
				Route UNKNOWN	Dose	Duration

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

<u>Date:</u> 03/16/05	<u>ISR Number:</u> 4610115-0	<u>Report Type:</u> Periodic	<u>Company Report#:</u> A0539504	<u>Age:</u>	<u>Gender:</u> Female	<u>I/FU:</u> I
<u>Outcome:</u>	<u>PT:</u> Dystonia		<u>Report Source:</u>	<u>Product:</u> Compazine	<u>Role:</u> PS	<u>Manufacturer:</u> Glaxosmithkline
				<u>Route:</u> UNKNOWN	<u>Dose:</u>	<u>Duration:</u>
<u>Date:</u> 03/16/05	<u>ISR Number:</u> 4610116-2	<u>Report Type:</u> Periodic	<u>Company Report#:</u> US-GLAXOSMITHKLINE-A0547388A	<u>Age:</u> 58 YR	<u>Gender:</u> Male	<u>I/FU:</u> I
<u>Outcome:</u>	<u>PT:</u> Drug Ineffective		<u>Report Source:</u>	<u>Product:</u> Compazine Chemotherapy Multiple Medications	<u>Role:</u> PS C C	<u>Manufacturer:</u> Glaxosmithkline
				<u>Route:</u> ORAL	<u>Dose:</u>	<u>Duration:</u>
<u>Date:</u> 03/25/05	<u>ISR Number:</u> 4620837-3	<u>Report Type:</u> Expedited (15-Day)	<u>Company Report#:</u> 163-20785-05020473	<u>Age:</u> 22 YR	<u>Gender:</u> Female	<u>I/FU:</u> F
<u>Outcome:</u>	<u>PT:</u> Blood Human Chorionic Gonadotropin Positive Nausea Pregnancy Test Urine Positive		<u>Report Source:</u> Health Professional	<u>Product:</u> Thalomid (Thalidomide) (50 Milligram, Capsules) Compazine (Prochlorperazine Edisylate)	<u>Role:</u> PS SS	<u>Manufacturer:</u>
<u>Other:</u>				<u>Route:</u> ORAL	<u>Dose:</u> SEE IMAGE, ORAL	<u>Duration:</u>
<u>Date:</u> 03/28/05	<u>ISR Number:</u> 4622067-8	<u>Report Type:</u> Expedited (15-Day)	<u>Company Report#:</u> KII-2005-0015547	<u>Age:</u> 50 YR	<u>Gender:</u> Female	<u>I/FU:</u> I
<u>Outcome:</u>	<u>PT:</u> Acidosis Hospitalization - Initial or Prolonged Other		<u>Report Source:</u> Study Health Professional Other	<u>Product:</u> Morphine Sulfate (Similar To Nda 19-516(Morphine Sulfate) Hydromorphone Hcl (Similar To Nda-21044) (Hydromorphone Hydrochloride) Phenothiazine (Phenothiazine) Warfarin (Warfarin) Organophosphate () Ace Inhibitor Nos() Hypnotics And Sedatives ()	<u>Role:</u> PS SS SS SS C C C	<u>Manufacturer:</u>
				<u>Route:</u> ORAL	<u>Dose:</u> ORAL	<u>Duration:</u>

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 04/06/05 **ISR Number:** 4628752-6 **Report Type:** Expedited (15-Day) **Company Report#:** 163-20785-05020473 **Age:** 22 YR **Gender:** Female **I/FU:** F

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Other	Blood Human Chorionic Gonadotropin Positive Pregnancy Test Urine Positive	Health Professional	Thalomid (Thalidomide) (50 Milligram, Capsules)	PS		ORAL	250 MG DAILY ORAL	
			Compazine (Prochlorperazine Edisylate)	SS				

Date: 04/08/05 **ISR Number:** 4630754-0 **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-399988 **Age:** 61 YR **Gender:** Male **I/FU:** I

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Other	Asthenia Confusional State Decreased Appetite Dehydration Drug Interaction Lethargy Nausea		Klonopin	PS	Roche	ORAL	TAKEN EVERY NIGHT. STARTED PRIOR TO 15 NOVEMBER TAKEN AT BEDTIME. STARTED PRIOR TO 15 NOVEMBER 2004	37 DAY
			Intron A Wellbutrin Trazodone	I I I	Roche	INTRAVENOUS ORAL ORAL	TAKEN EVERY NIGHT. STARTED PRIOR TO 15 NOVEMBER STARTED PRIOR TO 15 NOVEMBER 2004 AND REPORTED TO BE 'LONG TAKEN AT NIGHT. STARTED PRIOR TO 15 NOVEMBER 2004	
			Zocor	I		ORAL	STARTED PRIOR TO 15 NOVEMBER STARTED PRIOR TO 15 NOVEMBER 2004 AND REPORTED TO BE 'LONG TAKEN AT NIGHT. STARTED PRIOR TO 15 NOVEMBER 2004	
			Remeron	I		ORAL	STARTED PRIOR TO 15 NOVEMBER 2004 AND REPORTED TO BE 'LONG TAKEN AT NIGHT. STARTED PRIOR TO 15 NOVEMBER 2004	
			Multivitamin Nos	I		ORAL	STARTED PRIOR TO 15 NOVEMBER 2004 AND REPORTED TO BE 'LONG TAKEN AT NIGHT. STARTED PRIOR TO 15 NOVEMBER 2004	
			Glucosamine	I		ORAL	STARTED PRIOR TO 15 NOVEMBER 2004 AND REPORTED TO BE 'LONG-TERM AS 'LONG-TERM STARTED PRIOR TO 15 NOVEMBER 2004 AND REPORTED TO BE 'LONG-TERM AS 'LONG-TERM	
			Compazine	I		ORAL	STARTED PRIOR TO 15 NOVEMBER 2004 AND REPORTED TO BE 'LONG-TERM AS 'LONG-TERM	

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Date: 05/02/05		ISRN: 4653151-0	Report Type: Direct	Company Report#: CTU 247540	Age: 38 YR	Gender: Female	I/FU: 1
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Life-Threatening Hospitalization - Initial or Prolonged	Delusion Of Reference Hallucination, Auditory Psychotic Disorder Rhabdomyolysis	Perazine	PS		ORAL	100 MG ONCE A DAY ORAL	
Date: 05/05/05		ISRN: 4655650-4	Report Type: Expedited (15-Day)	Company Report#: KII-2005-0016261	Age: 36 YR	Gender: Male	I/FU: 1
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Hospitalization - Initial or Prolonged Other	Aggression Agitation Anion Gap Increased Asthenia Cerebral Haemorrhage Confusional State Cyanosis Depressed Level Of Consciousness Drug Screen Positive Fall Inadequate Analgesia Incorrect Dose Administered Lethargy Neurologic Neglect Syndrome Neurological Examination Abnormal Overdose Screaming Superior Sagittal Sinus Thrombosis Tachycardia Tremor White Blood Cell Count Increased	Study Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride) Other Hydromorphone Hcl (Similar To Nda 21-044) (Hydromorphone Hydrochloride) Fentanyl (Fentanyl) Compazine (Prochlorperazine Edisylate) Other Hypnotics And Sedatives () Antibiotics ()	PS SS SS SS SS SS	ORAL ORAL RECTAL	80 MG, Q8H, ORAL SEE IMAGE ORAL RECTAL	
Date: 06/13/05		ISRN: 4690140-4	Report Type: Expedited (15-Day)	Company Report#: DSA_26373_2005	Age: 36 YR	Gender: Female	I/FU: 1
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Hospitalization - Initial or Prolonged	Aggression Dry Mouth Hallucination Intentional Misuse	Foreign Health Professional Other	Tavor Atosil Sonata	PS SS SS	ORAL ORAL ORAL	3 MG ONCE PO 1250 MG ONCE PO 75 MG ONCE PO	
Date: 07/06/05		ISRN: 4708432-9	Report Type: Expedited (15-Day)	Company Report#: KII-2005-0017233	Age: 61 YR	Gender: Female	I/FU: 1
Outcome	PT						
Hospitalization - Initial or Prolonged	Blood Pressure Systolic Increased						

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Confusional State
Electrocardiogram Qt
Corrected Interval
Prolonged
Hypotension
Overdose
Sinus Bradycardia
Somnolence

Report Source

Study
Health
Professional
Other

Product

Oxycontin Tablets
(Oxycontin
Hydrochloride) Cr
Tablet
Antipsychotics ()
Ssr1 ()
Calcium Channel
Blockers ()
Benzodiazepine
Derivatives ()
Amitriptyline
(Amitriptyline)
Acetaminophen
W/Hydrocodone
Bitartrate
(Paracetamol,
Hydrocodone
Phenothiazine
(Phenothiazine)

Role

PS
SS
SS
SS
SS
SS
SS
SS
SS
SS

Route

ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL

Dose

ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL

Duration

Date: 07/19/05 **ISR Number:** 4720660-5 **Report Type:** Expedited (15-Day) **Company Report#:** KII-2005-0017471

Outcome
Hospitalization -
Initial or Prolonged
Other

PT

Aggression
Agitation
Blood Pressure Increased
Body Temperature
Increased
Depressed Level Of
Consciousness
Dyspnoea
Intentional Misuse
Lung Disorder
Multiple Drug Overdose
Restlessness
Sinus Tachycardia
Somnolence
Suicide Attempt
White Blood Cell Count
Increased

Report Source

Study
Health
Professional
Other

Product

Oxycodone
Hydrochloride
(Similar To Nda
20-553) (Oxycodone
Hydrochloride)
Decongestants And
Antiallergics ()
Tricyclic
Antidepressants ()
Phenothiazine
(Phenothiazine)

Role

PS
SS
SS
SS

Route

ORAL
ORAL
ORAL
ORAL

Dose

ORAL
ORAL
ORAL
ORAL

Duration

Date: 07/26/05 **ISR Number:** 4727105-X **Report Type:** Direct **Company Report#:** CTU 254283

Outcome
Hospitalization -
Initial or Prolonged
Required
Intervention to
Prevent Permanent
Impairment/Damage

PT

Livedo Reticularis
Rash

Report Source

Compazine
Ferrous Gluconate
Loperamide
Acetaminophen
Megestrol Acetate
Simvastatin
Metoprolol
Sertraline
Aspirin
Trazodone

Role

PS
C
C
C
C
C
C
C
C
C

Route

ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL

Dose

ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL
ORAL

Duration

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report**

Nitroglycerin C
 Albuterol C
 90/Ipratropium C
 Selenium Shampoo C
 Gatifloxacin C

Date: 07/28/05 **ISR Number:** 4730158-6 **Report Type:** Expedited (15-Day) **Company Report#:** DSA_26761_2005 **Age:** 38 YR **Gender:** Female **I/FU:** 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Intentional Misuse	Foreign Health Professional Other	Tavor	PS		ORAL	30000 MG ONCE PO	
	Miosis		Seroquel	SS				
	Multiple Drug Overdose		Taxilan	SS				

Date: 08/02/05 **ISR Number:** 4734287-2 **Report Type:** Expedited (15-Day) **Company Report#:** KII-2005-0017725 **Age:** 58 YR **Gender:** Female **I/FU:** 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Agitation	Study Health Professional Other	Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate) Unknown	PS		ORAL	SEE TEXT, ORAL	
	Blood Magnesium Decreased		Phenothiazine	SS		ORAL	ORAL	
	Blood Potassium Decreased		Benzodiazepine Derivatives	SS		ORAL	ORAL	
	Blood Pressure Increased		Acetaminophen					
	Body Temperature Increased		W/Oxycodone					
	Confusional State		(Paracetamol, Xoycodone Hydrochloride)	SS			SEE TEXT	
	Dysphagia		Acetylsalicylic Acid					
	Hypotension		In Combination With Other Drug	SS		TRANSDERMAL	Q3D, TRANSDERMAL	
	Hypovolaemia		Ssri	SS			SEE TEXT	
	Lung Infiltration		Antiepileptics	SS			HS	
	Multiple Drug Overdose		Antidepressants	SS				
	Paranoia							
	Rales							
	Renal Failure Acute							
	Restlessness							
	Somnolence							
	Tremor							
	Urine Abnormality							

Date: 08/18/05 **ISR Number:** 4748056-0 **Report Type:** Expedited (15-Day) **Company Report#:** US-GLAXOSMITHKLINE-A0570279A **Age:** 11 YR **Gender:** Female **I/FU:** F

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Drug Ineffective		Compazine	PS	Glaxosmithkline	UNKNOWN		
	Dyskinesia		Carafate	C				
	Feeling Abnormal		Bentyl	C				
	Gaze Palsy							
	Hypersensitivity							

Summary report for FOI selections:

Selection by inexact search of active ingredient: **PHENOTHIAZINE%**

Selection by inexact search of Tradename/Verbatim: **COMPАЗINE%**

Total number of reports: **366**

From: 01-NOV-1997 **To:** Present