FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/04/97ISR Number: 100000129Report Type:Expedited (15-DaCompany Report #B0050499
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Acidosis	Foreign	Zofran	PS		INTRAVENOUS	4MG	
Initial or Prolonged	Anaphylactic Shock							
Other								

Date:11/06/97ISR Number: 3005642-6Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Injection Site Oedema		Cefazolin	PS		INTRAVENOUS	2 GM IV QD	
Initial or Prolonged	Injection Site Pain		Diphenhydramine	SS			25 MG ;IV	
	Phlebitis						PUSH QD	
			Zofran	SS			4 MG IV PUSH	

Date:11/13/97ISR Number: 3005959-5Report Type:Direct Company Report #
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction		Prochlorperazine	PS			SEE IMAGE	
	Angioneurotic Oedema		Ondansetron	SS			SEE IMAGE	
	Choking Sensation		Cyclophosphamide	SS				
	Dyspnoea							
	Pharyngeal Oedema							
	Pharyngolaryngeal Pain							
	Tongue Oedema							

Date:11/14/97ISR Number: 3000764-8Report Type:Expedited (15-DaCompany Report #B0050168
Age:67 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Alkalosis Hypochloraemic	Foreign	Zofran Injection	PS		INTRAVENOUS	4 MG / DAY/	PER
	Anorexia	Study						
	Anxiety	Health				INTRAVENOUS		
	Diarrhoea	Professional	Cisplatin	C				
	Hyponatraemia		Vindesine Sulfate	C				
	Inappropriate		Electrolytes	C				
	Antidiuretic Hormone		Mannitol	C				
	Secretion		Amino Acid	C				
	Nausea		Benidipine	C				
	Palpitations		Simvastatin	C				
	Vomiting		Roxatidine	C				
			Trapidil	C				
			Carbazochrome	C				
			Tranexamic Acid	C				
			Bifidobacterium	C				
			Fosfestrol	C				
			Tegafur	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/04/97ISR Number: 3007576-XReport Type:Direct Company Report #
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Health	Zofran	PS		INTRAVENOUS	10 MG IVSS X1	
Initial or Prolonged	Blood Pressure Systolic	Professional	Decadron	SS		INTRAVENOUS	8 MG IVSS X 1	
Other	Increased		Prevalite	C				
	Chest Discomfort		Aldomet	C				
	Opisthotonus		Hydrodiuril	C				
	Tachycardia		K Lor	C				
			Mvi	C				
			Vitamin C	C				
			Vicodin	C				
			Sandostatin	C				
			Timoptic Eye Gtts	C				
			Imodium	C				

Date:12/08/97ISR Number: 3018236-3Report Type:Direct Company Report #
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health	Zofran	PS		INTRAVENOUS	32 MG	IVPB
		Professional	Taxol	SS		INTRAVENOUS		DRIP
							257 MG /24	HRS
			Benadryl	C				
			Tagamet	C				
			Decadron	C				

Date:12/15/97ISR Number: 3007145-1Report Type:Expedited (15-DaCompany Report #B0051693
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Arterial Occlusive Disease	Foreign Literature	Zofran	PS			ORAL 8MG/TWICE PER DAY/ORAL 13 DAY
	Constipation	Other	Ondansetron Hydrochloride	C			
	Intestinal Obstruction		Vincristine	C			
			Lomustine	C			
			Procarbazine	C			
			Carboplatin	C			

Date:12/22/97ISR Number: 3014308-8Report Type:Expedited (15-DaCompany Report #A0058007
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypertension	Health Professional	Zofran	PS		INTRAVENOUS	UNK/	UNK/
		Other	Gemcitabine	SS		INTRAVENOUS	1300	MG/WEEKLY/INT RAVENOUS
			Dexamethasone	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/13/98ISR Number: 3016679-5Report Type:Expedited (15-DaCompany Report #B035617
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acidosis	Foreign	Carboplatin	PS				
						INTRAVENOUS	450 MG IV	1 DAY
Life-Threatening	Cholelithiasis	Health	Uft	SS		ORAL	200 MG PO	8 WK
Hospitalization -	Condition Aggravated	Professional	Granisetron	SS				
						INTRAVENOUS	3-6 MG IV	3 DAY
Initial or Prolonged	Hepatic Failure		Ondansetron	SS				
						INTRAVENOUS	4 MG IV	1 DAY
	Hepatitis C		Carbocysteine	C				
	Hepatitis Fulminant		Bromhexine	C				
	Hepatomegaly		Roxithromycin	C				
	Hypotension		Levothyroxine Sodium	C				
	Hypovolaemia		Triazolam	C				
	Lymphadenopathy							
	Renal Atrophy							
	Renal Impairment							
	Thrombocytopenia							

Date:01/15/98ISR Number: 3017171-4Report Type:Expedited (15-DaCompany Report #B0049481
Age:53 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase	Foreign	Zofran	PS				
	Increased	Health	Zofran	SS				
	Arthralgia	Professional	Zofran	SS				
	Aspartate		Etoposide	C				
	Aminotransferase		Propofol	C				
	Increased		Iodine	C				
	Asthenia		Filgrastim	C				
	Gamma-Glutamyltransferase		Doxorubicin					
	Increased		Hydrochloride	C				
	Hepatitis		Cisplatin	C				
	Jaundice							
	Prothrombin Time							
	Prolonged							
	Pruritus							

Date:01/16/98ISR Number: 3016499-1Report Type:Expedited (15-DaCompany Report #ETH-97-142
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia	Health	Ethyol	PS				
Initial or Prolonged	Chills	Professional						
	Cold Sweat		Taxol	SS				
	Cyanosis							
	Hyperhidrosis		Zofran	SS				
	Hypersensitivity		Cimetidine	SS				
	Hypokalaemia		Tenormin	SS				
	Nausea		Magnesium Sulfate	SS				
	Paraesthesia		Decadron	SS				
	Urticaria		Carboplatin	C				
	Vomiting Projectile							

Date:01/20/98ISR Number: 3017325-7Report Type:Expedited (15-DaCompany Report #A0058007
Age:82 YR Gender:Male I/FU:F

Outcome	PT	Report Source
Hospitalization -	Hypertension	Health
Initial or Prolonged	Nervousness	Professional

Other

			Product	Role	Manufacturer	Route
Dose	Duration					
			Zofran	PS		
INTRAVENOUS	8 MG/ WEEKLY/					
INJ						
			Gemcitabine	SS		
INTRAVENOUS	1300 MG/					
WEEKLY						
			Darvocet-N	C		

Date:01/20/98ISR Number: 3017860-1Report Type:Expedited (15-DaCompany Report #A0057870
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Acidosis	Health	Zofran	PS		
INTRAVENOUS	10 MG THREE					
Life-Threatening	Hyperglycaemia	Professional				
TIMES PER DAY						
	Hyperkalaemia					
INTRAVENOUS						
	Renal Failure					
PUSH						
	Ventricular Tachycardia		Cisapride	C		

Date:01/20/98ISR Number: 3017865-0Report Type:Expedited (15-DaCompany Report #A0057870
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Acidosis	Health	Zofran	PS	Glaxo Wellcome	
INTRAVENOUS	10 MG / THREE					
Life-Threatening	Hyperglycaemia	Professional				
TIMES PER DAY						
	Hyperkalaemia					
/ INTRAVENOUS						
	Renal Failure					
PUSH						
	Ventricular Tachycardia		Cisapride	C		

Date:01/20/98ISR Number: 3019124-9Report Type:Expedited (15-DaCompany Report #B0049570
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Pain	Foreign	Zofran	PS		IV	1 TABLET/ TWICE PER DAY/ ORAL	48 HR
	Cough	Health	Zofran	SS				
	Dyspnoea	Professional						
	Laryngeal Pain							
			Doxorubicin Hydrochloride	C				
			Cyclophosphamide	C				
			Vindesine	C				
			Bleomycin	C				
			Prednisone	C				

Date:02/04/98ISR Number: 3024236-XReport Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Dermatitis		Ondansetron	PS		INTRAVENOUS	4 MG IV TID	
			Albuterol	C				
			Allopurinol	C				
			Ampho B	C				
			Gm-Csf	C				
			Clotriamazole	C				
			Levofloxacin	C				
			Vanc	C				

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Freedom Of Information (FOI) Report

Date:02/09/98ISR Number: 3124557-6Report Type:Periodic Company Report #A0050861
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Health	Zofran	PS		ORAL	8 MG AS	
	Dizziness	Professional					DIRECTED ORAL	
	Headache		Cyclophosphamide	C				
	Overdose		Doxorubicin Hydrochloride	C				

Date:02/09/98ISR Number: 3124559-XReport Type:Periodic Company Report #A0055029
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Failure	Consumer	Zofran	PS		ORAL	4 MG SIX TIMES PER DAY	
	Liver Function Test Abnormal						ORAL	
			Cisapride	C				
			Vicodin	C				

Date:02/10/98ISR Number: 3026757-2Report Type:Expedited (15-DaCompany Report #A0059948
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Health	Zofran	PS		ORAL	ORAL	
	Automatism Epileptic	Professional	Tamoxifen	C				
	Brain Oedema	Company	Carmustine	C				
	Coma	Representative	Dacarbazine	C				
	Confusional State		Cisplatin	C				
	Mydriasis		Dexamethasone	C				
			Lorazepam	C				
			Fentanyl	C				
			Hydromorphone	C				

Date:02/20/98ISR Number: 3032632-XReport Type:Expedited (15-DaCompany Report #B0053194
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Foreign	Zofran	PS				
	Aspartate Aminotransferase Increased		Zinacef	SS				
			Mivacron	SS				
			Diclofenac	SS		ORAL	ORAL	
			Sevoflurane	SS			PER DAY	
	Drug Interaction		Desflurane	SS			PER DAY	
	Gamma-Glutamyltransferase Increased		Oxygen	SS		INTRAVENOUS	SINGLE DOSE	
	Malaise		Fentanyl	SS			500 MG/ PER DAY/	
	Nausea							
	Pruritus		Ketorolac	SS			PER DAY	
			Metronidazole	SS		INTRAVENOUS	500 MG/ TWICE PER DAY/	
			Heparin	SS		SUBCUTANEOUS	5000 UNIT /TWICE PER DAY/	
			Albumin	SS				
			Immune Globulin	SS				
			Co-Codamol	SS				

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Freedom Of Information (FOI) Report

Date:03/02/98ISR Number: 3050231-0Report Type:Direct Company Report #
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis		Ondansetron	PS		INTRAVENOUS	4 MG IV Q 8	
	Pruritus						HR PRN	
			Tpn	C				

Date:03/02/98ISR Number: 3128438-3Report Type:Periodic Company Report #A0053568
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Toxicity	Health	Zofran	PS			SEE TEXT	
	Nausea	Professional						
	Sedation							
	Vomiting							

Date:03/02/98ISR Number: 3128440-1Report Type:Periodic Company Report #A0053718
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation	Health	Zofran	PS				
	Headache	Professional						
		Company						
		Representative						

Date:03/02/98ISR Number: 3128441-3Report Type:Periodic Company Report #A0054486
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Erythema	Health	Zofran	PS		INTRAVENOUS	32 MG /SEE	
	Injection Site Reaction	Professional					TEXT/INTRAVEN	

	Pruritus					
OUS						
	Vasodilatation					

Date:03/02/98ISR Number: 3128445-0Report Type:Periodic Company Report #A0054758
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Condition Aggravated	Health	Zofran	PS			8 MG / FOUR	
	Drug Tolerance Increased	Professional					TIMES PER	
	Nausea						DAY/	2 MON
	Vomiting							

Date:03/02/98ISR Number: 3128446-2Report Type:Periodic Company Report #A0054763
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypersensitivity	Health	Zofran	PS			INTRAVENOUS	32 MG / SEE
	Injection Site Urticaria	Professional					TEXT /	
	Pruritus						INTRAVENOUS	
			Cyclophosphamide	C				

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Freedom Of Information (FOI) Report

Date:03/02/98ISR Number: 3128449-8Report Type:Periodic Company Report #A0055131
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation	Health	Zofran	PS		INTRAVENOUS	10 MG /	SINGLE DOSE /
	Anxiety	Professional						
	Flushing							
	Hyperhidrosis		Dexamethasone	C				
			Granisetron	C				

Date:03/02/98ISR Number: 3128452-8Report Type:Periodic Company Report #A0055855
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Irritation	Health	Zofran	PS		INTRAVENOUS	32 MG / PER	DAY /
	Injection Site Reaction	Professional						
	Injection Site Urticaria							
	Pruritus		Dexamethasone	C				
	Rash Erythematous		Dilantin	C				
	Skin Irritation							
	Urticaria							

Date:03/02/98ISR Number: 3128455-3Report Type:Periodic Company Report #A0056264
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Erythema	Health	Zofran	PS		INTRAVENOUS	32 MG / SEE	TEXT /
	Injection Site Reaction	Professional						
	Pruritus							

Date:03/02/98ISR Number: 3128458-9Report Type:Periodic Company Report #A0056265
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Erythema	Health	Zofran	PS		INTRAVENOUS	32 MG / SEE TEXT /	
	Injection Site Reaction	Professional						
	Injection Site Urticaria					INTRAVENOUS		
	Urticaria							

Date:03/02/98ISR Number: 3128461-9Report Type:Periodic Company Report #A0056503
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Pressure Decreased	Health	Zofran	PS				
	Electrocardiogram Change	Professional	Metoclopramide	SS				

Date:03/02/98ISR Number: 3128462-0Report Type:Periodic Company Report #A0057652
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypersensitivity	Health	Zofran	PS		INTRAVENOUS	INTRAVENOUS	
	Vein Disorder	Professional Company Representative						

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Freedom Of Information (FOI) Report

Date:03/02/98ISR Number: 3128464-4Report Type:Periodic Company Report #A0058186
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anaphylactic Reaction	Health	Zofran	PS		INTRAVENOUS	4 MG / DOSE / INTRAVENOUS	SINGLE
		Professional						

Date:03/02/98ISR Number: 3128466-8Report Type:Periodic Company Report #A0058415
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Chills	Health	Zofran	PS		INTRAVENOUS	10 MG / INTRAVENOUS	
		Professional						
		Company Representative	Dexamethasone	C				

Date:03/02/98ISR Number: 3128469-3Report Type:Periodic Company Report #A0058416
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Chills	Health	Zofran	PS		INTRAVENOUS	30 MG / INTRAVENOUS	
		Professional						
		Company Representative	Lorazepam	C				
			Dexamethasone	C				

Date:03/02/98ISR Number: 3128471-1Report Type:Periodic Company Report #A0058417
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

		Chills	Health	Zofran	PS			
INTRAVENOUS	30 MG /							
		Feeling Cold	Professional					
INTRAVENOUS								
		Night Sweats	Company	Dexamethasone Inj	SS			
INTRAVENOUS	12 MG /							
			Representative					
INTRAVENOUS								
				Sodium Chloride	C			

Date:03/02/98ISR Number: 3128472-3Report Type:Periodic Company Report #A0059953
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dystonia	Health Professional	Zofran	PS				

Date:03/02/98ISR Number: 3128475-9Report Type:Periodic Company Report #A0060341
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dizziness	Health Professional	Zofran	PS		INTRAVENOUS		

Date:03/02/98ISR Number: 3129401-9Report Type:Periodic Company Report #A0049473
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source
	Eye Movement Disorder	Health Professional

			Company Representative				
				Product	Role	Manufacturer	Route
Dose	Duration						
				Zofran	PS		
4 MG							

Date:03/02/98ISR Number: 3129403-2Report Type:Periodic Company Report #A0049535
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Drug Ineffective	Health	Zofran	PS		
INTRAVENOUS	10 MG / PER					
		Professional				
DAY						

Date:03/02/98ISR Number: 3129406-8Report Type:Periodic Company Report #A0049808
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Injection Site Erythema	Health	Zofran	PS		
INTRAVENOUS						
	Injection Site Irritation	Professional				
		Company Representative				

Date:03/02/98ISR Number: 3129410-XReport Type:Periodic Company Report #A0049809
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Injection Site Erythema	Health	Zofran	PS		
INTRAVENOUS						
	Injection Site Irritation	Professional				
		Company Representative				

Date:03/02/98ISR Number: 3129413-5Report Type:Periodic Company Report #A0049810
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Erythema	Health	Zofran	PS		INTRAVENOUS		
	Injection Site Irritation	Professional Company Representative						

Date:03/02/98ISR Number: 3129417-2Report Type:Periodic Company Report #A0050099
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation	Health	Zofran	PS		ORAL	30 MG / PER	DAY
	Headache	Professional					5	DAY
	Hypoaesthesia	Company Representative	Topotecan	C				

Date:03/02/98ISR Number: 3129419-6Report Type:Periodic Company Report #A0050258
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Urticaria	Health	Zofran	PS		INTRAVENOUS	4 MG / SINGLE	DOSE
		Professional						
			Midazolam	C				

Fentanyl	C
Cephazolin	C
Neostigmine	C
Glycopyrronium Bromide	C
Metoclopramide	C
Povidone-Iodine	C

Date:03/02/98ISR Number: 3129421-4Report Type:Periodic Company Report #A0050472
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Urticaria	Health	Zofran	PS		UNKNOWN		
		Professional						

Date:03/02/98ISR Number: 3129424-XReport Type:Periodic Company Report #A0050682
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error	Health	Zofran	PS		INTRAMUSCULAR		
	Nausea	Professional	Ketorolac	C				
	Oedema							

Date:03/02/98ISR Number: 3129426-3Report Type:Periodic Company Report #A0050833
Age:24 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Grand Mal Convulsion	Health	Zofran	PS				
		Professional						

Date:03/02/98ISR Number: 3129429-9Report Type:Periodic Company Report #A0050966
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Headache	Health	Zofran	PS		INTRAVENOUS		
		Professional Company Representative	Zofran	SS		ORAL		

Date:03/02/98ISR Number: 3129432-9Report Type:Periodic Company Report #A0051311
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthma	Health	Zofran	PS		INTRAVENOUS		
		Professional	Zofran	SS		ORAL		
			Fluorouracil Doxurubicin Hydrochloride	C				
			Cyclophosphamide	C				
			Fluorouracil Doxrubicin Hydrochloride	C				
			Cyclophosphamide	C				

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Date:03/02/98ISR Number: 3129436-6Report Type:Periodic Company Report #A0052102
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site	Health	Zofran	PS		INTRAVENOUS		
	Extravasation	Professional						

Date:03/02/98ISR Number: 3129439-1Report Type:Periodic Company Report #A0052842
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective	Health	Zofran	PS		INTRAVENOUS		
	Vomiting	Professional						

Date:03/02/98ISR Number: 3129441-XReport Type:Periodic Company Report #A0052869
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation	Health	Zofran	PS				
	Headache	Professional						
		Company Representative						

Date:03/02/98ISR Number: 3144780-4Report Type:Periodic Company Report #9726870
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Consumer	Zoloft	PS		ORAL		
			Zofran	SS				

Date:03/16/98ISR Number: 3055296-8Report Type:Expedited (15-DaCompany Report #B0054448
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Epilepsy	Foreign Health Professional	Zofran	PS		INTRAVENOUS	8000 MG SINGLE DOSE	
			Fluorouracil	C		INTRAVENOUS		

Date:03/18/98ISR Number: 3057363-1Report Type:Expedited (15-DaCompany Report #B0051924
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Cerebral Cyst	Foreign	Zofran	PS		INTRAVENOUS	UNK/UNK/INTRA	
	Complications Of Maternal Exposure To Therapeutic Drugs	Health Professional				VENOUS		

Date:03/23/98ISR Number: 3059067-8Report Type:Expedited (15-DaCompany Report #B0054389
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Loss Of Consciousness Nausea Oculogyration Vomiting	Foreign Health Professional	Zofran	PS		INTRAVENOUS	4 MG / SINGLE DOSE /	

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Freedom Of Information (FOI) Report

Date:03/26/98ISR Number: 3060534-1Report Type:Expedited (15-DaCompany Report #B0054448
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Epilepsy	Foreign	Zofran	PS		INTRACAVERNOUS	1 MG/SINGLE	
Initial or Prolonged		Health				DOSE/INTRAVEN		
		Professional				OUS		
			Fluorouracil	C				

Date:03/26/98ISR Number: 3060536-5Report Type:Expedited (15-DaCompany Report #A0059948
Age:30 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Health	Zofran	PS		ORAL	ORAL	
	Brain Oedema	Professional	Tamoxifen	C				
	Coma	Company	Carmustine	C				
	Confusional State	Representative	Dacarbazine	C				
	Mydriasis		Cisplatin	C				
	Necrosis		Dexamethasone	C				
	Status Epilepticus		Lorazepam	C				
			Fentanyl	C				
			Hydromorphone	C				

Date:03/30/98ISR Number: 3058415-2Report Type:Expedited (15-DaCompany Report #B0054572
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain Lower	Foreign	Zofran	PS		ORAL	4 MG /TWICE	
	Abortion Missed					PER DAY/ORAL		
			Prochlorperazine	C				
			Procyclidine Hcl	C				
			Metoclopramide	C				
			Cyclizine	C				
			Co-Proxamol	C				

				Ondansetron Hydrochloride	C		
				Nizatidine	C		
				Ranitidine Hydrochloride	C		
				Hydrocortisone	C		

Date:04/03/98ISR Number: 3061170-3Report Type:Direct Company Report #
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dehydration		Carmustine	PS		INTRAVENOUS	300MG IV	
Initial or Prolonged	Nausea		Cisplatin	SS		INTRAVENOUS	50MG IV	
	Vomiting		Dacarbazine	SS		INTRAVENOUS	445 MG IV	
			Decadron	SS		INTRAVENOUS	10MG IV	
			Zofran	SS		INTRAVENOUS	15MG IV	
			Tamoxifen	C				

Date:04/03/98ISR Number: 3063165-2Report Type:Expedited (15-DaCompany Report #B0054798
Age:57 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Abdominal Pain
	Bronchospasm

	Chest Pain					
	Diarrhoea					
	Headache	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Hyperhidrosis	Foreign	Zofran Injection	PS		
INTRAVENOUS	4MG/ PER					
	Hypotension					
DAY/INTRAVENO						
	Rash Erythematous					
US						
	Visual Acuity Reduced		Ondansetron	C		

Date:04/09/98ISR Number: 3062488-0Report Type:Expedited (15-DaCompany Report #B0055154
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Blood Amylase Increased	Foreign	Zofran	PS		
INTRAVENOUS	INTRAVENOUS					
Initial or Prolonged	Lipase Increased		Methylprednisolone	SS		ORAL
ORAL						
	Pancreatitis		Frusemide	SS		
INTRAVENOUS	INTRAVENOUS					
			Omeprazole	SS		
INTRAVENOUS	INTRAVENOUS					
			Mycophenolate Mofetil	SS		ORAL
500 MG/TRICE						
PER DAY/ORAL						
			Tacrolimus	SS		ORAL
1 MG/TWICE						
PER DAY/ORAL						
			Insulin	C		
			Morphine	C		

Date:04/20/98ISR Number: 3065741-XReport Type:Expedited (15-DaCompany Report #B0055472
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Life-Threatening	Chills	Foreign	Zofran	PS			
INTRAVENOUS							
	Gingival Bleeding	Health	Irinotecan	C			
	Platelet Count Decreased	Professional	Fluorouracil	C			
	Purpura		Folinic Acid	C			
	Thrombocytopenia		Methylprednisolone	C			

Date:04/24/98ISR Number: 3068786-9Report Type:Expedited (15-DaCompany Report #B0055623
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Anaphylactic Reaction	Foreign	Zofran	PS		
INTRAVENOUS 4MG /						
	Condition Aggravated					
INTRAVENOUS						
	Cytomegalovirus Infection		Metoclopramide	C		
	Nausea		Metolazone	C		
	Respiratory Failure		Dobutamine	C		
	Shock		Dopamine	C		
			Mannitol	C		
			Methylprednisolone	C		
			Ganciclovir	C		

Date:04/24/98ISR Number: 3068787-0Report Type:Expedited (15-DaCompany Report #B0055643
Age:12 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Sinus Arrest	Foreign	Zofran	PS		
INTRAVENOUS INTRAVENOUS						
			Morphine	C		
			Cyclizine	C		
			Propofol	C		
			Suxamethonium	C		

			Isoflurane	C			
			Nitrous Oxide	C			
			Oxygen	C			

Date:04/27/98ISR Number: 3070557-4Report Type:Expedited (15-DaCompany Report #WAES 98045108
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fungal Infection	Foreign	Midamor	PS		ORAL	PO	
	Gastrointestinal Disorder	Health Professional	Heparin	SS				
	Sepsis		Acetaminophen	SS				
	Tooth Discolouration		Flucytosine	SS				
	Tooth Disorder		Tramadol	SS				
			Meperidine	SS				
			Amphotericin B	SS				
			Temazepam	SS				
			Cyclizine	SS				
			Ranitidine	SS				
			Teicoplanin	SS				
			Fluoxetine	SS				
			Ondansetron	SS				

Date:04/30/98ISR Number: 3071550-8Report Type:Expedited (15-DaCompany Report #B037112
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Tooth Discolouration	Foreign	Fungizone	PS		INTRAVENOUS	57 MG	
	Tooth Erosion	Health Professional	Pethidine	SS		INTRAVENOUS	150 MG	
			Temazepam	SS		ORAL	20 MG QD	
			Flucytosine	SS				
			Ondansetron	SS		INTRAVENOUS	150 MG QD	
			Ranitidine	SS				
			Fluoxetine	SS				
			Amoxicillin	SS				
			Metronidazole	SS		INTRAVENOUS	1500 MG QD	

			Tramadol	SS		
			Ciprofloxain	SS		ORAL
1500 MG QD						
			Cefuroxime	SS		
INTRAVENOUS	2250 MG QD					
			Erythromycin	SS		ORAL
1500 MG QD						
			Paracetamol	SS		
			Amiloride	SS		
			Teicoplanin	SS		
			Cyclizine	SS		
INTRAVENOUS	150 MG QD					
			Heparin	C		
			Clarithromycin	C		

Date:05/04/98ISR Number: 3073445-2Report Type:Expedited (15-DaCompany Report #B0054389
Age:35 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Circulatory Collapse	Foreign	Zofran	PS		ORAL	4 MG SINGLE	
Initial or Prolonged	Eye Rolling	Health					DOSE IV INJ	
Disability	Loss Of Consciousness	Professional	Propofol	C				
	Oculogyration		Fentanyl	C				
	Staring		Midazolam	C				
	Vomiting		Hartmann'S Solution	C				

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Freedom Of Information (FOI) Report

Date:05/06/98ISR Number: 3086691-9Report Type:Direct Company Report #
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrioventricular Block		Zofran	PS				
	First Degree		Demerol	SS				
	Atrioventricular Block Second Degree							
	Sinus Tachycardia							

Date:05/07/98ISR Number: 3074562-3Report Type:Expedited (15-DaCompany Report #B0044264
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Shock	Foreign	Zofran	PS		INTRAVENOUS	(INJECTION)	
	Blood Pressure Systolic Decreased	Literature	Methylprednisolone	C				
	Dermatitis	Health Professional	Cisplatin	C				
	Malaise		Etoposide	C				
	Nausea							
	Pruritus							
	Urticaria							
	Vomiting							

Date:05/11/98ISR Number: 3076558-4Report Type:Expedited (15-DaCompany Report #B0044264
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Shock	Foreign	Zofran	PS		INTRAVENOUS	INTRAVENOUS INJ	
	Blood Pressure Systolic Decreased	Literature	Methylprednisolone	C				
	Dermatitis	Health Professional	Cisplatin	C				
	Malaise		Etoposide	C				
	Nausea							
	Pruritus							
	Urticaria							
	Vomiting							

Date:05/18/98ISR Number: 3079357-2Report Type:Direct Company Report #
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills		Doxrubicin	PS	Gensia		50 MG VIALS L355 4-99	
	Flushing							
	Nausea		Cytoxan	SS			975 MG-500MG VIALS MJ ABF3IA 1/2000	
	Pyrexia							
	Vomiting							
			Dexamethasone	SS			10 MG	
			Zofran	SS				

Date:05/18/98ISR Number: 3080783-6Report Type:Expedited (15-DaCompany Report #R032557
Age: Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Magnesium Decreased
	Blood Phosphorus Decreased
	Dehydration

		Electrolyte Imbalance Hypochloraemia Hyponatraemia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Nausea	Study	Taxol	PS		
INTRAVENOUS	257 MG QD IV						
		Vomiting	Health	Uft	SS		ORAL
300 MG QD PO							
			Professional	Leucovorin	SS		ORAL
90 MG PO							
				Carboplatin	SS		
INTRAVENOUS	503 MG IV						
				Abh	SS		
				Zofran	SS		
				Phenergan	SS		
				Imodium	C		
				Iron	C		

Date:05/22/98ISR Number: 3082915-2Report Type:Expedited (15-DaCompany Report #B0056309
Age:9 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Congenital Anomaly	Anterior Chamber Disorder	Foreign	Zofran	PS		
Other	Complications Of Maternal	Health				
	Exposure To Therapeutic	Professional				
	Drugs					
	Congenital Nose					
	Malformation					
	Facial Dysmorphism					

Date:06/01/98ISR Number: 3087968-3Report Type:Expedited (15-DaCompany Report #B0056309
Age:9 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Congenital Anomaly	Complications Of Maternal	Foreign	Zofran	PS		ORAL
ORAL						
Other	Exposure To Therapeutic	Health				
	Drugs	Professional				
	Congenital Anomaly					
	Eye Disorder					
	Facial Dysmorphism					

Date:06/01/98ISR Number: 3088087-2Report Type:Expedited (15-DaCompany Report #B0056436
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blindness	Foreign	Zofran	PS		INTRAVENOUS	INTRAVENOUS	
	Chest Discomfort		Enoxaparin	C				
	Cyanosis		Ciprofloxacin	C				
	Dyspnoea		Isoflurane	C				
	Feeling Abnormal		Porpofol	C				
	Hyperhidrosis		Ketorolac	C				
	Pulse Pressure Decreased							

Date:06/15/98ISR Number: 3094814-0Report Type:Expedited (15-DaCompany Report #B0056064
Age:70 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Creatinine Increased
	Blood Urea Increased
	Condition Aggravated
	Haemoglobin Decreased

	Proteinuria Red Blood Cell Count Decreased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Thrombocytopenia	Foreign	Zofran	PS		INTRAVENOUS	4MG/PER
	White Blood Cell Count Decreased	Health Professional					DAY/INTRAVENO US
			Cisplatin	SS		INTRAVENOUS	80 MG/M2/PER DAY/INTRAVENO US INFUSION
			Mitomycin	SS		INTRAVENOUS	8 MG/M2/PER DAY INTRAVENOUS INFUSION
			Vindesine Sulfate	SS		INTRAVENOUS	3MG/M2/PER DAY/INTRAVENO US INFUSION
			Metoclopramide	C			
			Me-Prednisolone Na Succ.	C			
			Me-Prednisolone Na Succ.	C			
			Me-Prednisolone Na Succ.	C			

Date:06/17/98ISR Number: 3095166-2Report Type:Expedited (15-DaCompany Report #115/87442
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Dermatitis	Foreign	Cyclophosphamide	PS		INTRAVENOUS	IV

Initial or Prolonged	Hepatic Necrosis	Health	Ondansetron	SS		ORAL
ORAL						
	Jaundice	Professional Company Representative				

Date:06/23/98ISR Number: 3097342-1Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required	Headache		Ondansetron	PS		
INTRAVENOUS 1 MG/HR IV						
Intervention to Prevent Permanent Impairment/Damage			Morphine	C		

Date:06/23/98ISR Number: 3098268-XReport Type:Expedited (15-DaCompany Report #9726870
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required	Drug Ineffective	Health	Zoloft	PS		ORAL
100 MG TOTAL						
Intervention to	Drug Interaction	Professional				
DAILY ORAL						
Prevent Permanent			Zofran	SS		
INTRAVENOUS 16.00 MG						
Impairment/Damage						
TOTAL PRN						
INTRAVENOUS						
			Ortho-Est	C		

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Freedom Of Information (FOI) Report

Date:06/29/98ISR Number: 3099487-9Report Type:Expedited (15-DaCompany Report #B0054934
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intra-Uterine Death	Foreign	Zofran	PS		INTRAVENOUS	8MG	THREE
Other		Health						TIMES PER DAY
		Professional						

Date:06/29/98ISR Number: 3099489-2Report Type:Expedited (15-DaCompany Report #B0056349
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bradycardia	Foreign	Zofran	PS		INTRAVENOUS	8MG	
Initial or Prolonged	Electrocardiogram Qt	Health				INTRAVENOUS		
	Prolonged	Professional				INFUSION		
	Neutropenia		Cisplatin	C				
			Ifosfamide	C				
			Mesna	C				
			Dexamethasone	C				

Date:07/06/98ISR Number: 3102502-7Report Type:Expedited (15-DaCompany Report #115/87442
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dermatitis	Foreign	Cyclophosphamide	PS		INTRAVENOUS	750 MG/DAY;	
Hospitalization -	Drug Toxicity	Health				IV		
Initial or Prolonged	Hepatic Failure	Professional	Ondansetron	SS		ORAL		
Required	Hepatic Necrosis	Company	Enalapril	C				
Intervention to	Jaundice	Representative	Levothyroxine	C				
Prevent Permanent	Lethargy		Bumetanide	C				
Impairment/Damage	Liver Transplant		Prednisolone	C				

	Nausea					

Date:07/07/98ISR Number: 3103860-XReport Type:Direct Company Report #
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Extrapyramidal Disorder		Ondansetron	PS				
INTRAVENOUS							4 MG IV	
Intervention to Prevent Permanent Impairment/Damage	Tremor							

Date:07/07/98ISR Number: 3103936-7Report Type:Direct Company Report #
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactoid Reaction		Ondansetron	PS				
INTRAVENOUS							6 MG IV	-
Hospitalization - 4:45 AM	Angioneurotic Oedema							
Initial or Prolonged	Lung Infiltration		Prochlorperazine	C				
	Pneumonia		Metodopramide	C				
			Nasacort	C				
			Beconase	C				
			Azmacort	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/10/98ISR Number: 3104289-0Report Type:Expedited (15-DaCompany Report #B0057562
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign	Zofran	PS		ORAL	UNK / PER DAY	/ ORAL
	Blood Bilirubin Increased		Thyroxine Sodium	C				
	Dermatitis		Enalapril	C				
	Hepatitis		Mesna	C				
	Prothrombin Level Increased		Dexamethasone	C				
			Cyclophosphamide	C				
			Benztropine	C				

Date:07/14/98ISR Number: 3104993-4Report Type:Expedited (15-DaCompany Report #A0067482
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Respiratory Distress	Health Professional	Zofran	PS				
Hospitalization - Initial or Prolonged								
Other								

Date:07/17/98ISR Number: 3106143-7Report Type:Expedited (15-DaCompany Report #B0057752
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Myocardial Infarction	Foreign Health Professional	Zofran	PS				

Date:07/20/98ISR Number: 3106936-6Report Type:Expedited (15-DaCompany Report #B0057751
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Myocardial Infarction	Foreign	Zofran	PS				

	Nausea	Health					
	Vomiting	Professional					

Date:07/22/98ISR Number: 3108500-1Report Type:Expedited (15-DaCompany Report #B0056566
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Flushing	Foreign	Zofran	PS		ORAL	4 MG TWICE	
Hospitalization -	Jaundice	Health					PER DAY ORAL	
Initial or Prolonged	Lethargy	Professional	Cyclophosphamide	SS		UNKNOWN	UNKNOWN	
Disability	Liver Function Test		Mesna	C				
	Abnormal		Enalapril	C				
	Nausea		Thyroxine Sodium	C				
	Purpura		Bumetanide	C				

Date:07/22/98ISR Number: 3108502-5Report Type:Expedited (15-DaCompany Report #B0057671
Age:73 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Abdominal Pain Lower
Initial or Prolonged	Anxiety
Disability	Blood Pressure Increased

	Constipation					
	Dyspnoea					
	Fatigue	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Tachycardia	Foreign	Zofran	PS		ORAL
4 MG PER DAY						
		Health				
ORAL						
		Professional	Etoposide	C		
		Company	Loxoprofen	C		
		Representative	Rebamipide	C		
			Sennosides	C		

Date:07/29/98ISR Number: 3110842-0Report Type:Expedited (15-DaCompany Report #B0058253
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Bradycardia	Foreign	Zofran Injection	PS		
INTRAVENOUS	INTRAVNEOUS					
	Cardiac Arrest		Anesthetic	C		

Date:07/31/98ISR Number: 3111175-9Report Type:Expedited (15-DaCompany Report #B0058356
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Abdominal Pain Lower	Foreign	Zofran	PS		
INTRAMUSCULAR	4 MG/TWICE					
Initial or Prolonged	Abortion Missed	Health				
PER						
Other	Complications Of Maternal	Professional				
DAY/INTRAMUSC						
	Exposure To Therapeutic					
ULAR						
	Drugs		Zofran	SS		ORAL
4 MG/IN THE						
MORNING/ORAL						
			Prochlorperazine	C		
			Metoclopramide	C		
			Co-Proxamol	C		
			Nizatidine	C		

			Ranitidine Hydrochloride	C		
			Cyclizine	C		
			Hydrocortisone	C		

Date:08/03/98ISR Number: 3112431-0Report Type:Expedited (15-DaCompany Report #103110
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign Other	Rocephine	PS			2 GRAM DAILY	UNKNOWN
	Grand Mal Convulsion		Zoloft	SS		ORAL	1 DOSE FORM	DAILY
			Tegretol	SS		ORAL	600 MG DAILY	
			Zophren	SS				
INTRAVENOUS							2 MG 1 X PER	ONE DOSE
			Campto	C				
			Moscontin	C				
			Solupred	C				

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Freedom Of Information (FOI) Report

Date:08/03/98ISR Number: 3112534-0Report Type:Expedited (15-DaCompany Report #B0058365
Age:12 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Foreign	Zofran	PS		INTRAVENOUS	6 MG/	
	Hallucination	Health				INTRAVENOUS		
	Sedation	Professional				(INJECTION)		
	Vomiting		Methotrexate	C				

Date:08/06/98ISR Number: 3113857-1Report Type:Expedited (15-DaCompany Report #A0067482
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Health	Zofran	PS			32 MG	
Hospitalization -	Feeling Abnormal	Professional					MONTHLY	MON
Initial or Prolonged	Respiratory Distress		Carboplatin	C				
Other								

Date:08/06/98ISR Number: 3113943-6Report Type:Expedited (15-DaCompany Report #98F-10620
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Grand Mal Convulsion	Foreign	Tegretol	PS		ORAL	500 MG DAILY	
Initial or Prolonged		Health						
ORAL							6	WK
		Professional	Rocephine	SS			2 G DAILY,	
		Other					UNKNOWN	
			Zoloft	SS		ORAL	50 MG, DAILY,	
							ORAL	

			Zophren Solution	SS		
INTRAVENOUS	2 G, DAILY,					
INTRAVENOUS						
			Irinotecan Solution	C		

Date:08/06/98ISR Number: 3114330-7Report Type:Expedited (15-DaCompany Report #9823039
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Depressed Level Of	Foreign	Zoloft	PS		ORAL	50.00 MG	
Initial or Prolonged	Consciousness	Health					TOTAL DAILY	
	Epilepsy	Professional					ORAL	
	Grand Mal Convulsion	Other	Carbamezapine	SS		ORAL	600.00 MG	
	Pain						TOTAL ORAL	
	Peripheral Sensory		Ceftriaxone	SS			UNKNOWN	UNKNOWN
	Neuropathy		Ondansetron	SS			INTRAVENOUS	BID
							INTRAVENOUS	
			Irinotecan	C				
			Morphine Sulfate	C				
			Prednisolone	C				

Date:08/12/98ISR Number: 3115889-6Report Type:Expedited (15-DaCompany Report #130/87442
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Flushing	Consumer	Cyclophosphamide	PS				
Initial or Prolonged	Hepatic Necrosis	Company	Ondansetron	SS				
Other	Jaundice	Representative	Mesna	C				
	Lethargy		Enalapril	C				
	Purpura		Levothyroxine Sodium	C				
			Bumentanide	C				

			Prednisolone	C		
			Benzatropine Mesilate	C		
			Dexamethasone	C		

Date:08/14/98ISR Number: 3117299-4Report Type:Expedited (15-DaCompany Report #B0057885
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Alanine Aminotransferase Increased	Foreign Health Professional Company Representative	Zofran	PS				
	Antinuclear Antibody Positive		Carboplatin	C				
	Aspartate Aminotransferase Increased							
	Blood Alkaline Phosphatase Increased							
	Blood Bilirubin Increased							
	Blood Lactate Dehydrogenase Increased							
	Drug Toxicity							
	Gamma-Glutamyltransferase Increased							
	Hepatitis							
	Hepatocellular Damage							
	Inflammation							
	Jaundice							

Date:08/21/98ISR Number: 3119854-4Report Type:Direct Company Report #
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Pressure Systolic Decreased		Zofran	PS			4 MG IVP	X 1
	Dizziness							
	Hypersensitivity							
	Urticaria							

Date:08/24/98ISR Number: 3121032-XReport Type:Expedited (15-DaCompany Report #A0069299
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal	Consumer	Zofran	PS		ORAL	2 MG PER DAY	
	Exposure To Therapeutic							
ORAL							20	DAY
	Drugs							
	Intra-Uterine Death							

Date:08/24/98ISR Number: 3121159-2Report Type:Direct Company Report #
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Grand Mal Convulsion		Zofram	PS			4 MG	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/28/98ISR Number: 3123442-3Report Type:Expedited (15-DaCompany Report #A0069629
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Pancreatitis	Health	Zofran	PS			UNKNOWN	UNK/SEE TEXT
Initial or Prolonged		Professional	Gemcitabine	SS			UNKNOWN	UNK
Other			Vinorelbine Tartrate	C				
			Docetaxel	C				

Date:08/31/98ISR Number: 3123445-9Report Type:Expedited (15-DaCompany Report #A0000217
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrial Fibrillation	Health	Zofran	PS		INTRAVENOUS	30 MG/SINGLE	
Hospitalization -	Bronchospasm	Professional				DOSE/INTRAVEN		
Initial or Prolonged	Cardiac Enzymes Increased					OUS/INJECTION		
Other	Cardio-Respiratory Arrest		Nifedipine	C				
	Myocardial Infarction		Methotrexate	C				
	Pulmonary Oedema		Digoxin	C				
	Rales		Compazine	C				
	Tachycardia		Atenolol	C				
	Ventricular Tachycardia		Flurazepam Dihc1	C				
			Intravenous Fluid(S)	C				

Date:08/31/98ISR Number: 3123449-6Report Type:Expedited (15-DaCompany Report #G0018100
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Arrhythmia		Zofran	PS		INTRAVENOUS	30 MG/SEE	
Hospitalization -	Atrial Fibrillation					TEXT/INTRAVEN		
Initial or Prolonged	Bronchospasm					OUS/INJECTION		
Other	Cardiac Enzymes Increased		Methotrexate	C				

	Cardio-Respiratory Arrest		Compazine	C
	Pulmonary Oedema		Flurazepam Dihc1	C
	Rales		Intravenous Fluid(S)	C
	Tachycardia		Nifedipine	C
	Ventricular Tachycardia		Digoxin	C
			Atentolol	C

Date:09/03/98ISR Number: 3125729-7Report Type:Direct Company Report #
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Hyperbilirubinaemia		Cyclosporine	PS		
INTRAVENOUS	87.5 MG/HR.					
HELD TILL HR						
88 AND						
RESTARTED						
EACH 56 MG/HR						
			Zofran	SS		
1 MG/HR						
CONTINOUS						
INFUSION						
BEGINNING APP						
FOR 24 TILL						
			Mitoxantrone	C		
			Vp-16	C		
			It-Ara-C	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/03/98ISR Number: 3126486-0Report Type:Expedited (15-DaCompany Report #B0059328
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Eye Rolling	Foreign	Zofran	PS				
	Oculogyration	Health	Propofol	C				
	Vasoconstriction	Professional	Remifentanil Hcl	C				
		Company	Bupivacaine	C				
		Representative	Evening Primrose Oil	C				

Date:09/09/98ISR Number: 3126551-8Report Type:Expedited (15-DaCompany Report #B041014
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Encephalopathy	Foreign	Cyclophosphamide	PS				
Initial or Prolonged	Fatigue	Health	Ondansetron	SS		ORAL	PO	
Disability	Flushing	Professional	Enalapril	C				
	Hepatic Necrosis	Other	Mesna	C				
	Hyperbilirubinaemia		Thyroxine Sodium	C				
	Jaundice		Bumetanide	C				
	Lethargy		Prednisolone	C				
	Liver Function Test		Benztropine	C				
	Abnormal		Dexamethasone	C				
	Nausea							
	Purpura							

Date:09/10/98ISR Number: 3127986-XReport Type:Expedited (15-DaCompany Report #B0057222
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Activated Partial	Foreign	Zofran Injection	PS				
Hospitalization -	Thromboplastin Time	Study						
Initial or Prolonged	Prolonged	Health						
	Anaemia	Professional	Zofran Injection	SS				

	Anorexia			
PER				
	Duodenal Ulcer			
DAY/INTRAVENO				
	Duodenal Ulcer			
US				
	Haemorrhage	Nicoumalone	C	
	Fatigue	Cisplatin	C	
	Hypotension			
	Malaise			
	Melaena			
	Neutropenia			
	Pallor			
	Pancytopenia			
	Prothrombin Time			
	Prolonged			
	Sepsis			

Date:09/11/98ISR Number: 3127989-5Report Type:Expedited (15-DaCompany Report #B0057271
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Pulmonary Embolism	Foreign	Zofran Injection	PS		INTRAVENOUS	8 MG/TWICE	
Hospitalization -		Study						
PER								
Initial or Prolonged		Health						
DAY/INTRAVENO								
		Professional						
US								

Date:09/11/98ISR Number: 3127992-5Report Type:Expedited (15-DaCompany Report #B0057757
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Pressure Systolic	Foreign	Zofran Injection	PS		INTRAVENOUS	8 MG/SINGLE	
	Decreased	Study					DOSE/INTRAVEN	
	Cardiac Arrest	Health					OUS	
	Heart Rate Decreased	Professional	Acebutolol	C				
			Carbamazepine	C				

Date:09/11/98ISR Number: 3127994-9Report Type:Expedited (15-DaCompany Report #B0059295
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Pyrexia	Foreign	Zofran Injection	PS		INTRAVENOUS	8 MG/PER	
Initial or Prolonged	Urinary Tract Infection	Study					DAY/INTRAVENO	
	White Blood Cell Count	Health					US	
	Increased	Professional						

Date:09/11/98ISR Number: 3128518-2Report Type:Expedited (15-DaCompany Report #800#3#1998-15432 (000)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase	Health	Cyclophosphamide	PS		INTRAVENOUS	750 MILLIGRAM	
Initial or Prolonged	Increased	Professional	Ondansetron					
Disability	Encephalopathy		Hydrochloride	SS		ORAL		
	Fatigue		Enalapril	C				
	Flushing		Mesna	C				
	Hepatic Necrosis		Thyroxine	C				
	Hyperbilirubinaemia		Bumetanide	C				
	Jaundice		Prednisolone	C				
	Lethargy							
	Liver Transplant							

	Nausea					
	Purpura					

Date:09/16/98ISR Number: 3130003-9Report Type:Expedited (15-DaCompany Report #B0059559
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cerebrovascular Accident	Foreign	Zofran	PS		INTRAVENOUS	8 MG/SINGLE	
Initial or Prolonged		Health				DOSE/INTRAVEN		
Disability		Professional				OUS		
			Cancer Chemotherapy	C				

Date:09/16/98ISR Number: 3130004-0Report Type:Expedited (15-DaCompany Report #A0070243
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bronchospasm	Health	Zofran	PS		INTRAVENOUS	32 MG / PER	
Initial or Prolonged	Circulatory Collapse	Professional				DAY/		
Other	Grand Mal Convulsion					INTRAVENOUS	10 MON	
	Hypotension		Carboplatin	SS				
	Vomiting		Dexamethasone	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/16/98ISR Number: 3131344-1Report Type:Expedited (15-DaCompany Report #B0057751
Age:70 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Myocardial Infarction	Foreign Health Professional	Zofran	PS				

Date:09/16/98ISR Number: 3131347-7Report Type:Expedited (15-DaCompany Report #B0057752
Age:70 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Myocardial Infarction	Foreign Health Professional	Zofran	PS				

Date:09/17/98ISR Number: 3131641-XReport Type:Expedited (15-DaCompany Report #B0059559
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability Other	Cerebrovascular Accident	Foreign Health Professional	Zofran Paclitaxel Carboplatin Dexamethasone Clemastine Fumarate Ranitidine Hydrochloride Paracetamol	PS C C C C C C			INTRAVENOUS DOSE/INTRAVEN OUS	8 MG/SINGLE

Date:09/18/98ISR Number: 3132562-9Report Type:Expedited (15-DaCompany Report #A0069629
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Pancreatitis	Health Professional Other	Zofran Gemcitabine Vinorelbine Tartrate Docetaxel	PS SS C C				

Date:09/22/98ISR Number: 3133167-6Report Type:Direct Company Report #
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Grand Mal Convulsion		Zofran	PS			4 MG	

Date:09/24/98ISR Number: 3136205-XReport Type:Expedited (15-DaCompany Report #B0059295
Age:56 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Body Temperature Increased Urinary Tract Infection	Foreign Study Health	Zofran	PS		INTRAVENOUS	8 MG /PER DAY/INTRAVENO US	
		Professional	Gr205171a Injection	C		INTRAVENOUS	1.5 MG/PER DAY/INTRAVENO US	
			Diclofenac Sodium	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/29/98ISR Number: 3136580-6Report Type:Direct Company Report #
Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Pharyngeal Oedema		Dactinomycin	PS			2OOO MCG	
Initial or Prolonged	Tongue Oedema		Ondansetron	SS			8 MG	

Date:10/02/98ISR Number: 3137883-1Report Type:Expedited (15-DaCompany Report #A0070243
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bronchospasm	Health	Zofran	PS		INTRAVENOUS	32 MG/PER	
Initial or Prolonged	Circulatory Collapse	Professional					DAY/INTRAVENO	
Other	Grand Mal Convulsion					US	10	MON
	Hypotension		Carboplatin	SS			615 MG/UNK	
	Vomiting							

Date:10/05/98ISR Number: 3138374-4Report Type:Expedited (15-DaCompany Report #B0059900
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Respiratory Arrest	Foreign	Zofran	PS				
		Health						
		Professional						

Date:10/06/98ISR Number: 3138701-8Report Type:Expedited (15-DaCompany Report #B0059973
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Electrocardiogram Qt	Foreign	Zofran	PS		INTRAVENOUS	INTRAVENOUS	

Hospitalization - Initial or Prolonged Other	Prolonged Pulse Absent Ventricular Tachycardia	Health Professional	Propofol Fentanyl	C C	

Date:10/06/98ISR Number: 3138882-6Report Type:Expedited (15-DaCompany Report #D0002606
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Cardiac Failure Rash Macular Respiratory Failure Toxic Epidermal Necrolysis	Foreign Health Professional	Ondansetron Hydrochloride Phenytoin Septra Lorazepam Amitriptyline Cefotiam Hydrochloride Lormetazepam X-Ray Contrast Medium	PS SS SS SS SS SS SS SS		ORAL ORAL ORAL ORAL ORAL	8 MG/ML / SINGLE DOSE / INTRAVENOUS 1 TABLET / THREE TIMES PER / ORAL 1 TABLET / TWICE PER DAY / ORAL ORAL 25 MG / TWICE PER DAY / ORAL INTRAVENOUS 2 MG / PER DAY / ORAL	INTRAVENOUS

				Melperone Hydrochloride	SS		
				Enoxaparin	SS		
SUBCUTANEOUS	SUBCUTANEOUS						
				Valerian	SS		ORAL
ORAL							
				Dimenhydrinate	SS		

Date:10/07/98ISR Number: 3139227-8Report Type:Expedited (15-DaCompany Report #B0055623
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Anaphylactic Reaction	Foreign	Zofran	PS		
INTRAVENOUS 4 MG						
	Cytomegalovirus Infection					
INTRAVENOUS						
	Respiratory Failure		Metoclopramide	C		
	Shock		Metolazone	C		
			Dobutamine	C		
			Dopamine	C		
			Mannitol	C		
			Methylprednisolone	C		
			Ganciclovir	C		

Date:10/23/98ISR Number: 3146009-XReport Type:Expedited (15-DaCompany Report #A0072802
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Chest Pain	Health	Zofran	PS		
UNK / UNK /						
Initial or Prolonged	Conjunctival Hyperaemia	Professional				
INTRAVENOUS						
	Dizziness	Company				
	Feeling Hot	Representative				
	Hypotension					
	Nausea					
	Syncope					

Date:10/23/98ISR Number: 3146515-8Report Type:Expedited (15-DaCompany Report #B0059328
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diplopia	Foreign	Zofran	PS		INTRAVENOUS	8 MG; SINGLE DOSE;	
Other	Eye Rolling	Health Professional						
	Nystagmus							
	Oculogyration		Propofol	C		INTRAVENOUS		
	Vasoconstriction		Remifentanil Hci	C				
			Bupivacaine	C				
			Evening Primrose Oil	C				
			Ketoprofen	C				

Date:10/30/98ISR Number: 3150166-9Report Type:Expedited (15-DaCompany Report #B0060776
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Oedema	Foreign	Zofran Injection	PS		INTRAVENOUS	4 MG/PER DAY/INTRAVENO US	
	Vascular Purpura							
			Folic Acid Injection	SS		INTRAVENOUS	INTRAVENOUS	
			Fluorouracil	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/06/98ISR Number: 3153577-0Report Type:Expedited (15-DaCompany Report #B0059973
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Electrocardiogram Qt	Foreign	Zofran Injection	PS		INTRAVENOUS	INTRAVENOUS	
Hospitalization - Initial or Prolonged	Prolonged Oxygen Saturation	Health Professional	Propofol	C				
			Fentanyl	C				
Other	Decreased		Nitrous Oxide	C				
	Pco2 Decreased		Isoflurance	C				
	Pulse Absent							
	Ventricular Tachycardia							

Date:11/12/98ISR Number: 3156465-9Report Type:Direct Company Report #
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Rash Macular		Prilosec	PS	Merck Sharp Dohme	ORAL	20 MG QD PO	
	Rash Pruritic		Zofran	SS	Roche	ORAL	8 MG BID PO	

Date:11/19/98ISR Number: 3160212-4Report Type:Expedited (15-DaCompany Report #A0069299
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal	Health	Zofran	PS		ORAL	2 MG/PER	
	Exposure To Therapeutic Drugs	Professional					DAY/ORAL	20 DAY
	Intra-Uterine Death							

Date:11/19/98ISR Number: 3160472-XReport Type:Expedited (15-DaCompany Report #B0036855
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Disability		Angina Pectoris	Foreign	Zofran	PS		
INTRAVENOUS	UNKNOWN						
		Electrocardiogram	Literature				
INTRAVENOUS							
		Abnormal	Health				
		Myocardial Ischaemia	Professional				

Date:11/19/98ISR Number: 3160942-4Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Hypoventilation		Zofran	PS		
INTRAVENOUS	4MG IV					
	Nausea					
	Obstructive Airways Disorder					
	Stridor					
	Tongue Oedema					

Date:11/20/98ISR Number: 3161316-2Report Type:Expedited (15-DaCompany Report #A0075084
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Death	Health	Zofran	PS		
UNK/SINGLE						
		Professional				
DOSE/INTRAVEN						
OUS						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/27/98ISR Number: 3163601-7Report Type:Expedited (15-DaCompany Report #B0061556
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrioventricular Block Complete	Health Professional	Zofran Anesthetic	PS C				
	Atrioventricular Block First Degree							
	Atrioventricular Block Second Degree							

Date:11/27/98ISR Number: 3163837-5Report Type:Expedited (15-DaCompany Report #B0061434
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Foreign	Zofran	PS		INTRAVENOUS	8 MG /	TWICE PER DAY /
	Disorientation	Study						
	Hyperhidrosis	Health				INTRAVENOUS		
	Hypoglycaemia	Professional	Cisplatin	C				
	Loss Of Consciousness		Fluorouracil	C				
	Malaise							
	Urinary Incontinence							

Date:12/02/98ISR Number: 3169422-3Report Type:Direct Company Report #
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Culture Positive	Health	Adriamycin	PS				
	Chest Pain	Professional	Zofran	SS		INTRAVENOUS	32 MG IV X 1	
Other DISE	Feeling Hot							
	Hypotension		Ativan	C				
	Nausea		Neuprogen	C				
	Syncope		Infed (Iron					
	Vomiting		Dextrose)	C				

Date:12/03/98ISR Number: 3166606-5Report Type:Expedited (15-DaCompany Report #B0061434
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Foreign	Zofran	PS			8 MG/TWICE	
	Blood Pressure Decreased	Study					PER	
	Chest Pain	Health					DAY/INTRAVENO	
	Disorientation	Professional					US/ INJ	
	Dizziness		Cisplatin	C				
	Dyspnoea		Fluorouracil	C				
	Hyperhidrosis		Primolout	C				
	Hypotension		Estropipate	C				
	Nausea							
	Urinary Incontinence							

Date:12/03/98ISR Number: 3166674-0Report Type:Expedited (15-DaCompany Report #B0061789
Age:50 YR Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Angioneurotic Oedema
Hospitalization - Initial or Prolonged	Anorexia
	Blood Lactate Dehydrogenase Increased

	Dehydration						
	Dysphagia						
	Fungal Infection	Report Source	Product	Role	Manufacturer	Route	Dose
Duration							
	Gastrointestinal	Foreign	Zofran	PS			
INTRAVENOUS	8MG/TWICE PER						
	Haemorrhage	Study					
DAY/INTRAVENO							
	Haematemesis	Health					
US							
	Melaena	Professional	Fenofibrate	C			
	Pharyngitis		Morphine Sulphate	C			
	Pharyngolaryngeal Pain		Ranitidine				
	Pyrexia		Hydrochloride	C			
			Indomethacin	C			
			Fluconazole	C			
			Itraconazole	C			

Date:12/03/98ISR Number: 3287957-XReport Type:Periodic Company Report #0196922A
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Duration							
Other	Dry Mouth	Consumer	Transderm				
	Nausea		Scop-Scopolamine				
	Sedation		1.5mg-Nvch	PS			
1							
	Therapeutic Agent						
PATCH/Q3D/TTS							
	Toxicity		Zofran-Ondansetrone				
	Visual Disturbance		Dose Unk-Glaxo	SS	Glaxo	ORAL	
PO							
			Lorazepam	C			

Date:12/07/98ISR Number: 3168561-0Report Type:Direct Company Report #
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Duration							
	Diplopia		Zofran	PS			
INTRAVENOUS	8 MG IV Q 8						
	Headache						
HRS							

Date:12/11/98ISR Number: 3169601-5Report Type:Expedited (15-DaCompany Report #199813755HPD
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Claforan	PS			INTRAVENOUS	2 G TID IV 5 DAY
Life-Threatening	Blood Creatinine	Study	Novalgin	SS			INTRAVENOUS	QD IV 1 DAY
	Increased	Health	Novalgin	SS			INTRAVENOUS	QD IV 1 DAY
	Blood Urea Increased	Professional	Lasix	SS		ORAL	20 MG QD PO	1 DAY
	Dermatitis		Dolantin	SS			INTRAVENOUS	25 MG/DAY IV 1 DAY
	Epidermolysis Bullosa		Suprarenin	SS			INTRAVENOUS	TID IV 3 DAY
	Liver Function Test		Allopurinol	SS		ORAL	300 MG/DAY PO	15 DAY
	Abnormal		Augmentin	SS			INTRAVENOUS	2 G BID IV 5 DAY
	Oral Mucosal Eruption		Diflucan	SS		ORAL	200 MG BID PO	5 DAY
	Pruritus		Diflucan	SS		ORAL	200 MG BID PO	12 DAY
	Pyrexia		Paracetamol	SS		ORAL	PO	1 DAY
	Shock		Paracetamol	SS		ORAL	PO	2 DAY
	Stevens-Johnson Syndrome		Paracetamol	SS		ORAL	PO	1 DAY
	Toxic Epidermal		Paracetamol	SS		ORAL	PO	1 DAY
	Necrolysis		Gentamycin	SS			INTRAVENOUS	120 MG TID IV 1 WK
	White Blood Cell Count		Ciprobay	SS			INTRAVENOUS	QD IV 1 DAY
	Decreased		Dormicum	SS			INTRAVENOUS	10 MG/H IV 2 DAY
			Antra	SS			INTRAVENOUS	20 MG/DAY IV 6 DAY
			Antra	SS			INTRAVENOUS	20 MG/DAY IV 2 WK
			Zofran	SS			INTRAVENOUS	QD IV 6 DAY
			Zofran	SS			INTRAVENOUS	QD IV 3 DAY

15 MG/DAY THE	1	DAY			Methotrexat	SS	
5000 MG/DAY							
IVF	1	DAY			Methotrexat	SS	
15 MG/DAY THE	1	DAY			Methotrexat	SS	
TID PO	6	DAY			Imodium	SS	ORAL
TID PO	1	DAY			Imodium	SS	ORAL
INTRAVENOUS	Q2D IV		8	DAY	Multibionta	SS	
INTRAVENOUS	BID IV		2	DAY	Paspertin	SS	
INTRAVENOUS	BID IV		6	DAY	Paspertin	SS	
SUBCUTANEOUS	300 UG/DAY SC		12	DAY	Leucomax	SS	
QD PO	3	DAY			Pantozol	SS	ORAL
INTRAVENOUS	500-500-0-500				Metronidazol	SS	
MG IV	5	DAY					
SUBCUTANEOUS	SC		2	WK	Liquemin	SS	
5 DROP QD PO	6	DAY			Opium	SS	ORAL
5 DROP QD PO	2	DAY			Opium	SS	ORAL
1 MG/H IVF	9	DAY			Mst	SS	
INTRAVENOUS	QD IV		8	DAY	Vitalipid	SS	
0.5-0.5-0-0.5					Vancomycin	SS	
G IVF	9	DAY					
QD PO	1	DAY			Bifiteral	SS	ORAL
0-0-2-2 G IVF	5	DAY			Ancotil	SS	
INTRAVENOUS	3.75 MG/DAY				Dipidolor	SS	

IV			4	DAY
INTRAVENOUS		QD IV	4	DAY
0.5 G/DAY IVF	4	DAY		
SUBCUTANEOUS		50 IU/DAY SC	4	DAY
INTRAVENOUS		QD IV	4	DAY
INTRAVENOUS		40 MG/DAY IV	4	DAY
SUBCUTANEOUS		SC	2	DAY
400 ML/DAY				
IVF	2	DAY		
0.5 G/DAY IVF	1	DAY		
200 MG/DAY				
IVF	3	DAY		
INTRAVENOUS		200 MG/DAY IV	1	DAY
INTRAVENOUS		50 MG/DAY IV	1	DAY
INTRAVENOUS		50 MG/DAY IV	1	DAY

Tavegil	SS
Meronem	SS
Actrapid	SS
Psyquil	SS
Amphotericin B	SS
Neupogen	SS
Humanalbumin	SS
Zienam	SS
Dopamin	SS
Sobelin Solubile	SS
Isoptin	SS
Solu-Decortin H	SS
Ampho-Moronal	C
Fortecortin	C
Uromitexan	C
Dexamethason	C
Ifosfamid	C
Cytosin-Arabinosid	C
Vindesin	C
Leucovortin	C
Nutriflex	C
Vm-26 Bristol	C
Vergentan	C
Riopan	C
Magnorbin	C
Lipofundin Mct	C
Aminomel	C
Aminomix	C
Natriumbicarbonat	C
Uralyt-U Granulat	C
G5%	C
Nacl	C
Kcl-Perfusor	C
Glucose	C
Ferrosanol Duodenal	C

			Urbason	C		

Date:12/11/98ISR Number: 3169634-9Report Type:Expedited (15-DaCompany Report #D0002829
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Shock	Foreign	Zofran	PS		INTRAVENOUS	1 AMPOULE/	
	Stevens-Johnson Syndrome	Health					PER DAY/	
	Toxic Epidermal	Professional				INTRAVENOUS		
	Necrolysis		Zyloprim	SS		ORAL		
			Augmentin	SS			2 G/ TWICE	
							PER DAY/	
							INTRAVENOUS	
							INFUSION	
			Dipyrone	SS				
						INTRAVENOUS	1 AMPOULE /	
							PER DAY /	
							INTRAVENOUS	
			Multiple Mediction (Formulation Unknown)	SS				
			Multiple Medication	C				

Date:12/11/98ISR Number: 3170122-4Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hiccups		Ondansetron	PS			10MG Q 8	4 DAY
			Dexamethason	SS			10MG Q 6	4 DAY

					Cyclophosphamide	SS		
INTRAVENOUS	3500 IV	4	DAY					
					Etioisude	C		
					Carnystine	C		
					Mesna	C		
					Allonurinal	C		
					Fluranazole	C		
					Septra Ds	C		
					Acyclover	C		
					Mvi	C		

Date:12/11/98ISR Number: 3170128-5Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hiccups		Ondansetron	PS			24MG -DAY 1;	
							10MG X2 Q 12	2 DAY
			Dexamethasome	SS				
							40MG QD X 4D	4 DAY
			Cisplatin	SS				
							170MG ON 24H	
			Cytarabine	C				
			Ativan	C				
			Allopurinol	C				
			Mannital	C				

Date:12/14/98ISR Number: 3169982-2Report Type:Expedited (15-DaCompany Report #A0072802
Age:37 YR Gender:Female I/FU:F

Outcome
Hospitalization -
Initial or Prolonged

Other

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Chest Pain	Health	Zofran Injection	PS		INTRAVENOUS	32 MG/SINGLE	
	Conjunctival Hyperaemia	Professional					DOSE,	
	Dizziness	Company					INTRAVENOUS	
	Feeling Hot	Representative	Iron Dextran	C				
	Hypotension		Filgrastim	C				
	Loss Of Consciousness		Doxorubicin					
	Pulse Pressure Decreased		Hydrochloride	C				
	Vision Blurred		Docetaxel	C				
	Visual Disturbance							

Date:12/14/98ISR Number: 3170643-4Report Type:Expedited (15-DaCompany Report #109858
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Midazolam					
Life-Threatening	Blood Albumin Decreased	Study	Hydrochloride	PS		INTRAVENOUS	10 MG 1 X PER	
	Constipation	Health					HOUR	
	Dermatitis	Professional					INTRAVENOUS	
	Diarrhoea	Other	Heparin Sodium	SS		SUBCUTANEOUS	7500 IU DAILY	
	Fluid Retention						SUBCUTANEOUS	
	Fungal Infection		Allopurinol	SS		ORAL	300 MG DAILY	
	Gastrointestinal Disorder						ORAL	
	Hyperglycaemia		Omeprazole	SS		INTRAVENOUS	20 MG DAILY	
	Hypertension						INTRAVENOUS	
	Hypovitaminosis		Diflucan	SS		ORAL	200 MG 2 X	
	Lip Disorder						PER DAY ORAL	

	Neutropenia	Zofran	SS		
INTRAVENOUS	1 AMPULE 1 X				
	Pain				
PER DAY					
	Pruritus				
INTRAVENOUS					
	Pyrexia	Methotrexate	SS		
INTRATHECAL	15MG DAILY 1				
	Restlessness				
X PER ONE					
	Shock				
DOSE					
	Stevens-Johnson Syndrome				
INTRATHECAL;					
	Toxic Epidermal				
5000 MG DAILY					
	Necrolysis	Imodium	SS		ORAL
2 DOSE FORM 3					
X PER DAY					
ORAL					
		Multibionta	SS		
INTRAVENOUS	1 AMPULE 1 X				
PER 2 DAYS					
INTRAVNOUS					
		Metoclopramide Hydrochloride	SS		
INTRAVENOUS	1 AMPULE 2 X				
PER DAY					
INTRAVENOUS					
		Leucomax	SS		
SUBCUTANEOUS	300 MCG DAILY				
SUBCUTANEOUS					
		Pantoprazole	SS		ORAL
1 DOSE FORM 1					
X PER DAY					
ORAL					
		Acetaminophen	SS		ORAL
1 X PER ONE					
DOSE ORAL					
		Gentamycin	SS		
INTRAVENOUS	120 MG 3 X				
PER DAY					

INTRAVENOUS

Cefotaxime Sodium SS

INTRAVENOUS 2 GRAM 3 X

PER DAY

INTRAVENOUS

		Metronidazole	SS	
INTRAVENOUS	500 MG 3 X PER DAY			
INTRAVENOUS	5 DROP 1 X PER DAY	Opium	SS	ORAL
		Augmentin	SS	
INTRAVENOUS	2 GRAM 2 X PER DAY			
INTRAVENOUS		Morphine Sulfate	SS	
INTRAVENOUS	1 MG 1 X PER HOUR			
INTRAVENOUS		Vitalipid	SS	
INTRAVENOUS	1 AMPULE 1 X PER DAY			
INTRAVENOUS		Novalgin	SS	
INTRAVENOUS	1 AMPULE 1 X PER ONE DOSE			
INTRAVENOUS		Vancomycin	SS	
INTRAVENOUS	.5 GRAM 3 X PER DAY			
INTRAVENOUS		Lactulose	SS	ORAL
1 X PER OND DOSE	ORAL			
		Lasix	SS	ORAL
20 MG 1 X PER				

ONE DOSE ORAL			
INTRAVENOUS	2 GRAM 2 X	Ancotil	SS
PER DAY			
INTRAVENOUS			
INTRAVENOUS	3.75 MG DIALY	Piritramide	SS
INTRAVENOUS			
INTRAVENOUS	1 AMPULE 1 X	Tavegil	SS
PER DAY			
INTRAVENOUS			
INTRAVENOUS	.5 GRAM DIALY	Meropenem	SS
INTRAVENOUS			
SUBCUTANEOUS	50 IU DIAY	Insulin Human	SS
SUBCUTANEOUS			
INTRAVENOUS	1 AMPULE 1 X	Triflupromazine	SS
PER DAY			
INTRAVENOUS			
INTRAVENOUS	40 MG DAILY	Amphotericin B	SS
INTRAVENOUS			
SUBCUTANEOUS	1 AMPULE 1 X	Neupogen	SS
PER DAY			
SUBCUTANEOUS			
INTRAVENOUS	400 ML DAILY	Albumin Human	SS
INTRAVENOUS			
INTRAVENOUS	25 MG DAILY 1	Dolantin	SS
X PER ONE			
DOSE			

INTRAVENOUS			
INTRAVENOUS	.5 GRAM	Zienam	SS
DAILIY 1 X			
PER ONE DOSE			
INTRAVENOUS			
		Dopamine Hydrochloride	SS
INTRAVENOUS	200 MG DAILY		
INTRAVENOUS			
		Epinephrine	SS
INTRAVENOUS	1 AMPULE 3 X		
PER DAY			
INTRAVENOUS			
		Clindamycin	SS
INTRAVENOUS	200 MG DAILY		

1 X PER ONE DOSE INTRAVENOUS			
INTRAVENOUS	1 AMPULE 1 X PER ONE DOSE INTRAVENOUS	Ciprofloxacin	SS
INTRAVENOUS	50 MG DAILY 1 X PER PER ONE DOSE INTRAVENOUS	Verapamil Hydrochloride	SS
INTRAVENOUS	50 MG DIALY 1 X PER ONE DOSE INTRAVENOUS	Prednisolone	SS
		Ferrosanol Duodenal (Ferrous Glycine Sulfate)	C
		Urbason (Methylprednisolone)	C
		Ampho Moronal (Amphotericin B)	C
		Fortecortin (Dexaethasone)	C
		Nahco3 (Sodium Bicarbonate)	C
		Uralyt U (Potassium Sodium Hydrogen Citrate)	C
		Glucose 5% (Glucose)	C
		Sterofundin (Intravenous Solution Nos)	C
		Uromitexan (Mesna)	C

Dexamethason (Desamethasone)	C
Ifosfamide (Ifosfamide)	C
Cytosine Arabinoside (Cytarabine)	C
Vindesin (Vindesine)	C
Leucovorin (Leucovorin)	C
Nacl (Sodium Chloride)	C
Nutriflex (Amino Acids Nos)	C
Vm 26	C
Vergentan (Alizapride Hydrochloride)	C
Riopan (Magaldrate)	C
Magnorbin (Magnesium Ascorbate)	C
Lipofundin (Intravenous Fat Emulsion)	C
Aminomel (Amino Acids Nos / Minerals Nos)	C
Kcl (Potassium Chloride)	C

				Aminomix (Amino Acids Nos / Carbohydrates Nos / Electolytes Nos)	C		

Date:12/21/98ISR Number: 3172504-3Report Type:Expedited (15-DaCompany Report #A0075084
Age:22 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Health	Zofran	PS		INTRAVENOUS	4 MG / SINGLE	
		Professional						
DOSE /								
INTRAVENOUS								
			Ketorolac Trometamol	C				

Date:12/24/98ISR Number: 3176411-1Report Type:Expedited (15-DaCompany Report #1998PK45936
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Meronem	PS		INTRAVENOUS	500 MG DAILY	
Life-Threatening	Dermatitis	Health				IV		
	Epidermolysis Bullosa	Professional	Allopurinol	SS		ORAL	300 MG DAILY	
	Lip Disorder	Other				PO		
	Shock		Antra	SS		INTRAVENOUS	20 MG DAILY	
	Stevens-Johnson Syndrome					IV		
	Toxic Epidermal		Antra	SS		INTRAVENOUS	20 MG DAILY	
	Necrolysis					IV		
			Diflucan	SS		ORAL	200 MG BID PO	
			Zofran	SS				

15 MG DAILY		Methotrexate	SS
IT			
INTRAVENOUS	5000 MG DAILY	Methotrexate	SS
IV			
		Imodium	SS
		Paspertin	SS
		Multibionta	SS
		Multibionta	SS
		Multibionta	SS
		Multibionta	SS
		Multibionta	SS
		Multibionta	SS
		Multibionta	SS
		Multibionta	SS
		Novalgin	SS
		Vitalipid	SS
		Mst	SS
INTRAVENOUS	1 MG/HR DAILY		
IV			
		Augmentan	SS
INTRAVENOUS	2 G BID IV		
		Opium	SS
		Opium	SS
		Liquemin	SS
		Metronidazol	SS
		Claforan	SS
INTRAVENOUS	2 G TID IV		
		Ciprobay	SS
		Sobelin Solubile	SS
INTRAVENOUS	200 MG DAILY		
IV			
		Suprarenin	SS
		Dopamin	SS
INTRAVENOUS	200 MG DAILY		
IV			
		Zienam	SS
INTRAVENOUS	0.5 G DAILY		

IV				
		Dolantin	SS	
INTRAVENOUS	25 MG DAILY			
IV				
		Humanalbumin	SS	
INTRAVENOUS	400 ML DAILY			
IV				
		Neupogen	SS	
		Amphotericin B	SS	
INTRAVENOUS	40 MG DAILY			
IV				
		Dormicum	SS	
INTRAVENOUS	10 MG /HR			
DAILY IV				
		Solu Decortin H	SS	
INTRAVENOUS	50 MG DAILY			
IV				
		Isoptin	SS	
INTRAVENOUS	50 MG DAILY			
IV				
		Psyquil	SS	
		Actrapid	SS	
INTRAVENOUS	50 U DAILY IV			
		Tavegil	SS	
		Dipidolar	SS	
INTRAVENOUS	3.75 MG DAILY			
IV				
		Lasix	SS	ORAL
20 MG QD PO				
		Bifiteral	SS	
		Vancomycin	SS	
		Novalgin	SS	
		Gentamicin	SS	
INTRAVENOUS	120 MG TID IV			
		Paracetamol	SS	
		Paracetamol	SS	
		Paracetamol	SS	
		Paracetamol	SS	
		Pantozol	SS	

	Leucomax	SS	
300 MCG DAILY			
SQ			
	Paspertin	SS	
	Imodium	SS	
	Methotrexate	SS	
15 MG DAILY			
IT			
	Zofran	SS	
	Diflucan	SS	ORAL
200 MG BID PO			
	Ferrosanol Duodenal	C	
	Uralyt-U	C	
	Sterofundin	C	
	Dexamethason	C	
	Glucose 40%	C	
	Aminomix	C	
	Potassium Chloride	C	
	Aminomel	C	
	Lipofundin	C	
	Magnorbin	C	
	Riopan	C	
	Vergentan	C	
	Vm-26 Bristol	C	
	Nutriflex	C	
	Sodium Chloride	C	
	Leucovorin	C	
	Vindesin	C	
	Cytosin	C	
	Ifosfamid	C	
	Urumitexan	C	
	Glucose	C	
	Sodium Bicarbonate	C	
	Urbason	C	
	Ancotil	C	
INTRAVENOUS 2 G BID IV			
	Fortecortin	C	

			Ampho Moronal	C		

Date:12/28/98ISR Number: 3175963-5Report Type:Expedited (15-DaCompany Report #2950/11856
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Chest Pain	Foreign	Solu-Medrol Sterile Powder	PS			
Other	Implant Site Reaction	Consumer	Pharmorubicin	SS			
	Migration Of Implant	Company	Zophren (Ondansetron)	SS			
	Pleural Effusion	Representative	Acebutolol	C			
	Pleural Infection		Forzitec	C			

Date:12/30/98ISR Number: 3176783-8Report Type:Expedited (15-DaCompany Report #1998-12-0941
Age:87 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Anal Ulcer	Foreign	Gentalline	PS			
Hospitalization - Initial or Prolonged	Dyspnoea	Health Professional	Bleomycin	SS			
	Genital Ulceration		Farmorubicin	SS			
	Lymphoma	Other	Ondansetron	SS			
	Mouth Ulceration		Vinblastine	SS			
	Multi-Organ Failure		Vancomycin	SS			
	Pleural Effusion		Stablon	C			
	Pyrexia		Diantalvic	C			
	Rash Erythematous		Atarax	C			
	Rash Maculo-Papular		Zyrtec	C			
	Toxic Skin Eruption		Duphalac	C			
			Betneval	C			

Date:01/06/99ISR Number: 3179890-9Report Type:Expedited (15-DaCompany Report #303192
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Blister	Foreign	Neupogen	PS			2 DAY
Life-Threatening	Dermatitis	Health	Actrapid Human				

		Epidermolysis Bullosa	Professional	(Insulin Human)	SS	Novo Industri A/S	
SUBCUTANEOUS	50 IU SC						
		Hypertension		Allopurinol	SS		ORAL
300MG PO	15 DAY						
		Lip Disorder		Amoxicillin W/ Potassium			
		Shock		Clavulanate	SS		
		Stevens-Johnson Syndrome					
INTRAVENOUS	4GM IV	5 DAY		Amphotericin B	SS		
		Toxic Epidermal					
INTRAVENOUS	40MG IV			Ancotil	SS	Hoffman-La Roche, Inc	
		Necrolysis					
INTRAVENOUS	IV			Antra	SS	Astra Pharmaceutical Products, Inc.	
INTRAVENOUS	20MG IV						
				Bifiteral	SS	Philips-D	ORAL
PO	1 DAY						
				Ciprobay	SS	Bayer	
INTRAVENOUS	IV	1 DAY					
				Claforan	SS	Hoeschst Pharmaceuticals Incorporated	
INTRAVENOUS	6GM IV	5 DAY					
				Diflucan	SS	Pfizer Laboratories	ORAL
400MG PO	18 DAY						
				Dipidolor	SS	Janssen Pharmaceticals	
INTRAVENOUS	3.75 MG IV						
				Dolantin	SS	Hoechst Pharmaceuticals Incorporated	
INTRAVENOUS	25MG IV	1 DAY					

INTRAVENOUS	200MG IV							
INTRAVENOUS	240MG IV							
INTRAVENOUS	360MG IV	7	DAY					
INTRAVENOUS	IV	17	DAY					
PO	17	DAY						
INTRAVENOUS	50MG IV	1	DAY					
20MG PO	1	DAY						
SUBCUTANEOUS	300 MCG SC	12	DAY					
SUBCUTANEOUS	7500 IU SC							
INTRAVENOUS	.5GM IV	4	DAY					
INTRAMENINGEAL	IT	4	DAY					
INTRAVENOUS	IV	5	DAY					
INTRAVENOUS	IV	9	DAY					
INTRAVENOUS	IV	15	DAY					
INTRAVENOUS	IV	9	DAY					
PO	12	DAY						
500MG PO	7	DAY						
INTRAVENOUS	IV							
INTRAVENOUS	IV							
				Dopamin	SS			
				Dormicum	SS	Hoffman-La Roche		
				Gentamicin	SS			
				Humanalbumin	SS	Biotest-Serum-Institut Gmbh		
				Imodium	SS	Janssen Pharmaceuticals		ORAL
				Isoptin	SS	Knoll Pharmaceutical Company		
				Lasix	SS	Hoechst Pharmaceticals Incorporated		ORAL
				Leucomax	SS	Schering-Plough		
				Liquemin	SS	Hoffman-La Roche Inc		
				Meronem	SS	Zeneca		
				Methotrexat	SS	Lederle Laboratories		
				Metronidazole	SS			
				Mst	SS	Mundipharma Gmbh Frankfurt		
				Multibionta	SS	Merck E. Ag		
				Novalgin	SS	Hoechst Pharmaceticals		
				Opium Tincture	SS			ORAL
				Paracetamol	SS			ORAL
				Paspertin	SS	Kali-Chemie Aktiengesellschaft		
				Psyquil	SS	Heyden Von Ag Chemische Fabrik		

				Sobelin	SS	The Upjohn Company	
INTRAVENOUS	200MG IV	1	DAY				
				Solu-Decortin-H	SS	Merck E. Ag	
INTRAVENOUS	50MG IV	1	DAY				
				Suprarenin	SS	Hoechst Pharmaceuticals Incorporated	
INTRAVENOUS	IV						
				Travegil	SS	Sandoz Pharmaceuticals	
INTRAVENOUS	IV						
				Vancomycin	SS		
INTRAVENOUS	IV						
				Vitalipid Novum Adult	SS	Kabi-Vitrum	
INTRAVENOUS	IV	8	DAY				
				Zienam	SS	Merck Sharp & Dohme	
INTRAVENOUS	IV	1	DAY				
				Zofran	SS	Glaxo Laboratories Limited	
INTRAVENOUS	IV	11	DAY				

Date:01/11/99ISR Number: 3179365-7Report Type:Expedited (15-DaCompany Report #B0062748
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chest Pain	Foreign	Zofran	PS				
INTRAVENOUS	INTRAVENOUS							
Initial or Prolonged	Medication Error		Methylprednisolone	SS				
	Pleural Effusion		Epirubicin	SS				
INTRAVENOUS	INTRAVENOUS							
	Pleural Infection							
	Pleuritic Pain							

Date:01/11/99ISR Number: 3179622-4Report Type:Expedited (15-DaCompany Report #A0078410
Age:72 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Hyperhidrosis
Initial or Prolonged	Hypotension
	Lethargy

		Supraventricular Tachycardia					
		Tachycardia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health	Zofran Injection	PS		
INTRAVENOUS	4 MG / SINGLE						
			Professional				
DOSE /							
INTRAVENOUS							
				Thyroxine Sodium	C		
				Pravastatin Sodium	C		
				Frusemide	C		
				Int. / Long-Acting Insulin	C		
				Troglitazone	C		
				Colchicine	C		
				Ascorbic Acid	C		

Date:01/13/99ISR Number: 3180661-8Report Type:Expedited (15-DaCompany Report #2958/11856
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Hypokalaemia	Foreign	Solu-Medrol	PS		
INTRAVENOUS	80 G/DAY;IV					
Initial or Prolonged	Hyponatraemia	Consumer	Alizapride	SS		
INTRAVENOUS	300 MG/DAY;IV					
	Nausea	Company	Ranitidine	SS		
INTRAVENOUS	300 MG/DAY;IV					
	Vertigo	Representative	Cisplatin	SS		
INTRAVENOUS	150 MG/DAY;IV					
	Vomiting		Ondansetron	SS		
INTRAVENOUS	IV					
			Gemcitabine	SS		
INTRAVENOUS	3 GM/DAY;IV					

Date:01/19/99ISR Number: 3182003-0Report Type:Expedited (15-DaCompany Report #B0062989
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Hospitalization - Initial or Prolonged	Dermatitis	Foreign	Zofran Tablet	PS	ORAL 8 MG/ TWICE DAILY/ ORAL
	Diarrhoea	Study			
	Face Oedema	Health	Amprenavir	C	
	Headache	Professional	Combivir	C	
	Hypersensitivity		Abacavir Sulphate	C	
	Myalgia				
	Nausea				
	Pyrexia				
	Rash Generalised				

Date:01/19/99ISR Number: 3182327-7Report Type:Expedited (15-DaCompany Report #B043637
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Arrest	Foreign	Taxol	PS		INTRAVENOUS	IV	
		Health	Paraplatin	SS		INTRAVENOUS	IV	
		Professional	Ondansetron	SS		INTRAVENOUS	IV	

Date:01/19/99ISR Number: 3182371-XReport Type:Expedited (15-DaCompany Report #JAGER-42501
Age:34 YR Gender:Female I/FU:I

Outcome	PT
Death	Blister
Life-Threatening	Dermatitis
	Epidermolysis Bullosa
	Oral Mucosal Exfoliation
	Pruritus

Shock
Stevens-Johnson Syndrome
Toxic Epidermal

Dose	Duration			Report Source	Product	Role	Manufacturer	Route
Necrolysis				Foreign	Imodium	PS	Janssen	ORAL
4 MG 3 DAILY				Health				
ORAL				Professional	Dipidolor	SS	Janssen	
INTRAVENOUS	3.75 MG DAILY							
INTRAVENOUS					Allopurinol	SS		
					Antra	SS		
INTRAVENOUS	20 MG DAILY	5	DAY		Diflucan	SS		
					Zofran	SS		
INTRAVENOUS	1 DAILY	2	DAY		Methotrexat	SS		
INTRATHECAL	15 MG DAILY				Multibionta	SS		
INTRAVENOUS	ATL DAY	14	DAY		Paspertin	SS		
INTRAVENOUS	2 DAILY				Leucomax	SS		
SUBCUTANEOUS	300 MCG DAILY	11	DAY		Pantozol	SS		
					Paracetamol	SS		ORAL
DAILY					Gentamycin	SS		
INTRAVENOUS	120 MG 3							
DAILY	6	DAY			Claforan	SS		
INTRAVENOUS	2 G 3 DAILY	4	DAY		Metronidazol	SS		
INTRAVENOUS	500 MG 3							
DAILY	4	DAY			Liquemin	SS		
SUBCUTANEOUS	DAILY				Opium	SS		ORAL
1 DAILY	5	DAY			Augmentan	SS		
INTRAVENOUS	2 G 2 DAILY	4	DAY		Mst	SS		
INTRAVENOUS	1 MG/HR	8	DAY					

INTRAVENOUS	1 DAILY	7	DAY
INTRAVENOUS	SINGLE		
INTRAVENOUS	.5 G 3 DAILY		
SINGLE			
20 MG SINGLE			
INTRAVENOUS	2 G 2 DAILY		
INTRAVENOUS	1 DAILY		
INTRAVENOUS	.5 G DAILY		
SUBCUTANEOUS	50 UNITS		
DAILY			
INTRAVENOUS	1 DAILY		
INTRAVENOUS	40 MG 1 DAILY		
SUBCUTANEOUS	1 DAILY		
INTRAVENOUS	400 ML DAILY		
INTRAVENOUS	25 MG DAILY		
INTRAVENOUS	.5 G SINGLE		
INTRAVENOUS	200 MG DAILY		
INTRAVENOUS	3 DAILY		
INTRAVENOUS	200 MG SINGLE		
INTRAVENOUS	SINGLE		
INTRAVENOUS	50 MG SINGLE		
INTRAVENOUS	50 MG SINGLE		
INTRAVENOUS	10 MG/HR		
DAILY			

Vitalipid	SS	
Novalgin	SS	
Vancomycin	SS	
Bifiteral	SS	ORAL
Lasix	SS	ORAL
Ancotil	SS	
Tavegil	SS	
Meronem	SS	
Actrapid	SS	
Psyquil	SS	
Amphoterecin B	SS	
Neupogen	SS	
Human Albumin	SS	
Dolantin	SS	
Zienam	SS	
Dopamin	SS	
Suprarenin	SS	
Sobelin Solubile	SS	
Ciprobay	SS	
Isoptin	SS	
Solu-Decortin	SS	
Dormicum	SS	
Ampho-Moronal	C	
Glucose	C	
Fortecortin	C	
Glucose	C	
Sterofundin	C	

Magnorbin	C
Aminomel	C
Kaliumchlorid	C
Aminomix	C
Glukose	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/20/99ISR Number: 3182711-1Report Type:Expedited (15-DaCompany Report #990011
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Foreign	Morphine Sulfate	PS			INTRAVENOUS	1 MG Q1H IV
Hospitalization -	Dermatitis	Health	Allopurinol	SS		ORAL	300 MG QD PO	
Initial or Prolonged	Dermatitis Bullous	Professional	Omeprazole	SS			INTRAVENOUS	20 MG QD IV
	Stevens-Johnson Syndrome	Other	Diflucan	SS		ORAL	400 MG QD PO	
	Toxic Epidermal		Zofran	SS			INTRAVENOUS	1 AMP QD IV
	Necrolysis		Methotrexate Sodium	SS			15 MG QD IT	
			Methotrexate Sodium	SS			INTRAVENOUS	5000 MG QD IV
			Immodium	SS		ORAL	3 CAP BID PO	
			Multibionta	SS			INTRAVENOUS	1 INJ QD IV
			Metoclopramide Hcl	SS			INTRAVENOUS	2 AMP QD IV
			Molgramostim	SS			SUBCUTANEOUS	300 MCG QD SC
			Pantoprazol Sodium	SS		ORAL	1 TAB QD PO	
			Paraceatmol	SS		ORAL	500 MG	
							1-3/DAY PO	
			Gentamicin Sulfate	SS			INTRAVENOUS	360 MG QD IV
			Cefotaxime Sodium	SS			INTRAVENOUS	2 G TID IV
			Metronidazole	SS			INTRAVENOUS	500 TID IV
			Heparin Sodium	SS			SUBCUTANEOUS	10000 IU QD
							SC	
			Opium	SS		ORAL	5 DROP QD PO	
			Augmentin	SS			INTRAVENOUS	4 G QD IV

INTRAVENOUS	1 AMP QD IV
INTRAVENOUS	1 AMP QD IV
INTRAVENOUS	.5 G TID IV
1 TSP QD PO	
20 MG QD PO	
INTRAVENOUS	2 G QD IV
INTRAVENOUS	3.75 MG QD IV
INTRAVENOUS	1 AMP QD IV
INTRAVENOUS	.5 G QD IV
SUBCUTANEOUS	50 U QD SC
INTRAVENOUS	1 AMP QD IV
INTRAVENOUS	40 MG QD IV
INTRAVENOUS	1 AMP QD IV
INTRAVENOUS	400 ML QD IV
INTRAVENOUS	25 MG QD IV
INTRAVENOUS	3 AMP QD IV
INTRAVENOUS	200 MG QD IV
INTRAVENOUS	.5 G QD IV
INTRAVENOUS	200 MG QD IV
INTRAVENOUS	1 AMP QD IV
INTRAVENOUS	50 MG QD IV
INTRAVENOUS	50 MG QD IV
INTRAVENOUS	10 MG Q1H IV

Vitalipid	SS	
Metamizol Sodium	SS	
Vancomycin Hcl	SS	
Lactulose	SS	ORAL
Lasix	SS	ORAL
Flucytosine	SS	
Piritramide	SS	
Clemastine Fumarate	SS	
Meropenem	SS	
Human Insulin	SS	
Triflupromazine Hcl	SS	
Amphotericin B	SS	
Filgrastim	SS	
Plasma Protein	SS	
Pethidine	SS	
Epinephrine Hcl	SS	
Clindamycin Phosphate	SS	
Imipenem/Cilastatin Sodium	SS	
Dopamine Hcl	SS	
Ciprofloxacin	SS	
Verapamil Hcl	SS	
Prednisolone	SS	
Midazolam Hydrochloride	SS	
Methylprednisolone	C	
Eisen	C	
Amphotericin B	C	
Dexamethasone	C	

Sodiumhydrogencarbonate	C
Hexanatrium Trihydrogen Pentacitrate	C
Dexamethasonedihydrogenphosphate	C

			Cytosinarabinosid	C		
			Vindesin	C		
			Leucovorin Calcium	C		
			Nacl	C		
			Nutriflex	C		
			Magnesium Ascorbate	C		
			Lipofundin	C		
			Aminomel	C		
			Aminomix	C		

Date:01/22/99ISR Number: 3184666-2Report Type:Expedited (15-DaCompany Report #B0062874
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hypokalaemia	Foreign	Zantac	PS		INTRAVENOUS	INTRAVENOUS/I	
Initial or Prolonged	Hyponatraemia							
NJ								
	Nausea		Alizapride					
	Vertigo		Hydrochloride	SS		INTRAVENOUS	INTRAVENOUS	
	Vomiting		Medrol	SS		INTRAVENOUS	INTRAVENOUS	
			Cisplatin	SS		INTRAVENOUS	INTRAVENOUS	
			Zofran	SS		INTRAVENOUS	INTRAVENOUS	
			Gemcitabine	SS		INTRAVENOUS	INTRAVENOUS	
			Clonazepam	C				
			Diclofenac Sodium	C				
			Alprazolam	C				
			Omeprazole	C				
			Alvityl	C				
			Potassium Chloride	C				

Date:01/25/99ISR Number: 3185405-1Report Type:Expedited (15-DaCompany Report #B0063065
Age:87 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anal Ulcer	Foreign	Zofran (Formulation					

Hospitalization - Initial or Prolonged	Dyspnoea	Unknown)	PS	
	Genital Ulceration	Bleomycin Injection	SS	
INTRAVENOUS	INTRAVENOUS			
Other	Herpes Simplex	Gentamicin Injection	SS	
INTRAVENOUS	INTRAVENOUS			
	Lymphoma	Epirubicin Injection	SS	
INTRAVENOUS	INTRAVENOUS			
	Multi-Organ Failure	Vancomycin Injection	SS	
INTRAVENOUS	INTRAVENOUS			
	Pleural Effusion	Vinblastine		
	Pyrexia	Injection	SS	
INTRAVENOUS	INTRAVENOUS			
	Rash Erythematous	Prednisone	C	
	Rash Macular	Lactulose	C	
	Stomatitis	Betamethasone	C	
	Toxic Skin Eruption	Cetyl Palmitate	C	
		Cetirizine Hydrochloride	C	
		Tianeptine	C	
		Dextroprop + Paracetamol	C	
		Hydroxyzine	C	

Date:01/27/99ISR Number: 3186497-6Report Type:Direct Company Report #
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Clonic Convulsion		Zofran	PS	Glaxo Wellcome Inc			
INTRAVENOUS							4MG	
			Dilaudud	SS				
INTRAVENOUS							50 ML; IV	

			Benadryl	C		
			Methylergonovine	C		
			Midazolam	C		
			Propofol	C		
			Sevoflurane	C		

Date:01/27/99ISR Number: 3186894-9Report Type:Expedited (15-DaCompany Report #B0063198
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coma	Foreign	Zofran	PS		INTRAVENOUS	2 MG /	
Initial or Prolonged	Convulsion					INTRAVENOUS		
	Electroencephalogram		Mesna	SS		INTRAVENOUS	1 G / PER DAY	
	Abnormal					/ INTRAVENOUS		
	Epilepsy		Cyclophosphamide	SS		INTRAVENOUS	1 G / PER DAY	
	Hyponatraemia					/ INTRAVENOUS		
	Metabolic Disorder							

Date:01/27/99ISR Number: 3186896-2Report Type:Expedited (15-DaCompany Report #A0078410
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hyperhidrosis	Health	Zofran	PS		INTRAVENOUS	4 MG / SINGLE	
Initial or Prolonged	Hypotension	Professional				DOSE /		
Other	Lethargy					INTRAVENOUS		
	Supraventricular		Thyroxine	C				
	Tachycardia		Pravastatin	C				
	Tachycardia		Frusemide	C				
			Int./Long-Acting Insulin	C				
			Troglitazone	C				
			Colchicine	C				

				Ascorbic Acid	C		

Date:02/02/99ISR Number: 3190309-4Report Type:Expedited (15-DaCompany Report #LACT003990002
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Bifiteral					
Life-Threatening	Dermatitis		(Lactulose)	PS		ORAL	1X/D, PER	
	Lip Disorder						ORAL	
	Mucosal Erosion		Paspertin					
	Pruritus		(Metoclopramide					
	Pyrexia		Hydrochloride)	SS			INTRAVENOUS	2 DOSAGE
	Shock						FORMS IV	
	Stevens-Johnson Syndrome		Novalgin (Metamizole					
	Toxic Epidermal		Sodium)	SS			INTRAVENOUS	1 DOSAGE
	Necrolysis						FORMS, IV	
			Allopurinol					
			(Allopurinol)	SS		ORAL	300 MG, PER	
							ORAL	
			Augmentan					
			(Amoxicillin Sodium,					
			Clavulanate					
			Potassium)	SS			INTRAVENOUS	4 DOSAGE
							FORMS IV	
			Diflucan					
			(Fluconazole)	SS		ORAL	400 MG, PER	

ORAL				
		Ciprobaby (Ciprofloxacin Hydrochloride)	SS	
INTRAVENOUS	1 DOSAGE FORMS, IV			
		Gentamycin (Gentamicin Sulfate)	SS	
INTRAVENOUS	360 MG IV			
		Dormicum Perfusor (Midazolam Hydrochloride)	SS	
INTRAVENOUS	10 MG/H, IV			
		Vancomycin (Vancomycin)	SS	
INTRAVENOUS	1.5 GM IV			
		Vitalipid (Vitamins Nos)	SS	
INTRAVENOUS	1 DOSAGE FORMS, IV			
		Mst (Morphine Sulfate)	SS	
INTRAVENOUS	1 MG/H, IV			
		Opium (Opium Tincture)	SS	ORAL
185 DOSAGE FORMS, PER ORAL				
		Liquemin (Heparin)	SS	
SUBCUTANEOUS	7500 - 1000 7 IU/D SUBCUTANEOUS			
		Metronidazol Ratio 500 (Metronidazole)	SS	
INTRAVENOUS	3 DOSAGE FORMS, IV			
		Pantozol (Pantoprazole Sodium)	SS	ORAL
1 DOSAGE				

FORMS, PER			
ORAL			
		Leucomax (Molgramostim	SS
SUBCUTANEOUS	300 MICGM,		
SUBCUTANEOUS			
		Multibionta (Ascorbic Acid, Pyridoxine Hydrochloride Tocophe	SS
INTRAVENOUS	1 DOSAGE		
FORMS IV			
		Antra (Omeprazole)	SS
INTRAVENOUS	20 MG, IV	Solu-Decortin H (Prednisolone Sodium Succinate)	SS
INTRAVENOUS	50 MG, IV		
		Isoptin (Verapamil Hydrochloride)	SS
INTRAVENOUS	50 MG, IV		
		Sobelin Solubile (Clindamycin Phosphate)	SS
INTRAVENOUS	200 MG, IV		
		Suprarenin (Epinephrine)	SS
INTRAVENOUS	3 DOSAGE		
FORMS, IV			
		Dopamin (Dopamine Hydrochloride)	SS
INTRAVENOUS	200 MG, IV		
		Zienam (Imipenem, Cilastatin Sodium)	SS
INTRAVENOUS	.5 GM IV		
		Dolantin (Pethidine Hydrochloride)	SS
INTRAVENOUS	25 MG, IV		
		Humanalbumin 20% (Albumin Normal Human Serum)	SS
INTRAVENOUS	400		

MILLILITERS, IV				
		Riopan (Magaldrate)	SS	ORAL
3 DOSAGE FORMS, PER ORAL				
		Riopan (Magalgrate)	SS	ORAL
2 DOSAGE FORMS, PER ORAL				
		Vergentan (Alizapride Hydrochloride)	SS	
INTRAVENOUS	2 DOSAGE FORMS IV			
		Vm-26 Bristol (Teniposide)	SS	
INTRAVENOUS	170 MG IV			
		Nutriflex (Glucose, Amino Acids Nos, Electrolytes Nos)	SS	
INTRAVENOUS	1440-1920 ML/D IV			
		Aminomix (Glucose, Amino Acids Nos, Electrolytes Nos)	SS	
INTRAVENOUS	1000 MILLILITERS, IV			
		Leucovorin (Folinic Acid)	SS	
INTRAVENOUS	75 MG, IV			
		Vindesin (Vindesine)	SS	
INTRAVENOUS	5 MG IV			
		Cytosin-Arabinosid (Cytarabine)	SS	
INTRATRACHEAL	4MG,			

INTRATHECAL				
		Aminomel (Mineral Nos, Amino Acids Nos)	SS	
INTRAVENOUS	1920			
MILLILITERS				
IV				
		Lipofunding Mct (Soya Oil, Triglycerides)	SS	
250-500				
		Magnorbin (Magnesium Ascorbate)	SS	
INTRAVENOUS	2 DOSAGE			
FORMS IV				
		Ifosfamid (Ifosfamide)	SS	
INTRAVENOUS	1300 MG IV			
		Dexamethason (Dexamethasone)	SS	ORAL
170 MG PER				
ORAL,				
INTRATHECAL				
		Uromitexan (Mesna)	SS	
INTRAVENOUS	1200 MG IV			
		Fortecortin (Dexamethasone)	SS	ORAL
17 MG, PER				
ORAL				
		Ampho Moronal (Amphotericin B)	SS	ORAL
1 DOSAGE				
FORMS, PER				
ORAL				
		Imodium (Loperamide Hydrochloride)	SS	ORAL
6 DOSAGE				
FORMS, PER				
ORAL				
		Methotrexat (Methotrexate)	SS	
INTRATHECAL	15 MG,			

		Hydrochloride)	SS	
INTRAVENOUS	1 DOSAGE FORMS IV			
		Neupogen (Filgrastim)	SS	
SUBCUTANEOUS	1 DOSAGE FORMS, SUBCUTANEOUS			
		Amphotericin B (Amphotericin B)	SS	
INTRAVENOUS	40 MG IV			
		Psyquil (Triflupromazine)	SS	
INTRAVENOUS	1 DOSAGE FORMS IV 50 IU,			
		Actrapid (Insulin)	SS	
INTRAVENOUS	.5 GM, IV	Meronem (Meropenem)	SS	
INTRAVENOUS	1 DOSAGE FORMS, IV	Tavegil (Clemastine)	SS	
		Dipidolor (Piritramide)	SS	
INTRAVENOUS	3.75 MG IV			
		Ancotil (Flucytosine)	SS	
INTRAVENOUS	4 GM IV			
		Claforan (Cefotaxime Sodium)	SS	
INTRAVENOUS	6 GM, IV			
		Paracetamol 500 (Paracetamol)	SS	ORAL
1-3 X 1/D, PER ORAL				
		Lasix (Furosemide)	SS	ORAL
20 MG , PER ORAL				
		Ferrosanol Duodenal	C	
		Sterofundin	C	
		Nacl	C	

			Glucose	C		
			Kcl Perfusor	C		
			G5 (Glucose)	C		
			Urbason 40	C		
			Natriumbicarbonat	C		
			Uralyt U	C		

Date:02/10/99ISR Number: 3199998-1Report Type:Periodic Company Report #A0066726
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysarthria Tongue Oedema	Health Professional	Zofran Tablet	PS		ORAL	8 MG (SEE TEXT) ORAL	
			Zofran Injection	SS		INTRAVENOUS	INTRAVENOUS	

Date:02/10/99ISR Number: 3199999-3Report Type:Periodic Company Report #A0065620
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration Drug Ineffective Eating Disorder Vomiting	Consumer	Zofran Tablet	PS		ORAL	8 MG THREE TIMES PER DAY ORAL	
			Oxycodone Hydrochloride	C				
			Radiotherapy	C				
			Fosinopril Sodium	C				
			Diltiazem Hydrochloride	C				
			Naproxen	C				
			Quinine Sulphate	C				
			Zolipidem Tartrate	C				

			Aspirin	C		
			Amitriptyline	C		
			Vicodin	C		

Date:02/10/99ISR Number: 3296959-9Report Type:Periodic Company Report #A0063983
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective	Consumer	Zofran Tablet	PS		ORAL	8 MG TWICE PER DAY ORAL	
			Compazine	C				

Date:02/10/99ISR Number: 3296961-7Report Type:Periodic Company Report #A0064690
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Complications Of Maternal	Consumer	Zofran Tablet	PS		ORAL	8 MG PER DAY ORAL	
	Exposure To Therapeutic Drugs		Promethazine Hcl	C				
	Drug Ineffective							
	No Adverse Drug Effect							

Date:02/10/99ISR Number: 3296963-0Report Type:Periodic Company Report #A0065307
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective	Consumer	Zofran Tablet	PS		ORAL	8 MG ORAL EVERY FOUR TO SIX HOURS	
			Prednisone	C				
			Lorazepam	C				

			Compazine	C		
			Cancer Chemotherapy	C		

Date:02/10/99ISR Number: 3296966-6Report Type:Periodic Company Report #A0065558
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective	Consumer	Zofran Tablet	PS		ORAL	8 MG TWICE	PER DAY ORAL
			Cancer Chemotherapy	C				
			Compazine	C				
			Ranitidine Hydrochloride	C				
			Hydrocodone	C				
			Zolpidem Tartrate	C				
			Morphine Sulfate	C				
			Sertraline Hydrochloride	C				

Date:02/10/99ISR Number: 3296968-XReport Type:Periodic Company Report #A0073117
Age: Gender:Female I/FU:I

Outcome	PT	Report Source
	Dizziness	Health Professional

		Company Representative					
			Product	Role	Manufacturer	Route	Dose
Duration							
			Zofran Tablet	PS		ORAL	8 MG
ORAL							

Date:02/10/99ISR Number: 3296970-8Report Type:Periodic Company Report #A0076774
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Duration							
	Condition Aggravated	Consumer	Zofran Tablet	PS		ORAL	8 MG
TWICE PER DAY ORAL							
	Drug Ineffective						
	Nausea		Interferon	C			
			Salmeterol Xinafoate	C			
			Atenolol	C			
			Metoclopramide Hcl	C			
			Ranitidine Hydrochloride	C			
			Glibenclamide	C			
			Asmacort	C			
			Fluticasone Propionate	C			
			Fioricet	C			
			Ortho Cyclen	C			
			Cetirizine Hydrochloride	C			
			Hydrochlorothiazide	C			

Date:02/19/99ISR Number: 3202793-8Report Type:Expedited (15-DaCompany Report #B0061434
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Duration							
Other	Abdominal Pain	Foreign	Zofran Injection	PS		INTRAVENOUS	8 MG/TWICE PER
	Disorientation	Study					
	Dizziness	Health					
DAY/INTRAVENO							

	Hyperhidrosis	Professional			
US					
	Hypotension		Cisplatin	C	
	Malaise		Fluorouracil	C	
	Urinary Incontinence		Primolut	C	
			Estropipate	C	

Date:02/19/99ISR Number: 3203407-3Report Type:Expedited (15-DaCompany Report #A0082077
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Blood Pressure Decreased	Consumer	Zofran Injection	PS		
INTRAVENOUS INTRAVENOUS						
Hospitalization - Initial or Prolonged	Respiratory Failure		Pethidine Hydrochloride	C		

Date:02/22/99ISR Number: 3205038-8Report Type:Expedited (15-DaCompany Report #B044434
Age: Gender:Female I/FU:I

Outcome	PT
Death	Blister
Life-Threatening	Dermatitis
	Epidermolysis Bullosa
	Hyperglycaemia
	Hypertension

		Lip Ulceration Mycosis Fungoides Pain	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Pruritus	Foreign	Amphotericin B	PS		
INTRAVENOUS	40 MG IV						
		Pyrexia	Health	Neupogen	SS		
NI							
		Shock	Professional	Insulin Human	SS		
SUBCUTANEOUS	50 IU SC						
		Stevens-Johnson Syndrome		Allopurinol	SS		ORAL
300 MG PO	15 DAY						
		Toxic Epidermal Necrolysis		Amoxicillin W/Potassium Clavulanate	SS		
INTRAVENOUS	4 GM IV	5 DAY					
				Ancotil	SS		
INTRAVENOUS	40 MG IV						
				Antra	SS		
INTRAVENOUS	20 MG IV						
				Bifiteral	SS		ORAL
PO							
				Ciprobay	SS		
INTRAVENOUS	IV	1 DAY					
				Claforan	SS		
INTRAVENOUS	6 GM IV						
				Diflucan	SS		ORAL
400 MG PO	18 DAY						
				Dipidolor	SS		
INTRAVENOUS	3.75 MG IV						
				Dolantin	SS		
INTRAVENOUS	25 MG IV	1 DAY					
				Dopamine	SS		
INTRAVENOUS	200 MG IV						
				Dormicum	SS		
INTRAVENOUS	240 MG IV						
				Gentamicin	SS		
INTRAVENOUS	360 MG IV						
				Albumin Human	SS		
INTRAVENOUS	IV						
				Imodium	SS		ORAL
PO	31 DAY						
				Isoptin	SS		
INTRAVENOUS	50 MG IV	1 DAY					
				Lasix	SS		ORAL
20 MG PO	1 DAY						

SUBCUTANEOUS	300 MCG SC	12	DAY
SUBCUTANEOUS	7500 IU SC		
INTRAVENOUS	.5 GM IV		
INTRATHECAL	IT	4	DAY
INTRAVENOUS	IV	5	DAY
INTRAVENOUS	24 MG IV	9	DAY
INTRAVENOUS	IV	15	DAY
INTRAVENOUS	IV	9	DAY
PO	13	DAY	
500 MG PO	7	DAY	
INTRAVENOUS	IV		
INTRAVENOUS	IV		
INTRAVENOUS	200 MG IV	1	DAY
INTRAVENOUS	IV	11	DAY
INTRAVENOUS	,5 GM IV	1	DAY
INTRAVENOUS	50 MG IV	1	DAY
INTRAVENOUS	IV		
INTRAVENOUS	IV		
INTRAVENOUS	IV		
INTRAVENOUS	IV	8	DAY

Leucomax	SS	
Liquemin	SS	
Meronem	SS	
Methotrexate	SS	
Metronidazole	SS	
Mst (Morphine Tartrate)	SS	
Multibionta (Multivitamins)	SS	
Novalgin (Dipyrone)	SS	
Opium Tincture (Opium)	SS	ORAL
Paracetamol	SS	ORAL
Paspertin	SS	
Psyquil	SS	
Sobelin (Clindamycin)	SS	
Zofran (Ondansetron Hcl)	SS	
Zienam	SS	
Solu-Dacortin	SS	
Suprarenin	SS	
Tavegil	SS	
Vancomycin	SS	
Unknown (Reporter Did Not Know)	C	

Date:02/24/99ISR Number: 3206798-2Report Type:Expedited (15-DaCompany Report #WAES 99020839
Age:34 YR Gender:Female I/FU:I

Outcome PT

Death	Blister
Life-Threatening	Dermatitis
	Epidermolysis Bullosa
	Fungal Infection

		Hyperglycaemia Hypertension Mycosis Fungoides	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Pruritus	Other	Primaxin	PS		
INTRAVENOUS	.5 GM/IV						
		Pyrexia		Allopurinol	SS		ORAL
PO							
		Shock Skin Ulcer		Amoxicillin/Clavulanate Potassium	SS		
INTRAVENOUS	IV						
		Stevens-Johnson Syndrome		Amphotericin B	SS		
INTRAVENOUS	IV						
		Toxic Epidermal		Ancotil	SS		
INTRAVENOUS	IV						
		Necrolysis		Antra	SS		
INTRAVENOUS	IV						
				Bifiteral	SS		ORAL
PO							
				Ciprobay	SS		
INTRAVENOUS	IV						
				Claforan	SS		
INTRAVENOUS	IV						
				Diflucan	SS		ORAL
PO							
				Dipidolor	SS		
INTRAVENOUS	IV						
				Dolantin	SS		
INTRAVENOUS	IV						
				Dopamine Hcl	SS		
INTRAVENOUS	IV						
				Midazolam Maleate	SS		
INTRAVENOUS	IV						
				Gentamicin	SS		
INTRAVENOUS	IV						
				Albumin	SS		
INTRAVENOUS	IV						
				Imodium	SS		ORAL
PO							
				Isoptin	SS		
INTRAVENOUS	IV						
				Lasix	SS		ORAL
PO							
				Inj Granulocyte-Macrophage Colony Stimulating Factor			

		Preparations 300	SS
SUBCUTANEOUS	SC		
		Liquemin	SS
SUBCUTANEOUS	SC		
		Meronem	SS
INTRAVENOUS	IV		
		Methotrexate	SS
		Metronidazole	SS
INTRAVENOUS	IV		
		Morphine	SS
INTRAVENOUS	IV		
		Multibionta	SS
INTRAVENOUS	IV		
		Novalgin	SS
INTRAVENOUS	IV		
		Opium	SS ORAL
PO			
		Acetaminophen	SS ORAL
PO			
		Metoclopramide Mono Hcl Monohydrate	SS
INTRAVENOUS	IV		
		Triflupromazine	SS
INTRAVENOUS	IV		
		Clindamycin Hcl	SS
INTRAVENOUS	IV		
		Solu-Decortin	SS
INTRAVENOUS	IV		
		Suprarenin	SS
INTRAVENOUS	IV		
		Tavegil	SS
INTRAVENOUS	IV		
		Vancomycin	SS
INTRAVENOUS	IV		
		Vitalipid	SS
INTRAVENOUS	IV		
		Zofran	SS
INTRAVENOUS	IV		
		Neupogen	SS
		Actrapid	SS
SUBCUTANEOUS	SC		

Date:02/24/99ISR Number: 3207224-XReport Type:Expedited (15-DaCompany Report #WAES 99020839
Age:34 YR Gender:Female I/FU:I

Outcome	PT
Death	Blister
Life-Threatening	Dermatitis
	Hyperglycaemia
	Hypertension
	Lip Ulceration

Pruritus

		Pyrexia Shock Stevens-Johnson Syndrome	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Toxic Epidermal	Other	Inj Primaxin .5 Gm	PS		
INTRAVENOUS	.5 GM/IV	Necrolysis		Allopurinol 300 Mg	SS		ORAL
PO							
				Inj Amoxicillin/Clavulanate Potassium 4 Gm	SS		
INTRAVENOUS	IV						
				Inj Amphotericin B 40 Mg	SS		
INTRAVENOUS	IV						
				Inj Ancotil	SS		
INTRAVENOUS	IV						
				Antra 20 Mg	SS		
INTRAVENOUS	IV						
				Bifiteral	SS		ORAL
PO							
				Ciprobay	SS		
INTRAVENOUS	IV						
				Claforan 6 Gm	SS		
INTRAVENOUS	IV						
				Diflucan 400 Mg	SS		ORAL
PO							
				Inj Dipidolor 3.75 Mg	SS		
INTRAVENOUS	IV						
				Colantin 25 Mg	SS		
INTRAVENOUS	IV						
				Dopamine Hcl 200 Mg	SS		
INTRAVENOUS	IV						
				Midazolam Maleate 240 Mg	SS		
INTRAVENOUS	IV						
				Gentamicin 360 Mg	SS		
INTRAVENOUS	IV						
				Serum Albumin	SS		
INTRAVENOUS	IV						
				Imodium	SS		ORAL
PO							
				Isoptin 50 Mg	SS		
INTRAVENOUS	IV						
				Lasix 20 Mg	SS		ORAL
PO							

		Inj Granulocyte-Macrophage Colony Stimulating Factor Preparations 300	SS	
SUBCUTANEOUS	SC			
		Inj Liquemin 7500 Iu	SS	
SUBCUTANEOUS	SC			
		Inj Meronem .5 Gm	SS	
INTRAVENOUS	IV			
		Inj Methotrexate (Methotrexate Disodium Salt)	SS	
		Inj Metronidazole	SS	
INTRAVENOUS	IV			
		Inj Morphineo4 24 Mg	SS	
INTRAVENOUS	IV			
		Inj Multibionta	SS	
INTRAVENOUS	IV			
		Inj Novalgin	SS	
INTRAVENOUS	IV			
		Liq Opium	SS	ORAL
PO				
		Acetaminophen 500 Mg	SS	ORAL
PO				
		Metoclopramide Monohcl Monohydrate	SS	
INTRAVENOUS	IV			
		Triflupromazine	SS	
INTRAVENOUS	IV			
		Inj Clindamycin Hcl Monohydrate 200 Mg	SS	
INTRAVENOUS	IV			
		Inj Solu-Decortin-H 50 Mg	SS	
INTRAVENOUS	IV			
		Inj Suprarenin	SS	
INTRAVENOUS	IV			
		Tavegil	SS	
INTRAVENOUS	IV			
		Vancomycin	SS	
INTRAVENOUS	IV			
		Inj Vitalipid	SS	
INTRAVENOUS	IV			
		Zofran	SS	
INTRAVENOUS	IV			
		Neupogen	SS	
		Inj Human Actrapid 50 Iu	SS	
SUBCUTANEOUS	SC			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/25/99ISR Number: 3208007-7Report Type:Expedited (15-DaCompany Report #A0083094
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Spontaneous Complications Of Maternal	Consumer	Zofran (Formulation Unknown)	PS		INTRAVENOUS	INTRAVENOUS	
	Exposure To Therapeutic Drugs		Zofran Tablet	SS		ORAL	8 MG/PER DAY/ORAL	
			Intravenous Fluid(S)	C				

Date:02/25/99ISR Number: 3208012-0Report Type:Expedited (15-DaCompany Report #B0064017
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arrhythmia	Foreign	Zofran Tablet	PS		ORAL	ORAL	
	Supraventricular		Cisplatin (Formulation Unknown)	SS		INTRAVENOUS	INTRAVENOUS	
			Vinorelbine Tartrate	C				

Date:03/04/99ISR Number: 3219593-5Report Type:Periodic Company Report #A0055647
Age:11 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Reaction	Literature	Zofran Injection	PS		INTRAVENOUS	2 MG /SEE TEXT/	
	Breath Sounds Decreased	Health Professional				INTRAVENOUS		
	Bronchospasm		Propofol	C				
	Dyspnoea		Fentanyl	C				
	Flushing		Rocuronium Bromide	C				
	Hypersensitivity		Nitrous Oxide	C				
	Hypotension		Isoflurane	C				
	Obstructive Airways							

		Disorder		Pancuronium Bromide	C		
		Oxygen Saturation		Oxygen	C		
		Oxygen Saturation Decreased					
		Pruritus					
		Sensation Of Pressure					
		Tachycardia					

Date:03/04/99ISR Number: 3219597-2Report Type:Periodic Company Report #A0080844
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Grand Mal Convulsion	Health	Zofran Injection	PS		INTRAVENOUS	SINGLE DOSE	
		Professional				INTRAVENOUS		

Date:03/04/99ISR Number: 3219598-4Report Type:Periodic Company Report #A0077568
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Chest Pain	Health	Zofran	PS		INTRAVENOUS	2 MG SINGLE DOSE	
	Dyspnoea	Professional						
	Electrocardiogram St Segment Elevation	Company Representative				INTRAVENOUS		
	Ventricular Extrasystoles							
	Ventricular Tachycardia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/04/99ISR Number: 3219601-1Report Type:Periodic Company Report #A0063730
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal	Health	Zofran Injection	PS		INTRAVENOUS	4 MG SINGLE DOSE	
	Disturbance In Attention	Professional						
	Dystonia					INTRAVENOUS		
	Extrapyramidal Disorder		Propofol	C				
	Fatigue		Metoclopramide Hcl	C				
	Lethargy		Cephazolin Sodium	C				
	Opisthotonus		Isofluranec	C				
	Sinusitis		Cocaine	C				
			Adrenaline	C				
			Lignocaine	C				

Date:03/04/99ISR Number: 3219603-5Report Type:Periodic Company Report #A0060651
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angioneurotic Oedema	Health Professional	Zofran	PS				

Date:03/05/99ISR Number: 3214473-3Report Type:Expedited (15-DaCompany Report #B0061789
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Angioneurotic Oedema	Foreign	Zofran Injection	PS		INTRAVENOUS	8 MG/TWICE PER DAY/INTRAVENOUS	
Hospitalization - Initial or Prolonged	Anorexia	Study						
	Dehydration	Health						
	Dermatitis	Professional						
	Dysphagia		Fenofibrate	C				
	Gastrointestinal		Morphine Sulphate	C				
	Haemorrhage		Ranitidine					

Melaena	Hydrochloride	C	
Oesophageal Candidiasis	Indomethacin	C	
Oral Candidiasis	Fluconazole	C	
Pharyngitis	Intraconazole	C	
Pharyngolaryngeal Pain			
Pneumonia			
Pyrexia			
Vomiting			

Date:03/05/99ISR Number: 3438281-3Report Type:Periodic Company Report #A0067070
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Vision Blurred	Health Professional Company Representative	Zofran	PS	Glaxo Wellcome Inc			

Date:03/05/99ISR Number: 3438283-7Report Type:Periodic Company Report #A0067666
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Erythema	Health Professional	Zofran	PS	Glaxo Wellcome Inc		32 MG/INJECTION	
	Pruritus							
	Skin Irritation							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/99ISR Number: 3438285-0Report Type:Periodic Company Report #A0067667
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Erythema	Health	Zofran	PS	Glaxo Wellcome Inc		32	
	Pruritus	Professional					MG/INJECTION	15 MIN
	Skin Irritation							

Date:03/05/99ISR Number: 3438286-2Report Type:Periodic Company Report #A0067668
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Erythema	Health	Zofran	PS	Glaxo Wellcome Inc		32	
	Pain	Professional					MG/INJECTION	15 MIN
	Pruritus							
	Skin Irritation							

Date:03/05/99ISR Number: 3438287-4Report Type:Periodic Company Report #A0067669
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Erythema	Health	Zofran	PS	Glaxo Wellcome Inc		32	
	Pruritus	Professional					MG/INJECTION	20 MIN
	Skin Irritation							

Date:03/05/99ISR Number: 3438289-8Report Type:Periodic Company Report #A0067670
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Erythema	Health	Zofran	PS	Glaxo Wellcome Inc		32	

	Pruritus	Professional				
MG/INJECTION						
	Skin Irritation					

Date:03/05/99ISR Number: 3438290-4Report Type:Periodic Company Report #A0067671
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Erythema	Health	Zofran	PS	Glaxo Wellcome Inc			
INJECTION								
	Pruritus	Professional						
	Skin Irritation							

Date:03/05/99ISR Number: 3438293-XReport Type:Periodic Company Report #A0067693
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Vein Disorder	Health	Zofran	PS	Glaxo Wellcome Inc			
INTRAVENOUS	32 MG/SEE							
		Professional						
TEXT/INTRAVEN								
		Company						
OUS								
		Representative						

Date:03/05/99ISR Number: 3438485-XReport Type:Periodic Company Report #A0060459
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site	Health	Zofran Injection	PS				
INTRAVENOUS	INTRAVENOUS							
	Extravasation	Professional						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/99ISR Number: 3438486-1Report Type:Periodic Company Report #A0061172
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anxiety	Health Professional	Zofran (Formulation Unknown)	PS				
	Tremor		Cancer Chemotherapy	C				

Date:03/05/99ISR Number: 3438487-3Report Type:Periodic Company Report #A0061173
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation	Health Professional	Zofran (Formulation Unknown)	PS				

Date:03/05/99ISR Number: 3438488-5Report Type:Periodic Company Report #A0061700
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pallor	Health Professional	Zofran (Formulation Unknown)	PS				
			Dexamethasone (Formulation Unknown)	SS				

Date:03/05/99ISR Number: 3438489-7Report Type:Periodic Company Report #A0061910
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Erythema	Health Professional	Zofran (Formulation Unknown)	PS		INTRAVENOUS	32MG/INTRAVEN OUS	

Date:03/05/99ISR Number: 3438490-3Report Type:Periodic Company Report #A0062771
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hiccups	Health	Zofran Injection	PS		INTRAVENOUS	INTRAVENOUS	
		Professional	Cancer Chemotherapy	C				

Date:03/05/99ISR Number: 3438492-7Report Type:Periodic Company Report #A0062834
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hiccups	Health	Zofran Injection	PS		INTRAVENOUS	INTRAVENOUS	
		Professional	Cancer Chemotherapy	C				

Date:03/05/99ISR Number: 3438493-9Report Type:Periodic Company Report #A0063344
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Alopecia	Consumer	Zofran Injection	PS		INTRAVENOUS	5MG/PER	
	Dysgeusia					DAY/INTRAVENO		
	Sedation					US	1	WK
	Visual Disturbance		Morphine	C				
			Oral Contraceptive	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/99ISR Number: 3438494-0Report Type:Periodic Company Report #A0064338
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Migraine	Consumer	Zofran (Formulation Unknown)	PS		ORAL	TWICE PER DAY/ORAL	
			Lamivudine	C				
			Dapsone	C				
			Lithium Carbonate	C				
			Triazolam	C				
			Percocet	C				
			Dronabinol	C				
			Diazepam	C				
			Lorazepam	C				

Date:03/05/99ISR Number: 3438495-2Report Type:Periodic Company Report #A0065593
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Liver Function Test	Health Professional	Zofran (Formulation Unknown)	PS				

Date:03/05/99ISR Number: 3438496-4Report Type:Periodic Company Report #A0066115
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Erythema	Health Professional	Zofran (Formulation Unknown)	PS			8MG INJECTION	
		Company Representative						

Date:03/05/99ISR Number: 3438497-6Report Type:Periodic Company Report #A0066782
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dysarthria	Health	Zofran (Formulation					
	Feeling Drunk	Professional	Unknown)	PS			32MG/	
	Vision Blurred	Company Representative						

Date:03/05/99ISR Number: 3438498-8Report Type:Periodic Company Report #A0066784
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Burning Sensation	Health	Zofran Injection	PS			SEE	
	Rash Erythematous	Professional					TEXT/INFILTRA	
	Vein Discolouration	Company					TION	
		Representative						

Date:03/05/99ISR Number: 3438499-XReport Type:Periodic Company Report #A0066888
Age: Gender:Female I/FU:I

Outcome	PT	Report Source
	Dizziness	Health
	Visual Disturbance	Professional
		Company

		Representative				
			Product	Role	Manufacturer	Route
Dose	Duration					
			Zofran (Formulation Unknown)	PS		
INTRAVENOUS						

Date:03/05/99ISR Number: 3438500-3Report Type:Periodic Company Report #A0066894
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Disorientation	Health Professional	Zofran Injection	PS		
	Extrapyramidal Disorder	Company Representative	Paclitaxel	C		
			Diphenhydramine	C		
			Ranitidine Hydrochloride	C		
			Dexamethasone	C		

Date:03/05/99ISR Number: 3438501-5Report Type:Periodic Company Report #A0066908
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Dizziness	Health Professional	Zofran (Formulation Unknown)	PS		
	Visual Disturbance					
INTRAVENOUS	INTRAVENOUS	Company Representative				

Date:03/05/99ISR Number: 3438502-7Report Type:Periodic Company Report #A0066909
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Dizziness	Health Professional	Zofran (Formulation Unknown)	PS		
	Visual Disturbance					
INTRAVENOUS	INTRAVENOUS	Company Representative				

Date:03/05/99ISR Number: 3438503-9Report Type:Periodic Company Report #A0067159
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia	Health	Zofran (Formulation					
	Chest Discomfort	Professional	Unknown)	PS				
INTRAVENOUS	INTRAVENOUS							
	Confusional State	Company	Diphenhydramine Hcl	C				
		Representative	Cimetidine	C				

Date:03/05/99ISR Number: 3438504-0Report Type:Periodic Company Report #A0067795
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Tooth Disorder	Health	Zofran Injection	PS				
INTRAVENOUS	INTRAVENOUS							
		Professional						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/99ISR Number: 3438505-2Report Type:Periodic Company Report #A0068801
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Insomnia	Consumer	Zofran Injection	PS		INTRAVENOUS	4MG/THREE	
	Tachycardia						TIMES PER	
							DAY/INTRAVENO	
							US	
			Zofran Tablet	SS		ORAL	8MG/TWICE PER	
							DAY/ORAL	

Date:03/05/99ISR Number: 3438506-4Report Type:Periodic Company Report #A0070238
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dermatitis	Health	Zofran	PS	Glaxo Wellcome Inc		32 MG / SEE	
	Dizziness	Professional					TEXT	
	Face Oedema		Dexamethasone	C				
	Hypersensitivity		Paclitaxel	C				
	Urticaria		Carboplatin	C				
	Visual Disturbance		Diphenhydramine Hcl	C				

Date:03/05/99ISR Number: 3438507-6Report Type:Periodic Company Report #A0070893
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective	Consumer	Zofran	PS	Glaxo Wellcome Inc			
	Dry Mouth	Health	Hyoscine Patch	SS		TRANSDERMAL	TRANSDERMAL	
	Feeling Drunk	Professional	Lorazepam	C				
	Lethargy	Other						
	Nausea							

Vision Blurred

Date:03/05/99ISR Number: 3438508-8Report Type:Periodic Company Report #A0072011
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Reaction	Health Professional Company Representative	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	10 MG /	

Date:03/05/99ISR Number: 3438509-XReport Type:Periodic Company Report #A0072360
Age:18 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Neutropenia	Health Professional	Zofran	PS	Glaxo Wellcome Inc			
			Tot. Parenteral Nutrition	C				
			Sumatriptan Succinate	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/99ISR Number: 3438510-6Report Type:Periodic Company Report #A0076081
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective	Health	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	32 MG / SINGLE DOSE / INTRAVENOUS	
		Professional	Zofran Tablet	SS		ORAL	8 MG / TWICE PER DAY / ORAL	

Date:03/05/99ISR Number: 3438511-8Report Type:Periodic Company Report #A0077755
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Clonic Convulsion	Health	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	INTRAVENOUS	
		Professional	Hydromorphone Hcl Injection	SS		INTRAVENOUS	50 ML / INTRAVENOUS	

Date:03/05/99ISR Number: 3438512-XReport Type:Periodic Company Report #A0076147
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anxiety		Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	10 MG / SINGLE DOSE	
	Dystonia							
	Hallucination					INTRAVENOUS		

	Hypersensitivity		Diphenhydramine Hcl	SS			
INTRAVENOUS	35 MG /						
	Movement Disorder						
SINGLE DOSE /							
	Muscle Twitching						
INTRAVENOUS							
			Promethazine Hcl	C			
12.5 MB /							
SINGLE DOSE							

Date:03/08/99ISR Number: 3215223-7Report Type:Expedited (15-DaCompany Report #3800/50441
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Cleocin Phosphate	PS				
INTRAVENOUS	200 MG/DAY;IV							
Life-Threatening	Dermatitis	Health	Neupogen	SS				
	Hyperglycaemia	Professional	Actrapid (Human					
	Hypertension	Company	Insulin)	SS				
SUBCUTANEOUS	50 IU/DAY;SC							
	Lip Disorder	Representative	Allopurinol	SS		ORAL		
300 MG/DAY;								
	Mycosis Fungoides	Other						
ORAL								
	Neutropenia		Amoxicillin W/					
	Pain		Potassium					
	Pruritus		Clavulanate	SS				
INTRAVENOUS	4 GM/DAY;IV							
	Pyrexia		Amhpotericin B	SS				
INTRAVENOUS	40 MG/DAY;IV							
	Shock		Ancotil					
	Stevens-Johnson Syndrome		(Flucytosine)	SS				
INTRAVENOUS	IV							
			Antra (Omperazole)	SS				
INTRAVENOUS	20 MG/DAY; IV							
			Bifiteral					
			(Lactulose)	SS		ORAL		
ORAL								
			Ciprobay	SS				
INTRAVENOUS	IV							
			Claforan	SS				
INTRAVENOUS	6 GM/DAY;IV							
			Diflucan	SS		ORAL		
400								
MG/DAY;ORAL								
			Dipidolor					
			(Piritramide)	SS				
INTRAVENOUS	3.75 MG/DAY;							

				Dolantin (Pethidine Hcl)	SS		
INTRAVENOUS	25 MG/DAY; IV						
				Dopamine	SS		
				Dormicum (Midazolam)	SS		
				Gentamicin	SS		
				Human Albumin	SS		
				Imodium	SS		
				Isoptin	SS		
				Lasix	SS		
				Leucomax (Gm-Csf)	SS		
				Liquemin (Heparin)	SS		
				Meronem (Meropenem)	SS		
				Methotrexate	SS		
				Metronidazole	SS		
				Mst (Morphine Sulfate)	SS		
				Multibionta	SS		
				Novalgin (Metamizole)	SS		
				Opium Tincture	SS		
				Acetaminophen	SS		
				Paspertin (Metoclopramide)	SS		
				Psyquil (Triflupromazine)	SS		
				Solu-Decortin-H	SS		
				Suprarenin (Epinephrine)	SS		
				Tavegil (Clemastine)	SS		
				Vancomycin	SS		
				Vitalipid Novum Adult	SS		
				Zienam (Cilastatin/Imipenem)	SS		
				Zofran	SS		

Date:03/11/99ISR Number: 3217841-9Report Type:Expedited (15-DaCompany Report #A0085067
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Atrioventricular Block	Health	Zofran					

Initial or Prolonged	Coma	Professional	Injection-Premixed	PS		
INTRAVENOUS 32 MG/SINGLE						
Other						
DOSE/INTRAVEN						
OUS						

Date:03/22/99ISR Number: 3224376-6Report Type:Expedited (15-DaCompany Report #B0064819
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Chest Pain	Foreign	Zofran Injection	PS		
INTRAVENOUS IV						
Initial or Prolonged	Erythema	Health				
	Flushing	Professional				
	Headache					
	Hypertension					
	Panic Attack					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/26/99ISR Number: 3227636-8Report Type:Expedited (15-DaCompany Report #B0061789
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Angioneurotic Oedema	Foreign	Zofran Injection	PS		INTRAVENOUS	8 MG /	TWICE
Life-Threatening	Anorexia	Study						PER DAY /
Hospitalization -	Blood Lactate	Health						
Initial or Prolonged	Dehydrogenase Increased	Professional	Fenofibrate	C				
	Dehydration		Morphine Sulphate	C				
	Dermatitis		Ranitidine Hydrochloride	C				
	Dysphagia		Indomethacin	C				
	Gastrointestinal		Fluconazole	C				
	Haemorrhage		Itraconazole	C				
	Haematemesis							
	Haemorrhage							
	Melaena							
	Oesophageal Candidiasis							
	Oral Candidiasis							
	Pharyngitis							
	Pharyngolaryngeal Pain							
	Pneumonia							
	Pyrexia							
	Rash Erythematous							

Date:04/05/99ISR Number: 3232998-1Report Type:Direct Company Report #
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Feeling Hot		Ondansetron	PS		INTRAVENOUS	4 MG	IVP
Intervention to	Headache		Morphine	C				
Prevent Permanent	Nausea		Vicodin	C				
Impairment/Damage	Skin Ulcer		Fioricet	C				
			Chlorazepam	C				
			Imitrex	C				
			Oxycontin	C				

Date:04/05/99ISR Number: 3233004-5Report Type:Direct Company Report #
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Disorientation		Zofran	PS		INTRAVENOUS	8 MG IV Q 8	
	Feeling Abnormal							HOURS PRN

Date:04/07/99ISR Number: 3234565-2Report Type:Expedited (15-DaCompany Report #A0085067
Age:63 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atrioventricular Block	Health	Zofran					
Hospitalization -	Cardio-Respiratory Arrest	Professional	Injection-Premixed	PS		INTRAVENOUS	32 MG/SINGLE	
Initial or Prolonged	Coma							DOSE/INTRAVEN
Disability	Pleural Effusion							OUS/10
Other	Posturing							MINUTES
			Dexamethasone	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/09/99ISR Number: 3236716-2Report Type:Expedited (15-DaCompany Report #B0062989
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis	Foreign	Zofran Tablet	PS		ORAL	8 MG/TWICE	PER DAY/ORAL
	Diarrhoea	Study						
	Face Oedema	Health Professional	Ampronavir	C				
	Headache		Combivir	C				
	Myalgia		Abacavir Sulphate	C				
	Pruritus							
	Pyrexia							
	Urticaria							

Date:04/15/99ISR Number: 3246272-0Report Type:Periodic Company Report #107/63165
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Headache	Health Professional Company Representative	Adriamycin Pfs Sterile Solution (2 Mg)	PS		INTRAVENOUS	60 MG SQ.M.	1Q3WK IV
			Decadron	SS			1 DOSE	
			Zofran	SS			1 DOSE	
			Kytril	C				

Date:04/29/99ISR Number: 3249963-0Report Type:Expedited (15-DaCompany Report #A0090067
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma	Health Professional	Zofran (Formulation Unknown)	PS		INTRAVENOUS	4 MG / SINGLE	DOSE /

INTRAVENOUS				Morphine	C		
				Paracetamol	C		
				Combivent	C		
				Hydralazine	C		
				Piperacillin Sodium	C		
				Levofloxacin	C		

Date:05/10/99ISR Number: 3257997-5Report Type:Expedited (15-DaCompany Report #R039976
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign Study	Doxorubicin (Doxorubicin Hcl)	PS		INTRAVENOUS	132.6 MG IV	
	Hallucination	Health Professional	Dppe	SS		INTRAVENOUS	599.6 MG IV	
	Headache		Ondansetron (Ondansetron Hcl)	SS		8 MG IM		
			Indapamide	C				
			Nitrendipine	C				

Date:05/17/99ISR Number: 3263504-3Report Type:Expedited (15-DaCompany Report #R039976
Age: Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness

	Hallucination Headache					
		Report Source	Product	Role	Manufacturer	Route
Dose Duration						
		Foreign	Doxorubicin			
		Study	(Doxorubicin Hcl)	PS		
INTRAVENOUS 132.6 MG IV 1						
		Health				
CYCLES						
		Professional	Dppe	SS		
INTRAVENOUS 593.6 MG IV 1						
		Other				
CYCLES						
			Ondansetron			
			(Ondansetron Hcl)	SS		
INTRAMUSCULAR 8 MG IM 1						
CYCLES						
			Indapamide	C		
			Nitrendipine	C		

Date:05/17/99ISR Number: 3263605-XReport Type:Expedited (15-DaCompany Report #A0091732
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Cold Sweat	Health	Zofran			
	Cough	Professional	Injection-Premixed	PS		
INTRAVENOUS 32 MG						
	Dermatitis	Company				
INTRAVENOUS						
	Flushing	Representative	Carboplatin	C		
	Hypotension		Gemcitabine	C		
	Nasopharyngitis		Warfarin Sodium	C		

Date:05/17/99ISR Number: 3263815-1Report Type:Expedited (15-DaCompany Report #B0060776
Age:74 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Oedema	Foreign	Zofran Injection	PS		
INTRAVENOUS 4 MG/ PER						

Initial or Prolonged	Vascular Purpura					
DAY/						
INTRAVENOUS						
			Fluorouracil	C		

Date:05/21/99ISR Number: 3267646-8Report Type:Expedited (15-DaCompany Report #B0065674
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Amnesia	Foreign	Zofran (Formulation					
Initial or Prolonged	Asthenia	Health	Unknown)	PS				
INTRAVENOUS	SINGLE							
Other	Cerebrovascular Accident	Professional						
DOSE/INTRAVEN								
	Difficulty In Walking							
OUS								
	Disturbance In Attention		Hrt	C				
	Drug Effect Prolonged		Propofol	C				
	Dyskinesia		Alfentanil					
	Extrapyramidal Disorder		Hydrochloride	C				
	Flushing		Suxamethonium	C				
	Hemiparesis		Morphine	C				
	Movement Disorder		Oxygen	C				
	Sedation		Nitrous Oxide	C				
	Tachycardia		Sevoflurane	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/21/99ISR Number: 3267650-XReport Type:Expedited (15-DaCompany Report #B0066713
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abortion Missed	Foreign	Zofran Injection	PS		INTRAVENOUS	INTRAVENOUS	
Initial or Prolonged			Cyclizine	C				
			Pyridoxine	C				

Date:05/25/99ISR Number: 3269703-9Report Type:Direct Company Report #
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Chest Pain	Health	Zofran	PS		INTRAVENOUS	4MG IVPB	Q 8
Intervention to		Professional						
HRS							1	DAY
Prevent Permanent								
Impairment/Damage								

Date:05/26/99ISR Number: 3270494-6Report Type:Direct Company Report #
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaemia		Gemcitabine	PS		INTRAVENOUS	1000MG/M2	IV
	Confusional State		Zofran Iv	SS		INTRAVENOUS	8MG	IV
	Nausea							

Date:05/26/99ISR Number: 3270755-0Report Type:Direct Company Report #
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain		Carboplatin / Taxol	PS		INTRAVENOUS	650 MG	IV/

Initial or Prolonged	Asthenia					
360 MG IV						
	Clostridium Colitis		Zofran (Per Urcc			
	Decreased Appetite		3996)	SS		ORAL
24 MG PO						
	Diarrhoea		Decadron	C		
	Hyponatraemia		Prevacid	C		
	Nausea		Compazine	C		
			Hydrcodone	C		
			Darvocet	C		
			Baclofen	C		
			Lorazepam	C		

Date:06/01/99ISR Number: 3274403-5Report Type:Expedited (15-DaCompany Report #B0066844
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Haemolytic Anaemia	Foreign	Zofran Injection	PS		
INTRAVENOUS INTRAVENOUS						
Initial or Prolonged			Septra (Formulation			
			Unknown)	SS		ORAL
ORAL						
			Prednisone			
			(Formualtion			
			Unknown)	SS		ORAL
ORAL						
			Doxorubicin			
			Injection	SS		
INTRAVENOUS INTRAVEOUS						
			Procarbazine			
			(Formulation			
			Unknown)	SS		ORAL
ORAL						
			Vincristine			
			Injection	SS		
INTRAVENOUS INTRAVENOUS						

			Clorazepate Dipotassium	C		

Date:06/11/99ISR Number: 3281898-XReport Type:Expedited (15-DaCompany Report #A0083094
Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abortion Spontaneous	Health Professional	Zofran (Formulation Unknown)	PS		INTRAVENOUS	UNK / UNK /	
Disability						INTRAVENOUS		
Other			Zofran Tablet	SS		ORAL	8 MG / PER	DAY / ORAL
			Intravenous Fluid(S)	C				
			Anti-Emetic	C				

Date:06/28/99ISR Number: 3294428-3Report Type:Direct Company Report #
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Diarrhoea	Health	Ondansotron 2.5mg Iv	PS		INTRAVENOUS	2.5 MG IV Q	
	Face Oedema	Professional					3H	
	Gastroenteritis		Prevacid	C				
	Helicobacter		Flagyl	C				
	Nausea		Cipro	C				
	Tongue Oedema							

Date:07/15/99ISR Number: 3305153-4Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Arrhythmia		Zofran	PS				
	Myocardial Ischaemia							

Date:07/19/99ISR Number: 3306322-XReport Type:Expedited (15-DaCompany Report #A0096542
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arrhythmia	Literature	Zofran Injection	PS		INTRAVENOUS	2 MG / DOSE / INTRAVENOUS	SINGLE
	Chest Pain							
	Electrocardiogram St Segment Depression		Droperidol	C				
	Hypertension		Ropivacaine Hcl	C				
	Myocardial Ischaemia		Fentanyl	C				
	Tachycardia							
	Ventricular Extrasystoles							
	Ventricular Tachycardia							

Date:07/20/99ISR Number: 3307422-0Report Type:Expedited (15-DaCompany Report #280/50467
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Chills	Foreign	Adriamycin Rdf	PS		INTRAVENOUS	50 MG/SQ.M/DAY; IV	
Other	Pyrexia	Health Professional						
		Company Representative	Cyclophosphamide For Injection, Usp (Mfr					

Unk) SS

INTRAVENOUS 750

MG/SQ.M./DAY;

IV

Vincristine Sulfate Injection , Usp (Mfr Unk) SS

INTRAVENOUS 1.4

MG/SQ.M./DAY;

IV

Prednisone (Mfr Unk) SS ORAL

60 MG/DAY ;

ORAL

Ondansetron SS

8 MG/DAY

Date:08/01/99ISR Number: 3338317-4Report Type:Direct Company Report #
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bronchospasm	Health	Zofran	PS		INTRAVENOUS	4MG IV	DAILY
	Dizziness	Professional						

Date:08/06/99ISR Number: 3321953-9Report Type:Expedited (15-DaCompany Report #A0096542A
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arrhythmia	Literature	Ondansetron					
Required	Chest Pain	Health	Hydrochloride					
Intervention to	Electrocardiogram St	Professional	Injection					
Prevent Permanent	Segment Depression		(Ondansetron					
Impairment/Damage	Hypertension		Hydrochloride)	PS		INTRAVENOUS	2 MG/SINGLE	
	Myocardial Ischaemia							

DOSE/

	Tachycardia					
INTRAVENOUS						
	Ventricular Extrasystoles		Droperidol	C		
	Ventricular Tachycardia		Ropivacaine Hcl	C		
			Fentanyl	C		

Date:08/06/99ISR Number: 3321963-1Report Type:Expedited (15-DaCompany Report #A0098275A
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Coma	Foreign	Zofran Tablet			
	Convulsion	Health	(Ondansetron			
	Headache	Professional	Hydrochloride)	PS		ORAL
8 MG/TWICE						
	Nausea					
PER DAY/ORAL						
	Tremor		Dexamethasone	C		
	Vomiting		Fluorouracil	C		
			Folinic Acid	C		

Date:08/09/99ISR Number: 3322620-8Report Type:Direct Company Report #
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Vomiting		Cisplatin	PS		
INTRAVENOUS 157MG IV						
Initial or Prolonged			Dexamethasone	SS		
INTRAVENOUS 20MG IV						
			Ondansetron	SS		
INTRAVENOUS 20MG IV						
			Lidocaine Hcl 2%			
			Viscous Liquid	C		
			Nutrition Supl			
			Ensure /Vanilla Pwd	C		
			Ranitidine Hcl	C		

				Sodium Chloride	C		
				Fexofenadine Hcl	C		
				Cephradine	C		
				Beclomethasone	C		
				Spironolactone	C		
				Acetaminophen	C		
				Guaifenesin	C		
				Phytonadione	C		

Date:08/17/99ISR Number: 3327700-9Report Type:Expedited (15-DaCompany Report #B0069248A
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anuria	Foreign	Zofran Injection					
Hospitalization -	Blood Bilirubin Increased		(Ondansetron					
Initial or Prolonged	Chills		Hydrochloride)	PS				
INTRAVENOUS	INTRAVENOUS							
	Coombs Direct Test		Wellcovorin					
	Positive		(Formulation					
	Haemoglobin Decreased		Unknown) (Calcium					
	Haemolytic Anaemia		Folinate)	SS				
	Hypersensitivity		Oxaliplatin					
	Jaundice		Injection					
	Pyrexia		(Oxaliplatin)	SS				
INTRAVENOUS	INTRAVENOUS							
	Renal Impairment							

Date:08/20/99ISR Number: 3330878-4Report Type:Expedited (15-DaCompany Report #B0069208A
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aspartate	Foreign	Zofran Tablet					
	Aminotransferase		(Ondansetron					
	Increased		Hydrochloride)	PS		ORAL		
ORAL								
	Blood Bilirubin Increased		Tamoxifen					
	Hepatic Function Abnormal		(Formulation					
			Unknown) (Tamoxifen)	SS		ORAL		
ORAL								
			Doxorubicin					
			Hydrochloride	C				

			Cyclophosphamide	C		
			Methotrexate	C		
			Fluorouracil	C		
			Metoclopramide	C		

Date:08/25/99ISR Number: 3334902-4Report Type:Expedited (15-DaCompany Report #B0068775A
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Gaze Palsy Hypertonia		Zofran (Ondansetron Hydrochloride)	PS		INTRAVENOUS	4 MG/	SINGLE
Disability	Movement Disorder							
DOSE/ Required	Muscle Rigidity					INTRAVENOUS		
Intervention to Prevent Permanent Impairment/Damage	Sedation		Propofol Midazolam	C C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/27/99ISR Number: 3336898-8Report Type:Expedited (15-DaCompany Report #10083111
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Body Temperature Increased	Foreign Study	Ifosfamide	PS		INTRAVENOUS	3 GRAM, I/1	CYCLE IV
	Neutropenia Pharyngolaryngeal Pain Sepsis Tachycardia White Blood Cell Count Decreased	Health Professional	5-Fluorouracil (Fluorouracil)	SS		INTRAVENOUS	1100 MG, 1/1	CYCLE IV
			Leucovorin (Folinic Acid)	SS		INTRAVENOUS	44 MG, 1/1	CYCLE IV
			Mesna	SS		ORAL	2680 MG	CUMULAT, 1/1
			Ondansetron (Ondansetron Hcl)	SS		INTRAVENOUS	8 MG, 1/1	CYCLE IV
			Mitomycin-C (Mitomycin)	SS		INTRAVENOUS	9 MG, IV	
			Dexamethasone	SS			8MG, 1/1 DAY	

Date:08/31/99ISR Number: 3338375-7Report Type:Expedited (15-DaCompany Report #USA/99/01308/LEX
Age:45 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Leukopenia		Clozaril (Clozapine)	PS		ORAL	650 MG; ORAL	
Required Intervention to	Lymphoma Nausea		Zofran (Ondansetron Hydrochloride)	SS				

Prevent Permanent Impairment/Damage	White Blood Cell Count Increased		Chemotherapy	C		

Date:09/16/99ISR Number: 3348907-0Report Type:Expedited (15-DaCompany Report #1999AP04418
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Brain Oedema	Foreign	Diprivan	PS		INTRAVENOUS	1200 MG IV
Initial or Prolonged	Depressed Level Of Consciousness	Health Professional	Ondansetron	SS			4 MG
	Hypertonia	Other	Alfentanil	C			
	Muscle Rigidity		Cefuroxime	C			
			Metronidazole	C			

Date:09/16/99ISR Number: 3349608-5Report Type:Expedited (15-DaCompany Report #A0099427A
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Bronchospasm	Health	Zofran Tablet				
Required	Chronic Obstructive	Professional	(Ondansetron				
Intervention to	Airways Disease		Hydrochloride)	PS		ORAL	SEE TEXT ORAL
Prevent Permanent	Exacerbated		Compazine	C			
Impairment/Damage	Dyspnoea		Dexamethasone	C			
			Carboplatin	C			

Date:09/20/99ISR Number: 3352421-6Report Type:Expedited (15-DaCompany Report #B0059973A
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Electrocardiogram	Foreign	Zofran Injection					
Hospitalization -	Abnormal	Health	(Ondansetron					
Initial or Prolonged	Electrocardiogram Qt	Professional	Hydrochloride)	PS				
						INTRAVENOUS		INTRAVENOUS
Other	Prolonged		Propofol	C				
	Oxygen Saturation		Fentanyl	C				
	Decreased		Nitrous Oxide	C				
	Pco2 Decreased		Isoflurane	C				
	Pulse Absent		Magnesium Salt	C				
	Resuscitation							
	Ventricular Tachycardia							

Date:09/27/99ISR Number: 3358958-8Report Type:Expedited (15-DaCompany Report #B0071147A
Age:10 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Embolism	Foreign	Zofran (Formulation					
Initial or Prolonged	Haematemesis	Literature	Unknown)					
	Haemoglobin Decreased	Health	(Ondansetron					
	Haemorrhage	Professional	Hydrochloride)	PS				
						INTRAVENOUS	.15 MG/KG /	
	Hypotension							
							PER DAY /	
	Melaena							
							INTRAVENOUS	
	Pallor							
	Peripheral Coldness							
	Tachycardia							

Date:10/04/99ISR Number: 3363528-1Report Type:Expedited (15-DaCompany Report #B0070938A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Blindness Transient	Foreign	Zofran (Formulation					
Other		Health	Unknown)					
		Professional	(Ondansetron					

			Hydrochloride)	PS			

Date:10/15/99ISR Number: 3373424-1Report Type:Expedited (15-DaCompany Report #A0098275A
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Foreign	Zofran Tablet					
Hospitalization -	Convulsion	Health	(Ondansetron					
Initial or Prolonged	Headache	Professional	Hydrochlride)	PS		ORAL	8 MG/TWICE	
	Nausea						PER DAY/ORAL	
	Tremor		Dexamethasone	C				
	Vomiting		Fluorouracil	C				
			Folinic Acid	C				

Date:10/19/99ISR Number: 3375726-1Report Type:Expedited (15-DaCompany Report #B0071960A
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cardiac Disorder	Foreign	Zofran Tablet -					
Initial or Prolonged	Neutropenia	Study	Zydis (Ondansetron					
		Health	Hydrochloride)	PS		ORAL	8MG / SINGLE	
		Professional					DOSE/ ORAL	1 DAY

				Zofran Tablet - Zydis (Ondansetron Hydrochloride)	SS		ORAL
16 MG/ SINGLE DOSE/ ORAL	2 DAY						
				Epirubicin Hydrochloride	C		
				Cyclophosphamide	C		
				Fortecortin	C		
				Paracetamol	C		

Date:10/22/99ISR Number: 3380012-XReport Type:Expedited (15-DaCompany Report #B0072027A
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatic Function Abnormal	Foreign	Zofran	PS		INTRAVENOUS	2	
	Liver Function Test	Health					AMPOULE/TWICE	
	Abnormal	Professional					PER	
		Company					DAY/INTRAVENO	
		Representative					US	
			Cisplatin	C				
			Mitomycin	C				

Date:10/25/99ISR Number: 3381342-8Report Type:Expedited (15-DaCompany Report #A0103469A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Bicuspid Aortic Valve	Consumer	Zofran Injection (Ondansetron Hydrochloride)	PS		TRANSPLACENTAL	TWICE PER	
	Complications Of Maternal Exposure To Therapeutic Drugs						DAY/	
	Congenital Diaphragmatic						INTRAVENOUS	

	Anomaly		Zofran Tablet			
	Dextrocardia		(Ondansetron			
	Hypospadias		Hydrochloride)	SS		ORAL
4 MG/ THREE						
	Pulmonary Hypoplasia					
TIMES PER DAY						
	Wolff-Parkinson-White					
/ ORAL						
	Syndrome					

Date:10/25/99ISR Number: 3382353-9Report Type:Expedited (15-DaCompany Report #B0071960A
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Cardiac Disorder	Foreign	Zofran Tablaet-			
Initial or Prolonged	Neutropenia	Study	Zydis (Ondansetron			
		Health	Hydrochloride)	PS		ORAL
8MG SINGLE						
		Professional				
DOSE ORAL 1 DAY						
			Zofran Tablet- Zydis			
			(Ondansetron			
			Hydrochloride)	SS		ORAL
16 MG SINGLE						
DOSE ORAL 2 DAY						
			Epirubicin			
			Hydrochloride	C		
			Cyclophosphamide	C		
			Fortecortin	C		
			Paracetamol	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/28/99ISR Number: 3384030-7Report Type:Expedited (15-DaCompany Report #B0072378A
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Alkalosis Amnesia Aphonia	Foreign Literature Health Professional	Zofran (Formulation Unknown) (Ondansetron Hydrochloride)	PS			4 MG / SINGLE	
	Blood Creatine Phosphokinase Increased						DOSE /	
	Coma Confusional State Delirium Drug Interaction Eye Rolling Hypertension Movement Disorder Mydriasis Oculogyration Pco2 Increased Post Procedural Complication Pyrexia Tachycardia		Paroxetine (Formulation Unknown) (Paroxetine) Diclofenac Indomethacin Propofol Atracurium Besylate Oxygen Nitrous Oxide Enflurane Morphine	SS C C C C C C C C				

Date:11/01/99ISR Number: 3385414-3Report Type:Direct Company Report #
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Chills		Zofran 4 Mg Iv	PS			INTRAVENOUS	

Date:11/17/99ISR Number: 3400025-9Report Type:Expedited (15-DaCompany Report #B0072027A
Age:67 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatic Function Abnormal Liver Function Test	Foreign Health	Zofran Injection (Ondansetron					

	Abnormal	Professional	Hydrochloride)	PS	
INTRAVENOUS	2 AMPOULE				
		Company			
TWICE PER DAY					
		Representative			
INTRAVENOUS					
			Cisplatin	C	
			Mitomycin	C	

Date:11/23/99ISR Number: 3405391-6Report Type:Direct Company Report #
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Dermatitis	Health	Ondansetron (Zofran)	PS		
INTRAVENOUS	4MG IV X 2					
	Face Oedema	Professional				
	Hypotension					
	Oxygen Saturation Decreased					
	Tachycardia					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/23/99ISR Number: 3409284-XReport Type:Expedited (15-DaCompany Report #B0073279A
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Bilirubin Increased Hepatitis Liver Function Test Abnormal	Foreign	Zofran Tablet 8 Mg (Ondansetron Hydrochloride)	PS		ORAL	24 MG ORAL	
			Raltitrexed Injection 2 Mg (Raltitrexed)	SS		INTRAVENOUS	6 MG	PER DAY
			Irinotecan	C		INTRAVENOUS		

Date:11/26/99ISR Number: 3409511-9Report Type:Expedited (15-DaCompany Report #A0105858A
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aphonia Chills Hypotension Pharyngeal Oedema Pruritus Pyrexia Tongue Oedema Urticaria	Consumer	Zofran Tablet (Ondansetron Hydrochloride)	PS		ORAL	SEE TEXT / ORAL	

Date:12/01/99ISR Number: 3412630-4Report Type:Expedited (15-DaCompany Report #B0073574A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Shock	Foreign	Zantac (Formulation					

			Health Professional	Unknown) (Ranitidine Hydrochloride)	PS		
INTRAVENOUS	PER DAY/						
INTRAVENOUS				Zofran (Formulation Unknown) (Ondansetron Hydrochloride)	SS		
INTRAVENOUS	PER DAY /						
INTRAVENOUS				Cancer Chemotherapy	C		

Date:12/01/99ISR Number: 3412635-3Report Type:Expedited (15-DaCompany Report #B0073575A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Anaphylactic Reaction	Foreign Health Professional	Zantac (Formulation Unknown) (Ranitidine Hydrochloride)	PS		
INTRAVENOUS	50 MG/					
INTRAVENOUS			Zofran (Formulation Unknown) (Ondansetron Hydrochloride)	SS		
INTRAVENOUS	8 MG /					
INTRAVENOUS			Cancer Chemotherapy	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/08/99ISR Number: 3416370-7Report Type:Expedited (15-DaCompany Report #10093466
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Shock	Foreign	Paraplatine					
	Blood Pressure Decreased	Health	Inj(Carboplatin)	PS		INTRAVENOUS	500	MILLIGRAM,
	Chest Pain	Professional						1/1 CYCLE IV
	Eyelid Oedema							
	Loss Of Consciousness		Zophren (Ondansetron					
	Medication Error		Hcl)	SS				
	Rash Erythematous		Solu-Medrol					
	Tremor		(Methylprednisolone)	C				
			Endoxan					
			(Cyclophosphamide)	C				

Date:12/10/99ISR Number: 3419043-XReport Type:Expedited (15-DaCompany Report #D0005262A
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dermatitis	Foreign	Zofran Injection					
	Genital Ulceration	Health	(Ondansetron					
	Mouth Ulceration	Professional	Hydrochloride)	PS		INTRAVENOUS	INTRAVENOUS	
	Oral Mucosal Eruption		Zofran Tablet					
	Stevens-Johnson Syndrome		(Ondansetron					
	Toxic Epidermal		Hydrochloride)	SS		ORAL	1 TABLET /	
	Necrolysis						PER DAY /	
	Urticaria						ORAL	
			Multiple Medication					
			(Formulation					
			Unknown) (Multiple					
			Medication)	SS				
			Ranitidine					
			Hydrochloride	C				
			Multiple Medication	C				

Date:12/13/99ISR Number: 3420173-7Report Type:Expedited (15-DaCompany Report #B0074121A
Age:12 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Angioneurotic Oedema Hypokalaemia Shock Vomiting	Foreign Health Professional	Zofran Injection (Ondansetron Hydrochloride)	PS		INTRAVENOUS	PER DAY / INTRAVENOUS	

Date:12/13/99ISR Number: 3420602-9Report Type:Expedited (15-DaCompany Report #GB/99/01121/SIM03
Age:7 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Toxic Epidermal Necrolysis	Foreign Other	Sandimmun Neoral (Ciclosporin)	PS			45 MG, TWICE A DAY	
			Codeine Phosphate (Codeine Phosphate)	SS		ORAL	15 MG, ONCE A DAY, ORAL	
			Chlorpheniramine (Chlorphenamine)	SS			4 MG, AS NEEDED,	
			Paracetamol					

		(Paracetamol)	SS	ORAL
360 MG, AS NEEDED, ORAL				
		Vancomycin (Vancomycin)	SS	
INTRAVENOUS	270 MG, THREE TIMES A DAY, INTRAVENOUS INJECTION			
		Ceftazidime (Ceftazidime)	SS	
INTRAVENOUS	900 MG, THREE TIMES A DAY, INTRAVENOUS INJECTION			
		Tranexamic Acid (Tranexamic Acid)	SS	ORAL
400 MG, THREE TIMES A DAY, ORAL				
		Fludarabine (Fludarabine)	SS	
INTRAVENOUS	18 MG, ONCE A DAY, INTRAVENOUS INJECTION			
		Ondansetron (Ondansetron)	SS	
4 MG, AS NEEDED				
		Cyclophosphamide (Cyclophosphamide)	SS	
INTRAVENOUS	1.04 G, ONCE A DAY,			

INTRAVENOUS INJECTION		Immunoglobulin (Antithymocyte Immunoglobulin)	SS		
INTRAVENOUS	219 MG, ONCE A DAY, INTRAVENOUS INJECTION	Metoclopramide (Metoclopramide)	SS		
	5 MG, AS NEEDED	Meropenem (Meropenem)	SS		
INTRAVENOUS	360 MG, THREE TIMES A DAY, INTRAVENOUS INJECTION	Acyclovir (Aciclovir)	SS		
INTRAVENOUS	175 MG, THREE TIMES A DAY, INTRAVENOUS INJECTION	Fluconazole (Fluconazole)	SS	ORAL	
	50 MG, ONCE A DAY, ORAL	Nifedipine (Nifedipine)	SS	ORAL	
	5 MG, AS NEEDED, ORAL	Sandoglobulin (Immunoglobulin Human Normal)	SS		
INTRAVENOUS	7 G, WEEKLY, INTRAVENOUS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/13/99ISR Number: 3420825-9Report Type:Expedited (15-DaCompany Report #B0073574A
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Anaphylactic Shock Cardiac Arrest Respiratory Disorder	Foreign Health Professional	Zantac (Formulation Unknown) (Ranitidine Hydrochloride)	PS		INTRAVENOUS	50 MG / PER	Required DAY /
Intervention to Prevent Permanent Impairment/Damage			Zofran (Formulation Unknown) Ondansetron Hydrochloride)	SS		INTRAVENOUS	8 MG / PER	DAY /
			Dexamethasone (Formulation Unknown) (Dexamethasone)	SS		INTRAVENOUS		
			Paclitaxel	C				
			Valproate Sodium	C				
			Mebeverine Hydrochloride	C				
			Venorelbine Tartrate	C				
			Amifostine	C				

Date:12/14/99ISR Number: 3422116-9Report Type:Periodic Company Report #0196922A
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Toxicity Dry Mouth Nausea	Consumer Health Professional	Transderm Scop-Scopolamine 1.5mg-Nvch	PS		PATCH/Q3D/TTS	1	
	Sedation Visual Disturbance		Zofran-Ondansetrone					

			Dose Unk-Glaxo	SS	Glaxo	ORAL
PO						
			Lorazepam	C		

Date:12/20/99ISR Number: 3425941-3Report Type:Expedited (15-DaCompany Report #B0074230A
Age:7 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Toxic Epidermal Necrolysis	Foreign	Zofran (Formulation Unknown) (Ondansetron Hydrochloride)	PS		
AS REQUIRED						
			Zovirax (Formulation Unknown) (Acyclovir)	SS		
INTRAVENOUS 175 MG/ THREE						
TIMES PER DAY						
INTRAVENOUS						
			Fortaz (Formulation Unknonw) (Ceftazidime Sodium)	SS		
INTRAVENOUS 900 MG/ THREE						
TIME PER DAY						
INTRAVENOUS						
			Normal Immunoglobulin (Formulation Unknown) (Normal Immunoglobulin)	SS		
INTRAVENOUS WEEKLY/						
INTRAVENOUS						

		Nifedipine (Formulation Unknown) (Nifedipine)	SS		ORAL
AS REQUIRED/ ORAL					
		Fluconazole (Formulation Unknown) (Fluconazole)	SS		ORAL
PER DAY/ ORAL					
		Meropenem (Formulation Unknown) (Meropenem)	SS		
INTRAVENOUS	360 MG/ THREE TIMES PER DAY				
INTRAVENOUS		Metoclopramide (Formulation Unknown) (Metoclopramide)	SS		
AS REQUIRED					
		Normal Immunoglobulin (Formulation Unknown) (Normal Immunoglobulin)	SS		
INTRAVENOUS	PER DAY/				
INTRAVENOUS		Cyclophosphamide (Formulation Unknown) (Cyclophosphamide)	SS		
INTRAVENOUS	PER DAY/				
INTRAVENOUS		Fludarabine Phosphate (Formulation Unknown) (Fludarabine	SS		
INTRAVENOUS	PER DAY/				

INTRAVENOUS		Tranexamic Acid (Formulation Unknown) (Tranexamic Acid)	SS	ORAL
400 MG/ THREE TIMES PER DAY	ORAL			
		Vancomycin (Formulation Unknown) (Vancomycin)	SS	
INTRAVENOUS	270 MG/ THREE TIMES PER DAY			
INTRAVENOUS		Paracetamol (Formulation Unknown) (Acetaminophen)	SS	ORAL
PER DAY/ ORAL		Chlorpheniramine (Formulation Unknown) (Chlorpheniramine)	SS	
AS REQUIRED		Codeine Phosphate (Formulation Unknown) (Codeine Phosphate)	SS	ORAL
PER DAY/ ORAL		Cyclosporin (Formulation		

			Unknown) (Cyclosporine)	SS			45 MG/ TWICE PER DAY

Date:12/23/99ISR Number: 3429921-3Report Type:Expedited (15-DaCompany Report #PRIUSA1999009423
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Brain Hypoxia Bronchospasm Respiratory Gas Exchange Disorder	Health Professional	Levaquin (Injection) (Levofloxacin)	PS		INTRAVENOUS	250 MG, 1 TIME(S), IV	
			Propofol (Propofol)	SS			100 MG	
			Desflurane (Desflurane)	SS				
			Fentanyl	SS			150 MG	
			Rocuronium(Rocuronium)	SS			30 MG	
			Midazolam(Midazolam)	SS			2 MG	
			Lidocaine(Lidocaine)	SS			100 MG	
			Tubocurarine (Tubocurarine)	SS			3 MG	
			Succinyl Chloride (Suxamethonium Chloride)	SS			120 MG	
			Ondansetron (Ondansetron)	SS		INTRAVENOUS	4 MG, IV	
			Neostigmine Glycopyrrolate(Neostigmine)	SS			2.5 MG	

Date:12/27/99ISR Number: 3431504-6Report Type:Expedited (15-DaCompany Report #B0074121A
Age:12 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abdominal Pain	Foreign	Zofran Injection					
Hospitalization - Initial or Prolonged	Angioneurotic Oedema	Health Professional	(Ondansetron Hydrochloride)	PS		INTRAVENOUS	PER DAY /	
	Hypokalaemia							
	Oxygen Saturation Abnormal		Vincristine	C		INTRAVENOUS		
	Shock		Ceftriaxone	C				
	Vomiting							

Date:01/04/00ISR Number: 3436635-2Report Type:Expedited (15-DaCompany Report #PRIUSA1999009423
Age:45 YR Gender:Female I/FU:F

Outcome	PT
Death	Anxiety
Hospitalization - Initial or Prolonged	Brain Hypoxia
	Breath Sounds Decreased
	Bronchospasm
	Cardiac Arrest
	Depressed Level Of Consciousness
	Heart Rate Decreased
	Heart Rate Increased
	Oxygen Saturation Decreased
	Respiratory Depression
	Respiratory Gas Exchange

Disorder
Sinus Bradycardia

		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Health Professional	Levaquin (Injection) (Levofloxacin)	PS		
INTRAVENOUS	250 MG, 1 TIME(S), IV					
			Propofol (Propofol)	SS		
100 MG						
			Desflurane (Desflurane)	SS		
			Fentanyl	SS		
150 MG						
			Rocuronium (Rocuronium)	SS		
30 MG						
			Midazolam (Midazolam)	SS		
2 MG						
			Lidocaine (Lidocaine)	SS		
100 MG						
			Tubocurarine (Tubocurarine)	SS		
3 MG						
			Succinyl Chloride (Suxamethonium Chloride)	SS		
120 MG						
			Ondansetron (Ondansetron)	SS		
INTRAVENOUS	4 MG, IV					
			Neostigmine Glycopyrrolate (Neostigmine)	SS		
2.5 MG						

Date:01/11/00ISR Number: 3442664-5Report Type:Expedited (15-DaCompany Report #2000007465FR
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Hyperkalaemia	Health	Camptosar	PS		

	Renal Failure Acute	Professional Other	Fluorouracil (Fluorouracil)	SS			
			Metformin Hydrochloride (Metformin Hydrochloride)	SS			
5 DAY							
			Human Erythropoietin()	SS			
5 DAY							
			Ondansetron (Ondansetron)	SS			
5 DAY							
			Folinic Acid (Folinic Acid)	SS			
5 DAY							
			Oxaliplatin (Oxaliplatin)	C			

Date:01/18/00ISR Number: 3444977-XReport Type:Expedited (15-DaCompany Report #B0075478A
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatinine Increased	Foreign	Zofran (Formulation Unknown)					
	Hyperkalaemia		(Ondansetron Hydrochloride)	PS				
	Renal Failure Acute		Fluorouracil	C				
			Metformin Hydrochloride	C				
			Erythropoietin	C				

			Irinotecan	C		
			Oxaliplatin	C		

Date:01/27/00ISR Number: 3447371-0Report Type:Expedited (15-DaCompany Report #20000100329
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactoid Reaction	Foreign	Toprol-Xl	PS		ORAL	25 MG QD PO	
	Blister	Health	Chloraldurat	SS				
	Blood Urea Increased	Professional	Dexamethazon	SS				
	Conjunctivitis		Fortecortin	SS				
	Entropion		Fortecortin-Mono	SS				
	Genital Ulceration		Acc 200	SS				
	Glossitis		Glycerol	SS				
	Lip Ulceration		Adalat	SS				
	Rash Maculo-Papular		Ranitidine	SS				
	Stevens-Johnson Syndrome		Dimeticone, Activated/Silicon					
	Stomatitis		Dic	SS				
	Toxic Epidermal Necrolysis		Zofran	SS				
			Mono-Embolex	SS				
			Antra	SS				
			Zantic	SS				
			Bcnu	SS				
			Atosil	SS				
			Nasivinetten	SS				
			Paracetamol	SS				
			Imeson	SS				
			Timonil-Slow Release	C				
			Laxoberal "Thomae Karl"	C				
			Atropine	C				
			Furosemide	C				
			Neurocil	C				
			Thiopental	C				
			Succicuran	C				
			Sodium Chloride Injection	C				
			Bactrim Forte	C				
			Lactulose	C				
			Pancuronium	C				
			Lefax	C				
			Jonosteril	C				

			Doretonsin	C		
			Isoflurane	C		
			Dormicum "Roche"	C		
			Rocephin	C		

Date:01/27/00ISR Number: 3447772-0Report Type:Expedited (15-DaCompany Report #10241438
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebellar Syndrome Confusional State	Foreign Health	Amiklin Inj (Amikacin Sulfate)	PS		INTRAVENOUS	1 GRAM, 1 DAY	
	Difficulty In Walking	Professional				IV		
	Pyrexia Rash Erythematous Tremor	Other	Aracytine (Cytarabine) Idarubicin Zophren (Ondansetron	SS SS				

			Hcl)	SS			
PARENTERAL	2 MILLIGRAM,						
PAREN							
			Tranxene (Clorazepate Dipotassium)	SS			
			Primperan (Metoclopramide Hcl)	SS			
			Axepim Inj (Cefepime Hcl)	C			
			Flagyl (Metronidazole)	C			
			Fungizone Intravenous (Amphotericin B)	C			

Date:01/28/00ISR Number: 3448377-8Report Type:Expedited (15-DaCompany Report #200010
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Morphine Sulfate					
	Alkalosis	Literature	(Similar To Andas					
Other	Blood Calcium Increased	Health	74-769 And 74-862)	PS				
INTRAMUSCULAR	8 MG IM							
	Blood Creatine Phosphokinase Increased	Professional	Paroxetine Hcl	SS	`	ORAL	30 MG QD PO	2 DAYS PRIOR
	Clonic Convulsion		Ondansetron					
	Confusional State		Hydrochloride	SS			4 MG	
	Delirium		Diclofenac Sodium	C				
	Depressed Level Of Consciousness							
	Disorientation							
	Drug Interaction							
	Eye Rolling							
	Heart Rate Increased							
	Hypertension							
	Movement Disorder							
	Mydriasis							
	Oculogyration							
	Pco2 Increased							
	Pyrexia							

Reflexes Abnormal
Restlessness

Date:02/04/00ISR Number: 3452497-1Report Type:Expedited (15-DaCompany Report #B0076359A
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebellar Syndrome Confusional State Gait Disturbance	Foreign Other	Zofran Injection (Ondansetron Hydrochloride)	PS			INTRAVENOUS	INTRAVENOUS
	Pyrexia Rash Erythematous Tremor		Amikacin Sulfate (Formulation Unknown) (Amikacin Sulfate)	SS			INTRAVENOUS	INTRAVENOUS
			Idarubicin (Formulation Unknown) (Idarubicin)	SS			INTRAVENOUS	PER DAY,
			Cytarabine (Formulation				INTRAVENOUS	

				Unknown)			
				(Cytarabine)	SS		
INTRAVENOUS	PER DAY,						
INTRAVENOUS							
				Clorazepate Dipotassium (Clorazepate Dipotassium)	SS		ORAL
ORAL							
				Metoclopramide (Formulation Unknown) (Metoclopramide)	SS		
INTRAVENOUS	INTRAVENOUS						
				Cefepime	C		
				Metronidazole	C		
				Amphotericin	C		

Date:02/04/00ISR Number: 3452501-0Report Type:Expedited (15-DaCompany Report #B0076174A
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Dermatitis	Foreign	Zofran (Ondansetran			
Initial or Prolonged	Hypertension		Hydrochloride)	PS		
INTRAVENOUS INTRAVENOUS						
			Cyclophosphamide	C		
			Prednisolone	C		
			Methylprednisolone	C		

Date:02/08/00ISR Number: 3455712-3Report Type:Periodic Company Report #A0105606A
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Convulsion	Health	Zofran (Ondansetron			
Initial or Prolonged	Nervous System Disorder	Professional	Hydrochloride)	PS		ORAL
4MG FOUR						
TIMES PER DAY						

Date:02/08/00ISR Number: 3455713-5Report Type:Periodic Company Report #A0099588A
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation	Consumer	Zofran (Ondansetron Hydrochloride)	PS	8mg	ORAL		
			Compazine	C				
			Clonazepam	C				
			Paroxetine Hydrochloride	C				

Date:02/09/00ISR Number: 3455506-9Report Type:Expedited (15-DaCompany Report #2000010471FR
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebellar Syndrome	Health Professional Other	Aracytine (Cytarabine) Powder, Sterile	PS			INTRAVENOUS	365 MG, IV
	Confusional State							
	Difficulty In Walking							
	Pyrexia		Zavedos Solution, Sterile (Idarubicin Hydrochloride)	SS			INTRAVENOUS	15 MG, IV
	Rash Erythematous							
	Tremor		Amiklin (Amikacin)	SS			INTRAVENOUS	1 G, QD, IV
			Zophren (Ondansetron Hydrochloride)	SS				
			Tranxene					

				(Clorazepate Dipotassium)	SS		ORAL 30 MG, QD, ORAL
				Primperan (Metoclopramide)	SS		
INTRAVENOUS	30 MG, QD, IV						
				Azeprim	C		
				Flagyl (Metronidazole)	C		
				Furgizon	C		

Date:02/14/00ISR Number: 3458419-1Report Type:Expedited (15-DaCompany Report #B0076914A
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Disability	Inflammation Necrosis Peripheral Ischaemia	Foreign	Zofran (Formulation Unknown) (Ondansetron Hydrochloride(	PS		ORAL 8 MG / TWICE PER DAY / ORAL
			Cyclophosphamide (Formulation Unknown) (Cyclophosphamide)	SS		
INTRAVENOUS	UNK / UNK / INTRAVENOUS					
			Carboplatin (Formulation Unknown) (Carboplatin)	SS		
INTRAVENOUS	UNK / PER DAY / INTRAVENOUS					

Date:02/17/00ISR Number: 3459489-7Report Type:Expedited (15-DaCompany Report #HQ1081115FEB2000
Age:1 DY Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Asthenia	Consumer	Reglan Injection	PS		TRANSPLACENTAL	TRANSPLACENTA	
	Complications Of Maternal							
							L	4 WK
	Exposure To Therapeutic		Tpn	SS		TRANSPLACENTAL	TRANSPLACENTA	
	Drugs							
							L	4 MON
	Congenital Torticollis		Zofran	SS		TRANSPLACENTAL	TRANSPLACENTA	
	Dysphagia							
							L	4 MON
	Dystonia							
	Face Oedema							

Date:02/22/00ISR Number: 3461054-2Report Type:Expedited (15-DaCompany Report #99-178
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Propofol Injectable					
	Blood Creatinine Increased	Professional Other	Emulsion 10 Mg/Ml, Baxter	PS		SEE IMAGE		
	Blood Ph Increased		Fosphenytoin	SS		SEE IMAGE		
	Hypernatraemia		Appreselone	SS		SEE IMAGE		
	Hyperphosphataemia		Zofran	SS		SEE IMAGE		
	Hypocalcaemia		Nimotop	SS		SEE IMAGE		
	Hypotension		Dopamine	SS		SEE IMAGE		
			Tylenol	SS		SEE IMAGE		
			Pepcid Ad	SS		SEE IMAGE		
			Morphine	SS		SEE IMAGE		

			Neutraphos	SS			

SEE IMAGE

Date:02/23/00ISR Number: 3462053-7Report Type:Expedited (15-DaCompany Report #00P-056-0087027-00(0)
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebellar Syndrome Confusional State Gait Disturbance	Foreign Health Professional	Tranxene (Tranxene) (Clorazepate Dipotassium)	PS		ORAL	30 MG, 1 IN 1 D, PER ORAL	
	Pyrexia							
	Rash Erythematous		Amikacin (Amikacin)	SS		INTRAVENOUS	1 GM, 1 IN 1 D,	
	Tremor							
			Cytarabine (Cytarabine)	SS		INTRAVENOUS	365 MG, 1 IN 1 D,	
			Idarubicin Hydrochloride (Idarubicin Hydrochloride)	SS		INTRAVENOUS	15 MG, 1 IN 1 D,	
			Ondansetron Hydrochloride (Ondansetron Hydrochloride)	SS		INTRAVENOUS	INTRAVENOUS	
			Metoclopramide (Metoclopramide)	SS		INTRAVENOUS	30 MG, 1 IN 1	

D,

INTRAVENOUS

			Cefepime Hydrochloride (Cefepime Hydrochloride)	C		
			Metronidazole (Metonidazole Metronidazole)	C		

Date:02/25/00ISR Number: 3537091-6Report Type:Periodic Company Report #A0107938A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective	Consumer	Zofran Odt	PS	Glaxo Wellcome Inc	ORAL	ORAL	

Date:03/01/00ISR Number: 3470654-5Report Type:Periodic Company Report #A0109831A
Age:3 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Grand Mal Convulsion	Health Professional	Zofran Injection (Ondansetron Hjydrochloride)	PS				
Other							INTRAVENOUS	2.5 MG / UNK
							/ INTRAVENOUS	
			Cancer Chemotherapy	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/01/00ISR Number: 3470658-2Report Type:Periodic Company Report #A0104565A
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction	Health Professional Company Representative	Zofran (Formulation Unknown) (Ondansetron Hydrocholride)	PS		INTRAVENOUS	UNK /	UNK /

INTRAVENOUS

Date:03/01/00ISR Number: 3470664-8Report Type:Periodic Company Report #A0098582A
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other Required Intervention to Prevent Permanent Impairment/Damage	Agitation Chest Pain Cough Dyspnoea Nausea Throat Irritation Throat Tightness	Health Professional Company Representative	Zofran Injection (Ondansetron Hydrochloride)	PS		INTRAVENOUS	8 MG / SINGLE DOSE /	
			Zofran Tablet (Ondansetron Hydrochloride)	SS		ORAL	UNK /	UNK /

ORAL

Date:03/01/00ISR Number: 3470668-5Report Type:Periodic Company Report #A0083089A
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Reaction Angioneurotic Oedema Face Oedema Obstructive Airways	Health Professional	Zofran (Formulation Unknown) (Ondansetron Hydrochloride)	PS		INTRAVENOUS	4 MG /	UNK /

	Disorder					
INTRAVENOUS						
	Swelling					

Date:03/02/00ISR Number: 3468091-2Report Type:Expedited (15-DaCompany Report #B0075833A
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain	Foreign	Zofran Injection					
Initial or Prolonged	Constipation	Health	(Ondansetron					
	Ileus Paralytic	Professional	Hydrochloride)	PS				
INTRAVENOUS							8 MG /	WEEKLY
/ INTRAVENOUS								
			Cisplatin	C				
			Paclitaxel	C				

Date:03/02/00ISR Number: 3468103-6Report Type:Expedited (15-DaCompany Report #B0076842C
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apgar Score Low	Foreign	Zofran Injection					
	Complications Of Maternal	Health	(Ondansetron					
	Exposure To Therapeutic	Professional	Hydrochloride)	PS				
INTRAVENOUS							4 MG /	SINGLE
	Drugs							
DOSE /								
	Neonatal Apnoeic Attack							
INTRAVENOUS								
	Neonatal Respiratory Depression							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/02/00ISR Number: 3468104-8Report Type:Expedited (15-DaCompany Report #B0076842B
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apgar Score Low Complications Of Maternal Exposure To Therapeutic	Foreign Health Professional	Zofran Injection (Ondansetron Hydrochloride)	PS		INTRAVENOUS	SINGLE	DOSE/
	Drugs					INTRAVENOUS		
	Heart Rate Decreased Neonatal Apnoeic Attack Neonatal Disorder							

Date:03/03/00ISR Number: 3467740-2Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Injury	Health	Ondansetron / 8mg	PS		ORAL	8MG Q8H ORAL	
Initial or Prolonged	Road Traffic Accident	Professional	Dexamethasone 4mg	SS			10MG Q I2	
	Syncope						HOURS	

Date:03/03/00ISR Number: 3468964-0Report Type:Expedited (15-DaCompany Report #B0077870A
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Angina Pectoris	Foreign	Zofran Injection					
Initial or Prolonged	Arrhythmia		(Ondansetron					
	Electrocardiogram Qrs		Hydrochloride)	PS		INTRAVENOUS	INTRAVENOUS	
	Complex Prolonged		Remifentanil Hcl					
	Electrocardiogram Qt		(Formulation					
	Prolonged		Unknown)					
	Electrocardiogram St		(Remifentanil Hcl)	SS		INTRAVENOUS	INTRAVENOUS	
	Segment Elevation		Morphine					
	Hypokinesia		(Formulation					

		Ventricular Tachycardia	Unknown) (Morphine)	SS
INTRAVENOUS	INTRAVENOUS			
			Propacetamol (Formulation Unknown) (Propacetamol)	SS
INTRAVENOUS	INTRAVENOUS			
			Phlorogucinol (Formulation Unknown) (Phloroglucinol)	SS
INTRAVENOUS	INTRAVENOUS			
			Propofol (Formulation Unknown) (Propofol)	SS
INTRAVENOUS	INTRAVENOUS			
			Amiodarone (Formulation Unknown) (Amiodarone)	SS
			Ketoprofen	C
			Cefoxitin Sodium	C

Date:03/15/00ISR Number: 3475965-5Report Type:Expedited (15-DaCompany Report #HQ1081115FEB2000
Age:1 DY Gender:Female I/FU:F

Outcome	PT
Congenital Anomaly	Asthenia
	Complications Of Maternal Exposure To Therapeutic

		Drugs Dyskinesia Neonatal Dysphagia Dystonia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Face Oedema	Health	Reglan Injection	PS		
TRANSPLACENTAL	TRANSPLACENTA						
		Feeding Problem In	Professional				
L	4 MON						
		Newborn		Tpn	SS		
TRANSPLACENTAL	TRANSPLACENTA						
		Muscle Contractions					
L	4 MON						
		Involuntary		Zofran	SS		
TRANSPLACENTAL	TRANSPLACENTA						
		Nervous System Disorder					
L	4 MON						
		Torticollis					

Date:03/23/00ISR Number: 3479183-6Report Type:Expedited (15-DaCompany Report #A0114791A
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Hepatic Enzyme Increased Hepatitis Hyperglycaemia	Health Professional	Zofran Injection-Premixed (Ondansetron Hydrochloride)	PS		
INTRAVENOUS	24 MG, MONTHLY,					
INTRAVENOUS			Cyclophosphamide (Formulation Unknown) (Cyclophosphamide)	SS		
INTRAVENOUS	MONTHLY,					
INTRAVENOUS			Interferon Beta-1a (Formulation Unknown) (Interferon Beta-1a)	SS		
INTRAMUSCULAR	INTRAMUSCULAR					

Date:03/23/00ISR Number: 3479186-1Report Type:Expedited (15-DaCompany Report #A0077568A
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Arrhythmia	Literature	Zofran Injection					
	Supraventricular	Health	(Ondansetron					
	Chest Pain	Professional	Hydrochloride)	PS				
INTRAVENOUS	2 MG SINGLE							
	Condition Aggravated	Company						
DOSE,								
	Dyspnoea	Representative						
INTRAVENOUS								
	Electrocardiogram St		Droperidol	C				
	Segment Abnormal		Ropivacaine Hcl	C				
	Hypertension		Fentanyl	C				
	Myocardial Ischaemia							
	Supraventricular							
	Tachycardia							
	Ventricular Arrhythmia							
	Ventricular Tachycardia							

Date:03/23/00ISR Number: 3479204-0Report Type:Expedited (15-DaCompany Report #A0096542A
Age:60 YR Gender:Female I/FU:F

Outcome	PT
Required	Arrhythmia
Intervention to	Chest Pain
Prevent Permanent	Electrocardiogram St
Impairment/Damage	Segment Depression
	Hypertension

		Myocardial Infarction Ventricular Extrasystoles Ventricular Tachycardia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Literature Health Professional	Zofran Injection (Ondansetron Hydrochloride)	PS		
INTRAVENOUS	2 MG / SINGLE						
DOSE /							
INTRAVENOUS							
				Droperidol	C		
				Ropivacaine Hcl	C		
				Fentanyl	C		

Date:03/23/00ISR Number: 3479218-0Report Type:Expedited (15-DaCompany Report #A0115296A
Age:3 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Cyanosis Joint Stiffness	Health Professional	Zofran Injection (Ondansetron Hydrochloride)	PS		
INTRAVENOUS	2 MG/MIN /					
SINGLE DOSE						
/						
INTRAVENOUS						

Date:03/30/00ISR Number: 3482134-1Report Type:Expedited (15-DaCompany Report #B0064401A
Age:7 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Alanine Aminotransferase Increased Benign Congenital	Foreign Health Professional	Zofran Tablet (Ondansetron Hydrochloride)	PS		ORAL
ORAL						
	Hypotonia Blood Alkaline		Zofran Injection (Ondansetron			

		Phosphatase Increased		Hydrochloride)	SS		
INTRAMUSCULAR	4 MG/	Caesarean Section					
INTRAMUSCULAR		Complications Of Maternal Exposure To Therapeutic Drugs Congenital Central Nervous System Anomaly Cytomegalovirus Infection Deafness Developmental Delay Facial Dysmorphism Movement Disorder Posturing Tremor		Thiamine Domperidone Ranitidine Hydrochloride Cyclizine	C C C C		

Date:04/03/00ISR Number: 3482947-6Report Type:Direct Company Report #
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills Hypertension Tremor		Navelbine 30mg Zofran 32mg-Ivpb	PS SS				WEEKLY WEEKLY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/03/00ISR Number: 3484036-3Report Type:Expedited (15-DaCompany Report #B0079206A
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthma	Foreign	Zofran	PS				
INTRAVENOUS							8 MG /	MONTHLY /
	Bronchospasm							
	Cyanosis							
INTRAVENOUS								
	Drug Hypersensitivity		Mesna (Formulation Unknown) (Mesna)	SS				
	Dyspnoea							
INTRAVENOUS							200 MG /	MONTHLY /
INTRAVENOUS								
			Methylprednisolone (Methylprednisolone)	SS				
INTRAVENOUS							1 G / MONTHLY	/
/ INTRAVENOUS								
			Omeprazole	C				
			Prednisolone	C				
			Co-Trimoxazole	C				
			Co-Codamol	C				
			Cyclophosphamide	C				

Date:04/05/00ISR Number: 3484543-3Report Type:Expedited (15-DaCompany Report #B0079468A
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign	Zofran Injection (Ondansetron Hydrochloride)	PS				
	Epilepsy							
INTRAVENOUS	INTRAVENOUS							
	Muscle Twitching		Terbutaline	C				
	Opisthotonus							

Date:04/06/00ISR Number: 3485008-5Report Type:Expedited (15-DaCompany Report #A0113373A
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain	Foreign	Navelbine Injection					
Hospitalization - Initial or Prolonged	Anaemia	Literature	(Vinorelbine					
	Liver Function Test	Health	Tartrate)	PS		INTRAVENOUS	35 MG/ SEE	
Other	Abnormal	Professional						
	Neutropenia					INTRAVENOUS		
	Oedema		Doxorubicin					
	Pancreatitis		(Formulation					
	Pyrexia		Unknown)					
	Vomiting		(Doxorubicin)	SS			70 MG/ SEE	
							TEXT/ UNKNOWN	
			Zofran Injection					
			(Ondansetron					
			Hydrochloride)	SS		INTRAVENOUS	8 MG/ SEE	
							TEXT/	
						INTRAVENOUS		
			Me-Prednisolone Na					
			Succ. Injection					
			(Me-Prednisolone Na					
			Succ.)	SS		INTRAVENOUS	8 MG/ SEE	
							TEXT/	
						INTRAVENOUS		
			Clorazepate					
			Dipotassium					
			Injection					
			(Clorazepate					

			Dipotassium)	SS		
INTRAVENOUS	20 MG/ SEE					
TEXT/						
INTRAVENOUS						
			Thyroxine Sodium	C		
			Lithium Carbonate	C		
			Metoclopramide	C		
			Radiotherapy	C		
			Kytril	C		
			Alizapride Hydrochloride	C		
			Metopimazine	C		

Date:04/07/00ISR Number: 3484948-0Report Type:Direct Company Report #
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Aortic Aneurysm Bradycardia		Zofran 4mg/2ml Inj (Glaxo)	PS	Glaxo	
INTRAVENOUS 8 MG IV X 1						
	Coma					
	Confusional State					
	Hypotension					
	Hypoventilation					
	Skin Discolouration					

Date:04/10/00ISR Number: 3486542-4Report Type:Expedited (15-DaCompany Report #A0117039A
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Intestinal Obstruction	Consumer	Zofran Tablet (Ondansetron Hydrochloride)	PS		ORAL
8 MG / TWICE						
PER DAY /						
ORAL						
			Chlorambucil	C		
			Docusate Sodium	C		

Date:04/12/00ISR Number: 3487377-9Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Disorientation Movement Disorder	Health Professional	Zofran 2mg Iv	PS		INTRAVENOUS	2-4 MG IV Q 6 H PRN	

Date:04/12/00ISR Number: 3487560-2Report Type:Expedited (15-DaCompany Report #033-0955-M0000005
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Hepatic Failure Lobar Pneumonia Renal Failure Acute Shock	Foreign Health Professional	Acuilix Tablets (Hydrochlorothiazide, Quinapril) Zyloric (Allopurinol) Zophren (Ondansetron Hydrochloride) Nipent (Pentostatin)	PS SS SS SS		ORAL ORAL INTRAVENOUS ORAL	PER ORAL PER ORAL INTRAVENOUS 75 MG (DAILY), PER ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/20/00ISR Number: 3490804-4Report Type:Expedited (15-DaCompany Report #A0118311A
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Tremor	Health Professional	Zofran Tablet (Ondansetron Hydrochloride)	PS				

Date:04/20/00ISR Number: 3490832-9Report Type:Expedited (15-DaCompany Report #A0105858A
Age:55 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aphonia Chills Hypotension Pharyngeal Oedema Pruritus Pyrexia Tongue Oedema Urticaria	Health Professional	Zofran Tablet (Ondansetron Hydrochloride)	PS		ORAL	ORAL	

Date:04/28/00ISR Number: 3494330-8Report Type:Expedited (15-DaCompany Report #A0118763A
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Required Intervention to Prevent Permanent Impairment/Damage	Coma Dizziness Flushing Hypotension Respiratory Failure Vomiting	Health Professional	Zofran (Formulation Unknown) Zantac (Formulation Unknown) (Ranitidine Hydrochloride)	PS SS		INTRAVENOUS INTRAVENOUS	INTRAVENOUS INTRAVENOUS	

Date:05/10/00ISR Number: 3498979-8Report Type:Expedited (15-DaCompany Report #A0114791A
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Hepatitis Hyperglycaemia	Health Professional	Zofran Injection-Premixed (Ondansetron Hydrochloride)	PS		INTRAVENOUS	24 MG / MONTHLY /	
			Cyclophosphamide (Formulation Unknown) (Cyclophosphamide)	SS		INTRAVENOUS	MONTHLY /	
			Interferon Beta-La (Formulation Unknown) (Interferon Beta-La)	SS		INTRAMUSCULAR	3 MCG / WEEKLY /	
			Acyclovir	C		INTRAMUSCULAR		
			Alprazolam	C				
			Azathioprine	C				

Date:05/16/00ISR Number: 3501043-2Report Type:Expedited (15-DaCompany Report #A0118311A
Age:23 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Tremor	Health Professional	Zofran Injection (Ondansetron Hydrochloride)	PS	Glaxo Wellcome Inc	INTRAVENOUS	4 MG/ SINGLE	
Intervention to Prevent Permanent Impairment/Damage			Gabapentin	C		INTRAVENOUS	DOSE/	
			Int./Long-Acting Insulin	C				
			Salbutamol Sulphate	C				
			Metoclopramide Hcl	C				
			Tussin Dm	C				
			Bupropion Hydrochloride	C				
			Imipramine Oxide Hcl	C				
			Multivitamin	C				
			Risperidone	C				
			Cephazolin Sodium	C				
			Propofol	C				
			Midazolam Hydrochloride	C				
			Fentanyl	C				
			Bupivacaine Hydrochloride	C				

Date:05/22/00ISR Number: 3503551-7Report Type:Expedited (15-DaCompany Report #1999005153GB
Age:7 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Toxic Epidermal Necrolysis	Foreign Health Professional	Neosar	PS	Pharmacia And Upjohn Co	INTRAVENOUS	1044 MG, QD,	
		Other	Cyclosporin A (Ciclosporin)	SS		IV	45 MG, BID,	

UNK		Codeine Phosphate (Cyclophosphamide)	SS	ORAL
15 MG, QD,				
ORAL		Chlorpheniramine (Chlorphenamine)	SS	
4 MG, PRN,				
UNK		Paracetamol (Paracetamol)	SS	ORAL
360 MG, PRN,				
ORAL		Vancomycin (Vancomycin)	SS	
INTRAVENOUS	270 MG, TID,			
IV		Ceftazidime (Ceftazidime)	SS	
INTRAVENOUS	900 MG, TID,			
IV		Fludarabine (Fludarabine)	SS	
INTRAVENOUS	18 MG, QD, IV	Ondansetron (Ondansetron)	SS	
4 MG, PRN,				
UNK		Anti-Humanlymphozyte n-Globulin (Antilymphocyte		

		Immunoglobulin (Horse))	SS	
INTRAVENOUS	219 MG, QD, IV			
		Metoclopramide (Metoclopramide)	SS	
5 MG, PRN, UNK				
		Meropenem (Meropenem)	SS	
INTRAVENOUS	360 MG, TID, IV			
		Acyclovir (Aciclovir)	SS	
INTRAVENOUS	175 MG, TID, IV			
		Fluconazole (Fluconazole)	SS	ORAL
50 MG, QD, ORAL				
		Nifedipine (Nifedipine)	SS	ORAL
5 MG, PRN, ORAL				
		Sandoglobulin (Immunoglobulin Human Normal)	SS	
INTRAVENOUS	16.7 G, WEEKLY, IV			
		Cyklokapron (Tranexamic Acid) Tablet	SS	ORAL
400 MG, TID, ORAL				

Date:05/24/00ISR Number: 3504527-6Report Type:Expedited (15-DaCompany Report #A0120718A
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Dystonia Mental Impairment Movement Disorder	Health Professional	Zofran Omeprazole Capsule (Omeprazole) Cyclophosphamide Cytarabine	PS SS C C	Glaxo Wellcome Inc	INTRAVENOUS ORAL	.15 ML/KG/HR/ ORAL	

Date:06/05/00ISR Number: 3508602-1Report Type:Expedited (15-DaCompany Report #8-99133-128A
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Bilirubin Increased Hepatic Function Abnormal Hepatocellular Damage Liver Function Test Abnormal	Health Professional	Lodine Klaricid (Clarithromycin) Lastet (Etoposide) Neu-Up (Nartograstim) Randa (Cisplatin) Zofran (Ondansetron Hydrochloride) Klaricid Lastet Mucosolvan Neu-Up Radiation Therapy	PS SS SS SS SS SS C C C C C	Wyeth Ayerst Laboratories Inc	ORAL ORAL INTRAVENOUS SUBCUTANEOUS INTRAVENOUS ORAL	400 MG ORAL 400 MG DAILY 100 MG DAILY 50-100 MCG SC 80 MG DAILY 5 MG ORAL	26 DAY 6 WK 2 DAY 15 DAY 1 DAY 7 DAY

			Randa	C		
			Zofran	C		

Date:06/05/00ISR Number: 3509608-9Report Type:Expedited (15-DaCompany Report #A0117039A
Age:73 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation Intestinal Obstruction	Consumer	Zofran	PS	Glaxo Wellcome Inc	ORAL	8 MG /TWICE PER DAY/	
			Chlorambucil	C				
			Docusate Sodium	C				

Date:06/12/00ISR Number: 3512044-2Report Type:Expedited (15-DaCompany Report #A0118763A
Age:57 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Health	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS		UNKNOWN
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Depressed Level Of Consciousness Dizziness Flushing Hypotension Pulse Absent Respiratory Failure Vomiting	Professional	Zantac (Formulation Unknown) (Ranitidine Hydrochloride) Citalopram Hydrobromide	SS C		INTRAVENOUS		UNKNOWN

Date:06/14/00ISR Number: 3514800-3Report Type:Expedited (15-DaCompany Report #B0076952A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Complications Of Maternal Exposure To Therapeutic	Foreign Health	Zofran Folic Acid	PS C	Glaxo Wellcome Inc			

	Drugs	Professional	Calsium Salt	C			
	Heart Disease Congenital						
	Pulmonary Artery Atresia						
	Ventricular Hypoplasia						

Date:06/16/00ISR Number: 3514703-4Report Type:Direct Company Report #
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Diastolic Decreased		Gemzar 1gm Vials (Lilly)	PS	Lilly	INTRAVENOUS	1500MG IV Q WEEK	
	Dermatitis							
	Pruritus		Zofran 8mg Tablets (Glaxo)	SS	Glaxo		16MG PO Q WEEK	
	Pyrexia							
	Rash Erythematous							
	Skin Exfoliation		Compazine	C				
	Urticaria		Zofran	C				

Date:06/26/00ISR Number: 3519801-7Report Type:Expedited (15-DaCompany Report #A0120718A
Age:13 YR Gender:Female I/FU:F

Outcome
Hospitalization - Initial or Prolonged

Disability

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Communication Disorder	Health	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	.15	
	Conversion Disorder	Professional					ML/KG/HR/INTR	
	Drug Interaction						AVENOUS	
	Dystonia		Omeprazole Capsule					
	Encephalopathy		(Omeprazole)	SS		ORAL	ORAL	
	Mental Impairment		Zofran Tablet					
	Movement Disorder		(Ondansetron					
	Neurotoxicity		Hydrochloride)	SS		ORAL	ORAL	
	Speech Disorder		Methotrexate					
			(Formulation					
			Unknown)					
			(Methotrexate)	SS			INTRATHECAL	12 MG / PER
							DAY /	
							INTRATHECAL	
			Cyclophosphamide	C				
			Cytarabine	C				

Date:06/28/00ISR Number: 3521463-XReport Type:Expedited (15-DaCompany Report #A0122803A
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Bilirubin Increased	Health	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	32 MG/SEE	
Initial or Prolonged	Jaundice	Professional					TEXT/INTRAVEN	
	Liver Function Test						OUS	
	Abnormal		Nafcillin					
			(Nafcillin)	SS				
			Sertraline					
			Hydrochloride	C				
			Anzemet	C				

Date:06/29/00ISR Number: 3522246-7Report Type:Expedited (15-DaCompany Report #10422772
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Enzyme Increased Hepatic Necrosis Hepatitis Hyperglycaemia	Study Health Professional	Cytoxan Inj (Cyclophosphamide)	PS	Bristol Myers Squibb Co Pharmaceutical Research Institute	INTRAVENOUS	1/1 MONTH IV	
			Zofran (Ondansetron Hcl)	SS		INTRAVENOUS	24 MILLIGRAM,	1/1 MONTH IV
			Interferon Beta-1a	SS		INTRAMUSCULAR	IM	

Date:07/05/00ISR Number: 3523850-2Report Type:Direct Company Report #
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anxiety		Ondansetron	PS		INTRAVENOUS	4MG IV	
	Condition Aggravated Nausea		Sudafed Morphine Percocet Ibuprofen	C C C C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/11/00ISR Number: 3527332-3Report Type:Expedited (15-DaCompany Report #B0083692A
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apnoea	Foreign	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	UNK / UNK	/
	Bradycardia					INTRAVENOUS		
	Coma		Venlafaxine Hydrochloride	C				
			Alfentanil Hydrochloride	C				
			Propofol	C				
			Vecuronium	C				
			Cyclizine	C				

Date:07/17/00ISR Number: 3530747-0Report Type:Expedited (15-DaCompany Report #A0122803A
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Bilirubin Increased	Health Professional	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	32 MG/ SEE TEXT/	
	Blood Glucose Increased							
	Blood Urea Decreased					INTRAVENOUS		
	Jaundice		Nafcillin (Formulation Unknown) (Nafcillin)	SS				
	Liver Function Test Abnormal							
			Sertraline Hydrochloride	C				
			Anzemet	C				

Date:07/31/00ISR Number: 3538881-6Report Type:Expedited (15-DaCompany Report #A0124892A
Age:2 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Complications Of Maternal	Consumer	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	FOUR TIMES	

Initial or Prolonged	Exposure To Therapeutic						
PER							
Other	Drugs						
DAY/INTRAVENO							
	Dehydration						
US							
	Food Allergy		Zofran Tablet				
	Gastrointestinal Disorder		(Ondansetron				
	Movement Disorder		Hydrochloride)	SS			ORAL
AS REQUIRED/							
	Multiple Allergies						
ORAL							
	Pneumonia						
	Pyrexia						
	Screaming						
	Urticaria						
	Viral Infection						
	Vomiting						

Date:08/01/00ISR Number: 3539388-2Report Type:Expedited (15-DaCompany Report #B0084746A
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Fungal Infection	Foreign	Zofran	PS	Glaxo Wellcome Inc			
INTRAVENOUS	INTRAVENOUS							
Hospitalization -	Gastritis		Calcium Folinate					
Initial or Prolonged	Mucosal Inflammation		Injection (Calcium					
	Necrosis		Folinate)	SS				
INTRAVENOUS	INTRAVENOUS							
	Oesophageal Disorder		Metoclopramide Hcl					
	Oesophagitis		(Formulation					
	Sepsis		Unknown)					
			(Metoclopramide Hcl)	SS		ORAL		
ORAL								

				Fluorouracil (Formulation Unknown) (Fluorouracil)	SS		
INTRAVENOUS	INTRAVENOUS						
				Oxaliplatin Injection (Oxaliplatin)	SS		
INTRAVENOUS	INTRAVENOUS						
				Ondansetron Hydrochloride	C		

Date:08/08/00ISR Number: 3545176-3Report Type:Expedited (15-DaCompany Report #B0083574A
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Magnesium Decreased	Foreign	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	8 MG /	TWICE PER DAY /
	Cardiac Arrest	Health						
	Electrocardiogram Qt Corrected Interval Prolonged	Professional	Amsacrine Injection	SS		INTRAVENOUS	140 MG /	INTRAVENOUS INFUSION
	Prolonged		Etoposide	C				
	Hypokalaemia		Cytarabine	C				
	Ventricular Fibrillation		Allopurinol	C				
			Metronidazole	C				
			Sennosides	C				

Date:08/15/00ISR Number: 3551094-7Report Type:Expedited (15-DaCompany Report #B0085306A
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Hearing Impaired	Foreign	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	PER	

	Ototoxicity					
DAY/INTRAVENO						
US						
			Cisplatin Solution (Cisplatin)	SS		
INTRAVENOUS PER						
DAY/INTRAVENO						
US						
			Navelbine Injection (Vinorelbine Tartrate)	SS		

Date:08/15/00ISR Number: 3552925-7Report Type:Periodic Company Report #20000400233
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Amnesia	Consumer	Xylocaine	PS	Astrazeneca Lp	
	Nausea		Morphine	SS		
	Vomiting		Versed	SS		
			Diprivan	SS		
			Zofran	SS		
			Zemuron	SS		
			Inapsine	SS		
			Fentanyl Citrate	SS		
			Ephedrine	SS		
			Versed	SS		
			Diprivan	SS		
			Morphine	SS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/28/00ISR Number: 3559645-3Report Type:Direct Company Report #
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Torsade De Pointes Ventricular Tachycardia		Phenergan 12.5mg Iv X 2	PS		INTRAVENOUS	12.5MG IV X 2	
			Zofran 4mg Iv X 1	SS		INTRAVENOUS	4MG IV X 1	

Date:08/30/00ISR Number: 3561862-3Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion		Zofran	PS			4 MG/50 ML	D5W QD OVER 15 MINUTES
			D5rl With Mvi	C				
			Heparin	C				
			Saline Flushes	C				

Date:09/05/00ISR Number: 3565317-1Report Type:Expedited (15-DaCompany Report #A0126667A
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia	Health Professional	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	INTRAVENOUS	
	Confusional State Dysarthria		Ondansetron Hydrchloride Unspecified Tablet (Ondansetron Hydrochloride)	C		ORAL	ORAL	
			Aspirin	C				
			Unknown	C				

Date:09/06/00ISR Number: 3566524-4Report Type:Expedited (15-DaCompany Report #B0083574A
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Magnesium Decreased	Foreign	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	8 MG (TWICE	
	Cardiac Arrest	Health					PER DAY)	
	Drug Interaction	Professional					INTRAVENOUS	
	Electrocardiogram Qt Corrected Interval		Amsacrine Injection (Amsacrine)	SS		INTRAVENOUS	140 MG	
	Prolonged						INTRAVENOUS	
	Electrocardiogram Qt						INFUSION	
	Prolonged		Etoposide	C				
	Hypokalaemia		Cytarabine	C				
	Ventricular Fibrillation		Allopurinol	C				
			Metronidazole	C				
			Sennosides	C				

Date:09/11/00ISR Number: 3569315-3Report Type:Expedited (15-DaCompany Report #B0086871A
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis	Foreign	Zofran Preservative Free	PS	Glaxo Wellcome Inc	INTRAVENOUS	24 MG / PER	
	Jaundice						DAY /	
	Liver Disorder						INTRAVENOUS	
	Liver Function Test Abnormal		Cisplatin Injection					

			(Cisplatin)	SS		
INTRAVENOUS	52 MG / PER DAY / INTRAVENOUS					
			Fluorouracil Injection (Fluorouracil)	SS		
INTRAVENOUS	1000 MG / PER DAY / INTRAVENOUS					
			Calcium Folinate Sterile Powder (Calcium Folinate)	SS		
INTRAVENOUS	175 MG / PER DAY / INTRAVENOUS					
			Dextroprop. + Paracetamol Capsule (Propoxyphen + Acetaminop)	SS		ORAL
THREE TIMES PER DAY / ORAL						
			Glibenclamide	C		
			Metformin	C		

Date:09/13/00ISR Number: 3571222-7Report Type:Expedited (15-DaCompany Report #A0127054A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Complications Of Maternal Exposure To Therapeutic Drugs Intra-Uterine Death	Health Professional	Zofran	PS	Glaxo Wellcome Inc	

Date:09/13/00ISR Number: 3571226-4Report Type:Expedited (15-DaCompany Report #A0127057A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal Exposure To Therapeutic Drugs Intra-Uterine Death	Health Professional	Zofran	PS	Glaxo Wellcome Inc			

Date:09/13/00ISR Number: 3571229-XReport Type:Expedited (15-DaCompany Report #A0127336A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Congenital Anomaly	Chromosome Abnormality Complications Of Maternal Exposure To Therapeutic Drugs Ear Malformation Foetal Disorder Premature Baby Renal Cyst Syndactyly	Consumer	Zofran	PS	Glaxo Wellcome Inc			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/14/00ISR Number: 3570944-1Report Type:Direct Company Report #
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Akathisia		Ondansetron 4mg Iv					
	Dystonia		Q4hr Prn	PS				
INTRAVENOUS							4MG IV Q4HR	
PRN								

Date:09/14/00ISR Number: 3571834-0Report Type:Expedited (15-DaCompany Report #HQ0864911SEP2000
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation	Foreign	Morphine Sulfate	PS				
INTRAVENOUS							8.0 MG	
	Blood Creatine	Literature						
INTRAOPERATIV								
	Phosphokinase Increased	Other						
ELY								
	Clonic Convulsion		Ondansetron					
	Confusional State		(Ondansetron)	SS				
4 MG DURING								
	Delirium							
INDUCTION								
	Drug Interaction		Paroxetine					
	Dyskinesia		([Paroxetine)	SS		ORAL		
30 MG DAILY								
	Eye Disorder							
	Hyperreflexia							
	Hypertension							
	Post Procedural Complication							
	Pyrexia							

Date:09/15/00ISR Number: 3572015-7Report Type:Direct Company Report #
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Life-Threatening	Dyspnoea		Zofran 4 Mg	PS		
ONE DOSE						
	Hypoaesthesia					
	Paralysis					

Date:09/22/00ISR Number: 3578887-4Report Type:Expedited (15-DaCompany Report #10536688
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Lung Infiltration	Foreign	Blenoxane	PS	Bristol Myers Co	
INTRAVENOUS 25, IV						
		Health	G-Csf (Granulocyte			
		Professional	Csf)	SS		
		Other	Cisplatin	SS		
			Etoposide	SS		
			Ondansetron Hcl	SS		
			Dexamethasone	SS		

Date:09/25/00ISR Number: 3579384-2Report Type:Expedited (15-DaCompany Report #HQ0864911SEP2000
Age:49 YR Gender:Female I/FU:F

Outcome	PT
Other	Abnormal Behaviour
	Agitation
	Amnesia
	Blood Creatine
	Phosphokinase Increased
	Clonic Convulsion
	Confusional State

		Delirium					
		Drug Interaction					
		Eye Rolling	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Hyperreflexia	Literature	Morphine Sulfate			
		Hypertension		(Morphine Sulfate)	PS		
INTRAVENOUS	8.0 MG						
		Mydriasis					
INTRAOPERATIV							
		Pyrexia					
ELY							
		Restlessness					
INTRAVENOUS							
		Tachycardia		Ondansetron			
				(Ondansetron)	SS		
				Paroxetine			
				(Paroxetine)	SS		ORAL
ORAL							
				Diclofenac	C		
				Enflurane	C		
				Indomethacin	C		
				Nitrous Oxide	C		
				Oxygen	C		
				Propofol	C		

Date:09/26/00ISR Number: 3580567-6Report Type:Expedited (15-DaCompany Report #A0128321A
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Blindness	Health	Zofran	PS	Glaxo Wellcome Inc	
INTRAVENOUS	4 MG/ SIX					
Initial or Prolonged	Overdose	Professional				
TIMES PER						
DAY/						
INTRAVENOUS						
			Fluconazole	C		
			Amitriptyline Hcl	C		
			Famotidine	C		
			Augmentin	C		

Date:09/28/00ISR Number: 3584450-1Report Type:Expedited (15-DaCompany Report #HQ1090416SEP2000
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Back Pain Constipation Haemoglobin Decreased Hyponatraemia Ileus Paralytic	Health Professional	Codeine Sulfate, Usp (Codeine Sulfate, Tablet)	PS			INTRAVENOUS 85 MG,	
			Doxorubicin Hydrochloride (Doxorubicin Hydrochloride,)	SS			INTRAVENOUS 1 DAY	
			Zofran (Ondansetron Hydrochloride,)	SS			4 DAY	
			Magnesia W/Alumina (Aluminium Carbonate/ Magnesium Oxide)	C				
			Pamol (Paracetamol)	C				

Date:10/02/00ISR Number: 3585654-4Report Type:Expedited (15-DaCompany Report #B0088000A
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Myocardial Ischaemia Volvulus Of Bowel	Foreign Study

			Health Professional				
				Product	Role	Manufacturer	Route
Dose	Duration						
				Zofran	PS	Glaxo Wellcome Inc	ORAL
UNK / UNK / ORAL							

Date:10/04/00ISR Number: 3587622-5Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Bradycardia	Health	Ondansetron (Zofran)			
Required	Coma	Professional	2mg Iv X 1	PS		
INTRAVENOUS	2MG IV X 1					
Intervention to Prevent Permanent Impairment/Damage	Hypotension		Cefazolin	C		
			Mylanta Ms	C		
			Furosemide	C		
			Evalaprilat	C		
			Metoprolol	C		
			Droperidol	C		
			Reg Insulin	C		

Date:10/05/00ISR Number: 3589251-6Report Type:Expedited (15-DaCompany Report #2000031060GB
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Bronchospasm	Foreign	Solu-Medrol	PS	Pharmacia And Upjohn Co	
	Cyanosis	Health				
INTRAVENOUS	1 G, UNK, IV					
	Dyspnoea	Professional	Mesna (Mesna)	SS		
INTRAVENOUS	100 MG/ML					
	Malaise	Other				
UNK, IV						
			Ondansetron (Ondansetron)	SS		
INTRAVENOUS	8 MG, UNK, IV					
			Omeprazole (Omeprazole)	C		
			Prednisolone			

				(Prednisolone)	C		
				Co-Trimoxazole (Sulfamethoxazole, Trimethoprim)	C		
				Co-Codamol (Paracetamol, Codeine Phosphate)	C		
				Cyclophosphamide (Cyclophosphamide)	C		

Date:10/06/00ISR Number: 3590986-XReport Type:Expedited (15-DaCompany Report #B0088545A
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Constipation Renal Colic	Foreign Health Professional	Zofran Bms188797 Injection	PS SS	Glaxo Wellcome Inc	
INTRAVENOUS 187 MG / UNK / INTRAVENOUS INFUSION						
			Doxorubicin Injection (Doxorubicin)	SS		
INTRAVENOUS 85 MG / UNK / INTRAVENOUS INFUSION						
			Codeine (Formulation Unknown) (Codeine)	SS		

			Magnesium Oxide	C		
			Paracetamol	C		

Date:10/06/00ISR Number: 3590990-1Report Type:Expedited (15-DaCompany Report #10546257
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Arterial Occlusive	Foreign	Mesnex	PS	Asta Pharma Ag	
Other	Disease	Health	Sendoxan (Cyclophosphamide)	SS		
	Feeling Cold	Professional	Zofran (Ondansetron Hcl)	SS		
	Liver Function Test Abnormal	Other	Prednisolone (Prednisolone)	C		
	Pain In Extremity		Imurel (Azathioprine Sodium)	C		
			Renitec (Enalapril Maleate)	C		
			Furix (Furosemide)	C		
			Voltaren (Diclofenac Sodium)	C		
			Restovar (Ethinyl Estradiol + Lynestrenol)	C		

Date:10/10/00ISR Number: 3592035-6Report Type:Expedited (15-DaCompany Report #2000-09-1530
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Agranulocytosis	Foreign	Halazepam	PS	Schering Corp Sub Schering Plough Corp	ORAL
Hospitalization - ORAL MON	Leukopenia	Health				
Initial or Prolonged	Lymphocytosis	Professional	Metamizole Magnesium			
	Plasmacytosis	Distributor	Capsules	SS		ORAL
575 MG PRN						
	Pyrexia					
ORAL						
			Metamizole Magnesium Injectable	SS		
INTRAVENOUS 8 GM/DAY						

INTRAVENOUS			
ORAL	MON		
INTRAVENOUS	2 MG		
INTRAVENOUS			
INTRAVENOUS	4 MG		
INTRAVENOUS			
10 MG			
INTRAVENOUS	INTRAVENOUS		
INTRAVENOUS	INTRAVENOUS		
INTRAVENOUS	INTRAVENOUS		
INTRAVENOUS	INTRAVENOUS		
INTRAVENOUS	INTRAVENOUS		
INTRAVENOUS	INTRAVENOUS		
INTRAVENOUS	INTRAVENOUS		
INTRAVENOUS	INTRAVENOUS		
		Alprazolam Orals	SS
		Morphine Injectable	SS
		Zofran	SS
		Adalat	SS
		Midazolam	SS
		Sevorane (Sevoflurane)	SS
		Rocuronium Bromide	SS
		Propofol	SS
		Atropine	SS
		Neostigmine Methylsulfate	SS
		Fentanest	SS
		Remifentanil Injectable	SS

ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/10/00ISR Number: 3592085-XReport Type:Expedited (15-DaCompany Report #817#1#2000-03326
Age:32 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Arterial Occlusive	Health	Cyclophosphamide	PS	Asta Medica Inc		600 MILLIGRAM	
	Disease	Professional	Uromitexan (Mesna)	SS				
	Chills		Zofran (Ondansetron Hydrochloride)	SS				
	Liver Function Test Abnormal		Prednisolone (Prednisolone)	C				
	Pain In Extremity		Imurel (Azathioprine)	C				
	Pulse Absent		Renitec (Enalapril Maleate)	C				
			Furix (Furosemide)	C				
			Restovar (Ethinylestradiol, Lynestrenol)	C				
			Voltaren (Diclofenac Sodium)	C				

Date:10/16/00ISR Number: 3595991-5Report Type:Expedited (15-DaCompany Report #B0064401A
Age:7 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal	Foreign	Zofran	PS	Glaxo Wellcome Inc	ORAL	ORAL	
	Exposure To Therapeutic Drugs	Health Professional	Zofran Injection (Ondansetron Hydrochloride)	SS				
	Cytomegalovirus Infection						INTRAMUSCULAR	4 MG/
	Deafness						INTRAMUSCULAR	
	Developmental Delay		Thiamine	C				
	Dystonia		Domperidone	C				
	Facial Dysmorphism		Ranitidine Hydrochloride	C				
	Hypotonia		Cyclizine	C				
	Liver Function Test Abnormal							
	Movement Disorder							
	Nervous System Disorder							
	Posturing							

Tremor

Date:10/16/00ISR Number: 3596200-3Report Type:Expedited (15-DaCompany Report #10536696
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Toxicity	Foreign	Platinol	PS				
INTRAVENOUS						IV		
	Lung Disorder	Health	Bleomycin Sulfate	SS	Bristol Myers Co			
INTRAVENOUS						IV		
	Lung Infiltration	Professional	Etoposide	SS				
INTRAVENOUS						IV		
	Pulmonary Function Test Abnormal	Other	Zofran (Odansetron Hcl)	SS				
			G-Csf (Granulocyte Csf)	SS				
			Metoclopramide Hcl	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/17/00ISR Number: 3596588-3Report Type:Direct Company Report #
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Urticaria		Zofran	PS		INTRAVENOUS	4MGM IV	
			Versed	C				
			Propofol	C				

Date:10/20/00ISR Number: 3598190-6Report Type:Expedited (15-DaCompany Report #B0089472A
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation		Ondansetron	PS	Glaxo Wellcome	INTRAMUSCULAR	4MG PER DAY	1 DAY
	Back Disorder		Doxycycline	C		ORAL	100MG TWICE	PER DAY
	Chest Discomfort							
	Chest Pain		Fluoxetine	C		ORAL		
	Dyspnoea		Paracetamol	C		ORAL	1G FOUR TIMES	PER DAY
	Musculoskeletal Disorder							
	Opisthotonus		Diclofenac	C		ORAL	50MG THREE	TIMES PER DAY
	Pharyngeal Oedema							
	Throat Tightness		Cefuroxime	C	Glaxo Wellcome	INTRAVENOUS	750MG THREE	TIMES PER DAY
	Tremor							
			Metronidazole	C		INTRAVENOUS	500MG THREE	TIMES PER DAY
			Pethidine	C		INTRAMUSCULAR		

Date:10/23/00ISR Number: 3599074-XReport Type:Expedited (15-DaCompany Report #B0088000A
Age:75 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Myocardial Ischaemia Volvulus Of Bowel		Ondansetron	PS	Glaxo Wellcome	ORAL	8MG TWICE PER DAY	2 DAY
			Dexamethasone	SS		ORAL	1 DAY	
			Fluorouracil	C			INTRAVENOUS	2 DAY

Date:10/23/00ISR Number: 3599897-7Report Type:Expedited (15-DaCompany Report #B0088000A
Age:75 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Volvulus Of Bowel	Foreign Study Health Professional	Zofran	PS	Glaxo Wellcome Inc	ORAL	8 MG / TWICE PER DAY / ORAL	
			Dexamethasone (Dexamethasone)	SS		ORAL	ORAL	
			Fluorouracil	C				

Date:10/23/00ISR Number: 3600448-9Report Type:Expedited (15-DaCompany Report #B0089472A
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Agitation Chest Discomfort Chest Pain Dyspnoea Opisthotonus Pharyngeal Oedema Throat Tightness Tremor	Foreign	Zofran Doxycycline Fluoxetine Paracetamol Diclofenac Cefuroxine Sodium Metronidazole Pethidine	PS C C C C C C	Glaxo Wellcome Inc		INTRAMUSCULAR	INTRAMUSCULAR

			Hydrochloride	C		

Date:10/24/00ISR Number: 3599703-0Report Type:Expedited (15-DaCompany Report #B0089706A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Blood Pressure Increased		Ondansetron			
	Bradycardia		Hydrochloride	PS	Glaxo Wellcome	
INTRAVENOUS 1AMP PER DAY 1 DAY						
	Loss Of Consciousness		Hydrocortisone			
	Muscle Rigidity		Sodium Succinate	SS	Glaxo Wellcome	
UNKNOWN						
	Respiratory Arrest					
	Urinary Incontinence					

Date:10/25/00ISR Number: 3601362-5Report Type:Expedited (15-DaCompany Report #800#3#2000-03884 (000)
Age:7 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Toxic Epidermal	Health	Cyclophosphamide	PS	Asta Medica Inc	
INTRAVENOUS 1,044 GRAM IV						
	Necrolysis	Professional	Cyclosporin A (Ciclosporin)	SS		
90 MG						
			Codeine Phosphate	SS		ORAL
15 MG PO						
			Paracetamol (Paracetamol)	SS		ORAL
360 MG PO						
			Vancomycin (Vancomycin)	SS		
INTRAVENOUS 810 MG IV						
			Ceftazidime (Ceftazidime)	SS		
INTRAVENOUS 2700 MG IV						
			Tranexamic Acid (Tranexamic Acid)	SS		ORAL
1200 MG PO						
			Fludarabine (Fludarabine)	SS		
INTRAVENOUS 18 MG IV						
			Ondansetron			

		(Ondansetron)	SS	
4 MG				
		Antihuman Lymphocyte Immunoglobulin (Antilymphocyte Immunoglobulin Horse)	SS	
INTRAVENOUS	219 MG IV			
		Metoclopramide (Metoclopramide)	SS	
5 MG				
		Meropenem (Meropenem)	SS	
INTRAVENOUS	1080 MG IV			
		Acyclovir (Acyclovir)	SS	
INTRAVENOUS	525 MG IV			
		Fluconazole (Fluconazole)	SS	ORAL
50 MG PO				
		Nifedipine (Nifedipine)	SS	ORAL
5 MG PO				
		Sandoglobulin (Immunoglobulin Human Normal)	SS	
INTRAVENOUS	7 G IV			
		Chlorpheniramine	C	

Date:10/25/00ISR Number: 3601957-9Report Type:Expedited (15-DaCompany Report #B0089706A
Age: Gender:Male I/FU:I

Outcome
Required
Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Pressure Increased	Foreign	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	1 AMPOULE/	
	Bradycardia	Health					PER DAY/	
	Loss Of Consciousness	Professional					INTRAVENOUS	
	Respiratory Arrest		Hydrocortisone Na Succ. (Formulation Unknown) (Hydrocortisone Na Succ.)	SS				
	Urinary Incontinence							

Date:10/25/00ISR Number: 3600344-7Report Type:Expedited (15-DaCompany Report #A0129923A
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Complications Of Maternal Exposure To Therapeutic Drugs		Zofran	PS	Glaxo Wellcome	ORAL		
	Congenital Hydrocephalus							
	Fallot'S Tetralogy							

Date:10/30/00ISR Number: 3603001-6Report Type:Direct Company Report #
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness		Ondansetron 2 Mg / Ml Glaxowellcome	PS	Glaxowellcom	4 MG ONCE		
	Oxygen Saturation Decreased					INTRAVENOUS BOLUS		

Date:10/30/00ISR Number: 3603375-6Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose	Duration
	Extrapyramidal Disorder		Zofran	Injectable	PS	Glaxo Wellcome Inc			
	Hypersensitivity								

Date:10/30/00ISR Number: 3603785-7Report Type:Expedited (15-DaCompany Report #A0129923A
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Complications Of Maternal	Health	Zofran	PS	Glaxo Wellcome Inc	ORAL	ORAL	
	Exposure To Therapeutic Drugs	Professional						
	Fallot'S Tetralogy							
	Hydrocephalus							

Date:11/01/00ISR Number: 3604034-6Report Type:Expedited (15-DaCompany Report #B0090503A
Age: Gender:Male I/FU:I

Outcome	PT
Congenital Anomaly	Anal Atresia
	Complications Of Maternal
	Exposure To Therapeutic Drugs

	Congenital Anomaly Congenital Bladder Anomaly	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Genital Disorder Male		Ondansetron	PS	Glaxo Wellcome	ORAL	
	Intestinal Fistula		Lactulose	C		ORAL	10ML TWICE
	Skin Hypertrophy						PER DAY 15 DAY
			Nitrofurantoin	C		ORAL	50MG FOUR
							TIMES PER DAY 5 DAY
			Cyclizine	C	Glaxo Wellcome		
							INTRAMUSCULAR 5 DAY

Date:11/01/00ISR Number: 3605382-6Report Type:Expedited (15-DaCompany Report #B0090503A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Congenital Anomaly	Anal Atresia	Foreign	Zofran	PS	Glaxo Wellcome Inc	ORAL	4 MG/ ORAL
	Bladder Disorder	Other	Lactulose	C			
	Complications Of Maternal		Nitrofurantoin	C			
	Exposure To Therapeutic		Cyclizine	C			
	Drugs						
	Congenital Anomaly						
	Genital Disorder Male						
	Intestinal Fistula						
	Skin Hypertrophy						

Date:11/03/00ISR Number: 3605703-4Report Type:Expedited (15-DaCompany Report #A0126667A
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Amnesia		Zofran	PS	Glaxo Wellcome		
INTRAVENOUS	12MG						
Initial or Prolonged	Blood Phosphorus						
CUMULATIVE							
Disability	Decreased						
DOSE	1 DAY						

	Confusional State		Zofran	SS	Glaxo Wellcome	ORAL
	Dysarthria		Baby Aspirin	C		
	Red Blood Cell		Polypharmacy	C		
	Sedimentation Rate					
	Increased					

Date:11/03/00ISR Number: 3605708-3Report Type:Expedited (15-DaCompany Report #A0130940A
Age:6 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Anaphylactic Reaction		Zofran	PS	Glaxo Wellcome	
INTRAVENOUS 4MG SIX TIMES						
	Coma					
PER DAY 3 DAY						
	Respiratory Distress		Ceftazidime	C	Glaxo Wellcome	
	Stridor		Amikacin	C		
			Kcl	C		
			Albuterol	C	Glaxo Wellcome	
RESPIRATORY						
(INHALATION)						
			Lasix	C		
			Prednisone	C		
			Prograft	C		
			Captopril	C	Glaxo Wellcome	
			Norvasc	C		
			Ursodiol	C		
			Zantac	C	Glaxo Wellcome	
UNKNOWN						

Date:11/03/00ISR Number: 3606964-8Report Type:Expedited (15-DaCompany Report #A0126667A
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Amnesia	Health	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	INTRAVENOUS	
Initial or Prolonged	Blood Phosphorus	Professional	Ondansetron					
Disability	Decreased		Hydrochloride	SS		ORAL	ORAL	
	Cerebrovascular Accident		Aspirin	C				
	Confusional State							
	Dysarthria							
	Red Blood Cell							
	Sedimentation Rate							
	Increased							

Date:11/03/00ISR Number: 3606966-1Report Type:Expedited (15-DaCompany Report #A0130940A
Age:6 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction	Health	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	4 MG / SIX	
	Coma	Professional					TIMES PER DAY	
	Respiratory Distress						/ INTRAVENOUS	
	Stridor		Ceftazidime Sodium	C				
			Amikacin	C				
			Ranitidine Hydrochloride	C				
			Potassium Chloride	C				
			Ursodeoxycholic Acid	C				
			Salbutamol Sulphate	C				
			Frusemide	C				
			Prednisone	C				
			Tacrolimus	C				
			Captopril	C				
			Amlodipine	C				

Date:11/03/00ISR Number: 3607037-0Report Type:Expedited (15-DaCompany Report #10587160
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Abdominal Pain Upper Gastritis	Foreign Health Professional	Cytoxan	PS	Bristol Myers Squibb Co Pharmaceutical Research Institute	INTRAVENOUS	1200	MILLIGRAM, IV
	Nausea	Other	Uromitexan Inj(Mesna)	SS		INTRAVENOUS	400	MILLIGRAM, IV
			Zophren (Ondansetron Hcl)	SS		INTRAVENOUS	IV	
			Vastarel (Trimetazidine Hcl)	C				
			Raniplex (Ranitidine Hcl)	C				
			Amlor (Amlodipine Besylate)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/06/00ISR Number: 3606529-8Report Type:Expedited (15-DaCompany Report #B0089706A
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased		Ondansetron					
Disability	Dyspnoea		Hydrochloride	PS	Glaxo Wellcome			
INTRAVENOUS	1AMP PER DAY	1	DAY					
Other	Headache		Hydrocortisone					
	Hypertension		Sodium Succinate	C	Glaxo Wellcome			
INTRAVENOUS		1	DAY					
	Loss Of Consciousness							
	Malaise							
	Mydriasis							
	Respiratory Arrest							
	Urinary Incontinence							

Date:11/07/00ISR Number: 3608304-7Report Type:Direct Company Report #
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Pressure Systolic		Zofran	PS				
INTRAVENOUS	32MF + 20 MG							
	Increased							
IV Q 3 WEEKS								
	Bradycardia		Taxotere	SS				
INTRAVENOUS	140MG IV Q 3							
	Chest Discomfort							
WEEKS								
	Cough		Dexamethasone	SS				
	Dizziness							
	Erythema							
	Flushing							
	Hyperhidrosis							

Date:11/07/00ISR Number: 3608442-9Report Type:Expedited (15-DaCompany Report #B0089706A
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased	Foreign	Zofran	PS	Glaxo Wellcome Inc			
INTRAVENOUS	1 AMPOULS/							

Disability	Blood Pressure Systolic	Health			
PER DAY/					
Required	Increased	Professional			
INTRAVENOUS					
Intervention to	Dyspnoea		Hydrocortisone Na		
Prevent Permanent	Headache		Succ.	C	
Impairment/Damage	Loss Of Consciousness				
	Malaise				
	Mydriasis				
	Respiratory Arrest				
	Urinary Incontinence				

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Eyelid Function Disorder		Adriamycin	PS		
INTRAVENOUS 117 MG IV Q						
	Facial Palsy					
21 DAYS						
	Mastication Disorder		Cytoxan	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:11/09/00ISR Number: 3610306-1Report Type:Expedited (15-DaCompany Report #B0090517A
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest	Foreign	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	4 MG/	
Hospitalization - Initial or Prolonged	Ventricular Fibrillation	Health Professional	Midazolam	C		INTRAVENOUS		

Date:11/09/00ISR Number: 3610320-6Report Type:Expedited (15-DaCompany Report #2000INN0044
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Haemoglobin Decreased	Foreign	Innohep	PS	Dupont Pharmaceuticals Co	SUBCUTANEOUS	14000 IU SC	
Life-Threatening	Melaena	Health						
Other	Prothrombin Time Ratio Decreased	Professional Other	Sintrom (Acenocoumarol)	SS		ORAL	PO	
			Zofran (Ondansetron Hydrochloride)	SS		ORAL	2 DOSES PO	
			Ni (Fentanyl)	SS		TRANSPLACENTAL	1 DOSE TP	

Date:11/09/00ISR Number: 3608765-3Report Type:Expedited (15-DaCompany Report #B0090517A
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Cardiac Arrest		Zofran	PS	Glaxo Wellcome	
INTRAVENOUS						
Hospitalization - Initial or Prolonged	Ventricular Fibrillation		Midazolam	C		

Date:11/13/00ISR Number: 3610795-2Report Type:Direct Company Report #
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Angioneurotic Oedema		Zofran	PS	Glaxo Wellcome	
Q6 HOUR, PRN						
	Coma					
	Dystonia					
	Oxygen Saturation Decreased					

Date:11/15/00ISR Number: 3612578-6Report Type:Expedited (15-DaCompany Report #JAGER42501
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Blister	Foreign	Protostat	PS	Rw Johnson	
Life-Threatening	Lip Ulceration	Health			Pharmaceutical	
	Pruritus	Professional			Research Institute	
	Shock				Div Ortho Pharm	
INTRAVENOUS 500 MG, 3 IN						
	Stevens-Johnson Syndrome					
1 DAY(S), IV						
	Toxic Epidermal Necrolysis		Imodium (2 Mg Capsule) (Loperamide Hydrochloride)	SS		ORAL
4 MG, 3 IN 1						

DAY(S), ORAL				
		Allopurinol(Allopurinol)	SS	ORAL
MG, DAILY, ORAL				
		Dipidolor(7.5 Mg/Ml Injection) (Piritramide)	SS	
INTRAVENOUS	MG, DAILY, IV			
		Antra(Ampoule) (Omeprazole)	SS	
INTRAVENOUS	MG, DAILY, IV; 20 MG, DAILY, IV			
		Zofran (Ondansetron)	SS	
INTRAVENOUS	1 IN 1 DAY(S), IV			
		Multibionta(Multibionta)	SS	
INTRAVENOUS	ALT DAY, IV			
		Leucomax(Molgramostim)	SS	
SUBCUTANEOUS	MCG, DAILY, SUBCU (DAILY 05-AUG-96): 1-3 (SEE IMAGE)			
		Paracetamol(Paracetamol)	SS	
		Vancomycin(Ampoule) (Vancomycin)	SS	
INTRAVENOUS	0.5 G, 3 IN 1 DAY(S), IV			
		Novalgin(Ampoule) (Metamizole)	SS	
INTRAVENOUS	1 IN 1 TIME			

(S), IV INTRAVENOUS DAY(S), IV INTRAVENOUS INTRAVENOUS DAY(S), IV (1 DAILY 07-AUG-96): 5 DROPS/DAY (DAILY 06-AUG-96): 7500 - 10000 I.E. INTRAVENOUS DAY(S), IV INTRAVENOUS 1 DAY(S), IV INTRAVENOUS TIME(S), IV INTRAVENOUS TIME(S), IV INTRAVENOUS 1 TIME(S), IV	1 IN 1 1 MG/HR, IV 2 G, 2 IN 1 2 G, 3 IN 1 120 MG, 3 IN 50 MG, 1 IN 1 1 IN 1 200 MG, 1 IN	Vitalipid(Vitalipid) Mst(Morphine) Augmentan(Clavulanic Acid) Opium(Opium) Liquemin(Ampoule) (Heparin) Claforan(Cefotaxime) Gentamycin(Gentamicin) Isoptin(Verapamil) Ciprobay(Ciprofloxacin) Sobelin Solubile(Clindamycin) Suprarenin(Ampoule)	SS SS SS SS SS SS SS SS SS

(Epinephrine) SS

INTRAVENOUS 3 IN 1

DAY(S), IV

Dopamin(Ampoule)
(Dopamine) SS

INTRAVENOUS MG, DAILY, IV

		Zienam(Imipenem)	SS
INTRAVENOUS	0.5 G, 1 IN 1 TIME(S), IV		
		Dolantin(Pethidine)	SS
INTRAVENOUS	MG, DAILY, IV		
		Human Albumin 20 %(Human Albumin)	SS
INTRAVENOUS	ML, DAILY, IV		
		Neupogen(Filgrastim)	SS
SUBCUTANEOUS	1 IN 1 DAY(S), SUBCU		
		Dormicum(Ampoule) (Midazolam)	SS
INTRAVENOUS	10 MG/HR, DAILY, IV		
		Solu-Decortin(Predni solone)	SS
INTRAVENOUS	50 MG, 1 IN 1 TIME(S), IV		
		Amphoterecin B(Ampoule) (Amphotericin B)	SS
INTRAVENOUS	40 MG, 1 IN 1 DAY(S), IV		
		Psyquil(Ampoule) (Trifluprom azine)	SS
INTRAVENOUS	1 IN 1 DAY(S), IV		
		Actrapid(Ampoule) (Insulin Rapid Act.)	SS
SUBCUTANEOUS	U, DAILY, SUBCU		
		Meronem(Ampoule) (Meropenem)	SS
INTRAVENOUS	G, DAILY, IV		
		Tavegil(Ampoule) (Clemastine)	SS
INTRAVENOUS	1 IN 1 DAY(S), IV		

		Ancotil(Ampoule 2 G) (Flucytosine)	SS	
INTRAVENOUS	2 G, 2 IN 1 DAY(S), IV			
		Lasix(Furosemide)	SS	ORAL
	20 MG, 1 IN 1 TIME(S), ORAL			
		Bifiteral(Lactulose)	SS	ORAL
	1 IN 1 TIME(S), ORAL			
		Pantozol(Pantoprazole)	SS	ORAL
	1 IN 1 DAY(S), ORAL			
		Paspertin(Ampoule) (Metoclopramide)	SS	
INTRAVENOUS	2 IN 1 DAY(S), IV			
		Methotrexat (Methotrexate)	SS	
INTRAVENOUS	MG, DAILY, THECAL (SEE IMAGE)			
		Diflucan	SS	ORAL
	200 MG, 2 IN 1 DAY(S), ORAL			
		Ampho-Moronal	C	
		Aminomel	C	
		Aminomix	C	
		Glukose 40%	C	
		Kaliumchlorid	C	
		Lipofundin Mct 10%	C	
		Fortecortin	C	
		Sterofundin	C	
		Magnorbin 20%	C	
		Glucose	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/15/00ISR Number: 3612824-9Report Type:Expedited (15-DaCompany Report #A0131771A
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Consumer	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	INTRAVENOUS	
			Thyroxine Sodium	C				

Date:11/15/00ISR Number: 3611244-0Report Type:Expedited (15-DaCompany Report #A0131771A
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Zofran	PS	Glaxo Wellcome	INTRAVENOUS		
			Synthroid	C	Glaxo Wellcome	ORAL		

Date:11/20/00ISR Number: 3613245-5Report Type:Expedited (15-DaCompany Report #B0091423A
Age:19 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Malaise		Zophren	PS	Glaxo Wellcome	INTRAVENOUS		
	Oxygen Saturation Decreased		Daunorubicine	SS		INTRAVENOUS		
	Pyrexia							
	Urticaria							

Date:11/20/00ISR Number: 3614527-3Report Type:Expedited (15-DaCompany Report #10587160
Age:59 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Foreign	Cytoxan	PS	Bristol Myers Squibb Co Pharmaceutical Research Institute	INTRAVENOUS	1200	
	Gastritis	Health Professional						
	Nausea							

			Other				
MILLIGRAM,							
IV							
				Uromitexan Inj	SS		
INTRAVENOUS	400						
MILLIGRAM,							
IV							
				Zophren	SS		
INTRAVENOUS	IV						
				Vastarel	C		
				Raniplex	C		
				Anlor	C		
				Soprol	C		
				Zyrtec	C		

Date:11/20/00ISR Number: 3614884-8Report Type:Expedited (15-DaCompany Report #B0091423A
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Malaise	Foreign	Zofran	PS	Glaxo Wellcome Inc			
INTRAVENOUS	INTRAVENOUS							
Initial or Prolonged	Oxygen Saturation Decreased		Daunorubicin Solution					
	Pyrexia		(Daunorubicin)	SS				
INTRAVENOUS	INTRAVENOUS							
	Urticaria							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/22/00ISR Number: 3615126-XReport Type:Expedited (15-DaCompany Report #B0089805A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arterial Thrombosis		Ondansetron Hydrochloride	PS	Glaxo Wellcome		UNKNOWN	

Date:11/22/00ISR Number: 3615130-1Report Type:Expedited (15-DaCompany Report #B0091421A
Age:59 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain Upper		Zophren	PS	Glaxo Wellcome		INTRAVENOUS	2MGML PER DAY 1 DAY
Initial or Prolonged	Gastritis		Uromitexan	SS		ORAL	400MG PER DAY 1 DAY	
	Nausea		Endoxan	SS			INTRAVENOUS	1200MG PER DAY 1 DAY
			Raniplex	C	Glaxo Wellcome	ORAL		
			Zyrtec	C	Glaxo Wellcome			
			Amlor	C		ORAL		
			Vastarel	C		ORAL		
			Soprol	C				

Date:11/22/00ISR Number: 3615136-2Report Type:Expedited (15-DaCompany Report #B0091706A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Retinal Artery Thrombosis		Zofran	PS	Glaxo Wellcome		UNKNOWN	

Date:11/22/00ISR Number: 3616816-5Report Type:Expedited (15-DaCompany Report #B0091421A
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Abdominal Pain Upper Nausea	Foreign	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	2 MG/ML / PER DAY /
			Cyclophosphamide (Formulation Unknown) (Cyclophosphamide)	SS		INTRAVENOUS	PER DAY /
			Mesna (Formulation Unknown) (Mesna)	SS		INTRAVENOUS	PER DAY /
			Ranitidine Hydrochloride	C		ORAL	
			Amlodipine Besylate	C			
			Trimetazidine Hcl	C			
			Bisoprolol Fumarate	C			
			Cetirizine Hydrochloride	C			

Date:11/22/00ISR Number: 3616817-7Report Type:Expedited (15-DaCompany Report #B0089805A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arterial Thrombosis	Foreign Health Professional	Zofran	PS	Glaxo Wellcome Inc			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/22/00ISR Number: 3616818-9Report Type:Expedited (15-DaCompany Report #B0091706A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Retinal Artery Thrombosis	Foreign Health Professional	Zofran	PS	Glaxo Wellcome Inc			

Date:11/22/00ISR Number: 3616837-2Report Type:Expedited (15-DaCompany Report #10605905
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Artery Thrombosis	Foreign Health Professional Other	Etopophos Preservative Free	PS	Bristol Myers Squibb Co Pharmaceutical Research Institute	INTRAVENOUS	180	MILLIGRMAS, 5/1 CYCLE IV
			Platinol Inj(Cisplatin)	SS		INTRAVENOUS	40 MILLGRAM, 5/1 CYCLE IV	
			Bleomycin	SS		INTRAVENOUS	IV	
			Decadron (Dexamethasone)	SS		INTRAVENOUS	IV	
			Zofran (Ondansetron Hcl)	SS		ORAL		
			Paracetamol (Paracetamol)	C				
			Guaifenesin (Guaifenesin)	C				
			Stemetil (Prochlorperazine)	C				
			Novaluzid (Mg Hydrox + Mg Carb + Alum Hydrox)	C				

Date:11/22/00ISR Number: 3616843-8Report Type:Expedited (15-DaCompany Report #10605954
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Arterial Thrombosis	Foreign Health Professional	Etopophos Preservative Free	PS	Bristol Myers Squibb Co Pharmaceutical Research Institute	INTRAVENOUS	220 MILLIGRAMS, IV	
			Platinol Inj (Cisplatin)	SS		INTRAVENOUS	44 MILLIGRAM, IV	
			Bleomycin	SS		INTRAVENOUS	30000 INTERNATIONAL UNIT, IV	
			Decadron (Dexamethasone)	SS		INTRAVENOUS	16 MILLIGRAM, IV	
			Zofran (Onsansetron Hcl)	SS		ORAL	16 MILLIGRAM, ORAL	
			Lasix (Furosemide)	C				
			Paracetamol					

				(Paracetamol)	C			
				Stemetil (Prochlorperazine)	C			
				Losec (Omeprazole)	C			
				Imovane (Zopiclone)	C			

Date:11/24/00ISR Number: 3617214-0Report Type:Expedited (15-DaCompany Report #WAES 00117024
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Foreign	Decadron Phosphate	PS	Merck And Co Inc	INTRAVENOUS	16 MG	5 DAY
Disability	Ascites	Health Professional	Zofran (Ondansetron Hydrchloride)	SS		ORAL	16 MG	
	Glomerular Filtration Rate Abnormal	Other	Etoposide	SS		INTRAVENOUS	190 MG	5 DAY
	Liver Function Test Abnormal		Bleomycin	SS		INTRAVENOUS	30000 IU	1 DAY
			Cisplatin	SS		INTRAVENOUS	40 MG	5 DAY
	Renal Impairment		Novaluzid	C				
	Renal Infarct		Solvipect	C				
	Retinal Artery Thrombosis		Stemetil	C				
	Retinal Vascular Occlusion		Acetaminophen	C				
	Scan Abdomen Abnormal							

Date:11/24/00ISR Number: 3617219-XReport Type:Expedited (15-DaCompany Report #WAES 00117025
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Arterial Stenosis	Foreign	Decadron Phosphate	PS	Merck And Co Inc	INTRAVENOUS	16 MG	5 DAY
	Arterial Thrombosis	Health Professional	Cisplatin	SS		44 MG	5 DAY	
	Echocardiogram Abnormal		Etoposide	SS		220 MG	5 DAY	
	Exercise Test Abnormal	Other	Bleomycin	SS		INTRAVENOUS	30000 IU;	
	Pain In Extremity					30000 IU;	1 DAY	

	Peripheral Vascular Disorder		Zofran (Ondansetron Hydrochloride)	SS		ORAL 16 MG
	Poor Peripheral Circulation Ultrasound Doppler Abnormal		Acetaminophen	C		
			Bisacodyl	C		
			Furosemide	C		
			Omeprazole Magnesium	C		
			Prochlorperazine Maleate	C		
			Zopiclone	C		

Date:11/24/00ISR Number: 3617384-4Report Type:Expedited (15-DaCompany Report #033-0955-M0000005
Age:69 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death	Cardiovascular Disorder	Foreign	Accuretic	PS	Parke Davis	ORAL PER ORAL
Hospitalization -	Hepatic Failure	Health	Zyloric(Allopurinol)	SS		ORAL PER ORAL
Initial or Prolonged	Lobar Pneumonia Renal Failure Acute	Professional	Zophren(Ondansetron Hydrochloride)	SS		INTRAVENOUS INTRAVENOUS
			Nipent(Pentostatin)	SS		ORAL 75 MG (DAILY), PER ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/27/00ISR Number: 3616666-XReport Type:Expedited (15-DaCompany Report #B0092449A
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Pancreatitis	Health	Zofran	PS	Glaxo Wellcome	INTRAVENOUS		
		Professional	Tracrium	SS	Glaxo Wellcome	INTRAVENOUS		
			Zinacef	SS	Glaxo Wellcome	INTRAVENOUS		

Date:11/28/00ISR Number: 3618296-2Report Type:Expedited (15-DaCompany Report #B0092449A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Pancreatitis	Foreign	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	UNK / UNK /	
		Health				INTRAVENOUS		
		Professional	Atracurium Besylate Infusion	SS		INTRAVENOUS	UNK / UNK /	
			Zinacef Infusion (Cefuroxime Sodium)	SS		INTRAVENOUS	UNK / UNK /	

Date:11/30/00ISR Number: 3620376-2Report Type:Periodic Company Report #PRIUSA2000000394
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatic Function Abnormal	Health Professional	Levaquin	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	INTRAVENOUS	SEE IMAGE	
			Unasyn					

		(Sultamicillin)	SS
INTRAVENOUS	3 G, 1 TIME (S), IV		
		Rocephin (Ceftriaxone Sodium)	SS
INTRAVENOUS	1 G, DAILY, IV		
		Heparin (Heparin)	SS
INTRAVENOUS	SEE IMAGE		
		Ondansetron (Ondansetron)	SS
INTRAVENOUS	4 MG, 2 IN 1 DAY (S), IV		
		Famotidine (Famotidine)	SS
INTRAVENOUS	20 MG, DAILY, IV		
		Lasix	C
		Hydrocortisone	C
		Insulin	C
		Levothyroxine	C
		Digoxin	C
		Morphine	C
		Metoprolol	C
		Dopamine	C

Date:12/01/00ISR Number: 3619969-8Report Type:Expedited (15-DaCompany Report #B0092628A
Age:55 YR Gender:Male I/FU:F

Outcome	PT
Death	Haemoglobin Decreased
Life-Threatening	Melaena
	Phlebitis
	Prothrombin Level

Decreased

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Zophren	PS	Glaxo Wellcome	ORAL	2UNIT per day	
	Sintrom	SS		ORAL	12MG per day	
	Fentanyl Citrate	SS				
	Innohep	SS				

Date:12/05/00ISR Number: 3621748-2Report Type:Expedited (15-DaCompany Report #B0092769A
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - INTRAVENOUS	Haemoptysis	Consumer	Zophren	PS	Glaxo Wellcome		8MG per day	14 DAY
Initial or Prolonged	Mouth Haemorrhage		Bactrim	C	Glaxo Wellcome		UNKNOWN	4800MG per day
	Thrombocytopenia							
			Cortancyl	C			UNKNOWN	35MG per day
			Lederfoline	C	Glaxo Wellcome		UNKNOWN	50MG per day
			Lexomil	C		ORAL	.25UNIT Per day	
			Videx	C		ORAL	400MG per day	
			Viracept	C		ORAL	10UNIT Twice per day	
			Zerit	C		ORAL	80MG per day	

Date:12/05/00ISR Number: 3622765-9Report Type:Expedited (15-DaCompany Report #B0092628A
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Haemoglobin Decreased	Foreign	Zofran	PS	Glaxo Wellcome Inc	ORAL	ORAL	
Life-Threatening	Melaena		Nicoumalone Tablet 4 Mg (Nicoumalone)	SS		ORAL	ORAL	
	Prothrombin Level Decreased		Fentanyl Citrate (Formulation Unknown) (Fentanyl Citrate)	SS			1 UNIT	
			Tinzaparin Sodium Solution (Tinzaparin Sodium)	SS			1 UNIT	

Date:12/06/00ISR Number: 3623613-3Report Type:Expedited (15-DaCompany Report #B0092769A
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Haemoptysis	Foreign	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	TWICE PER DAY	
	Mouth Haemorrhage							
	Thrombocytopenia		Co-Trimoxazole	C				
			Prednisolone	C				
			Calcium Folinate	C				
			Bromazepam	C				
			Didanosine	C				
			Nelfinavir Mesylate	C				
			Stavudine	C				

Date:12/12/00ISR Number: 3626593-XReport Type:Expedited (15-DaCompany Report #A0129923A
Age: Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abortion Induced	Health	Zofran	PS	Glaxo Wellcome	ORAL	4MG See text	72 DAY
Hospitalization - Initial or Prolonged Congenital Anomaly	Complications Of Maternal Exposure To Therapeutic Drugs Congenital Central Nervous System Anomaly Congenital Hydrocephalus Fallot'S Tetralogy	Professional	No Therapy	C				

Date:12/13/00ISR Number: 3629118-8Report Type:Expedited (15-DaCompany Report #A0129923A
Age: Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abortion Induced	Health	Zofran	PS	Glaxo Wellcome Inc	ORAL	4 MG/ SEE	
Hospitalization - Initial or Prolonged Congenital Anomaly	Cerebral Cyst Complications Of Maternal Exposure To Therapeutic Drugs Fallot'S Tetralogy Foetal Disorder Hydrocephalus	Professional	No Therapy	C			TEXT/ ORAL	

Date:12/18/00ISR Number: 3633369-6Report Type:Expedited (15-DaCompany Report #10605954
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent	Arterial Thrombosis	Foreign Health Professional Other	Etopophos Preservative Free	PS	Bristol Myers Squibb Co Pharmaceutical Research Institute		INTRAVENOUS MILLIGRAM,	220

Impairment/Damage

1/1 CYCLE IV

INTRAVENOUS 44 MILLIGRAM,

1/1 CYCLE IV

INTRAVENOUS 30000

INTERNATIONAL

UNIT, 1/1

CYCLE IV

INTRAVENOUS 16 MILLIGRAM,

IV

16 MILLIGRAM,

ORAL

Platinol Inj (Cisplatin)	SS	
Bleomycin	SS	
Decadron (Dexamethasone)	SS	
Zofran (Ondansetron Hcl)	SS	ORAL
Lasix	C	
Paracetamol	C	
Stemetil	C	
Losec	C	
Imovane	C	
Toilax	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/19/00ISR Number: 3634418-1Report Type:Expedited (15-DaCompany Report #10605905
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Abdominal Pain Renal Artery Thrombosis Renal Infarct	Foreign Health Professional	Etopophos Preservative Free	PS	Bristol Myers Squibb Co Pharmaceutical Research Institute		INTRAVENOUS	180MG, 5/1 CYCLE IV
			Platinol Inj (Cisplatin)	SS			INTRAVENOUS	40 MG, 5/1 CYCLE IV
			Bleomycin Sulfate	SS			INTRAVENOUS	30000 INTERNATIONAL UNIT, IV
			Zofran (Ondansetron Hcl)	SS		ORAL	16 MG, 1/1	DAY ORAL
			Paracetamol (Paracetamol)	C				
			Decadron (Dexamethasone)	C			16 MG, 1/1	DAY
			Solvipect (Guaifenesin)	C				
			Stemetil (Prochlorperazine)	C				
			Novaluzid (Mg Hydrox + Mg Carb + Alum Hydrox)	C				

Date:12/21/00ISR Number: 3634579-4Report Type:Expedited (15-DaCompany Report #A0134507A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Ileus Paralytic		Zofran	PS	Glaxo Wellcome	INTRAVENOUS		
	Intestinal Obstruction							

Date:12/22/00ISR Number: 3636012-5Report Type:Expedited (15-DaCompany Report #A0134507A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Gastrointestinal Motility Disorder	Health Professional	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	INTRAVENOUS	
	Intestinal Obstruction	Company Representative						

Date:12/28/00ISR Number: 3637896-7Report Type:Expedited (15-DaCompany Report #A0126667A
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebrovascular Accident	Health Professional	Zofran	PS	Glaxo Wellcome	INTRAVENOUS	12MG	
cumulative Disability								
							dose	1 DAY
			Zofran	SS	Glaxo Wellcome	ORAL		
			Baby Aspirin	C				
			Polypharmacy	C				

Date:12/28/00ISR Number: 3639050-1Report Type:Expedited (15-DaCompany Report #10605905
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Renal Artery Thrombosis	Foreign Study Health Professional	Etopophos Preservative Free	PS	Bristol Myers Squibb Co Pharmaceutical Research Institute		INTRAVENOUS	180 MG, 5/1
		Other					CYCLE IV	
			Platinol Inj (Cisplatin)	SS			INTRAVENOUS	40 MG, 5/1
							CYCLE IV	
			Decadron (Dexamethasone)	SS			INTRAVENOUS	16 MG, 1/1
							DAY IV	
			Zofran (Ondansetron Hcl)	SS		ORAL	16 MG, 1/1	
							DAY ORAL	
			Bleomycin Sulfate	SS			INTRAVENOUS	30000
							INTERNATIONAL	
							UNIT, IV	
			Paracetamol (Paracetamol)	C				
			Solvipect (Guaifenesin)	C				
			Novaluzid (Mg Hydrox + Me Carb + Alum Hydrox)	C				
			Stemetil (Prochlorperazine)	C				

Date:12/29/00ISR Number: 3639753-9Report Type:Expedited (15-DaCompany Report #2000SE01079
Age:50 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Rash Papular Renal Failure Acute	Foreign Health Professional Other	Prilosec Bactrim Ds Leustatin Lexomil Primperan Zophren Gaviscon No Match Topalgic "Nippon" Visceralgine Forte Tablets	PS SS SS SS SS SS C C C C	Astrazeneca Lp	ORAL ORAL ORAL ORAL	20 MG DAILY 1 DF DAILY PO INTRAVENOUS IV 1.5 MG DAILY PO 10 MG TID PO INTRAVENOUS	7.2 MG DAILY 8 MG BID IV

Date:01/02/01ISR Number: 3640995-7Report Type:Expedited (15-DaCompany Report #A0126667A
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Amnesia Confusional State Dysarthria Sensory Loss	Health Professional	Zofran Ondansetron Hydrochloride (Ondansetron Hydrochloride) Aspirin	PS SS C	Glaxo Wellcome Inc	 ORAL	INTRAVENOUS ORAL	INTRAVENOUS

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/04/01ISR Number: 3641024-1Report Type:Expedited (15-DaCompany Report #A0128321A
Age:55 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blindness	Health	Zofran	PS	Glaxo Wellcome	INTRAVENOUS	4MG Six times	
Initial or Prolonged	Overdose	Professional						
							per day	2 DAY
			Diflucan	C				
			Elavil	C	Glaxo Wellcome			
			Pepcid	C				
			Augmentin	C				

Date:01/08/01ISR Number: 3643599-5Report Type:Expedited (15-DaCompany Report #A0128321A
Age:55 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blindness	Health	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	4 MG / SIX	
Initial or Prolonged	Cerebrovascular Accident	Professional						
							TIMES PER DAY	
	Overdose							
							/ INTRAVENOUS	
			Fluconazole	C				
			Amitriptyline Hcl	C				
			Famotidine	C				
			Augmentin	C				

Date:01/16/01ISR Number: 3649759-1Report Type:Periodic Company Report #2000UW01506
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia	Consumer	Diprivan	PS	Astrazeneca Uk Ltd			
	Nausea		Diprivan	SS				
	Vomiting		Morphine	SS				
			Morphine	SS				
			Lidocaine	SS				
			Fentanyl	SS				
			Ephedrine	SS				
			Versed	SS				

Versed	SS	
Zemuron	SS	
Zofran	SS	
Inapsine	SS	

Date:01/17/01ISR Number: 3648138-0Report Type:Expedited (15-DaCompany Report #A0136353A
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Respiratory Arrest		Zofran	PS	Glaxo Wellcome	INTRAVENOUS		

Date:01/17/01ISR Number: 3648151-3Report Type:Expedited (15-DaCompany Report #B0095011A
Age:63 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Zophren	PS	Glaxo Wellcome	ORAL	8MG Per day	1 DAY
	Leukopenia		Fluorouracil	SS		INTRAVENOUS	100MG per day	
			Campto	SS		INTRAVENOUS	315MG per day	
			Elvorine	SS	Glaxo Wellcome	PARENTERAL	175MG Per day	1 DAY
			Levothyrox	C	Glaxo Wellcome	ORAL	50MCG Per day	

Date:01/18/01ISR Number: 3649222-8Report Type:Expedited (15-DaCompany Report #B0095396A
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Ileus Paralytic		Ondansetron					
Hospitalization -	Sepsis		Hydrochloride	PS	Glaxo Wellcome	ORAL	1UNIT per day	2 DAY
Initial or Prolonged	Shock		Navelbine	SS	Glaxo Wellcome			
INTRAVENOUS							50MG per day	1 DAY
			Cisplatyl	C				
INTRAVENOUS							50MG per day	1 DAY
			Deroxat	C		ORAL		
			Imovane	C		ORAL		
			Lexomil	C		ORAL	1.5MG per day	
			Medrol	C		ORAL	32MG per day	
			Persantine	C		ORAL	75MG Three times per day	
			Primperan	C		ORAL	15MG per day	
			Stilnox	C		ORAL	10MG per day	
			Triatec	C		ORAL	2.5MG Per day	
			Vasten	C		ORAL	20MG per day	

Date:01/22/01ISR Number: 3651257-6Report Type:Expedited (15-DaCompany Report #B0095241A
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Myositis		Zophren	PS	Glaxo Wellcome			
INTRAVENOUS								
Initial or Prolonged						BOLUS		
8MG per day							20 DAY	
			Fluorouracil	SS				
INTRAVENOUS							2200MG per day	
							20 DAY	

Cortancyl SS ORAL
30 MON

Irinotecan SS
INTRAVENOUS
BOLUS
266MG per day 20 DAY

Calcium Folinate SS Glaxo Wellcome
INTRAVENOUS 148MG per day 20 DAY

Date:01/22/01ISR Number: 3652844-1Report Type:Expedited (15-DaCompany Report #B0095011A
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Leukopenia	Foreign	Zofran	PS	Glaxo Wellcome Inc	ORAL	8 MG / PER DAY / ORAL	
			Fluorouracil (Formulation Unknown)	SS		INTRAVENOUS	INTRAVENOUS	
			Irinotecan Solution	SS		INTRAVENOUS	INTRAVENOUS	
			Calcium Folinate (Formulation Unknown)	SS		PARENTERAL	175 MG / PER DAY / PARENTERAL	
			Thyroxine Sodium	C				

Date:01/22/01ISR Number: 3653076-3Report Type:Expedited (15-DaCompany Report #A0136353A
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Respiratory Arrest	Health Professional	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	SINGLE DOSE INTRAVENOUS	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/23/01ISR Number: 3653467-0Report Type:Expedited (15-DaCompany Report #B0095241A
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Myositis	Foreign	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS BOLUS		
			Fluorouracil (Formulation Unknown) (Fluorouracil)	SS		INTRAVENOUS	INTRAVENOUS	
			Prednisone Tablet (Prednisone)	SS		ORAL	ORAL	
			Irinotecan Solution (Irinotecan)	SS		INTRAVENOUS BOLUS	INTRAVENOUS	
			Calcium Folinate Sterile Powder (Calcium Folinate)	SS		INTRAVENOUS	INTRAVENOUS	

Date:01/25/01ISR Number: 3654017-5Report Type:Direct Company Report #
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Extrapyramidal Disorder		Ondansetron	PS				
			Albuterol	C				
			Salmeterol	C				
			Diltiazem Hcl	C				
			Fosinopril Na	C				
			Simvastatin	C				
			Nitroglycerin	C				
			Lansoprazole	C				
			Aspirin	C				

			Ipratropium Bromide	C		
			Guaifenesin	C		
			Vitamin E	C		
			Triamcinolone	C		

Date:01/26/01ISR Number: 3655076-6Report Type:Expedited (15-DaCompany Report #B0095985A
Age:2 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Pancreatitis	Health	Zofran	PS	Glaxo Wellcome	ORAL
1.5MG Per day 9 DAY						
Initial or Prolonged	Sepsis	Professional	Fungizone	SS		ORAL
Other			Polymixin B Sulfate	SS	Glaxo Wellcome	ORAL
			Baktar	SS	Glaxo Wellcome	ORAL
			Tobramycin	SS		
RESPIRATORY						
(INHALATION)						
			Vancomycin	SS		
INTRAVENOUS						
			Itraconazole	SS		ORAL
			Norfloxacin	SS		ORAL
			Azactam	SS		
INTRAVENOUS						
			Piperacillin Sodium	SS		
INTRAVENOUS						
			Carbenin	C		
INTRAVENOUS						

Date:01/26/01ISR Number: 3655078-XReport Type:Expedited (15-DaCompany Report #B0096162A
Age:32 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arterial Occlusive		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	8MG per day	1 DAY
	Disease		Sendoxan	SS		INTRAVENOUS	600MG per day	1 DAY
	Blood Lactate		Uromitexan	SS		INTRAVENOUS	240MG per day	1 DAY
	Dehydrogenase Increased		Voltaren	C		UNKNOWN		
	Chills		Furix	C		UNKNOWN		
	Gamma-Glutamyltransferase		Restovar	C		UNKNOWN		
	Increased		Renitec	C		UNKNOWN		
	Pain In Extremity		Prednisolon	C		UNKNOWN		
	Systemic Lupus Erythematosus		Imurel	C	Glaxo Wellcome			

Date:01/29/01ISR Number: 3656777-6Report Type:Expedited (15-DaCompany Report #B0095985A
Age:24 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Function Abnormal	Foreign Study	Zofran	PS	Glaxo Wellcome Inc	ORAL	1.5 MG (PER DAY)	ORAL
Other	Pancreatitis							
	Sepsis	Health Professional	Amphotericin (Amphotericin B)	SS		ORAL	ORAL	
		Other	Aerosporin (Polymyxin B Sulfate)	SS		ORAL	ORAL	
			Septra (Sulfamethoxazole/Trimetho)	SS		ORAL	ORAL	
			Tobramycin					

			(Tobramycin)	SS			
RESPIRATORY							
(INHALATION)	INHALED						
			Norfloxacin (Norfloxacin)	SS			ORAL
ORAL							
			Aztreonam (Aztreonam)	SS			
INJECTION							
			Piperacillin Sodium (Piperacillin Sodium)	SS			
INJECTION							
			Vancomycin (Vancomycin)	SS			
INJECTION							
			Itraconazole (Itraconazole)	SS			ORAL
ORAL							
			Carbenim (Carbenim)	SS			
INJECTION							

Date:01/29/01ISR Number: 3656778-8Report Type:Expedited (15-DaCompany Report #B0096162A
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Arterial Occlusive	Foreign	Zofran	PS	Glaxo Wellcome Inc	
INTRAVENOUS	INTRAVENOUS					
	Disease		Cyclophosphamide			
	Blood Lactate		Injection			
	Dehydrogenase Increased		(Cyclophosphamide)	SS		
INTRAVENOUS	INTRAVENOUS					
	Chills		Mesna Injection			
	Gamma-Glutamyltransferase		(Mesna)	SS		
INTRAVENOUS	INTRAVENOUS					
	Increased		Diclofenac Sodium	C		
	Pain In Extremity		Frusemide	C		
			Restovar	C		
			Renitec	C		
			Prednisolone	C		

			Azathioprine	C			

Date:01/29/01ISR Number: 3657283-5Report Type:Expedited (15-DaCompany Report #10587160
Age:59 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Gastritis Nausea	Foreign Health Professional	Cytoxan	PS	Bristol Myers Squibb Co Pharmaceutical Research Institute	INTRAVENOUS	1200	MILLIGRAM, IV
		Other	Uromitexan Inj (Mesna)	SS		INTRAVENOUS	400	MILLIGRAM, IV
			Uromitexan Tabs (Mesna)	SS		ORAL	400	MILLIGRAM, ORAL
			Zophren (Ondansetron Hcl)	SS		INTRAVENOUS	IV	
			Vastarel (Trimetazidine Hcl)	C				
			Raniplex (Ranitidine Hcl)	C				
			Amlor (Amlodipine Besylate)	C				
			Soprol (Bisoprolol Hemifumarate)	C				
			Zyrtec (Cetirizine Hcl)	C				

Date:01/31/01ISR Number: 3657637-7Report Type:Expedited (15-DaCompany Report #B0096164A
Age:18 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase		Zyloric	PS	Glaxo Wellcome	ORAL	100MG Per day	3 YR
	Increased		Duroferon	C				
	Arthralgia		Etalpha	C				
	Aspartate		Tenormin	C				
	Aminotransferase		Renitec	C				
	Increased		Plendil	C				
	Drug Interaction		Prednisolone	C				
			Zofran	I	Glaxo Wellcome		INTRAVENOUS	8MG per day 1 DAY
			Sendoxan	I			INTRAVENOUS	500MG Single dose 1 DAY
			Uromitexan	I			INTRAVENOUS	300MG per day 1 DAY

Date:01/31/01ISR Number: 3657639-0Report Type:Expedited (15-DaCompany Report #B0096475A
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Creatinine Renal Clearance Decreased		Ondansetron Hydrochloride	PS	Glaxo Wellcome		INTRAVENOUS	16MG per day 7 DAY
	Pruritus		Omeprazole	SS		ORAL	20MG per day	
	Rash Papular		Bromazepam	SS		ORAL	1.5MG per day	11 DAY
			Bactrim	SS	Glaxo Wellcome	ORAL	1UNIT per day	7 DAY
			Cladribine	SS		ORAL	7.2MG per day	7 DAY
			Loratadine	C		ORAL	2UNIT per day	4 DAY

			Gaviscon	C		ORAL
1UNIT per day	1	DAY				
			Cisapride	C		ORAL
1UNIT per day	4	DAY				
			Metoclopramide	C		ORAL
30MG per day	3	DAY				
			Tramadol	C		ORAL
2UNIT per day	1	DAY				
			Visceralgine	C		ORAL
1UNIT per day						
			Soya Extract	C		
UNKNOWN	1	MON				

Date:02/05/01ISR Number: 3662753-XReport Type:Expedited (15-DaCompany Report #B0096475A
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Foreign	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	UNK / UNK / INTRAVENOUS	
	Creatinine Renal Clearance Decreased		Omeprazole Granules (Omeprazole)	SS		ORAL	UNK / PER DAY	
	Lymphadenopathy						/ ORAL	
	Oedema		Bromazepam Tablet (Bromazepam)	SS		ORAL	UNK / UNK / ORAL	
	Pruritus							
	Pyrexia							
	Rash Papular		Septra Tablet (Sulfamethoxazole/Trimetho)	SS		ORAL	UNK / UNK / ORAL	
			Cladribine Solution (Cladribine)	SS		ORAL	UNK / UNK / ORAL	
			Loratadine	C				
			Gaviscon	C				

				Cisapride	C		
				Metoclopramide	C		
				Tramadol Hydrochloride	C		
				Tiemonium Methyl Sulphate	C		
				Soya	C		

Date:02/05/01ISR Number: 3662757-7Report Type:Expedited (15-DaCompany Report #B0096164A
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Foreign	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	2MG/ML / UNK / INTRAVENOUS	
	Arthralgia Aspartate Aminotransferase Increased Drug Interaction		Allopurinol Tablet (Allopurinol)	SS		ORAL	100 MG / PER DAY / ORAL	
			Cyclophosphamide Injection (Cyclophosphamide)	SS		INTRAVENOUS	500 MG / SINGLE DOSE / INTRAVENOUS	
			Mesna Injection (Mesna)	SS		INTRAVENOUS	100 MG/M1 / UNK / INTRAVENOUS	
			Ferrous Sulfate	C				
			Atenolol	C				
			Alfacalcidol	C				
			Renitec	C				
			Prednisolone	C				

			Felodipine	C		

Date:02/06/01ISR Number: 3660380-1Report Type:Direct Company Report #USP 53679
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Sublimaze	PS	Abbott Laboratories			
			Zofran (Ondansetron)	SS	Glaxo Wellcome			

Date:02/09/01ISR Number: 3663058-3Report Type:Expedited (15-DaCompany Report #B0091421A
Age:59 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain Upper		Zophren	PS	Glaxo Wellcome			
INTRAVENOUS							2MGML Per day	1 DAY
Initial or Prolonged	Nausea		Endoxan	SS				
INTRAVENOUS							1200MG per	
day							1	DAY
			Uromitexan	SS		ORAL		
400MG per day							1	DAY
			Raniplex	C	Glaxo Wellcome	ORAL		
			Amlor	C		ORAL		
			Vastarel	C		ORAL		
			Soprol	C				
			Zyrtec	C	Glaxo Wellcome			

Date:02/09/01ISR Number: 3663840-2Report Type:Expedited (15-DaCompany Report #2001043057AU
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Arthritis Bacterial	Foreign	Zyvox	PS	Pharmacia And Upjohn			
	Aseptic Necrosis Bone	Health			Co			
INTRAVENOUS							600 MG, BID,	
	Convulsion	Professional						
IV								
	Dermatitis	Other	Xylocaine	SS				
	Drug Interaction		Midazolam	SS				

	Mental Disorder	Ondansetron	SS	
		Propofol	SS	
		Suxamethonium	SS	
		Clonidine Hydrochloride	SS	
		Cefazolin	SS	
IV				
		Gentamicin	SS	
		Morphine	SS	
		Stemetil Tablet	SS	ORAL
ORAL				
		Marcaine	SS	
		Bupivicaine	SS	

Date:02/13/01ISR Number: 3664548-XReport Type:Expedited (15-DaCompany Report #B0095985A
Age:2 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased
Other	Aspartate Aminotransferase Increased
	C-Reactive Protein Increased
	Leukopenia
	Pancreatitis

Streptococcal Infection

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health	Zofran	PS	Glaxo Wellcome	ORAL	1.5MG Per day	9 DAY
Professional	Fungizone	SS		ORAL	25MG Three times per day	311 DAY
	Polymixin B Sulfate	SS	Glaxo Wellcome	ORAL	311 DAY	
	Baktar	SS	Glaxo Wellcome	ORAL	.5MG Twice per day	
	Tobramycin	SS			RESPIRATORY (INHALATION)	1ML Three times per day 295 DAY
	Neo-Minophagen C	C				
	Etoposide	C			5 DAY	
	Cyclocide	C			5 DAY	
	Mitoxantrone	C			3 DAY	
	Cytarabine	C			1 DAY	
	Hydrocortone	C	Glaxo Wellcome		1 DAY	
	Methotrexate	C			1 DAY	

Date:02/13/01ISR Number: 3665220-2Report Type:Expedited (15-DaCompany Report #B0091421A
Age:59 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Gastritis	Foreign	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	2 MG/ML / PER Initial or Prolonged DAY /	

INTRAVENOUS			Cyclophosphamide (Formulation Unknown) (Cyclosphosphamide)	SS			
INTRAVENOUS	PER DAY /						
INTRAVENOUS			Mesna (Formulation Unknown) (Mesna)	SS			ORAL
PER DAY /							
ORAL			Ranitidine Hydrochloride	C			
			Amlodipine Besylate	C			
			Trimetazidine Hcl	C			
			Bisoprolol Fumarate	C			
			Cetirizine Hydrochloride	C			

Date:02/16/01ISR Number: 3667984-0Report Type:Expedited (15-DaCompany Report #B0095985A
Age:24 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Body Temperature Increased	Foreign Study	Ondansetron Hydrochloride Syrup					
Other	Leukopenia	Health	(Non-Us Product)	PS	Glaxo Wellcome Inc	ORAL	1.5 MG/ PER	
Required	Pancreatitis	Professional					DAY/ORAL	
Intervention to Prevent Permanent Impairment/Damage	Sepsis Streptococcal Infection		Septra (Formulation Unknown) (Sulfamethoxazol/Trimetho)	SS		ORAL	.5MG/TWICE	
PER DAY/ORAL								
			Tobramycin (Formulation Unknown) (Tobamycin)	SS				
RESPIRATORY								

(INHALATION) 1 M1/THREE

TIMES PER

DAY/INHALED

	Amphotericin (Formulation Unknown) (Amphotericin B)	C	ORAL

25 MG/THREE

TIMES PER

DAY/ORAL

	Aserosprin (Formulation Unknown) (Polymyxin B Sulfate)	C	ORAL

TWICE PER

DAY/ORAL

	Strong Neo Minophagen C	C
	Etoposide	C
	Cytarabine	C
	Mitozantrone	C
	Hydrocortisone	C
	Methotrexate	C

Date:02/20/01ISR Number: 3667212-6Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Zydis / 5 Mg	PS				
			Zyprexa Zydis 5mg	SS				

Date:02/21/01ISR Number: 3667932-3Report Type:Direct Company Report #
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Urinary Tract Infection		Zofran (8-24mg Qd)	PS		
TRANSPLACENTAL ZOFRAN 8MG -24MG QD VIA TPN						

Date:02/21/01ISR Number: 3669812-6Report Type:Expedited (15-DaCompany Report #EMADSS2001000353
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Blood Creatinine Increased Creatinine Renal Clearance Decreased	Foreign Health Professional	Leustatin	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	
INTRAVENOUS 0.1, DAILY, IV	Rash Papular					
			Mopral (Omeprazole)	SS		ORAL
20 MG, DAILY, ORAL						
			Bactrim Faible (Bactrim)	SS		ORAL
1, 1 IN 1 DAILY, ORAL						
			Lexomil (Bromazepam)	SS		ORAL
1.5 MG, DAILY, ORAL						
			Zophren (Ondansetron Hydrochloride)	SS		ORAL
16 MG, DAILY, ORAL						
			Tramadol Hydrochloride Sr(Unspecified)			

(Tramadol Hydrochloride)	C
Primperan (Metoclopramide)	C
Visceralgine (Tiemonium Mesilate)	C
Gaviscon (Gaviscon /Old Form/)	C

Date:02/22/01ISR Number: 3667987-6Report Type:Direct Company Report #
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	No Adverse Drug Effect		Zofran	PS			8MG ->14MG QD	

Date:02/23/01ISR Number: 3668816-7Report Type:Direct Company Report #USP 53733
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Fentanyl	PS	Abbott			
			Zofran	SS	Cerenex			

Date:03/02/01ISR Number: 3672192-3Report Type:Expedited (15-DaCompany Report #B0099428A
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Sinus Bradycardia	Consumer	Ondansetron	PS	Glaxo Wellcome	INTRAMUSCULAR	4MG Per day	2 DAY
			Fentanyl	C		INTRAVENOUS		
			Morphine	C		INTRAVENOUS		
			Propofol	C		INTRAVENOUS		
			Cyclizine	C	Glaxo Wellcome	INTRAVENOUS		

Date:03/05/01ISR Number: 3678654-7Report Type:Periodic Company Report #A0119627A
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction	Health	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	32 MG / SINGLE DOSE / INTRAVENOUS	
	Dermatitis	Professional						
		Company						
		Representative	Cyclophosphamide	C				
			Methotrexate	C				
			Flurorouracil	C				
			Cimetidine	C				
			Paclitaxel	C				

Date:03/05/01ISR Number: 3678660-2Report Type:Periodic Company Report #A0119628A
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction	Health	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	32 MG / SINGLE DOSE / INTRAVENOUS	
	Dizziness	Professional						
	Vision Blurred	Company						
		Representative	Cyclophosphamide	C				
			Methotrexate	C				
			Fluorouracil	C				
			Dexamethasone	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/01ISR Number: 3678663-8Report Type:Periodic Company Report #A0119629A
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction	Health	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	32 MG /	
	Chest Discomfort	Professional					SINGLE DOSE /	
	Hypoxia	Company					INTRAVENOUS	
	Rash Erythematous	Representative	Cyclophosphamide	C				
			Methotrexate	C				
			Fluorouracil	C				
			Dexamethasone	C				

Date:03/05/01ISR Number: 3678671-7Report Type:Periodic Company Report #A0109831A
Age:3 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Grand Mal Convulsion	Health	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	2.5 MG /	
Initial or Prolonged		Professional					INTRAVENOUS	
Other			Cancer Chemotherapy	C				

Date:03/05/01ISR Number: 3678681-XReport Type:Periodic Company Report #A0132154A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hypoaesthesia	Health	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	20 MG /	
Initial or Prolonged	Paraesthesia	Professional					SINGLE DOSE /	
Required		Company					INTRAVENOUS	
Intervention to		Representative	Doxorubicin					
Prevent Permanent			Hydrochloride	C				
Impairment/Damage			Dexamethasone	C				

Date:03/05/01ISR Number: 3678684-5Report Type:Periodic Company Report #A0122371A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	SINGLE DOSE /	
	Photopsia	Professional				INTRAVENOUS		
			Multiple Medication	C				

Date:03/05/01ISR Number: 3678685-7Report Type:Periodic Company Report #A0112603A
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Face Oedema	Health	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	4 MG / SINGLE	
Hospitalization -	Respiratory Disorder	Professional					DOSE /	
Initial or Prolonged		Company				INTRAVENOUS		
Required		Representative	Midazolam					
Intervention to			Hydrochloride	C				
Prevent Permanent			Fentanyl	C				
Impairment/Damage			Cephazolin Sodium	C				

Date:03/05/01ISR Number: 3678686-9Report Type:Periodic Company Report #A0113020A
Age:14 YR Gender:Male I/FU:I

Outcome
Life-Threatening
Required

Intervention to Prevent Permanent Impairment/Damage							
	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Anaphylactic Reaction	Health	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	7 MG / SEE
	Chills	Professional				TEXT /	
	Drug Ineffective					INTRAVENOUS	
	Dyspnoea		Methotrexate	C			
	Flushing						
	Loss Of Consciousness						
	Pruritus						

Date:03/06/01ISR Number: 3675402-1Report Type:Expedited (15-DaCompany Report #B0099428A
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Sinus Bradycardia	Foreign	Zofran	PS	Glaxo Wellcome Inc	4 MG / PER	
						DAY /	
						INTRAMUSCULAR	
			Fentanyl	C			
			Morphine	C			
			Propofol	C			
			Cyclizine	C			

Date:03/26/01ISR Number: 3688836-6Report Type:Expedited (15-DaCompany Report #A0141181A
Age:12 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Extrapyramidal Disorder		Zofran	PS	Glaxo Wellcome	ORAL	8MG Six times Initial or Prolonged
						per day	3 DAY
			Vincristine	C			
			Methotrexate	C			

Date:03/28/01ISR Number: 3691948-4Report Type:Expedited (15-DaCompany Report #A0141181A
Age:12 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Extrapyramidal Disorder	Health	Zofran	PS	Glaxo Wellcome Inc	ORAL	8 MG / SIX	
Initial or Prolonged		Professional					TIMES PER DAY	
							/ ORAL	
			Vincristine	C				
			Methotrexate	C				

Date:04/10/01ISR Number: 3701108-6Report Type:Expedited (15-DaCompany Report #B0102783A
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Pancytopenia	Consumer	Zophren	PS	Glaxo Wellcome	ORAL	16MG Per day	27 DAY
Initial or Prolonged			Omeprazole	SS		ORAL	20MG Per day	9 DAY

Date:04/11/01ISR Number: 3702383-4Report Type:Expedited (15-DaCompany Report #A0142451A
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Gastrointestinal Disorder		Zofran	PS	Glaxo Wellcome	ORAL	8MG Four	
Initial or Prolonged	Headache						times per day	1 MON
Other	Pyrexia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/12/01ISR Number: 3704299-6Report Type:Expedited (15-DaCompany Report #B0102783A
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pancytopenia	Foreign	Zofran	PS	Glaxo Wellcome Inc	ORAL	16 MG (PER DAY)	
			Omeprazole Granules (Omeprazole)	SS		ORAL	20 MG (PER DAY)	

Date:04/16/01ISR Number: 3704671-4Report Type:Expedited (15-DaCompany Report #A0145046A
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blindness		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	32MG Three times per day	4 DAY
	Medication Error							
	Overdose							
	Vision Blurred							

Date:04/16/01ISR Number: 3706878-9Report Type:Expedited (15-DaCompany Report #A0142451A
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Headache Pyrexia	Health Professional Company Representative	Zofran Tablet (Ondansetron Hydrochloride)	PS	Glaxo Wellcome Inc	ORAL	8 MG, FOUR TIMES PER DAY, ORAL	

Date:04/17/01ISR Number: 3706433-0Report Type:Direct Company Report #
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal Exposure To Therapeutic		Zofran (Glaxo Smithkline)	PS	Glaxo Smithkline	INTRAVENOUS	4MG Q4H IV	
	Drugs		Mvi 12	C				
	Intra-Uterine Death		Folic Acid	C				
			Dextrose	C				
			Amino Acids	C				
			Lipids	C				

Date:04/19/01ISR Number: 3707408-8Report Type:Expedited (15-DaCompany Report #B0104267A
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asphyxia		Ondansetron	PS	Glaxo Wellcome	UNKNOWN		
			Gaviscon	C		ORAL	25MG per day	50 DAY
			Prednisolone	C		ORAL		

Date:04/19/01ISR Number: 3708168-7Report Type:Expedited (15-DaCompany Report #A0145046A
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Overdose	Consumer	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	32 MG (THREE TIMES PER DAY)	
	Vision Blurred							

INTRAVENOUS 4 DAY

Date:04/25/01ISR Number: 3711365-8Report Type:Expedited (15-DaCompany Report #B0104267A
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asphyxia	Foreign	Zofran	PS	Glaxo Wellcome Inc			
			Gaviscon	C				
			Prednisolone	C				

Date:04/26/01ISR Number: 3710950-7Report Type:Expedited (15-DaCompany Report #A0144979A
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amniocentesis Abnormal		Zofran	PS	Glaxo Wellcome			
UNKNOWN								
	Complications Of Maternal Exposure To Therapeutic Drugs							
	Placental Insufficiency							
	Stillbirth							

Date:04/30/01ISR Number: 3713821-5Report Type:Expedited (15-DaCompany Report #A0144979A
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amniocentesis Abnormal	Health Professional	Zofran	PS	Glaxo Wellcome Inc			
	Complications Of Maternal Exposure To Therapeutic Drugs							
	Placental Insufficiency							
	Stillbirth							

Date:05/02/01ISR Number: 3716704-XReport Type:Periodic Company Report #2000AU01729
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia	Consumer	Xylocaine W/					
	Nausea		Epinephrene	PS	Astrazeneca Lp			
	Vomiting		Diprivan	SS				
			Diprivan	SS				
			Ephedrine	SS				
			Fentanyl Citrate	SS				
			Inapsine	SS				
			Morphine	SS				
			Morphine	SS				
			Versed	SS				
			Versed	SS				
			Zemuron	SS				
			Zofran	SS				

Date:05/03/01ISR Number: 3716077-2Report Type:Expedited (15-DaCompany Report #A0145046A
Age:35 YR Gender:Female I/FU:F

Outcome	PT
Other	Dysphagia
	Haemoglobin Decreased
	Medication Error

	Overdose					
	Pyrexia					
	Vision Blurred	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
			Zofran	PS	Glaxo Wellcome	
INTRAVENOUS	32MG Three					
times per day	DAY					

Date:05/07/01ISR Number: 3717301-2Report Type:Expedited (15-DaCompany Report #A0146552A
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Constipation		Zofran	PS	Glaxo Wellcome	
4 DAY						
Initial or Prolonged	Gastrointestinal Motility		Codeine	SS		
	Disorder		Doxorubicin	C		
INTRAVENOUS						
	Renal Colic		Investigational Drug	C		
INTRAVENOUS						
			Magnesium Hydroxide	C		
			Acetaminophen	C		

Date:05/07/01ISR Number: 3719241-1Report Type:Expedited (15-DaCompany Report #A0145046A
Age:35 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Dysphagia	Consumer	Zofran	PS	Glaxo Wellcome Inc	
INTRAVENOUS	32 MG /					
	Haemoglobin Decreased					
THREE TIMES						
	Medication Error					
PER DAY						
	Overdose					
INTRAVENOUS						
	Pyrexia					
	Vision Blurred					
	Visual Disturbance					

Date:05/09/01ISR Number: 3719657-3Report Type:Expedited (15-DaCompany Report #22000-008
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation	Foreign Study	Codeine	PS				
	Ileus Paralytic	Health Professional	Zofran (Ondansetron Hcl)	SS				
	Pain	Other	Bms 188797 (Investigational)	C				
	Renal Disorder		Doxorubicin For Injection	C				
			Megnesia W/Alumina (Magnesium Hydroxide)	C				
			Pamol (Acetaminophen)	C				

Date:05/09/01ISR Number: 3720932-7Report Type:Expedited (15-DaCompany Report #HQ0475003MAY2001
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electrocardiogram Qt Prolonged	Health Professional	Reglan	PS	Ah Robins Co			
	Gastrointestinal Haemorrhage		Zofran (Ondansetron Hydrochloride)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/10/01ISR Number: 3720783-3Report Type:Expedited (15-DaCompany Report #A0146552A
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation Renal Colic	Health Professional Other	Zofran Codeine (Codeine) (Formulation Unknown) Doxorubicin Trial Medication Magnesium Hydroxide Paracetamol	PS SS C C C C	Glaxo Wellcome Inc			

Date:05/16/01ISR Number: 3724888-2Report Type:Expedited (15-DaCompany Report #2001054710US
Age:34 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Study Health Professional	Adrucil Irinotecan Solution, Sterile Leucovorin (Folinic Acid) Percocet(Oxycodone Hydrochloride, Oxycodone Terephthalate)	PS SS SS SS	Pharmacia And Upjohn Co	 ORAL	INTRAVENOUS INTRAVENOUS INTRAVENOUS ORAL	820 MG, WEEKLY, CYCLE 3, IV 205 MG, WEEKLY, CYCLE 3, IV 33 MG, WEEKLY, CYCLE 3, IV

			Ondansetron	SS		ORAL
80 MG, ORAL						
			Lorazepam	C		
			Dss	C		

Date:05/17/01ISR Number: 3728309-5Report Type:Expedited (15-DaCompany Report #EM2001-0589
Age:43 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Arthralgia	Foreign	Proleukin; Chiron			
	Erythema	Literature	Corporation			
	Fixed Eruption	Other	(Aldesleukin)			
	Oedema		Injection	PS	Chiron Corporation	
			Ondansetron (Ondansetron)	SS		
			Tropisetron(Ropisetron)	SS		
			Paracetamol(Paracetamol)	SS		
			Dtic (Dacarbazine)	C		
			Vindesine (Vindesine)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/18/01ISR Number: 3726246-3Report Type:Expedited (15-DaCompany Report #200113417FR
Age:85 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pneumonitis	Foreign Other	Lovenox	PS	Aventis Pharmaceutical Products Inc	ORAL	300 MG/DAY PO	1 WK
			Heparin-Fraction, Sodium Salt (Lovenox)	SS		SUBCUTANEOUS	SC	
			Amiodarone Hydrochloride (Cordarone) Tablets	SS		ORAL	200 MG QD PO	5 YR
			Enalapril Maleate (Renitec) Tablets	SS		ORAL	5 MG QD PO	4 YR
			Paracetamol (Dafalgan) Capsules	SS		ORAL	3 G/DAY PO	8 DAY
			Acetylsalicylate Lysine (Kardegic) Powder (Lyophilisate)	SS		ORAL	75 MG QD PO	4 YR
			Digoxin (Hemigoxine Nativelle) Tablets	SS		ORAL	0.125 MG QD PO	4 YR
			Movicol Powder (Lyophilisate)	SS		ORAL	PO	
			Domperidone	SS		ORAL	ORAL	
			Cacit	SS		ORAL	PO	
			Ondansetron Hydrochloride (Zophren)	SS		ORAL	PO	

Date:05/21/01ISR Number: 3725782-3Report Type:Expedited (15-DaCompany Report #B0105115A
Age:72 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aphasia		Ondansetron Hydrochloride	PS	Glaxo Wellcome	INTRAVENOUS	4MG	Continuous
	Apnoea							
	Blood Pressure Increased							
	Cyanosis		Omeprazole	C				UNKNOWN
	Depressed Level Of Consciousness		Ketoprofen	C				UNKNOWN
			Atenolol	C				UNKNOWN
	Dyspnoea		Amlodipine	C				UNKNOWN
	Dystonia		Aspirin	C				UNKNOWN
	Flushing		Anaesthetic	C				UNKNOWN
	Heart Rate Increased							
	Hyperhidrosis							
	Hypertension							
	Oxygen Saturation Decreased							
	Respiratory Rate Decreased							

Date:05/22/01ISR Number: 3726483-8Report Type:Expedited (15-DaCompany Report #B0105124A
Age:56 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Amnesia
	Diplopia
	Dissociation

		Drug Interaction					
		Headache					
		Irritability	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Loss Of Consciousness		Ondansetron			
		Mood Altered		Hydrochloride	PS	Glaxo Wellcome	
INTRAVENOUS	4MG per day						
		Muscle Spasms		Lipitor	SS		
UNKNOWN							
		Opisthotonus		Spironolactone	C		
UNKNOWN							
		Restlessness		Calcium Carbonate	C		
UNKNOWN							
		Tachycardia		Droperidol	C		
UNKNOWN							
				Midazolam	C		
UNKNOWN							
				Fentanyl	C		
UNKNOWN							
				Propofol	C		
UNKNOWN							
				Rocuronium	C		
UNKNOWN							

Date:05/23/01ISR Number: 3727928-XReport Type:Expedited (15-DaCompany Report #B0105115A
Age:72 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Life-Threatening		Apnoea	Foreign	Zofran	PS	Glaxo Wellcome Inc	
INTRAVENOUS	4 MG						
		Blood Pressure Increased	Health				
INTRAVENOUS							
		Cyanosis	Professional	Omeprazole	C		
		Depressed Level Of		Ketoprofen	C		
		Consciousness		Amlodipine	C		
		Diplopia		Aspirin	C		
		Dystonia		Anesthetic	C		
		Feeling Abnormal					
		Flushing					
		Heart Rate Decreased					
		Hyperhidrosis					
		Oxygen Saturation Decreased					
		Respiratory Rate					

	Decreased					
	Speech Disorder					

Date:05/24/01ISR Number: 3728735-4Report Type:Expedited (15-DaCompany Report #B0105124A
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anxiety	Foreign	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	SINGLE DOSE /	
Initial or Prolonged	Diplopia	Health				INTRAVENOUS		
	Dissociation	Professional	Spironolactone	C				
	Drug Interaction		Calcium Carbonate	C				
	Dystonia		Droperidol	C				
	Headache		Midazolam	C				
	Irritability		Fentanyl	C				
	Loss Of Consciousness		Propofol	C				
	Mood Altered		Rocuronium Bromide	C				
	Muscle Spasms							
	Opisthotonus							
	Restlessness							
	Tachycardia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/01ISR Number: 3731718-1Report Type:Expedited (15-DaCompany Report #A0146911A
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Brain Neoplasm		Zofran	PS	Glaxo Wellcome	ORAL	8MG	See text
	Grand Mal Convulsion		Chemotherapy	C			UNKNOWN	

Date:06/01/01ISR Number: 3731721-1Report Type:Expedited (15-DaCompany Report #A0149184A
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Electrolyte Imbalance		Zofran	PS	Glaxo Wellcome	INTRAVENOUS		
	Hypoproteinaemia		Transfusion	C				
	Papilloedema		Platinum	C				
	Vision Blurred		Etoposide	C				

Date:06/01/01ISR Number: 3732283-5Report Type:Expedited (15-DaCompany Report #EMADSS2001003212
Age:85 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pneumonitis	Foreign Health Professional	Ultram	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	150 MG, 2 IN	1 DAILY, ORAL
			Lovenox (Heparin-Fraction, Sodium Salt)	SS				
			Cordarone (Amiodarone Hydrochloride)	SS			5	YR
			Renitec (Enalapril Maleate)	SS			4	YR
			Dafalgan					

			(Paracetamol)	SS		ORAL
3, DAILY,						
ORAL						
			Kardegic (Acetylsalicylate Lysine)	SS		
4 YR						
			Digoxin (Digoxin)	SS		
4 YR						
			Movicol (Movicol)	SS		
			Domperidone (Domperidone)	SS		
			Cacit (Cacit)	SS		
			Zophren (Ondansetron Hydrochloride)	SS		

Date:06/05/01ISR Number: 3733923-7Report Type:Expedited (15-DaCompany Report #A0149184A
Age:49 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Vision Blurred	Foreign	Zofran	PS	Glaxo Wellcome Inc	
INTRAVENOUS INTRAVENOUS						
		Health Professional	Blood	C		
			Platinum Salt	C		
			Etoposide	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/05/01ISR Number: 3733925-0Report Type:Expedited (15-DaCompany Report #A0146911A
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Brain Neoplasm Grand Mal Convulsion	Foreign Health Professional	Zofran Cancer Chemotherapy	PS C	Glaxo Wellcome Inc	ORAL	8 MG/ORAL	

Date:06/07/01ISR Number: 3734734-9Report Type:Direct Company Report #USP 54095
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Zofran	PS	Glaxo Smithkline			

Date:06/07/01ISR Number: 3735966-6Report Type:Expedited (15-DaCompany Report #HQ0475003MAY2001
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electrocardiogram Qt Prolonged Gastrointestinal Haemorrhage Ventricular Tachycardia	Health Professional	Reglan Zofran (Ondansetron Hydrochloride)	PS SS	Ah Robins Co	INTRAVENOUS	INTRAVENOUS	

Date:06/12/01ISR Number: 3737260-6Report Type:Expedited (15-DaCompany Report #B0109909A
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Flushing Nervous System Disorder Visual Disturbance		Ondansetron Hydrochloride	PS	Glaxo Wellcome	INTRAVENOUS	8MG per day	1 DAY

Date:06/13/01ISR Number: 3739942-9Report Type:Direct Company Report #USP 54139
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Zofran	PS	Cerenex			
			Precedex	SS	Abbott Hospital			

Date:06/15/01ISR Number: 3741123-XReport Type:Expedited (15-DaCompany Report #B0109909A
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Flushing	Foreign	Zofran	PS	Glaxo Wellcome Inc	INTRAVENOUS	INTRAVENOUS	
Initial or Prolonged	Nervous System Disorder							
	Visual Disturbance							

Date:06/21/01ISR Number: 3743440-6Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome
Life-Threatening
Hospitalization -
Initial or Prolonged
Required
Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cardiac Disorder		Zofran (Glaxo					
	Complications Of Maternal		Wellcome)	PS	Glaxo Wellcome		8MG X 2 DAILY	
	Exposure To Therapeutic						FIRST	
	Drugs						TRIMESTER-LAS	
	Diaphragmatic Disorder						T TRIMESTER	
	Gastrointestinal Disorder							
	Genital Disorder Female							
	Microcephaly							
	Renal Cyst							
	Syndactyly							

Date:07/02/01ISR Number: 3750348-9Report Type:Expedited (15-DaCompany Report #A0144979A
Age:34 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal		Zofran	PS	Glaxo Wellcome	ORAL	8MG Three	
	Exposure To Therapeutic						times per day	
	Drugs		Propylthiouracil	C		ORAL	100MG Three	
	Intra-Uterine Death						times per day	
	Oligohydramnios		Antiemetic	C				
	Placental Insufficiency							

Date:07/06/01ISR Number: 3753928-XReport Type:Expedited (15-DaCompany Report #A0152415A
Age:12 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination, Auditory	Literature	Zofran	PS	Glaxo Wellcome Inc			
	Hallucination, Visual	Health	Mirtazapine					
	Serotonin Syndrome	Professional	(Formulation					

			Unknown)			
			(Mirtazapine)	SS		
15 MG/AT						
NIGHT						
			Cancer Chemotherapy	C		
			Morphine	C		

Date:07/06/01ISR Number: 3753971-0Report Type:Expedited (15-DaCompany Report #A0144979A
Age:34 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal	Health	Zofran	PS	Glaxo Wellcome Inc	ORAL	8 MG/THREE	
	Exposure To Therapeutic	Professional					TIMES PER DAY	
	Drugs						ORAL	
	Intra-Uterine Death		Propylthiouracil	C				
	Oligohydramnios		Anti-Emetic	C				
	Stillbirth							

Date:07/12/01ISR Number: 3756358-XReport Type:Expedited (15-DaCompany Report #B0113047A
Age:2 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Consumer	Ondansetron Hydrochloride	PS	Glaxo Wellcome	ORAL	3MG per day	16 DAY
			Kayexalate	SS		ORAL		
			Alfacalcidol	SS		ORAL		

			Enteral Nutrition	C		
UNKNOWN						
			Eprex	C		
UNKNOWN						
			Calcium	C		
UNKNOWN						
			Growth Hormone	C		
UNKNOWN						

Date:07/13/01ISR Number: 3757337-9Report Type:Expedited (15-DaCompany Report #A0153183A
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Neutropenia		Zofran	PS	Glaxo Wellcome			
INTRAVENOUS								
Initial or Prolonged			Zosyn	SS				

Date:07/16/01ISR Number: 3759287-0Report Type:Expedited (15-DaCompany Report #A0153183A
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Neutropenia	Health	Zofran	PS	Glaxo Wellcome Inc			
INTRAVENOUS	INTRAVENOUS							
Initial or Prolonged	White Blood Cell Count	Professional	Piperacillin Sodium	SS				
UNK								
	Decreased							

Date:07/16/01ISR Number: 3760070-0Report Type:Expedited (15-DaCompany Report #B0113047A
Age:24 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Foreign	Zofran	PS	Glaxo Wellcome Inc	ORAL		
TWICE PER DAY								
/ ORAL								
			Na Polystyrene Sulfonate (Na Polystyrene					

			Sulfonate)	SS		ORAL
ORAL						
			Alfacalcidol (Alfacalcidol)	SS		ORAL
ORAL						
			Enteral Product	C		
			Eprex	C		
			Calcium Salt	C		
			Growth Hormone	C		

Date:07/17/01ISR Number: 3759275-4Report Type:Expedited (15-DaCompany Report #B0113905A
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Bradycardia	Health Professional	Ondansetron Hydrochloride	PS	Glaxo Wellcome	ORAL
2TAB per day	Gait Disturbance					
Disability	Vomiting					

Date:07/17/01ISR Number: 3761618-2Report Type:Periodic Company Report #200022269US
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Rash Erythematous	Health Professional	Taxotere	PS	Aventis Pharmaceutical Products Inc	
INTRAVENOUS IV 1 DAY						
			Ondansetron	SS		
INTRAVENOUS 32 MG ONCE IV 1 DAY						
			Diphenhydramine Hydrochloride (Benadryl)	C		

			Dexamethasone	C		
			Ondansetron Hydrochloride (Zofran)	C		

Date:07/19/01ISR Number: 3761851-XReport Type:Expedited (15-DaCompany Report #B0113905A
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Bradycardia Gait Disturbance Nausea Vomiting	Foreign Health Professional Company Representative	Zofran	PS	Glaxo Wellcome Inc	ORAL	ORAL	

Date:08/06/01ISR Number: 3770869-2Report Type:Expedited (15-DaCompany Report #A0153183A
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neutropenia White Blood Cell Count Decreased		Zofran Zosyn	PS SS	Glaxo Wellcome	ORAL	1TSP Three times per day	INTRAVENOUS

Date:08/08/01ISR Number: 3772848-8Report Type:Expedited (15-DaCompany Report #A0153183A
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neutropenia	Health Professional	Zofran	PS	Glaxo Wellcome Inc	ORAL	1 TEASPOON / THREE TIMES PER DAY /	

ORAL

			Piperacillin Sodium Injection (Piperacillin Sodium)	SS		
INTRAVENOUS	INTRAVENOUS					

Date:08/13/01ISR Number: 3774988-6Report Type:Expedited (15-DaCompany Report #A0155953A
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion		Zofran	PS	Glaxo Wellcome		4MG Six times per day	
	Dehydration							
	Pyrexia							

Date:08/20/01ISR Number: 3779622-7Report Type:Expedited (15-DaCompany Report #B0116839A
Age:5 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Alanine Aminotransferase		Zofran	PS	Glaxo Wellcome	ORAL	3.5ML Per day	3 DAY
Other	Increased		Methotrexate	C				
INTRAVENOUS							145MG per day	1 DAY
	Gamma-Glutamyltransferase		Cytarabine	C				
INTRATHECAL							30MG per day	1 DAY
	Increased		Asparaginase	C				
INTRAMUSCULAR							2U3 per day	1 DAY
	Hepatic Function Abnormal		Methotrexate	C				
INTRATHECAL							12.5MG per day	1 DAY
	Platelet Count Decreased							
			Hydrocortisone Sodium Succinate	C	Glaxo Wellcome			
INTRATHECAL								

				Atropine Sulphate	C		
INTRAVENOUS	.25MG per day	1	DAY				
				Baktar	C	Glaxo Wellcome	
10MG per day	1	DAY					
				Polymixin B Sulphate	C	Glaxo Wellcome	ORAL
75IU4 per day							
				Juvela	C		ORAL
50MG per day	1	DAY					
				Ubidecarenone	C		
10MG per day	1	DAY					
				Thiopental Sodium	C		
75MG per day	1	DAY					

Date:08/20/01ISR Number: 3781203-6Report Type:Expedited (15-DaCompany Report #A0155953A
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion	Health	Zofran	PS	Glaxo Wellcome Inc		4 MG/ SIX	
Initial or Prolonged	Dehydration	Professional					TIMES PER DAY	
	Pyrexia							

Date:08/23/01ISR Number: 3782774-6Report Type:Expedited (15-DaCompany Report #B0116839A
Age:5 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Alanine Aminotransferase	Foreign	Ondansetron					
Required	Increased	Study	Hydrochloride Syrup					
Intervention to	Gamma-Glutamyltransferase	Health	(Non-Us Product)	PS		ORAL	3.5 M1/ PER	
Prevent Permanent	Increased	Professional					DAY/ ORAL	
Impairment/Damage	Hepatic Function Abnormal		Methotrexate	C				
	Platelet Count Decreased		Cytarabine	C				
			Colaspase	C				
			Methotrexate	C				
			Hydrocortisone Na Succ.	C				
			Atropine Sulphate	C				
			Co-Trimoxazole	C				

Polymixin B Sulphate	C
Juvela	C
Ubidecarenone	C
Thiopentone Sodium	C

Date:08/24/01ISR Number: 3783050-8Report Type:Expedited (15-DaCompany Report #10546
Age:79 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Foreign	Caelyx (Doxorubicin					
Life-Threatening	Loss Of Consciousness	Health	Hcl Liposome					
	Respiratory Arrest	Professional	Injection)	PS		INTRAVENOUS	40 MG/M2	IV
	Shock	Distributor	Zophren	SS				

Date:08/28/01ISR Number: 3783480-4Report Type:Expedited (15-DaCompany Report #B0116839A
Age:5 YR Gender:Male I/FU:F

Outcome	PT
Disability	Alanine Aminotransferase
Other	Increased
	Anorexia
	Gamma-Glutamyltransferase
	Increased
	Hepatic Function Abnormal
	Platelet Count Decreased
	Sedation

Vomiting

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
3.5ML Per day	3 DAY		Zofran	PS	Glaxo Wellcome	ORAL
INTRAVENOUS	145MG per day 1 DAY		Methotrexate	C		
INTRATHECAL	30MG per day 1 DAY		Cytarabine	C		
INTRAMUSCULAR	2U3 per day 1 DAY		Asparaginase	C		
INTRATHECAL	12.5MG per day 1 DAY		Methotrexate	C		
INTRATHECAL			Hydrocortisone Sodium Succinate	C	Glaxo Wellcome	
INTRAVENOUS	.25MG per day 1 DAY		Atropine Sulphate	C		
10MG per day	1 DAY		Baktar	C	Glaxo Wellcome	
75IU4 per day			Polymixin B Sulphate	C	Glaxo Wellcome	ORAL
50MG per day	1 DAY		Juvela	C		ORAL
10MG per day	1 DAY		Ubidecarenone	C		
75MG per day	1 DAY		Thiopental Sodium	C		

Date:09/03/01ISR Number: 3787746-3Report Type:Expedited (15-DaCompany Report #2001069815FR
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Bone Marrow Depression	Foreign	Aracytine			
Life-Threatening	Cardio-Respiratory Arrest	Health	(Cytarabine) Powder,			
	Clostridium Colitis	Professional	Sterile	PS		
INTRAVENOUS	4 G, QD, IV					
	Gastrointestinal Necrosis	Other	Vepsid (Etoposide)	SS		
INTRAVENOUS	320 MG, QD,					
	Laparotomy					
IV						

				Zophren (Ondansetron Hydrochloride)	SS		
INTRAVENOUS	8 MG, QD, IV						
				Neupogen (Filgrastim)	SS		
INTRAVENOUS	250 UG, QD, IV						
				Claforan (Cefotaxime Sodium)	C		
				Ciflox (Ciprofloxacin)	C		

Date:09/04/01ISR Number: 3786881-3Report Type:Expedited (15-DaCompany Report #B0091706A
Age:28 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain		Zofran	PS	Glaxo Wellcome	ORAL	16MG per day	7 DAY
	Blood Creatinine		Cisplatin	SS				
INTRAVENOUS							10	DAY
	Increased		Etoposide	SS				
INTRAVENOUS	190MG per day						10	DAY
	Blood Lactate		Bleomycin	SS				
INTRAVENOUS	30000UNIT per day						12	DAY
	Dehydrogenase Increased							
	Hepatic Enzyme Increased		Decadron	SS				
INTRAVENOUS	16MG per day						5	DAY
	Renal Artery Thrombosis		Paracet	C		ORAL	1G per day	1 DAY
	Renal Infarct		Stemetil	C	Glaxo Wellcome	ORAL	25MG per day	3 DAY
			Novaluzid	C		ORAL	10ML per day	1 DAY
			Solvipect	C		ORAL	10ML per day	1 DAY

Date:09/05/01ISR Number: 3787340-4Report Type:Expedited (15-DaCompany Report #A0159412A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypovolaemia		Zofran	PS	Glaxo Wellcome	ORAL	8MG Twice per day	3 WK

				Prenatal Vitamins	C		

Date:09/05/01ISR Number: 3787349-0Report Type:Expedited (15-DaCompany Report #B0118504A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Output Decreased		Ondansetron Hydrochloride	PS	Glaxo Wellcome	INTRAVENOUS		
Hospitalization - Initial or Prolonged	Cardiomyopathy							
	Circulatory Collapse		Ondansetron Hydrochloride	SS	Glaxo Wellcome	ORAL	UNKNOWN	
			Cisplatin	SS				
			Gemzar	SS			UNKNOWN	
			Chemotherapy	C			UNKNOWN	

Date:09/05/01ISR Number: 3788619-2Report Type:Expedited (15-DaCompany Report #N129938
Age:24 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Health Professional	Kayexalate (Sodium Polystyrene Sulfonate) (See Attached Pages For Additional Suspect	PS		ORAL	PO	
			Un-Alfa (Alfacalcidol) (See Attached Pages For Additional Suspect Drugs)	SS		ORAL	PO	
			Zophren (Ondansetron)	SS		ORAL	3 MG PO	16 DAY
			Eprex (Epoetin Alfa)	C				
			Eucalcic (Calcium)	C				
			Growth Hormone (Recombinant Human					

			Growth Hormone)	C		

Date:09/06/01ISR Number: 3787897-3Report Type:Expedited (15-DaCompany Report #A0159412A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hypovolaemia		Zofran	PS	Glaxo Wellcome	ORAL	8MG Twice per	
Initial or Prolonged							day	3 WK
			Prenatal Vitamins	C				

Date:09/06/01ISR Number: 3787906-1Report Type:Expedited (15-DaCompany Report #B0118504A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Output Decreased		Ondansetron					
Hospitalization -	Cardiomyopathy		Hydrochloride	PS	Glaxo Wellcome		INTRAVENOUS	
Initial or Prolonged	Circulatory Collapse		Ondansetron					
			Hydrochloride	SS	Glaxo Wellcome	ORAL		
			Cisplatin	SS			UNKNOWN	
			Gemzar	SS			UNKNOWN	
			Chemotherapy	C			UNKNOWN	

Date:09/07/01ISR Number: 3789881-2Report Type:Expedited (15-DaCompany Report #B0091706A
Age:28 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased Hepatic Enzyme Increased Renal Artery Thrombosis	Foreign Health Professional	Zofran (Formulation Unknown) (Ondansetron Hydrochloride)	PS		ORAL		
			Cisplatin (Formulation Unknown) (Cisplatin)	SS				
INTRAVENOUS	INTRAVENOUS							
			Etoposide (Formulation Unknown) (Etoposide)	SS				
INTRAVENOUS	INTRAVENOUS							
			Bleomycin (Formulation Unknown) (Bleomycin)	SS				
INTRAVENOUS	INTRAVENOUS							
			Dexamethasone (Formultion Unknown) (Dexamethasone)	SS				
INTRAVENOUS	INTRAVENOUS							
			Paracetamol	C				
			Prochlorperazine	C				
			Novaluzid	C				
			Solvipect	C				

Date:09/10/01ISR Number: 3789555-8Report Type:Expedited (15-DaCompany Report #B0089805A
Age:38 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arterial Disorder Arterial Thrombosis Limb		Ondansetron Hydrochloride	PS	Glaxo Wellcome	ORAL	16MG per day	5 DAY
Other	Cerebral Artery Occlusion		Cisplatin	SS				
UNKNOWN	44MG per day 5 DAY							
	Facial Palsy		Etoposide	SS				
UNKNOWN	220MG per day 5 DAY							
	Pain In Extremity		Bleomycin	SS				
UNKNOWN	30000IU per							

Pulse Pressure Decreased

day	5	DAY					
			Decadron	SS			
INTRAVENOUS	16MG per day	5	DAY				
			Toilax	C			
UNKNOWN							
			Lasix	C			ORAL
15MG per day							
			Paracet	C			ORAL
1G per day							
			Stemetil	C	Glaxo Wellcome		ORAL
25MG per day							
			Losec	C			ORAL
20MG per day	5	DAY					
			Imovane	C			ORAL
7.5MG per day							
			Serevent	C	Glaxo Wellcome		
RESPIRATORY							
(INHALATION)	1PUFF Twice						
per day							
			Pulmicort	C			
RESPIRATORY							
(INHALATION)	400MG Three						
times per day							
			Bricanyl	C			
UNKNOWN							
			Stemetil	C	Glaxo Wellcome		
UNKNOWN	8MG As						
required							
			Fluticasone	C	Glaxo Wellcome		
RESPIRATORY							
(INHALATION)	250UG Per day						

Date:09/10/01ISR Number: 3789558-3Report Type:Expedited (15-DaCompany Report #B0113047A
Age:2 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Ondansetron Hydrochloride	PS	Glaxo Wellcome	ORAL	3MG per day	16 DAY

			Kayexalate	SS		ORAL
			Alfacalcidol	SS		ORAL
			Enteral Nutrition	C		
UNKNOWN						
			Eprex	C		
UNKNOWN						
			Calcium	C		
UNKNOWN						
			Growth Hormone	C		
UNKNOWN						

Date:09/10/01ISR Number: 3789560-1Report Type:Expedited (15-DaCompany Report #B0118705A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Clonic Convulsion		Zophren	PS	Glaxo Wellcome	
INTRAVENOUS						
Initial or Prolonged	Malignant Melanoma		Zophren	SS	Glaxo Wellcome	ORAL
			Seresta	SS		ORAL
			Multivitamins	SS		
UNKNOWN						
			Chemotherapy	C		

Date:09/11/01ISR Number: 3790237-7Report Type:Expedited (15-DaCompany Report #B0119024A
Age:16 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Acute Respiratory		Ondansetron			
Life-Threatening	Distress Syndrome		Hydrochloride	PS	Glaxo Wellcome	
INTRAVENOUS	2 DAY					
Hospitalization -	Blood Lactate		Cyclophosphamide	SS		
INTRAVENOUS	4.2G per day 2 DAY					
Initial or Prolonged	Dehydrogenase Increased		Uromitexan	SS		
INTRAVENOUS	4.2G per day 2 DAY					
	Cardiac Arrest		Prednisone	C		
UNKNOWN						
	Chest Pain		Di-Antalvic	C		
UNKNOWN						
	Chills		Frusemide	C		
UNKNOWN						

		Circulatory Collapse		Sodium Chloride	C		
UNKNOWN							
		Diarrhoea		Calcium Carbonate	C		
UNKNOWN							
		Hypotension		Alizapride	C		
INTRAVENOUS	3UNIT per day						
		Injury Asphyxiation		Sterogyl	C		
UNKNOWN							
		Oxygen Saturation Decreased					
		Pericardial Effusion					
		Pericarditis					
		Peripheral Coldness					
		Pulmonary Oedema					
		Pyrexia					
		Sepsis					
		Sinus Tachycardia					
		Vomiting					

Date:09/11/01ISR Number: 3791174-4Report Type:Expedited (15-DaCompany Report #B0116839A
Age:5 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Alanine Aminotransferase	Foreign	Ondansetron					
Required	Increased	Study	Hydrochloride Syrup					
Intervention to	Anorexia	Health	(Non-Us Product)	PS		ORAL	3.5 ML PER	
Prevent Permanent	Condition Aggravated	Professional					DAY / ORAL	
Impairment/Damage	Gamma-Glutamyltransferase		Methotrexate	C				
	Increased		Cytarabine	C				
	Oral Intake Reduced		Colaspase	C				
	Platelet Count Decreased		Hydrocortisone Na					
	Sedation		Succ.	C				
	Vomiting		Atropine Sulphate	C				
			Co-Trimoxazole	C				

			Polymixin B Sulphate	C			
			Juvela	C			
			Ubidecarenone	C			
			Thiopentone Sodium	C			

Date:09/11/01ISR Number: 3791441-4Report Type:Expedited (15-DaCompany Report #A0159412A
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypovolaemia	Health Professional	Zofran Tablet (Ondansetron Hydrochloride)	PS		ORAL	8 MG / TWICE PER DAY / ORAL	
			Prenatal	C				

Date:09/11/01ISR Number: 3791522-5Report Type:Expedited (15-DaCompany Report #B0118504A
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Output Decreased	Foreign	Zofran (Ondansetron Hydrochloride)	PS		INTRAVENOUS	2 MG/ M1/	
Hospitalization - Initial or Prolonged	Cardiomyopathy	Health Professional						
	Circulatory Collapse					INTRAVENOUS		
			Zofran Tablet (Ondansetron Hydrochloride)	SS		ORAL	AS REQUIRED/ ORAL	
			Cisplatin (Cisplatin)	SS				
			Gemcitabine (Gemcitabine)	SS				
			Cancer Chemotherapy	C				

Date:09/12/01ISR Number: 3790575-8Report Type:Expedited (15-DaCompany Report #B0119026A
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain		Ondansetron					
Life-Threatening	Aplasia		Hydrochloride	PS	Glaxo Wellcome			
						INTRAVENOUS	8MG per day	4 DAY
Hospitalization -	Cardio-Respiratory Arrest		Cytarabine	SS				
						INTRAVENOUS	4G per day	5 DAY
Initial or Prolonged	Clostridium Colitis		Etoposide	SS				
						INTRAVENOUS	320MG per day	4 DAY
	Diarrhoea		Filgrastim	SS				
						INTRAVENOUS	250UG per day	8 DAY
	Intestinal Infarction		Ciflox	C				
						UNKNOWN		
	Pyrexia		Claforan	C				
						UNKNOWN		
	Splenic Rupture		Metronidazole	C				
						UNKNOWN		

Date:09/12/01ISR Number: 3792202-2Report Type:Expedited (15-DaCompany Report #B0089805A
Age:38 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization -	Arterial Thrombosis
Initial or Prolonged	Cerebral Artery Occlusion
Other	Facial Palsy
	Feeling Cold
	Pain In Extremity
	Peripheral Vascular
	Disorder

Pulse Absent

			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Health Professional	Zofran (Formulation Unknown) (Ondansetron Hydrochloride)	PS		ORAL
ORAL							
				Cisplatin (Formulation Unknown) (Cisplatin)	SS		
				Etoposide (Formulation Unknown) (Etoposide)	SS		
				Bleomycin (Formulation Unknown) (Bleomycin)	SS		
				Dexamethasone (Formulation Unknown) (Dexamethasone)	SS		
INTRAVENOUS	INTRAVENOUS						
				Bisacodyl	C		
				Frusemide	C		
				Paracetamol	C		
				Prochlorperazine	C		
				Omeprazole	C		
				Zopiclone	C		
				Salmeterol Xinafoate	C		
				Budesonide	C		
				Terbutaline Sulphate	C		
				Prochlorperazine	C		
				Fluticasone Propionate	C		

Date:09/12/01ISR Number: 3792205-8Report Type:Expedited (15-DaCompany Report #B0113047A
Age:24 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Death	Foreign	Zofran (Formulation Unknown) (Ondansetron			

	Hydrochloride)	PS	ORAL
TWICE PER DAY/ORAL			
	Na Polystyrene Sulfonate (Formulation Unknown) (Na Polystyrene	SS	ORAL
ORAL			
	Alfacalcidol (Formulation Unknown) (Alfacalcidol)	SS	ORAL
ORAL			
	Enteral Product (Unspecifi	C	
	Eprex	C	
	Calcium Salt	C	
	Growth Hormone	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/17/01ISR Number: 3793465-XReport Type:Expedited (15-DaCompany Report #B0119705A
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Hepatitis B		Ondansetron Hydrochloride	PS	Glaxo Wellcome	INTRAVENOUS	4MG Per day	8 DAY
	Immune System Disorder		Famotidine	C		INTRAVENOUS	20MG Per day	28 DAY
	Malaise		Famotidine	C		ORAL	40MG Twice per day	28 DAY
	Pyrexia		Epirubicin	C		INTRAVENOUS	70MG Per day	1 DAY
			Fluorouracil	C		INTRAVENOUS	750MG Per day	1 DAY
			Cyclophosphamide	C		ORAL	100MG Twice per day	8 DAY
			Dexamethasone	C		INTRAVENOUS	4MG Per day	1 DAY

Date:09/17/01ISR Number: 3794668-0Report Type:Expedited (15-DaCompany Report #B0119024A
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening Hospitalization - Initial or Prolonged	Acute Respiratory Distress Syndrome Blood Creatine Phosphokinase Increased	Foreign	Zofran Unspecified Injectable (Ondansetron Hydrochloride)	PS		INTRAVENOUS	INTRAVENOUS INFUSION	
	Blood Lactate Dehydrogenase Increased Cardiac Arrest Diarrhoea		Cyclophosphamide Solution (Cyclophosphamide)	SS		INTRAVENOUS	INTRAVENOUS INFUSION	
	Dyspnoea Injury Asphyxiation		Mesna Solution					

		Oxygen Saturation		(Mesna)	SS		
INTRAVENOUS	INTRAVENOUS						
		Decreased					
INFUSION							
		Pericardial Effusion		Prednisone	C		
		Pericarditis		Di-Antalvic	C		
		Peripheral Coldness		Frusemide	C		
		Pulmonary Oedema		Sodium Chloride	C		
		Pyrexia		Calcium Carbonate	C		
		Sepsis		Alizapride			
		Vomiting		Hydrochloride	C		
				Ergocalciferol	C		

Date:09/17/01ISR Number: 3794680-1Report Type:Expedited (15-DaCompany Report #B0119026A
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Aplasia	Foreign	Zofran Unspecified			
Life-Threatening	Cardio-Respiratory Arrest		Injectable			
Hospitalization -	Clostridium Colitis		(Ondansetron			
Initial or Prolonged	Gastrointestinal Necrosis		Hydrochloride)	PS		
INTRAVENOUS	INTRAVENOUS					
	Pyrexia					
INFUSION						
	Splenic Rupture		Cytarabine Solution			
			(Cytarabine)	SS		
INTRAVENOUS	INTRAVENOUS					
INFUSION						
			Etoposide Solution			
			(Etoposide)	SS		
INTRAVENOUS	INTRAVENOUS					
INFUSION						
			Filgrastim Solution			
			(Filgrastim)	SS		
INTRAVENOUS	INTRAVENOUS					
INFUSION						
			Ciflox	C		
			Claforan	C		

				Metronidazole	C		

Date:09/18/01ISR Number: 3795531-1Report Type:Expedited (15-DaCompany Report #10960441
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Function Abnormal Jaundice	Foreign Health Professional Company Representative	Taxol Inj Syn (Paclitaxel)	PS		INTRAVENOUS	120 MILLIGRAM, 1/1 CYCLE IV	
			Loxonin (Loxoprofen Sodium)	SS		ORAL	180 MILLIGRAM, ORAL	
			Zantac (Ratidine Hcl)	SS		INTRAVENOUS	50 MILLIGRAM, IV	
			Nolvadex (Tamoxifen Citrate)	SS		ORAL	30 MILLIGR AM, ORAL	
			Zofran (Ondansetron Hcl)	SS		INTRAVENOUS	IV	
			Mucosta (Rebamipide)	C		ORAL	300 MILLIGRAM, ORAL	
			Decadron (Dexamethasone)	C				
			Chlor-Trimetron (Chlorpheniramine Maleate)	C				

Date:09/20/01ISR Number: 3796203-XReport Type:Expedited (15-DaCompany Report #WAES 01083552
Age:76 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Burning Sensation	Foreign Study	Tab Dexamethasone Unk	PS		ORAL	DAILY/PO	
	Dizziness Dyspepsia	Health Professional	Cap Placebo (Unspecified) Unk	SS		ORAL	PO; DAILY/PO	
	Faeces Discoloured Haematemesis		Infusion (Form) Cisplatin Unk	SS			INTRAVENOUS	127
	Haemoglobin Decreased						MG/DAILY/IV	
	Hiccups Inflammation		Infusion (Form) Ondansetron Unk	SS			INTRAVENOUS	32
	Oesophagitis						MG/DAILY/IV	
			Infusion (Form) Vinorelbine Tartrate Unk	SS			INTRAVENOUS	50
							MG/DAILY/IV	
			Lasonil	C				
			Temazepam	C				

Date:09/21/01ISR Number: 3796941-9Report Type:Direct Company Report #
Age:44 YR Gender:Female I/FU:I

Outcome	PT
Other	Dyspnoea Pruritus

Vein Discolouration

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
			Zofran	PS	Glaxo Wellcome	INTRAVENOUS	4MG ONE TIME	IV

Date:09/21/01ISR Number: 3797356-XReport Type:Expedited (15-DaCompany Report #B0119705A
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Hepatic Function Abnormal Hepatitis B Malaise Pyrexia	Foreign Health Professional	Zofran Injection (Ondansetron Hydrochloride)	PS		INTRAVENOUS	4 MG PER DAY/INTRAVENO US	
			Famotidine	C				
			Epirubicin	C				
			Fluorouracil	C				
			Cyclophosphamide	C				
			Dexamethasone	C				

Date:09/24/01ISR Number: 3797143-2Report Type:Expedited (15-DaCompany Report #B0119913A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Transient Ischaemic Attack		Zofran	PS	Glaxo Wellcome			

Date:10/01/01ISR Number: 3801627-8Report Type:Expedited (15-DaCompany Report #A0159412A
Age:33 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Hypovolaemia		Zofran 8MG Twice per day 3 WK	PS	Glaxo Wellcome	ORAL
			Prenatal Vitamins	C		

Date:10/02/01ISR Number: 3802293-8Report Type:Expedited (15-DaCompany Report #B0119913A
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cerebral Infarction	Consumer	Zofran 8MG Twice per day	PS	Glaxo Wellcome	ORAL		
Hospitalization - Initial or Prolonged	Loss Of Consciousness						3	DAY
	Transient Ischaemic Attack		Propranolol Hydrochloride 80MG Per day	C				
			Exemestane	C		ORAL		

Date:10/05/01ISR Number: 3806821-8Report Type:Expedited (15-DaCompany Report #A0159412A
Age:33 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypovolaemia	Health Professional	Zofran Tablet (Ondansetron Hydrochloride) 8 MG / TWICE PER DAY / ORAL	PS		ORAL		
			Prenatal	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/09/01ISR Number: 3805428-6Report Type:Expedited (15-DaCompany Report #B0113905A
Age:68 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Condition Aggravated		Ondansetron Hydrochloride	PS	Glaxo Wellcome	ORAL	4MG Twice per	
Disability	Gait Disturbance						day	6 MON
	Nausea Vomiting		Medrol	C		ORAL		

Date:10/10/01ISR Number: 3807110-8Report Type:Expedited (15-DaCompany Report #B0119913A
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Cerebral Infarction Loss Of Consciousness Transient Ischaemic Attack	Foreign	Ondansetron Hydrochloride (Formulation Unknown)					
			(Ondansetron	PS		ORAL	8 MG / TWICE	
							PER DAY /	
							ORAL	3 DAY
			Propranolol Hydrochloride	C				
			Exemestane	C				

Date:10/16/01ISR Number: 3810159-2Report Type:Expedited (15-DaCompany Report #B0113905A
Age:68 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Condition Aggravated	Foreign Health	Zofran Tablet (Ondansetron					
Disability	Gait Disturbance	Professional	Hydrochloride)	PS		ORAL	4 MG / TWICE	
	Vomiting	Company					PER DAY /	

Representative
ORAL
Medrol C

Date:10/17/01ISR Number: 3809822-9Report Type:Expedited (15-DaCompany Report #B0122387A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Induced		Ondansetron	PS	Glaxo Wellcome	INTRAVENOUS	8MG As required	
	Complications Of Maternal Exposure To Therapeutic Drugs							
	Intra-Uterine Death							
	Vaginal Haemorrhage							

Date:10/17/01ISR Number: 3811038-7Report Type:Direct Company Report #
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia		Zofran 4mg Glaxo Wellcome	PS	Glaxo Wellcome	INTRAVENOUS	4MG ONCE IV	BOLUS

BOLUS

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/23/01ISR Number: 3813635-1Report Type:Expedited (15-DaCompany Report #B0122387A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Induced	Foreign	Zofran Injection					
	Complications Of Maternal Exposure To Therapeutic	Health Professional	(Ondansetron Hydrochloride)	PS		INTRAVENOUS	8 MG /	AS REQUIRED /
	Drugs							
	Intra-Uterine Death					INTRAVENOUS		
	Vaginal Haemorrhage							

Date:10/25/01ISR Number: 3814642-5Report Type:Direct Company Report #
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arrhythmia		Zofran	PS		INTRAVENOUS	4 MG IVP Q 12 HRS	
			Pepcid	C				

Date:11/01/01ISR Number: 3817885-XReport Type:Expedited (15-DaCompany Report #B0124508A
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypersensitivity		Zophren	PS	Glaxo Wellcome	INTRAVENOUS	8MG per day	1 DAY
	Paraesthesia		Cisplatin	SS		INTRAVENOUS	97MG per day	1 DAY
	Rhinorrhoea		Methylprednisolone Sodium Succinate	SS		INTRAVENOUS		1 DAY
			Fluorouracil	C		INTRAVENOUS	1940MG per day	2 DAY

			Calcium Folinate	C	Glaxo Wellcome	
INTRAVENOUS	194MG per day 2 DAY					

Date:11/02/01ISR Number: 3819955-9Report Type:Expedited (15-DaCompany Report #01P-056-0112298-00
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Diarrhoea Malaise Rash Erythematous Vomiting	Foreign Health Professional Other	Tranxene (Clorazepate Dipotassium)			
			(Clorazepate Dipotassium)	PS		
INTRAVENOUS	20 MG, 1 IN 1 D,					
INTRAVENOUS						
			Cyclophosphamide	SS		
INTRAVENOUS	1200 MG, 1 IN 1 D,					
INTRAVENOUS						
			Ondansetron Hydrochloride	SS		
INTRAVENOUS	8 MG, 1 IN 1 D,					
INTRAVENOUS						
			Doxorubicin Hydrochloride	SS		
INTRAVENOUS	120 MG, 1 IN 1,					
INTRAVENOUS						

Date:11/15/01ISR Number: 3824488-XReport Type:Expedited (15-DaCompany Report #B0125643A
Age:53 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Back Pain		Zophren	PS	Glaxo Wellcome	ORAL	2UNIT per day	
	Bundle Branch Block Right		Cisplatine	SS		INTRAVENOUS		
	Dyspnoea		Vinorelbine	C	Glaxo Wellcome	INTRAVENOUS		
	Nodal Arrhythmia							

Date:11/19/01ISR Number: 3827605-0Report Type:Expedited (15-DaCompany Report #801#3#2001-18454 (000)
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea	Health Professional	Endoxan (Cyclophosphamide)	PS		INTRAVENOUS	1200 MILLIGRAM	1 DAY
	Malaise							
	Rash Erythematous							
	Vomiting							
			Adriblastine (Doxorubicin Hydrochloride)	SS		INTRAVENOUS	120 MG I.V.	
			Tranxene (Clorazepate Dipotassium)	SS		INTRAVENOUS	20 MG I.V.	
			Zophren (Ondansetron Hydrochloride)	SS		INTRAVENOUS	8 MG I.V.	

Date:11/21/01ISR Number: 3827108-3Report Type:Expedited (15-DaCompany Report #B0126387A
Age:3 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Blindness		Zofran	PS	Glaxo Wellcome	
INTRAVENOUS 3MG Unknown						
	Oculogyration		Propacetamol	C		
UNKNOWN						
	Visual Disturbance					

Date:11/28/01ISR Number: 3830598-3Report Type:Expedited (15-DaCompany Report #A0167910A
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Complications Of Maternal		Zofran	PS	Glaxo Wellcome	ORAL
4MG See						
	Exposure To Therapeutic					
dosage text						
	Drugs		Prenatal Vitamins	C		
	Stillbirth					

Date:11/30/01ISR Number: 3846464-3Report Type:Periodic Company Report #HQ3960101AUG2001
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Leukopenia	Health	Zosyn			
Initial or Prolonged	Neutropenia	Professional	(Piperacillin/Tazoba			
Disability			ctam, Injection)	PS		
INTRAVENOUS INTRAVENOUS						
Other			Zofran (Ondansetron			
			Hydrochloride)	SS		
INTRAVENOUS INTRAVENOUS						
			Antineoplastic			
			Agents			
			(Antineoplastic			
			Agents)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/04/01ISR Number: 3833444-7Report Type:Expedited (15-DaCompany Report #B0128082A
Age:4 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion		Zofran	PS	Glaxo Wellcome		UNKNOWN	4MG See dosage text
	Muscle Rigidity							
			Chemotherapy	C			UNKNOWN	
			Acyclovir	C	Glaxo Wellcome		UNKNOWN	

Date:12/06/01ISR Number: 3834784-8Report Type:Expedited (15-DaCompany Report #B0126387A
Age:3 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Blindness		Zofran	PS	Glaxo Wellcome		INTRAVENOUS	3MG Unknown
Other	Oculogyration		Propacetamol	C			UNKNOWN	

Date:12/13/01ISR Number: 3839341-5Report Type:Expedited (15-DaCompany Report #A128398
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Interaction	Health Professional Company Representative	Zoloft Tablets	PS				
	Respiratory Arrest		Ondansetron	SS				

Date:12/18/01ISR Number: 3842324-2Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Growth Retardation		Zofran Zofran	PS		ORAL	1MG 1 PER DAY	

	Maternal Drugs Affecting					ORAL
	Foetus					
	Weight Decreased					
	Weight Gain Poor					

Date:12/19/01ISR Number: 3840975-2Report Type:Expedited (15-DaCompany Report #A0169666A
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Fatigue		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	8MG Four	
	Movement Disorder							times per day
	Myalgia		Ativan	C				
	Tremor		Fentanyl	C		OTHER		

Date:12/21/01ISR Number: 3842782-3Report Type:Expedited (15-DaCompany Report #B0121681A
Age:0 DY Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Caesarean Section		Zofran	PS	Glaxo Wellcome	INTRAVENOUS		
Hospitalization -	Hypometabolism		Xylocaine	SS		UNKNOWN		
Initial or Prolonged	Hypotonia Neonatal		Ropivacaine	SS		UNKNOWN		
	Maternal Drugs Affecting							
	Foetus							
	Neonatal Apnoeic Attack							
	Somnolence Neonatal							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/28/01ISR Number: 3846493-XReport Type:Expedited (15-DaCompany Report #S01-FRA-02478-01
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Serum Serotonin Increased	Foreign Health Professional Other	Citalopram Zophren (Ondansetron Hydrochloride)	PS SS				

Date:01/02/02ISR Number: 3846138-9Report Type:Expedited (15-DaCompany Report #B0130182A
Age:13 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bulbar Palsy		Ondansetron	PS	Glaxo Wellcome	INTRAVENOUS	24MG per day	42 DAY
			Cytarabine	C		INTRAVENOUS	125MG per day	4 DAY
			Vincristine	C		INTRAVENOUS	2MG Cyclic	
			Daunorubicin	C		INTRAVENOUS	41MG Unknown	
			Frusemide	C	Glaxo Wellcome	INTRAVENOUS	30MG As required	
			Metoclopramide	C		INTRAVENOUS	12MG Unknown	7 DAY
			Paracetamol	C	Glaxo Wellcome	ORAL	450MG per day	
			Allopurinol	C	Glaxo Wellcome	ORAL	65MG per day	34 DAY
			Prednisolone	C		ORAL	4G per day	3 DAY
			Calcium Carbonate	C		ORAL	UNKNOWN	
			Ranitidine	C	Glaxo Wellcome			
			Methotrexate	C		INTRATHECAL	12MG Cyclic	
			Amoxycillin	C		ORAL	750MG per day	5 DAY
			Cyclophosphamide	C		INTRAVENOUS	1670MG Single	

dose	1	DAY						
					Nystatin	C		ORAL
400000U								
Unknown								
					Benzydamine	C		ORAL
					Chlorhexidine	C		ORAL
40ML per day								
					Morphine	C		ORAL
60MG per day	4	DAY						
					Ceftazidime	C	Glaxo Wellcome	
INTRAVENOUS	6G per day		4	DAY				
					Vancomycin	C		
INTRAVENOUS	2G per day		10	DAY				
					Fluconazole	C		
INTRAVENOUS	200MG per day		1	DAY				
					Amphotericin	C		
INTRAVENOUS			11	DAY				
					Meropenem	C		
INTRAVENOUS	3G per day		8	DAY				
					Metronidazole	C	Glaxo Wellcome	
INTRAVENOUS	1.2G per day		2	DAY				
					Gentamicin	C	Glaxo Wellcome	
INTRAVENOUS	240MG Unknown		10	DAY				
					Lenograstim	C		
SUBCUTANEOUS	263MCG							
Unknown	7	DAY						
					Rasburicase	C		
INTRAVENOUS	112MG per day		4	DAY				
					Asparaginase	C		
INTRAMUSCULAR	9600IU See							
dosage text								

Date:01/18/02ISR Number: 3855911-2Report Type:Expedited (15-DaCompany Report #B0131054A
Age:24 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cyanosis Pharyngitis Rash Erythematous	Foreign	Zofran Tablet (Ondansetron Hydrochloride)	PS		ORAL	300 MG PER DAY ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/22/02ISR Number: 3855221-3Report Type:Expedited (15-DaCompany Report #304844
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis		Kytril	PS	Roche		1	DAY
			Endoxan	SS			500 MG/M2.	
			Farmorubicine	SS			FIRST COURSE.	29 DAY
			Zophren	SS			5	DAY
			Fluorouracil	SS			500 MG/M2.	
			Primperan	SS			FIRST COURSE.	29 DAY
			Motilium	C			1	DAY

Date:01/23/02ISR Number: 3856134-3Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11674629
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis		Endoxan Inj	PS	Bristol-Myers Squibb Company		INTRAVENOUS	
			Farmorubicin	SS			INTRAVENOUS	
			5-Fu	SS			INTRAVENOUS	
			Kytril	SS			INTRAVENOUS	
			Zophren	SS		ORAL		
			Primperan	SS			INTRAVENOUS	
			Motilium	C				

Date:01/23/02ISR Number: 3859633-3Report Type:Expedited (15-DaCompany Report #2002088573FR
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Lesion Hepatitis	Foreign Health Professional Other	Farmorubicin(Epirubicin Hydrochloride)Powder, Sterile	PS			INTRAVENOUS	160 MG, CYCLIC, IV
			Endoxan(Cyclophosphamide)	SS			INTRAVENOUS	800 MG, CYCLIC, IV
			Fluorouracil(Fluorouracil)	SS			INTRAVENOUS	800 MG, CYCLIC, IV
			Primperan(Metoclopramide)	SS			INTRAVENOUS	IV
			Zophren(Ondansetron Hydrochloride)	SS			ORAL	ORAL
			Kytril (Granisetron)	SS			INTRAVENOUS	IV
			Motilium (Domperidone)	C				

Date:01/24/02ISR Number: 3860256-0Report Type:Expedited (15-DaCompany Report #304844
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis	Foreign Other	Kytril (Granisetron) Endoxan (Cyclophosphamide)	PS SS		INTRAVENOUS	INTRAVENOUS	
							INTRAVENOUS	800 MG 1 PER ONE DOSE

				Farmorubicine (Epirubicin Hydrochloride)	SS		
INTRAVENOUS	160 MG 1 PER ONE DOSE						
INTRAVENOUS				Zophren (Ondansetron Hydrochloride)	SS		ORAL
ORAL				Fluorouracil (Fluorouracil)	SS		
INTRAVENOUS	800 MG 1 PER ONE DOSE						
INTRAVENOUS				Primperan (Metoclopramide Hydrochloride)	SS		
INTRAVENOUS	INTRAVENOUS			Motilium (Domperidone)	C		

Date:01/25/02ISR Number: 3857853-5Report Type:Expedited (15-DaCompany Report #A0173334B
Age: Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Caesarean Section		Zofran	PS	Glaxo Wellcome	INTRAVENOUS		
	Congenital Intestinal Malformation Kidney Malformation Maternal Drugs Affecting Foetus		Zofran	SS	Glaxo Wellcome	ORAL		

Date:01/28/02ISR Number: 3858971-8Report Type:Expedited (15-DaCompany Report #B0131054A
Age:2 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Cyanosis Pharyngitis Rash Erythematous		Zofran	PS	Glaxo Wellcome	ORAL

300MG Per day 1 DAY

Date:01/28/02ISR Number: 3861442-6Report Type:Expedited (15-DaCompany Report #801#3#2002-18783 (000)
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Hepatitis	Health Professional	Endoxan (Cyclophosphamide)	PS			INTRAVENOUS	800 MILLIGRAM
			Farmorubicin (Epirubicin)	SS			INTRAVENOUS	160 MG I.V.
			Fluorouracil (Fluorouracil)	SS			INTRAVENOUS	800 MG I.V.
			Kytril (Granisetron)	SS			INTRAVENOUS	I.V.
			Zophren (Ondansetron Hydrochloride)	SS		ORAL	P.O.	
			Primperan (Metoclopramide)	SS			INTRAVENOUS	I.V.
			Motilium (Domperidone)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/29/02ISR Number: 3860872-6Report Type:Expedited (15-DaCompany Report #B0133033A
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase		Zophren	PS	Glaxo Wellcome			
INTRAVENOUS							24MG per day	1 DAY
Initial or Prolonged	Increased		Solumedrol	SS				
INTRAVENOUS								1 DAY
	Aspartate		Cisplatin	SS				
INTRAVENOUS							80MGM2 per	
	Aminotransferase							
day								
	Increased		Metoclopramide	SS				
INTRAVENOUS							60MG per day	1 DAY
	Blood Alkaline		Kytril	SS	Glaxo Wellcome	ORAL		
4MG per day	5 DAY							
	Phosphatase Increased		Cetornan	C				
UNKNOWN								
	Gamma-Glutamyltransferase		Di-Antalvic	C				
UNKNOWN								
	Increased		Eprex	C				
UNKNOWN							4285.7IU per	
	Infectious Mononucleosis							
day								
	Liver Function Test		Forlax	C				
UNKNOWN								
	Abnormal		Gemzar	C				
INTRAVENOUS							1250MGM2 per	
day	9 DAY							
			Iskedyl	C				
UNKNOWN								
			Miniphase	C				
UNKNOWN								
			Morphine	C				
UNKNOWN							60MG per day	
			Taxotere	C				
UNKNOWN								
			Xanax	C		ORAL		
.5MG Twice								
per day								
			Sodium Fluoride	C	Glaxo Wellcome			
UNKNOWN								

Date:01/29/02ISR Number: 3860874-XReport Type:Expedited (15-DaCompany Report #B0133237A
Age:56 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaemia		Zophren	PS	Glaxo Wellcome	INTRAVENOUS	8MG per day	1 DAY
Life-Threatening	Hypoproteinaemia		Solumedrol	SS		INTRAVENOUS	60MG per day	1 DAY
	Sudden Death		Unspecified Medication	C		INTRAVENOUS	2.3MG per day	2 DAY
			Doxorubicin	C		UNKNOWN		
			Epirubicin	C		UNKNOWN		
			Ifosfamide	C		UNKNOWN		

Date:01/29/02ISR Number: 3860875-1Report Type:Expedited (15-DaCompany Report #B0133246A
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis		Zophren	PS	Glaxo Wellcome	ORAL	5 DAY	
			Primperan	SS	Glaxo Wellcome	INTRAVENOUS		1 DAY
			Farmorubicine	SS		INTRAVENOUS		1 DAY
			Kytril	SS	Glaxo Wellcome	INTRAVENOUS		1 DAY
			Endoxan	SS		INTRAVENOUS		1 DAY
			Fluorouracil	SS		INTRAVENOUS		
			Domperidone	C		UNKNOWN		

Date:01/29/02ISR Number: 3860876-3Report Type:Expedited (15-DaCompany Report #B0133247A
Age:53 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain
	Eczema
	Pyrexia
	Rash Generalised
	Rash Maculo-Papular

Rash Pustular

Stomatitis

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
INTRAVENOUS	1UNIT Per day 2 DAY		Zophren	PS	Glaxo Wellcome	
INTRAVENOUS	1UNIT Per day		Calcium Folinate	SS	Glaxo Wellcome	
INTRAVENOUS	1UNIT Per day		Fluorouracil	SS		
INTRAVENOUS	1UNIT Per day		Oxaliplatin	SS		
UNKNOWN			Prednisolone	C		

Date:01/29/02ISR Number: 3862025-4Report Type:Expedited (15-DaCompany Report #2002SE00540
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Angioneurotic Oedema	Foreign	Zestril	PS		ORAL	10 MG DAILY;	
Hospitalization - Initial or Prolonged	Dysphonia Dyspnoea Laryngeal Oedema Stridor	Health Professional Other	Zofran Glivec Tramal Diamicron Zocor Imodium	SS SS C C C C			PO 4 MG; DAILY 100 MG BID	

Date:01/31/02ISR Number: 3863260-1Report Type:Expedited (15-DaCompany Report #02002
Age:5 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Dyspnoea Face Oedema Stridor	Health Professional	Busulfex (Busulfan) Injection, 6 Mg/Ml	PS			INTRAVENOUS 9.9 MG IV, OVER 2 HOURS	

Zofran, 2mg/Ml SS

INTRAVENOUS 2 MG IV, 30

MINUTES PRIOR

Date:02/01/02ISR Number: 3861870-9Report Type:Expedited (15-DaCompany Report #WAES 0201USA02610
Age:47 YR Gender:Female I/FU:I

Outcome	PT
Death	Atherosclerosis
Hospitalization - Initial or Prolonged	Bladder Disorder
	Blindness
Other	Blood Cholesterol Increased
	Blood Potassium Increased
	Blood Thyroid Stimulating Hormone Increased
	Blood Triglycerides Increased
	Blood Uric Acid Increased
	Cardiac Failure Congestive
	Cardiac Murmur
	Cardiomyopathy
	Carotid Bruit
	Cerebrovascular Accident
	Constipation
	Coronary Artery Disease
	Crepitations
	Diabetes Mellitus
	Diabetic Gastroparesis

		Diabetic Nephropathy					
		Diarrhoea					
		Dysphagia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Electrocardiogram Change		Rezulin	PS		ORAL
		Fall		Rezulin	SS		ORAL
		Heart Sounds Abnormal		Rezulin	SS		ORAL
		Hypertension		Premarin	SS		ORAL
		Hypoxia		Rezulin	SS		ORAL
		Malaise		Zofran	SS		
		Medication Error		Zaroxolyn	SS		ORAL
19	DAY						
		Menopausal Symptoms		Vasotec	SS	Merck & Co., Inc	ORAL
		Myocardial Infarction		Hydrodiuril	C		ORAL
		Nausea		Vicodin Tablets	C		
		Neurogenic Bladder		Oxygen	C		
		Pneumonia		Rocephin	C		
1	DAY						
		Renal Failure Chronic		Magnesia [Milk Of]	C		
		Rhinorrhoea		Metamucil	C		
		Transient Ischaemic		Vitamins			
		Attack		(Unspecified)	C		
		Upper Respiratory Tract		Compazine	C		
INTRAVENOUS							
		Infection		Morphine Sulfate	C		
INTRAVENOUS							
		Urinary Retention		Bumex	C		
		Vertigo		Diuril	C		ORAL
		Vestibular Disorder		Fleet Enema	C		
		Visual Acuity Reduced		Dulcolax	C		
		Vomiting		Delsym	C		
		Weight Increased		Cephalexin	C		
				Metoclopramide Hydrochloride	C		
				Pepcid	C		ORAL
				Propulsid	C		
				Demadex	C		
				Potassium Chloride	C		
				Levothyroxine Sodium	C		
				Zestril	C		
				Imodium A-D	C		
				Bacitracin	C		
				Magnesium Oxide	C		
				Xanax	C		
				Humulin R	C		
				Darvocet-N	C		
				Influenza Virus			

				Vaccine	C
1	DAY				
				Pneumovax (Pneumococcal Vaccine 14 Polyvalent)	C
1	DAY				
				Tridil	C
INTRAVENOUS		2	DAY		
				Nitroglycerin	C
				Lanoxin	C
				Primacor	C
				[Therapy Unspecified]	C
				Cepacol Throat Lozenges	C
				Antivert	C
				Humulin 70/30	C
				Coreg	C
				Coumadin	C
				Bactroban	C
				Heparin	C
INTRAVENOUS		2	DAY		

				Phoslo	C		
				Monopril	C		
				Phenergan (Promethazine Hydrochloride)	C		
				Allopurinol	C		
				Captopril	C		
				Kayexalate	C		
				Lipitor	C		
				Lasix (Furosemide)	C		
				Aspirin	C		
				Zoloft	C		
				Tylenol	C		
				Versed	C		
1 DAY							
				Citrucel	C		
				Colace	C		
				Benadryl	C		
				Lovenox	C		
				Hydrodiuril	C		

Date:02/01/02ISR Number: 3863634-9Report Type:Periodic Company Report #A0141181A
Age:12 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Coordination Abnormal Extrapyramidal Disorder Nystagmus Tremor Vomiting	Health Professional	Zofran Tablet (Ondansetron Hydrochloride) Vincristine Methotrexate	PS C C		ORAL	8 MG / SIX TIMES PER DAY / ORAL	

Date:02/04/02ISR Number: 3863816-6Report Type:Direct Company Report #CTU 160641
Age:1 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthma		Zofran Injection					

	Maternal Drugs Affecting	2mg/Ml				
	Foetus	Glaxo/Wellcome	PS	Glaxo/Wellcome		
INTRAVENOUS	8MG QID IV					
	Neonatal Disorder	Zofran Tablet 8mg				
	Oesophagitis	Glaxo/Wellcome	SS	Glaxo/Wellcome	ORAL	
8MG QID ORAL						
	Respiratory Disorder	Diphenhydramine	C			
	Neonatal	Cimetidine	C			
		Levothyroxine	C			
		Tpn/Lipids	C			
		Ferrous Sulfate	C			

Date:02/05/02ISR Number: 3863189-9Report Type:Expedited (15-DaCompany Report #A0175006A
Age:48 YR Gender:Female I/FU:I

Outcome	PT
Death	Cardiac Failure
	Congestive
	Condition Aggravated
	Congestive Cardiomyopathy
	Ischaemic Cardiomyopathy
	Myocardial Infarction
	Renal Failure Acute

Renal Failure Chronic
Right Ventricular Failure

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Zofran	PS	Glaxo Wellcome		UNKNOWN	
	Rezulin	SS	Glaxo Wellcome	ORAL	400MG Per day	
	Premarin	SS				
	Lanoxin	C	Glaxo Wellcome			
	Nitroglycerin	C	Glaxo Wellcome			
	Zoloft	C				
	Levothyroxine	C	Glaxo Wellcome			

Date:02/05/02ISR Number: 3865342-7Report Type:Expedited (15-DaCompany Report #B0133235A
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angioneurotic Oedema Drug Interaction Dysphonia	Foreign	Zofran (Ondansetron Hydrochloride)	PS		ORAL	4 MG / PER	
	Dyspnoea						DAY / ORAL	
	Laryngeal Oedema Stridor		Imatinib Mesylate (Formulation Unknown) (Imatinib Mesylate)	SS		ORAL	100 MG /	
							TWICE PER DAY	
							/ ORAL	
			Lisinopril (Formulation Unknown) (Lisinopril)	SS		ORAL	10 MG / PER	
							DAY / ORAL	
			Tramadol Hydrochloride	C				
			Simvastatin	C				
			Loperamide					

Hydrochloride C

Date:02/07/02ISR Number: 3867267-XReport Type:Expedited (15-DaCompany Report #WAES 0201USA02610
Age:47 YR Gender:Female I/FU:I

Outcome	PT
Death	Abdominal Pain Lower
Hospitalization - Initial or Prolonged	Abdominal Pain Upper
Other	Atelectasis
	Autonomic Neuropathy
	Bacteria Urine Identified
	Bilirubin Conjugated Increased
	Blindness
	Blood Albumin Decreased
	Blood Calcium Decreased
	Blood Cholesterol Increased
	Blood Glucose Increased
	Blood Lactate Dehydrogenase Increased
	Blood Magnesium Increased
	Blood Potassium Increased
	Breath Sounds Decreased
	Cardiac Failure

		Congestive					
		Cardiomegaly					
		Cardiomyopathy					
		Carotid Bruit	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Cerebrovascular Accident	Consumer	Tab Vasotec	PS		ORAL
PO							
		Chest Discomfort		Rezulin	SS		ORAL
SEE IMAGE							
		Chest Pain		Premarin	SS		ORAL
PO							
		Condition Aggravated		Zofran	SS		
		Constipation		Zaroxolyn	SS		ORAL
PO							
		Cough		Antivert	C		
		Diabetes Mellitus		Bactroban	C		
		Diabetes Mellitus		Benadryl	C		
		Inadequate Control		Bumex	C		
		Diabetic Gastroparesis		Cepacol Throat			
		Diabetic Nephropathy		Lozenges	C		
		Diabetic Ulcer		Citrucel	C		
		Dysphagia		Colace	C		
		Dyspnoea Paroxysmal		Compazine	C		
		Nocturnal		Coreg	C		
		Dysuria		Coumadin	C		
		Fall		Darvocet-N	C		
		Flushing		Delsym	C		
		Gallop Rhythm Present		Demadex	C		
		Gastrooesophageal Reflux		Diuril	C		
		Disease		Dulcolax	C		
		Heart Sounds Abnormal		Fleet Enema	C		
		Hypothyroidism		Humulin 70/30	C		
		Hypoxia		Humulin R	C		
		Insomnia		Hydrodiuril	C		
		Mitral Valve Incompetence		Imodium A-D	C		
		Myocardial Infarction		Kayexalate	C		
		Neurogenic Bladder		Lanoxin	C		
		Oliguria		Lasix (Furosemide)	C		
		Paraesthesia		Lipitor	C		
		Pco2 Increased		Lovenox	C		
		Pitting Oedema		Metamucil	C		
		Pleural Effusion		Monopril	C		
		Pneumonia		Pepcid	C		
		Protein Total Increased		Phenergan			
		Pulmonary Oedema		(Promethazine			
		Renal Failure Chronic		Hydrochloride)	C		
		Rhinorrhoea		Phoslo	C		
		Transient Ischaemic		Pneumovax			

Attack	
Tricuspid Valve Incompetence	
Upper Respiratory Tract Infection	
Urinary Retention	
Vertigo	
Viral Infection	
Vomiting	
Weight Increased	
White Blood Cell Count Increased	
(Pneumococcal Vaccine	C
Primacor	C
Propulsid	C
Rocephin	C
Tridil	C
Tylenol	C
Versed	C
Vicodin Tablets	C
Xanax	C
Zestril	C
Zoloft	C
(Therapy Unspecified)	C
Allopurinol	C
Aspirin	C
Bacitracin	C
Captopril	C
Cephalexin	C

			Heparin	C			
			Influenza Virus Vaccine	C			
			Levothyroxine Sodium	C			
			Magnesia (Milk Of)	C			
			Magnesium Oxide	C			
			Metoclopramide Hydrochloride	C			
			Morphine Sulfate	C			
			Nitroglycerin	C			
			Oxygen	C			
			Potassium Chloride	C			
			Vitamins (Unspecified)	C			

Date:02/08/02ISR Number: 3868522-XReport Type:Expedited (15-DaCompany Report #A0152415A
Age:12 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other Required Intervention to Prevent Permanent Impairment/Damage	Hallucinations, Mixed Serotonin Syndrome	Literature Health Professional	Ondansetron Hydrochloride (Formulation Unknown) (Ondansetron	PS				
			Mirtazapine (Formulation Unknown) (Mirtazapine)	SS		ORAL	15 MG AT NIGHT ORAL	
			Cancer Chemotherapy	C				
			Morphine	C				

Date:02/11/02ISR Number: 3868947-2Report Type:Expedited (15-DaCompany Report #MPI-2002-00040(0)
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Cardiac Failure Congestive Cardiomyopathy	Consumer Health Professional	Zaroxolyn Tablets (Strength Unspecified)					

	Cerebrovascular Accident	(Metolazone		
	Condition Aggravated	(Unspecified)	PS	ORAL
PO				
	Diabetic Gastroparesis	Rezulin		
	Laboratory Test Abnormal	(Troglitazone)	SS	ORAL
400				
	Myocardial Infarction			
MILLIGRAM,				
	Pneumonia			
DAILY, PO				
	Transient Ischaemic	Vasotec (Enalapril		
	Attack	Maleate)	SS	
		Premarin (Estrogens		
		Conjugated)	SS	ORAL
PO				
		Zofran (Ondansetron		
		Hydrochloride)	SS	
		Lanoxin (Digoxin)	C	
		Nitroglycerin		
		(Glyceryl		
		Trinitrate)	C	
		Zoloft (Sertraline		
		Hydrochloride)	C	
		Aspirine		
		(Acetylsalicylic		

Acid)	C
Lasix (Furosemide)	C
Lipitor (Atorvastatin)	C
Kayexalate (Sodium Polystyrene Sulfonate)	C
Captopril (Captopril)	C
Hydrochlorothiazide (Hydrochlorothiazide)	C
Allopurinol (Allopurinol)	C
Zestril (Lisinopril)	C
Levothyroxine (Levothyroxine)	C
Potassium Chloride (Potassium Chloride)	C
Demadex (Torasemide)	C
Propulsid (Cisapride)	C
Pepcid (Famotidine)	C
Metoclopramide (Metoclopramide)	C
Cefalexin (Cefalexin)	C
Delsym (Dextromethorphan Hydrobromide)	C
Monopril (Fosinopril Sodium)	C
Phoslo (Calcium Acetate)	C
Bactroban Ointment	C
Coumadin (Warfarin Sodium)	C
Coreg	C
Humulin Insulin 70/30 (Humulin 70/30)	C
Antivert (Ancovert)	C
Pneumovax (Pneumococcal Vaccine)	C
Vicodin (Vicodin)	C
Milk Of Magnesia (Magnesium	

Hydroxide)	C
Metamucil (Psyllium Hydropholic Mucilloid)	C
Multiple Vitamins (Multiple Vitamins)	C
Compazine (Prochlorperazine Edisylate)	C
Morphine Sulphate (Morphine Sulfate)	C
Bumex (Bumetanide)	C
Menovin	C
Diuril	

(Chlorothiazide)	C
Fleet Enema (Fleet Enema)	C
Dulcolax (Bisacodyl)	C
Tylenol (Paracetamol)	C
Versed (Midazolam Hydrochloride)	C
Citrucel (Methylcellulose)	C
Colace (Docusate Sodium)	C
Primacor (Milrinone)	C
Benadryl (Diphenhydramine Hydrochloride)	C
Lovenox (Heparin-Fraction, Sodium Salt)	C
Flu Shot (Influenza Virus Vaccine Polyvalent)	C
Darvocet (Di-Gesic)	C
Humulin R (Insulin Human)	C
Xanax (Alprazolam)	C
Magnesium Oxide (Magnesium Oxide)	C
Bacitracin Ointment	C
Imodium A-D (Loperamide Hydrochloride)	C
Cepacol Lozenges (Cetylpyridinium Chloride)	C

Date:02/14/02ISR Number: 3869211-8Report Type:Direct Company Report #USP 54746
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Zosyn	PS	Lederle Laboratories			
			Zofran	SS	Glaxo Wellcome			

Date:02/22/02ISR Number: 3875278-3Report Type:Expedited (15-DaCompany Report #3318
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Hepatitis		Cyclophosphamide	PS		INTRAVENOUS	800 MG, IV	1 DAY
			Epirubicin	SS		INTRAVENOUS	180 MG/90MG, IV	1 DAY
			Fluorouracil	SS		INTRAVENOUS	800 MG, IV	1 DAY
			Granisetron	SS		INTRAVENOUS	IV	1 DAY
			Ondansetron Hydrochloride	SS		ORAL	PO	3 DAY
			Metoclopramide	SS		INTRAVENOUS	IV	1 DAY

Date:02/22/02ISR Number: 3875647-1Report Type:Expedited (15-DaCompany Report #WAES 01083552
Age:76 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Abdominal Pain Upper	Foreign	Tab Dexamethasone	PS		ORAL	DAILY/PO
Initial or Prolonged	Burning Sensation	Study	Cap Placebo	SS		ORAL	PO; DAILY/ PO
	Dyspepsia	Health	Infusion (Form)				
	Faeces Discoloured	Professional	Cisplatin	SS		INTRAVENOUS	127MG/DAILY/I
	Haematemesis						V
	Haemoglobin Decreased		Infusion (Form)				
	Hiccups		Ondansetron	SS		INTRAVENOUS	32 MG/ DAILY/
	Inflammation						IV
	Oesophagitis		Infusion (Form)				
	Vomiting		Vinorelbine Tartrate	SS		INTRAVENOUS	50 MG/DAILY/IV
			Lasonil	C			
			Temazepam	C			

Date:02/25/02ISR Number: 3873112-9Report Type:Expedited (15-DaCompany Report #A0169666A
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Fatigue		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	8MG Four times per day
	Headache						
	Movement Disorder		Ativan	C			
	Multiple Sclerosis		Fentanyl	C		OTHER	
	Myalgia						
	Tremor						

Date:02/25/02ISR Number: 3873120-8Report Type:Expedited (15-DaCompany Report #B0260105A
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Pressure Decreased	Consumer	Alkeran	PS	Glaxo Wellcome	INTRAVENOUS	270MG per day	1 DAY
Initial or Prolonged	Heart Rate Increased		Zyloric	SS	Glaxo Wellcome	ORAL	300MG Per day	
	Hyperpyrexia		Zophren	SS	Glaxo Wellcome	INTRAVENOUS	8MG per day	
	Renal Failure		Vitamine K1 Roche	SS		ORAL	10MG Per day	
	Vomiting		Triflucan	SS		ORAL	200MG Per day	
			Fungizone	SS		ORAL	1G Per day	

Date:02/27/02ISR Number: 3891583-9Report Type:Periodic Company Report #A0163667A
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction	Health	Zofran Injection					
Initial or Prolonged	Extrapyramidal Disorder	Professional	(Ondansetron					
	Muscle Contractions		Hydrochloride)	PS			8 MG/THREE	
	Involuntary						TIMES PER	
	Respiratory Arrest						DAY/ INTRA	
	Respiratory Distress		Venlafaxine					
	Serotonin Syndrome		Hydrochloride					
	Tardive Dyskinesia		(Formulation					
			Unknown)					
			(Venlafaxine	SS				
			Morphine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/27/02ISR Number: 3891587-6Report Type:Periodic Company Report #A0156505A
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Pain Chills Dyspnoea Electrocardiogram	Health Professional	Zofran (Formulation Unknown) (Ondansetron Hydrochloride)	PS		INTRAVENOUS	4 MG/INTRAVENOUS	
	Abnormal							
	Hypotension							

Date:02/28/02ISR Number: 3878069-2Report Type:Expedited (15-DaCompany Report #WAES 01108570
Age:67 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Chills Difficulty In Walking	Foreign Study	Tab Decadron Tablets Unk	PS		ORAL	20 MG/DAILY/PO	
	Pain In Extremity	Health Professional	Inj Gemcitabine Unk	SS		INTRAVENOUS	IV	
	Tremor	Other	Inj Cisplatin Unk	SS		INTRAVENOUS	IV	
			Inj Ondansetron Unk	SS		INTRAVENOUS	IV	
			Cap Placebo (Unspecified) Unk	SS		ORAL	PO	
			Acetaminophen	C				
			Acetaminophen (+) Codeine Phosph	C				
			Diclofenac	C				
			Estrogens (Unspecified)	C				
			Furosemide	C				
			Sodium Chloride	C				
			Vitamin E	C				
			Vitamins (Unspecified)	C				

Date:03/01/02ISR Number: 3875981-5Report Type:Expedited (15-DaCompany Report #B0260872A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arrhythmia		Zofran	PS	Glaxo Wellcome	INTRAVENOUS		
	Myocardial Infarction							

Date:03/05/02ISR Number: 3877428-1Report Type:Expedited (15-DaCompany Report #B0261037A
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	8MG per day	
Hospitalization - Initial or Prolonged	Grand Mal Convulsion							
Other	Hypersensitivity							
	Thrombophlebitis							
	Uveitis							

Date:03/06/02ISR Number: 3880201-1Report Type:Periodic Company Report #10993020
Age: Gender:Male I/FU:I

Outcome	PT	Report Source
Other	Hypersensitivity	Health Professional

		Company Representative					
			Product	Role	Manufacturer	Route	Dose Duration
			Taxol(Paclitaxel)	PS		INTRAVENOUS	15 MILLILITER, IV
			Zofran (Ondansetron Hcl)	SS			
			Saline	C			

Date:03/08/02ISR Number: 3879890-7Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11750312
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Chest Pain		Paraplatine Inj	PS	Bristol-Myers Squibb Company	INTRAVENOUS	
	Dyspnoea						
	Urticaria		Zophren	SS		INTRAVENOUS	
			Polaramine	C			
			Dexamethasone	C			
			Plitican	C		INTRAVENOUS	
			Tagamet	C		INTRAVENOUS	

Date:03/13/02ISR Number: 3881813-1Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11756210
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased		Fungizone Os	PS	Apothecon	ORAL	
	Pyrexia		Zyloric	SS		ORAL	
	Renal Impairment		Vitamin K1	SS		ORAL	
	Tachycardia		Zophren	SS		INTRAVENOUS	
	Vomiting		Triflucan	SS		ORAL	

				Alkeran	SS		
INTRAVENOUS	1	DAY					

Date:03/13/02ISR Number: 3883217-4Report Type:Expedited (15-DaCompany Report #B0260186A
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erysipelas	Foreign	Zofran Solution (Ondansetron Hydrochloride)	PS		INTRAVENOUS	INTRAVENOUS	
			Navelbine (Formulation Unknown) (Vinorelbine Tartrate)	SS		INTRAVENOUS	INTRAVENOUS	
			Metoclopramide Hcl (Formulation Unknown) (Metoclopramide Hcl)	SS		INTRAVENOUS	INTRAVENOUS	
			Oxaliplatin Solution 100 Mg (Oxaliplatin)	SS		INTRAVENOUS	INTRAVENOUS	
			Me-Prednisolone Na Succ. Solution (Me-Prednisolone Na Succ.)	SS		INTRAVENOUS	INTRAVENOUS	
			Tropisetron Hydrochloride					

				Solution (Tropisetron Hydrochloride)	SS		
INTRAVENOUS	INTRAVENOUS						
				Celecoxib	C		

Date:03/14/02ISR Number: 3882425-6Report Type:Direct Company Report #CTU 163344
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Pressure Decreased		Zofran 4mg/2ml	PS		INTRAVENOUS	PRN/IV	
Initial or Prolonged	Hypertension							
	Vomiting							

Date:03/15/02ISR Number: 3883161-2Report Type:Expedited (15-DaCompany Report #D0038123A
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Grand Mal Convulsion		Zofran	PS	Glaxo Wellcome	ORAL		
Initial or Prolonged	Psychotic Disorder							

Date:03/18/02ISR Number: 3883871-7Report Type:Expedited (15-DaCompany Report #A0361528A
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apnoea		Wellbutrin	PS	Glaxo Wellcome	ORAL		
	Convulsion		Zofran	SS	Glaxo Wellcome	INTRAVENOUS		
	Depressed Level Of		Versed	SS		INTRAVENOUS		
	Consciousness		Fentanyl	SS		INTRAVENOUS		
	Drug Interaction		Toradol	SS		INTRAVENOUS		
	Heart Rate Increased							
	Hyperventilation							

Date:03/20/02ISR Number: 3886187-8Report Type:Direct Company Report #CTU 163766
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Claustrophobia		Zofran	PS		INTRAVENOUS	4MG IVP	
	Dizziness							
	Feeling Hot							

Date:03/25/02ISR Number: 3887325-3Report Type:Expedited (15-DaCompany Report #A0362425A
Age:22 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Amniocentesis Abnormal		Zofran	PS	Glaxo Wellcome	INTRAVENOUS		14 WK
Initial or Prolonged	Blood Pressure Increased		Phenergan					
	Complications Of Maternal		Suppositories	C	Glaxo Wellcome	RECTAL	25MG As	
	Exposure To Therapeutic						required	53 DAY
	Drugs		Prenatal Vitamins	C				
	Maternal Drugs Affecting		Keflex	C	Glaxo Wellcome	250MG Four		
	Foetus						times per day	
			Tagamet	C	Glaxo Wellcome	400MG Twice		
							per day	

Date:03/25/02ISR Number: 3887326-5Report Type:Expedited (15-DaCompany Report #A0362425B
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Amniocentesis Abnormal		Zofran	PS	Glaxo Wellcome	INTRAVENOUS		14 WK
Initial or Prolonged	Anaemia Neonatal		Phenergan					
	Apgar Score Low		Suppositories	C	Glaxo Wellcome	RECTAL	25MG As	
	Blood Ph Decreased						required	53 DAY
	Blood Pressure Increased		Prenatal Vitamins	C				
	Caesarean Section		Keflex	C	Glaxo Wellcome		250MG Four	
	Coagulation Disorder						times per day	
	Neonatal		Tagamet	C	Glaxo Wellcome		400MG Twice	
	Complications Of Maternal						per day	
	Exposure To Therapeutic							
	Drugs							
	Maternal Drugs Affecting							
	Foetus							
	Premature Baby							
	Premature Labour							
	Protein Urine Present							
	Scan Brain							

Date:03/25/02ISR Number: 3888003-7Report Type:Direct Company Report #CTU 163989
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest		Zofran	PS				
Hospitalization -	Myocardial Infarction		Paraplatin (I Don'T					
Initial or Prolonged			Suspect Paraplatin)	SS				
Required			Decadron	SS				
Intervention to								
Prevent Permanent								
Impairment/Damage								

Date:03/27/02ISR Number: 3889368-2Report Type:Expedited (15-DaCompany Report #D0038123A
Age:64 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation		Zofran	PS	Glaxo Wellcome	ORAL	1	DAY
Initial or Prolonged	Grand Mal Convulsion		Carboplatin	SS				
INTRAVENOUS							540MGL	Single
	Laboratory Test Abnormal							
dose							1	DAY
	Mental Disorder		Dexamethason	C				
INTRAVENOUS							4MG	Single
dose							1	DAY
			Mcp	C	Glaxo Wellcome			
UNKNOWN								
			Vomex	C				
UNKNOWN								

Date:04/02/02ISR Number: 3894214-7Report Type:Expedited (15-DaCompany Report #200203-1994(0)
Age:63 YR Gender:Male I/FU:I

Outcome	PT
Death	Aneurysm
	Blood Bilirubin Increased
	Diarrhoea
	Haematocrit Decreased
	Haemoglobin Decreased
	Mean Cell Volume Increased
	Multi-Organ Failure
	Platelet Count Decreased

		Red Blood Cell Count Decreased Red Cell Distribution Width Increased Weight Increased	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Consumer	Diphenhydramine (Diphenhydramine)	PS		
				Norvasc(Amlodipine Besilate)	SS		ORAL
PER ORAL							
				Diflucan (Fluconazole)	SS		
INTRAVENOUS	200 MG/ISO						
OSM							
100ML,INTRAVE							
NOUS							
				Inderal (Propranolol Hydrochloride)	SS		
				Fat Emulsions(Fat Emulsions)	SS		
				Morphine(Morphine)	SS		
				Potassium(Potassium)	SS		
				Sodium Chloride(Sodium Chloride)	SS		
				Naloxone(Naloxone)	SS		
				Epogen(Epoetin Alfa)	SS		
				Parathyroid Extract(Parathyroid Extract)	SS		
				Magnesium Sulfate(Magnesium Sulfate)	SS		
				Levaquin(Levofloxacin)	SS		
				Mannitol(Mannitol)	SS		
				Lorazepam(Lorazepam)	SS		
				Desmopressin(Desmopressin)	SS		
				Phytonadione(Phytomenadione)	SS		
				Famotidine(Famotidine)	SS		
				Ondansetron Hydrochloride(Ondans			

etron Hydrochloride) SS
Piperacillin(Piperac
illin) SS
Clindamycin(Clindamy
cin) SS
Albumin Normal Human
Serum(Albumin Normal
Human Serum) SS
Prilosec(Omeprazole) SS
Tylenol(Paracetamol) SS
Lonox(Lomotil) SS
Buspar(Buspirone
Hydrochloride) SS
Norepinephrine
(Norepinephrine) SS
Dopamine (Dopamine) SS
Metronidazole(Metron
idazole) SS
Bisacodyl(Bisacodyl) SS

Pamidronate

RECTAL PER RECTAL

Disodium(Pamidronate Disodium)	SS
Lidocaine(Lidocaine)	SS
Ventolin(Salbutamol)	SS
Trace Elements(Trace Elements)	SS
Acetaminophen(Paracetamol)	SS

Date:04/03/02ISR Number: 3893503-XReport Type:Expedited (15-DaCompany Report #A0363644A
Age: Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Complications Of Maternal		Zofran	PS	Glaxo Wellcome	INTRAVENOUS		
	Exposure To Therapeutic Drugs		Antibiotics (Unspecified)	C		INTRAVENOUS		
	Deafness Congenital							
	Maternal Drugs Affecting Foetus							
	Pneumonia							

Date:04/05/02ISR Number: 3894842-9Report Type:Expedited (15-DaCompany Report #B0262760A
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Hyperhidrosis		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	8MG per day	1 DAY
	Hypotension		Zofran	SS	Glaxo Wellcome	RECTAL	16MG per day	1 DAY
	Hypothermia		Trazodone	SS		ORAL	50MG per day	
	Malaise		Venlafaxine	SS		ORAL	150MG per day	
			Cloxazolam	C		ORAL	2MG per day	
			Toremifene	C		ORAL	60MG per day	
			Chemotherapy	C		UNKNOWN		

Date:04/10/02ISR Number: 3896984-0Report Type:Expedited (15-DaCompany Report #A0365101A
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Apnoea		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	4MG Single	
Life-Threatening	Brain Death						dose	1 DAY
Hospitalization -	Brain Oedema		Isoflurane	C		RESPIRATORY		
Initial or Prolonged	Haemorrhage Intracranial					(INHALATION)		
Other	Hypertensive Crisis		Fentanyl	C		INTRAVENOUS		
	Postoperative Wound		Midazolam	C		INTRAVENOUS		
	Complication							

Date:04/10/02ISR Number: 3899372-6Report Type:Direct Company Report #CTU 165421
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Apnoea		Ondansetron 4mg,					
	Brain Death		Injectable					
	Brain Oedema		Glaxosmithkline	PS	Glaxosmithkline	INTRAVENOUS		
	Haemorrhage Intracranial					BOLUS	4MG ONE TIME	
	Post Procedural					INTRAVENOUS		
	Complication					BOLUS		
	Procedural Hypertension		Fentanyl	C				
			Midazolam	C				
			Isoflurane	C				

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Freedom Of Information (FOI) Report

Date:04/11/02ISR Number: 3897620-XReport Type:Expedited (15-DaCompany Report #A0361528A
Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Apnoea		Wellbutrin	PS	Glaxo Wellcome	ORAL		
	Clonic Convulsion		Zofran	SS	Glaxo Wellcome	INTRAVENOUS		1 DAY
	Coma		Versed	C		INTRAVENOUS		
	Drug Interaction		Fentanyl	C		INTRAVENOUS		
	Heart Rate Increased		Toradol	C		INTRAVENOUS		
	Hyperventilation		Sevoflurane	C		RESPIRATORY (INHALATION)		
	Memory Impairment							
	Muscle Rigidity		Propofol	C		INTRAVENOUS		
	Respiratory Rate Increased							

Date:04/12/02ISR Number: 3900662-9Report Type:Expedited (15-DaCompany Report #2002099934FR
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia	Foreign	Solu-Medrol(Methylprednisolone) Powder, Sterile	PS		INTRAVENOUS	120 MG, QD,	
	Chest Pain	Health Professional						
	Feeling Abnormal							
	Hyperhidrosis	Other				IV		
	Hypotension		Zophren(Ondansetron Hydrochloride)	SS		INTRAVENOUS	IV	
	Hypoxia							
	Malaise		Eloxatin(Oxaliplatin)	SS		INTRAVENOUS	150 MG, QD,	
	Urinary Incontinence					IV		
			Elvorine(Calcium Levofolinate)	SS		INTRAVENOUS	175 MG, QD,	

IV

Date:04/17/02ISR Number: 3902044-2Report Type:Expedited (15-DaCompany Report #2001080388JP
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Acute Respiratory Distress Syndrome	Foreign Health Professional	Idamycin(Idarubicin) Powder,Sterile	PS		INTRAVENOUS DRIP	15 MG , DAILY, CYCLIC	
	Asthma	Other						
	Chest Pain							
	Disseminated Intravascular Coagulation		Cylocide(Cytarabine)	SS		INTRAVENOUS DRIP	120 MG, DAILY, CYCLIC, IV DRIP	
	Leukopenia							
	Lung Disorder							
	Lung Infiltration							
	Necrosis							
	Pneumonia		Zofran (Ondansetron Hydrochloride)	SS		INTRAVENOUS DRIP	4 MG, QD, IV DRIP	
	Pulmonary Oedema							
	Pyrexia							
	Respiratory Failure							
	Thrombocytopenia		Primperan (Metoclopramide)	SS		INTRAVENOUS DRIP	20 MG, QD, IV DRIP	
			Marzulene S (Sodium Galenate)	SS		ORAL	1.5 G, TID, ORAL	
			Neurer	SS		ORAL	600 MG , TID, ORAL	
			Amikamycin (Amikacin					

				Sulfate)	SS			
INTRAVENOUS								DRIP
200 MG , QD,								
IV DRIP								
				Pentcillin (Piperacillin Sodium)	SS			
INTRAVENOUS								DRIP
4 G, BID , IV								
DRIP								
				Carbazochrome Sodium Sulfonate (Carbazochrome Sodium Sufonate)	C			

Date:04/18/02ISR Number: 3901481-XReport Type:Expedited (15-DaCompany Report #B0054572A
Age:25 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Missed		Ondansetron	PS	Glaxo Wellcome	ORAL	4MG Twice per	
	Complications Of Maternal						day	9 DAY
	Exposure To Therapeutic		Prochlorperazine	C	Glaxo Wellcome		INTRAMUSCULAR	12.5MG
	Drugs						Variable dose	4 DAY
	Maternal Drugs Affecting		Procyclidine	C	Glaxo Wellcome		INTRAVENOUS	5MG Twice per
	Foetus						day	
			Metoclopramide	C	Glaxo Wellcome		INTRAMUSCULAR	2 DAY
			Cyclizine	C	Glaxo Wellcome		INTRAMUSCULAR	2 DAY
			Coproxamol	C		ORAL	2TAB per day	
			Ondansetron	C	Glaxo Wellcome		INTRAMUSCULAR	2 DAY
			Nizatidine	C		ORAL	150MG Twice	

per day

Ranitidine C Glaxo Wellcome
Hydrocortisone C Glaxo Wellcome
INTRAVENOUS 100MG Twice

per day

Date:04/18/02ISR Number: 3901482-1Report Type:Expedited (15-DaCompany Report #B0058356A
Age:25 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abortion Missed		Zofran	PS	Glaxo Wellcome	INTRAMUSCULAR	4MG Twice per	
Initial or Prolonged	Complications Of Maternal							
day								10 DAY
Other	Exposure To Therapeutic		Zofran	SS	Glaxo Wellcome	ORAL	4MG In the	
	Drugs							
morning								8 DAY
	Maternal Drugs Affecting		Prochlorperazine	C	Glaxo Wellcome			
INTRAMUSCULAR								4 DAY
	Foetus		Metoclopramide	C	Glaxo Wellcome			
INTRAMUSCULAR								5 DAY
			Metoclopramide	C	Glaxo Wellcome	ORAL		
25 DAY								
			Coproxamol	C		ORAL		
3 DAY								
			Nizatidine	C		ORAL		
150MG Twice								
per day								3 DAY
			Ranitidine Hydrochloride	C	Glaxo Wellcome	ORAL		
			Cyclizine	C	Glaxo Wellcome			
INTRAMUSCULAR								2 DAY
			Cyclizine	C	Glaxo Wellcome	ORAL		
50MG Single								
dose								1 DAY
			Hydrocortisone	C	Glaxo Wellcome			
INTRAVENOUS	100MG Twice							
per day								
			Coproxamol	C		ORAL		
2 DAY								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/22/02ISR Number: 3903749-XReport Type:Expedited (15-DaCompany Report #304844
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hepatitis		Kytril	PS	Roche			1 DAY
Initial or Prolonged			Endoxan	SS			500 MG/M2.	
							FIRST COURSE.	29 DAY
			Farmorubicine	SS			FIRST COURSE.	29 DAY
			Zophren	SS			5	DAY
			Fluorouracil	SS			500 MG/M2.	
							FIRST COURSE.	29 DAY
			Primperan	SS			1	DAY
			Motilium	C				

Date:04/23/02ISR Number: 3906154-5Report Type:Expedited (15-DaCompany Report #304844
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hepatitis	Foreign	Kytril (Granisetron)	PS		INTRAVENOUS	INTRAVENOUS	
Initial or Prolonged		Other	Endoxan (Cyclophosphamide)	SS		INTRAVENOUS	800 MG 1 PER	
							ONE DOSE	
							INTRAVENOUS	
			Farmorubicine (Epirubicin Hydrochloride)	SS		INTRAVENOUS	160 MG 1 PER	
							ONE DOSE	
							INTRAVENOUS	

				Zophren (Ondansetron Hydrochloride)	SS		ORAL
ORAL							
				Fluorouracil (Fluorouracil)	SS		
INTRAVENOUS	800 MG 1 PER						
ONE DOSE							
INTRAVENOUS							
				Primperan (Metoclopramide Hydrochloride)	SS		
INTRAVENOUS	INTRAVENOUS						
				Motilium (Domperidone)	C		

Date:04/26/02ISR Number: 3906931-0Report Type:Expedited (15-DaCompany Report #B0266020A
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Myocardial Infarction		Zofran	PS	Glaxo Wellcome			
UNKNOWN								
			Decadron	SS				
UNKNOWN								
			Cisplatin	SS				
UNKNOWN								
			Etoposide	SS				
UNKNOWN								

Date:04/26/02ISR Number: 3908825-3Report Type:Expedited (15-DaCompany Report #FR8959816APR2002
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diabetes Insipidus	Health Professional	Lederfoline (Leucovorin Calcium,					
Other		Other	Injection, 0)	PS				
INTRAVENOUS	50 MG WITHIN							
6								
HOURS/INTRAVE								
NOUS	1 DAY							

						Ledertrexate (Methotrexate, Injection, 0)	SS		
SEE IMAGE	16	DAY							
						...	SS		
						Primperan (Metoclopramide, 0)	SS		
INTRAVENOUS	INTRAVENOUS	3	DAY						
						Zophren (Ondansetron Hydrochloride, 0)	SS		
INTRAVENOUS		3	DAY						
						Lutenyl (Nomegestrol Acetate)	C		
						Deroxat (Paroxetine Hydrochloride)	C		
						Azantac (Ranitidine Hydrochloride)	C		
						Dicynone (Etamsilate)	C		
						Zyloric (Allopurinol)	C		

Date:05/01/02ISR Number: 3909252-5Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11674629
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis		Endoxan Inj	PS	Bristol-Myers Squibb Company			
INTRAVENOUS								
			Farmorubicin	SS				
INTRAVENOUS								
			5-Fu	SS				
INTRAVENOUS								
			Kytril	SS				
INTRAVENOUS								
			Zophren	SS		ORAL		
			Primperan	SS				
INTRAVENOUS								
			Motilium	C				

Date:05/02/02ISR Number: 3909789-9Report Type:Expedited (15-DaCompany Report #D0038295A
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Retching Salivary Hypersecretion		Zofran Vomex Vitamin B Complex Vitamin C Nutriflex Clinomel Vitalipid Adult	PS C C C C C C	Glaxo Wellcome	INTRAVENOUS INTRAVENOUS INTRAVENOUS INTRAVENOUS INTRAVENOUS INTRAVENOUS INTRAVENOUS	3AMP 1AMP 1AMP 1AMP 3AMP 1AMP	per day per day per day per day per day per day

Date:05/07/02ISR Number: 3911832-8Report Type:Expedited (15-DaCompany Report #B0261037A
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Other	Agitation Drug Hypersensitivity Grand Mal Convulsion Phlebitis		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	8MG	per day

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/09/02ISR Number: 3913385-7Report Type:Expedited (15-DaCompany Report #A0367199A
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation	Health Professional	Ondansetron	PS	Glaxo Wellcome			
	Gastrointestinal Disorder		Vinorelbine Tartrate	SS	Glaxo Wellcome	ORAL	6MG Per day	
	Neutropenia		Buprenorphine	SS				
			Ferrous Sulfate	SS		ORAL	80MG Per day	
			Cisplatin	C				
			Paracetamol	C	Glaxo Wellcome			
			Methylprednisolone	C				
			Metopimazine	C				
			Epoetin Alfa	C				

INTRAVENOUS 80MGM2 See dosage text

SUBCUTANEOUS 10000IU Three times per week

Date:05/10/02ISR Number: 3913838-1Report Type:Expedited (15-DaCompany Report #B0260872A
Age:94 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrial Fibrillation	Health Professional	Zofran	PS	Glaxo Wellcome			
Hospitalization - Initial or Prolonged	Myocardial Infarction		Benserazide + Levodopa	C		ORAL	INTRAVENOUS	4MG Unknown
Other	Troponin I Increased		Amiloride + Hydrochlorothiazide	C		ORAL		
			Aspirin	C		ORAL		
			Gliclazide	C		ORAL		

Date:05/14/02ISR Number: 3915519-7Report Type:Expedited (15-DaCompany Report #WAES 0204NOR00010
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Myocardial Infarction	Health Professional	Decadron Tablets	PS	Merck & Co., Inc	
			Cisplatin	SS		
			Etoposide	SS		
			Ondansetron Hydrochloride	SS		

Date:05/16/02ISR Number: 3918426-9Report Type:Expedited (15-DaCompany Report #WAES 0204NOR00010
Age:36 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Myocardial Infarction	Foreign Other	Tab Decadron Tablets (Dexamethasone)	PS		
			Tab Cisplatin	SS		
			Etoposide	SS		
			Ondansetron Hydrochloride	SS		

Date:05/17/02ISR Number: 3918879-6Report Type:Expedited (15-DaCompany Report #2002105888FR
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Lung Infiltration	Foreign Health Professional	Solu-Medrol (Methylprednisolone)	PS		
INTRAVENOUS 120 MG, QD, IV						
		Other	Lederfolin (Calcium			

				Folinate)	SS		ORAL
300 MG, QD,							
ORAL							
				Zophren (Ondansetron Hydrochloride)	SS		
				Fluoro-Uracil (Fluorouracil)	SS		
INTRAVENOUS	2090 MG, IV						
				Campto (Irinotecan Hydrochloride)	SS		
INTRAVENOUS	270 MG, IV						
				Atropine	SS		
INTRAVENOUS	IV						
				Durogesic (Fentanyl)	SS		
				Movicol (Sodium Bicarbonate, Potassium Chloride, Sodium Chloride, Macrogol)	SS		
50 UG							
				Lasilix (Furosemide)	SS		
				Gentamicin (Gentamicin)	SS		
				Rocefin (Ceftriaxone Sodium)	SS		

Date:05/22/02ISR Number: 3922660-1Report Type:Expedited (15-DaCompany Report #3671
Age:10 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Dysphonia		Cisplatin	PS		
29 MG						
	Eyelid Ptosis		Vincristine	SS		
500 MICROGRAM						
			Actinomycin D	SS		
1.1 MG						
			Ondansetron	SS		
2 MG						

Date:05/23/02ISR Number: 3920477-5Report Type:Expedited (15-DaCompany Report #B0266020A
Age:36 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Myocardial Infarction		Zofran	PS	Glaxo Wellcome	ORAL	16MG per day	5 DAY
Hospitalization -			Decadron	SS				
INTRAVENOUS							16MG per day	5 DAY
Initial or Prolonged			Cisplatin	SS				
UNKNOWN							210MG per day	5 DAY
			Etoposide	SS				
UNKNOWN							1G per day	5 DAY

Date:05/23/02ISR Number: 3920486-6Report Type:Expedited (15-DaCompany Report #B0268381A
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dystonia		Ondansetron	PS	Glaxo Wellcome			
INTRAVENOUS							8MG Single	
Initial or Prolonged	Oculogyration							
dose							1	DAY
			Propofol	C				
INTRAVENOUS							200MG Single	
dose							1	DAY
			Morphine	C				
INTRAVENOUS							10MG Single	
dose							1	DAY
			Sevoflurane	C				
RESPIRATORY								
(INHALATION)							1	DAY

Date:05/23/02ISR Number: 3922127-0Report Type:Expedited (15-DaCompany Report #2002106737FR
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source
Hospitalization -	Thrombocytopenia	Foreign
Initial or Prolonged		Health

Professional
Other

			Product	Role	Manufacturer	Route
Dose	Duration					
			Solu-Medrol(Methylprednisolone) Powder, Sterile	PS		
INTRAVENOUS	60 MG, WEEKLY, IV					
			Zophren(Ondansetron Hydrochloride)	SS		
INTRAVENOUS	40 MG, WEEKLY, IV					
			Cisplatin(Cisplatin)	SS		
INTRAVENOUS	8 MG, WEEKLY, IV					

Date:05/28/02ISR Number: 3923297-0Report Type:Expedited (15-DaCompany Report #B0266020A
Age:36 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Chest Pain	Consumer	Zofran	PS	Glaxo Wellcome	ORAL
16MG per day	5 DAY					
Hospitalization -	Coronary Artery		Decadron	SS		
INTRAVENOUS	16MG per day 5 DAY					
Initial or Prolonged	Thrombosis		Cisplatin	SS		
UNKNOWN	210MG per day 5 DAY					
	Myocardial Infarction		Etoposide	SS		
UNKNOWN	1G per day 5 DAY					

Date:05/29/02ISR Number: 3924113-3Report Type:Expedited (15-DaCompany Report #D0038123A
Age:64 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Aggression		Zofran	PS	Glaxo Wellcome	ORAL
1TAB Per day						
Initial or Prolonged	Disinhibition		Carboplatin	SS		
INTRAVENOUS						

	Grand Mal Convulsion		Dexamethason	C			
INTRAVENOUS	4MG Single						
	Impulsive Behaviour						
dose	1 DAY						
	Mania		Mcp	C	Glaxo Wellcome	ORAL	
	Psychotic Disorder		Vomex	C			
UNKNOWN							

Date:05/30/02ISR Number: 3927862-6Report Type:Expedited (15-DaCompany Report #2002105888FR
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Lung Infiltration	Foreign	Solu-Medrol(Methylpr			
Initial or Prolonged	Lymphangiosis	Health	ednisolone) Powder,			
	Carcinomatosa	Professional	Sterile	PS		
INTRAVENOUS	120 MG, QD,					
		Other				
IV						
			Camptosar (Irinotecan)			
			Solution, Sterile	SS		
INTRAVENOUS	270 MG, IV					
			Lederfolin (Calcium			
			Folinate)	SS		ORAL
300 MG, QD,						
ORAL						
			Zophren (Ondansetron			
			Hydrochloride)	SS		
INTRAVENOUS	IV					
			Fluoro-Uracil(Fluoro			
			uracil)	SS		
INTRAVENOUS	2090 MG,, IV					
			Atropine(Atropine)	SS		
INTRAVENOUS	IV					
			Durogesic (Fentanyl)	SS		
			Movicol (Sodium Bicarbonate, Potassium Chloride, Sodium Chloride, Macrogol)	SS		
50 UG						

				Lasilix(Furosemide)	SS		
				Gentamicin(Gentamicin)	SS		
				Rocefin(Ceftriaxone Sodium)	SS		
				Zestril (Lisinopril)	C		

Date:05/31/02ISR Number: 3926340-8Report Type:Expedited (15-DaCompany Report #B0268947A
Age: Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Anencephaly		Zofran	PS	Glaxo Wellcome		UNKNOWN	

Date:05/31/02ISR Number: 3927251-4Report Type:Expedited (15-DaCompany Report #2002105888FR
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Lung Disorder Lung Infiltration Lymphangiosis Carcinomatosa	Foreign Health Professional	Solu-Medrol (Methylprednisolone) Powder, Sterile	PS			INTRAVENOUS	120 MG, QD, IV
			Camptosar (Irinotecan) Solution, Sterile	SS			INTRAVENOUS	270 MG, IV
			Lederfolin (Calcium Folinate)	SS		ORAL	300 MG, QD,	ORAL
			Zophren (Ondansetron Hydrochloride)	SS			INTRAVENOUS	IV
			Fluoro-Uracil	SS			INTRAVENOUS	2090 MG, IV
			Atropine	SS			INTRAVENOUS	IV
			Durogesic (Fentanyl)	SS				

				Movicol (Sodium Bicarbonate, Potassium Chloride, Sodium Chloride, Macrogol)	SS			
50 UG								
				Lasilix (Furosemide)	SS			
				Gentamicin	SS			
				Rocefin (Ceftriaxone Sodium)	SS			
				Zestril (Lisinopril)	C			

Date:06/03/02ISR Number: 3926788-1Report Type:Expedited (15-DaCompany Report #A0369832A
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrioventricular Block		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	4MG As required	2 DAY
	First Degree							
	Bundle Branch Block Left		Morphine	C		UNKNOWN		
	Post Procedural		Reglan	C	Glaxo Wellcome	UNKNOWN		
	Complication		Ancef	C	Glaxo Wellcome	UNKNOWN		
	Tachycardia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/12/02ISR Number: 3931864-3Report Type:Expedited (15-DaCompany Report #A0370435B
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dysstasia		Zofran	PS	Glaxo Wellcome	ORAL		
	Inability To Crawl		Unknown Vitamins	C		ORAL		
	Mobility Decreased							
	Muscle Disorder							
	Spine Malformation							

Date:06/19/02ISR Number: 3935133-7Report Type:Expedited (15-DaCompany Report #B0270949A
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion		Zofran	PS	Glaxo Wellcome		UNKNOWN	
	Tremor		Anaesthetic	C			UNKNOWN	

Date:06/26/02ISR Number: 3940416-0Report Type:Expedited (15-DaCompany Report #02P-056-0194731-00
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Culture Positive	Foreign	Tranxene					
Required	Bone Pain	Health	(Clorazepate					
Intervention to	Cerebrovascular Disorder	Professional	Dipotassium)					
Prevent Permanent	Coma	Other	(Clorazepate					
Impairment/Damage	Cyanosis		Dipotassium)	PS				
	Depressed Level Of		Ketoprofen	SS				
	Consciousness		Paracetomol/Dextropr					
	Headache		opoxyphene	SS				
	Meningitis Bacterial		Ondansetron					
	Myalgia		Hydrochloride	SS			INTRAVENOUS	300 MG,
	Respiratory Arrest						INTRAVENOUS	
	Streptococcal Infection		Nalbuphine					
	Urinary Tract Infection		Hydrochloride	SS				
	Vomiting		Omeprazole	SS				
			Metoclopramide	SS				

Date:06/27/02ISR Number: 3941319-8Report Type:Expedited (15-DaCompany Report #B0270903A
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Back Pain	Foreign	Zofran Injection 2 Mg/Ml (Ondansetron Hydrochloride)	PS		INTRAVENOUS	INTRAVENOUS	
	Blood Potassium Increased		Betamethasone Na Po4 Injection (Betamethasone Na Po4)	SS		INTRAVENOUS	INTRAVENOUS	
	Cardiac Failure							
	Cardiomegaly							
	Colon Cancer Stage Iv							
	Diarrhoea		Oxaliplatin Sterile Powder (Oxaliplatin)	SS		INTRAVENOUS		
	Flushing							
	Myocardial Fibrosis					INFUS		
	Pain In Extremity		Fluorouracil	C				
	Pericardial Effusion		Epirubicin	C				
	Pleural Effusion		Mitomycin	C				
	Pulmonary Embolism		Calcium Folinate	C				
	Pulmonary Infarction							
	Pulmonary Oedema							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/27/02ISR Number: 3941323-XReport Type:Expedited (15-DaCompany Report #B0271011A
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Cardiac Arrest	Foreign Health Professional	Zofran Injection (Ondansetron Hydrochloride)	PS		INTRAVENOUS	INTRAVENOUS	

Date:06/28/02ISR Number: 3942291-7Report Type:Periodic Company Report #300708
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Nausea Palmar-Plantar Erythrodysaesthesia Syndrome Skin Ulcer Vomiting	Health Professional	Xeloda (Capecitabine) 500 Mg	PS		ORAL	4 GRAM DAILY	ORAL
			Coumadin (Warfarin Sodium)	SS		ORAL	ORAL	
			K-Dur (Potassium Chloride)	SS		ORAL	16 MEQ 2 PER DAY	ORAL
			Nexium (Esomeprazole)	SS		ORAL	30 MG DAILY	ORAL
			Oxycontin (Oxycodone)	SS		ORAL	120 MG 3 PER DAY	ORAL
			Zyrtec (Cetirizine Hydrochloride)	SS		ORAL	20 MG DAILY	ORAL
			Roxicodone					

	(Oxycodone Hydrochloride)	SS	ORAL
5 MG 1 PER PRN ORAL			
	Buspar (Buspirone Hydrochloride)	SS	ORAL
50 MG 2 PER DAY ORAL			
	Lasix (Furosemide)	SS	ORAL
40 MG DAILY ORAL			
	Remeron (Mirtazapine)	SS	ORAL
30 MG DAILY ORAL			
	Ativan (Lorazepam)	SS	ORAL
1 MG 1 PER PRN ORAL			
	Phenergan (Promethazine Hydrochloride)	SS	ORAL
25 MG 1 PER PRN ORAL			
	Vioxx (Rofecoxib)	SS	ORAL
25 MG 1 PER PRN ORAL			
	Zofran (Ondansetron Hydrochloride)	SS	ORAL
8 MG 1 PER PRN ORAL			
	Carafate (Sucralfate)	SS	ORAL
1 PER 4 HOUR ORAL			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/02/02ISR Number: 3942971-3Report Type:Direct Company Report #CTU 171505
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Zofran 4mg/2ml Injection	PS				

Date:07/03/02ISR Number: 3944629-3Report Type:Expedited (15-DaCompany Report #B0271608A
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia Chest Pain Feeling Abnormal Hyperhidrosis	Foreign	Zofran (Formulation Unknown) (Ondansetron Hydrochloride)	PS			INTRAVENOUS	INTRAVENOUS
	Hypotension Hypoxia Malaise Urinary Incontinence		Calcium Folinate (Formulation Unknown) (Calcium Folinate)	SS			INTRAVENOUS	175 MG SINGLE
							DOSE	
			Oxaliplatin (Formulation Unknown) (Oxaliplatine)	SS			INTRAVENOUS	150 MG SINGLE
							DOSE	
			Me-Prednisolone Na Succ. (Formulation Unknown) (Me-Prednisolone Na Succ.)	SS			INTRAVENOUS	120 MG SINGLE
							DOSE	

INTRAVENOUS

Date:07/03/02ISR Number: 3944630-XReport Type:Expedited (15-DaCompany Report #B0271758A
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diabetes Insipidus Fluid Retention	Foreign	Zofran (Formulation Unknown) (Ondansetron Hydrochloride)	PS		INTRAVENOUS	INTRAVENOUS	
			Calcium Folinate (Formulation Unknown) (Calcium Folinate)	SS		INTRAVENOUS	50 MG	
			Metoclopramide Hcl (Formulation Unknown) (Metoclopramide Hcl)	SS		INTRAVENOUS	INTRAVENOUS	
			Methotrexate (Formulation Unknown) (Methotrexate)	SS		INTRAVENOUS	INTRAVENOUS	
			Nomegestrol Acetate	C				
			Paroxetine Hydrochloride	C				
			Ranitidine					

			Hydrochloride	C		
			Ethamsylate	C		
			Allopurinol	C		

Date:07/08/02ISR Number: 3944736-5Report Type:Direct Company Report #CTU 171740
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Headache		Zofran 4mg/2 Ml			
	Respiratory Arrest		Glaxo Wellcome	PS	Glaxo Wellcome	
INTRAVENOUS IV X 1						
			Fentanyl In Or	SS		
IV						

Date:07/08/02ISR Number: 3944851-6Report Type:Direct Company Report #CTU 171634
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Electrocardiogram Qt Prolonged		Zofran 4mg/2ml			
			Glaxo-Wellcome	PS	Glaxo-Wellcome	
INTRAVENOUS 4MG IV X 1						
	Electrocardiogram R On T Phenomenon					

Date:07/09/02ISR Number: 3947139-2Report Type:Expedited (15-DaCompany Report #A0373200A
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Blood Pressure Increased	Health	Zofran Unspecified			
	Headache	Professional	Injectable			
	Heart Rate Increased		(Ondansetron			
	Respiratory Arrest		Hydrochloride)	PS		
INTRAVENOUS INTRAVENOUS						
			Fentanyl	C		
			Vicodin	C		

Date:07/09/02ISR Number: 3948075-8Report Type:Expedited (15-DaCompany Report #B0270949A
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Clonic Convulsion	Foreign	Ondansetron Hydrochloride (Formulation Unknown)					
Other	Muscle Twitching	Health	(Ondansetron	PS			4 MG	
	Tremor	Professional	Midazolam	C				
			Fentanyl	C				
			Rocuronium Bromide	C				
			Hydrocortisone	C				
			Propofol	C				
			Indomethacin	C				
			Neostigmine	C				
			Glycopyrronium Bromide	C				
			Nitrous Oxide	C				
			Methotrexate	C				
			Prednisolone	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/10/02ISR Number: 3945936-0Report Type:Expedited (15-DaCompany Report #A0362425A
Age:22 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypertension		Zofran	PS	Glaxo Wellcome	OTHER	14 WK	
			Phenergan Suppositories	C	Glaxo Wellcome	RECTAL	25MG As required	53 DAY
			Prenatal Vitamins	C				
			Keflex	C	Glaxo Wellcome		250MG Four times per day	
			Tagamet	C	Glaxo Wellcome		400MG Twice per day	

Date:07/10/02ISR Number: 3945937-2Report Type:Expedited (15-DaCompany Report #A0362425B
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Amniocentesis Abnormal		Zofran	PS	Glaxo Wellcome	OTHER	14 WK	
Hospitalization - Initial or Prolonged	Anaemia Neonatal		Phenergan Suppositories	C	Glaxo Wellcome	RECTAL	25MG As required	53 DAY
Disability	Apgar Score Low							
Other	Blood Ph Decreased		Prenatal Vitamins	C				
	Blood Pressure Increased		Keflex	C	Glaxo Wellcome		250MG Four times per day	
	Caesarean Section		Tagamet	C	Glaxo Wellcome		400MG Twice per day	
	Coagulopathy							
	Complications Of Maternal							
	Exposure To Therapeutic Drugs							
	Hypoxic Encephalopathy							

	Maternal Drugs Affecting Foetus Neonatal Disorder Protein Urine Present Small For Dates Baby					

Date:07/11/02ISR Number: 3948500-2Report Type:Expedited (15-DaCompany Report #2002113684FR
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased	Foreign Health Professional	Aracytine (Cytarabine) Powder, Sterile	PS		INTRAVENOUS	IV	
	Blood Alkaline Phosphatase Increased Gamma-Glutamyltransferase Increased	Other	Zavedos (Idarubicin Hydrochloride) Powder, Sterile	SS		INTRAVENOUS	15.5 MG, QD, IV	
	Hepatitis Cholestatic Pancreatitis		Solu-Medrol (Methylprednisolone) Powder, Sterile	SS		INTRAVENOUS	40 MG, BID, IV	
			Zophren (Ondansetron Hydrochloride)	SS		INTRAVENOUS	2 MG, BID, IV	
			Tienam (Imipenem, Cilastatin)	C				
			Targocid	C				
			Flagyl	C				
			Ambisome (Amphotericine B, Liposome)	C				
			Neupogen					

(Filgrastim) C

Date:07/12/02ISR Number: 3948471-9Report Type:Expedited (15-DaCompany Report #3856
Age:24 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign	Cytarabine	PS		INTRAVENOUS	3.3 G IV	3 DAY
	Dialysis	Health Professional	Ciprofloxacin	SS		INTRAVENOUS	260 MG IV	3 DAY
	Encephalopathy	Other	Ranitidine	SS		INTRAVENOUS	30 MG IV	2 DAY
	Liver Function Test		Ondansetron Hydrochloride	SS		INTRAVENOUS	4 MG PRN IV	4 DAY
	Abnormal		Tobramycin	SS		INTRAVENOUS	80 MG IV	3 DAY
			Amphotericine B, Liposome	SS		INTRAVENOUS	15 MG IV	

Date:07/12/02ISR Number: 3948477-XReport Type:Expedited (15-DaCompany Report #3860
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Arthralgia		Cytarabine	PS		INTRAVENOUS	9.8 G, IV	8 DAY
	Dermatitis		Mitoxantrone	SS		INTRAVENOUS	16.6 MG, IV	3 DAY
	Erythema		Ondansetron	SS		ORAL	16 MG, PO	6 DAY
	Joint Swelling		Famciclovir	C				
	Nail Bed Tenderness		Fluconazole	C				
	Rash		Bactrim Ds	C				

Date:07/16/02ISR Number: 3950341-7Report Type:Expedited (15-DaCompany Report #A0373523A
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Apnoea Blindness Cardio-Respiratory Arrest Confusional State Cyanosis Dysphoria Hyperreflexia Malaise	Health Professional	Zofran Unspecified Injectable (Ondansetron Hydrochloride)	PS C C			
INTRAVENOUS	4 MG / SEE DOSAGE TEXT / INTRAVENOUS						

Date:07/17/02ISR Number: 3949440-5Report Type:Expedited (15-DaCompany Report #A0373915A
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electrocardiogram Qt Prolonged Electrocardiogram R On T Phenomenon	Health Professional	Zofran	PS	Glaxo Wellcome	INTRAVENOUS	4MG Single dose	

Date:07/17/02ISR Number: 3949446-6Report Type:Expedited (15-DaCompany Report #B0270165A
Age:44 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hypersensitivity	Health Professional	Zofran	PS	Glaxo Wellcome	SUBCUTANEOUS	4MG Unknown	
	Injection Site Erythema		Stemetil	C	Glaxo Wellcome	SUBCUTANEOUS	12.5UNIT Unknown	
	Metastatic Neoplasm							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/17/02ISR Number: 3949448-XReport Type:Expedited (15-DaCompany Report #B0271011A
Age:77 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest	Health	Zofran	PS	Glaxo Wellcome	INTRAVENOUS		
Hospitalization - Initial or Prolonged	Loss Of Consciousness	Professional	Paracetamol	C	Glaxo Wellcome	ORAL	1000MCG Twice per day	

Date:07/19/02ISR Number: 3951141-4Report Type:Direct Company Report #USP 54956
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Zofran (Ondansetron Hydrochloride)	PS	Glaxo Wellcome			
			Levaquin (Levofloxacin)	SS	Orthomcneil			

Date:07/19/02ISR Number: 3951157-8Report Type:Direct Company Report #USP 54973
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error Pharmaceutical Product Complaint		Fentanyl Citrate (Fentanyl Citrate)	PS	Abbott			
			Zofran (Ondansetron Hydrochloride)	SS	Glaxo Wellcome			

Date:07/23/02ISR Number: 3951815-5Report Type:Direct Company Report #CTU 172721
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Zofran 4mg /2 Ml Vial	PS				

Date:07/25/02ISR Number: 3953126-0Report Type:Expedited (15-DaCompany Report #B0271011A
Age:77 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Arrhythmia		Zofran	PS	Glaxo Wellcome	INTRAVENOUS		
Hospitalization -	Blood Pressure		Paracetamol	C	Glaxo Wellcome	ORAL	1000MCG Twice	
Initial or Prolonged	Fluctuation						per day	
	Loss Of Consciousness							

Date:07/26/02ISR Number: 3953753-0Report Type:Expedited (15-DaCompany Report #B0271608A
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anxiety		Zophren	PS	Glaxo Wellcome	INTRAVENOUS		45 MIN
	Bradycardia		Elvorine	SS	Glaxo Wellcome	INTRAVENOUS	175MG Single	
	Chest Pain						dose	
	Hyperhidrosis		Eloxatine	SS		INTRAVENOUS	150MG Single	
	Hypotension						dose	
	Hypoxia		Solumedrol	SS		INTRAVENOUS	120MG Single	
	Malaise						dose	10 MIN
	Urinary Incontinence							

Date:07/26/02ISR Number: 3953759-1Report Type:Expedited (15-DaCompany Report #B0274662A
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspartate		Zophren	PS	Glaxo Wellcome	INTRAVENOUS	2MG Twice per	
Hospitalization -	Aminotransferase							
day							4	DAY
Initial or Prolonged	Increased		Aracytine	SS				
INTRAVENOUS							4	DAY
	Bilirubin Conjugated		Zavedos	SS				
INTRAVENOUS	15.5MG Per							
	Increased							
day							2	DAY
	Blood Alkaline		Solumedrol	SS				
INTRAVENOUS	40MG Twice							
	Phosphatase Increased							
per day							13	DAY
	Blood Bilirubin Increased		Tienam	C				
UNKNOWN							26	DAY
	Cholestasis		Targocid	C				
UNKNOWN							37	DAY
	Gamma-Glutamyltransferase		Flagyl	C	Glaxo Wellcome			
UNKNOWN							8	DAY
	Increased		Zovirax	C	Glaxo Wellcome			
UNKNOWN							11	DAY
	Pancreatitis Acute		Ambisome	C				
UNKNOWN							20	DAY
			Neupogen	C				
UNKNOWN							16	DAY
			Red Cell Transfusion	C				
INTRAVENOUS								
			Transfusion Of Platelets	C				
INTRAVENOUS								
			Oflocet	C				
UNKNOWN							11	DAY

Date:07/26/02ISR Number: 3955350-XReport Type:Expedited (15-DaCompany Report #EMADSS2002004342
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Diplopia	Foreign	Prepulsid (10 Mg					

Initial or Prolonged	Nystagmus	Health Professional	Tablet) (Cisapride)	PS		ORAL
10 MG, 3 IN 1 DAY(S), ORAL						
			Durogesic (Patch) (Fentanyl)	SS		
			Mopral (Omeprazole)	SS		
INTRAVENOUS	40 MG, DAILY, IV					
			Zophren (Ondansetron Hydrochloride)	SS		ORAL
16 MG, DAILY, ORAL						
			Methylprednisolone (Methylprednisolone)	SS		
INTRAVENOUS	120 MG, DAILY, IV					
			Cetornan (Ornithine Oxoglurate)	SS		
			Actiskenan (Morphine Sulfate)	SS		
UNKNOWN	PRN, UNKNOWN					
			Xanax (Alprazolam)	SS		
UNKNOWN						
			Largactil (Chlorpromazine Hydrochloride)	SS		
UNKNOWN						
			Gemzar (Gemcitabine Hydrochloride)	SS		
INTRAVENOUS	SEE IMAGE					
			Oxaliplatin (Oxaliplatin)	SS		
INTRAVENOUS	SEE IMAGE					

Date:07/29/02ISR Number: 3954548-4Report Type:Expedited (15-DaCompany Report #A0375740A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Respiratory Arrest		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	4MG	Unknown

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/29/02ISR Number: 3956184-2Report Type:Expedited (15-DaCompany Report #MAG-2002-0000044
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pancreatitis	Foreign Health Professional Other	Morphine Sulfate Ir Tablet (Morphine Sulfate, Morphine Sulfate) Ir Tablet	PS		ORAL	ORAL	
			Mopral (Omeprazole)	SS		ORAL	ORAL	
			Zophren (Ondansetron Hydrochloride)	SS				
			Contramal (Tramadol Hydrochloride)	SS				
			Sectral "Akita" (Acebutolol Hydrochloride)	SS		ORAL	2 UNIT,	DAILY, ORAL
			Dafalgan (Paracetamol)	SS		ORAL	ORAL	
			Zinnat (Cefuroxime Axetil)	C				
			Etomidate (Etomidate)	C				
			Ultiva (Remifentanil Hydrochloride)	C				
			Pavulon (Pancuronium Bromide)	C				
			Exacyl (Tranexamic Acid)	C				
			Trasylol (Aprotinin)	C				
			Heparine (Heparin)	C				
			Protamine (Protamine)	C				
			Aspegic (Acetylsalicylate Lysine)	C				
			Tahor (Atorvastatin Calcium)	C				
			Tanganil (Ethanolamine Acetylleucinate)	C				

				Serc (Betahistine Hydrochloride)	C		

Date:07/30/02ISR Number: 3955029-4Report Type:Expedited (15-DaCompany Report #B0274842A
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chest Discomfort		Zophren	PS	Glaxo Wellcome			
INTRAVENOUS								1 DAY
Initial or Prolonged	Dyspnoea							
	Erythema							
	Nausea							
	Oedema							
	Tachycardia							

Date:07/31/02ISR Number: 3957003-0Report Type:Expedited (15-DaCompany Report #EMADSS2002004461
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pancreatitis	Foreign	Tramadol	PS		ORAL	ORAL	
		Health Professional	Sectral (Acebutolol Hydrochloride)	SS		ORAL	ORAL	
			Dafalgan (Paracetamol)	SS		ORAL	ORAL	
			Mopral (Omeprazole)	SS		ORAL	ORAL	
			Zophren (Ondansetron Hydrochloride)	SS				
			Sevredol (Morphine Sulfate)	SS				
			Zinnat (Cefuroxime Axetil)	C				
			Etomidate	C				
			Ultiva (Remifentanil Hydrochloride)	C				
			Pavulon (Pancuronium Bromide)	C				
			Exacyl (Tranexamic Acid)	C				
			Trasylol (Aprotinin)	C				
			Heparine (Heparin)	C				
			Protamine	C				
			Aspegic (Acetylsalicylate Lysine)	C				
			Tahor (Atorvastatin)	C				
			Serc (Betahistine)	C				
			Tanganil (Ethanolamine Acetylleucinate)	C				

Date:07/31/02ISR Number: 3957112-6Report Type:Expedited (15-DaCompany Report #2002CG01106
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Diplopia	Foreign	Mopral	PS	
INTRAVENOUS	40 MG QD IV				
Initial or Prolonged	Nystagmus	Health	Prepulsid	SS	ORAL
10 MG TID PO					
		Professional	Zophren	SS	ORAL
8 MG BID PO					
		Other	Solu-Medrol	SS	
INTRAVENOUS	120 MG QD IV				
			Gemzar	SS	
INTRAVENOUS	1200 MG DAILY				
IV					
			Gemzar	SS	
INTRAVENOUS	1200 MG DAILY				
IV					
			Gemzar	SS	
INTRAVENOUS	1200 MG DAILY				
IV					
			Oxaliplatin	SS	
INTRAVENOUS	120 MG DAILY				
IV					
			Oxaliplatin	SS	
INTRAVENOUS	120 MG DAILY				
IV					
			Oxaliplatin	SS	
INTRAVENOUS	120 MG DAILY				
IV					
			Cetornan	SS	
			Xanax	SS	
			Durogesic	SS	
			Actiskenan	SS	
			Largactil	SS	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/01/02ISR Number: 3956404-4Report Type:Expedited (15-DaCompany Report #B0274802A
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Purpura		Zophren	PS	Glaxo Wellcome			
INTRAVENOUS							8MG Per day	1 DAY
Initial or Prolonged	Pyrexia		Cisplatyl	SS				
INTRAVENOUS							75MG Per day	1 DAY
	Sepsis		Elvorine	SS	Glaxo Wellcome			
INTRAVENOUS								1 DAY
			Fluorouracil	SS				
INTRAVENOUS							2450MG Weekly	11 MON
			Solumedrol	C				
UNKNOWN								

Date:08/01/02ISR Number: 3958134-1Report Type:Expedited (15-DaCompany Report #1657643A
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Condition Aggravated	Literature	Unspecified					
	Stiff-Man Syndrome	Health Professional	Cyclobenzaprine Product	PS				
INTRATHECAL							2000U/ML, ITP	
			Morphine	SS				
INTRATHECAL							6 MG/ML, ITP	
			Oxycodone	SS				
30-35 MG/DAY								
			Lansoporazole	SS				
30 MG/DAY								
			Amitriptyline	SS				
75 MG/DAY								
			Ondansetron	SS				
24 MG/DAY								
			Diazepam	SS				
15 MG/DAY								

Date:08/05/02ISR Number: 3957573-2Report Type:Expedited (15-DaCompany Report #A0373200A
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Life-Threatening	Blood Pressure Increased		Zofran	PS	Glaxo Wellcome	
INTRAVENOUS	1 DAY					
Other	Headache		Fentanyl	C		
INTRAVENOUS						
	Heart Rate Increased		Vicodin	C		
	Respiratory Arrest					

Date:08/06/02ISR Number: 3958036-0Report Type:Expedited (15-DaCompany Report #B0271011A
Age:77 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Arrhythmia		Zofran	PS	Glaxo Wellcome	
INTRAVENOUS						
Hospitalization -	Blood Pressure		Paracetamol	C	Glaxo Wellcome	ORAL
1000MCG Twice						
Initial or Prolonged	Fluctuation					
per day						
	Bradycardia					
	Loss Of Consciousness					

Date:08/06/02ISR Number: 3958038-4Report Type:Expedited (15-DaCompany Report #B0275342A
Age:13 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Anaphylactic Shock		Zofran	PS	Glaxo Wellcome	
UNKNOWN						
	Circulatory Collapse		Betamethasone	C	Glaxo Wellcome	
UNKNOWN						
	Cyanosis					
	Respiratory Arrest					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/06/02ISR Number: 3958293-0Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11953254
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cyanosis	Health Professional	Taxol Inj Syn	PS	Bristol-Myers Squibb Company	INTRAVENOUS		
	Discomfort						1	DAY
	Dizziness		Paraplatin	SS	Bristol-Myers Squibb Company	INTRAVENOUS		
	Hypotension						1	DAY
	Loss Of Consciousness		Polaramine	SS		INTRAVENOUS		
	Malaise		Tagamet	SS		INTRAVENOUS		
	Tonic Convulsion		Plitican	SS		INTRAVENOUS		
			Zophren	SS		INTRAVENOUS	2 mg/ml	
			Dexamethasone	SS				

Date:08/12/02ISR Number: 3960662-XReport Type:Expedited (15-DaCompany Report #A0369832A
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrioventricular Block		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	4MG As	
	First Degree						required	2 DAY
	Bundle Branch Block Left		Morphine	C		UNKNOWN		
	Sinus Tachycardia		Reglan	C	Glaxo Wellcome	UNKNOWN		
			Ancef	C	Glaxo Wellcome	UNKNOWN		

Date:08/14/02ISR Number: 3963206-1Report Type:Expedited (15-DaCompany Report #200212574EU
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Pancreatitis Acute	Foreign	Metronidazole					

Hospitalization - Other (Fagil) PS
INTRAVENOUS 1.5 MG /DAY
Initial or Prolonged
IV 3 DAY

Ranitidine Hydrochloride (Zantac) SS ORAL
600 MG /DAY

PO 3 DAY

Ranitidine Hydrochloride(Zantac) SS
INTRAVENOUS 150 MG/DAY IV

Augmentin SS
INTRAVENOUS IV

Ondansetron Hydrochloride(Zofran) SS
Rocuronium Bromide SS
1 DAY

Propofol SS
1 DAY

Fentanyl SS
1 DAY

Metamizole Sodium (Nolotil) C
INTRAVENOUS 8 MG/DAY IV 2 DAY

Metamizole Sodium (Nolotil) C ORAL
575 MG/DAY PO

Metamizole Sodium (Nolotil) C
INTRAVENOUS 2 G /DAY IV 1 DAY

Date:08/19/02ISR Number: 3963424-2Report Type:Expedited (15-DaCompany Report #A0376521A
Age: Gender:Female I/FU:F

Outcome PT
Other Complications Of Maternal Exposure To Therapeutic Drugs

	Thyroid Function Test						
	Abnormal						
	Thyroid Neoplasm	Report Source	Product	Role	Manufacturer	Route	
Dose	Duration						
	Thyroiditis		Zofran	PS	Glaxo Wellcome	ORAL	

Date:08/19/02ISR Number: 3963426-6Report Type:Expedited (15-DaCompany Report #B0276534A
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Back Pain	Foreign	Zophren	PS	Glaxo Wellcome	
INTRAVENOUS	7 DAY					
	Blood Culture Positive		Profenid	SS		
INTRAVENOUS	1 DAY					
	Bone Pain		Tranxene	SS		ORAL
7 DAY						
	C-Reactive Protein		Prodafalgan	SS		
INTRAVENOUS	2G Four times					
	Increased					
per day	6 DAY					
	Coma		Nubain	SS		
INTRAVENOUS	6 DAY					
	Cyanosis		Cefamandole	C		
	Headache		Primperan	C	Glaxo Wellcome	
2 DAY						
	Heart Rate Increased		Mopral	C		
	Meningitis Pneumococcal		Biprofenid	C		ORAL
3 DAY						
	Musculoskeletal Stiffness					
	Myalgia					
	Neck Pain					
	Nervous System Disorder					
	Neutrophil Count Increased					
	Prostration					
	Pyrexia					
	Respiratory Arrest					
	Vomiting					
	White Blood Cell Count Increased					

Date:08/21/02ISR Number: 3964472-9Report Type:Expedited (15-DaCompany Report #B0277091A
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Haemoglobin Decreased	Health	Zofran	PS	Glaxo Wellcome	PARENTERAL		
	Sudden Death	Professional	Chemotherapy	SS		UNKNOWN		

Date:08/21/02ISR Number: 3966589-1Report Type:Expedited (15-DaCompany Report #B0276589A
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pruritus	Foreign	Zofran Injectioni (Ondansetron Hydrochloride)	PS		INTRAVENOUS	INTRAVENOUS	
			Dexamethasone	C				
			Irinotecan	C				

Date:08/26/02ISR Number: 3966007-3Report Type:Expedited (15-DaCompany Report #A0373915A
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electrocardiogram Qt		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	4MG Single	
	Prolonged							
dose	1 DAY							
	Electrocardiogram R On T Phenomenon							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/27/02ISR Number: 3966341-7Report Type:Expedited (15-DaCompany Report #B0277131A
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Bullous		Zophren	PS	Glaxo Wellcome	ORAL	8MG Twice per day	6 DAY
	Dermatosis							
	Neutrophilia		Cisplatyl	SS			INTRAVENOUS	170MG Single dose
	Rash Pustular							1 DAY
			Vepeside	SS			INTRAVENOUS	170MG per day 3 DAY

Date:08/27/02ISR Number: 3968281-6Report Type:Expedited (15-DaCompany Report #B0277041A
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Pancreatitis Acute	Foreign	Amox. Trihyd+Pot.Clavulan. (Formulation Unknown)	PS			INTRAVENOUS	INTRAVENOUS
			Ranitidine Hydrochloride Tablet (Ranitidine Hydrochloride)	SS		ORAL	ORAL	
			Ranitidine Hydrochloride Unspecified Injectable	SS			INTRAVENOUS	INTRAVENOUS
			Dipyrone Tablet	SS		ORAL	575 MG AS REQUIRED,	ORAL
			Metronidazole (Formulation					

				Unknown)	SS		
INTRAVENOUS	INTRAVENOUS						
				Dipyrone (Formulation Unknown)	SS		
INTRAVENOUS	INTRAVENOUS						
				Midazolam (Formulation Unknown)	SS		
INTRAVENOUS	INTRAVENOUS						
				Fentanyl (Formulation Unknown)	SS		
INTRAVENOUS	INTRAVENOUS						
				Propofol (Formulation Unknown)	SS		
INTRAVENOUS	INTRAVENOUS						
				Ondansetron Hydrochloride (Formuation Unknown)	SS		
INTRAVENOUS	INTRAVENOUS						
				Rocuronium Bromide (Formulation Unknown)	SS		
INTRAVENOUS	INTRAVENOUS						

Date:08/28/02ISR Number: 3967023-8Report Type:Expedited (15-DaCompany Report #B0277432A
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coronary Artery Surgery		Zophren	PS	Glaxo Wellcome			1 DAY
Initial or Prolonged	Pancreatitis		Sectral	SS		ORAL	2UNIT per day	
			Dafalgan	SS	Glaxo Wellcome	ORAL		3 DAY
			Mopral	SS		ORAL		5 DAY
			Sevredol	SS	Glaxo Wellcome			1 DAY

				Contramal	SS		
1	DAY						
				Aspegic	C		
				Tahor	C		
				Tanganil	C		
				Serc	C		
				Zinnat	C	Glaxo Wellcome	
2	DAY						
				Etomidate	C		
2	DAY						
				Ultiva	C	Glaxo Wellcome	
2	DAY						
				Pavulon	C		
2	DAY						
				Exacyl	C		
2	DAY						
				Trasylol	C		
2	DAY						
				Heparine	C		
2	DAY						
				Protamine	C		
2	DAY						

Date:08/28/02ISR Number: 3967083-4Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12012399
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bone Marrow Depression Pyrexia		Endoxan	PS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Uromitexan	SS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Bactrim	SS		ORAL		
			Granocyte	SS		SUBCUTANEOUS		
			Zophren	SS		INTRAVENOUS		

Date:08/28/02ISR Number: 3969663-9Report Type:Expedited (15-DaCompany Report #200213308FR
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agranulocytosis	Foreign	Lovenox 20 Mg/0.2 Ml					
Hospitalization - Initial or Prolonged	Anxiety	Other	Solution For Injection	PS				
	Diarrhoea						SUBCUTANEOUS	20 MG QD SC
	Epistaxis		Solutions For Parental Nutrition Nos (Clinomel) Solution For Infusion	SS				
	Nausea							
	Pancytopenia							
	Respiratory Tract Congestion						INTRAVENOUS	2 L QD IV
	Septic Shock		Alprazolam (Xanax) Tablets	SS		ORAL	0.25 MG BID	PO 9 DAY
	Stevens-Johnson Syndrome							
			Ondansetron Hydrochloride (Zophren) Coated Tablets	SS		ORAL	8 MG BID PO	8 DAY
			Omeprazole (Mopral) Solution For Injection	SS			INTRAVENOUS	40 MG QD IV

Date:08/28/02ISR Number: 4000678-0Report Type:Periodic Company Report #A0157950A
Age:57 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation	Health Professional	Lotronex Tablet (Alosetron Hydrochloride)	PS		ORAL	1 MG/ TWICE	PER DAY/ ORAL
	Drug Ineffective							
			Zofran (Formulation					

			Unknown) (Ondansetron Hydrochloride)	SS			
6 MON							

Date:08/29/02ISR Number: 3967698-3Report Type:Expedited (15-DaCompany Report #A0167910A
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arterial Thrombosis		Zofran	PS	Glaxo Wellcome	ORAL	4MG See dosage text	
	Complications Of Maternal Exposure To Therapeutic Drugs Maternal Drugs Affecting Foetus Premature Labour Stillbirth Thrombosis Umbilical Cord Vascular Disorder		Prenatal Vitamins	C				

Date:08/29/02ISR Number: 3967707-1Report Type:Expedited (15-DaCompany Report #B0277600A
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - INTRAVENOUS	Interstitial Lung Disease		Zophren	PS	Glaxo Wellcome			16 DAY
Initial or Prolonged			Lederfoline	SS	Glaxo Wellcome	ORAL	300MG cumulative dose	16 DAY
			Fluoro-Uracile	SS			INTRAVENOUS 2090MG cumulative dose	16 DAY

				Campto	SS		
INTRAVENOUS	270MG						
cumulative							
dose	15	DAY					
				Atropine	SS		
INTRAVENOUS		15	DAY				
				Solumedrol	SS		
INTRAVENOUS	120MG per day	15	DAY				
				Durogesic	C		
TRANSDERMAL							
				Movicol	C		ORAL
				Lasilix	C	Glaxo Wellcome	
UNKNOWN							
				Gentamicine	C	Glaxo Wellcome	
UNKNOWN							
				Rocephine	C		
UNKNOWN							

Date:08/29/02ISR Number: 3967708-3Report Type:Expedited (15-DaCompany Report #B0277918A
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Platelet Count Decreased		Zophren	PS	Glaxo Wellcome	
INTRAVENOUS	8MG Weekly 4 WK					
Initial or Prolonged			Cisplatine	SS		
INTRAVENOUS	40MG Weekly 4 WK					
			Solumedrol	SS		
INTRAVENOUS	60MG Weekly 4 WK					

Date:08/29/02ISR Number: 3967710-1Report Type:Expedited (15-DaCompany Report #D0038977A
Age:25 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Grand Mal Convulsion		Zofran	PS	Glaxo Wellcome	
INTRAVENOUS	4MG Single					
Initial or Prolonged	Hangover					
dose	1 DAY					
	Loss Of Consciousness		Ultiva	C	Glaxo Wellcome	
INTRAVENOUS	1 DAY					
	Respiratory Failure		Disoprivan	C		
INTRAVENOUS	1 DAY					

			Mivacron	C	Glaxo Wellcome	
INTRAVENOUS	6MG Single					
dose	1 DAY					
			Dipidolor	C		
INTRAVENOUS	3.75MG Single					
dose	1 DAY					

Date:08/29/02ISR Number: 3968611-5Report Type:Direct Company Report #CTU 175337
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Coordination Abnormal		Zofran	PS		
4 MG IV						
	Euphoric Mood					
	Nystagmus					

Date:08/29/02ISR Number: 3969205-8Report Type:Direct Company Report #CTU 175302
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Hiccups		Zofran 2 Mg/Ml	PS		
INTRAVENOUS						
						BOLUS
16 MG QD						
INTRAVENOUS						
BOLUS						
			Zofran 8 Mg Sl	SS		
SUBLINGUAL	8 MG TID PRN					
SUBLINGUAL						
			Idamycin	C		
			Ara-C	C		
			Merrem	C		

Date:09/04/02ISR Number: 3969844-4Report Type:Expedited (15-DaCompany Report #A0367199A
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anaemia		Ondansetron	PS	Glaxo Wellcome			
Initial or Prolonged	Constipation		Vinorelbine Tartrate	SS	Glaxo Wellcome	ORAL	6MG Per day	
	Gastrointestinal Disorder		Buprenorphine	SS				
	Neutropenia		Ferrous Sulfate	SS		ORAL	80MG Per day	
			Cisplatin	C				
INTRAVENOUS	80MGM2 See dosage text							
			Paracetamol	C	Glaxo Wellcome			
			Methylprednisolone	C				
			Metopimazine	C				
			Epoetin Alfa	C				
SUBCUTANEOUS	10000IU Three times per week							

Date:09/04/02ISR Number: 3969861-4Report Type:Expedited (15-DaCompany Report #D0039187A
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Diarrhoea		Zofran	PS	Glaxo Wellcome			
INTRAVENOUS	8MG per day							22 DAY
Initial or Prolonged	General Physical Health		Opium	C		ORAL	8DROP per day	38 DAY
	Deterioration							
	Ileus Paralytic							
	Neutropenia							
	Pain							
	Pyrexia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/05/02ISR Number: 3972867-2Report Type:Expedited (15-DaCompany Report #200212574EU
Age:27 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization -	Pancreatitis Acute	Foreign Other	Metronidazole (Flagyl)	PS		INTRAVENOUS	1.5 MG/DAY IV	3 DAY
Initial or Prolonged			Ranitidine Hydrochloride (Zantac)	SS		ORAL	600 MG/DAY PO	3 DAY
			Ranitidine Hydrochloride (Zantac)	SS		INTRAVENOUS	150 MG/DAY IV	
			Augmentin	SS		INTRAVENOUS	IV	
			Metamizole Sodium (Nolotil)	SS		INTRAVENOUS	8 MG/DAY IV	2 DAY
			Metamizole Sodium (Nolotil)	SS		ORAL	575 MG/DAY PO	
			Metamizole Sodium (Nolotil)	SS		INTRAVENOUS	2 G/DAY IV	1 DAY
			Ondansetron Hydrochloride (Zofran)	SS				
			Fentanyl	SS				1 DAY
			Rocuronium Bromide	SS				1 DAY
			Propofol	SS				1 DAY
			Cefotaxime	C				
			Tobramycin	C				
			Imipenem	C				

Date:09/06/02ISR Number: 3973220-8Report Type:Expedited (15-DaCompany Report #B0277534A
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Diplopia Nystagmus	Foreign	Zofran (Formulation Unknown) (Ondansetron Hydrochloride)	PS	ORAL	8 MG / TWICE PER DAY / ORAL
			Omeprazole (Formulation Unknown) (Omeprazole)	SS	INTRAVENOUS	40 MG / PER DAY / INTRAVENOUS
			Cisapride (Cisapride)	SS	ORAL	10 MG / THREE TIMES PER DAY / ORAL
			Methylprednisolone (Methylprednisolone)	SS	INTRAVENOUS	120 MG / PER DAY / INTRAVENOUS
			Gemcitabine (Gemcitabine)	SS	INTRAVENOUS	1.2 MG / CYCLIC / INTRAVENOUS
			Oxaliplatin			

				(Oxaliplatin)	SS		
INTRAVENOUS	120 MG /						
CYCLIC /							
INTRAVENOUS							

Date:09/09/02ISR Number: 3973944-2Report Type:Expedited (15-DaCompany Report #200213308FR
Age:65 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Agranulocytosis	Foreign	Lovenox 20 Mg/0.2 Ml			
Hospitalization -	Anxiety	Other	Solution For			
Initial or Prolonged	Diarrhoea		Injection	PS		
SUBCUTANEOUS 20 MG QD SC						
	Epistaxis		Solutions For			
	Hypotension		Parenteral Nutrition			
	Hypothermia		Now (Clinomel)			
	Nausea		Solution For			
	Pancytopenia		Infusion	SS		
INTRAVENOUS 2 L QD IV						
	Pulmonary Congestion		Alprazolam (Xanax)			
	Septic Shock		Tablets	SS		ORAL
0.25 MG BID						
	Stevens-Johnson Syndrome					
PO 9 DAY						
			Ondansetron Hydrochloride (Zophren) Coated			
			Tablets	SS		ORAL
8 MG BID PO 8 DAY						

Date:09/09/02ISR Number: 3973994-6Report Type:Expedited (15-DaCompany Report #200213450FR
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Hypoprothrombinaemia	Foreign	Methotrexate	PS		
INTRAVENOUS IV 52 DAY						
Initial or Prolonged		Other	Furosemide (Lasilix)			
			Tablets	SS		ORAL
PO 41 DAY						

					Vincristine Sulfate (Oncovin) Solution For Injection	SS	
INTRAVENOUS	IV	41	DAY				
					Ondansetron Hydrochloride (Zophren) Tablets	SS	ORAL
PO	6	WK					
					Calcium Folinate (Lederfoline)	SS	
INTRAVENOUS	IV	40	DAY				
					Asparaginase	C	
					...	C	
					Clavulanate Potassium, Amoxicillin Trihydrate (Ciblor)	C	
					Morphine	C	
					Bromazepam (Lexomil)	C	
					Omeprazole (Mopral)	C	
					Chlorpromazine Hydrochloride (Largactil)	C	
					Methylprednisolone Soduim Succinate (Solu-Medrol)	C	
					Propacetamol Hydrochloride (Pro-Dafalgan)	C	
					Morphine Sulfate (Skenan)	C	

Morphine Sulfate	C
Dexamethasone (Decadron)	C
Metoclopramide (Primperan)	C
Phloroglucinol, Trimethylphlorogluci nol (Spasfon)	C
Paracetamol (Dafalgan)	C
Metopimazine (Vogalene)	C
Clonazepam (Rivotril)	C
Amitriptyline Hydrochloride (Laroxyl)	C
Mesna	C
Urate Oxidase(Uricozyme)	C

Date:09/10/02ISR Number: 3972730-7Report Type:Expedited (15-DaCompany Report #B0278410A
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion		Zophren	PS	Glaxo Wellcome	INTRAVENOUS	2MG Single	
Initial or Prolonged	Cyanosis							
dose								
	Eye Movement Disorder		Minirin	C		INTRAVENOUS	24UG	
	Fatigue							
cumulative								
	Respiratory Arrest							
dose	2 DAY							
	Vomiting		Solumedrol	C		INTRAVENOUS	180MG	
cumulative								
dose	2 DAY							
			Zinnat	C	Glaxo Wellcome	UNKNOWN	2250MG	

cumulative

dose 2 DAY

Date:09/10/02ISR Number: 3973745-5Report Type:Expedited (15-DaCompany Report #0750331A
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Post Procedural Pain	Study Health Professional	Tranderm Scop-Scopolamine	PS		TRANSDERMAL	1	PATCH/OD/TTS
			Ondansetron	SS		INTRAVENOUS	IV	

Date:09/11/02ISR Number: 3973367-6Report Type:Expedited (15-DaCompany Report #B0278139A
Age:65 YR Gender:Male I/FU:I

Outcome	PT
Death	Agranulocytosis
Hospitalization - Initial or Prolonged	Anaemia
	Diarrhoea
	Epistaxis
	Hypotension
	Hypothermia
	Leukopenia
	Pancytopenia

Pulmonary Congestion
Stevens-Johnson Syndrome
Thrombocytopenia

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Zophren	PS	Glaxo Wellcome	INTRAVENOUS	8MG Twice per day	8 DAY
	Lovenox	SS		SUBCUTANEOUS	.2ML Per day	
	Clinomel	SS		INTRAVENOUS	2L Per day	
	Xanax	SS		SUBLINGUAL	.25MG Twice per day	9 DAY
	Mopral	SS		INTRAVENOUS	40MG Per day	
	Perfusion	C				

Date:09/11/02ISR Number: 3974109-0Report Type:Expedited (15-DaCompany Report #4206
Age:24 MON Gender:Male I/FU:I

Outcome PT

Hyperammonaemia

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Vincristine Sulfate	PS		INTRAVENOUS	0.8MG	1 DAY
	Doxorubicin	SS		INTRAVENOUS	13 MG	1 DAY
	Promethazine Hydrochloride	SS		INTRAVENOUS		1 DAY
	Ondansetron Hydrochloride	SS		INTRAVENOUS		1 DAY
	Colaspase	SS		INTRAVENOUS		

Date:09/13/02ISR Number: 3974848-1Report Type:Expedited (15-DaCompany Report #B0277918A
Age:57 YR Gender:Male I/FU:F

Outcome PT Report Source Product Role Manufacturer Route Dose Duration

Hospitalization -	Thrombocytopenia			Zophren	PS	Glaxo Wellcome	
INTRAVENOUS	8MG Weekly	4	WK				
Initial or Prolonged				Cisplatine	SS		
INTRAVENOUS	40MG Weekly	4	WK				
				Solumedrol	SS		
INTRAVENOUS	60MG Weekly	4	WK				

Date:09/13/02ISR Number: 3974854-7Report Type:Expedited (15-DaCompany Report #D0039187A
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Diarrhoea		Zofran	PS	Glaxo Wellcome	
INTRAVENOUS	8MG per day	22 DAY				
Initial or Prolonged	General Physical Health		Opium	C		ORAL
8DROP per day	38 DAY					
	Deterioration					
	Ileus Paralytic					
	Neutropenia					
	Pain					
	Pyrexia					

Date:09/16/02ISR Number: 3976657-6Report Type:Expedited (15-DaCompany Report #200213450FR
Age:14 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Hypoprothrombinaemia	Foreign	Methotrexate	PS		
INTRAVENOUS	IV 52 DAY					
Initial or Prolonged		Other	Furosemide (Lasilix) Tablet	SS		ORAL
PO	41 DAY					
			Vincristine Sulfate (Oncovin) Solution For Injection	SS		
INTRAVENOUS	IV 41 DAY					
			Ondansetron Hydrochloirde (Zophren) Tablets	SS		ORAL
PO	42 DAY					

				Calcium Folinate (Lederfoline)	SS
INTRAVENOUS	IV	40	DAY		
				Asparginase	C
				Clavulanate Potassium, Amoxicillin Trihydrate (Ciblor)	C
				Morphine	C
				Urate Oxidase (Uricozyme)	C
				Bromazepam (Lexomil)	C
				Omeprazole (Mopral)	C
				Chlorpromazine Hydrochloride (Largactil)	C
				Methylprednisolone Sodium Succinate (Solu-Medrol)	C
				Propacetamol Hydrochloride (Pro-Dafalgan)	C
				Morphine Sulfate (Skenan)	C
				Morphine Sulfate	C
				Dexamethasone (Decadron)	C
				Metoclopramide (Primperan)	C
				Phloroglucinol, Trimethylphlorogluci nol (Spasfon)	C
				Paracetamol (Dafalgan)	C
				Metopimazine (Vogalene)	C
				Clonazepam (Rivotril)	C
				Amitriptyline Hydrochloride (Laroxyl)	C
				Mesna	C
				Cytarabine (Aracytine)	C
				Cyclophosphamide (Endoxan)	C
				Mercaptopurine	

			(Purinethol)	C		

Date:09/16/02ISR Number: 3976784-3Report Type:Expedited (15-DaCompany Report #2002AP02803
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Hypertonia	Foreign Health Professional	Marcain With Adrenaline Morphine Sulfate	PS SS			7.5 MG ONCE	
		Other	Diprivan	SS		INTRAVENOUS	200 MG ONCE	IV
			Sevorane	SS				
			Nitrous Oxide	SS				
			Zofran	SS		INTRAVENOUS	4 MG DAILY IV	

				Suxamethonium	SS			
200 ONCE								
Date:09/17/02ISR Number: 3976093-2Report Type:Expedited (15-DaCompany Report #B0277600A								
Age:62 YR Gender:Male I/FU:F								
Outcome	PT		Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Dyspnoea			Zophren	PS	Glaxo Wellcome		
INTRAVENOUS								
Initial or Prolonged	Intestinal Obstruction			Lederfoline	SS	Glaxo Wellcome	ORAL	
300MG								
	Lung Disorder							
cumulative								
	Lymphangiosis							
dose								
	Carcinomatosa			Fluoro-Uracile	SS			
INTRAVENOUS	2090MG							
cumulative								
dose								
				Campto	SS			
INTRAVENOUS	270MG							
cumulative								
dose								
				Atropine	SS			
INTRAVENOUS								
				Solumedrol	SS			
INTRAVENOUS	120MG per day							
				Durogesic	C			
TRANSDERMAL								
				Movicol	C		ORAL	
				Lasilix	C	Glaxo Wellcome		
UNKNOWN								
				Gentamicine	C	Glaxo Wellcome		
UNKNOWN	48	HR						
				Rocephine	C			
UNKNOWN	14	DAY						
				Zestril	C			
UNKNOWN	1	YR						

Date:09/17/02ISR Number: 3976104-4Report Type:Expedited (15-DaCompany Report #B0279310A
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypoprothrombinaemia		Zophren	PS	Glaxo Wellcome	ORAL	6 WK	
			Oncovin	SS				
			Methotrexate Roger Bellon	SS				
			Lederfoline	SS	Glaxo Wellcome			
			Lasilix Faible	SS	Glaxo Wellcome	ORAL	6 WK	
			Asparaginase	C				
			Ciblor	C	Glaxo Wellcome			
			Chlorhydrate De Morphine	C				
			Uricozyme	C				
			Lexomil	C				
			Mopral	C				
			Largactil	C				
			Solumedrol	C				
			Prodafalgan	C				
			Skenan	C	Glaxo Wellcome			
			Actiskenan	C	Glaxo Wellcome			
			Decadron	C				
			Primperan	C	Glaxo Wellcome			
			Spasfon	C				
			Dafalgan	C	Glaxo Wellcome			
			Vogalene	C				
			Rivotril	C				

INTRAVENOUS 6 WK

INTRAVENOUS 7 WK

INTRAVENOUS 5 WK

INTRAMUSCULAR 6 WK

UNKNOWN

UNKNOWN

UNKNOWN

UNKNOWN

UNKNOWN

UNKNOWN

UNKNOWN

UNKNOWN

UNKNOWN

UNKNOWN

UNKNOWN

UNKNOWN

UNKNOWN

UNKNOWN

UNKNOWN

UNKNOWN

Laroxyl	C	Glaxo Wellcome
Mesna	C	

UNKNOWN

UNKNOWN

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/17/02ISR Number: 3978411-8Report Type:Expedited (15-DaCompany Report #2002AP02803
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Hypertonia Muscle Rigidity	Foreign Health Professional	Marcain With Adrenaline Morphine Sulfate	PS SS			7.5 MG	ONCE
	Muscle Spasms	Other	Diprivan	SS		INTRAVENOUS	200 MG	ONCE
			Sevorane	SS		IV		
			Nitrous Oxide	SS				
			Zofran	SS		INTRAVENOUS	4 MG	DAILY IV
			Suxamethonium	SS			200	ONCE

Date:09/25/02ISR Number: 3982223-9Report Type:Expedited (15-DaCompany Report #0759553A
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Ineffective	Study Health Professional	Transderm Scop-Scopolamine 1.5mg-Nvch	PS		PATCH/QD/TTS	1	
			Ondansetron	SS		INTRAVENOUS	4MG /2ML/I.V.	

Date:10/02/02ISR Number: 3983877-3Report Type:Direct Company Report #CTU 177789
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia		Zofran (Ondansetron)	PS		INTRAVENOUS	4 MG IV X 1	
	Headache							
	Hypoaesthesia							

	Tonic Convulsion					
	Vomiting					

Date:10/02/02ISR Number: 3984400-XReport Type:Expedited (15-DaCompany Report #2002126471FR
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angina Unstable	Foreign	Solu-Medrol (Methylprednisolone)					
	Condition Aggravated	Health						
	Dizziness	Professional	Powder, Sterile	PS				
						INTRAVENOUS	120 MG, IV	
		Other	Plitican (Alizapride Hydrochloride)	SS				
						INTRAVENOUS	IV	
			Navelbine (Vinorelbine Ditartrate)	SS				
						INTRAVENOUS	48 MG, IV	
			Cisplatin (Cisplatin)	SS				
						INTRAVENOUS	150 MG, IV	
			Zophren (Ondansetron Hydrochloride)	SS				
						INTRAVENOUS	IV	

Date:10/02/02ISR Number: 3987976-1Report Type:Expedited (15-DaCompany Report #B0274802A
Age:63 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Haemoglobin Decreased
	Purpura
	Rash

		Staphylococcal Sepsis White Blood Cell Count Decreased	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign	Zofran Injection (Ondansetron Hydrochloride)	PS		
INTRAVENOUS	8 MG / PER						
DAY /							
INTRAVENOUS							
				Cisplatin Injection (Cisplatin)	SS		
INTRAVENOUS	75 MG PER DAY						
/							
INTRAVENOUS							
				Calcium Folinate Injection (Calcium Folinate)	SS		
INTRAVENOUS	INTRAVENOUS						
				Fluorouracil (Formulation Unknown) (Fluorouracil)	SS		
INTRAVENOUS	2450 MG						
WEEKLY /							
INTRAVENOUS							
				Me-Prednisolone Na Succ.	C		

Date:10/07/02ISR Number: 3984777-5Report Type:Expedited (15-DaCompany Report #B0280775A
Age: Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Silent Myocardial Infarction		Zofran	PS	Glaxo Wellcome	ORAL
1TAB Single dose							

	Troponin Increased		Cisplatin	SS		
UNKNOWN						

Date:10/07/02ISR Number: 3985795-3Report Type:Direct Company Report #CTU 178009
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Bradycardia		Zofran			
	Cardiac Arrest		8mg/Glaxowellcome	PS	Glaxowellcome	
INTRAVENOUS 8MG X 1 IV						
	Syncope Vasovagal					

Date:10/08/02ISR Number: 3985538-3Report Type:Expedited (15-DaCompany Report #A0379632A
Age:73 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Agitation	Health	Zofran	PS	Glaxo Wellcome	
INTRAVENOUS 4MG See						
Initial or Prolonged	Delusion	Professional				
dosage text 90 MIN						
Other	Dyskinesia		Droperidol	SS		
UNKNOWN						
	Moaning		Reglan	SS	Glaxo Wellcome	
INTRAVENOUS 1 DAY						
			Celebrex	C		ORAL
			Pepcid	C		ORAL
20MG As						
required						
			Demerol	C		
INTRAMUSCULAR 50MG Per day						
			Dilaudid	C		
INTRATHECAL						
			Bupivacaine	C		
INTRATHECAL						
			Clonidine	C		
INTRATHECAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/08/02ISR Number: 3985539-5Report Type:Expedited (15-DaCompany Report #A0382459A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Body Temperature		Zofran	PS	Glaxo Wellcome	UNKNOWN		
	Decreased		Morphine	C		INTRATHECAL		
			Fentanyl	C		INTRATHECAL		

Date:10/08/02ISR Number: 3985552-8Report Type:Expedited (15-DaCompany Report #B0281051A
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angina Pectoris	Consumer	Zophren	PS	Glaxo Wellcome	INTRAVENOUS		
			Plitican	SS		INTRAVENOUS		
			Solumedrol	SS				
			Navelbine	SS	Glaxo Wellcome	INTRAVENOUS	1	DAY
			Cisplatine	SS				

Date:10/09/02ISR Number: 3986375-6Report Type:Expedited (15-DaCompany Report #D0039497A
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Apnoea		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	4MG Single	
	Arrhythmia					dose	1	DAY
	Blood Pressure Increased		Ultiva	C	Glaxo Wellcome	INTRAVENOUS	.12UGKM	
	Loss Of Consciousness					Single dose	1	DAY
	Respiratory Depression		Dipidolor	C		INTRAVENOUS	5MG Single	
						dose	1	DAY

Date:10/09/02ISR Number: 3986376-8Report Type:Expedited (15-DaCompany Report #D0039499A
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Apnoea		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	4MG Single	
	Arrhythmia						dose	1 DAY
	Blood Pressure Increased		Ultiva	C	Glaxo Wellcome	INTRAVENOUS	.12UGKM	
	Loss Of Consciousness						Single dose	1 DAY
			Dipidolor	C		INTRAVENOUS	5MG Single	
							dose	1 DAY

Date:10/16/02ISR Number: 3990732-1Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12069118
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Injury	Other	Paraplatin	PS	Bristol-Myers Squibb Company	Other	INTRAVENOUS	
			Paraplatin	SS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Cytoxan	SS	Bristol-Myers Squibb Company			
			Taxotere	SS				
			Taxotere	SS				
			Adriamycin	SS				
			Tamoxifen	SS				
			Doxil	SS				
			Doxil	SS				
			Ondansetron	SS				

Interrupted

from

30-Apr-96 to

08-Jan-99.

				Ondansetron	SS		

Interrupted

from

30-Apr-96 to

08-Jan-99.

				Herceptin	C		
				Navelbine	C		

Date:10/17/02ISR Number: 3991175-7Report Type:Expedited (15-DaCompany Report #A0382901A
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electrocardiogram Qt		Zofran	PS	Glaxo Wellcome	ORAL		WK
	Prolonged		Anti-Epileptic Drugs (Unspecified)	C				
			Prevacid	C				

Date:10/17/02ISR Number: 3991176-9Report Type:Expedited (15-DaCompany Report #A0383278A
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Angina Pectoris		Zophren	PS	Glaxo Wellcome			UNKNOWN
Initial or Prolonged	Cardiac Disorder		Navelbine	SS	Glaxo Wellcome			
INTRAVENOUS							48MG per day	
	Malaise		Cisplatin	C				
1 DAY								
			Plitican	C				
1 DAY								
			Solumedrol	C				
1 DAY								

Date:10/17/02ISR Number: 3991355-0Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12076113
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis	Health Professional	Endoxan-Asta	PS	Bristol-Myers Squibb Company			
			Uromitexan	SS	Bristol-Myers Squibb Company			
			Adriblastine	SS				
			Oncovin	SS				
			Zophren	SS				
			Mabthera	SS				
			Solu-Medrol	C				
			Zelitrex	C				
			Mopral	C				
			Fungizone	C	Apothecon			
			Cortancyl	C				

Date:10/17/02ISR Number: 3994825-4Report Type:Direct Company Report #CTU 178935
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardio-Respiratory Arrest		Zofran Injection	PS		INTRAVENOUS	4 MG IV	Q12HRS PRN
			Morphine Pca	SS		INTRAVENOUS	PCA IV	
			Ferrodegueis	C				
			Enalapril	C				
			Gabapentin	C				
			Warfarin	C				
			Kci	C				

			Actos	C		
			70/30 Insulin	C		
			Vicodin	C		
			Zofran	C		
			Morphine	C		
			Serevent	C		

Date:10/22/02ISR Number: 3996202-9Report Type:Direct Company Report #CTU 179250
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Anxiety		Zofran 4mg Iv	PS		
INTRAVENOUS 4MG IV ONCE						
	Confusional State		Synthroid	C		
	Paranoia		Asa	C		
			Calcium	C		
			Tenormin	C		
			Baclofen	C		
			Imipramine	C		
			Colace	C		
			Zantac	C		
			Evoxac	C		
			Fosamax	C		
			Neurontin	C		
			Dexadrine	C		

Date:10/23/02ISR Number: 3994908-9Report Type:Expedited (15-DaCompany Report #B0274802A
Age:63 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	C-Reactive Protein		Zophren	PS	Glaxo Wellcome	
INTRAVENOUS 8MG Per day 1 DAY						
Initial or Prolonged	Increased		Cisplatyl	SS		
INTRAVENOUS 75MG Per day 1 DAY						
	Chills		Elvorine	SS	Glaxo Wellcome	
INTRAVENOUS 1 DAY						
	Haemoglobin Decreased		Fluorouracil	SS		
INTRAVENOUS 2450MG Weekly 2 DAY						
	Purpura		Solumedrol	C		
UNKNOWN						
	Pyrexia					

Skin Nodule
Staphylococcal Sepsis
White Blood Cell Count
Decreased

Date:10/24/02ISR Number: 4013778-6Report Type:Periodic Company Report #HQ0160225JAN2002
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated Oedema	Consumer	Premarin (Conjugated Estrogens, Tablet, Unspec)	PS		ORAL		
			Rezulin (Troglitazone,)	SS		ORAL	400 MG DAILY,	
			Zofran (Ondansetron Hydrochloride,)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/25/02ISR Number: 3996315-1Report Type:Expedited (15-DaCompany Report #B0126387A
Age:30 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Binocular Eye Movement	Health	Zofran	PS	Glaxo Wellcome	INTRAVENOUS	3MG	Unknown
Other	Disorder	Professional	Propacetamol	C		UNKNOWN		
	Blindness							
	Hypertensive Crisis							
	Oculogyration							
	Visual Disturbance							

Date:10/25/02ISR Number: 3996330-8Report Type:Expedited (15-DaCompany Report #B0282841A
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis	Consumer	Zophren	PS	Glaxo Wellcome	UNKNOWN	3UNIT	Cyclic 63 DAY
			Adriblastine	SS		UNKNOWN	4UNIT	Cyclic
			Endoxan	SS		UNKNOWN	4UNIT	Cyclic 89 DAY
			Oncovin	SS		UNKNOWN	3UNIT	Cyclic 63 DAY
			Uromitexan	SS		UNKNOWN	4UNIT	Cyclic 89 DAY
			Rituximab	SS		UNKNOWN	3UNIT	Cyclic 63 DAY
			Zelitrex	C	Glaxo Wellcome	UNKNOWN		
			Mopral	C		UNKNOWN		
			Fungizone	C		UNKNOWN		
			Cortancyl	C		UNKNOWN		
			Solumedrol	C		UNKNOWN		
			Kytril	C	Glaxo Wellcome	UNKNOWN		
			Vepeside	C		UNKNOWN		

Date:10/31/02ISR Number: 4000637-8Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12076113
Age:67 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis	Health Professional	Endoxan-Asta	PS	Bristol-Myers Squibb Company			
			Uromitexan	SS	Bristol-Myers Squibb Company			
			Adriblastine	SS				
			Oncovin	SS				
			Zophren	SS				
			Mabthera	SS				
			Solu-Medrol	C				
			Zelitrex	C				
			Mopral	C				
			Fungizone	C	Apothecon			
			Cortancyl	C				

Date:11/04/02ISR Number: 4002468-1Report Type:Expedited (15-DaCompany Report #B0126387A
Age:30 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypertensive Crisis	Health Professional	Zofran	PS	Glaxo Wellcome	INTRAVENOUS	3MG	Unknown
	Oculogyration		Propacetamol	C		INTRAVENOUS	400MG	Four times per day
Disability	Visual Disturbance							
Other			Chemotherapy	C				
UNKNOWN								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/04/02ISR Number: 4002477-2Report Type:Expedited (15-DaCompany Report #B0283891A
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site		Zofran	PS	Glaxo Wellcome	INTRAMUSCULAR	1	DAY
	Inflammation		Zofran	C	Glaxo Wellcome	ORAL		
	Injection Site Necrosis		Omeprazole	C		UNKNOWN		
			Amlodipine	C		UNKNOWN		
			Insulin	C		UNKNOWN		
			Metamizole	C		UNKNOWN		

Date:11/11/02ISR Number: 4006936-8Report Type:Expedited (15-DaCompany Report #B0284361A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Failure		Zofran	PS	Glaxo Wellcome	ORAL	2MG per day	
			Amoxycillin	C	Glaxo Wellcome	UNKNOWN	2G Three times per day	

Date:11/12/02ISR Number: 4008289-8Report Type:Direct Company Report #CTU 180789
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Chloride Decreased		Zofran (Gsk)	PS	Gsk	INTRAVENOUS	4MG IV X 1	
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Blood Potassium Decreased							
	Speech Disorder							
	Tongue Oedema							

Date:11/13/02ISR Number: 4008408-3Report Type:Expedited (15-DaCompany Report #A0385945A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Colonic Obstruction		Zofran	PS	Glaxo Wellcome	ORAL	1	MON
Initial or Prolonged			Oxaliplatin	C				
			Chemotherapy	C				

Date:11/13/02ISR Number: 4008413-7Report Type:Expedited (15-DaCompany Report #B0280775A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Myocardial Infarction		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	8MG Single	
Initial or Prolonged							dose	
Other			Cisplatin	SS				
UNKNOWN								

Date:11/13/02ISR Number: 4008415-0Report Type:Expedited (15-DaCompany Report #D0039731A
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anaemia		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	8MG per day	
Initial or Prolonged			Cisplatin	C		INTRAVENOUS	75MGM2 per	
day	1	DAY						
			Solu-Decortin	C				
UNKNOWN	100MG per day	1	DAY					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/14/02ISR Number: 4012303-3Report Type:Expedited (15-DaCompany Report #EMADSS2002006741
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia Blood Disorder	Foreign Health	Durogesic (Patch) (Fentanyl)	PS		TRANSDERMAL	TRANSD	
	Bone Marrow Toxicity Brain Scan Abnormal Cytomegalovirus	Professional	Debridat (Trimebutine Maleate)	SS		INTRAVENOUS	300 MG, DAILY, IV	
	Chorioretinitis							
	Diffuse Large B-Cell Lymphoma		Imovane (Zopiclone)	SS		ORAL	7.5 MG, DAILY, ORAL	
	Epilepsy Gastritis Hypertension		Tazocilline (Pip/Tazo)	SS		INTRAVENOUS	12 MG, DAILY, IV	
	Leukopenia Lymphocyte Count Abnormal Megaloblasts Increased Neutropenia		Largactil (Chlorpromazine Hydrochloride)	SS		ORAL	25 MG, DAILY, ORAL	
	Spinal Myelogram Abnormal Thrombocytopenia Wernicke'S Encephalopathy		Zophren (Ondansetron Hydrochloride)	SS		ORAL	16 MG, DAILY, ORAL	
			Hydrosol Polyvitamin (Hydrosol Polyvitamine B.O.N.)	SS		ORAL	ORAL	
			Morphine Adrian (Morphine)	SS				
			Solu-Medrol (Methylprednisolone Sodium Succinate)	SS				
			Foscarvir (Foscarnet)	SS			6 G DAILY	
			Neupogen					

				(Filgrastim)	SS		
300 MCG, DAILY							
				Morphine Chlorhydrate (Morphine)	C		
				Cymevan (Ganciclovir Sodium)	C		
				Triflucan (Fluconazole)	C		
				Amikline (Amikacin)	C		
				Clinomel	C		
				Omeprazole (Omeprazole)	C		
				Skenan (Morphine Sulfate)	C		

Date:11/15/02ISR Number: 4014250-XReport Type:Expedited (15-DaCompany Report #200213450FR
Age:14 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agranulocytosis	Foreign	Methotrexate	PS				
INTRAVENOUS	IV						7	WK
Initial or Prolonged	Hypoprothrombinaemia	Other	Furosemide (Lasilix) Tablets	SS		ORAL		
PO							5	WK
			Vincristine Sulfate (Oncovin) Solution For Injection	SS				
INTRAVENOUS	IV						5	WK
			Ondansetron Hydrochloride					

				(Zophren) Tablets	SS		ORAL
PO		6	WK				
				Calcium Folinate (Lederfoline)	SS		
INTRAVENOUS	IV	5	WK				
				Asparaginase	C		
				Clavulanate Potassium, Amoxicillin Trihydrate (Ciblor)	C		
				Urate Oxidase (Uricozyme)	C		
				Bromazepam (Lexomil)	C		
				Omeprazole (Mopral)	C		
				Chlorpromazine Hydrochloride (Largactil)	C		
				Methylprednisolone Sodium Succinate (Solu-Medrol)	C		
				Propacetamol Hydrochloride (Pro-Dafalgan)	C		
				Morphine Sulfate (Skenan)	C		
				Morphine Sulfate	C		
				Dexamethasone (Decadron)	C		
				Metoclopramide (Primperan)	C		
				Phloroglucinol, Trimethylphlorogluci nol (Spasfon)	C		
				Paracetamol (Dafalgan)	C		
				Metopimazine (Vogalene)	C		
				Clonazepam (Rivotril)	C		
				Amitriptyline Hydrochloride (Laroxyl)	C		
				Mesna	C		
				Cytarabine (Aracytine)	C		
				Cyclophosphamide (Endoxan)	C		
				Mercapopurine			

			(Purinethol)	C		

Date:11/18/02ISR Number: 4014931-8Report Type:Expedited (15-DaCompany Report #2002CG01683
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Encephalopathy	Foreign	Foscavir	PS				
	Hypertension	Health	Foscavir	SS				
	Status Epilepticus	Professional	Hydrosol Polyvitaine					
		Other	B.O.N.	SS				
			Morpine	SS				
			Durogesic	SS				
			Solumedrol	SS		SUBCUTANEOUS	5 MG DAILY SQ	
			Neupogen	SS				
			Imovane	SS		INTRAVENOUS	40 MG QD IV	

Debridat	
"Parke-Davis"	SS
Vitamin B1 B6 B12	SS
Viramune	SS
Epivir	SS
Videx	SS
Zophren	SS
Tazocilline	SS
Largactil	SS
Mopral	C

Date:11/19/02ISR Number: 4011461-4Report Type:Expedited (15-DaCompany Report #B0284893A
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia		Zophren	PS	Glaxo Wellcome	ORAL	8MG Twice per day	
	Cytomegalovirus							
	Chorioretinitis		Largactil	SS		ORAL	25MG Per day	124 DAY
	Encephalopathy		Durogesic	SS		TOPICAL		20 DAY
	Gastritis		Tazocilline	SS		INTRAVENOUS	4MG Three times per day	14 DAY
	Hypertension							
	Leukopenia		Imovane	SS		ORAL	7.5MG Per day	28 DAY
	Megaloblasts Increased		Debridat	SS		INTRAVENOUS	150MG Twice per day	20 DAY
	Neutropenia							
	Thrombocytopenia		Skenan	C	Glaxo Wellcome	UNKNOWN		
	Wernicke'S Encephalopathy		Foscavir	C		UNKNOWN		
			Mopral	C		UNKNOWN		
			Valcyte	C		UNKNOWN		8 DAY
			Clinomel	C		UNKNOWN		

				Morphine	C		
SUBCUTANEOUS	6	DAY					
				Solumedrol	C		
UNKNOWN							
				Cymevan	C		
UNKNOWN	10	DAY					
				Triflucan	C		
UNKNOWN	4	DAY					
				Amiklin	C		
UNKNOWN	6	DAY					
				Gaviscon	C	Glaxo Wellcome	
UNKNOWN	5	DAY					
				Pentacarinat	C		
				Morphine	C		
SUBCUTANEOUS	6	DAY					
				Neupogen	C		
4 DAY							

Date:11/19/02ISR Number: 4012851-6Report Type:Direct Company Report #CTU 181351
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Torsade De Pointes		Ondansetron 4 Mg Iv	PS		INTRAVENOUS	4 MG IV ONCE;	Required

0900
Intervention to
Prevent Permanent
Impairment/Damage

Date:11/19/02ISR Number: 4015038-6Report Type:Expedited (15-DaCompany Report #B0282841A
Age:67 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis	Foreign	Zofran (Formulation Unknown) (Ondansetron Hydrochloride)	PS			3 UNIT /	CYCLIC /

	Doxorubicin Hydrochloride (Formulation Unknown) (Doxorubicin	SS	
4 UNIT / CYCLIC /			
	Cyclophosphamide (Formulation Unknown) (Cyclophosphamide)	SS	
4 UNIT / CYCLIC			
	Vincristine Sulphate (Formulation Unknown) (Vincristine Sulfate)	SS	
3 UNIT / CYCLIC			
	Mesna (Formulation Unknown) (Mesna)	SS	
4 UNIT / CYCLIC			
	Rituximab (Formulation Unknown) (Rituximab)	SS	
3 UNIT / CYCLIC			
	Valaciclovir Hydrochlorid	C	
	Omeprazole	C	
	Amphotericin	C	
	Prednisone	C	
	Me-Prednisolone Na Succ.	C	
	Granisetron Hydrochloride	C	
	Etoposide	C	

Date:11/20/02ISR Number: 4012672-4Report Type:Direct Company Report #CTU 181394
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Torsade De Pointes		Ondansetron 4mg Iv	PS		INTRAVENOUS	4MG IV	ONCE
Required Intervention to Prevent Permanent Impairment/Damage								

Date:11/22/02ISR Number: 4016119-3Report Type:Expedited (15-DaCompany Report #2002134624FR
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aplasia Pyrexia Renal Failure Acute	Foreign Health Professional	Solu-Medrol(Methylprednisolone) Powder, Sterile	PS		INTRAVENOUS	120 MG, IV	
		Other	Pyostacin(Pristinamycin)	SS		ORAL	3000 MG, QD,	ORAL
			Voltarene(Diclofenac Sodium)	SS		ORAL	100 MG, QD,	ORAL
			Navelbine	SS		INTRAVENOUS	45 MG, IV	

			Zophren(Ondansetron Hydrochloride)	SS		
INTRAVENOUS	8 MG, IV					
			Cisplatin"Dakota Pharm"(Cisplatin)	SS		
INTRAVENOUS	110 MG, IV					

Date:11/25/02ISR Number: 4017140-1Report Type:Expedited (15-DaCompany Report #12117925
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Bradykinesia	Literature	Paclitaxel	PS		
INTRAVENOUS 90 MILLIGRAM, 1 MONTH IV	Parkinsonism	Health Professional Company Representative				
	Speech Disorder		Prochlorperazine	SS		
			Ondansetron (Ondasetron Hcl)	SS		
			Carbidopa + Levodopa	C		

Date:11/27/02ISR Number: 4015726-1Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12118311
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Spleen Disorder		Cisplatin	PS	Bristol-Myers Squibb Company	
ALTERNATING DOSES: 45 MG AND 40 MG 6 DAY	Thrombosis					
			Vepesid	SS	Bristol-Myers Squibb Company	ORAL
6 DAY						
			Bleomycin Sulfate	SS	Bristol-Myers Squibb Company	
2 DAY						
			Zofran	SS		ORAL
			Decadron	SS		ORAL
			Lasix	C		ORAL
			Zopiclone	C		ORAL

			Losec	C		
			Diazepam	C		ORAL

Date:11/27/02ISR Number: 4015813-8Report Type:Expedited (15-DaCompany Report #B0285693A
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cholestasis		Ranitidine	PS	Glaxo Wellcome	INTRAVENOUS	1INJ Four	
Initial or Prolonged	Hepatic Necrosis							
times per day							4	DAY
	Hepatitis		Zophren	SS	Glaxo Wellcome	INTRAVENOUS	1INJ Twice	
per day							18	DAY
			Di Antalvic	SS		ORAL	1CAP Three	
times per day							11	DAY
			Diprivan	SS		INTRAVENOUS	1INJ Per day	4 DAY
			Intralipide	SS		INTRAVENOUS		4 DAY
			Sevoflurane	SS		INTRAVENOUS	1INJ Twice	
per day							4	DAY

Date:12/02/02ISR Number: 4017535-6Report Type:Expedited (15-DaCompany Report #B0280775A
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Myocardial Infarction	Health	Zofran	PS	Glaxo Wellcome	INTRAVENOUS	8MG Single	
Initial or Prolonged		Professional						
dose								
Other			Cisplatin	SS				
UNKNOWN	65MG per day							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/02/02ISR Number: 4017550-2Report Type:Expedited (15-DaCompany Report #B0285631A
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Splenic Infarction	Consumer	Zofran	PS	Glaxo Wellcome	ORAL	6	DAY
Hospitalization - Initial or Prolonged	Thrombosis		Cisplatin	SS				
			Etoposide	SS		ORAL	6	DAY
			Bleomycin	SS			6	DAY
			Decadron	SS		ORAL	6	DAY
			Lasix	C	Glaxo Wellcome			
			Zopiklone	C		ORAL		
			Vival	C		ORAL		
			Losec	C		ORAL		

Date:12/02/02ISR Number: 4017551-4Report Type:Expedited (15-DaCompany Report #B0285705A
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angle Closure Glaucoma	Health	Zophren	PS	Glaxo Wellcome	INTRAVENOUS	1	DAY
		Professional	Medrol	SS		INTRAVENOUS	1	DAY
			5 Fluorouracile	SS			1	DAY
			Epirubicine	SS			1	DAY
			Cyclophosphamide	SS			1	DAY

Date:12/03/02ISR Number: 4018242-6Report Type:Expedited (15-DaCompany Report #B0286029A
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bone Marrow Depression	Consumer	Zophren	PS	Glaxo Wellcome	INTRAVENOUS	8MG	Single

Pyrexia
dose 1 DAY
Renal Failure Acute

Pyostacine	SS			ORAL
1000MG Three times per day				
Solumedrol	SS			
INTRAVENOUS 120MG Single dose 1 DAY				
Voltarene	SS	Glaxo Wellcome		ORAL
100MG Per day 24 DAY				
Navelbine	SS	Glaxo Wellcome		
INTRAVENOUS 45MG Single dose 1 DAY				
Cisplatine	SS			
INTRAVENOUS 110MG Single dose 1 DAY				

Date:12/03/02ISR Number: 4018509-1Report Type:Expedited (15-DaCompany Report #WAES 0211NOR00012
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Splenic Infarction	Health	Decadron Tablets	PS	Merck & Co., Inc	ORAL	6	DAY
Hospitalization - Initial or Prolonged	Thrombosis	Professional	Cisplatin	SS		ORAL	5	DAY
			Bleomycin	SS		ORAL	1	DAY
			Bleomycin	SS		ORAL	1	DAY
			Etoposide	SS		ORAL	5	DAY
			Ondansetron Hydrochloride	SS		ORAL	6	DAY
			Furosemide	C				
			Zopiclone	C		ORAL		
			Diazepam	C				
			Omeprazole Magnesium	C		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/03/02ISR Number: 4021383-0Report Type:Expedited (15-DaCompany Report #FR9349320NOV2002
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Aspiration Bone Marrow Abnormal Condition Aggravated	Health Professional Other	Tazocilline (Piperacillin/Tazobactam, Injection)	PS			INTRAVENOUS	4 G 3X PER 1 DAY;
	Encephalopathy Hypertension						INTRAVENOUS	14 DAY
	Lymphopenia Neutropenia Thrombocytopenia		Debridat (Trimebutine Maleate, , 0)	SS			INTRAVENOUS	150 MG 2X PER 1 DAY,
	Wernicke'S Encephalopathy						INTRAVENOUS	20 DAY
			Durogesic (Fentanyl, , 0)	SS			TRANSDERMAL	20 DAY
			Imovane (Zopiclone, , 0)	SS		ORAL	7.5 MG 1X PER 1 DAY,	ORAL
			Largactil (Chlorpromazine Hydrochloride, , 0)	SS		ORAL	25 MG 1X PER 1 DAY,	ORAL
			Mopral (Omeprazole, , 0)	SS		ORAL	ORAL	
			Zophren (Ondansetron Hydrochloride, , 0)	SS		ORAL	8 MG 2X PER 1 DAY,	ORAL
			Solu-Medrol (Methylprednisolone Sodium Succinate)	C				
			Skenan (Morphine					

Sulfate)	C
Foscavir (Foscarnet Sodium)	C
Valcyte (Valganciclovir)	C
Pentacarinat (Pentamidine Isethionate)	C
Morphine (Morphine)	C
Cymevan (Ganciclovir Sodium)	C
Triflucan (Fluconazole)	C
Amiklin (Amikacin)	C
Gaviscon (Sodium Alginate/Sodium Bicarbonate)	C

Date:12/04/02ISR Number: 4018763-6Report Type:Expedited (15-DaCompany Report #B0285819A
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Biopsy Liver Abnormal		Zophren	PS	Glaxo Wellcome			
INTRAVENOUS							2UNIT Per day	18 DAY
Initial or Prolonged	Drug Toxicity		Di Antalvic	SS		ORAL		
3UNIT Per day	11 DAY							
	Hepatic Necrosis		Intralipide	SS				
INTRAVENOUS							1UNIT Per day	4 DAY
	Hepatic Siderosis		Raniplex	SS	Glaxo Wellcome			
INTRAVENOUS							4UNIT Per day	4 DAY
	Hepatic Steatosis		Diprivan	SS				
INTRAVENOUS							1UNIT Per day	4 DAY
	Hepatitis Cholestatic		Sevoflurane	SS				
INTRAVENOUS							2UNIT Twice	
per day	4 DAY							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/06/02ISR Number: 4020205-1Report Type:Direct Company Report #CTU 182281
Age:2 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Rash Pruritic		Zofran 0.5 Mg	PS		INTRAVENOUS	0.5 MG Q 6 H	IV

Date:12/11/02ISR Number: 4021257-5Report Type:Expedited (15-DaCompany Report #B0284361A
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hepatic Failure	Health	Zofran	PS	Glaxo Wellcome	ORAL	2MG per day	1 DAY
Hospitalization - Initial or Prolonged		Professional	Amoxycillin	C	Glaxo Wellcome	INTRAVENOUS	2G Three times per day	
			Hydroxychloroquine	C		ORAL	200MG per day	
			Doxazosin	C		ORAL	12MG Per day	
			Lisinopril	C		ORAL	20MG Per day	
			Frusemide	C	Glaxo Wellcome	ORAL	250MG Per day	
			Prednisolone	C		ORAL	7.5MG Per day	
			Azathioprine	C	Glaxo Wellcome	ORAL	100MG Per day	
			Eprex	C		SUBCUTANEOUS	2000U Three times per week	
			Alfacalcidol	C		ORAL	.25MCG Per day	

Date:12/11/02ISR Number: 4021260-5Report Type:Expedited (15-DaCompany Report #B0285819A
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Toxicity	Consumer	Zophren	PS	Glaxo Wellcome			
INTRAVENOUS							2UNIT Per day	18 DAY
Initial or Prolonged	Haemoglobin Decreased		Di Antalvic	SS		ORAL		
3UNIT Per day	11 DAY							
	Hepatic Necrosis		Intralipide	SS				
INTRAVENOUS							1UNIT Per day	4 DAY
	Hepatic Siderosis		Raniplex	SS	Glaxo Wellcome			
INTRAVENOUS							4UNIT Per day	4 DAY
	Hepatic Steatosis		Diprivan	SS				
INTRAVENOUS							1UNIT Per day	4 DAY
	Hepatitis Cholestatic		Sevoflurane	SS				
INTRAVENOUS							2UNIT Twice	
per day	4 DAY							

Date:12/11/02ISR Number: 4024543-8Report Type:Expedited (15-DaCompany Report #102107ISR
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Splenic Infarction		Cisplatin	PS				
Initial or Prolonged	Splenic Vein Thrombosis		Etoposide	SS		ORAL		
215 MILLIGRAM								
BY MOUTH/P.O.	6 DAY							
			Bleomycin	SS				
SUBCUTANEOUS							SUBCUTANEOUS	6 DAY
			Ondansetron Hydrochloride	SS		ORAL		
16 MILLIGRAM								
BY MOUTH/P.O.	6 DAY							
			Dexamethasone	SS		ORAL		
16 MILLIGRAM								
BY MOUTH/P.O.	6 DAY							
			Furosemide	C				
			Zopiclone	C				
			Diazepam	C				
			Omeprazole	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/13/02ISR Number: 4022664-7Report Type:Expedited (15-DaCompany Report #B0285705A
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Angle Closure Glaucoma		Zophren	PS	Glaxo Wellcome			
INTRAVENOUS							8MG per day	1 DAY
Initial or Prolonged	Visual Acuity Reduced		Medrol	SS				
INTRAVENOUS								1 DAY
Other			5 Fluorouracile	SS				
INTRAVENOUS							800MG per day	1 DAY
			Farmorubicine	SS				
INTRAVENOUS							120MG per day	1 DAY
			Endoxan	SS				
INTRAVENOUS							800MG per day	1 DAY
			Plitican	C				
INTRAVENOUS								1 DAY
			Atacand	C		ORAL		

Date:12/16/02ISR Number: 4027601-7Report Type:Expedited (15-DaCompany Report #PHRM2002FR02989
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bone Marrow Depression	Foreign	Voltarene (Diclofenac Sodium) Enteric-Film-Coated Tablet	PS		ORAL	100 MG, QD,	ORAL
	Pyrexia	Health						
	Renal Failure Acute	Professional						
		Other						
			Cisplatin (Cisplatin) Solution For Injection	SS			110 MG,	ONCE/SINGLE,
INTRAVENOUS								
			Navelbine "Pierre Fabre" (Vinorelbine Ditartrate) Solution For Injection	SS	Pierre Fabre		45 MG,	
INTRAVENOUS								

ONCE/SINGLE,

INTRAVENOUS

			Zophren (Ondansetron Hydrochloride) Solution For Injection	SS		ORAL

8 MG,

ONCE/SINGLE,

ORAL

			Solu-Medrol (Methylprednisolone Sodium Succinate) Solution For Injection	SS		ORAL

120 MG,

ONCE/SINGLE,

ORAL

			Pyostacine (Pristinamycin) Tablet	SS		ORAL

1000 MG, TID,

ORAL

Date:12/19/02ISR Number: 4025687-7Report Type:Expedited (15-DaCompany Report #B0287860A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Interstitial Lung Disease	Health	Zofran	PS	Glaxo Wellcome	UNKNOWN	4MG per day	
Hospitalization - Initial or Prolonged		Professional	Gemcitabine	SS		UNKNOWN		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/23/02ISR Number: 4027486-9Report Type:Expedited (15-DaCompany Report #B0287860A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Hypersensitivity		Zofran	PS	Glaxo Wellcome		UNKNOWN	4MG per day
Hospitalization - Initial or Prolonged	Eosinophilic Pneumonia		Gemcitabine	SS			UNKNOWN	
			Total Body Irradiation	SS			UNKNOWN	

Date:12/24/02ISR Number: 4034036-XReport Type:Expedited (15-DaCompany Report #B0285693A
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cholestasis Hepatic Necrosis Hepatic Steatosis	Foreign Other	Zantac Injection (Ranitidine Hydrochloride)	PS			INTRAVENOUS	1 INJECTION/ FOUR TIMES PER DAY/ INTRAV
	Hepatitis		Zofran Injection (Ondansetron Hydrochloride)	SS			INTRAVENOUS	1 INJECTION/ TWICE PER DAY/ INTRAVENOUS
			Di-Antalvic Capsule (Di-Antalvic)	SS		ORAL	1 CAPSULE /	THREE TIMES PER DAY/ ORAL

				Propofol Injection (Propofol)	SS		
INTRAVENOUS	1 INJECTION / PER DAY/ INTRAVENOUS						
				Soybean Oil Infusion (Soybean Oil)	SS		
INTRAVENOUS	PER DAY/ INTRAVENOUS						
				Sevoflurane Injections	SS		
INTRAVENOUS	1 INJECTION/ TWICE PER DAY/ INTRAVENOUS						

Date:12/30/02ISR Number: 4032154-3Report Type:Expedited (15-DaCompany Report #B0287860A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest X-Ray Abnormal Drug Hypersensitivity		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	4MG Single dose	1 DAY
	Dyspnoea		Gemcitabine	SS		INTRAVENOUS	230MG Weekly	15 DAY
	Eosinophilic Pneumonia Oxygen Saturation Decreased		Total Body Irradiation Cefoperazone	SS C		INTRAVENOUS	2G per day	7 DAY
	Pyrexia		Cefoperazone	C		INTRAVENOUS	2G per day	2 DAY
	Rash Generalised		Panthenol	C		INTRAVENOUS	1.5G per day	27 DAY
			Ranitidine Hydrochloride	C	Glaxo Wellcome	INTRAVENOUS	100MG per day	10 DAY
			Pirenzepine	C		INTRAVENOUS	20MG per day	9 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/31/02ISR Number: 4036733-9Report Type:Expedited (15-DaCompany Report #B0287860A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Hypersensitivity Eosinophilic Pneumonia Oxygen Saturation Decreased Rash Generalised	Foreign Health Professional Company Representative	Zofran Injection (Ondansetron Hydrochloride)	PS		INTRAVENOUS	4 MG./SINGLE DOSE/INTRAVENOUS	
			Gemcitabine (Formulation Unknown) (Gemcitabine)	SS		INTRAVENOUS	230 MG/WEEKLY/INTRAVENOUS	
			Radiotherapy (Formulation Unknown) (Radiotherapy)	SS				
			Cefoperazone Sodium	C				
			Cefoperazone Sodium	C				
			Panthenol	C				
			Ranitidine Hydrochloride	C				
			Pirenzepine	C				

Date:01/03/03ISR Number: 4034679-3Report Type:Expedited (15-DaCompany Report #B0287860A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest X-Ray Abnormal Drug Hypersensitivity		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	4MG Single dose	1 DAY
	Dyspnoea		Gemcitabine	SS		INTRAVENOUS	230MG Weekly	15 DAY
	Eosinophilic Pneumonia		Total Body					

		Oxygen Saturation Decreased			Irradiation	SS		
INTRAVENOUS	2G per day	7	DAY		Cefoperazone	C		
		Pyrexia			Cefoperazone	C		
INTRAVENOUS	2G per day	2	DAY					
		Rash Generalised			Panthenol	C		
INTRAVENOUS	1.5G per day	27	DAY					
					Ranitidine Hydrochloride	C	Glaxo Wellcome	
INTRAVENOUS	100MG per day	10	DAY					
					Pirenzepine	C		
INTRAVENOUS	20MG per day	9	DAY					

Date:01/06/03ISR Number: 4035888-XReport Type:Expedited (15-DaCompany Report #B0288670A
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Myocardial Infarction		Ondansetron	PS	Glaxo Wellcome			
UNKNOWN								
Initial or Prolonged			Cisplatin	SS				
UNKNOWN	65MG per day							
Other								

Date:01/13/03ISR Number: 4041001-5Report Type:Direct Company Report #CTU 184265
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Pyrexia		Carboplatin	PS				
INTRAVENOUS	132 MG IV WK							
Initial or Prolonged			Vincristine	SS				
INTRAVENOUS	1.1 MG IV QWK							
			Bactrim	SS				
1 TSP PO								
3D/WK BID,								
WED/THURS/FRI								

Q WEEK

			Zofran	SS		ORAL

4 MG PO Q12

HOURS PRN

Date:01/13/03ISR Number: 4041061-1Report Type:Expedited (15-DaCompany Report #B0287860A
Age:56 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chest X-Ray Abnormal	Health	Zofran	PS	Glaxo Wellcome	INTRAVENOUS	4MG Single	
Initial or Prolonged	Drug Hypersensitivity	Professional						
dose							1	DAY
	Dyspnoea		Gemcitabine	SS		INTRAVENOUS	280MG Weekly	15 DAY
	Eosinophilic Pneumonia		Total Body Irradiation	SS				
	Oxygen Saturation Decreased		Cefoperazone	C		INTRAVENOUS	2G per day	7 DAY
	Pyrexia		Cefoperazone	C		INTRAVENOUS	2G per day	2 DAY
			Panthenol	C		INTRAVENOUS	1.5G per day	27 DAY
			Ranitidine Hydrochloride	C	Glaxo Wellcome	INTRAVENOUS	100MG per day	10 DAY
			Pirenzepine	C		INTRAVENOUS	20MG per day	9 DAY

Date:01/15/03ISR Number: 4042198-3Report Type:Expedited (15-DaCompany Report #B0289264A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Oxygen Saturation Decreased		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	4MG	
Initial or Prolonged								
Continuous							1	MIN
	Respiratory Distress		Amiodarone	C		UNKNOWN		

Date:01/22/03ISR Number: 4044750-8Report Type:Direct Company Report #CTU 185034
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Diverticulum		Forane	PS				
	Hypertension		Midazolam	SS				
	Large Intestine Perforation		Fentanyl	SS				
	Livedo Reticularis		Lidocaine	SS				
	Oxygen Saturation Decreased		Propofol	SS				
	Procedural Complication		Anectine	SS				
			Zofran	SS				
			Inapsine	SS				
			Decadron	SS				
			Norcuron	SS				

Date:01/28/03ISR Number: 4047986-5Report Type:Expedited (15-DaCompany Report #B0289264A
Age:78 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Apnoea		Zofran	PS	Glaxo Wellcome	INTRAVENOUS	4MG Single	
Life-Threatening	Pneumonia							
							dose	1 MIN
Hospitalization - Initial or Prolonged	Post Procedural Complication		Amiodarone	C		INTRAVENOUS	50MG Twenty four times	
	Respiratory Arrest							
							per day	3 DAY
	Respiratory Distress		Diltiazem Hydrochloride	C	Glaxo Wellcome	ORAL	240MG In the morning	
			Indomethacin	C		ORAL	60MG In the morning	
			Ticarcillin					

				Sodium+Potassium Clavulanate	C	Glaxo Wellcome	
INTRAVENOUS	3.1G Four times per day	14 DAY					
				Methylprednisolone Sodium Succinate	C		
INTRAVENOUS	40MG Four times per day	6 DAY					
				Calcium Salt	C		
INTRAVENOUS	1AMP Twice per day						
				Gluconate Salt	C		
UNKNOWN							

Date:01/29/03ISR Number: 4050230-6Report Type:Expedited (15-DaCompany Report #200310083BFR
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Respiratory Distress Syndrome	Foreign Health	Ciflox (Ciprofloxacin)	PS				
INTRAVENOUS	INTRAVENOUS							
	Lung Disorder	Professional Other	Aracytine (Cytarabine)	SS				
			Belustine (Lomustine)	SS				
			Zavedos (Idarubucin Hydrochloride)	SS				
INTRAVENOUS	1.5 MG, TOTAL DAILY,							
INTRAVENOUS								
			Zophren (Ondansetron Hydrochloride)	SS				
			Granocyte (Lenograstim)	SS				
SUBCUTANEOUS	SUBCUTANEOUS							
			Uricozyme	C				
			Fortum	C				
			Vancomycine	C				
			Amphotericin	C				
			Tienam	C				

Date:01/31/03ISR Number: 4050414-7Report Type:Expedited (15-DaCompany Report #2003143583FR
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Respiratory Distress Syndrome Pneumonia	Foreign Health Professional	Aracytine (Cytarabine) Powder, Sterile	PS				
			Zavedos(Idarubicin Hydrochloride) Powder, Sterile	SS				
			Belustine (Lomustine)	SS		ORAL	360 MG, ORAL	
			Ciflox(Ciprofloxacin)	SS				
			Zophren (Ondansetron Hydrochloride)	SS				
			Granocyte(Lenograstim)	SS				
			Uricozyme (Urate Oxidase)	C				
			Fortum (Ceftazidime Pentahydrate)	C				
			Vancomycin	C				
			Amphotericin B	C				
			Tienan (Imipenem Cilastatin)	C				
INTRAVENOUS	180 MG, IV							
INTRAVENOUS	1.5 MG, IV							
INTRAVENOUS	IV							
INTRAVENOUS	IV							
SUBCUTANEOUS	SUBCUTANEOUS							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/05/03ISR Number: 4051197-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0373523A
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Apnoea		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG See	
Initial or Prolonged	Blindness						dosage text	1 DAY
	Cardio-Respiratory Arrest		Unknown Anesthesia	C				
	Confusional State		Morphine	C				
	Cyanosis							
	Dysphoria							
	Hyperreflexia							
	Malaise							

Date:02/05/03ISR Number: 4051199-0Report Type:Expedited (15-DaCompany Report #CA-GLAXOSMITHKLINE-A0393824A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion		Zofran	PS	Glaxosmithkline	ORAL		
	Deafness		Fentanyl	SS				
	Dizziness		Demerol	SS				
	Medication Error							
	Overdose							

Date:02/07/03ISR Number: 4052484-9Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0291601A
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Acute Respiratory		Zophren	PS	Glaxosmithkline	INTRAVENOUS		
Initial or Prolonged	Distress Syndrome		Aracytine	SS		INTRAVENOUS	180MG Per day	7 DAY
	Interstitial Lung Disease		Belustine	SS		ORAL	360MG Per day	1 DAY
			Ciflox	SS		INTRAVENOUS		
			Zavedos	SS		INTRAVENOUS	1.5MG Per day	5 DAY

			Granocyte	SS		
SUBCUTANEOUS						
			Uricozyme	C		
			Fortum	C	Glaxosmithkline	
			Vancomycine	C		
			Amphotericine	C		
			Tienam	C		

Date:02/07/03ISR Number: 4054215-5Report Type:Expedited (15-DaCompany Report #03P-163-0209491-00
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Abdominal Pain	Foreign	Kaletra Soft Gelatin			
Disability	Convulsion	Health Professional	Capsules (Kaletra) (Lopinavir/Ritonavir)			
		Other	(Lopinavir/Ritonavir	PS		
6 CAPSULE, 1						
IN 1 D						
			Fuzeon	SS		
SUBCUTANEOUS 90 MG,						
SUBCUTANEOUS						
			Zidovudine	SS		
200 MG, 1 IN						
1 D						
			Lamivudine	SS		
25 MG, 1 IN 1						
D						
			Ondansetron Hydrochloride	SS		
8 MG, 1 IN 1						
D						
			Naloxone	SS		
0.2 MG, 1 IN						

1 D

			Paroxetine Hydrochloride	SS		

20 MG, 1 IN 1

D

			Ceftriaxone	C		
			Clindamycin	C		

Date:02/10/03ISR Number: 4055055-3Report Type:Expedited (15-DaCompany Report #A0394473A
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Abdominal Pain Convulsion	Study Health Professional	Epivir Tablet (Lamivudine)	PS		ORAL
Disability			Retrovir Tablet (Zidovudine)	SS		ORAL
			T-20 Injection (T-20)	SS		

Dose Duration

SUBCUTANEOUS 90 MG/TWICE PER DAY/SUBCUTANEOUS

			Zofran (Ondansetron Hydrochloride)	SS		ORAL
			Paxil (Paroxetine Hydrochloride)	SS		
			Kaletra (Kaletra)	SS		
			Naloxone (Naloxone)	SS		
			Ceftriaxone	C		
			Clindamycin	C		

Date:02/11/03ISR Number: 4055746-4Report Type:Direct Company Report #CTU 186447
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Coma Oxygen Saturation Decreased Respiratory Rate Decreased		Zofran 2mg/Ml, 2ml Vial (Glaxo) Versed Droperidol Atropine Ancef Ephedrine Intrathecal Morphine Fentanyl	PS C C C C C C C	Glaxo	INTRAVENOUS	4MG IV PUSH	

Date:02/11/03ISR Number: 4058962-0Report Type:Expedited (15-DaCompany Report #EM2002-0205
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Catheter Related Infection Staphylococcal Bacteraemia	Study Health Professional	Proleukin; Chiron Corporation(Aldesleukin) Injection Zofran (Ondansetron Hydrochloride) Protonix(Pantoprazole) Ativan(Lorazepam) Demerol(Pethidine Hydrochloride) Lomotil(Diphenoxylate Hydrochloride,	PS SS SS SS SS	Chiron Corporation			

Atropine Sulfate)	SS
Gm-Csf (Granulocyte Macrophage Colony Stim Factor)	SS
Ambien(Zolpidem Tartrate)	SS
Hycodan(Hydrocodone Bitartrate)	SS
Claritin(Loratadine)	SS
Dtic(Dacarbazine)	SS
Cisplatin(Cisplatin)	SS
Vinorelbine(Vinorelbine)	SS
Interferon(Interferon)	SS
Iv Fluids()	SS
Vancomycin(Vancomycin)	SS

Date:02/12/03ISR Number: 4054645-1Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12172748
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alveolitis Pulmonary Embolism		Taxol	PS	Bristol-Myers Squibb Company	INTRAVENOUS		
	Respiratory Failure		Carboplatin	SS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Zofran	SS		ORAL		

Date:02/13/03ISR Number: 4055487-3Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0396259A
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Single dose	1 DAY
	Oxygen Saturation Decreased Respiratory Rate Decreased		Ancef Atropine Droperidol	C C C	Glaxosmithkline			

			Ephedrine	C		
			Versed	C		
			Morphine	C		
INTRATHECAL						
			Fentanyl	C		
INTRAVENOUS						

Date:02/19/03ISR Number: 4056866-0Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0292606A
Age:4 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Blood Urea Abnormal		Zofran	PS	Glaxosmithkline	
RESPIRATORY						
Initial or Prolonged	Post Procedural Vomiting					
(INHALATION)	1 DAY					
			Sevoflurane	SS		
RESPIRATORY						
(INHALATION)	1 DAY					

Date:02/19/03ISR Number: 4060082-6Report Type:Expedited (15-DaCompany Report #2003-DE-00355GD(0)
Age:37 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Body Temperature
Initial or Prolonged	Increased

		Cyanosis Dehydration Drug Ineffective	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Heart Rate Increased Oliguria Peripheral Coldness	Literature	Clonidine (Clonidine) (Nr) (Clonidine-Hcl)	PS		
60 MG (Q.I.D.)	2 DAY	Renal Failure Acute					
		Somnolence		Lorazepam (Lorazepam)	SS		
6 MG (T.I.D.)	2 DAY						
				Midazolam (Midazolam)	SS		
15 MG	2 DAY						
				Dexamethasone (Dexamethasone)	SS		
6 MG	1 DAY						
				Ondansetron (Ondansetron)	SS		
24 MG (T.I.D.)	2 DAY						
				Naltrexone (Naltrexone)	C		

Date:02/20/03ISR Number: 4057479-7Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0292676A
Age:63 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization - Initial or Prolonged		Gastrointestinal Disorder		Zophren	PS	Glaxosmithkline	ORAL
2.5UNIT Per day	11 DAY						
				Oncovin	SS		
INTRAVENOUS	11 DAY						
				Cyclophosphamide	C		ORAL
				Doxorubicine	C		
INTRAVENOUS							
				Lexomil	C		ORAL
				Cortancyl	C		ORAL
				Chop	C		
UNKNOWN							

				Adriblastine	C			
UNKNOWN								
				Endoxan	C			
UNKNOWN								
				Stablon	C			
UNKNOWN								
				Imovane	C			
UNKNOWN								
				Contramal	C			
UNKNOWN								
				Primperan	C	Glaxosmithkline		
UNKNOWN								
				Diprosone	C			OTHER

Date:02/21/03ISR Number: 4058528-2Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0292862A
Age:25 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Abdominal Pain	Consumer	Ondansetron	PS	Glaxosmithkline			
INTRAVENOUS							1	DAY
	Blood Amylase Increased		Morphine	SS				
INTRAVENOUS							1	DAY
	Pancreatitis		Fentanyl	SS				
INTRAVENOUS							1	DAY
			Ketorolac	SS				
INTRAVENOUS							1	DAY

Date:02/24/03ISR Number: 4062863-1Report Type:Expedited (15-DaCompany Report #2003-DE-00355GD(1)
Age:37 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Body Temperature Increased
	Cyanosis
	Dehydration
	Depressed Level Of Consciousness

		Drug Ineffective Drug Withdrawal Syndrome Heart Rate Increased Peripheral Coldness Renal Failure Acute Weight Decreased	Report Source	Product	Role	Manufacturer	Route	
Dose	Duration							
60 MG (Q.I.D.)	2 DAY			Clonidine (Clonidine) (Nr) (Clonidine-Hcl)	PS			
6 MG (T.I.D.)	2 DAY			Lorazepam (Lorazepam) (Nr)	SS			
15 MG	2 DAY			Midazolam (Midazolam) (Nr)	SS			
6 MG	1 DAY			Dexamethasone (Dexamethasone) (Nr)	SS			
24 MG (T.I.D.)	2 DAY			Ondansetron (Ondansetron) (Nr)	SS			
				Naltrexone	C			

Date:02/25/03ISR Number: 4065253-0Report Type:Expedited (15-DaCompany Report #2002135591FR
Age:68 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization - Initial or Prolonged		Angle Closure Glaucoma Headache	Foreign Health Professional Other	Farmorubicin (Epirubicin Hydrochloride, Powder, Sterile	PS		
INTRAVENOUS	100 MG/M2, CYCLIC, IV						
				Solu-Medrol(Methylprednisolone) Powder, Sterile	SS		
INTRAVENOUS	80 MG, IV						
				Fluorouracil(Fluorouracil)	SS		
INTRAVENOUS	500 MG/M2, IV						

			Endoxan(Cyclophosphamide)	SS	
INTRAVENOUS	500 MG/M2, IV				
			Plitican(Alizapride Hydrochloride)	SS	
INTRAVENOUS	100 MG, IV				
			Zophren (Ondansetron Hydrochloride)	SS	
INTRAVENOUS	8 MG, IV				
			Tanakan	C	

Date:02/26/03ISR Number: 4084903-6Report Type:Periodic Company Report #A0359457A
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Consumer	Zofran Unspecified Injectable (Ondansetron Hydrochloride)	PS				
INTRAVENOUS	INTRAVENOUS							
			Levetiracetam	C				
			Carbamazepine	C				
			Progesterone	C				
			Lorazepam	C				
			Amoxicillin Trihydrate	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/26/03ISR Number: 4084904-8Report Type:Periodic Company Report #A0175116A
Age:59 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased	Health Professional	Zofran Injection (Ondansetron Hydrochloride)	PS		INTRAVENOUS	SEE DOSAGE TEXT/INTRAVENOUS	
			Nitroglycerine	C				
			Promethazine Hcl	C				

Date:02/26/03ISR Number: 4084905-XReport Type:Periodic Company Report #A0380166A
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Extrapyramidal Disorder Laryngospasm Stridor	Health Professional	Zofran Unspecified Injectable (Ondansetron Hydrochloride)	PS		INTRAVENOUS	SINGLE DOSE SINGLE DOSE/INTRAVENOUS	
			Propofol (Formulation Unknown) (Propofol)	SS				
			Fentanyl	C				
			Desflurane	C				
			Midazolam	C				
			Dexamethasone	C				
			Cephazolin Sodium	C				
			Adrenaline+Bupivacainehcl	C				
			Vicodin	C				

Date:02/26/03ISR Number: 4084906-1Report Type:Periodic Company Report #A0372142A
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Nausea Sedation Vomiting	Health Professional	Zofran Unspecified Injectable (Ondansetron Hydrochloride)	PS		INTRAVENOUS	2 MG/SEE	
			Fentanyl Unspecified Injectable (Fentanyl)	SS		INTRAVENOUS	75 MCG/INTRAVENOUS	

DOSAGE TEXT/INTRAVENOUS

Date:02/26/03ISR Number: 4084908-5Report Type:Periodic Company Report #A0369756A
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Ineffective Pregnancy Vomiting	Health Professional	Zofran Orally Disintegrating Tablets (Ondansetron Hydrochloride)	PS		ORAL	4 MG/SEE	

DOSAGE

TEXT/ORAL

Date:02/27/03ISR Number: 4061719-8Report Type:Periodic Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-11941770
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injury		Taxol Inj	PS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Paraplatin Inj	SS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Platinol Inj	SS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Procrit	SS		INTRAVENOUS		
			Tissue Plasminogen Activator	SS		INTRAVENOUS		
			Zofran	SS		INTRAVENOUS		
			Gemzar	SS		INTRAVENOUS		

Date:02/28/03ISR Number: 4062498-0Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0167910A
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arterial Thrombosis		Zofran	PS	Glaxosmithkline	ORAL	4MG See dosage text	
	Complications Of Maternal Exposure To Therapeutic Drugs		Prenatal Vitamins	C				
	Maternal Drugs Affecting Foetus							
	Stillbirth							
	Umbilical Cord							

Abnormality

Date:02/28/03ISR Number: 4062524-9Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0292904A
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Myelitis Paraplegia		Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG Single dose	1 DAY
			Solumedrol	C		INTRAVENOUS	120MG Single dose	1 DAY
			Elvorine	C	Glaxosmithkline	INTRAVENOUS	1	DAY

Date:03/04/03ISR Number: 4065399-7Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12195632
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Shock Asthma		Paraplatine	PS	Bristol-Myers Squibb Company	INTRAVENOUS	Re-introduced as follows: Cycle 1 on 27-Jan-2003, Cycle 2 on	
			Taxol	SS	Bristol-Myers Squibb Company	INTRAVENOUS	Re-introduced as follows: Cycle 1 on 27-Jan-2003,	

Cycle 2 on

		Zophren	SS	
INTRAVENOUS	Re-administer			
ed on				
17-Feb-2003				
		Caelyx	C	
		Holoxan	C	Bristol-Myers Squibb Company
		Solupred	C	
Re-administer				
d on				
17-Feb-2003				
		Azantac	C	
Re-administer				
d on				
17-Feb-2003				
		Polaramine	C	
Re-administer				
d on				
17-Feb-2003				
		Solu-Medrol	C	
Re-administer				
d on				
17-Feb-2003				

Date:03/04/03ISR Number: 4065577-7Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0292623A
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Pressure Decreased	Consumer	Zophren	PS	Glaxosmithkline			
INTRAVENOUS	8MG per day	2	DAY					
Initial or Prolonged	Epilepsy		Ethyol	SS				
INTRAVENOUS	1G Per day	2	DAY					

	Malaise			Oxaliplatin	C		
UNKNOWN							
				Kytril	C	Glaxosmithkline	
UNKNOWN	3MG Per day	2	DAY				
				Eloxatine	C		
INTRAVENOUS	110MG Per day	1	DAY				
				5 Fluorouracil	C		
INTRAVENOUS	500MG Per day	2	DAY				
				Rivotril	C		
UNKNOWN							

Date:03/04/03ISR Number: 4066778-4Report Type:Direct Company Report #USP 55573
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Medication Error		Zofran (Ondanserton)	PS	Gsk	
			Hand Sanitizer	SS	Gsk	

Date:03/07/03ISR Number: 4067981-XReport Type:Expedited (15-DaCompany Report #IT-GLAXOSMITHKLINE-B0293948A
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Asphyxia		Ondansetron	PS	Glaxosmithkline	
INTRAMUSCULAR	1 DAY					
	Shock		Ketorolac Trometamol	C		
INTRAMUSCULAR	1 DAY					

Date:03/11/03ISR Number: 4073627-7Report Type:Expedited (15-DaCompany Report #4915
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Blood Glucose Abnormal		Morphine	PS		
INTRAVENOUS	1 DAY					
	Blood Immunoglobulin G		Fentanyl	SS		
INTRAVENOUS	1 DAY					
	Abnormal		Ketorolac	SS		
INTRAVENOUS	1 DAY					
	Blood Immunoglobulin M		Ondansetron	SS		
INTRAVENOUS	1 DAY					
	Increased					
	Haemoglobin Abnormal					
	Pancreatitis					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/11/03ISR Number: 4074279-2Report Type:Expedited (15-DaCompany Report #GBR-2003-0000494
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Anaesthetic Complication	Foreign	Morphine Sulfate					
	Blood Glucose Abnormal	Health	(Morphine Sulfate)					
	Cardiolipin Antibody	Professional	Unknown	PS			INTRAVENOUS	INTRAVENOUS
	Positive	Other	Fentanyl (Fentanyl)	SS			INTRAVENOUS	INTRAVENOUS
	Haemoglobin Abnormal		Keterolac					
	Pancreatitis		(Keterolac)	SS			INTRAVENOUS	INTRAVENOUS
			Ondansetron					
			(Ondansetron)	SS			INTRAVENOUS	INTRAVENOUS

Date:03/13/03ISR Number: 4070847-2Report Type:Periodic Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-11941770
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injury		Taxol Inj	PS	Bristol-Myers Squibb Company		INTRAVENOUS	
			Paraplatin Inj	SS	Bristol-Myers Squibb Company		INTRAVENOUS	
			Platinol Inj	SS	Bristol-Myers Squibb Company		INTRAVENOUS	
			Procrit	SS			INTRAVENOUS	
			Tissue Plasminogen Activator	SS			INTRAVENOUS	
			Zofran	SS			INTRAVENOUS	
			Gemzar	SS			INTRAVENOUS	

Date:03/13/03ISR Number: 4071152-0Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0396259A
Age:79 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Single	
	Oxygen Saturation							
	Decreased		Ancef	C	Glaxosmithkline		dose	1 DAY
	Respiratory Rate		Atropine	C				
	Decreased		Droperidol	C				
			Ephedrine	C				
			Versed	C				
			Morphine	C		INTRATHECAL		
			Fentanyl	C		INTRAVENOUS		

Date:03/20/03ISR Number: 4078196-3Report Type:Direct Company Report #USP 55504
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Zofran	PS	Glaxo Welcome			
	Somnolence		Tizanide	SS	Eon			

Date:03/24/03ISR Number: 4076712-9Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0294917A
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chills		Zophren	PS	Glaxosmithkline	INTRAVENOUS	1UNIT Per day	1 DAY
Initial or Prolonged	Pyrexia		Lederfoline	C	Glaxosmithkline	UNKNOWN		1 DAY
			Oxaliplatin	C		UNKNOWN	105MG Per day	1 DAY
			Chemotherapy	C		UNKNOWN		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/27/03ISR Number: 4079562-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0401594A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Supraventricular		Zofran	PS	Glaxosmithkline			
	Tachycardia		Kytril	SS	Glaxosmithkline			

Date:03/27/03ISR Number: 4079573-7Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0295276A
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Thrombocytopenia		Zophren	PS	Glaxosmithkline	ORAL	2UNIT per day	5 DAY
Initial or Prolonged			Temozolomide	SS		ORAL	1UNIT Per day	5 DAY
			Depakine	C		ORAL	4UNIT per day	
			Equanil	C		ORAL	2UNIT per day	
			Risperdal	C		ORAL		
			Mopral	C		ORAL	1UNIT Per day	
			Neurontin	C			UNKNOWN	800MG Twice per day
			Epitomax	C			UNKNOWN	200MG Twice per day
			Loxapac	C			INTRAMUSCULAR	50MG Unknown

Date:03/28/03ISR Number: 4080314-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0295212A
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chest Pain		Zophren	PS	Glaxosmithkline			
INTRAVENOUS	2MGML Per day	1 DAY						

Initial or Prolonged	Chills		Rituximab	SS			
INTRAVENOUS	600MG per day 1 DAY						
	Hypotension						
	Malaise						

Date:03/31/03ISR Number: 4087526-8Report Type:Expedited (15-DaCompany Report #2003152715FR
Age:11 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Bradyphrenia	Foreign	Solu-Medrol			
Initial or Prolonged	Confusional State	Health	(Methylprednisolone)			
	Demyelination	Professional	Powder, Sterile	PS		
	Disorientation	Other	Zophren (Ondansetron			
	Drug Level Above		Hydrochoride)	SS		
INTRAVENOUS	IV					
	Therapeutic		Methotrexate "Roger			
	Micturition Disorder		Bellon"			
	Nausea		(Methotrexaye)	SS		
INTRAVENOUS	11 G, CYCLIC,					
	Vomiting					
IV						
			Zelitrex			
			(Valaciclovir)	SS		ORAL
4 DF, ORAL						

Date:04/01/03ISR Number: 4082581-3Report Type:Expedited (15-DaCompany Report #AU-GLAXOSMITHKLINE-B0278150A
Age:31 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Drug Exposure During		Zofran	PS	Glaxosmithkline	ORAL
4MG Unknown 66 DAY						
	Pregnancy					
	Drug Withdrawal Syndrome					
	Hyperemesis Gravidarum					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/01/03ISR Number: 4082587-4Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0295621A
Age:11 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cognitive Disorder		Zophren	PS	Glaxosmithkline			
INTRAVENOUS								5 DAY
Initial or Prolonged	Confusional State		Zelitrex	SS	Glaxosmithkline	ORAL		
4UNIT per day	3 DAY							
	Demyelination		Solumedrol	SS				
UNKNOWN							20MG per day	5 DAY
	Disorientation		Methotrexate	SS				
INTRAVENOUS							11G Cyclic	7 MON
	Micturition Disorder							
	Nausea							
	Vomiting							

Date:04/03/03ISR Number: 4084328-3Report Type:Expedited (15-DaCompany Report #US-ROCHE-334616
Age:5 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Supraventricular Tachycardia		Granisetron Hydrochloride	PS	Roche			
INTRAVENOUS								6 DAY
	Vomiting		Zofran	SS				
INTRAVENOUS								8 DAY
			Vincristin	C				
INTRAVENOUS								
			Methotrexate	C				
INTRAVENOUS								
			Oncaspar	C				
INTRAMUSCULAR								

Date:04/08/03ISR Number: 4086283-9Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-A0383278A
Age:72 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Angina Pectoris		Zophren	PS	Glaxosmithkline			
UNKNOWN								
Initial or Prolonged	Cardiac Disorder		Navelbine	SS	Glaxosmithkline			
INTRAVENOUS							48MG per day	

	Malaise		Cisplatin	C		
1 DAY						
			Plitican	C		
1 DAY						
			Solumedrol	C		
1 DAY						

Date:04/08/03ISR Number: 4086486-3Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0401594A
Age:5 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Supraventricular		Zofran	PS	Glaxosmithkline	
	Tachycardia		Kytril	SS	Glaxosmithkline	

Date:04/14/03ISR Number: 4090002-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0296291A
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Dyspnoea		Zophren	PS	Glaxosmithkline	
INTRAVENOUS 8MG Per day 1 DAY						
Initial or Prolonged	Malaise		Eloxatine	SS		
INTRAVENOUS 130MG Per day 1 DAY						
	Nausea					
	Vomiting					

Date:04/14/03ISR Number: 4090004-3Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0296385A
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Laryngeal Dyspnoea		Zophren	PS	Glaxosmithkline	
INTRAVENOUS 8MG Per day 1 DAY						
Initial or Prolonged			Taxotere	C		
INTRAVENOUS 140MG Per day 1 DAY						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/15/03ISR Number: 4090772-0Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0296290A
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain	Consumer	Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG Per day	1 DAY
Initial or Prolonged	Diarrhoea		Eloxatine	SS		INTRAVENOUS	200MG Per day	1 DAY
	Drug Hypersensitivity							
	Dyspnoea							
	Erythema							
	Nausea							

Date:04/15/03ISR Number: 4090774-4Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0296359A
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hypotension	Consumer	Zophren	PS	Glaxosmithkline	INTRAVENOUS	16MG Single	
Initial or Prolonged	Malaise						dose	1 DAY
	Tachycardia		Vogalene	SS		INTRAVENOUS	2UNIT Single	
	Visual Disturbance						dose	1 DAY
			Polaramine	C		INTRAVENOUS	1UNIT Single	
							dose	1 DAY
			Solupred	C		ORAL	140MG Per day	1 DAY
			Solumedrol	C				
			Azantac	C	Glaxosmithkline			
			Chemotherapy	C				

Date:04/17/03ISR Number: 4092242-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0404306A
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Colitis Ischaemic		Zofran	PS	Glaxosmithkline	ORAL
4MG Three						
Initial or Prolonged						
times per day 2 WK						
			Dicyclomine	C		ORAL
			Narcotic	C		ORAL

Date:04/17/03ISR Number: 4092246-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0281051A
Age:72 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Angina Pectoris	Consumer	Zophren	PS	Glaxosmithkline	
INTRAVENOUS						
Initial or Prolonged			Plitican	SS		
INTRAVENOUS						
			Solumedrol	SS		
			Navelbine	SS	Glaxosmithkline	
INTRAVENOUS 1 DAY						
			Cisplatine	SS		

Date:04/17/03ISR Number: 4092248-3Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0288670A
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Myocardial Infarction	Consumer	Ondansetron	PS	Glaxosmithkline	
UNKNOWN						
Initial or Prolonged			Cisplatin	SS		
UNKNOWN 65MG per day						
Other						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/17/03ISR Number: 4092258-6Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0297080A
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Motor Dysfunction		Zofran Injection	PS	Glaxosmithkline			

Date:04/18/03ISR Number: 4093195-3Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0403779A
Age:67 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Electrocardiogram Qt	Health	Zofran	PS	Glaxosmithkline	ORAL	24MG Per day	1 DAY
Initial or Prolonged	Corrected Interval	Professional	E7070	SS			INTRAVENOUS	402MGM2 See dosage text
	Prolonged							
			Irinotecan	C			INTRAVENOUS	
			Melatonin	C		ORAL		
			Ativan	C		ORAL	1TAB Per day	
			Decadron	C		ORAL	1 DAY	

Date:04/22/03ISR Number: 4094855-0Report Type:Expedited (15-DaCompany Report #IE-GLAXOSMITHKLINE-B0297352A
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Consumer	Zofran	PS	Glaxosmithkline		UNKNOWN	
	Diarrhoea		Campto	SS			UNKNOWN	
	Dyspepsia		Dexamethasone	SS			UNKNOWN	
	Insomnia		Atropine	SS			UNKNOWN	
			No Concurrent Medication	C				

Date:04/24/03ISR Number: 4096939-XReport Type:Expedited (15-DaCompany Report #IT-GLAXOSMITHKLINE-B0297699A
Age:77 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hepatic Necrosis		Ondansetron	PS	Glaxosmithkline			
INTRAVENOUS							2	DAY
Initial or Prolonged	Hepatorenal Failure		Ranitidine	SS	Glaxosmithkline			
INTRAVENOUS							2	DAY
	Pancreatic Enzymes		Atenolol	C		ORAL	2	DAY
	Abnormal		Buprenorphine Hydrochloride	C				
INTRAVENOUS							2	DAY
			Tramadol Hydrochloride	C				
INTRAVENOUS							2	DAY

Date:04/25/03ISR Number: 4097549-0Report Type:Periodic Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-12175600
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Injury	Other	Taxol	PS	Bristol-Myers Squibb Company			
			Paraplatin	SS	Bristol-Myers Squibb Company			
			Platinol	SS	Bristol-Myers Squibb Company			
			Procrit	SS				
			Tissue Plasminogen Activator	SS				
			Zofran	SS				
			Anzemet	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/28/03ISR Number: 4098660-0Report Type:Expedited (15-DaCompany Report #IT-GLAXOSMITHKLINE-B0297698A
Age:80 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Ammonia Increased		Ondansetron	PS	Glaxosmithkline			
						INTRAVENOUS		2 DAY
Hospitalization -	Bilirubin Conjugated		Ranitidine	SS	Glaxosmithkline			
						INTRAVENOUS		2 DAY
Initial or Prolonged	Increased		Allopurinol	C	Glaxosmithkline	ORAL		
							2	DAY
	Blood Amylase Increased		Isosorbide Dinitrate	C		ORAL		
							2	DAY
	Blood Bilirubin Increased		Ketorolac Trometamol	C				
						INTRAVENOUS		2 DAY
	Blood Creatinine		Lisinopril	C		ORAL		
							2	DAY
	Increased		Tamsulosin					
	Coma		Hydrochloride	C		ORAL		
							2	DAY
	Hepatic Necrosis		Tramadol					
	Hepatorenal Failure		Hydrochloride	C				
						INTRAVENOUS		2 DAY
	Jaundice Hepatocellular		Warfarin Sodium	C	Glaxosmithkline	ORAL		
							1	DAY
	Lipase Increased							

Date:04/28/03ISR Number: 4101691-5Report Type:Direct Company Report #CTU 191675
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenopia		Zofran 40 Mg/20 Ml					
	Diplopia		Inj. Glaxosmithkline	PS	Glaxosmithkline			
							32 MG IV IN	
							50 CC MS	6 WK
			Decadron	C				
			Cytoxan	C				

Date:04/29/03ISR Number: 4099787-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0405390A
Age:73 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Respiratory Arrest		Zofran Injection	PS	Glaxosmithkline	INTRAVENOUS	8MG Three Hospitalization - times per day	1 DAY
Initial or Prolonged								

Date:05/01/03ISR Number: 4101744-1Report Type:Expedited (15-DaCompany Report #NL-GLAXOSMITHKLINE-B0297866A
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Consumer	Ondansetron Hydrochloride	PS	Glaxosmithkline	UNKNOWN	8MG Unknown	
			Clonidine Hydrochloride	C		UNKNOWN	.15MG Unknown	
			Lorazepam	C		UNKNOWN	1MG Unknown	
			Dexamethasone	C		UNKNOWN	1.5MG Unknown	
			Midazolam	C		UNKNOWN	15MG Per day	
			Naltrexone Hydrochloride	C		UNKNOWN	50MG Unknown	
			Opioid Agent	C		UNKNOWN		

Date:05/02/03ISR Number: 4102335-9Report Type:Expedited (15-DaCompany Report #IE-GLAXOSMITHKLINE-B0297352A
Age:82 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Consumer	Zofran	PS	Glaxosmithkline	UNKNOWN		
	Diarrhoea		Campto	SS		UNKNOWN		
	Dyspepsia		Dexamethasone Sodium Phosphate	SS		UNKNOWN		
	Insomnia							

			Diphenoxylate Hydrochloride + Atropine Sulfate	SS			
UNKNOWN							
			Corsodyl Mouthwash Mint	C	Glaxosmithkline		
UNKNOWN							
			Nitrazepam	C			
UNKNOWN							
			Mycostatin	C			
UNKNOWN							

Date:05/05/03ISR Number: 4108176-0Report Type:Expedited (15-DaCompany Report #EMADSS2003003442
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Cardiac Arrest Coma Hepatic Necrosis Hepatocellular Damage Hepatorenal Syndrome	Foreign Health Professional	Tramadol Hydrochloride (Unspecified) (Tramadol Hydrochloride)	PS		INTRAVENOUS	600 MG, DAILY, IV	
			Toradol (Ketorolac Tromethamine)	SS		INTRAVENOUS	120 MG, DAILY, IV	
			Zofran (Ondansetron Hydrochloride)	SS		INTRAVENOUS	8 MG, IV	
			Ranitidine (Ranitidine)	SS		INTRAVENOUS	50 MG, DAILY, IV	
			Zestril (Lisinopril)	C				
			Zyloric (Allopurinol)	C				
			Coumadin (Warfarin Sodium)	C				
			Omnic (Tamsulosin Hydrochloride)	C				

			Carvasin (Isosorbide Dinitrate)	C		

Date:05/05/03ISR Number: 4108177-2Report Type:Expedited (15-DaCompany Report #EMADSS2003003450
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Cardiomyopathy Hepatic Necrosis Hepatorenal Syndrome Lipase Increased Pancreatic Enzymes	Foreign Health Professional	Tramadol Hydrochloride (Unspecified) (Tramadol Hydrochloride)	PS		
INTRAVENOUS 600 MG, IV	Increased		Temgesic (Buprenorphine)	SS		
INTRAVENOUS 0.6 MG, DAILY, IV			Zofran (Ondansetron Hydrochloride)	SS		
INTRAVENOUS 8 MG, DAILY, IV			Ranitidine (Ranitidine)	SS		
INTRAVENOUS 50 MG, DAILY, IV			Igroseles (Tenoretic)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/07/03ISR Number: 4107569-5Report Type:Direct Company Report #CTU 192467
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia		Zofran 4 Mg Glaxosmithkline	PS	Glaxosmithkline	INTRAVENOUS	4 MG ONCE	INTRAVENOUS

Date:05/15/03ISR Number: 4109925-8Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0299313A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Chest Pain		Zofran	PS	Glaxosmithkline	INTRAVENOUS		
	Myocardial Infarction							
	Myocardial Rupture							

Date:05/15/03ISR Number: 4109956-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0393611A
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated		Zofran	PS	Glaxosmithkline	ORAL	8MG Three times per day	
	Drug Exposure During Pregnancy							
	Oral Intake Reduced							
	Vomiting							

Date:05/15/03ISR Number: 4114033-6Report Type:Direct Company Report #CTU 193115
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coma		Zofran 4 Mg/Ml					

Initial or Prolonged	Convulsion		Glaxosmithkline	PS	Glaxosmithkline	
INTRAVENOUS	4 MG ONCE IV					
	Cyanosis					
PUSH						
	Muscle Rigidity		Dilaudid 2 Mg/Ml			
	Respiratory Arrest		Abbott	SS	Abbott	
INTRAVENOUS	2 MG ONCE IV					
	Staring					
PUSH						
			Nexium	C		
			Hormones	C		

Date:05/16/03ISR Number: 4110566-7Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0296385A
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Laryngeal Dyspnoea	Consumer	Zophren	PS	Glaxosmithkline	
INTRAVENOUS	8MG Per day 1 DAY					
Initial or Prolonged			Taxotere	SS		
INTRAVENOUS	140MG Per day 1 DAY					

Date:05/19/03ISR Number: 4111134-3Report Type:Expedited (15-DaCompany Report #CA-GLAXOSMITHKLINE-A0407959A
Age:42 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Anaemia
Initial or Prolonged	Blood Iron Decreased
	Hypotension
	Nausea
	Neutrophil Count Decreased
	Pyrexia

Sinus Tachycardia

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Ondansetron	PS	Glaxosmithkline			
	Blinded Trial Medication	C	Glaxosmithkline			

Date:05/19/03ISR Number: 4115094-0Report Type:Expedited (15-DaCompany Report #A0400443A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety Atrial Fibrillation Discomfort Heart Rate Increased	Literature Health Professional	Zofran Unspecified Injectable (Ondansetron Hydrochloride)	PS		INTRAVENOUS	4 MG/SEE DOSAGE TEXT/INTRAVENOUS	
	Hypertension Post Procedural Nausea Post Procedural Vomiting							
			Midazolam	C				
			Propofol	C				
			Isoflurane	C				
			Fentanyl	C				
			Ketorolac Trometamol	C				
			Lactated Ringer'S Inj	C				

Date:05/20/03ISR Number: 4112244-7Report Type:Expedited (15-DaCompany Report #ES-GLAXOSMITHKLINE-B0299437A
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia Cardiac Failure		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Twice per day	2 DAY
			Dipyrone	C		INTRAVENOUS	1G Three	

times per day	2 DAY						
				Enoxaparin	C		
SUBCUTANEOUS	40MG Per day	8 DAY					
				Tramadol Hydrochloride	C		
INTRAVENOUS	100MG Three						
times per day	2 DAY						
				Ceftriaxone	C		
INTRAVENOUS	1G Three						
times per day	11 DAY						
				Metronidazole	C	Glaxosmithkline	
INTRAVENOUS	.5MG Three						
times per day	11 DAY						

Date:05/20/03ISR Number: 4114358-4Report Type:Expedited (15-DaCompany Report #A02200301164
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Rash Papular Skin Discolouration Vomiting	Health Professional	Floxatine - (Oxaliplatin) - Solution - 5 Mg/Ml	PS		
INTRAVENOUS	160 MG OTHER,					
INTRAVENOUS						
NOS	3 HR					
			Plitican - (Alizapride Hydrochloride) - Solution - 50 Mg	SS		
INTRAVENOUS	100 MG, ONCE,					
INTRAVENOUS						
NOS	15 MON					

				Zophren - (Ondansetron Hydrochloride) - Solution - 2 Mg/Ml	SS			
INTRAVENOUS	8 MG ONCE							
INTRAVENOUS								
NOS	A FEW							
MINS	MIN							
				Largactil (Chlorpromazine Hydrochloride)	C			
				Solumedrol (Methylprednisolone Sodium Succinate)	C			
				Vogalene (Metopimazine)	C			
				Xanax (Alprazolam)	C			

Date:05/20/03ISR Number: 4114493-0Report Type:Expedited (15-DaCompany Report #EMADSS2003003442
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Amylase Increased	Foreign	Tramadol Hydrochloride (Tramadol Hydrochloride)	PS				
Hospitalization - Initial or Prolonged	Cardiac Arrest	Health Professional						
	Coma							
	Hepatic Necrosis							
INTRAVENOUS							600 MG	DAILY
	Hepatorenal Syndrome							
IV								
	Hyperammonaemia		Toradol (Ketorolac Tromethamine)	SS				
	Jaundice Hepatocellular							
INTRAVENOUS							120 MG	DAILY
	Lipase Increased							
IV								
			Zofran (Ondansetron Hydrochloride)	SS				
INTRAVENOUS	8 MG IV							
			Ranitidine	SS				
INTRAVENOUS	50 MG DAILY							
IV								

				Zestril (Lisinopril)	C			
				Zyloric (Allopurinol)	C			
				Coumadin (Warfarin Sodium)	C			
				Omnic (Tamsulosin Hydrochloride)	C			
				Carvasin (Isosorbide Dinitrate)	C			

Date:05/20/03ISR Number: 4115726-7Report Type:Expedited (15-DaCompany Report #US-SHR-03-007375
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Anaemia Myelodysplastic Syndrome Myeloid Metaplasia Thrombocytopenia	Study Health Professional	Leukine(Sargramostim) Injection	PS		SUBCUTANEOUS	5 UG/M2/DAY (DAY 3 TO APHERESIS), SUBCUTANEOUS	
			Cyclophosphamide(Cyclophosphamide)	SS		INTRAVENOUS	4 GM/M2 X 1 DOSE (DAY 1),	1 DAY
			Mesna(Mesna)	SS		INTRAVENOUS	4 GM/M2X 1 DOSE(DAY 1),	1 DAY

				Taxol (Paclitaxel)	SS	
INTRAVENOUS 250 MG/M2, 1 DOSE (DAY 2),						
INTRAVENOUS	1	DAY				
				G-Csf (Granulocyte Colony Stimulating Factor)	SS	
SUBCUTANEOUS 10 MICROG/KG/DAY DAY 10 TO APHERESIS, SUBCUTANEOUS						
				Dilantin(Phenytoin Sodium)	SS	ORAL
SEE IMAGE	5	DAY				
				Zofran (Ondansetron Hydrochloride)	SS	ORAL
8MG QID DAY -9 TO DAY MINUS 1, ORAL	9	DAY				
				Busulfan(Busulfan)	SS	ORAL
1 MG/KG Q6H X12DOSES DAY-8 TO -6, ORAL	3	DAY				
				Melphalan(Melphalan)	SS	
50 MG/M2 X 2 DOSES DAY-5 AND -4	2	DAY				
				Thiotepa(Thiotepa)	SS	
250 MG/M2 X 2DOSES DAY -3						

AND -2 2 DAY

Infusion Of Il-2
Treated Pbsc'S() SS

1 DAY

Il-2() SS

INTRAVENOUS 6 X

10^6IU/M2(STA

RTED DAY 0),

INTRAVENOUS 28 DAY

Bactrim C

Date:05/22/03ISR Number: 4113937-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0405390A
Age:73 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Convulsion	Health	Zofran Injection	PS	Glaxosmithkline	INTRAVENOUS	32MG	
Hospitalization - cumulative	Respiratory Arrest	Professional						
Initial or Prolonged								
dose							1	DAY
Other			Morphine Sulfate	SS	Glaxosmithkline	INTRAVENOUS	2MG Single	
dose								
			Labetalol	C	Glaxosmithkline	INTRAVENOUS	10MG per day	1 DAY

Date:05/22/03ISR Number: 4113961-5Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0300055A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction	Consumer	Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG per day	
Initial or Prolonged	Medication Error		5 Fluorouracil	SS		INTRAVENOUS	1000MGM2 per	
Other								
day								
			Primperan	C	Glaxosmithkline	INTRAVENOUS	30MG per day	
			0.9% Nacl	C	Glaxosmithkline	INTRAVENOUS	50ML per day	
			Glucose 5% + Nacl +					

		Kcl	C	
INTRAVENOUS	1L per day			
		Folinic Acid	C	Glaxosmithkline
INTRAVENOUS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/02/03ISR Number: 4120386-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0403779A
Age:67 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Electrocardiogram Qt Prolonged	Health Professional	Zofran	PS	Glaxosmithkline	ORAL	24MG Per day	1 DAY
			E7070	SS		INTRAVENOUS	402MG See dosage text	
			Irinotecan	C		INTRAVENOUS		
			Melatonin	C		ORAL		
			Ativan	C		ORAL	1TAB Per day	
			Decadron	C		ORAL	1 DAY	

Date:06/02/03ISR Number: 4120388-9Report Type:Expedited (15-DaCompany Report #CA-GLAXOSMITHKLINE-A0407959A
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia Blood Iron Decreased Hypotension Nausea Neutrophil Count Decreased Pyrexia Sinus Tachycardia White Blood Cell Count Decreased	Health Professional	Ondansetron	PS	Glaxosmithkline	ORAL	8MG See dosage text	
			Blinded Trial Medication	SS	Glaxosmithkline	ORAL		7 DAY

Date:06/09/03ISR Number: 4124448-8Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0299313A
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Chest Pain		Zofran	PS	Glaxosmithkline	
INTRAVENOUS						
	Myocardial Infarction					
	Ventricle Rupture					

Date:06/11/03ISR Number: 4128081-3Report Type:Expedited (15-DaCompany Report #2003163111FR
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Blood Creatinine	Foreign	Solu-Medrol(Methylpr			
	Cytolytic Hepatitis	Health	ednisolone) Powder,			
	Fall	Professional	Sterile	PS		
INTRAVENOUS 80 MG, QD, IV						
	Hyperpyrexia	Other	Navelbine(Vinorelbin			
	Malaise		e Ditartrate)	SS		
INTRAVENOUS 45 MG, QD, IV						
	Rhabdomyolysis		Zophren (Ondansetron			
			Hydrochloride)	SS		
INTRAVENOUS IV						
			Praxilene			
			(Naftidrofuryl			
			Oxalate)	C		
			Atenolol	C		
			Co-Approvel	C		
			Alpress	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/16/03ISR Number: 4128788-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0410818A
Age:24 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Feeling Hot Flushing Nausea Nystagmus Vomiting		Zofran Iv Decadron Ativan	PS C C	Glaxosmithkline	INTRAVENOUS	4MG See dosage text 10MG Single dose 1MG Single dose	1 DAY 1 DAY

Date:06/16/03ISR Number: 4128862-6Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0302112A
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Interstitial Lung Disease Liver Disorder		Ondansetron	PS	Glaxosmithkline			

Date:06/16/03ISR Number: 4130374-0Report Type:Expedited (15-DaCompany Report #2003143583FR
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Acute Pulmonary Oedema Acute Respiratory Distress Syndrome Bronchospasm Cholestasis Febrile Bone Marrow Aplasia	Foreign Health Professional Other	Aracytine(Cytarabine) Powder, Sterile Zavedos(Idarubicin Hydrochloride) Powder, Sterile	PS SS		INTRAVENOUS INTRAVENOUS	180 MG, QD, D1-D7, IV 15 MG, QD, D1-D5, IV	

		Haemodynamic Instability	Belustine(Lomustine)	SS	ORAL 360 MG, D1,
		Hypoxia			ORAL
		Inflammation	Ciflox(Ciprofloxacin)	SS	INTRAVENOUS
	IV	Interstitial Lung Disease			
		Pleural Effusion	Zophren(Ondanestron Hydrochloride)	SS	INTRAVENOUS
	IV	Pneumonia			
		Rectal Haemorrhage	Granocyte(Lenograstim)	SS	SUBCUTANEOUS
		Renal Failure Acute			
	SUBCUTANEOUS				
			Uricozyme (Urate Oxidase)	C	
			Fortum (Ceftazidime Pentahydrate)	C	
			Vancomycin	C	
			Amphotericin B	C	
			Tienam (Imipenem, Cilastatin)	C	
			Paracetamol	C	
			Cervoxan (Vinburnine)	C	
			Ciprofloxacin	C	

Date:06/16/03ISR Number: 4130658-6Report Type:Expedited (15-DaCompany Report #2003163602CH
Age:57 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Atrial Fibrillation
Other	Hepatocellular Damage
	Hepatotoxicity
	Hyperbilirubinaemia
	Post Procedural

Complication
Troponin I

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Health Professional	Fragmin(Dalteparin Sodium) Solution, Sterile	PS				
Other						
	Cordarone(Amiodarone Hydrochloride)	SS		ORAL	SEE IMAGE	
	Ben-U-Ron(Paracetamol) Suppository	SS				
					RECTAL	2-4 G DAILY,
					RECTAL	
	Dafalgin (Paracetamol)	SS		ORAL	2-4 G, DAILY,	
					ORAL	
	Zofran(Ondansetron Hydrochloride)	SS				
					INTRAVENOUS	4 MG, SINGLE,
					IV	
	Methadone(Methadone)	SS				
					SUBCUTANEOUS	8 MG, QD,
					SUBCUTANEOUS	
	Lexotanil(Bromazepam)	SS		ORAL	3 MG, DAILY,	
					ORAL	
	Lasix	C				
	Cordarone	C				
	Torem	C				
	Potassium Chloride	C				
	Marcoumar	C				
	Actrapid Mc	C				
	Aspirine	C				
	Ulcogant	C				
	Paspertin	C				
	Lopressor	C				

Efexor	C
Concor	C
Digoxin	C
Reniten	C
Novalgin	C
Morphine	C
Lopirin	C
Antra	C

Date:06/17/03ISR Number: 4129980-9Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0291601A
Age:72 YR Gender:Female I/FU:F

Outcome	PT
Death	Acute Respiratory
Hospitalization - Initial or Prolonged	Distress Syndrome
	Blood Alkaline Phosphatase Increased
	C-Reactive Protein Increased
	Cholestasis
	Creatinine Renal Clearance Decreased
	Dyspnoea
	Febrile Bone Marrow Aplasia
	Gamma-Glutamyltransferase Increased

	Haemodynamic Instability					
	Hypoxia					
	Inflammation	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Lung Disorder	Consumer	Zophren	PS	Glaxosmithkline	
INTRAVENOUS						
	Pleural Effusion		Aracytine	SS		
INTRAVENOUS	180MG Per day 7 DAY					
	Pulmonary Oedema		Belustine	SS		ORAL
360MG Per day 1 DAY						
	Rales		Ciflox	SS		
INTRAVENOUS						
	Rectal Haemorrhage		Zavedos	SS		
INTRAVENOUS	15MG Per day 5 DAY					
	Renal Failure Acute		Granocyte	SS		
SUBCUTANEOUS						
			Uricozyme	C		
			Fortum	C	Glaxosmithkline	
			Vancomycine	C		
			Amphotericine	C		
			Tienam	C		
			Perfalgan	C	Glaxosmithkline	
UNKNOWN						

Date:06/18/03ISR Number: 4130730-0Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-A0412284A
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Alanine Aminotransferase	Consumer	Navelbine	PS	Glaxosmithkline	
INTRAVENOUS	45MG Per day					
	Increased		Zophren	SS	Glaxosmithkline	
	Aspartate		Solumedrol	C		
	Aminotransferase		Trentadil	C		
	Increased		Plavix	C		
	Blood Creatine		Praxilene	C		
	Phosphokinase Increased		Atenolol	C		
	Blood Creatinine		Co-Aprovel	C		
	Increased		Alpress	C		
	Cytolytic Hepatitis					
	Fall					
	Gamma-Glutamyltransferase					
	Increased					
	Malaise					
	Pyrexia					

	Rhabdomyolysis						

Date:06/20/03ISR Number: 4133866-3Report Type:Expedited (15-DaCompany Report #200310083BFR
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Pulmonary Oedema	Foreign	Ciflox					
Hospitalization -	Acute Respiratory	Health	(Ciprofloxacin)	PS		INTRAVENOUS	INTRAVENOUS	
Initial or Prolonged	Distress Syndrome	Professional	Aracytine					
Other	Bronchospasm	Other	(Cytarabine)	SS			180 MG, TOTAL	
	Cholestasis						DAILY	
	Haemodynamic Instability		Belustine					
	Inflammation		(Lomustine)	SS			360 MG, TOTAL	
	Interstitial Lung Disease						DAILY,	
	Lung Disorder		Zavedos (Idarubicin					
	Pleural Effusion		Hydrochloride)	SS			INTRAVENOUS	1.5 MG, TOTAL
	Rales						DAILY,	
	Rectal Haemorrhage						INTRAVENOUS	
	Renal Failure Acute		Zophren (Ondansetron					
			Hydrochloride)	SS				
			Granocyte					
			(Lenograstim)	SS				
			Uricozyme	C				
			Fortum	C				

Vancomycine	C
Amphotericin B	C
Tienam	C
Perfalgan/Gfr/	C
Elohes	C
Zovirax	C
Triatec	C

Date:06/25/03ISR Number: 4135309-2Report Type:Expedited (15-DaCompany Report #WAES 0306FRA00080
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Encephalopathy		Decadron Phosphate	PS	Merck & Co., Inc	INTRAVENOUS		64 DAY
Hospitalization - Initial or Prolonged	Epistaxis		Ondansetron Hydrochloride	SS		INTRAVENOUS		64 DAY
	Hepatic Failure							
	Hepatomegaly		Oxaliplatin	SS		INTRAVENOUS		64 DAY
	Jaundice		Gemcitabine	SS		INTRAVENOUS		64 DAY
	Phlebothrombosis		Fluoxetine	C		ORAL		
	Venoocclusive Liver Disease		Zolpidem Tartrate	C		ORAL		

Date:06/27/03ISR Number: 4136582-7Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0295276A
Age:44 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Thrombocytopenia	Consumer	Zophren	PS	Glaxosmithkline	ORAL	2UNIT per day	5 DAY
			Temozolomide	SS		ORAL	1UNIT Per day	5 DAY
			Depakine	C		ORAL	4UNIT per day	
			Equanil	C		ORAL	2UNIT per day	
			Risperdal	C		ORAL		
			Mopral	C		ORAL	1UNIT Per day	

			Neurontin	C		
UNKNOWN	800MG Twice per day					
			Epitomax	C		
UNKNOWN	200MG Twice per day					
			Loxapac	C		
INTRAMUSCULAR	50MG Unknown					

Date:06/27/03ISR Number: 4136588-8Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0302687A
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Hypoventilation		Zofran	PS	Glaxosmithkline	
INTRAVENOUS	4MG Single					
	Pain					
dose	1 DAY					
	Tachyarrhythmia		Paracetamol	C	Glaxosmithkline	ORAL
1G per day						
	Urticaria Generalised		Amethocaine	C		
TOPICAL						
	Vasospasm		Sevoflurane	C		
RESPIRATORY						
(INHALATION)						
			Nitrous Oxide	C		
RESPIRATORY						
(INHALATION)						
			Oxygen	C		
RESPIRATORY						
(INHALATION)						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/27/03ISR Number: 4139288-3Report Type:Expedited (15-DaCompany Report #HQWYE672118JUN03
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Atrial Fibrillation Hepatocellular Damage Hyperhidrosis	Foreign Study Health	Cordarone (Amiodarone, Injection)	PS		INTRAVENOUS	SEE IMAGE	1 DAY
	Malaise Troponin I Increased	Professional Other	Ben-U-Ron (Paracetamol)	SS		RECTAL	2/4 G/DAY,	
	Vomiting					RECTAL	4	DAY
			Cordarone (Amiodarone Tablet)	SS		ORAL	200 MG 3 X	PER 1 WK
			Dafalgan (Paracetamol)	SS		ORAL	TABLET/1G,	
			Fragmin (Heparin-Fraction, Sodium, Salt)	SS		ORAL	4	DAY
						SUBCUTANEOUS	5000 IU 1 X	PER 1 DAY,
						SUBCUTANEOUS	3	DAY
			Methadone (Methadone)	SS		SUBCUTANEOUS	8-16 MG	DAILY, SC
							2	DAY
			Zofran (Ondansetron Hydrochloride)	SS		INTRAVENOUS	4 MG 1 X PER	1 DAY,
						INTRAVENOUS	1	DAY
			Lasix (Furosemide)	C				
			Torem (Torasemide)	C				
			Kcl-Retard					

(Potassium Chloride)	C
Marcoumar (Phenprocoumon)	C
Actrapid Human (Insulin Human)	C
Aspirin (Acetylslicylic Acid)	C
Ulcogant (Sucralfate)	C
Paspertin (Metoclopramide Hydrochloride)	C
Lopresor (Metoprolol Tartrate)	C
Lexotanil (Bromazepam)	C
Morphine (Morphine)	C
Lopirin (Captopril)	C
Antra (Omeprazole)	C
Effexor (Venlafaxine Hydrochloride)	C
Digoxin (Digoxin)	C

Date:06/30/03ISR Number: 4137300-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0413611A
Age:72 YR Gender: I/FU:I

Outcome	PT
Other	Chills
	Neuroleptic Malignant

		Syndrome Pyrexia					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
				Zofran	PS	Glaxosmithkline	
				Morphine	C		

Date:06/30/03ISR Number: 4137319-8Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0302860A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Abortion Induced		Zofran	PS	Glaxosmithkline	
WK						
Congenital Anomaly	Complications Of Maternal		Promethazine	C		ORAL
25MG Twice						
	Exposure To Therapeutic					
per day 8	DAY					
	Drugs		Buccastem	C		ORAL
3MG per day 2	DAY					
	Drug Exposure During		Maxolon	C	Glaxosmithkline	
UNKNOWN						
	Pregnancy					
	Foetal Disorder					
	Hydrocephalus					

Date:07/02/03ISR Number: 4139728-XReport Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0303092A
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Loss Of Consciousness		Ondansetron	PS	Glaxosmithkline	
INTRAVENOUS 4MG Single						
Initial or Prolonged						
dose 1	DAY					
			Paracetamol	C	Glaxosmithkline	ORAL
1G Single						
dose						
			Ketoprofen	C		ORAL
200MG Single						
dose						

				Propofol	C		
INTRAVENOUS	1000MCG per day						
				Alfentanil	C		
INTRAVENOUS	1000MCG per day						

Date:07/03/03ISR Number: 4140777-6Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0414767A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal Exposure To Therapeutic Drugs Intra-Uterine Death Maternal Drugs Affecting Foetus Ultrasound Antenatal Screen Abnormal		Zofran	PS	Glaxosmithkline	ORAL		

Date:07/08/03ISR Number: 4143045-1Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0303341A
Age:29 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Alanine Aminotransferase Increased Angiopathy Aspartate Aminotransferase Increased

	Bilirubin Conjugated Increased					
	Blood Alkaline Phosphatase Increased	Report Source	Product Zophren	Role PS	Manufacturer Glaxosmithkline	Route INTRAVENOUS
	Budd-Chiari Syndrome		Soludecadron	SS		INTRAVENOUS
20MG per day	Diarrhoea		Oxaliplatin	SS		INTRAVENOUS
163MG per day	Epistaxis		Gemzar	SS		INTRAVENOUS
1630MG per day	Gamma-Glutamyltransferase Increased		Prozac	C		ORAL
20MG per day	General Physical Health Deterioration		Stilnox Rivotril	C C		ORAL ORAL
14DROP per day	Haemoglobin Decreased					
	Hepatic Encephalopathy		Lexomil	C		ORAL
	Hepatic Failure		Taxol	C		INTRAVENOUS
	Hepatic Pain		Herceptin	C		INTRAVENOUS
	Hepatomegaly Hyperammonaemia Jaundice Platelet Count Decreased Portal Hypertension Prothrombin Time Abnormal Pyrexia Venoocclusive Disease Vomiting					

Date:07/08/03ISR Number: 4143046-3Report Type:Expedited (15-DaCompany Report #AU-GLAXOSMITHKLINE-B0303382A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Abortion		Zofran	PS	Glaxosmithkline	UNKNOWN
	Complications Of Maternal Exposure To Therapeutic					

	Drugs Maternal Drugs Affecting Foetus					

Date:07/10/03ISR Number: 4144532-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0303481A
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Chills	Consumer	Zophren	PS	Glaxosmithkline	
INTRAVENOUS 8MG per day	1 DAY					
Initial or Prolonged	Hypersensitivity		Eloxatine	SS		
INTRAVENOUS	1 DAY					
	Tremor		Glucose 5 %	C		

Date:07/10/03ISR Number: 4147148-7Report Type:Expedited (15-DaCompany Report #2003-07-0220
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Dyspnoea	Foreign	Polaramine			
Life-Threatening	Extrasystoles	Health	(Dexchlorpheniramine			
	Metastases To Lung	Professional	Maleate) Injectable			
	Oesophageal Cancer	Other	Solution	PS		
INTRAVENOUS INTRAVENOUS						
	Metastatic		Methylprednisolone			
			Injectable	SS		
INTRAVENOUS INTRAVENOUS						
			Paclitaxel			
			Injectable	SS		
INTRAVENOUS INTRAVENOUS						
			Ranitidine			
			Hydrochloride			

				Injectable	SS		
INTRAVENOUS	INTRAVENOUS						
				Zophren (Ondansetron) Injectable Solution	SS		
INTRAVENOUS	INTRAVENOUS						
				Paraplatin	C		
				Fluoro-Uracil	C		

Date:07/11/03ISR Number: 4146229-1Report Type:Direct Company Report #CTU 197723
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dyspnoea		Ondansetron	PS			4MG	
	Nausea							
	Oropharyngeal Swelling							
	Tachycardia							

Date:07/17/03ISR Number: 4155482-XReport Type:Expedited (15-DaCompany Report #A0412284A
Age:76 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatinine Increased	Foreign Health	Navelbine Injection (Vinorelbine					
	Cytolytic Hepatitis	Professional	Tartrate)	PS				
INTRAVENOUS	45 MG / PER							
	Fall	Other						
DAY /								
	Malaise							
INTRAVENOUS								
	Pyrexia		Zofran					
	Rhabdomyolysis		(Ondansetron Hydrochloride)	SS				
			Me-Prednisolone Na Succ.	C				
			Bamifylline Hydrochloride	C				
			Clopidogrel Bisulphate	C				
			Naftidrofuryl Oxalate	C				

				Atenolol	C		
				Coaprovel	C		
				Prazosin Hydrochloride	C		

Date:07/18/03ISR Number: 4149423-9Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0304036A
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dyspnoea	Consumer	Ranitidine	PS	Glaxosmithkline	INTRAVENOUS	1	DAY
Life-Threatening	Extrasystoles		Zophren	SS	Glaxosmithkline		1	DAY
			Polaramine	SS		INTRAVENOUS	1	DAY
			Methylprednisolone	SS		INTRAVENOUS	1	DAY
			Paclitaxel	SS		INTRAVENOUS	1	DAY
			Paraplatine	C				
			Fluorouracil	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/21/03ISR Number: 4153154-9Report Type:Expedited (15-DaCompany Report #2003167784FR
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bundle Branch Block Right Carotid Artery Atheroma Gamma-Glutamyltransferase	Foreign Health Professional	Solu-Medrol (Methylprednisolone) Powder, Sterile	PS		INTRAVENOUS	60 MG, IV	
	Increased Ischaemic Stroke	Other	Cisplatin "Dakota Pharm" (Cisplatin)	SS		INTRAVENOUS	118 MG, QD, IV	
	Normochromic Normocytic Anaemia Ventricular Hypertrophy		Gemzar (Gemcitabine Hydrochloride)	SS		INTRAVENOUS	1680MG, QD, IV	
			Zophren (Ondansetron Hydrochloride)	SS			8 MG, QD	
			Plavix (Clopidogrel Sulfate)	C				
			Diamicron (Gliclazide)	C				
			Zocor (Simvastatin)	C				

Date:07/22/03ISR Number: 4151413-7Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0304102A
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Carotid Artery Atheroma Dysarthria		Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG Single dose	1 DAY
Other	Facial Palsy		Solumedrol	SS		INTRAVENOUS	60MG Single dose	1 DAY
	Gamma-Glutamyltransferase Increased		Cisplatine	SS		INTRAVENOUS	118MG Single dose	1 DAY
	Ischaemic Stroke							

		Normochromic Normocytic		Gemzar	SS		
INTRAVENOUS	1680MG Single	Anaemia					
dose	1 DAY						
		Paraesthesia		Plavix	C		ORAL
1TAB Per day							
		Ventricular Hypertrophy		Diamicron	C		ORAL
1TAB Per day							
				Zocor	C		ORAL
20MG See							
dosage text							

Date:07/23/03ISR Number: 4155474-0Report Type:Expedited (15-DaCompany Report #B0301517A
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Blood Creatinine	Foreign	Ondansetron			
Hospitalization -	Increased	Health	Hydrochloride			
Initial or Prolonged	Cytolytic Hepatitis	Professional	(Ondansetron			
	Pyrexia	Other	Hydrochloride)	PS		
INTRAVENOUS	INTRAVENOUS					
	Rhabdomyolysis		Vinorelbine Tartrate (Formulation Unknown) (Vinorelbine Tartrate)	SS		
INTRAVENOUS	45 MG / PER					
DAY/						
INTRAVENOUS						
			Me-Prednisolone Na Succ. Solution (Me-Prednisolone Na Succ.)	SS		
INTRAVENOUS	PER DAY /					
INTRAVENOUS						
			Bamifylline Hydrochloride	C		

				Clopidogrel Bisulphate	C		
				Naftidrofuryl Oxalate	C		
				Atenolol	C		
				Coaprovel	C		
				Prazosin Hydrochloride	C		

Date:07/28/03ISR Number: 4155098-5Report Type:Expedited (15-DaCompany Report #NL-GLAXOSMITHKLINE-B0304595A
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Arterial Thrombosis Limb		Ondansetron Hydrochloride	PS	Glaxosmithkline			
Hospitalization - Initial or Prolonged	Foot Amputation		Cisplatine	C				
						INTRAVENOUS	200MG per day	
			Bleomycine	C				
							15UNIT per day	
			Etoposide	C				
			Homeopathy	C				
			Olanzapine	C				
							30MG per day	

Date:07/28/03ISR Number: 4158417-9Report Type:Expedited (15-DaCompany Report #2003169020FR
Age:100 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Foreign Health Professional	Adriblastine(Doxorubicin Hydrochloride) Powder, Sterile	PS				
	Blood Osmolarity Decreased					INTRAVENOUS	15 MG, CYCLIC, IV	
	Depressed Level Of Consciousness	Other	Oncovin(Vincristine Sulfate)	SS				
	Hyponatraemia					INTRAVENOUS	0.4 MG, CYCLIC, IV	
	Inappropriate							

	Antidiuretic Hormone Secretion		Soludecadron(Dexamethasone Sodium Phosphate)	SS		ORAL 40 MG, ORAL
			Zophren (Ondansetron Hydrochloride)	SS		ORAL ORAL
			Temesta(Lorazepam)	SS		ORAL 1 MG, ORAL

Date:07/29/03ISR Number: 4159564-8Report Type:Expedited (15-DaCompany Report #102778ISR
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Arterial Thrombosis Limb	Foreign	Etoposide	PS		INTRAVENOUS	INTRAVENOUS	
Hospitalization - (NOS)	Foot Amputation	Health Professional	Cisplatin	SS		INTRAVENOUS	200 MILLIGRAM	
Initial or Prolonged Disability ,		Other						
			Bleomycin	SS		INTRAVENOUS	INTRAVENOUS	
			Ondansetron Hydrochloride	SS				
			Magnesium Chloride Anhydrous	C				
			Olanzapine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/29/03ISR Number: 4200500-3Report Type:Periodic Company Report #WAES 0305USA02284
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Fatigue	Health	Cap Emend Unk	PS		ORAL	125 MG/1X/PO	
		Professional	Zofran Unk	SS				
		Company	Dexamethasone Unk	SS				
		Representative	Aranesp	C				
			Cytoxan	C				
			Neulasta	C				
			Epirubicin Hydrochloride	C				
			Fluorouracil	C				

Date:07/30/03ISR Number: 4158818-9Report Type:Expedited (15-DaCompany Report #CH-GLAXOSMITHKLINE-B0304822A
Age:67 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Erythema		Zofran	PS	Glaxosmithkline	ORAL	5	DAY
Initial or Prolonged	Pyrexia		Temozolomide	SS		ORAL	5	DAY
	Rash Macular		Valproic Acid	C		ORAL	500MG Three times per day	
			Lamotrigine	C	Glaxosmithkline	ORAL	25MG Per day	
			Oxazepam	C		ORAL	15MG Twice per day	
			Pravastatine	C		ORAL	40MG per day	

Date:07/31/03ISR Number: 4160375-8Report Type:Expedited (15-DaCompany Report #5590
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Life-Threatening	Arterial Thrombosis	Health	Etoposide	PS			
INTRAVENOUS	20 MG/ML						
Hospitalization -	Foot Amputation	Professional					
FREQ, IV							
Initial or Prolonged			Cisplatin	SS			
INTRAVENOUS	200 MG, IV						
Disability			Bleomycin	SS			
INTRAVENOUS	15 UNITS						
FREQ, IV							
			Ondansetron	SS			
2 MG/ML							
			Magnesium Chloride Anhydrous	C			
			Olanzapine	C			

Date:08/01/03ISR Number: 4159338-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0305026A
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Bone Marrow Depression		Zophren	PS	Glaxosmithkline	
INTRAVENOUS	8MG Per day					
Initial or Prolonged	Dysphagia		Lederfoline	SS	Glaxosmithkline	
INTRAVENOUS	760MG Per day					
	Sepsis		Tranxene	SS		
INTRAVENOUS	20MG Per day					
			Fluorouracil	SS		
INTRAVENOUS	3760MG per					
day						
			Eloxatine	SS		
INTRAVENOUS	190MG per day					

Date:08/01/03ISR Number: 4202868-0Report Type:Periodic Company Report #KDL031091
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Malignant Neoplasm	Health	Procrit	PS		
	Progression	Professional	Paclitaxel	SS		
INTRAVENOUS	IV					

				Carboplatin	SS		
INTRAVENOUS	IV						
				Cisplatin	SS		
INTRAVENOUS	IV						
				Ondansetron Hydrochloride	SS		
INTRAVENOUS	IV						
				Dolasetron Mesylate	SS		
INTRAVENOUS	IV						

Date:08/04/03ISR Number: 4160392-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0305230A
Age:100 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia		Zophren	PS	Glaxosmithkline	ORAL	6	DAY
Initial or Prolonged	Blood Osmolarity		Oncovin	SS				
INTRAVENOUS	.4MG Per day	4	DAY					
	Decreased		Soludecadron	SS		ORAL	40MG Per day	4 DAY
	Disturbance In Attention		Adriamycine	SS				
INTRAVENOUS	15MG Per day	4	DAY					
	Fluid Retention		Temesta	SS		ORAL	1MG Per day	
	Hyperproteinaemia							
	Hyponatraemia							
	Urine Abnormality							

Date:08/04/03ISR Number: 4160639-8Report Type:Direct Company Report #CTU 199172
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Convulsion		Ondansetron (Zofran)	PS				
INTRAVENOUS	4MG Q 24 PRN							
Other	Grand Mal Convulsion							
IV (0.107								
Required	Tardive Dyskinesia							
MG/KG/DOSE)								
Intervention to								
Prevent Permanent								
Impairment/Damage								

Date:08/04/03ISR Number: 4161180-9Report Type:Direct Company Report #USP 50153
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Zofran Injection Ondansetron Hcl	PS	Cerenex Pharmaceuticals (Glaxo)	INJ		
			Atropine Sulfate Injection Atropine Sulfate	SS	American Regent	INJ		

Date:08/06/03ISR Number: 4162462-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0419341A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Bilirubin Increased Drug Exposure During Pregnancy Drug Exposure Via Breast Milk Hepatic Failure Neonatal Disorder		Zofran	PS	Glaxosmithkline			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/09/03ISR Number: 4166504-4Report Type:Expedited (15-DaCompany Report #A02200301890
Age:52 YR Gender:Male I/FU:I

Outcome	Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged			Bone Marrow Depression Dysphagia Enterococcal Infection	Health Professional	Eloxatine 0 (Oxaliplatin) - Powder - 5 Mg/Ml	PS		
INTRAVENOUS	190 MG	OTHER, 1 DAY	Sepsis		Tranxene 0 (Clorazepate Dipotassium) - Solution - 20 Mg	SS		
INTRAVENOUS	20 MG,	OD			Fluorouracile - (Fluorouracil) - Solution - Unit Dose: Unknown	SS		
INTRAVENOUS	3760 MG	OTHER 1 DAY			Lederfolin -(Calcium Folinate)- Solution - Unit Dose: Unknown	SS		
INTRAVENOUS	760 MG	OD			Zophren- (Ondansetron Hydrochloride) - Solution - Unit Dose: Unknown	SS		
INTRAVENOUS	8 MG	OD						

Date:08/12/03ISR Number: 4169037-4Report Type:Expedited (15-DaCompany Report #030801-PM0092-00
Age:52 YR Gender:Male I/FU:I

Outcome	Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged			Bone Marrow Depression Dysphagia Enterococcal Infection	Foreign Health Professional	Tranxene (Clorazepate Dipotassium)	PS		
INTRAVENOUS	20 MG,	QD,	Sepsis	Other				
INTRAVENOUS					Oxaliplatin	SS		
INTRAVENOUS	190 MG,							
INTRAVENOUS								

			Fluorouracil	SS		
INTRAVENOUS	3760 MG,					
INTRAVENOUS						
			Calcium Folinate	SS		
INTRAVENOUS	760 MG, QD,					
INTRAVENOUS						
			Ondansetron Hydrochloride	SS		
INTRAVENOUS	8 MG, QD,					
INTRAVENOUS						

Date:08/14/03ISR Number: 4168440-6Report Type:Direct Company Report #USP 50379
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Zofran	PS	Glaxo Wellcome			
INJ								
			Sandostatin	SS	Sandoz			
INJ								

Date:08/25/03ISR Number: 4177682-5Report Type:Expedited (15-DaCompany Report #03H-167-0229056-00
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Foreign Health Professional	Isoflurane (Forene Liquid For Inhalation) (Isoflurane)					
			(Isoflurane) Propofol Injection	PS				

		(Propofol)		
		(Propofol)		
		(Propofol)	SS	
		Fentanyl	SS	
		Ondansetron	SS	

Date:09/02/03ISR Number: 4176994-9Report Type:Expedited (15-DaCompany Report #IE-GLAXOSMITHKLINE-B0297352A
Age:82 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia		Zofran	PS	Glaxosmithkline		UNKNOWN	
	Diarrhoea		Campto	SS			UNKNOWN	
	Dyspepsia		Dexamethasone Sodium Phosphate	SS			UNKNOWN	
	Insomnia		Diphenoxylate Hydrochloride + Atropine Sulfate	SS			UNKNOWN	
			Corsodyl Mouthwash Mint	C	Glaxosmithkline		UNKNOWN	
			Nitrazepam	C			UNKNOWN	
			Mycostatin	C			UNKNOWN	

Date:09/02/03ISR Number: 4177003-8Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041733A
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Diplopia		Zofran	PS	Glaxosmithkline	ORAL	2	DAY
Initial or Prolonged	Visual Disturbance		Zofran	C	Glaxosmithkline		INTRAVENOUS	1 DAY

Date:09/03/03ISR Number: 4177808-3Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0295621A
Age:11 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cognitive Disorder		Zophren	PS	Glaxosmithkline			
INTRAVENOUS							5	DAY
Initial or Prolonged	Confusional State		Zelitrex	SS	Glaxosmithkline	ORAL		
4UNIT per day							3	DAY
	Demyelination		Solumedrol	SS				
UNKNOWN							20MG per day	5 DAY
	Micturition Disorder		Methotrexate	SS				
INTRAVENOUS							7	MON
	Nausea							
	Vomiting							

Date:09/04/03ISR Number: 4179011-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0424298A
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypoaesthesia		Zofran	PS	Glaxosmithkline			
INTRAVENOUS							4MG Per day	0 DAY
	Injection Site Irritation		Synthroid	C	Glaxosmithkline			
	Vasculitis		Hydrochlorothiazide	C				
			Lidocaine	C				
			Milk Of Magnesia	C	Glaxosmithkline			

Date:09/04/03ISR Number: 4179038-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0410818A
Age:24 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Drug Ineffective
Initial or Prolonged	Feeling Hot
	Flushing

Nystagmus

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
INTRAVENOUS	4MG See dosage text	Health Professional	Zofran	PS	Glaxosmithkline	
10MG Single dose	1 DAY		Decadron	C		
1MG Single dose	1 DAY		Ativan	C		

Date:09/05/03ISR Number: 4180103-XReport Type:Expedited (15-DaCompany Report #ES-GLAXOSMITHKLINE-B0307701A
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Dose	Duration	Report Source	Product	Role	Manufacturer	Route
Life-Threatening	Priapism				Zofran	PS	Glaxosmithkline	
INTRAVENOUS		24MG per day	6 DAY		Ranitidine	SS	Glaxosmithkline	
INTRAVENOUS		50MG per day	6 DAY		Chlorpromazine	SS	Glaxosmithkline	
INTRAVENOUS		25MG per day	3 DAY		Alprazolam	C		ORAL
.5MG per day	1 DAY							

Date:09/08/03ISR Number: 4180908-5Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0308311A
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Dose	Duration	Report Source	Product	Role	Manufacturer	Route
Other	Depressed Level Of Consciousness				Ondansetron	PS	Glaxosmithkline	
INTRAVENOUS		4MG Single dose	1 DAY					
	Dyspnoea				Propofol	C		
INTRAVENOUS		200MG per day						

	Swollen Tongue		Suxamethonium	C	Glaxosmithkline	
INTRAVENOUS	100MG per day					

Date:09/16/03ISR Number: 4190949-XReport Type:Expedited (15-DaCompany Report #2003037115
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Angioneurotic Oedema	Foreign	Atarax (Tablet)			
	Chest Discomfort	Health	(Hydroxyzine			
	Nervous System Disorder	Professional	Hydrochloride)	PS		ORAL
25 MG ORAL						
			Ondansetron			
			Hyrochloride			
			(Ondansetron			
			Hydrochloride)	SS		
INTRAVENOUS	8 MG					
INTRAVENOUS						
			Oxaliplatin			
			(Oxaliplatin)	SS		
INTRAVENOUS	160 MG					
INTRAVENOUS						
			Methylprednisolone			
			Sodium Succinate			
			(Methylprednisolone			
			Sodium Succinate)	SS		
INTRAVENOUS	INTRAVENOUS					

Date:09/22/03ISR Number: 4190406-0Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041733A
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Diplopia		Zofran	PS	Glaxosmithkline	ORAL
2 DAY						
Initial or Prolonged	Visual Disturbance		Zofran	C	Glaxosmithkline	
INTRAVENOUS	1 DAY					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/24/03ISR Number: 4192998-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0414767A
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Spontaneous		Zofran	PS	Glaxosmithkline	ORAL	1TAB	Single
	Complications Of Maternal						dose	1 DAY
	Exposure To Therapeutic Drugs							
	Maternal Drugs Affecting Foetus							

Date:09/30/03ISR Number: 4198010-5Report Type:Expedited (15-DaCompany Report #AU-GLAXOSMITHKLINE-B0300590A
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Balance Disorder		Zofran	PS	Glaxosmithkline	INTRAVENOUS		
	Deafness		Buscopan	C			INTRAVENOUS	20MG Per day 13 DAY
	Dysarthria		Temazepam	C		ORAL	7	DAY
	Neuropathy		Serc	C		ORAL	6MG per day	7 DAY
			Omeprazole	C			INTRAVENOUS	40MG Per day 14 DAY
			Aminophylline	C		ORAL	16	DAY

Date:09/30/03ISR Number: 4198019-1Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0309552A
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Jaundice		Zofran	PS	Glaxosmithkline	ORAL	1	DAY
	Liver Function Test Abnormal		Anaesthetics	C		ORAL		

Date:09/30/03ISR Number: 4198026-9Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0309876A
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Hypertension Mydriasis Pallor Syncope	Consumer	Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG Single dose	1 DAY
Other			Caelyx	SS		INTRAVENOUS	80MG Single dose	1 DAY

Date:09/30/03ISR Number: 4203681-0Report Type:Expedited (15-DaCompany Report #2003037115
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Angioneurotic Oedema Chest Discomfort Nervous System Disorder Urticaria	Foreign Health Professional	Atarax (Tablet) (Hydroxyzine Hydrochloride)	PS		ORAL	25 MG ORAL	
			Ondansetron Hydrochloride (Ondansetron Hydrochloride)	SS		INTRAVENOUS	8 MG,	INTRAVENOUS
			Oxaliplatin (Oxaliplatin)	SS		INTRAVENOUS	160 MG,	INTREVENOUS
			Methylprednisolone Sodium Succinate (Methylprednisolone					

				Sodium Succinate)	SS			
INTRAVENOUS	INTRAVENOUS							
				Dexchlorpheniramine Maleate (Dexchlorpheniramine Maleate)	C			

Date:10/08/03ISR Number: 4205979-9Report Type:Expedited (15-DaCompany Report #6190
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Erythema Multiforme	Literature	Vancomycin	PS				
INTRAVENOUS							1 G BID	3 DAY
	Shock	Health Professional	Acyclovir	SS				
	Toxic Epidermal Necrolysis		Etoposide	SS				
			Dexamethasone	SS				
			Gentamicin	SS				
			Fluconazole	SS				
			Ceftazidime	SS				
			Imipenem	SS				
			Idarubicin	SS				
			Ara-C	SS				
			Ondansetron	SS				

Date:10/10/03ISR Number: 4205875-7Report Type:Expedited (15-DaCompany Report #AU-GLAXOSMITHKLINE-B0300590A
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Balance Disorder		Zofran	PS	Glaxosmithkline			
INTRAVENOUS								
Initial or Prolonged	Deafness		Buscopan	C				
INTRAVENOUS							20MG Per day	13 DAY
	Dysarthria		Temazepam	C		ORAL		
11 DAY								
	Neuropathy		Serc	C		ORAL		
6MG per day	7 DAY							
			Omeprazole	C				
INTRAVENOUS							40MG Per day	14 DAY
			Amitriptyline	C		ORAL		
16 DAY								

Date:10/14/03ISR Number: 4209846-6Report Type:Direct Company Report #CTU 203798
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia		Zofran (Ondansetron) 4mg Vial					
	Feeling Abnormal							
	Loss Of Consciousness		Glaxosmithkline	PS	Glaxosmithkline	INTRAVENOUS	4 MG	ONCE
						BOLUS		
						INTRAVENOUS		
						BOLUS		
			Prozac	C				
			Vioxx	C				
			Skelaxin	C				
			Seroquel	C				

Date:10/15/03ISR Number: 4210412-7Report Type:Expedited (15-DaCompany Report #2003-07-0220
Age:65 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dyspnoea	Foreign	Polaramine					
Life-Threatening	Supraventricular Extrasystoles	Health Professional Other	(Dexchlorpheniramine Maleate) Injectable Solution	PS		INTRAVENOUS		INTRAVENOUS
			Methylprednisolone Injectable	SS		INTRAVENOUS		INTRAVENOUS

				Paclitaxel Injectable	SS		
INTRAVENOUS	INTRAVENOUS						
				Ranitidine Hydrochloride Injectable	SS		
INTRAVENOUS	INTRAVENOUS						
				Zophren (Ondansetron) Injectable Solution	SS		
INTRAVENOUS	INTRAVENOUS						
				Paraplatin	C		
				Fluoro-Uracil	C		

Date:10/16/03ISR Number: 4209783-7Report Type:Expedited (15-DaCompany Report #IE-GLAXOSMITHKLINE-B0311507A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Respiratory Arrest		Zofran	PS	Glaxosmithkline	UNKNOWN		

Date:10/22/03ISR Number: 4213823-9Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0312063A
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Blindness		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	4MG per day	1 DAY
Other	Migraine		Augmentin	C	Glaxosmithkline	UNKNOWN		

Date:10/24/03ISR Number: 4217121-9Report Type:Expedited (15-DaCompany Report #ES-GLAXOSMITHKLINE-B0311664A
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Arrest		Zofran	PS	Glaxosmithkline	INTRAVENOUS		
	Hypotension							
	Ventricular Tachycardia							

Date:10/24/03ISR Number: 4217485-6Report Type:Direct Company Report #CTU 204543
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anaphylactic Reaction		Zofran 4 Mg	PS		INTRAVENOUS	4 MG IVP (1 Initial or Prolonged DOSE)	

Date:10/27/03ISR Number: 4220731-6Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11953254
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cyanosis		Taxol Inj Syn	PS	Bristol-Myers Squibb Company			
Life-Threatening	Death					INTRAVENOUS		1 DAY
	Dizziness		Paraplatin	SS	Bristol-Myers Squibb Company			
	Hypotension					INTRAVENOUS		1 DAY
	Malaise		Polaramine	SS		INTRAVENOUS		
	Tonic Convulsion		Tagamet	SS		INTRAVENOUS		
			Plitican	SS		INTRAVENOUS		
			Zophren	SS		INTRAVENOUS	2 mg/ml	
			Dexamethasone	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/28/03ISR Number: 4219595-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0312397A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Vith Nerve Paralysis		Zophren	PS	Glaxosmithkline			

Date:10/28/03ISR Number: 4223457-8Report Type:Expedited (15-DaCompany Report #B0311559A
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Binocular Eye Movement	Literature	Zofran (Formulation Unknown)					
	Disorder	Health						
	Blood Pressure Increased	Professional	(Ondansetron Hydrochloride)	PS		INTRAVENOUS	4 MG /	INTRAVENOUS
	Clonus							
	Coma							
	Drug Ineffective		Midazolam	C				
	Dystonia		Fentanyl	C				
	Encephalopathy		Propofol	C				
	Extrapyramidal Disorder		Isoflurane	C				
	Grimacing		Nitrous Oxide	C				
	Heart Rate Increased							
	Hypoventilation							
	Memory Impairment							
	Muscle Rigidity							
	Oculogyration							
	Oxygen Saturation Decreased							
	Retching							
	Upper Motor Neurone Lesion							

Date:10/30/03ISR Number: 4222192-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0311988A
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain		Zophren	PS	Glaxosmithkline	OTHER		

Initial or Prolonged	Aspiration	Oncovin	SS	
INTRAVENOUS				
	Intestinal Obstruction	Adriamycin	C	
INTRAVENOUS				
	Vomiting	Dexamethasone	C	
INTRAVENOUS				

Date:10/31/03ISR Number: 4223385-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0304036A
Age:65 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dyspnoea		Ranitidine	PS	Glaxosmithkline			
INTRAVENOUS								1 DAY
Life-Threatening	Supraventricular		Zophren	SS	Glaxosmithkline			
1 DAY								
	Extrasystoles		Polaramine	SS				
INTRAVENOUS								1 DAY
			Methylprednisolone	SS				
INTRAVENOUS								1 DAY
			Paclitaxel	SS				
INTRAVENOUS								1 DAY
			Paraplatine	C				
			Fluorouracil	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/04/03ISR Number: 4225466-1Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0432090A
Age:11 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dizziness		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Single	
Life-Threatening	Headache						dose	0 DAY
Disability	Oxygen Saturation		Cefuroxim	C	Glaxosmithkline	INTRAVENOUS		
Other	Decreased		Biaxin	C				
	Respiratory Failure							

Date:11/07/03ISR Number: 4232067-8Report Type:Direct Company Report #CTU 205582
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Headache		Ondansetron	PS				

Date:11/14/03ISR Number: 4235380-3Report Type:Direct Company Report #CTU 206121
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Urticaria		Zofran 2mg/Ml 2.0ml Mdv (Glaxo)	PS	Glaxo	INTRAVENOUS	4MG IV PUSH Q	6-8 PRN
			Tpn	C				
			Ambien	C				
			Phenergan	C				
			Vicodin	C				
			Belladin	C				
			Lorazepam	C				

Date:11/14/03ISR Number: 4235696-0Report Type:Expedited (15-DaCompany Report #6539
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dermatitis Bullous		Docetaxel	PS				
						INTRAVENOUS	100 MG, IV	1 DAY
			Pamidronate Disodium	SS				
						INTRAVENOUS	90 MG, IV	1 DAY
			Ondansetron	SS		ORAL	8 MG, PO/IV	

Date:11/21/03ISR Number: 4239413-XReport Type:Direct Company Report #CTU 206551
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tachycardia		Ondansetron 2 Mg/Ml	PS				
						INTRAVENOUS	4 MG IV PUSH	
							Q 8 H	
			Iv Hydration	C				

Date:12/01/03ISR Number: 4243303-6Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0042483A
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Diarrhoea		Zofran	PS	Glaxosmithkline	ORAL	8MG Twice per	
Hospitalization -	Fatigue							
							day	9 DAY
Initial or Prolonged	Headache		Carboplatin	C				
						INTRAVENOUS	950MG	
	Nausea							
							cumulative	
							dose	3 DAY
			Taxol	C				
						INTRAVENOUS	320MG Per day	3 DAY

				Fortecortin	C		
UNKNOWN	20MG per day						
				Navoban	C		
UNKNOWN	5MG per day						

Date:12/02/03ISR Number: 4243886-6Report Type:Expedited (15-DaCompany Report #DK-GLAXOSMITHKLINE-B0315457A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Acne		Ondansetron	PS	Glaxosmithkline			
	Alopecia		Trandate	SS	Glaxosmithkline			
	Aplasia Cutis Congenita		Propyl-Thyracil	SS				
	Maternal Drugs Affecting Foetus							
	Twin Pregnancy							

Date:12/03/03ISR Number: 4246123-1Report Type:Direct Company Report #CTU 207325
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Extrapyramidal Disorder		Zofran	PS				
INTRAVENOUS	4 MG IV							
Initial or Prolonged	Headache		Oral Contraceptives	C				
	Musculoskeletal Pain		Mdi	C				
	Nausea							
	Neck Pain							

Date:12/12/03ISR Number: 4250917-6Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0442575A
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dehydration		Zofran	PS	Glaxosmithkline			
UNKNOWN								
Initial or Prolonged	Fatigue		Compazine	SS	Glaxosmithkline			
UNKNOWN								
	Nausea							
	Vomiting							

Date:12/17/03ISR Number: 4252748-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0316882A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Culture Positive		Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG Per day	5 DAY
Initial or Prolonged	Escherichia Infection		Primperan	SS	Glaxosmithkline	INTRAVENOUS	2UNIT Per day	
	Febrile Bone Marrow		Efferalgan Codeine	SS		ORAL	3UNIT Per day	12 DAY
	Aplasia		Effexor	SS		ORAL	2UNIT Per day	
	Pneumocystis Jiroveci		Vincristine	SS		INTRAVENOUS	2MG Cyclic	
	Infection		Vogalene	SS		ORAL	15MG Per day	5 DAY
	Septic Shock		Uromitexan	C				
	Small Intestinal Obstruction		Endoxan	C				
			Aracytine	C				
	Streptococcal Infection		Methotrexate	C				
			Adriablastin	C				
			Prednisone	C				

Date:12/18/03ISR Number: 4255492-8Report Type:Expedited (15-DaCompany Report #FRWYE458812DEC03
Age:47 YR Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged

Other

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Small Intestinal Obstruction	Health Professional Other	Effexor (Venlafaxine Hydrochloride, Unspec, 0)	PS		ORAL	2 DOSE 1X PER	1 DAY
			Efferalgan Codeine (Paracetamol/Codeine Phosphate)	SS		ORAL	3 DOSE 1X PER	1 DAY 12 DAY
			Primperan (Metoclopramide)	SS			INTRAVENOUS 2 DOSE 1X PER	1 DAY
			Vincristine Sulfate (Vincristine Sulfate)	SS			INTRAVENOUS 2 MG 1X PER 1	CYC
			Vogalene (Metopimazine)	SS		ORAL	15 MG 1X PER	1 DAY 5 DAY
			Zophren (Ondansetron Hydrochloride)	SS			INTRAVENOUS 8 MG 1X PER 1	DAY 5 DAY

Date:12/19/03ISR Number: 4255093-1Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0317127A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Pulmonary Oedema Myocardial Infarction	Health Professional	Zophren	PS	Glaxosmithkline			

Date:12/23/03ISR Number: 4258688-4Report Type:Direct Company Report #CTU 208676
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Generalised Erythema		Dexamethasone Inj	PS				
INTRAVENOUS							20MG/100ML IV	
Initial or Prolonged	Palpitations							
D5W								
	Wheezing		Ondansetron Inj	SS				
INTRAVENOUS							32 MG /100 ML	
D5W IV								
			Prochlorperazine	C				
			Rabeprazole	C				
			Lortab	C				

Date:12/30/03ISR Number: 4260539-9Report Type:Expedited (15-DaCompany Report #SE-GLAXOSMITHKLINE-B0317215A
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyskinesia		Zofran	PS	Glaxosmithkline	ORAL		
1TAB								
	Extrapyramidal Disorder							
Alternate								
days							3	MON
			Ketogan	SS				
UNKNOWN								
			Dialysis	C				
UNKNOWN								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/07/04ISR Number: 4265659-0Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0432090A
Age:11 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dizziness	Health	Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Single	
Life-Threatening	Headache	Professional					dose	0 DAY
Disability	Oxygen Saturation		Cefuroxim	C	Glaxosmithkline	INTRAVENOUS		
Other	Decreased Respiratory Failure		Biaxin	C				

Date:01/09/04ISR Number: 4268698-9Report Type:Expedited (15-DaCompany Report #2003186497CA
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Failure	Foreign	Pharmorubicin					
Other	Cardiotoxicity	Health	(Epirubicin					
	Dyspnoea	Professional	Hydrochloride)					
	Hypotension	Other	Powder, Sterile	PS		INTRAVENOUS	100 MG, D	
	Pulmonary Oedema						1&8, EVERY 4	
							WEEKS, IV	
			Adrucil (Fluorouracil)					
			Solution, Sterile	SS		INTRAVENOUS	850 MG, D	
							1&8, EVERY 4	
							WEEKS, IV	
			Procytox (Cyclophosphamide)	SS		ORAL	125 MG, D 1	
							4,E VERY 4	
							WEEKS, ORAL	
			Novotrimel Ds (Sulfamethoxazole,					

		Trimethoprim)	SS	ORAL

800 MG,

D10-20, EVERY

4 WEEKS, ORAL

		Zofran (Ondansetron Hydrochloride)	SS	ORAL

24 MG, D1-8,

EVERY 4

WEEKS, ORAL

		Dexamethasone (Dexamethasone)	SS	

INTRAVENOUS 10 MG, D 1&8,

EVERY 4

WEEKS, IV

		Losec	C	
		Paroxetine Hydrochloride (Paroxetine Hydrochloride)	C	
		Desmopressin (Desmopressin)	C	
		Vitamin E	C	
		Oxazepam	C	

Date:01/12/04ISR Number: 4269581-5Report Type:Expedited (15-DaCompany Report #2003186498CA
Age:50 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Atrial Fibrillation
	Cardiac Failure
	Cardiotoxicity
	Congestive Cardiomyopathy

		Ejection Fraction Decreased Mitral Valve Incompetence Tricuspid Valve Incompetence Ventricular Hypokinesia Ventricular Tachycardia	Report Source Foreign Health Professional Other	Product	Role	Manufacturer	Route
Dose	Duration						
INTRAVENOUS	95 MG, CYCLE 6, D1 & D 8, Q4 WKS, IV			Pharmorubicin (Epirubicin Hydrochloride) Powder, Sterile	PS		
INTRAVENOUS	800 MG, CYCLE 6, D1 & D 8, Q4WKS, IV			Adrucil (Fluorouracil) Solution, Sterile	SS		
125 MG, CYCLE 6, D1 4, Q 4 WKS, ORAL				Procytox(Cyclophosphamide)	SS		ORAL
800 MG, BID, D 10-20, Q 4 WKS, ORAL				Sulfamethoxazole W/Trimethoprim(Sulfatmethoxazole, Trimethoprim)	SS		ORAL
8 MG, TID, D 1-8, Q 4 WKS, ORAL				Zofran (Ondansetron Hydrochloride)	SS		ORAL
INTRAVENOUS	10 MG, QD, D			Dexamethasone (Dexamethasone)	SS		

1& D 8, Q 4

WKS, IV

Bromazepam	C
Nexium	C
Trazodone Hydrochloride	C
Vitamin	C
Venlafaxine Hydrochloride (Venlafaxine Hydrochloride)	C

Date:01/14/04ISR Number: 4269980-1Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12476594
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Health Professional	Holoxan	PS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Uromitexan	SS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Zophren	SS		INTRAVENOUS		
			Cortancyl	SS		INTRAVENOUS		
			Novantrone	C		INTRAVENOUS		
			Navelbine	C		INTRAVENOUS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/14/04ISR Number: 4270438-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0419748A
Age:78 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Back Pain		Zofran Injection	PS	Glaxosmithkline	INTRAVENOUS	1MG Single	
Initial or Prolonged	Blood Pressure Decreased							
dose							1	DAY
Other	Dizziness							
	Flushing							
	Tachycardia							

Date:01/14/04ISR Number: 4270460-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0318787A
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Renal Failure	Consumer	Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG Per day	5 DAY
Initial or Prolonged	Status Epilepticus		Holoxan	SS		INTRAVENOUS	800MGM2 per	
day							5	DAY
			Uromitexan	SS		INTRAVENOUS	1000MGM2 per	
day							5	DAY
			Navelbine	C	Glaxosmithkline	INTRAVENOUS	20MGM2 per	
day							1	DAY
			Novantrone	C		INTRAVENOUS		1 DAY

Date:01/14/04ISR Number: 4270461-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0318811A
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Haemolytic Uraemic		Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG Cyclic	366 DAY

Initial or Prolonged		Syndrome		Gemzar	SS		
INTRAVENOUS	1680MG Cyclic 363 DAY						
		Thrombocytopenia		Coversyl	C		ORAL
1UNIT Per day							
				Aspegic	C		ORAL
1UNIT Per day							
				Lasilix Faible	C	Glaxosmithkline	ORAL
1UNIT Per day							

Date:01/14/04ISR Number: 4273002-6Report Type:Expedited (15-DaCompany Report #2003186497CA
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Cardiac Failure	Foreign	Pharmorubicin			
Other	Cardiotoxicity	Health	(Epirubicin			
	Hypotension	Professional	Hydrochloride)			
	Pulmonary Oedema	Other	Powder, Sterile	PS		
INTRAVENOUS	100 MG, D1&					
8, EVERY 4						
WEEKS, IV						
			Adrucil			
			(Fluorouracil)			
			Solution, Sterile	SS		
INTRAVENOUS	850 MG, D1 &					
8, EVERY 4						
WEEKS, IV						
			Procytox			
			(Cyclophosphamide)	SS		ORAL
125MG, D 1 4,						
EVERY 4						
WEEKS, ORAL						
			Novotrimel Ds			
			(Sulfamethoxazole,			
			Trimethropim)	SS		ORAL
800 MG,						
D10-20, EVERY						
4 WEEKS, ORAL						
			Zofran (Ondansetron			
			Hydrochloride)	SS		ORAL
24 MG, D1-8,						

EVERY 4

WEEKS, ORAL

				Dexamethasone (Dexamethasone)	SS		
INTRAVENOUS	10 MG, D1& 8,						

EVERY 4WEEKS,

IV

				Losec	C		
				Paroxetine Hydrochloride (Paroxetine Hydrochloride)	C		
				Desmopressin (Desmoprresin)	C		
				Vitamin E	C		
				Oxazepam	C		

Date:01/15/04ISR Number: 4274221-5Report Type:Expedited (15-DaCompany Report #2003186498CA
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Arrhythmia	Foreign	Pharmorubicin					
Other	Atrial Fibrillation	Health	(Epirubicin					
	Cardiac Failure	Professional	Hydrochloride)					
	Congestive Cardiomyopathy	Other	Powder, Sterile	PS				
INTRAVENOUS	95 MG, CYCLE							
	Gastrooesophageal Reflux							
6 DL, & D 8,								
	Disease							
Q4 WKS, IV								
	Hypokinesia		Adrucil					
	Mitral Valve Incompetence		(Fluorouracil)Soluti					
	Tricuspid Valve		on, Sterile	SS				
INTRAVENOUS	800 MG, CYCLE							
	Incompetence							
6, DL & D 8,								
	Ventricular Tachycardia							
Q4WKS, IV								
			Procytox (Cyclophosphamide)	SS		ORAL		
125 MG, CYCLE								

6, DL 4 Q 4 WKS, ORAL		Sulfamethoxazole W/Trimethoprim (Sulfamethoxazole, Trimethoprim)	SS	ORAL
800 MG, BID, D 10-20 Q, 4 WKS, ORAL		Zofran (Ondansetron Hdyrochloride)	SS	ORAL
8 MG, TID, D 1-8, Q4 WKS, ORAL		Dexamethasone (Dexamethasone)	SS	
INTRAVENOUS	10 MG, QD, D L & D 8, Q 4 WKS, IV	Bromazepam	C	
		Nexium	C	
		Trazodone Hydrochloride	C	
		Vitamin E	C	
		Venlafaxine Hydrochloride (Venlafaxine Hydrochloride)	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/22/04ISR Number: 4277443-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0319476A
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Thrombocytopenia	Consumer	Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG Twice per day	
			Claforan	SS		INTRAVENOUS	2G Six times per day	6 DAY
			Tiberal	SS		INTRAVENOUS	1G Twice per day	6 DAY
			Mopral	SS		ORAL	20MG Per day	
			Lovenox	SS		ORAL	40MG Per day	4 DAY
			Perfalgan	SS	Glaxosmithkline	INTRAVENOUS	1G Four times per day	
			Primperan	C	Glaxosmithkline			
			Depakine	C				
			Morphine	C				
			Vancomycine	C				
			Rifater	C		ORAL		
			Danaparoide Sodique	C				

Date:01/22/04ISR Number: 4277444-4Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0319483A
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Consumer	Zophren	PS	Glaxosmithkline	ORAL		
			Motilium	SS		ORAL		
	Aspartate Aminotransferase Increased		Caelyx	SS		INTRAVENOUS	35MG Single dose	1 DAY
			Ziagen	C	Glaxosmithkline	ORAL	300MG Twice	

	Blood Alkaline					
per day						
	Phosphatase Increased		Kaletra	C		ORAL
3UNIT Twice						
	Gamma-Glutamyltransferase					
per day						
	Increased		Viread	C		ORAL
245MG Per day						
	Hyperaesthesia					
	Pain					

Date:01/23/04ISR Number: 4278400-2Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12476594
Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Convulsion	Health Professional	Holoxan	PS	Bristol-Myers Squibb Company	
INTRAVENOUS						
			Uromitexan	SS	Bristol-Myers Squibb Company	
INTRAVENOUS						
			Zophren	SS		
INTRAVENOUS						
			Solu-Medrol	SS		
INTRAVENOUS						
			Novantrone	C		
INTRAVENOUS						
			Navelbine	C		
INTRAVENOUS						

Date:01/26/04ISR Number: 4280143-6Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040102969
Age:39 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased

		Blood Alkaline Phosphatase Increased Burning Sensation	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Gamma-Glutamyltransferase Increased Hyperaesthesia	Foreign Health Professional	Motilium (Domepridone) Tablets	PS		ORAL	ORAL
		Pain		Caelyx (Doxorubicin Hydrochloride) Liposome Injection	SS			INTRAVENOUS 35 MG, IN 1 DAY, INTRAVENOUS
				Zophren (Ondansetron Hydrochloride) Unknown	SS		ORAL	ORAL
				Ziagen (Abacavir Sulfate) Kalerta (Kalerta) Viread (Idoxuridine)	C C C			

Date:01/27/04ISR Number: 4279464-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0494497A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Colitis Ischaemic		Zofran	PS	Glaxosmithkline		UNKNOWN
			Unspecified Medication	C			

Date:01/27/04ISR Number: 4280690-7Report Type:Expedited (15-DaCompany Report #04H-163-0247688-00
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent	Chest Discomfort Flushing Hyperventilation	Health Professional	Morphine Sulfate Injection 4mg/Ml (Morphine Sulfate				

Impairment/Damage				Injection, Usp) (Morphine Sulfate)	PS		
INTRAVENOUS	4 MG, ONCE,						
INTRAVENOUS							
				Ondansetron Hydrochloride	SS		
INTRAVENOUS	ONCE,						
INTRAVENOUS							

Date:01/27/04ISR Number: 4281157-2Report Type:Expedited (15-DaCompany Report #US-SHR-04-020001
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension Abdominal Pain Liver Function Test	Study Health Professional	Leukine (Sargramostin) Injection	PS				
SUBCUTANEOUS	5 UG/KG/DAY (DAY 3-APHERISIS),							
SUBCUTANEOUS								
	Abnormal Pyrexia Venoocclusive Liver Disease Weight Increased		Interleukin-2 (Interleukin-2)	SS				
SEE IMAGE								
			G-Csf (Granulocyte Colony Stimulating Factor)	SS				
SUBCUTANEOUS	10 UG/KG/DAY (DAY 10-APHERISIS)							

,

SUBCUTANEOUS

DAY 0

250 MG/M2, 1

DOSE (DAY2)

250 MG/M2

(DAY-3 & -2)

50 MG/M2

(DAY-5 & -4)

SEE IMAGE

8 MG, 4X/DAY,

D-9 THROUGH ,

ORAL

1MG/KG/Q6H

DAY -8

THROUGH - 6,

ORAL

4 GM/M2/3

DIVIDED DOSES

(DAY 1)

Peripheral Blood Stem Cells (Incubated With Il-2)()	SS	
Taxol (Paclitaxel)	SS	
Thiotepa (Thiotepa)	SS	
Melphalan (Melphalan)	SS	
Dilantin (Phenytoin Sodium)	SS	ORAL
Zofran /Gfr/(Ondansetron Hydrochloride)	SS	ORAL
Busulfan (Busulfan)	SS	ORAL
Mesna (Mesna) 4gm/M2	SS	
Cyclophosphamide		

				(Cyclophosphamide)	C		
4 GM/M2, 1							
DOSE (DAY 1)							
				Voriconazole (Voriconazole)	C		
				Caspofungin (Caspofungin)	C		

Date:01/28/04ISR Number: 4280186-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0318787A
Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Epilepsy		Zophren	PS	Glaxosmithkline			
INTRAVENOUS	8MG Per day						5	DAY
Initial or Prolonged	Status Epilepticus		Holoxan	SS				
INTRAVENOUS	800MGM2 per day						5	DAY
			Uromitexan	SS				
INTRAVENOUS	1000MGM2 per day						5	DAY
			Solumedrol	SS				
INTRAVENOUS	3G per day						5	DAY
			Navelbine	C	Glaxosmithkline			
INTRAVENOUS	20MGM2 per day						1	DAY
			Novantrone	C				
INTRAVENOUS	8MGM2 per day						1	DAY

Date:01/28/04ISR Number: 4280189-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0319854A
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Acute Pulmonary Oedema		Zophren	PS	Glaxosmithkline			
INTRAVENOUS	8MG per day						1	DAY
Initial or Prolonged	Dyspnoea		Tegeline	SS	Glaxosmithkline			
INTRAVENOUS							5	DAY
	Haemorrhage		Oncovin	SS				
INTRAVENOUS	2MG per day						1	DAY
	Lung Disorder		Victan	SS		ORAL	2MG Per day	
	Myalgia		Diffu-K	SS	Glaxosmithkline	ORAL	2UNIT Per day	
	Painful Respiration		Cortancyl	SS		ORAL		

	Paraesthesia	Stablon	C	ORAL

				Depamide	C		ORAL
				Lasilix	C	Glaxosmithkline	ORAL
40MG Unknown							
				Isoptine	C		ORAL
				Nitriderm	C	Glaxosmithkline	
TRANSDERMAL							
				Noroxine	C	Glaxosmithkline	ORAL
14 DAY							
				Perfalgan	C	Glaxosmithkline	
INTRAVENOUS	10 DAY						

Date:01/30/04ISR Number: 4284695-1Report Type:Expedited (15-DaCompany Report #WAES 0401ESP00002
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Rash Erythematous	Foreign	Cap Aprepitant 125			
		Study	Mg	PS		ORAL
SEE IMAGE						
		Health	Cap Placebo			
		Professional	(Unspecified)	SS		ORAL
DAILY/PO						
			Tab Dexamethasone 4			
			Mg	SS		ORAL
12						
MG/DAILY/PO						
			Cap Ondansetron 8 Mg	SS		ORAL
8 MG/BID/PO						
			Cap Placebo			
			(Unspecified)	SS		ORAL
DAILY/PO						
			Tab Dexamethasone 4			
			Mg	SS		ORAL
12						
MG/DAILY/PO						
			Cap Ondansetron 8 Mg	SS		ORAL
8 MG/BID/PO						
			Cyclophosphamide (+)			
			Epirubicin	C		
			Lorazepam	C		

Date:02/02/04ISR Number: 4283592-5Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0320508A
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Per day	2 DAY
	Convulsion		Sevredol	C	Glaxosmithkline	UNKNOWN		1 DAY
	Loss Of Consciousness							
	Rash							
	Respiratory Arrest							

Date:02/03/04ISR Number: 4284140-6Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0496016A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Exposure During		Zofran	PS	Glaxosmithkline	ORAL	8MG Twice per day	
	Pregnancy							
	Eye Haemorrhage		No Concurrent Medications	C				

Date:02/04/04ISR Number: 4285114-1Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0319476A
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Disease Recurrence		Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG Twice per day	
	Empyema							
	Meningioma		Claforan	SS		INTRAVENOUS	2G Six times per day	6 DAY
	Thrombocytopenia							
			Tiberal	SS		INTRAVENOUS	1G Twice per	

day	6 DAY					
			Mopral	SS		ORAL
20MG Per day						
			Lovenox	SS		ORAL
40MG Per day	4 DAY					
			Perfalgan	SS	Glaxosmithkline	
INTRAVENOUS	1G Four times					
per day						
			Primperan	SS	Glaxosmithkline	
INTRAVENOUS	1G Four times					
per day						
			Depakine	SS		ORAL
500MG Four						
times per day						
			Morphine	SS		
			Vancomycine	C		
			Rifater	C		ORAL
			Danaparoide Sodique	C		

Date:02/10/04ISR Number: 4292989-9Report Type:Expedited (15-DaCompany Report #GBR-2004-0000869
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Bruxism	Foreign	Morphine (Morphine			
Hospitalization -	Hypertonia	Health	Sulfate) Ir Tablet	PS		ORAL
30 MG, DAILY,						
Initial or Prolonged	Hypotension	Professional				
ORAL						
Other	Loss Of Consciousness	Other	Ondansetron			
	Malaise		(Ondansetron)	SS		
INTRAVENOUS	4 MG, TWICE,					
	Nausea					
INTRAVENOUS						
	Rash		Paracetamol	C		
	Respiratory Arrest		Ferrous Sulphate			
	Respiratory Depression		(Ferrous Sulfate)	C		
	Tachycardia		Prednisolone			
	Vomiting		(Prednisolone)	C		
			Methotrexate			
			(Methotrexate)	C		
			Sulphasalazine			

			(Sulfasalazine)	C			

Date:02/12/04ISR Number: 4293664-7Report Type:Expedited (15-DaCompany Report #CA-BRISTOL-MYERS SQUIBB COMPANY-12495446
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Gastritis Ileus	Health Professional	Cisplatin	PS	Bristol-Myers Squibb Company	INTRAVENOUS		2 DAY
			Pemetrexed Disodium	SS		INTRAVENOUS	days 1 and 8	4 DAY
			Gemcitabine	SS				
			Zofran	SS				4 DAY
			Amitriptyline	C				
			Decadron	C				4 DAY

Date:02/12/04ISR Number: 4293744-6Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0321947A
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bruxism		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Unknown	1 DAY
Hospitalization - Initial or Prolonged	Convulsion Rash		Prednisolone	C	Glaxosmithkline	ORAL	5MG per day	
			Ferrous Sulphate	C	Glaxosmithkline	ORAL	200MG per day	
	Respiratory Arrest		Paracetamol	C	Glaxosmithkline	ORAL	1G per day	
			Methotrexate	C		ORAL	10MG per day	
			Sulphasalazine	C		ORAL	50MG per day	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/04ISR Number: 4294658-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0497744A
Age:1 DY Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Exposure During Pregnancy Drug Withdrawal Syndrome Feeling Jittery Tremor		Zofran	PS	Glaxosmithkline			

Date:02/16/04ISR Number: 4295097-6Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0320508A
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased	Health	Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Per day	2 DAY
Hospitalization - Initial or Prolonged	Convulsion	Professional	Sevredol	C	Glaxosmithkline	ORAL	30MG per day	1 DAY
Other	Haemoglobin Decreased		Prednisolone	C	Glaxosmithkline	ORAL		
	Loss Of Consciousness		Ferrous Sulphate	C	Glaxosmithkline	ORAL		
	Post Procedural Pain		Paracetamol	C	Glaxosmithkline			
	Rash		Sulphasalazine	C		ORAL		
	Respiratory Arrest		Diclofenac	C		ORAL	25MG per day	
	Vomiting		Thyroxine	C	Glaxosmithkline	ORAL		
			Folic Acid	C		ORAL		

Date:02/16/04ISR Number: 4295133-7Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0321939A
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Eczema		Zophren	PS	Glaxosmithkline	INTRAVENOUS	2UNIT Per day	1 DAY
	Prurigo		Plitican	SS		INTRAVENOUS	2UNIT Per day	1 DAY
	Pruritus		Carbolevure	SS		ORAL	2UNIT Per day	YR
	Rash Erythematous		Gemzar	SS		INTRAVENOUS	1750MG Per	

		Rash Papular						
day	1	DAY						
		Scratch		Diovenor	SS			ORAL
600MG Per day		YR						
		Toxic Skin Eruption						

Date:02/19/04ISR Number: 4300584-8Report Type:Direct Company Report #CTU 212599
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Febrile Neutropenia		Odansetron	PS				
1ST COURSE								
Initial or Prolonged			Dexamethasone	SS				
			Gemcitabine	SS				
			Vinorelbine	SS				

Date:02/19/04ISR Number: 4301416-4Report Type:Expedited (15-DaCompany Report #2004198784FR
Age:22 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Alanine Aminotransferase
Initial or Prolonged	Increased
	Aspartate
	Aminotransferase
	Increased
	Blood Bilirubin Increased
	Cholestasis
	Gamma-Glutamyltransferase
	Increased

Hepatocellular Damage
Jaundice

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Health	Solu-Medrol (Methylprednisolone)	PS				
Professional Other	Azantac (Ranitidine Hydrochloride)	SS		ORAL		
	Visceralgine Forte (Metamizole Sodium, Tiemonium Methylsulphate)	SS		ORAL	1 DF, QD,	ORAL
	Zyloric(Allopurinol)	SS		ORAL	900 MG, ORAL	
	Ciflox (Ciprofloxacin)	SS			INTRAVENOUS	200 MG, BID, IV
	Zophren (Ondansetron Hydrochloride)	SS			INTRAVENOUS	16 MG, BID, IV
	Rocephin (Ceftriaxone Sodium)	SS				
	Zovirax(Aciclovir)	SS				
	Primperan(Metoclopramide)	SS				
	Duphalac(Lactulose)	SS				
	Acupan(Nefopam Hydrochloride)	SS				
	Trimebutine (Trimebutine)	SS				
	Mopral	C				
	Oncovin	C				
	Endoxan	C				
	Cerubidine	C				
	Methotrexate	C				
	Aracytine	C				

Date:02/20/04ISR Number: 4300386-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0322744A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Akinesia	Consumer	Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG Single	
Hospitalization -	Arteriospasm Coronary							
dose							1	DAY
Initial or Prolonged	Chest Discomfort		Endoxan	C				
1155MG Single								
	Coma							
dose								
	Ejection Fraction		Mesna	C				
	Decreased		Solumedrol	C				
	Myocardial Infarction		Cotareg	C				
	Respiratory Distress							
	Troponin Increased							
	Ventricular Dysfunction							

Date:02/23/04ISR Number: 4302321-XReport Type:Expedited (15-DaCompany Report #WAES 0402DEU00054
Age:72 YR Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Drug Interaction
Other	Pancreatitis
	Post Procedural

Complication
Rhabdomyolysis

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Zocor	PS	Merck & Co., Inc	ORAL		
	Acetaminophen	SS				
	Amiodarone	SS				
	Amlodipine Maleate	SS				
	Aspirin	SS				
	Atorvastatin Calcium	SS				
	Captopril	SS				
	Cefotiam	SS				
	Clonidine	SS				
	Dexamethasone	SS				
	Dexpanthenol	SS				
	Diazepam	SS				
	Dopamine Hydrochloride	SS				
	Enalapril Maleate	SS				
	Enoximone	SS				
	Epinephrine Hydrochloride	SS				
	Etomidate	SS				
	Fenoterol And Ipratropium Bromide	SS				
	Sufentanil	SS				
	Flunitrazepam	SS				
	Furosemide	SS				
	Isosorbide Dinitrate	SS				
	Lidocaine	SS				
	Lormetazepam	SS				
	Cozaar	SS				
	Metoclopramide	SS				
	Metoprolol	SS				
	Verapamil	SS				
	Molsidomine	SS				
	Neostigmine Bromide	SS				
	Nifedipine	SS				
	Nitroglycerin	SS				
	Norepinephrine Hydrochloride	SS				
	Omeprazole	SS				
	Ondansetron	SS				
	Pancuronium Bromide	SS				
	Piperacillin Sodium And Tazobactam Sodium	SS				

Piritramide	SS
Propofol	SS
Radiographic Contrast Medium (Unspecified)	SS

Date:02/25/04ISR Number: 4303719-6Report Type:Expedited (15-DaCompany Report #200412143GDDC
Age:19 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Erythema
Hospitalization - Initial or Prolonged	Hypotension
	Post Procedural Complication

	Pruritus Swelling Face Wheezing	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
			Flagyl "Aventis"	PS	Aventis Pharmaceuticals Inc.	
dose: UNK						
			Thiopentone	SS		
dose: UNK						
			Suxamethonium	SS		
dose: UNK						
			Fentanyl	SS		
dose: UNK						
			Morphine	SS		
dose: UNK						
			Verapamil	SS		
dose: UNK						
			Bupivacaine	SS		
dose: 0.5 %						
			Cefuroxime	SS		
dose: UNK						
			Ephedrine	SS		
dose: UNK						
			Ondansetron	SS		
dose: UNK						
			Iodine	SS		
dose: UNK						

Date:02/25/04ISR Number: 4303881-5Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0324054A
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Anaesthetic Complication		Suxamethonium	PS	Glaxosmithkline	
UNKNOWN						
Hospitalization -	Bronchospasm		Ondansetron	SS	Glaxosmithkline	
UNKNOWN						
Initial or Prolonged	Hypotension		Cefuroxime Sodium	SS	Glaxosmithkline	
UNKNOWN						
	Pruritus		Thiopentone	SS		
UNKNOWN						
	Rash Erythematous		Fentanyl	SS		
UNKNOWN						
	Rash Generalised		Morphine	SS		
UNKNOWN						

	Stridor		Verapamil	SS		
UNKNOWN						
	Swelling Face		Bupivacaine	SS		
UNKNOWN						
	Wheezing		Flagyl	SS	Glaxosmithkline	
UNKNOWN						
			Ephedrine	SS		
UNKNOWN						
			Iodine	SS		
			No Concurrent Medications	C		

Date:02/25/04ISR Number: 4304444-8Report Type:Expedited (15-DaCompany Report #2004-UK-00153UK
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Anaesthetic Complication	Foreign	Morphine (0015/0122/0208/0157			
Hospitalization - Initial or Prolonged	Erythema	Health Professional	) (Morphine)	PS		
	Hypertension		Thiopentone (Thiopental)	SS		
	Hypotension		Suxamethonium (Suxamethonium)	SS		
	Post Procedural Complication		Fentanyl (Fentanyl)	SS		
	Pruritus		Verapamil (Verapamil)	SS		
	Stridor		Bupivacaine (Bupivacaine)	SS		
	Swelling Face					
	Wheezing					
STRENTGH =						
0.5%						
			Cefuroxime (Cefuroxime)	SS		
			Flagyl	SS		
			Ephedrine (Ephedrine)	SS		
			Ondansetron (Ondansetron)	SS		
			Iodine (Iodine)	SS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/25/04ISR Number: 4304451-5Report Type:Expedited (15-DaCompany Report #04-02-0282
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Erythema	Foreign	Verapamil Hcl Er -					
Hospitalization -	Hypotension	Other	Ipi Tablets	PS				
Initial or Prolonged	Pruritus		Thiopentone	SS				
	Stridor		Suxamethonium	SS				
	Swelling Face		Fentanyl	SS				
	Wheezing		Cefuroxime	SS				
			Bupivacaine	SS			0.5%	
			Morphine	SS				
			Flagyl	SS				
			Ephedrine	SS				
			Ondansetron	SS				
			Iodine	SS				

Date:02/25/04ISR Number: 4305960-5Report Type:Expedited (15-DaCompany Report #04P-167-0250766-00
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Erythema	Foreign	Isoptin (Verapamil)					
Hospitalization -	Hypotension	Health	(Verapamil)	PS				
Initial or Prolonged	Pruritus	Professional	Bupivacaine	SS				
	Stridor		Thiopental	SS				
	Swelling Face		Suxamethonium	SS				
	Wheezing		Fentanyl	SS				
			Morphine	SS				
			Cefuroxime	SS				
			Metronidazole	SS				
			Ephedrine	SS				
			Ondansetron	SS				
			Iodine	SS				

Date:02/25/04ISR Number: 4307023-1Report Type:Expedited (15-DaCompany Report #GBR-2004-0000916
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Generalised Erythema	Foreign	Morphine Sulfate					

Hospitalization - SEE IMAGE	Hypertension	Health	(Morphine Sulfate)	PS
Initial or Prolonged	Hypotension	Professional	Thiopentone	
	Pruritus	Other	(Thiopental)	SS
	Stridor		Suxamethonium	
	Swelling Face		(Suxamethonium)	SS
	Wheezing		Fentanyl (Fentanyl)	SS
			Verapamil	
			(Verapamil)	SS
			Bupivacaine	
			(Bupivacaine)	SS
0.5%				
			Cefuroxime	
			(Cefuroxime)	SS
			Metronidazole	
			(Metronidazole)	SS
			Ephedrine	
			(Ephedrine)	SS
			Ondasetron	
			(Ondansetron)	SS
			Iodine (Iodine)	SS

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/26/04ISR Number: 4306975-3Report Type:Direct Company Report #CTU 213299
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Ineffective		Metoclopramide	PS			10 MG Q 3 HR	
	Hallucination, Visual		Ondasertron	SS		INTRAVENOUS	4 MG IV X 2 DOSES	
	Hypnagogic Hallucination							
			Ampicillin	C				
			Aspirin	C				
			Metoprolol	C				
			Hydromorphone	C				
			Metoclopramide	C				
			Pantoprazole	C				
			Acetaminophen	C				
			Gentamicin	C				
			Glyburide	C				
			Regular Insulin	C				

Date:02/27/04ISR Number: 4306889-9Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0323814A
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Consumer	Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	4MG Per day	2 DAY
	Haemoglobin Decreased		Sevredol	SS	Glaxosmithkline	ORAL	10MG Three times per day	1 DAY
	Hypertonia							
	Hypotension		Paracetamol	C	Glaxosmithkline	UNKNOWN		
	Loss Of Consciousness		Ferrous Sulphate	C	Glaxosmithkline	UNKNOWN		
	Nausea		Prednisolone	C	Glaxosmithkline	UNKNOWN		
	Rash		Methotrexate	C		UNKNOWN		
	Respiratory Arrest		Sulphasalazine	C		UNKNOWN		
	Respiratory Depression							
	Tachycardia							

Vomiting

Date:02/27/04ISR Number: 4307746-4Report Type:Direct Company Report #CTU 213348
Age:4 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Maternal Drugs Affecting Foetus		Ondansetron (Zofran) 4 Mg	PS		ORAL	4-8 MG PO TID	
	Nervous System Disorder						PRN NAUSEA	
	Trichotillomania							

Date:03/02/04ISR Number: 4309326-3Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0323740A
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Brain Scan Abnormal	Health	Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG Twice per day	
	Choreoathetosis	Professional						
	Confusional State		Vp 16	C		INTRAVENOUS		
	Dystonia		Carboplatine	C		INTRAVENOUS		
	Nervous System Disorder							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/03/04ISR Number: 4309835-7Report Type:Expedited (15-DaCompany Report #200410724FR
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alkalosis		Taxotere	PS	Aventis			
Hospitalization -	Blood Glucose Increased				Pharmaceuticals Inc.			
INTRAVENOUS								
Initial or Prolonged	Blood Urea Increased		Zophren	SS		ORAL		
	Lung Disorder		Prozac	C		ORAL		
	Nausea		Inexium	C		ORAL		
	Normochromic Normocytic		Solupred	C		ORAL		
	Anaemia		Anafranil	C		ORAL		
	Oxygen Saturation							
	Decreased							
	Pain							
	Pneumonitis							

Date:03/03/04ISR Number: 4310557-7Report Type:Expedited (15-DaCompany Report #DK-GLAXOSMITHKLINE-B0323951A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Dependence		Zofran	PS	Glaxosmithkline			
UNKNOWN								

Date:03/03/04ISR Number: 4310558-9Report Type:Expedited (15-DaCompany Report #DK-GLAXOSMITHKLINE-B0323952A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Dependence		Zofran	PS	Glaxosmithkline			

Date:03/08/04ISR Number: 4313533-3Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0324210A
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dyspnoea	Consumer	Zophren	PS	Glaxosmithkline	ORAL	16MG Per day	6 DAY

Hospitalization -	Dyspnoea Exacerbated	Taxotere	SS		
INTRAVENOUS 75MGM2 See					
Initial or Prolonged	Hypoxia				
dosage text 1 DAY					
	Interstitial Lung Disease	Prozac	C		ORAL
80MG per day					
	Normochromic Normocytic	Inexium	C		ORAL
80MG Per day					
	Anaemia	Solupred	C	Glaxosmithkline	ORAL
60MG Per day					
	Oxygen Saturation	Anafranil	C		ORAL
20MG Per day 4 MON					
	Decreased	Doliprane	C	Glaxosmithkline	
	Respiratory Alkalosis	Buspar	C		
	Respiratory Depression	Forlax	C		
		Motilium	C		
		Vogalene	C		
		Neorecormon	C		
SUBCUTANEOUS 30000UNIT					
Weekly					
		Tardyferon B9	C		
		Neurontin	C		ORAL
600MG Three					
times per day					
		Radiotherapy	C		
		Cisplatin	C		
		Navelbine	C	Glaxosmithkline	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/10/04ISR Number: 4315421-5Report Type:Expedited (15-DaCompany Report #7477
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bruxism	Foreign	Morphine	PS		ORAL	30 MG	1 DAY
Initial or Prolonged	Convulsion	Health	Ondansetron	SS				
INTRAVENOUS							4 MG FREQ UNK	1 DAY
	Hypertonia	Professional	Paracetamol	C				
	Hypotension	Other	Ferrous Sulphate	C				
	Loss Of Consciousness		Prednisolone	C				
	Nausea		Methotrexate	C				
	Rash		Sulphasalazine	C				
	Respiratory Arrest							
	Respiratory Depression							
	Tachycardia							
	Vomiting							

Date:03/12/04ISR Number: 4317078-6Report Type:Expedited (15-DaCompany Report #8003398
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Wall Disorder	Foreign	Keppra	PS		ORAL	1500 MG PO	
Initial or Prolonged	Alanine Aminotransferase	Health	Vincristin	SS				
	Increased	Professional	Vincristin	SS				
	Aspartate	Company	Cecenu	SS				
	Aminotransferase	Representative	Cecenu	SS				
	Increased	Other	Natulan	SS				
	Blood Alkaline		Zofran	SS				
	Phosphatase Increased		Vergentan	SS				
	Gamma-Glutamyltransferase							
	Increased							

Date:03/17/04ISR Number: 4320323-4Report Type:Expedited (15-DaCompany Report #PERI00204000637
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hyponatraemia	Foreign	Coversyl					

Initial or Prolonged	Inappropriate	Health	(Perindopril)	PS	ORAL
2 MG QD PO					
	Antidiuretic Hormone	Professional	Zofran (Ondansetron		
	Secretion	Other	Hydrochloride)	SS	
INTRAVENOUS	DAILY IV				
			Panadol		
			(Paracetamol)	SS	ORAL
4 G DAILY PO					
			Cefazolin		
			(Cefazolin)	SS	
INTRAVENOUS	1 G DAILY IV				
			Tramal (Tramadol		
			Hydrochloride)	SS	ORAL
150 MG DAILY					
PO					
			Optimol (Timolol		
			Maleate)	C	
			Nexium	C	

Date:03/22/04ISR Number: 4321079-1Report Type:Direct Company Report #CTU 214874
Age:78 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Anxiety
Required	Bronchospasm
Intervention to	Dyskinesia
Prevent Permanent	Dystonia
Impairment/Damage	Formication

	Grand Mal Convulsion Nasal Congestion					
		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
			Zofran (Ondansetron)	PS		
INTRAVENOUS	2 MG IV X 1					

Date:03/22/04ISR Number: 4321114-0Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0321939A
Age:73 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Eczema		Zophren	PS	Glaxosmithkline	
INTRAVENOUS	2UNIT Per day 1 DAY					
Initial or Prolonged	Pruritus		Plitican	SS		
INTRAVENOUS	2UNIT Per day 1 DAY					
	Rash Erythematous		Carbolevure	SS		ORAL
2UNIT Per day	YR					
	Rash Papular		Gemzar	SS		
INTRAVENOUS	1750MG Per					
	Toxic Skin Eruption					
day	1 DAY					
			Diovenor	SS		ORAL
600MG Per day	YR					

Date:03/25/04ISR Number: 4327901-7Report Type:Expedited (15-DaCompany Report #AU-JNJFOC-20040304171
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Hyponatraemia	Foreign	Tramal (Tramadol			
Initial or Prolonged	Inappropriate	Health	Hydrochloride)	PS		
150 MG, IN 1						
	Antidiuretic Hormone	Professional				
DAY,						
	Secretion					
INJECTION						
	Post Procedural		Zofran (Ondansetron			
	Complication		Hydrochloride)			
			Injection	SS		
4 MG, 3 IN 1						
DAY,						

INJECTION			Cephazolin Sodium (Cefazolin) Injection	SS		
1 G, 1 IN, INJECTION			Coversyl (Perindopril)	SS		ORAL
2 MG, ORAL			Optimol (Timolol Maleate)	C		
			Panadol (Paracetamol)	C		
			Nexium (Esomeprazole)	C		

Date:03/29/04ISR Number: 4325982-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0326788A
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Consumer	Zophren	PS	Glaxosmithkline			
INTRAVENOUS							1AMP	See dosage text
Life-Threatening	Hyperbilirubinaemia							
			Aracytine	SS			8	DAY
INTRAVENOUS							100MGM2 per day	6 DAY
			Primperan	SS	Glaxosmithkline			
INTRAVENOUS								4 DAY
			Zavedos	SS				
INTRAVENOUS							8MGM2 per day	1 DAY
			Belustine	SS		ORAL		
200MGM2 per day							1	DAY
			Tenordate	C		ORAL		
1UNIT per day								
			Acupan	C				
UNKNOWN								
			Lasilix	C	Glaxosmithkline			
UNKNOWN								

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Anomaly Of External Ear Congenital Apnoea Asthenia	Literature Health Professional	Zofran (Formulation Unknown) (Ondansetron Hydrochloride)	PS				
TRANSPLACENTAL	TRANSPLACENTA Body Height Below Normal RY							
	Bradycardia Neonatal Cervical Spinal Stenosis Chondrodystrophy		Zantac (Formulation Unknown) (Ranitidine Hydrochloride)	SS				
TRANSPLACENTAL	TRANSPLACENTA Congenital RY							
	Musculoskeletal Anomaly Congenital Nose Malformation Finger Hypoplasia		Compazine (Formulation Unknown) (Prochlorperazine)	SS				
TRANSPLACENTAL	TRANSPLACENTA Hyperreflexia RY							
	Maternal Drugs Affecting Foetus Micrognathia Movement Disorder Multiple Congenital		Diphenhydramine Hydrochloride (Formulation Unknown) (Diphenhydramine	SS				
TRANSPLACENTAL	TRANSPLACENTA Abnormalities RY							
	Neonatal Respiratory Distress Syndrome Premature Baby		Metoclopramide Hcl (Formulation Unknown) (Metoclopramide Hcl)	SS				
TRANSPLACENTAL	TRANSPLACENTA RY							
			Emgel (Formulation Unknown) (Erythromycin)	SS				
TRANSPLACENTAL	TRANSPLACENTA RY							
			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:03/31/04ISR Number: 4327618-9Report Type:Expedited (15-DaCompany Report #200411273FR
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety		Taxotere	PS	Aventis Pharmaceuticals Inc.			
	Asthenia							
	Drug Ineffective		Vogalene	SS				
	Hiccups		Zophren	SS				
	Insomnia		Gemzar	SS				
			Hypnovel	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/31/04ISR Number: 4328186-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0504844A
Age:17 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Angioneurotic Oedema		Zofran	PS	Glaxosmithkline	ORAL	8MG Single	
	Laryngospasm						dose	1 DAY
			Cytoxan	C				
			Dactinomycin	C				
			Vincristine	C				
			Compazine	C	Glaxosmithkline			
			Dexamethasone	C				

Date:04/01/04ISR Number: 4329749-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0321882A
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alanine Aminotransferase	Consumer	Azantac	PS	Glaxosmithkline	ORAL	4 DAY	
Hospitalization -	Increased		Zyloric	SS	Glaxosmithkline	ORAL	900MG Per day	11 DAY
Initial or Prolonged	Aspartate		Zophren	SS	Glaxosmithkline		INTRAVENOUS	8MG Twice per
	Aminotransferase						day	12 DAY
	Increased		Zovirax	SS	Glaxosmithkline		UNKNOWN	
	Blood Bilirubin Increased		Solumedrol	SS			INTRAVENOUS	40MG Per day 24 DAY
	Jaundice Cholestatic		Visceralgine	SS		ORAL	1UNIT Per day	8 DAY
	Septic Shock		Ciflox	SS			INTRAVENOUS	200MG Twice
							per day	14 DAY
			Rocephine	SS			UNKNOWN	12 DAY
			Primperan	SS	Glaxosmithkline		UNKNOWN	
			Duphalac	SS			UNKNOWN	

					Acupan	SS		
UNKNOWN		4	DAY					
					Debridat	SS		
UNKNOWN								
					Mopral	C		
UNKNOWN		3	DAY					
					Oncovin	C		
INTRAVENOUS								
					Endoxan	C		
INTRAVENOUS								
					Cerubidine	C		
INTRAVENOUS		3	DAY					
					Methotrexate	C		
INTRATRACHEAL								
					Aracytine	C		
INTRATRACHEAL								
					Vancocine	C		
UNKNOWN								
					Oflocet	C		
UNKNOWN								

Date:04/01/04ISR Number: 4332058-2Report Type:Direct Company Report #CTU 215682
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Dystonia		Ondansetron 4 Mg Injection	PS		
INTRAVENOUS	4 MG Q8 HOURS					
IV						
			Fentanyl	C		
			Famotidine	C		
			Cefepime	C		
			Bupivicaine	C		

Date:04/02/04ISR Number: 4330647-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0505127A
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Death		Zofran	PS	Glaxosmithkline	
INTRAVENOUS	2MG Single					
Life-Threatening	Oxygen Saturation					
dose	0 DAY					
Disability	Decreased					
Other						

Date:04/02/04ISR Number: 4334088-3Report Type:Expedited (15-DaCompany Report #WAES 0402DEU00107
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Duodenitis	Foreign	Tab Decadron					
	Haematemesis	Study	(Dexamethasone) 8 Mg	PS		ORAL	20 MG PO	3 DAY
	Hiatus Hernia	Health	Cap 0869-Blinded					
	Oesophagitis	Professional	Therapy	SS		ORAL	PO	3 DAY
			Inj Ondansetron	SS			INTRAVENOUS	IV 1 DAY
			Cap Blinded Therapy	SS		ORAL	PO	3 DAY
			Inj Cisplatin	SS			INTRAVENOUS	70 MG/M2 IV 1 HR
			Inj Docetaxel	SS			INTRAVENOUS	25 MG/M2 IV 1 HR
			Tab Blinded Therapy	SS		ORAL	PO	3 DAY
			Furosemide	C				
			Lactulose	C				
			Metoprolol Succinate	C				
			Mirtazapine	C				
			Nadroparin	C				
			Oxazepam	C				
			Polyethylene Glycol	C				

Date:04/07/04ISR Number: 4334500-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0323740A
Age:16 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Choreoathetosis	Health Professional	Zophren	PS	Glaxosmithkline		INTRAVENOUS	8MG Twice per day 3 DAY
	Confusional State							
	Dyskinesia		Vp 16	SS			INTRAVENOUS	144MG per day 3 DAY
	Dystonia		Carboplatine	C			INTRAVENOUS	576MG per day 1 DAY
	Electroencephalogram Abnormal							
	Extrapyramidal Disorder							

	Visual Disturbance					

Date:04/07/04ISR Number: 4334540-0Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0328132A
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blister	Consumer	Zophren	PS	Glaxosmithkline	ORAL	5	WK
Initial or Prolonged	Epidermal Necrosis		Noctran	SS		ORAL	5	WK
	Erythema		Ethyol	SS				
INTRAVENOUS							5	WK
	Inflammation							
	Mucosal Erosion							
	Oral Pain							
	Pyrexia							
	Rash							
	Stevens-Johnson Syndrome							

Date:04/07/04ISR Number: 4334541-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0328134A
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anxiety		Zophren	PS	Glaxosmithkline			
INTRAVENOUS							2UNIT	per day
Initial or Prolonged	Asthenia		Vogalene	SS				
INTRAVENOUS							6UNIT	per day
	Hiccups		Taxotere	SS				
INTRAVENOUS							2UNIT	per day
	Insomnia		Gemzar	SS				
INTRAVENOUS							2UNIT	per day

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/12/04ISR Number: 4339471-8Report Type:Expedited (15-DaCompany Report #2004207481FR
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening	Hyperbilirubinaemia	Foreign Health Professional	Aracytine(Cytarabine) Powder, Sterile	PS		INTRAVENOUS	100 MG/M2, UNK, IV	
		Other	Zavedos (Idarubicin Hydrochloride) Powder, Sterile	SS		INTRAVENOUS	8 MG/M2, SINGLE, IV	
			Primperan (Metoclopramide)	SS		INTRAVENOUS	1 VIAL/8 HOURS MAX, IV	
			Belustine (Lomustine)	SS		ORAL	200 MG/M2, UNK, ORAL	
			Zophren (Ondansetron Hydrochloride)	SS		INTRAVENOUS	2 MG/ML, 1 VIAL/12 HOURS, IV	
			Tenordate	C				
			Acupan (Nefopam Hydrochloride)	C				
			Lasilix	C				

Date:04/14/04ISR Number: 4338504-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0328958A
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Arterial Thrombosis	Consumer	Zophren	PS	Glaxosmithkline	INTRAVENOUS	9	DAY

Initial or Prolonged		Creatinine Renal		Neulasta	SS			
SUBCUTANEOUS	6MG Per day	1 DAY						
		Clearance Decreased		Largactil	SS			
INTRAVENOUS	12MG Per day	1 DAY						
		Dehydration		Cisplatine	SS			
INTRAVENOUS	70MG Per day	4 DAY						
		Leg Amputation		Etoposide	SS			
INTRAVENOUS	250MG Per day	4 DAY						
		Neutrophil Count		Bleomycine	SS			
INTRAVENOUS	30MG Per day	4 DAY						
		Decreased		Primperan	SS	Glaxosmithkline		
UNKNOWN		9 DAY						
		Pancytopenia		Solumedrol	SS			
UNKNOWN		9 DAY						
		Peripheral Ischaemia		Polaramine	SS			
UNKNOWN		2 DAY						
		Renal Failure		Loxen	SS		ORAL	
1 DAY								
		Rhabdomyolysis						
		Sepsis						
		Thrombocytopenia						
		Vomiting						
		White Blood Cell Count Decreased						

Date:04/14/04ISR Number: 4338507-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0329118A
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dermatitis Exfoliative	Consumer	Zophren	PS	Glaxosmithkline			
INTRAVENOUS	8MG per day							
Initial or Prolonged	Oedema Peripheral		Gemzar	SS				
INTRAVENOUS	2.4MG per day							
	Pruritus		Solumedrol	SS				
INTRAVENOUS	40MG per day							
	Rash		Vogalene	C		ORAL		
2.5MG Twice								
	Rash Erythematous							
per day	7 DAY							
	Rash Generalised							
	Rash Papular							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/15/04ISR Number: 4342778-1Report Type:Expedited (15-DaCompany Report #WAES 0402DEU00107
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Arrest	Foreign	Tab Decadron Tablets					
	Duodenitis	Study	(Dexamethasone)	PS		ORAL	20 MG PO; PO;	
	Haematemesis						8 MG PO	3 DAY
	Hiatus Hernia		Cap 0869-Blinded					
	Hypokalaemia		Therapy	SS		ORAL	PO	3 DAY
	Oesophagitis		Inj Ondansetron	SS			INTRAVENOUS	32 MG IV 1 DAY
	Ventricular Arrhythmia		Cap Blinded Therapy	SS		ORAL	PO	3 DAY
			Inj Cisplatin	SS			INTRAVENOUS	70 MG/M[2] IV 1 HR
			Inj Docetaxel	SS			INTRAVENOUS	25 MG/M[2] IV 1 HR
			Tab Blinded Therapy	SS		ORAL	PO	3 DAY
			Furosemide	C				
			Lactulose	C				
			Metoprolol Succinate	C				
			Mirtazapine	C				
			Nadroparin	C				
			Oxazepam	C				
			Polyethylene Glycol	C				

Date:04/19/04ISR Number: 4344207-0Report Type:Expedited (15-DaCompany Report #B0328629A
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Caesarean Section	Foreign	Zofran (Formulation					
Other	Complications Of Maternal	Literature	Unknown)					
Required	Exposure To Therapeutic	Health	(Ondansetron					
SEE TEXT	Drugs	Professional	Hydrochloride)	PS				
Intervention to	Gestational Diabetes		Metoclopramide	C				
Prevent Permanent	Maternal Drugs Affecting		Promethazine	C				
Impairment/Damage	Foetus		Hydration Therapy	C				
	Premature Rupture Of							

Membranes

Date:04/19/04ISR Number: 4344385-3Report Type:Expedited (15-DaCompany Report #2004198784FR
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cholestasis	Foreign	Solu-Medrol (Methylprednisolone)					
Hospitalization - Initial or Prolonged	Cytolytic Hepatitis	Health Professional	Powder, Sterile	PS		INTRAVENOUS	SEE IMAGE	
	Hepatocellular Damage							
	Septic Shock	Other	Azantac (Ranitidine Hydrochloride)	SS		ORAL		
			Visceralgine Forte Tablets (Metamizole, Tiemonium Methylsulphate)	SS		ORAL	1 DF,	QD,
			Zyloric (Allopurinol)	SS		ORAL	900 MG,	QD,
			Ciflox (Ciprofloxacin)	SS		INTRAVENOUS	200 MG,	BID,
			Zophren (Ondansetron Hydrochloride)	SS		IV	16 MG,	BID,
			Rocephin					

(Ceftriaxone Sodium)	SS
Zovirax (Aciclovir)	SS
Primperan (Metoclopramide)	SS
Duphalac (Lactulose)	SS
Acupan (Nefopam Hydrochloride)	SS
Trimebutine (Trimebutine)	SS
Mopral	C
Oncovin	C
Endoxan	C
Cerubidine	C
Methotrexate	C
Aracytine	C
Vancomycin	C
Ofloxacin	C

Date:04/20/04ISR Number: 4345194-1Report Type:Expedited (15-DaCompany Report #US-SHR-04-020001
Age:17 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Germ Cell Cancer Malignant Neoplasm Progression	Study Health Professional	Leukine (Sargramostim) Injection	PS		SEE IMAGE		
	Pneumonitis Pyrexia		Interleukin-2 (Interleukin-2)	SS		INCUBATED		
	Venoocclusive Liver Disease					WITH PBSC		
	Weight Increased		G-Csf (Granulocyte Colony Stimulating Factor)	SS		SUBCUTANEOUS	10 UG/KG/DAY	(DAY 10-APHERESIS), SUBCUTANEOUS

	Peripheral Blood Stem Cells (Incubated With Il-2) ( )	SS	
DAY 0 250 MG/M2, 1 DOSE (DAY 2)	Taxol (Paclitaxel)	SS	
	Zofran/Gfr/ (Ondansetron Hydrochloride	SS	ORAL
8 MG, 4X/DAY, DAY -9 THROUGH, ORAL	Busulfan (Busulfan)	SS	ORAL
1 MG/KG/Q6H DAY -8 THROUGH -6, ORAL	Mesna (Mesna) 4 Gm/M2	SS	
4GM/M2/3 DIVIDED DOSES (DAY 1)	Cyclophosphamide (Cyclophosphamide)	SS	
4 GM/M2, 1 DOSE (DAY 1)	Thiotepa (Thiotepa)	SS	
250 MG/M2 (DAY -3 & 2)	Dilantin (Phenytoin		

			Sodium)	SS		ORAL
SEE IMAGE						
ORAL						
			Melphalan (Melphalan)	SS		
50 MG/M2						
(DAY-5 & -4)						
			Voriconazole (Voriconazole)	C		
			Caspofungin (Caspofungin)	C		

Date:04/22/04ISR Number: 4344087-3Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0329820A
Age:22 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Delayed Recovery From	Consumer	Ondansetron	PS	Glaxosmithkline	INTRAVENOUS		
Initial or Prolonged	Anaesthesia					BOLUS	4MG per day	
Disability	Depressed Level Of		Citalopram	SS		ORAL		
Other	Consciousness		Oxycodone	SS				
UNKNOWN							5MG per day	
	Drug Interaction		Propofol	SS		INTRAVENOUS		
						BOLUS	150MG per day	
			Fentanyl	SS		INTRAVENOUS		
						BOLUS	100MCG per	
day								
			Dexamethasone	SS		INTRAVENOUS		
						BOLUS	10MG per day	
			Ketorolac	C				
UNKNOWN							30MG per day	
			Atracurium	C	Glaxosmithkline			
UNKNOWN							10MG per day	
			Isoflurane	C				
UNKNOWN								

				Nitrous Oxide	C		
UNKNOWN							
				Co-Proxamol	C		
UNKNOWN							

Date:04/23/04ISR Number: 4344855-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0393389A
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Drug Ineffective		Zofran	PS	Glaxosmithkline	
INTRAVENOUS 2ML Unknown 2 DAY						
	Pharmaceutical Product					
	Complaint					

Date:04/23/04ISR Number: 4344856-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0395151A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Drug Ineffective		Zofran	PS	Glaxosmithkline	
UNKNOWN						
			Cisplatin	C		

Date:04/23/04ISR Number: 4344857-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0398142A
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Therapeutic Response		Zofran	PS	Glaxosmithkline	
UNKNOWN						
	Decreased					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/23/04ISR Number: 4344858-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0399774A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation		Zofran	PS	Glaxosmithkline			
			Chemotherapy	C				

Date:04/23/04ISR Number: 4344859-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0405391A
Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran Injection	PS	Glaxosmithkline	INTRAVENOUS	8MG Three times per day	1 DAY
			Morphine	C		INTRAVENOUS	2MG Unknown	1 DAY
			Tigan	C	Glaxosmithkline	INTRAMUSCULAR	200MG Unknown	1 DAY
			Mylanta	C		ORAL	30CC Unknown	1 DAY
			Donnatal	C		UNKNOWN	30CC Unknown	1 DAY
			Viscous Lidocaine	C		UNKNOWN	30CC Unknown	1 DAY
			Pepcid	C		INTRAVENOUS	20MG Unknown	1 DAY

Date:04/23/04ISR Number: 4344860-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0407871A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Single dose	4 HR
	Oculogyration							
			Unspecified Medications	C				

Date:04/23/04ISR Number: 4344861-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0412689A
Age:9 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Grand Mal Convulsion		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG See Initial or Prolonged dosage text	
Other			Zofran	SS	Glaxosmithkline	ORAL	4MG Single dose	
			Toradol	C		INTRAMUSCULAR	15MG per day	
			Ativan	C		UNKNOWN	3MG Single dose	
			Morphine	C		UNKNOWN	3MG Unknown	
			Amoxil	C	Glaxosmithkline		400MG Twice per day	
			Nifedipine	C	Glaxosmithkline		1 DAY	

Date:04/23/04ISR Number: 4344862-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0423372A
Age:11 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline			

Date:04/23/04ISR Number: 4344863-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0425502A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Flushing		Zofran	PS	Glaxosmithkline	INTRAVENOUS		
			Carboplatin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/23/04ISR Number: 4344864-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0426909A
Age:32 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dystonia		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Single	
dose	1 DAY							
			Oxytocin	C				
UNKNOWN		1 DAY						
			Ancef	C	Glaxosmithkline			
UNKNOWN		1 DAY						
			Ephedrine	C				
UNKNOWN	50MG Per day	1 DAY						
			Labetalol	C	Glaxosmithkline			
UNKNOWN	10MG Per day	1 DAY						
			Atropine	C				
UNKNOWN	.4MG Per day	1 DAY						
			Bupivacaine	C				
EPIDURAL	12MG Per day	1 DAY						
			Fentanyl	C				
EPIDURAL	10MCG Per day	1 DAY						

Date:04/23/04ISR Number: 4344865-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0427540A
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Depression		Zofran	PS	Glaxosmithkline	INTRAVENOUS		
	Diarrhoea		Zofran	SS	Glaxosmithkline	ORAL	4MG Twice per	
	Drug Exposure During							
day	3 WK							
	Pregnancy		Prenatal Vitamins	C				
	Headache							
	Insomnia							
	Irritability							
	Panic Attack							

Date:04/23/04ISR Number: 4344866-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0429507A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During Pregnancy Drug Ineffective		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG	Unknown

Date:04/23/04ISR Number: 4344867-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0430016A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Oculogyration		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG	Single dose
			Unknown Medication	C				

Date:04/23/04ISR Number: 4344868-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0431076A
Age:83 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL	8MG Twice per day	
			Zofran	SS	Glaxosmithkline	INTRAVENOUS	30MG per day	
			Dilaudid	C				
			Duragesic	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/23/04ISR Number: 4344869-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0431213A
Age:25 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation		Zofran	PS	Glaxosmithkline	UNKNOWN	8MG Four times per day	
	Drug Exposure During Pregnancy		Pepcid Ac	SS		ORAL	10MG Six times per day	
			Pepcid	SS		INTRAVENOUS	8	DAY

Date:04/23/04ISR Number: 4344870-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0433116A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypotension		Zofran	PS	Glaxosmithkline	INTRAVENOUS	2MG Single dose	

Date:04/23/04ISR Number: 4344871-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0442338A
Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Chest Pain		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Per day	1 DAY
	Headache		Saline	C	Glaxosmithkline			
	Hyperhidrosis							
	Injection Site Erythema							
	Pallor							

Date:04/23/04ISR Number: 4344874-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0442339A
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Flushing		Zofran	PS	Glaxosmithkline	
INTRAVENOUS	4MG Per day 1 DAY					
	Respiratory Rate Increased		Morphine	SS		
			Prilosec	C		
			Lopid	C		
			Zyrtec	C	Glaxosmithkline	
			Celexa	C		

Date:04/23/04ISR Number: 4344875-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0442341A
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Pain		Zofran	PS	Glaxosmithkline	
INTRAVENOUS	4MG Per day 0 DAY					
	Tremor		Morphine	SS		
			Darvocet	C		
			Antibiotics	C		

Date:04/23/04ISR Number: 4344876-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0442529A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Urticaria		Zofran	PS	Glaxosmithkline	
UNKNOWN						
			Chemotherapy	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/23/04ISR Number: 4344877-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0442611A
Age:14 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	INTRAVENOUS		5 DAY
	Headache		Sodium Bicarbonate	SS		INTRAVENOUS		
	Nausea		Methotrexate	C				
	Vomiting		Leucovorin	C	Glaxosmithkline			
			Vincristine	C				
			Prednisone	C				
			Doxorubicin	C				
			Cytoxan	C				

Date:04/23/04ISR Number: 4344878-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0442641A
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dystonia		Zofran	PS	Glaxosmithkline	INTRAVENOUS	20MG Single	
Other						dose	0	DAY
			Benadryl	C	Glaxosmithkline			
			Dexamethasone	C				
			Paclitaxel	C				
			Carboplatin	C				

Date:04/23/04ISR Number: 4344879-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0444180A
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diarrhoea		Zofran	PS	Glaxosmithkline	UNKNOWN		
	Nausea							
	Vomiting							

Date:04/23/04ISR Number: 4344880-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0491767A
Age:70 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Back Pain		Zofran	PS	Glaxosmithkline	INTRAVENOUS	12MG Unknown	1 DAY
	Blood Pressure Decreased		Decadron	C		ORAL	20MG Unknown	
	Dizziness		Cimetidine	C	Glaxosmithkline	INTRAVENOUS		
	Flushing		Taxol	C		INTRAVENOUS		
	Tachycardia		Carboplatin	C		INTRAVENOUS		

Date:04/23/04ISR Number: 4344881-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0492260A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	INTRAVENOUS		

Date:04/23/04ISR Number: 4344882-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0493949A
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Bradycardia		Zofran	PS	Glaxosmithkline	INTRAVENOUS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/23/04ISR Number: 4344883-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0497583A
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Exposure During Pregnancy Drug Ineffective		Zofran Phenergan	PS SS	Glaxosmithkline Glaxosmithkline	UNKNOWN UNKNOWN		

Date:04/23/04ISR Number: 4348683-9Report Type:Expedited (15-DaCompany Report #2004209540FR
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Exfoliative Localised Oedema Oedema Peripheral Pruritus Rash Erythematous Rash Papular	Foreign Health Professional Other	Solu-Medrol (Methylprednisolone) Powder, Sterile Gemzar (Gemcitabine Hydrochloride) Zophren (Ondansetron Hydrochloride) 2mg/Ml Vogalene (Metopimazine)	PS SS SS C		INTRAVENOUS INTRAVENOUS INTRAVENOUS IV	40 MG, 2.4 G, 8 MG, CYCLIC,	CYCLIC, IV CYCLIC, IV

Date:04/26/04ISR Number: 4346031-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0400175A
Age:33 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Myalgia		Zofran	PS	Glaxosmithkline	ORAL	3	DAY

Rash Morbilliform

Date:04/26/04ISR Number: 4346032-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0427373A
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL	4MG Four	
	Pharmaceutical Product						times per day	2 YR
	Complaint		Morphine	C				
			Methadone	C	Glaxosmithkline			
			Keppra	C				
			Desipramine	C				
			Prevacid	C				
			Fluoxetine	C				
			Zelnorm	C				

Date:04/26/04ISR Number: 4346152-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0369756A
Age:32 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dehydration		Zofran	PS	Glaxosmithkline	ORAL	4MG See	
	Drug Ineffective						dosage text	5 WK
	Pregnancy							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/26/04ISR Number: 4346153-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0405401A
Age:12 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Vomiting		Zofran	PS	Glaxosmithkline	ORAL		

Date:04/26/04ISR Number: 4346154-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0421202A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During		Zofran	PS	Glaxosmithkline		UNKNOWN	
	Pregnancy							
	Vomiting							

Date:04/26/04ISR Number: 4346155-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0424574A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL		
			Irinotecan	C				
			5-Fluorouracil	C				
			Leucovorin	C	Glaxosmithkline			

Date:04/26/04ISR Number: 4346156-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0443180A
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Night Blindness		Zofran	PS	Glaxosmithkline	ORAL	8MG Three	
	Vision Blurred							
							times per day	5 DAY
			Demerol	C				
			Hctz	C				

Date:04/26/04ISR Number: 4346157-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0443200A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Nausea		Zofran	PS	Glaxosmithkline			

Date:04/26/04ISR Number: 4346158-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0492272A
Age:83 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL	8MG Twice per day	3 DAY
			Blood Pressure Medication	C				

Date:04/26/04ISR Number: 4346159-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0493459A
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diarrhoea		Zofran	PS	Glaxosmithkline	ORAL	8MG Twice per day	1 WK
	Pruritus							
	Rash		Velcade	SS		INTRAVENOUS		
	Urticaria		Lopressor	C				
			Lisinopril	C				

			Plavix	C	
			Levoxyl	C	Glaxosmithkline
			Lipitor	C	
			Ativan	C	

Date:04/26/04ISR Number: 4346367-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0373629A
Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL	8MG	Unknown 1 MON
	Nausea		Benadryl	C	Glaxosmithkline			
	Normal Delivery							
	Vomiting							

Date:04/26/04ISR Number: 4346368-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0389714A
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Chills		Zofran	PS	Glaxosmithkline	ORAL	4MG Per day	MON
	Dizziness		Ativan	C				
	Nausea							
	Pharmaceutical Product Complaint							
	Stomach Discomfort							
	Tremor							
	Vomiting							

Date:04/26/04ISR Number: 4346369-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0394867A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Alkaline Phosphatase Increased		Zofran	PS	Glaxosmithkline	ORAL	8MG Twice per day	
			Doxil	C				

			Xanax	C		
			Cozaar	C		

Date:04/26/04ISR Number: 4346370-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0395463A
Age:35 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diarrhoea		Zofran	PS	Glaxosmithkline	ORAL	8MG Single	
	Dizziness						dose	1 DAY
	Drug Exposure During Pregnancy							
	Hypersensitivity							
	Nausea							
	Pruritus							
	Syncope							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/26/04ISR Number: 4346372-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0401977A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anorexia		Zofran	PS	Glaxosmithkline	ORAL	8MG Per day	1 DAY
	Hypersomnia		Taxol	C		INTRAVENOUS		1 DAY
	Sedation		Zofran	C	Glaxosmithkline	INTRAVENOUS		1 DAY
			Carboplatin	C		INTRAVENOUS		1 DAY

Date:04/26/04ISR Number: 4346373-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0403061A
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dementia		Zofran	PS	Glaxosmithkline	ORAL	8MG Three times per day	
	Dysphagia							
			Ranitidine	C	Glaxosmithkline	ORAL		
			Gabitril	C		ORAL		
			Celebrex	C		ORAL		
			Wellbutrin	C	Glaxosmithkline	ORAL		
			Lasix	C	Glaxosmithkline	ORAL		
			Premarin	C		ORAL		
			Trileptal	C		ORAL		
			Clonazepam	C		ORAL		
			Oxycodone	C		ORAL		
			Remeron	C		ORAL		

Date:04/26/04ISR Number: 4346374-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0403515A
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Feeling Abnormal		Zofran	PS	Glaxosmithkline	ORAL	6 MON	
	Nausea		Phenergan	C	Glaxosmithkline	ORAL		
	Normal Delivery							

Therapeutic Response
Unexpected

Date:04/26/04ISR Number: 4346375-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0405004A
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cognitive Disorder		Zofran	PS	Glaxosmithkline	ORAL	8MG Single	
	Drug Exposure During							
dose								1 DAY
	Pregnancy							
	Speech Disorder							

Date:04/26/04ISR Number: 4346376-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0406046A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL	8MG Twice per day	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/26/04ISR Number: 4346377-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0406578A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	OTHER		

Date:04/26/04ISR Number: 4346378-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0407367A
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL	8MG Twice per	
	Nausea						day	
	Vomiting		Taxol	C				
			Carboplatin	C				

Date:04/26/04ISR Number: 4346379-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0407527A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL	1	DAY
	Vomiting							

Date:04/26/04ISR Number: 4346380-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0407841A
Age:80 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Stomach Discomfort		Zofran	PS	Glaxosmithkline	ORAL		
	Vomiting							

Date:04/26/04ISR Number: 4346381-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0408666A
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL		
			Compazine	C	Glaxosmithkline			

Date:04/26/04ISR Number: 4346382-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0409896A
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Weight Increased		Zofran	PS	Glaxosmithkline	ORAL	8MG Per day	3 WK
			Reglan	C	Glaxosmithkline	ORAL		

Date:04/26/04ISR Number: 4346383-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0411642A
Age:35 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation		Zofran	PS	Glaxosmithkline	ORAL	4MG Three times per day	3 DAY
	Drug Exposure During Pregnancy		Unknown Medication	C		ORAL		
	Intestinal Obstruction		Sudafed	C	Glaxosmithkline	ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/26/04ISR Number: 4346384-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0412964A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Menstruation Irregular		Zofran	PS	Glaxosmithkline	ORAL	4MG Four times per day	
			Metoclopramide	C	Glaxosmithkline			
			Dicyclomine	C				
			Promethazine	C				
			Chlordiazepoxide + Clidinium Bromide	C				
			Levsin	C				

Date:04/26/04ISR Number: 4346385-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0423396A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL		
			Tagamet	C	Glaxosmithkline			
			Decadron	C				

Date:04/26/04ISR Number: 4346386-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0425671A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anxiety		Zofran	PS	Glaxosmithkline	ORAL	2	WK
	Depression		Zoloft	C				
	Drug Exposure During Pregnancy		Ptu	C				
			Zantac 75	C	Glaxosmithkline			
	Mood Swings		Reglan	C	Glaxosmithkline			
	Suicidal Ideation		Benadryl	C	Glaxosmithkline			

Date:04/26/04ISR Number: 4346387-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0427541A
Age:10 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Crying		Zofran	PS	Glaxosmithkline		4MG Twice per	
	Drug Exposure Via Breast						day	1 DAY
	Milk		None	C				
	Insomnia							
	Irritability							
	Sluggishness							

Date:04/26/04ISR Number: 4346388-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0428986A
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation		Zofran	PS	Glaxosmithkline	ORAL	.5TAB Twice	
	Drug Exposure During						per day	2 MON
	Pregnancy		None	C				

Date:04/26/04ISR Number: 4346389-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0430615A
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Headache		Zofran	PS	Glaxosmithkline	ORAL	8MG Three	
							times per day	

			Emend	SS		ORAL
			Dexamethasone	C		

Date:04/26/04ISR Number: 4346390-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0431739A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Feeling Jittery		Zofran	PS	Glaxosmithkline	ORAL	4MG Per day	3 WK
	Tremor		Prilosec	C				
			Levlen	C				

Date:04/26/04ISR Number: 4346393-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0439296A
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL		
			Compazine	C	Glaxosmithkline			

Date:04/26/04ISR Number: 4346394-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0442320A
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation		Zofran	PS	Glaxosmithkline	ORAL	8MG Twice per	
	Headache						day	
	Paraesthesia							

Date:04/26/04ISR Number: 4346395-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0493997A
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Bradycardia		Zofran	PS	Glaxosmithkline	ORAL		

Date:04/26/04ISR Number: 4346396-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0495748A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dizziness		Zofran	PS	Glaxosmithkline	ORAL	8MG	Variable
							dose	
			Chemotherapy	C				

Date:04/26/04ISR Number: 4346397-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0498773A
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Migraine		Zofran	PS	Glaxosmithkline	ORAL	4	MON
			Benadryl	C	Glaxosmithkline			
			Adriamycine	C				
			Taxol	C				
			Cytosine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/26/04ISR Number: 4346398-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0498834A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Orthostatic Hypotension		Zofran	PS	Glaxosmithkline	ORAL	8MG Five times per day	3 YR
			Anafranil	C				
			Ativan	C				
			Benadryl	C	Glaxosmithkline			
			Pepcid	C				

Date:04/26/04ISR Number: 4346399-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0500148A
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anorexia		Zofran	PS	Glaxosmithkline	ORAL	8MG As required	4 DAY
	Drug Exposure During Pregnancy		Prenatal Vitamins	C				

Date:04/26/04ISR Number: 4346400-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0500154A
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL	4MG Three times per day	4 WK

Date:04/28/04ISR Number: 4349385-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0508336A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Disability	Tourette'S Disorder		Zofran	PS	Glaxosmithkline	INTRAVENOUS
Other			Radiation	C		

Date:04/30/04ISR Number: 4350927-4Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0320508A
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Per day	2 DAY
Hospitalization -	Bruxism		Sevredol	SS	Glaxosmithkline	ORAL	30MG per day	1 DAY
Initial or Prolonged	Convulsion		Prednisolone	C	Glaxosmithkline	ORAL		
Other	Hypertonia		Ferrous Sulphate	C	Glaxosmithkline	ORAL		
	Loss Of Consciousness		Paracetamol	C	Glaxosmithkline			
	Nausea		Sulphasalazine	C		ORAL		
	Rash		Diclofenac	C		ORAL	25MG per day	
	Respiratory Arrest		Thyroxine	C	Glaxosmithkline	ORAL		
	Tachycardia		Folic Acid	C		ORAL		
	Vomiting		Methotrexate	C				

Date:04/30/04ISR Number: 4350929-8Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0321947A
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bruxism		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Unknown	1 DAY
Hospitalization -	Convulsion		Prednisolone	C	Glaxosmithkline	ORAL	5MG per day	
Initial or Prolonged	Rash		Ferrous Sulphate	C	Glaxosmithkline	ORAL	200MG per day	
	Respiratory Arrest		Paracetamol	C	Glaxosmithkline	ORAL	1G per day	
			Methotrexate	C		ORAL	10MG per day	

			Sulphasalazine	C		ORAL 50MG per day

Date:04/30/04ISR Number: 4350931-6Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0323814A
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hypertonia		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	4MG Per day	2 DAY
Initial or Prolonged	Hypotension		Sevredol	SS	Glaxosmithkline	ORAL	10MG Three times per day	1 DAY
	Loss Of Consciousness							
	Nausea		Paracetamol	C	Glaxosmithkline	UNKNOWN		
	Rash		Ferrous Sulphate	C	Glaxosmithkline	UNKNOWN		
	Respiratory Arrest		Prednisolone	C	Glaxosmithkline	UNKNOWN		
	Respiratory Depression		Methotrexate	C		UNKNOWN		
	Tachycardia		Sulphasalazine	C		UNKNOWN		
	Vomiting							

Date:04/30/04ISR Number: 4354028-0Report Type:Expedited (15-DaCompany Report #2004-115265-NL
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Delayed Recovery From		Dexamethasone	PS		INTRAVENOUS		
Initial or Prolonged	Anaesthesia					BOLUS	10 MG	
Disability	Depressed Level Of		Fentanyl	SS		INTRAVENOUS		
	Consciousness					BOLUS	100 UG	
	Drug Interaction		Citalopram	SS		ORAL	DF	
			Ondansetron	SS		INTRAVENOUS		

							BOLUS
4 MG							
				Propofol	SS		
INTRAVENOUS							
							BOLUS
150 MG							
				Ketorolac	C		
				Atracurium	C		
				Isoflurane	C		
				Nitrous Oxide	C		
				Oxycodone	C		
				Co-Proxamol	C		

Date:05/03/04ISR Number: 4354014-0Report Type:Expedited (15-DaCompany Report #2004GB00939
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Delayed Recovery From	Foreign	Propofol	PS				
INTRAVENOUS							150 MG	IV
Initial or Prolonged	Anaesthesia	Health	Citalopram	SS				
Disability	Depressed Level Of	Professional	Ondansetron	SS				
INTRAVENOUS							4 MG	IV
Required	Consciousness	Other	Fentanyl	SS				
INTRAVENOUS							100 UG	IV
Intervention to	Drug Interaction		Dexamethasone	SS				
INTRAVENOUS							10 MG	IV
Prevent Permanent			Oxycodone	SS				
5 MG DAILY								
Impairment/Damage			Ketorolac	C				
			Atracurium	C				
			Isoflurane	C				
			Nitrous Oxide	C				
			Co-Proxamol	C				
			Salbutamol	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/05/04ISR Number: 4353569-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0326788A
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Zophren	PS	Glaxosmithkline	INTRAVENOUS	1AMP See	
Life-Threatening	Hyperbilirubinaemia						dosage text	8 DAY
			Aracytine	SS		INTRAVENOUS	100MGM2 per	
							day	6 DAY
			Primperan	SS	Glaxosmithkline	INTRAVENOUS		4 DAY
			Zavedos	SS		INTRAVENOUS	8MGM2 per day	5 DAY
			Belustine	SS		ORAL	200MGM2 per	
							day	1 DAY
			Tenordate	C		ORAL	1UNIT per day	
			Acupan	C			UNKNOWN	
			Lasilix	C	Glaxosmithkline		UNKNOWN	

Date:05/12/04ISR Number: 4357044-8Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0329820A
Age:22 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Consumer	Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	4MG Per day	
Disability	Drug Interaction		Citalopram	SS		ORAL		
Other			Oxycodone	SS				
UNKNOWN							5MG per day	
			Propofol	SS		INTRAVENOUS		
						BOLUS	150MG Per day	

				Fentanyl	SS		
INTRAVENOUS							
							BOLUS
100MG Per day							
				Dexamethasone	SS		
INTRAVENOUS							
							BOLUS
10MG Per day							
				Ketorolac	C		
UNKNOWN	30MG per day						
				Atracurium	C	Glaxosmithkline	
UNKNOWN	10MG Per day						
				Isoflurane	C		
UNKNOWN							
				Nitrous Oxide	C		
UNKNOWN							
				Co-Proxamol	C		
UNKNOWN							

Date:05/14/04ISR Number: 4360691-0Report Type:Expedited (15-DaCompany Report #2004207481FR
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Hyperbilirubinaemia	Foreign	Aracytine			
Life-Threatening		Health Professional	(Cytarabine) Powder, Sterile	PS		
INTRAVENOUS	100 MG/M2, IV					
		Other	Zavedos (Idarubicin Hydrochloride) Powder, Sterile	SS		
INTRAVENOUS	8 MG/M2,					
SINGLE, IV						
			Primperan (Metoclopramide)	SS		
INTRAVENOUS	1 VIAL/8					
HOURS MAX, IV						
			Belustine (Lomustine)	SS		ORAL
200 MG/M2,						
ORAL						
			Zophren (Ondansetron Hydrochloride)	SS		
INTRAVENOUS	2 MG/ML					
VIAL/12						
HOURS, IV						

Tenordate	C
Acupan (Nefopam Hydrochloride)	C

			Lasilix	C		

Date:05/17/04ISR Number: 4359020-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0508336A
Age:16 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Therapeutic Response		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Twice per	
Other	Unexpected							day
	Tourette'S Disorder		Radiation	C				

Date:05/25/04ISR Number: 4364447-4Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0319483A
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper		Zophren	PS	Glaxosmithkline	ORAL		
	Alanine Aminotransferase Increased		Motilium	SS		ORAL		
			Caelyx	SS			INTRAVENOUS	35MG Single
	Aspartate Aminotransferase Increased							dose 1 DAY
			Ziagen	C	Glaxosmithkline	ORAL	300MG Twice	
	Blood Alkaline Phosphatase Increased		Kaletra	C		ORAL	3UNIT Twice	per day
	Gamma-Glutamyltransferase Increased		Viread	C		ORAL	245MG Per day	
	Hyperaesthesia							
	Pain							

Date:05/25/04ISR Number: 4369050-8Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040102969
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Alanine Aminotransferase Increased	Foreign Health Professional	Motilium (Domperidone) Tablets	PS		ORAL	ORAL	
	Aspartate Aminotransferase Increased		Caelyx (Doxorubicin Hydrochloride) Liposome Injection	SS		INTRAVENOUS	35 MG, IN 1 DAY,	
	Blood Alkaline Phosphatase Increased						INTRAVENOUS	
	Gamma-Glutamyltransferase Increased		Zophren (Ondansetron Hydrochloride)	SS		ORAL	ORAL	
	Hepatocellular Damage Hyperaesthesia Neuralgia Pain In Extremity		Ziagen (Abacavir Sulfate) Unknown Kaletra (Kaletra) Unknown Viread (Idoxuridine) Unknown	C C C				

Date:05/27/04ISR Number: 4366599-9Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0333484A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Colitis Ischaemic		Zofran	PS	Glaxosmithkline	UNKNOWN		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/08/04ISR Number: 4373238-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0513561A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Amblyopia		Zofran	PS	Glaxosmithkline		8MG Per day	
	Drug Exposure During Pregnancy							
	Toe Deformity							

Date:06/08/04ISR Number: 4373239-1Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0513569A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Drug Exposure During		Zofran	PS	Glaxosmithkline		8MG Per day	
	Pregnancy							
	Toe Deformity							

Date:06/10/04ISR Number: 4379143-7Report Type:Expedited (15-DaCompany Report #2004-0007110
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Health Professional	Viread (Tenofovir Disoproxil Fumarate) (300 Milligram, Tablet)	PS		ORAL	1 IN 1 D,	
	Aspartate Aminotransferase Increased						ORAL	
	Blood Alkaline Phosphatase Increased		Caelyx (Doxorubicin Hydrochloride) (Injection)	SS			INTRAVENOUS	
	Drug Ineffective							
	Gamma-Glutamyltransferase Increased		Kaletra (Kaletra)	SS		ORAL	ORAL	
	Hepatic Function Abnormal		Viracept (Nelfinavir Mesilate)	SS				
	Hyperaesthesia		Motilium					

	Neuralgia	(Domperidone)	SS	ORAL
ORAL				
	Paraesthesia	Zophen (Ondansetron		
	Renal Failure	Hydrochloride)	SS	ORAL
ORAL				
		Ziagen (Abacavir		
		Sulfate)	SS	ORAL
300 MG, 2 IN				
1 D, ORAL				
		Zalcitabine		
		(Zalcitabine)	C	
		Lamivudine		
		(Lamivudine)	C	
		Efavirenz		
		(Efavirenz)	C	
		Stavudine		
		(Stavudine)	C	
		Indinavir		
		(Indinavir)	C	
		Nelfinavir		
		(Nelfinavir)	C	
		Ritonavir		
		(Ritonavir)	C	
		Didanosine		
		(Didanosine)	C	
		Idoxuridine		
		(Idoxuridine)	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/14/04ISR Number: 4377039-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0335062A
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Erythema	Consumer	Zophren	PS	Glaxosmithkline	ORAL	1UNIT per day	1 MON
	Pigmentation Disorder		Radiotherapy	SS			1	MON
	Skin Exfoliation		Ethyol	SS		INTRAVENOUS	375MG per day	1 MON
	Skin Lesion		Solupred	C	Glaxosmithkline	ORAL	20MG per day	1 DAY
	Toxic Skin Eruption		Keal	C		ORAL	2UNIT per day	3 MON

Date:06/24/04ISR Number: 4385319-5Report Type:Direct Company Report #CTU 221467
Age:19 HR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Withdrawal Syndrome		Ondansetron (Zofran)	PS			4 MG BID	
Initial or Prolonged	Neonatal		Zantac	C				
	Neonatal Apnoeic Attack		Prenatal Vitamins	C				
	Neonatal Disorder							
	Nystagmus							

Date:06/25/04ISR Number: 4385028-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0295621A
Age:11 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cognitive Disorder	Consumer	Zophren	PS	Glaxosmithkline			
INTRAVENOUS							5	DAY
Initial or Prolonged	Confusional State		Zelitrex	SS	Glaxosmithkline	ORAL	4UNIT per day	3 DAY
	Demyelination		Solumedrol	SS				
UNKNOWN							20MG per day	5 DAY
	Disorientation		Methotrexate	SS				
INTRAVENOUS							7	MON
	Micturition Disorder							
	Nausea							

Vomiting

Date:06/28/04ISR Number: 4389067-7Report Type:Expedited (15-DaCompany Report #04P-056-0263854-00
Age:37 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Abdominal Pain Abdominal Pain Upper Abdominal Tenderness Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Asthenia Blood Alkaline Phosphatase Increased Drug Intolerance Dysaesthesia Folate Deficiency Gamma-Glutamyltransferase Increased Hepatocellular Damage Hyperaesthesia Hyperlactacidaemia Neuralgia Neutropenia Oedema Pain

		Pancreatic Disorder Pancytopenia Pulmonary Hypertension	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Rash Renal Failure Renal Failure Chronic Transaminases Increased	Foreign Other	Kaletra Soft Gelatin Capsules (Kaletra) (Lopinavir/Ritonavir)	PS		ORAL
3 CAPSULE, 2 IN 1 D, PER ORAL							
				Ritonavir	SS		
				Didanosine	SS		
				Stavudine	SS		
				Indinavir	SS		
				Nelfinavir Mesilate	SS		
				Doxorubicin Hydrochloride	SS		
INTRAVENOUS	35 MG, 1 IN 1 D, INTRAVENOUS						
				Zidovudine W/Lamivudine	SS		
				Gabapentin	SS		
				Viread	SS		ORAL
245 MG, 1 IN 1 D, PER ORAL							
				Abacavir Sulfate	SS		ORAL
300 MG, 2 IN 1 D, PER ORAL							
				Ondansetron Hydrochloride	SS		ORAL
PER ORAL							
				Motilium	SS		ORAL
PER ORAL							
				Zalcitabine	C		
				Lamivudine	C		
				Efavirenz	C		
				Idoxuridine	C		

Date:07/07/04ISR Number: 4391453-6Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0336838A
Age:6 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Acute Respiratory		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS		
Hospitalization -	Distress Syndrome		Tazocin	C		UNKNOWN		
Initial or Prolonged	Sepsis		Chemotherapy	C				
Other			Anaesthetics	C				
			Antibiotics	C				
			Colloids	C				

Date:07/07/04ISR Number: 4391470-6Report Type:Expedited (15-DaCompany Report #AU-GLAXOSMITHKLINE-B0337615A
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction		Zofran	PS	Glaxosmithkline	UNKNOWN		
	Hypersensitivity							

Date:07/09/04ISR Number: 4393716-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0517250A
Age:54 YR Gender:Male I/FU:I

Outcome	PT
Other	Agitation
	Circulatory Collapse
	Feeling Jittery

	Insomnia Mania Tremor	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Vocal Cord Disorder		Zofran	PS	Glaxosmithkline	
INTRAVENOUS						
			Toprol Xl	C		
			Lasix	C	Glaxosmithkline	
			Coumadin	C	Glaxosmithkline	
			Xanax	C		
			Synthroid	C	Glaxosmithkline	
			Lovenox	C		
			Chemotherapy	C		

Date:07/12/04ISR Number: 4394938-1Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0337178A
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Skin Necrosis	Consumer	Zophren	PS	Glaxosmithkline	
INTRAVENOUS 2MG Single						
Initial or Prolonged	Vasculitis					
dose 1 DAY						
			Fervex	SS		ORAL
1 DAY						
			Lasilix	SS	Glaxosmithkline	ORAL
40MG Unknown						
			Deticene	SS		
INTRAVENOUS 1000MG Single						
dose 1 DAY						
			Lexomil	SS		ORAL
12MG Per day 2 DAY						
			Dafalgan	C	Glaxosmithkline	ORAL
6 DAY						
			Bronchokod	C	Glaxosmithkline	
UNKNOWN 6 DAY						
			Oropivalone	C		
UNKNOWN 6 DAY						
			Hexaspray	C		
UNKNOWN 6 DAY						

Date:07/12/04ISR Number: 4394954-XReport Type:Expedited (15-DaCompany Report #CH-GLAXOSMITHKLINE-B0338422A
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Automatism	Consumer	Zofran	PS	Glaxosmithkline	INTRAVENOUS	16MG per day	1 DAY
Hospitalization -	Blood Sodium Decreased		Endoxan	SS		INTRAVENOUS	4600MG per	
Initial or Prolonged	Depressed Level Of							
day							1	DAY
Disability	Consciousness		Uromitexan	SS		INTRAVENOUS	4000MG per	
	Dizziness							
day							1	DAY
	Inappropriate		Dexamethasone	SS		ORAL	15MG per day	1 DAY
	Antidiuretic Hormone		Motilium	SS		ORAL	80MG per day	1 DAY
	Secretion							
	Meningitis							
	Nausea							
	Polyuria							
	Somnolence							
	Status Epilepticus							
	Urine Sodium Decreased							
	Vomiting							

Date:07/13/04ISR Number: 4396297-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0517258A
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Health	Zofran	PS	Glaxosmithkline	UNKNOWN		
	Post Procedural Complication	Professional	Unknown	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/15/04ISR Number: 4398260-9Report Type:Expedited (15-DaCompany Report #CH-BRISTOL-MYERS SQUIBB COMPANY-12640470
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Inappropriate	Health	Endoxan	PS	Bristol-Myers Squibb			
Hospitalization -	Antidiuretic Hormone	Professional			Company			
Initial or Prolonged	Secretion		Uromitexan	SS	Bristol-Myers Squibb			
Other					Company			
			Zofran	SS				
			Domperidone	SS		ORAL		
			Dexacortin	SS		ORAL		

							INTRAVENOUS	1 DAY
							INTRAVENOUS	1 DAY
							1 DAY	
							1 DAY	

Date:07/16/04ISR Number: 4399535-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0518548A
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Paraesthesia		Zofran	PS	Glaxosmithkline			
	Paralysis Flaccid							
			Diazide	C				
			Advil	C	Glaxosmithkline			
			Norvasc	C				
			Adriamycin	C				

							INTRAVENOUS	20MG Single
							dose	0 DAY

Date:07/16/04ISR Number: 4405263-4Report Type:Expedited (15-DaCompany Report #2004US002185
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Paraesthesia Oral	Health	Aloxi					
	Paralysis Flaccid	Professional	(Palonosetronhydrochloride) Injection, 0.25mg/5ml	PS				

							INTRAVENOUS	

BOLUS

0.25 MG,

SINGLE, IV

BOLUS

		Zofran (Ondansetron Hydrochloride)	SS
INTRAVENOUS	20 MG,		
SINGLE,			
INTRAVENOUS			
		Normal Saline (Sodium Chloride)	C
		Adriamycin (Doxorubicin)	C
		Taxotere (Docetaxel)	C
		Benadryl "Warner-Lambert" (Diphenydramine Hydrochloride)	C
		Zantac (Ranitidine Hydrochloride)	C
		Decadron (Dexamethasone)	C
		Norvasc (Amlodipine)	C
		Dyazide (Triamterene, Hydrochlorothiazide)	C
		Advil (Ibuprofen)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/19/04ISR Number: 4402771-7Report Type:Expedited (15-DaCompany Report #DRON00204000324
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Diastolic Decreased	Study Health Professional	Marinol (Marinol)	PS		ORAL	2.5 MG BID	PO, SEE IMAGE
	Dizziness Fatigue Feeling Abnormal Nausea Oral Intake Reduced Syncope		Ondansetron (Ondansetron)	SS		INTRAVENOUS	16 MG DAILY	IV, SEE IMAGE
			Dexamethasone (Dexamethasone)	SS		ORAL	20 MG DAILY	PO
			Vitamin C	C				
			Glucosamine	C				
			Calcium	C				
			Folic Acid	C				
			Centrum	C				
			Lisinopril	C				
			Hydrochlorothiazide	C				
			Vitamin E	C				
			Aspirine (Acetylsalicylic Acid)	C				

Date:07/19/04ISR Number: 4402773-0Report Type:Expedited (15-DaCompany Report #DRON00204001114
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased Chest Pain Febrile Neutropenia Gastrooesophageal Reflux Disease	Study Health Professional	Marinol (Dronabinol)	PS		ORAL	2 DF DAILY PO	
			Ondansetron (Ondansetron)	SS		INTRAVENOUS	16 MG ONCE IV	
			Dexamethasone (Dexamethasone)	SS		ORAL	20 MG ONCE PO	
			Carboplatin					

		Muscle Spasms		(Carboplatin)	SS		
INTRAVENOUS	465 MG ONCE						
		Pancytopenia					
IV							
		White Blood Cell Count Increased		Gemzar (Gemcitabine Hydrochloride)	SS		
INTRAVENOUS	1830 MG ONCE						
IV, 1830 MG							
ONCE IV							
				Verapamil	C		
				Glucotrol (Glipizide)	C		
				Lisinopril	C		

Date:07/19/04ISR Number: 4403798-1Report Type:Expedited (15-DaCompany Report #DRON00204001047
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Pain	Study	Marinol (Dronabinol)	PS		ORAL	2.5 MG BID PO	
	Headache	Health Professional	Ondansetron (Ondansetron)	SS				
INTRAVENOUS	16 MG ONCE IV							
			Dexamethasone (Dexamethasone)	SS		ORAL	20 MG DAILY	
PO								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/20/04ISR Number: 4402274-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0518552A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Abortion Spontaneous Depression Drug Exposure During Pregnancy Haemorrhage		Zofran No Concurrent Medication	PS C	Glaxosmithkline	ORAL	1 MON	

Date:07/22/04ISR Number: 4404720-4Report Type:Expedited (15-DaCompany Report #2004US002185
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Paraesthesia Paralysis Flaccid		Zofran	PS	Glaxosmithkline	INTRAVENOUS	20MG Single	dose 0 DAY
			Dyazide	C	Glaxosmithkline			
			Advil	C	Glaxosmithkline			
			Norvasc	C				
			Adriamycin	C				
			Taxotere	C				
			Aloxi	C		INTRAVENOUS		
			Diphenhydramine	C				
			Ranitidine	C	Glaxosmithkline			
			Decadron	C				
			Normal Saline	C	Glaxosmithkline			

Date:07/23/04ISR Number: 4409729-2Report Type:Expedited (15-DaCompany Report #DRON00204002000
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia Biopsy Bone Marrow	Study Health	Marinol (Dronabinol)	PS		ORAL	2.5 MG BID PO, 2.5 MG	

	Abnormal	Professional				
QID PO						
	Nausea		Dexamethasone			
	Pneumonia Klebsiella		(Dexamethasone)	SS		ORAL
20 MG ONCE PO						
	Pneumonitis		Ondansetron			
	Sepsis		(Ondansetron)	SS		
INTRAVENOUS 16 MG ONCE IV						
	Vomiting		Fosinopril			
			(Fosinopril)	C		
			Adalat (Nifedipine)	C		
			Metformin			
			(Metformin)	C		
			Terazosin			
			(Terazosin)	C		

Date:07/26/04ISR Number: 4407849-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0339667A
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Erythema	Consumer	Zophren	PS	Glaxosmithkline	
INTRAVENOUS 8MG per day 1 DAY						
Initial or Prolonged	Eyelid Oedema		Cisplatine	SS		
INTRAVENOUS 140MG per day 1 DAY						
	Ill-Defined Disorder		Gemzar	SS		
INTRAVENOUS 2200MG per						
day 1 DAY						
			Neurontin	C		ORAL
3UNIT per day						
			Inexium	C		ORAL
1UNIT per day						
			Aspegic	C		ORAL
250MG per day						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/26/04ISR Number: 4407850-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0339757A
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills Hyperthermia	Consumer	Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG Single	dose
			Azantac	SS	Glaxosmithkline	INTRAVENOUS	50MG Single	dose
			Polaramine	SS		INTRAVENOUS	5MG Single	dose
			Taxol	SS		INTRAVENOUS	300MG Single	dose
			Carboplatine	SS		INTRAVENOUS	310MG Single	dose
			Solumedrol	SS		INTRAVENOUS	120MG Single	dose
			Zophren	C	Glaxosmithkline	ORAL		
			Durogesic	C		UNKNOWN		
			Sevredol	C	Glaxosmithkline	UNKNOWN		
			Movicol	C		UNKNOWN		
			Peristaltine	C		UNKNOWN		
			Zoloft	C		UNKNOWN		
			Imovane	C		UNKNOWN		
			Tardyferon	C		UNKNOWN		

Date:07/27/04ISR Number: 4408845-9Report Type:Expedited (15-DaCompany Report #2004US002185
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia		Zofran	PS	Glaxosmithkline	INTRAVENOUS	20MG Single	
Initial or Prolonged	Diastolic Dysfunction							
dose							0	DAY
	Haemangioma		Dyazide	C	Glaxosmithkline			
1TAB Per day								
	Heart Rate Increased		Advil	C	Glaxosmithkline			
	Hypoaesthesia		Norvasc	C				
10MG Per day								
	Malformation Venous		Adriamycin	C				
70MG Every								
	Migraine							
two weeks								
	Mitral Valve Incompetence		Taxotere	C				
150MG Every								
	Muscle Tightness							
two weeks								
	Musculoskeletal		Aloxi	C				
INTRAVENOUS								
	Discomfort		Diphenhydramine	C				
	Oedema Peripheral		Ranitidine	C	Glaxosmithkline			
	Paraesthesia		Decadron	C				
	Paraesthesia Oral		Normal Saline	C	Glaxosmithkline			
	Paralysis Flaccid		Zyrtec	C	Glaxosmithkline			
1TAB Per day								
	Transient Ischaemic		Calcium	C				
1500MG Per								
	Attack							
day								
	Visual Disturbance		Vitamin E	C				
			Centrum Silver	C				

Date:07/27/04ISR Number: 4408852-6Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0519239A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anxiety		Zofran	PS	Glaxosmithkline	INTRAMUSCULAR	10MG per day	
Initial or Prolonged	Blood Pressure Decreased		Zofran	SS	Glaxosmithkline	ORAL		
4MG Twice per								
	Catatonia							
day								
	Drug Exposure During		Prozac	C				
	Pregnancy		Ambien	C				
	Insomnia		Phenergan	C	Glaxosmithkline			

	Syncope Vasovagal		Tigan	C	Glaxosmithkline

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/27/04ISR Number: 4409768-1Report Type:Direct Company Report #CTU 223654
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Swollen Tongue		Zofran 2mg/Ml					
Hospitalization -	Throat Tightness		Glaxosmithkline	PS	Glaxosmithkline			
INTRAVENOUS							4MG	NOW
Initial or Prolonged	Urticaria							
INTRAVENOUS								
Required			Lipitor	C				
Intervention to			Lasix	C				
Prevent Permanent			Lisinopril	C				
Impairment/Damage			Coumadin	C				
			Synthroid	C				
			Hydrocodone	C				
			Alprazolam	C				
			Paxil	C				

Date:07/27/04ISR Number: 4409810-8Report Type:Direct Company Report #CTU 223655
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Erythema		Zofran 2mg/Ml					
	Pruritus		Glaxosmithkline	PS	Glaxosmithkline			
INTRAVENOUS							8MG	NOW
INTRAVENOUS								

Date:07/28/04ISR Number: 4410636-XReport Type:Direct Company Report #CTU 223793
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Chest Pain		Zofran 4 Mg / Iv					
Required	Coma		C099722 2/2007	PS				
INTRAVENOUS							4 MG-PRN-	IV
Intervention to	Lethargy							
Prevent Permanent								
Impairment/Damage								

Date:07/28/04ISR Number: 4413381-XReport Type:Expedited (15-DaCompany Report #2003152715FR
Age:11 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradyphrenia Confusional State Demyelination Disorientation Drug Level Increased	Foreign Health Professional Other	Solu-Medrol (Methylprednisolone) Powder, Sterile Zophren (Ondansetron Hydrochloride)	PS SS		INTRAVENOUS INTRAVENOUS	IV 11 G, CYCLIC, IV	
	Micturition Disorder Nausea Nuclear Magnetic Resonance Imaging Abnormal Vomiting		Methotrexate "Roger Bellon" (Methotrexate) Zelitrex (Valaciclovir)	SS SS	Roger Bellon	INTRAVENOUS ORAL	4 DF, ORAL	

Date:08/02/04ISR Number: 4413190-1Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0340937A
Age:51 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Acute Generalised Exanthematous Pustulosis Aphthous Stomatitis Dermatitis Bullous

	Erythema					
	Inflammation					
	Oedema Peripheral	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Pain In Extremity	Consumer	Zophren	PS	Glaxosmithkline	
UNKNOWN						
	Pyrexia		Becilan	SS		ORAL
250MG Three						
	Rash Erythematous					
times per day						
			Neurontin	SS		ORAL
55 DAY						
			Taxotere	SS		
INTRAVENOUS	110MG Monthly					
			Caelyx	SS		
INTRAVENOUS	70MG Monthly					

Date:08/03/04ISR Number: 4414021-6Report Type:Expedited (15-DaCompany Report #2004US002185
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Asthenia	Health	Zofran	PS	Glaxosmithkline	
INTRAVENOUS	20MG Single					
Initial or Prolonged	Blood Pressure Systolic	Professional				
dose	0 DAY					
	Increased		Dyazide	C	Glaxosmithkline	
1TAB Per day						
	Diastolic Dysfunction		Advil	C	Glaxosmithkline	
	Haemangioma		Norvasc	C		
10MG Per day						
	Heart Rate Increased		Adriamycin	C		
70MG Every						
	Hypoaesthesia					
two weeks						
	Malformation Venous		Taxotere	C		
150MG Every						
	Migraine					
two weeks						
	Mitral Valve Incompetence		Aloxi	C		
INTRAVENOUS						
	Muscle Tightness		Diphenhydramine	C		
	Musculoskeletal		Ranitidine	C	Glaxosmithkline	
	Discomfort		Decadron	C		
	Oedema Peripheral		Normal Saline	C	Glaxosmithkline	

	Paraesthesia		Zyrtec	C	Glaxosmithkline	
1TAB Per day						
	Paraesthesia Oral		Calcium	C		
1500MG Per						
	Paralysis Flaccid					
day						
	Transient Ischaemic		Vitamin E	C		
	Attack		Centrum Silver	C		
	Visual Disturbance					

Date:08/03/04ISR Number: 4414045-9Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0340418A
Age:37 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blindness Transient		Zofran	PS	Glaxosmithkline			
INTRAVENOUS	4MG Single							
	Feeling Abnormal							
dose	0 DAY							
	Sensory Disturbance		No Concurrent					
	Vision Blurred		Medication	C				

Date:08/03/04ISR Number: 4418014-4Report Type:Expedited (15-DaCompany Report #2004US002185
Age:56 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Asthenia
Initial or Prolonged	Haemangioma
Other	Hypoaesthesia
	Malformation Venous
	Muscle Tightness
	Musculoskeletal
	Discomfort
	Nervous System Disorder
	Oedema Peripheral
	Paraesthesia Oral

		Paralysis Flaccid Photopsia Transient Ischaemic Attack	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional	Aloxi(Palonosetron Hydrochloride) Injection, 0.25mg/5mi	PS		
INTRAVENOUS							BOLUS
0.25 MG MG, SINGLE, IV BOLUS							
				Zofran (Ondansetron Hydrochloride)	SS		
INTRAVENOUS	20 MG, SINGLE, INTRAVENOUS						
				Normal Saline (Sodium Chloride)	C		
				Adriamycin (Doxorubicin)	C		
				Taxotere (Docetaxel)	C		
				Benadryl "Warner-Lambert" (Diphenydramine Hydrochloride)	C		
				Zantac (Ranitidine Hydrochloride)	C		
				Decadron (Dexamethasone)	C		
				Norvasc (Amlodipine)	C		
				Dyazide (Triamterene, Hydrochlorothazide)	C		
				Advil (Ibuprofen)	C		
				Zyrtec (Cetirizine Hydrochloride)	C		
				Calcium (Calcium)	C		
				Vitamin E (Tocopherol)	C		
				Centrum Silver (Ascorbic Acid,			

			Calcium, Minerals Nos, Retinol, Tocopheryl Acetate, Acetylsalicylic Acid	C C		

Date:08/04/04ISR Number: 4415368-XReport Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12651675
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills Hyperthermia		Taxol	PS	Bristol-Myers Squibb Company	INTRAVENOUS	Therapy	dates: 11-May to 01-Jun-2004
			Carboplatin	SS	Bristol-Myers Squibb Company	INTRAVENOUS	Therapy	dates: 11-May to 01-Jun-2004
			Polaramine	SS		INTRAVENOUS		
			Solu-Medrol	SS		INTRAVENOUS		

			Azantac	SS		
INTRAVENOUS						
			Zophren	SS		
INTRAVENOUS						
			Solupred	C		
			Durogesic	C		
			Sevredol	C		
			Movicol	C		
			Peristaltine	C		
			Zoloft	C		
			Imovane	C		
			Tardyferon	C		

Date:08/04/04ISR Number: 4416254-1Report Type:Direct Company Report #CTU 224222
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angioneurotic Oedema		Ondansetron	PS		INTRAVENOUS	8 MG IV Q 6 H	1 DOSE
	Drug Exposure During Pregnancy							
	Tongue Oedema							

Date:08/05/04ISR Number: 4416358-3Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0518796A
Age:31 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Exposure During		Zofran	PS	Glaxosmithkline	SUBCUTANEOUS		4 DAY
	Pregnancy		Normal Saline	C	Glaxosmithkline			
	Drug Ineffective							
	Injection Site Erythema							
	Injection Site Pain							
	Medication Error							
	Nausea							
	Vomiting							

Date:08/05/04ISR Number: 4423253-2Report Type:Expedited (15-DaCompany Report #DRON00204001047
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Potassium Decreased	Study	Marinol (Dronabinol)	PS		ORAL	2.5 MG BID PO	
	Chest Pain	Health Professional	Ondansetron (Ondansetron)	SS		INTRAVENOUS	16 MG ONCE IV	
	Glycosylated Haemoglobin Increased		Dexamethasone (Dexamethasone)	SS		ORAL	20 MG DAILY	
	Haemoglobin Decreased							
	Headache						PO	
			Ultracet (Tramadol)	C				
			Novolin (Insulin)	C				

Date:08/06/04ISR Number: 4417254-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0518796A
Age:31 YR Gender:Female I/FU:F

Outcome	PT
Other	Drug Exposure During Pregnancy
	Drug Ineffective
	Injection Site Erythema
	Injection Site Pain
	Medication Error
	Nausea

	Vomiting						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Zofran	PS	Glaxosmithkline	SUBCUTANEOUS	4 DAY
			Normal Saline	C	Glaxosmithkline		

Date:08/06/04ISR Number: 4417278-0Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0340922A
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - UNKNOWN	Alanine Aminotransferase		Zophren	PS	Glaxosmithkline		
Initial or Prolonged INTRAVENOUS	Increased		Augmentin Iv	SS	Glaxosmithkline		
	Aspartate		Fraxiparine	SS		SUBCUTANEOUS	
	Aminotransferase		Mopral	SS		INTRAVENOUS	
	Increased		Eupantol	SS		ORAL	
	Vomiting		Perfalgan	SS	Glaxosmithkline	INTRAVENOUS	

Date:08/06/04ISR Number: 4417320-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0518796A
Age:31 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Drug Exposure During	Health	Zofran	PS	Glaxosmithkline	SUBCUTANEOUS	4 DAY
	Pregnancy	Professional	Normal Saline	C	Glaxosmithkline		
	Drug Ineffective						
	Injection Site Erythema						
	Injection Site Pain						
	Medication Error						
	Nausea						
	Vomiting						

Date:08/06/04ISR Number: 4417343-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0340922A
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase	Consumer	Zophren	PS	Glaxosmithkline			UNKNOWN
Initial or Prolonged	Increased		Augmentin Iv	SS	Glaxosmithkline			INTRAVENOUS
	Aspartate		Fraxiparine	SS				SUBCUTANEOUS
	Aminotransferase		Mopral	SS				INTRAVENOUS
	Increased		Eupantol	SS		ORAL		
	Vomiting		Perfalgan	SS	Glaxosmithkline			INTRAVENOUS

Date:08/06/04ISR Number: 4423432-4Report Type:Expedited (15-DaCompany Report #2004225238FR
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Pressure Decreased	Foreign	Clitaxel(Paclitaxel)					
Initial or Prolonged	Chills	Health	Solution, Sterile	PS				INTRAVENOUS
	Haemoglobin Decreased	Professional					300 MG,	CYCLIC, IV
	Hyperthermia	Other	Carboplatin(Carboplatin) Solution, Sterile	SS				INTRAVENOUS
	Neutrophil Count Increased						310 MG,	CYCLIC , IV
	Respiratory Rate Increased		Solu-Medrol(Methylprednisolone) Powder, Sterile	SS				INTRAVENOUS
			Ranitidin Nm(Ranitidine				120 MG, IV	

		Hydrochloride)	
		Tablet	SS
INTRAVENOUS	50 MG, IV		
		Polaramine(Dexchlorpheniramine Maleate)	SS
INTRAVENOUS	5 MG , IV		
		Zophren(Ondansetron Hydrochloride)	SS
INTRAVENOUS	8 MG, IV		
		Solupred(Prednisolone Sodium Sulfobenzoate)	C
		Durogesic	C
		Sevredol	C
		Movicol	C
		Peristaltine (Cascara Dry Extract)	C
		Zoloft	C
		Imovane	C
		Tardyferon	C

Date:08/09/04ISR Number: 4420998-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0520751A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged required	Drug Exposure During Pregnancy		Zofran	PS	Glaxosmithkline	ORAL	4MG As	7 WK
Other	Hypertension Necrosis Premature Baby Stillbirth		Multivitamin	C				

Date:08/09/04ISR Number: 4420999-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0520751B
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Exposure During		Zofran	PS	Glaxosmithkline		4MG As	

	Pregnancy					
required						
	Eye Disorder		Multivitamin	C		
	Premature Baby					
	Strabismus					

Date:08/10/04ISR Number: 4422335-9Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0341563A
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Gamma-Glutamyltransferase	Consumer	Augmentin Iv	PS	Glaxosmithkline	
INTRAVENOUS	1 DAY					
Initial or Prolonged	Increased		Zophren	SS	Glaxosmithkline	
UNKNOWN						
	Nausea		Fraxiparine	SS		
SUBCUTANEOUS						
	Transaminases Increased		Mopral	SS		
INTRAVENOUS						
	Vomiting		Eupantol	SS		ORAL
			Perfalgan	SS	Glaxosmithkline	
INTRAVENOUS						
			Topalgic (France)	SS		
UNKNOWN						
			Diprivan	C		
UNKNOWN	1 DAY					
			Nimbex	C	Glaxosmithkline	
UNKNOWN	1 DAY					
			Durogesic	C		
UNKNOWN						
			Lexomil	C		ORAL
			Debridat	C		
UNKNOWN						
			Morphine	C		
UNKNOWN						
			Primperan	C	Glaxosmithkline	
UNKNOWN						
			Allochrysine	C		ORAL

			Corticoids	C		
UNKNOWN						
			Ultiva	C	Glaxosmithkline	
UNKNOWN	1 DAY					

Date:08/17/04ISR Number: 4431000-3Report Type:Expedited (15-DaCompany Report #DRON00204001047
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Back Pain	Study	Marinol (Dronabinol)	PS		ORAL	2.5 MG BID PO	
Initial or Prolonged	Blood Potassium Decreased	Health	Ondansetron					
	Chest Pain	Professional	(Ondansetron)	SS				
INTRAVENOUS	16 MG ONCE IV							
	Glycosylated Haemoglobin		Dexamethasone					
	Increased		(Dexamethasone)	SS		ORAL	20 MG DAILY	
	Haemoglobin Decreased							
PO								
	Headache		Ultracet (Tramadol)	C				
	Myocardial Infarction		Novolin (Insulin)	C				
	Prothrombin Time Prolonged							

Date:08/18/04ISR Number: 4428813-0Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0522219A
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Exposure During		Zofran	PS	Glaxosmithkline	ORAL	8MG Twice per	
	Pregnancy							
day								
	Vaginal Haemorrhage		Prenatal Vitamins	C				
			Progesterone	C				

Date:08/18/04ISR Number: 4428832-4Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0342076A
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Areflexia	Consumer	Azantac	PS	Glaxosmithkline			
INTRAVENOUS							1UNIT Per day	1 DAY
Initial or Prolonged	Deafness		Zophren	SS	Glaxosmithkline			
INTRAVENOUS							1UNIT per day	1 DAY
	Paraesthesia		Polaramine	SS				
INTRAVENOUS							1UNIT per day	1 DAY
	Polyneuropathy		Solumedrol	SS				
INTRAVENOUS								1 DAY
			Cisplatine	SS				
INTRAVENOUS							160MG per day	1 DAY
			Taxol	SS				
INTRAVENOUS							250MG per day	1 DAY

Date:08/23/04ISR Number: 4430853-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0522644A
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety		Zofran	PS	Glaxosmithkline			
INTRAVENOUS							24MG See	
	Blindness Unilateral							
dosage text							3	MON
			Ativan	C				
			Zolpidem	C				
			Percocet	C				
			Fluorouracil	C				
			Leucovorin	C	Glaxosmithkline			
			Ferrous Sulfate	C	Glaxosmithkline			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/24/04ISR Number: 4431410-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0522219A
Age:24 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Exposure During		Zofran	PS	Glaxosmithkline	ORAL	8MG Twice per	
	Pregnancy						day	
	Vaginal Haemorrhage		Prenatal Vitamins	C				
			Progesterone	C				

Date:08/25/04ISR Number: 4434295-5Report Type:Expedited (15-DaCompany Report #2004056277
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Generalised Exanthematous Pustulosis	Foreign Health	Neurontin (Gabapentin)	PS		ORAL	100 MG, ORAL	
	Aphthous Stomatitis	Professional	Pyridoxine Hydrochloride (Pyridoxine Hydrochloride)	SS			750 MG (25-	
	Clostridial Infection						MG, TID)	
	Enterobacter Infection							
	General Physical Health Deterioration							
	Inflammation		Ondansetron Hydrochloride	SS				
	Oedema Peripheral		Docetaxel (Docetaxel)	SS			INTRAVENOUS	110 MG
	Pain In Extremity						(CYCLIC),	
	Rash Erythematous						INTRAVENOUS	
	Skin Lesion		Doxorubicin Hydrochloride	SS			INTRAVENOUS	70 MG
	Staphylococcal Infection						(CYCLIC),	
							INTRAVENOUS	

Date:08/31/04ISR Number: 4439198-8Report Type:Expedited (15-DaCompany Report #2004056277
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Generalised Exanthematous Pustulosis	Foreign Health	Neurontin (Gabapentin)	PS		ORAL	100 MG, ORAL	
	Aphthous Stomatitis C-Reactive Protein Increased Clostridial Infection	Professional	Pyridoxine Hydrochloride (Pyridoxine Hydrochloride)	SS			750 MG (250 MG, 3 IN 1 D)	
	Enterobacter Infection Inflammation Neutrophil Count Increased Oedema Peripheral Pain In Extremity Pyrexia		Ondansetron Hydrochloride (Ondansetron Hydrochloride) Docetaxel (Docetaxel)	SS SS			INTRAVENOUS	110 MG
	Rash						(CYCLIC),	
	Rash Erythematous Scar Skin Lesion Staphylococcal Infection		Doxorubicin Hydrochloride (Doxorubicin Hydrochloride)	SS			INTRAVENOUS	70 MG
							(CYCLIC),	
							INTRAVENOUS	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/01/04ISR Number: 4439059-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0523789A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Exposure During Pregnancy Medication Error Rash		Zofran	PS	Glaxosmithkline	SUBCUTANEOUS		1 DAY

Date:09/02/04ISR Number: 4440052-6Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0524065A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dementia		Zofran	PS	Glaxosmithkline	ORAL	8MG	Unknown
			No Concurrent Medication	C				

Date:09/02/04ISR Number: 4446325-5Report Type:Expedited (15-DaCompany Report #B0343337A
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Subcorneal Pustular Dermatosis	Foreign Literature Health Professional	Ondansetron Hydrochloride (Ondansetron Hydrochloride)	PS				
			Amox. Trihyd+Pot. Clavulan	C				
			Ketorolac Trometamol	C				
			Ranitidine Hydrochloride	C				
			Dalteparin Sodium	C				

Date:09/07/04ISR Number: 4455130-5Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0340922A
Age:40 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Gamma-Glutamyltransferase	Consumer	Augmentin Iv	PS	Glaxosmithkline	INTRAVENOUS	1	DAY
Initial or Prolonged	Increased		Zophren	SS	Glaxosmithkline	UNKNOWN		
	Nausea		Fraxiparine	SS	Glaxosmithkline	SUBCUTANEOUS		
	Transaminases Increased		Mopral	SS		INTRAVENOUS		
	Vomiting		Eupantol	SS		ORAL		
			Perfalgan	SS	Glaxosmithkline	INTRAVENOUS		
			Topalgic (France)	SS		UNKNOWN		

Date:09/07/04ISR Number: 4455131-7Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0341563A
Age:40 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Gamma-Glutamyltransferase	Consumer	Augmentin Iv	PS	Glaxosmithkline	INTRAVENOUS	1	DAY
Initial or Prolonged	Increased		Zophren	SS	Glaxosmithkline	UNKNOWN		
	Nausea		Fraxiparine	SS	Glaxosmithkline	SUBCUTANEOUS		
	Transaminases Increased		Mopral	SS		INTRAVENOUS		
	Vomiting		Eupantol	SS		ORAL		
			Perfalgan	SS	Glaxosmithkline	INTRAVENOUS		
			Topalgic (France)	SS		UNKNOWN		
			Diprivan	C		UNKNOWN	1	DAY
			Nimbex	C	Glaxosmithkline	UNKNOWN	1	DAY
			Durogesic	C		UNKNOWN		

				Lexomil	C		ORAL
				Debridat	C		
UNKNOWN							
				Morphine	C		
UNKNOWN							
				Primperan	C	Glaxosmithkline	
UNKNOWN							
				Allochrysine	C		ORAL
				Corticoids	C		
UNKNOWN							
				Ultiva	C	Glaxosmithkline	
UNKNOWN	1 DAY						

Date:09/08/04ISR Number: 4446535-7Report Type:Expedited (15-DaCompany Report #2004229510FR
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Areflexia Deafness Paraesthesia	Health Professional Other	Solu-Medrol(Methylprednisolone) Powder, Sterile	PS		INTRAVENOUS	IV	
	Polyneuropathy		Ranitidina Dorom (Ranitidine Hydrochloride)	SS		INTRAVENOUS	IV	
			Cisplatin (Cisplatin) Solution, Sterile	SS		INTRAVENOUS	160 MG, IV	
			Clitaxel (Paclitaxel) Solution, Sterile	SS		INTRAVENOUS	250 MG, QD, IV	
			Polaramine (Dexchlorpheniramine Maleate)	SS		INTRAVENOUS	5 MG, IV	
			Zophren (Ondansetron Hydrochloride)	SS		INTRAVENOUS	1 DF, IV	

Date:09/09/04ISR Number: 4444869-3Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0519239A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anxiety	Consumer	Zofran	PS	Glaxosmithkline	INTRAMUSCULAR	10MG per day	
Initial or Prolonged	Blood Pressure Decreased		Zofran	SS	Glaxosmithkline	ORAL	4MG Twice per	
	Catatonia						day	
	Drug Exposure During		Prozac	C				
	Pregnancy		Ambien	C				
	Formication		Phenergan	C	Glaxosmithkline			
	Insomnia		Tigan	C	Glaxosmithkline			
	Syncope Vasovagal							

Date:09/13/04ISR Number: 4448195-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0522644A
Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Health	Zofran	PS	Glaxosmithkline	INTRAVENOUS	24MG See	
	Blindness Unilateral	Professional					dosage text	3 MON
			Ativan	C				
			Zolpidem	C				
			Percocet	C				
			Fluorouracil	C				
			Leucovorin	C	Glaxosmithkline			
			Ferrous Sulfate	C	Glaxosmithkline			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/15/04ISR Number: 4451719-8Report Type:Expedited (15-DaCompany Report #2004229510FR
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Areflexia Deafness Paraesthesia	Foreign Health Professional	Solu-Medrol (Methylprednisolone) Powder, Sterile	PS		INTRAVENOUS	SINGLE, IV	
	Polyneuropathy	Other	Ranitidina (Dorom (Ranitidine Hydrochloride, Ranitidine Hydrochloride)	SS		INTRAVENOUS	1 DF, SINGLE, IV	
			Cisplatin (Cisplatin) Solution, Sterile	SS		INTRAVENOUS	160 MG, SINGLE, IV	
			Clitaxel (Paclitaxel, Paclitaxel) Solution, Sterile	SS		INTRAVENOUS	250 MG, SINGLE, IV	
			Polaramine (Dexchlorpheniramine Maleate)	SS		INTRAVENOUS	1 DF, SINGLE, IV	
			Zophren (Ondansetron Hydrochloride)	SS		INTRAVENOUS	1 DF, SINGLE, IV	

Date:09/20/04ISR Number: 4459192-0Report Type:Direct Company Report #CTU 227692
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Erythema		Tylenol #3 30/30 Mg	PS		ORAL	2 TABS ONE	TIME ORAL
			Zofran Odt 4 Mg	SS		ORAL	4 MG ONE TIME	ORAL

Date:09/21/04ISR Number: 4457609-9Report Type:Expedited (15-DaCompany Report #B0260872A
Age:94 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrial Fibrillation	Foreign	Zofran Injection					
Hospitalization - Initial or Prolonged	Myocardial Infarction	Health Professional	(Ondansetron Hydrochloride)	PS		INTRAVENOUS	4 MG/	Required
Intervention to Prevent Permanent Impairment/Damage			Benserazide + Levodopa	C				
			Amiloride + Hctz	C				
			Aspirin	C				
			Gliclazide	C				

Date:09/22/04ISR Number: 4455952-0Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0522219A
Age:24 YR Gender:Female I/FU:F

Outcome	PT
Other	Drug Exposure During Pregnancy

Vaginal Haemorrhage

			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional	Zofran	PS	Glaxosmithkline	ORAL
8MG Twice per day							
				Prenatal Vitamins	C		
				Progesterone	C		

Date:09/22/04ISR Number: 4455954-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0525996A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Congenital Anomaly	Drug Exposure During Pregnancy		Zofran	PS	Glaxosmithkline	
4MG Twice per day	4 MON					
	Heart Disease Congenital		No Concurrent Medication	C		

Date:09/30/04ISR Number: 4463252-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0345675A
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Malaise	Consumer	Zophren	PS	Glaxosmithkline	
INTRAVENOUS	8MG Per day 1 DAY					
	Pruritus		Lederfoline	SS	Glaxosmithkline	
INTRAVENOUS	325MG Per day 2 DAY					
	Rash Erythematous		Eloxatine	SS		
INTRAVENOUS	160MG Per day 1 DAY					
	Tremor		Fluoro-Uracile	SS		
INTRAVENOUS	650MG Per day 2 DAY					

Date:09/30/04ISR Number: 4463253-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0345681A
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chills	Consumer	Zophren	PS	Glaxosmithkline			
INTRAVENOUS							8MG Per day	1 DAY
Initial or Prolonged	Pyrexia		Lederfoline	SS	Glaxosmithkline			
INTRAVENOUS							325MG Per day	1 DAY
			Eloxatine	SS				
INTRAVENOUS							140MG Per day	1 DAY
			Fluoro-Uracile	SS				
INTRAVENOUS							650MG Per day	1 DAY

Date:09/30/04ISR Number: 4463254-1Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0345796A
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chills	Consumer	Zophren	PS	Glaxosmithkline			
INTRAVENOUS							8MG Per day	
Initial or Prolonged	Pyrexia		Lederfoline	SS	Glaxosmithkline			
INTRAVENOUS							380MG Per day	
			Eloxatine	SS				
INTRAVENOUS							160MG Per day	
			Fluoro-Uracile	SS				
INTRAVENOUS							750MG Per day	

Date:09/30/04ISR Number: 4463255-3Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0345820A
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chills	Consumer	Zophren	PS	Glaxosmithkline			
INTRAVENOUS							8MG Per day	2 DAY
Initial or Prolonged	Malaise		Lederfoline	SS	Glaxosmithkline			
INTRAVENOUS							325MG Per day	1 DAY
	Pyrexia		Solumedrol	SS				
INTRAVENOUS							80MG Per day	2 DAY
			Eloxatine	SS				
INTRAVENOUS							120MG Per day	1 DAY
			Fluoro-Uracile	SS				
INTRAVENOUS							750MG Per day	3 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/30/04ISR Number: 4464157-9Report Type:Direct Company Report #CTU 228363
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective Pharmaceutical Product Complaint		Zofran -Ondansetron- 2 Mg/ 1 Ml 2 Ml Vials Glaxosmithkline	PS	Glaxosmithkline	INTRAVENOUS	4 MG	EVERY 30 MIN.

Date:10/04/04ISR Number: 4468053-2Report Type:Expedited (15-DaCompany Report #2004229510FR
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Areflexia Deafness Paraesthesia Polyneuropathy	Foreign Health Professional Other	Solu-Medrol (Methylprednisolone) Powder,Sterile Ranitidina Dorom (Ranitidine Hydrochloride, Ranitidine Hydrochloride Tablet Cisplatin (Cisplatin) Solution, Sterile Cilataxel (Paclitaxel,Paclitaxel) Solution, Sterile	PS SS SS SS		INTRAVENOUS INTRAVENOUS INTRAVENOUS INTRAVENOUS	SINGLE, IV 1 DF, SINGLE, 160 MG, 250 MG,	IV SINGLE, IV SINGLE, IV

			Polaramine(Dexchlorpheniramine Maleate)	SS		
INTRAVENOUS	1 DF, SINGLE, IV					
			Zophren(Ondansetron Hydrochloride)	SS		
INTRAVENOUS	1 DF, SINGLE, IV					

Date:10/06/04ISR Number: 4467299-7Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0346453A
Age:81 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dyskinesia		Zofran	PS	Glaxosmithkline	INTRAVENOUS		0 DAY
Initial or Prolonged	Dystonia		Atenolol	C		ORAL	25MG per day	
Disability	Joint Injury		Aspirin	C	Glaxosmithkline	ORAL	75MG per day	
Other			Paracetamol	C	Glaxosmithkline	ORAL	500MG per day	
			Diclofenac	C		ORAL	50MG per day	

Date:10/07/04ISR Number: 4471879-2Report Type:Expedited (15-DaCompany Report #2004IC000876
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chills	Foreign	5-Fluorouracil					
Initial or Prolonged	Dizziness	Health	(Fluorouracil)	PS		INTRAVENOUS	750 MG; DAILY;	
	Pyrexia	Professional						
			Lederfoline (Generic					

			Unknonwn)	SS		
INTRAVENOUS	325 MG;					
DAILY;						
INTRAVENOUS						
			Solumedrol (Generic Unknown)	SS		
INTRAVENOUS	80 MG;					
INTRAVENOUS						
			Zophren (Ondansetron Hydrochloride)	SS		
INTRAVENOUS	8 MG;					
INTRAVENOUS						
			Eloxatine (Olaiplatin)	SS		
INTRAVENOUS	120 MG;					
DAILY;						
INTRAVENOUS						

Date:10/08/04ISR Number: 4472634-XReport Type:Expedited (15-DaCompany Report #2004-09-1793
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cough Cytolytic Hepatitis Neutropenia Pyrexia	Foreign Health Professional Other	Aerius (Desloratadine) Tablets 'Like Clarinex'	PS		ORAL	ORAL	
			Endoxan	SS				
INTRAVENOUS	880 MG							
INTRAVENOUS								
			Farmorubicin	SS				
INTRAVENOUS	135 MG							
INTRAVENOUS								
			Rulide Tablets (Roxithromycin)	SS		ORAL	300 MG QD	

ORAL

			Fluorouracil	SS		
INTRAVENOUS	880 MG					
INTRAVENOUS						
			Polery Syrup	SS		ORAL
ORAL						
			Zophren (Ondansetron)	SS		
8 MG						
			Doliprane Tablets	SS		ORAL
500-2500MG QD						
ORAL						
			Zophren (Ondansetron)	C		
			Doliprane	C		

Date:10/12/04ISR Number: 4471588-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0345681A
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Chills	Consumer	Zophren	PS	Glaxosmithkline	
INTRAVENOUS	8MG Per day 1 DAY					
Initial or Prolonged	Pyrexia		Lederfoline	SS	Glaxosmithkline	
INTRAVENOUS	325MG Per day 1 DAY					
	Rash Macular		Eloxatine	SS		
INTRAVENOUS	140MG Per day 1 DAY					
			Fluoro-Uracile	SS		
INTRAVENOUS	650MG Per day 1 DAY					

Date:10/13/04ISR Number: 4478526-4Report Type:Expedited (15-DaCompany Report #8968
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Chills	Foreign	Lederfoline	PS		
INTRAVENOUS	325 MG DAILY					
Initial or Prolonged	Malaise	Other				
IV						
	Pyrexia		Oxaliplatin	SS		
INTRAVENOUS	120 MG DAILY					
IV						
			Fluorouracil	SS		
INTRAVENOUS	325 MG DAILY					

				Solu-Medrol	SS		
INTRAVENOUS	80 MG DAILY IV						
				Zophren	SS		
INTRAVENOUS	6 MG DAILY IV						

Date:10/13/04ISR Number: 4478527-6Report Type:Expedited (15-DaCompany Report #8964
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills	Foreign	Lederfoline	PS		INTRAVENOUS	325 MG DAILY IV	
	Pruritus	Other						
	Pyrexia		Oxaliplatin	SS		INTRAVENOUS	140 MG DAILY IV	
	Rash Erythematous							
			Fluorouracil	SS		INTRAVENOUS	650 MG DAILY IV	
			Ondansetron Hydrochloride	SS		INTRAVENOUS	5 MG DAILY IV	

Date:10/15/04ISR Number: 4479305-4Report Type:Expedited (15-DaCompany Report #2004237194FR
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cytolytic Hepatitis	Foreign	Farmorubicin (Epirubicin Hydrochloride)	PS		INTRAVENOUS	135 MG, CYCLIC	IV
	Laboratory Test Interference	Health Professional						
	Neutropenia	Other						
	Prothrombin Time Ratio Abnormal		Cyclophosphamide (Cyclophosphamide) Powder, Sterile	SS		INTRAVENOUS	880 MG,	

CYCLIC, IV			Fluorouracil (Fluorouracil)	SS			
INTRAVENOUS	880 MG, CYCLIC, IV		Desloratadine (Desloratadine)	SS			ORAL
ORAL			Acodin Infantil Jarabe (Codeine) Syrup	SS			ORAL
ORAL			Zophren (Ondansetron Hydrochloride)	SS			
8 MG			Duorol (Paracetamol) Tablet	SS			ORAL
500 MG, ORAL			Solu-Medrol (Methylprednisolone Sodium Succinate)	C			
			Solupred (Prednisolone Sodium Sulfobenzoate)	C			

Date:10/20/04ISR Number: 4490768-0Report Type:Expedited (15-DaCompany Report #B0347476A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Drug Exposure During Pregnancy	Foreign Study	Zofran (Ondansetron Hydrochloride)	PS		TRANSPLACENTAL	TRANSPLACENTAL	
	Duodenal Atresia	Literature						
		Health Professional						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/21/04ISR Number: 4481345-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0339667A
Age:48 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Erythema		Zophren	PS	Glaxosmithkline			
INTRAVENOUS							8MG per day	1 DAY
Initial or Prolonged	Eyelid Oedema		Cisplatine	SS				
INTRAVENOUS							140MG per day	
	Face Oedema		Gemzar	SS				
INTRAVENOUS							2200MG per	
							day	
			Neurontin	C		ORAL		
							3UNIT per day	
			Inexium	C		ORAL		
							1UNIT per day	
			Aspegic	C		ORAL		
							250MG per day	
			Plitican	C				
							UNKNOWN	
			Solumedrol	C				
							UNKNOWN	

Date:10/21/04ISR Number: 4481347-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0342076A
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Areflexia	Consumer	Azantac	PS	Glaxosmithkline			
INTRAVENOUS							1UNIT Per day	1 DAY
Initial or Prolonged	Deafness		Zophren	SS	Glaxosmithkline			
INTRAVENOUS							1UNIT per day	1 DAY
	Paraesthesia		Polaramine	SS				
INTRAVENOUS							1UNIT per day	1 DAY
	Polyneuropathy		Solumedrol	SS				
INTRAVENOUS								1 DAY
			Cisplatine	SS				
INTRAVENOUS							160MG per day	1 DAY
			Taxol	SS				
INTRAVENOUS							250MG per day	1 DAY

Date:10/27/04ISR Number: 4487092-9Report Type:Expedited (15-DaCompany Report #CA-GLAXOSMITHKLINE-B0347473A
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Drug Exposure During Pregnancy Hydronephrosis		Ondansetron	PS	Glaxosmithkline			

Date:10/27/04ISR Number: 4487107-8Report Type:Expedited (15-DaCompany Report #CH-GLAXOSMITHKLINE-B0349155A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia		Zofran	PS	Glaxosmithkline			
						INTRAVENOUS	24MG per day	4 DAY
	Bundle Branch Block Left		Zavedos	SS				
						INTRAVENOUS		2 DAY
			Nexium	C		ORAL	40MG per day	
			Dafalgan	C	Glaxosmithkline	ORAL	2500MG per day	1 DAY
			Duphaston	C		ORAL	10MG Twice per day	3 DAY
			Valtrex	C	Glaxosmithkline	ORAL	500MG Twice per day	
			Cytosar	C				
						INTRAVENOUS		5 DAY
			Konakion	C				
						INTRAVENOUS		
			Azactam	C				
						INTRAVENOUS		
			Targocid	C				
						INTRAVENOUS		
			Liquemine	C	Glaxosmithkline			
						INTRAVENOUS		
			Diflucan	C		ORAL	200MG Per day	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/27/04ISR Number: 4490852-1Report Type:Expedited (15-DaCompany Report #2004IC000877
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dizziness Pruritus Rash Erythematous Tremor	Foreign Health Professional	5-Fluorouracil (Fluorouracil)	PS		INTRAVENOUS	650 MG; DAILY; INTRAVENOUS	
			Lederfoline (Generic Unknown)	SS		INTRAVENOUS	325 MG, INTRAVENOUS	
			Zophren (Ondansetron Hydrochloride)	SS		INTRAVENOUS	8 MG; DAILY; INTRAVENOUS	
			Eloxatine (Oxaliplatin)	SS		INTRAVENOUS	160 MG; DAILY; INTRAVENOUS	

Date:10/27/04ISR Number: 4490934-4Report Type:Expedited (15-DaCompany Report #2004237194FR
Age:31 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cough Cytolytic Hepatitis Neutropenia Pyrexia	Foreign Health Professional Other	Farmorubicin(Epirubicin Hydrochloride) Powder, Sterile	PS		INTRAVENOUS	135 MG, CYCLIC, IV	
			Cyclophosphamide (Cyclophosphamide) Powder, Sterile	SS		INTRAVENOUS	880 MG,	

CYCLIC, IV			Fluorouracil (Fluorouracil) Solution, Sterile	SS	
INTRAVENOUS	800 MG, CYCLIC, IV				
			Desloratadine (Desloratadine)	SS	ORAL
ORAL			Acodin Infantil Jarabe (Codeine) Syrup	SS	ORAL
ORAL			Zophren (Ondansetron Hydrochloride)	SS	
8 MG			Duorol (Paracetamol) Tablet	SS	ORAL
500 MG, ORAL			Roxitromicina Pharmacia (Roxithromycin) Tablet	SS	ORAL
150 MG, QD, ORAL			Solu-Medrol (Methylprednisolone Sodium Succinate)	C	
			Solupred (Prednisolone Sodium Sulfobenzoate)	C	

Date:10/28/04ISR Number: 4488038-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0125304A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Congenital Anomaly		Zofran	PS	Glaxosmithkline			MON
	Failure To Thrive							
	Low Set Ears							
	Microcephaly							
	Renal Cyst							
	Small For Dates Baby							
	Speech Disorder							
	Developmental							
	Syndactyly							

Date:10/29/04ISR Number: 4492535-0Report Type:Expedited (15-DaCompany Report #2004CG02134
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Ventricular Tachycardia	Foreign	Mopral	PS		ORAL	20 MG DAILY	
Initial or Prolonged		Health					PO	
		Professional	Solu-Medrol	SS				
INTRAVENOUS	60 MG ONCE IV							
		Other	Solu-Medrol	SS				
INTRAVENOUS	60 MG ONCE IV							
			Solu-Medrol	SS				
INTRAVENOUS	60 MG ONCE IV							
			Solu-Medrol	SS				
INTRAVENOUS	60 MG ONCE IV							
			Zophren	SS				
INTRAVENOUS	1 DF ONCE IV							
			Zophren	SS				
INTRAVENOUS	1 DF ONCE IV							
			Zophren	SS				
INTRAVENOUS	1 DF ONCE IV							
			Zophren	SS				
INTRAVENOUS	1 DF ONCE IV							
			Taxotere	SS				
INTRAVENOUS	132 MG ONCE							
IV								

			Taxotere	SS			
INTRAVENOUS	132 MG ONCE IV						
			Taxotere	SS			
INTRAVENOUS	132 MG ONCE IV						
			Taxotere	SS			
INTRAVENOUS	132 MG ONCE IV						
			Stilnox	SS			ORAL
1.5 DF DAILY PO							
			Seresta	SS			ORAL
50 MG DAILY PO							

Date:10/29/04ISR Number: 4492541-6Report Type:Expedited (15-DaCompany Report #2004GB02380
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration	Foreign	Heminevrin	PS				3 - 4 TDS PRN
	Vomiting	Health Professional	Omeprazole	SS		ORAL	20 MG DAILY PO	
		Other	Clonidine	SS		ORAL	0.1 MG PRN PO	
			Diazepam	SS		ORAL	10 MG PRN PO	
			Lorazepam	SS		ORAL	2.5 MG PRN PO	
			Temazepam	SS		ORAL	20 MG HS PO	
			Rohypnol	SS		ORAL	1 MG HS PO	
			Chlorpromazine	SS		ORAL	50 MG PRN PO	
			Octreotide	SS			SUBCUTANEOUS	100 UG Q12H SQ
			Metoclopramide	SS			SUBCUTANEOUS	10 MG Q8H SQ

1 - 2 BD	Buccastem	SS
10 MG PRN PO	Buscopan	SS ORAL
1/2 - 1 DAILY	Naltrexone	SS

			Acupan	SS		
2 - 3 TDS PRN						
			Voltarol	SS		ORAL
25 MG TID PO						
			Zofran	SS		ORAL
8 MG PRN PO						

Date:10/29/04ISR Number: 4534121-XReport Type:Direct Company Report #USP 56910
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Medication Error		Zofran	PS	Glaxosmithkline	
INJECTABLE						
			Fentanyl	SS	Abbott	
INJECTABLE						

Date:11/02/04ISR Number: 4492966-9Report Type:Expedited (15-DaCompany Report #A02200403139
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Supraventricular Tachycardia	Health Professional	Stilnox - (Zolpidem) - Tablet - 10 Mg	PS		ORAL
15 MG OD,						
			Solu-Medrol - (Methylprednisolone Sodium Succinate) - Powder- Unit Dose: Unknown	SS		
INTRAVENOUS	20 MG OD,					
INTRAVENOUS						
NOS	1 DAY					
			Mopral - (Omeprazole) - Capsule - 20 Mg	SS		ORAL
20 MG OD						
			Zophren - (Ondansetron Hydrochloride) - Solution - Unit Dose			

				: Unknown	SS		
INTRAVENOUS	1 UNIT OD,						
INTRAVENOUS							
NOS	1 DAY						
				Taxotere - (Docetaxel) - Solution - Unit Dose : Unknown	SS		
INTRAVENOUS	132 MG OTHER,						
INTRAVENOUS							
NOS	1 DAY						
				Seresta - (Oxazepam) - Tablet - 50 Mg	SS		ORAL
50MG OD							

Date:11/02/04ISR Number: 4493841-6Report Type:Expedited (15-DaCompany Report #2004240651CH
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Bradycardia	Foreign	Zavedos			
	Bundle Branch Block Left	Health Professional	(Idarubicin Hydrochloride)	PS		
INTRAVENOUS	IV					
		Other	Zofran (Ondansetron Hydrochloride)	SS		
INTRAVENOUS	IV					
			Dafalgan	C		
			Duphaston (Dydrogesterone)	C		
			Valtrex (Valciclovir Hydrochloride)	C		
			Cytosar	C		

				Konakion (Phytomenadione)	C		
				Azactam (Aztreonam)	C		
				Targocid	C		
				Liquemin	C		
				Diflucan (Fluconazole)	C		

Date:11/03/04ISR Number: 4491429-4Report Type:Expedited (15-DaCompany Report #PHRM2004FR03208
Age:33 YR Gender:Female I/FU:I

Outcome	Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged			Confusional State Hyperhidrosis		Syntocinon	PS	Novartis Sector: Pharma	
INTRAVENOUS	6 ml, once	1440 MIN						
			Hypothermia		Droleptan	SS		
INTRAVENOUS	1 DF/day	1440 MIN						
			Urine Amphetamine Positive		Morphine Hydrochloride	SS		
INTRATHECAL	100 ug,							
ONCE/SINGLE								
					Zophren	SS		
INTRAVENOUS	1 DF/day	1440 MIN						
					Ephedrine Hydrochloride	SS		
INTRAVENOUS	2 DF/day	1440 MIN						
					Marcaine	SS		
INTRATHECAL	10 mg,							
ONCE/SINGLE								
					Lactated Ringer'S Injection	C		
2.5 l,								
ONCE/SINGLE		1440 MIN						
					Lexomil	C		ORAL
					Seropram	C		
					Prozac	C		

Date:11/09/04ISR Number: 4496850-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0349467A
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Consumer	Zophren	PS	Glaxosmithkline	INTRAVENOUS	1UNIT per day	1 DAY
	Hyperhidrosis		Droleptan	SS		INTRAVENOUS	1UNIT per day	1 DAY
	Hypothermia		Morphine Chlorhydrate	SS		INTRATHECAL	100MCG Single dose	
			Syntocinon	SS		INTRAVENOUS	6ML per day	1 DAY
			Ephedrine	SS		INTRAVENOUS	2UNIT per day	1 DAY
			Marcaine	SS		INTRATHECAL	100MG Single dose	
			Lexomil	C		UNKNOWN		
			Prozac	C		UNKNOWN		
			Ringer Lactate	C		INTRAVENOUS	2.5L per day	1 DAY

Date:11/10/04ISR Number: 4497857-5Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0350281A
Age:35 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Dreams		Ondansetron	PS	Glaxosmithkline	ORAL	4MG Per day	1 DAY
	Dyskinesia		Co-Codamol	C		ORAL		
	Feeling Hot		Ibuprofen	C	Glaxosmithkline	ORAL		
	Nausea		Morphine	C				
	Sleep Disorder		Indomethacin	C				
			Dalteparin	C				
INTRAVENOUS								0 DAY
RECTAL								2 DAY
SUBCUTANEOUS							2500 per day	1 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/10/04ISR Number: 4501306-8Report Type:Expedited (15-DaCompany Report #2004238696SE
Age:66 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Colitis Ischaemic	Foreign Health Professional	Adriamycin(Doxorubicin Hydrochloride) Solution, Sterile	PS		INTRAVENOUS	80 MG,	CYCLIC, IV
		Other	Sendoxan(Cyclophosphamide)	SS		INTRAVENOUS	1200 MG,	CYCLIC , IV
			Oncovin(Vincristine Sulfate)	SS		INTRAVENOUS	2 MG, IV	
			Deltison(Magnesium Trisilicate, Calcium Phosphate)	SS		ORAL	50 MG , ORAL	
			Sofran	SS		INTRAVENOUS	8 MG IV	
			Allopurinol(Allopurinol)	SS		ORAL	300 MG, ORAL	

Date:11/11/04ISR Number: 4499229-6Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0351135A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration	Consumer	Zofran	PS	Glaxosmithkline	ORAL	8MG As	required
			Heminevrin	SS		ORAL		
			Omeprazole	SS		ORAL	20MG Per day	
			Clonidine	SS		ORAL	.1MG As	required

			Diazepam	SS		ORAL	10MG As required
			Lorazepam	SS		ORAL	2.5MG As required
			Temazepam	SS		ORAL	20MG As required
			Rohypnol	SS		ORAL	1MG As required
			Chlorpromazine	SS	Glaxosmithkline	ORAL	50MG As required
SUBCUTANEOUS	100MCG See dosage text		Octreotide	SS			
SUBCUTANEOUS	10MG See dosage text		Metoclopramide	SS	Glaxosmithkline		
			Buccastem	SS		ORAL	
			Buscopan	SS		ORAL	10MG As required
			Naltrexone	SS		ORAL	
			Acupan	SS		ORAL	
			Voltarol	SS	Glaxosmithkline	ORAL	25MG Three times per day

Date:11/12/04ISR Number: 4503460-0Report Type:Expedited (15-DaCompany Report #2004242951FR
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills Malaise Pyrexia	Foreign Health Professional	Solu-Medrol (Methylprednisolone) Powder, Sterile	PS				
INTRAVENOUS							80 MG, QD, IV	
			Leucovorin Calcium					

				(Calcium Folinate)			
				Solution, Sterile	SS		
INTRAVENOUS	325 MG, QD, IV						
				Ondansetron	SS		
INTRAVENOUS	8 MG, QD, IV						
				Dacplat (Oxaliplatin) Powder, Sterile	SS		
INTRAVENOUS	120 MG, QD, IV						
				Fluorouracil Solution, Sterile	SS		

Date:11/12/04ISR Number: 4507598-3Report Type:Expedited (15-DaCompany Report #WAES 0411USA00716
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Arrest	Foreign	Decadron	PS		ORAL	PO	
	Duodenitis	Study	Decadron	SS		ORAL	20 MG/ 1X/ PO	
	Haematemesis	Health	Decadron	SS		ORAL	8 MG/ AM/ PO	
	Hiatus Hernia	Professional	Placebo	SS		ORAL	PO	
	Hypokalaemia		Dexamethasone	SS		ORAL	8 MG/ HS/ PO	
	Oesophagitis		Ondansetron	SS		ORAL	8 MG/ BID/ PO	
	Ventricular Arrhythmia		Cisplatin	SS				
INTRAVENOUS	IV							
	Vomiting		Docetaxel	SS				
			Ondansetron	SS				
INTRAVENOUS	32 MG/ 1X/ IV							
			Furosemide	C				
			Lactulose	C				
			Metoprolol Succinate	C				
			Mirtazapine	C				
			Nadroparin	C				
			Oxazepam	C				
			Polyethylene Glycol	C				

Date:11/15/04ISR Number: 4500649-1Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12651675
Age:79 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills Hyperthermia	Health Professional	Taxol	PS	Bristol-Myers Squibb Company	INTRAVENOUS		Therapy dates: 11-May to 01-Jun-2004
			Carboplatine	SS		INTRAVENOUS		Therapy dates: 11-May to 01-Jun-2004
			Polaramine	SS		INTRAVENOUS		
			Solu-Medrol	SS		INTRAVENOUS		
			Azantac	SS		INTRAVENOUS		
			Zophren	SS		INTRAVENOUS		
			Solupred	C				
			Durogesic	C				
			Sevredol	C				
			Movicol	C				
			Peristaltine	C				
			Zoloft	C				
			Imovane	C				
			Tardyferon	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/15/04ISR Number: 4501007-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0350288A
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Epilepsy		Zophren	PS	Glaxosmithkline			
INTRAVENOUS							2	DAY
Initial or Prolonged	Insomnia		Deroxat	SS	Glaxosmithkline	ORAL		
20MG per day							47	DAY
	Myoclonus		Alkeran	SS	Glaxosmithkline			
INTRAVENOUS							1	DAY
	Tremor		Radiotherapy	C				
6 DAY								
			Xanax	C				
UNKNOWN							47	DAY

Date:11/15/04ISR Number: 4501014-3Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0351135A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration		Zofran	PS	Glaxosmithkline	ORAL		
8MG As								
	Foreign Body Aspiration							
required								
			Heminevrin	SS		ORAL		
			Omeprazole	SS		ORAL		
20MG Per day								
			Clonidine	SS		ORAL		
.1MG As								
required								
			Diazepam	SS		ORAL		
10MG As								
required								
			Lorazepam	SS		ORAL		
2.5MG As								
required								
			Temazepam	SS		ORAL		
20MG As								
required								

			Rohypnol	SS		ORAL
1MG As required						
			Chlorpromazine	SS	Glaxosmithkline	ORAL
50MG As required						
			Octreotide	SS		
SUBCUTANEOUS	100MCG See dosage text					
			Metoclopramide	SS	Glaxosmithkline	
SUBCUTANEOUS	10MG See dosage text					
			Buccastem	SS		ORAL
			Buscopan	SS		ORAL
10MG As required						
			Naltrexone	SS		ORAL
			Acupan	SS		ORAL
			Voltarol	SS	Glaxosmithkline	ORAL
25MG Three times per day						

Date:11/15/04ISR Number: 4503789-6Report Type:Expedited (15-DaCompany Report #2004CG02203
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaesthetic Complication	Foreign Health	Marcaine Spinal 0.5% Heavy	PS				
	Confusional State							
INTRATHECAL							10 MG	ONCE IT
	Drug Screen Positive	Professional	Droleptan	SS				
INTRAVENOUS							1 DF	ONCE IV
	Hyperhidrosis	Other	Synthcinon	SS				
INTRAVENOUS							6 ML	ONCE IV
	Hypothermia		Ephedrine Hydrochloride	SS				
	Laboratory Test							
INTRAVENOUS							2 DF	ONCE IV
	Interference		Zophren	SS				
INTRAVENOUS							1 DF	ONCE IV
	Therapeutic Response		Morphine Hydrochloride	C				
	Delayed							
INTRATHECAL							100 UG	ONCE IT
			Lexomil	C				

	Serotonin Release Inhibitor	C
	Lactated Ringer'S	

Injection C

Date:11/16/04ISR Number: 4501916-8Report Type:Expedited (15-DaCompany Report #PHFR2004GB04138
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration		Voltarol	PS	Novartis Sector:			
	Foreign Body Aspiration				Pharma	ORAL	25 mg, TID	
			Heminevrin	SS		ORAL		
			Omeprazole	SS		ORAL	20 mg/day	
			Clonidine	SS		ORAL	.1 mg, PRN	
			Diazepam	SS		ORAL	10 mg, PRN	
			Lorazepam	SS		ORAL	2.5 mg, PRN	
			Temazepam	SS		ORAL	20 mg, PRN	
			Rohypnol	SS		ORAL	1 mg, PRN	
			Chlorpromazine	SS		ORAL	50 mg, PRN	
			Octreotide	SS			SUBCUTANEOUS	100 ug Q12H
			Metoclopramide	SS			SUBCUTANEOUS	10 mg Q8H
			Buccastem	SS		ORAL		
			Buscopan	SS		ORAL	10 mg, PRN	
			Naltrexone	SS		ORAL		
			Acupan	SS		ORAL		
			Zofran	SS		ORAL	8 mg, PRN	

Date:11/17/04ISR Number: 4503384-9Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0055470A
Age:66 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Discomfort		Zofran	PS	Glaxosmithkline			
INTRAVENOUS	4MG Twice per							

		Cold Sweat					
day							
		Cyanosis	Ciproxin	C			
INTRAVENOUS	200MG Twice						
		Dyspnoea					
per day	6 DAY						
		Feeling Abnormal	Zinacef	C	Glaxosmithkline		
INTRAVENOUS	1.5G Three						
		Hypersensitivity					
times per day	6 DAY						
		Paraesthesia	Isoflurane	C			
RESPIRATORY							
		Pulse Abnormal					
(INHALATION)	1 DAY						
		Visual Disturbance	Propofol	C			
INTRAVENOUS	20MG per day 1 DAY						
			Gentamycin	C	Glaxosmithkline		
1 DAY							
			Fentanyl	C			
1 DAY							
			Df118	C	Glaxosmithkline		
1 DAY							

Date:11/17/04ISR Number: 4503385-0Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0056436A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Blindness		Ondansetron	PS	Glaxosmithkline	
INTRAVENOUS	16MG per day 2 DAY					
	Chest Discomfort		Enoxaparin	C		
SUBCUTANEOUS	40MG per day 12 DAY					
	Cyanosis		Ciprofloxacin	C		ORAL
1000MG per						
	Dyspnoea					
day	9 DAY					
	Feeling Abnormal		Isoflurane	C		
RESPIRATORY						
	Hyperhidrosis					
(INHALATION)						
	Paraesthesia		Propofol	C		
INTRAVENOUS						
	Pulse Pressure Decreased		Ketorolac	C		
INTRAVENOUS						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/18/04ISR Number: 4504590-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0525996A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Caesarean Section		Zofran	PS	Glaxosmithkline		4MG See	
Life-Threatening	Death						dosage text	4 MON
Hospitalization - Initial or Prolonged	Drug Exposure During Pregnancy		Vitamins	C				
			Phenergan	C	Glaxosmithkline			
Disability	Feeding Problem In Newborn		Unisom	C				
Congenital Anomaly			Vitamin B6	C				
Other	Food Intolerance							
	Heart Disease Congenital							
	Hypoplastic Left Heart Syndrome							
	Neonatal Tachypnoea							
	Pigmentation Disorder							
	Poor Peripheral Circulation							
	Pulse Pressure Decreased							
	Tachypnoea							
	Ventricular Hypoplasia							

Date:11/18/04ISR Number: 4507575-2Report Type:Expedited (15-DaCompany Report #2004-UK-01140UK
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Foreign Body Aspiration	Foreign Health Professional	Catapres (0015/5009r) (Clonidine)	PS		ORAL	0.1 MG (0.1 MG, AS REQUIRED)	PO
		Other	Buscopan (0015/5005r/0074r) (Hyoscine Butylbromide) (Nr)	SS		ORAL	10 MG AS REQUIRED (,	

AS REQUIRED) PO				
	Heminevrin (Clomethiazole Edisilate) (Nr)	SS		ORAL
PO				
	Omeprazole (Omeprazole) (Nr)	SS		ORAL
20 MG DAILY (NR) PO				
	Diazepam (Diazepam) (Nr)	SS		ORAL
10 MG AS REQUIRED (, AS REQUIRED) PO				
	Lorazepam (Lorazepam) (Nr)	SS		ORAL
2.5 MG AS REQUIRED (, AS REQUIRED) PO				
	Temazepam (Temazepam) (Nr)	SS		ORAL
20 MG AS REQUIRED (, AS REQUIRED) PO				
	Rohypnol (Flunitrazepam) (Nr)	SS		ORAL
1 MG AS				

REQUIRED (, AS REQUIRED) PO		Chlorpromazine (Chlorpromazine) (Nr)	SS	ORAL
50 MG AS REQUIRED PO		Octreotide (Octreotide) (Nr)	SS	
SUBCUTANEOUS	100 MCG EVERY 12 HOURS (, EVERY 12 HOURS) SC	Metoclopramide (Metoclopramide) (Nr)	SS	
SUBCUTANEOUS	10 MG EVERY 8 HOURS (, EVERY 8 HOURS) SC			
PO		Buccastem (Prochlorperazine Maleate) (Nr)	SS	ORAL
PO		Naltrexone (Naltrexone) (Nr)	SS	ORAL
PO		Acupan (Nefopam Hydrochloride) (Nr)	SS	ORAL
25 MG THREE TIMES DAILY		Voltarol (Diclofenac Sodium) (Nr)	SS	ORAL

(25 NR, THREE

TIMES DAILY)

PO

			Zofran (Ondansetron Hydrochloride) (Nr)	SS		ORAL

8 MG AS

REQUIRED (,

AS REQUIRED)

PO

Date:11/19/04ISR Number: 4505583-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0132060A
Age:21 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abdominal Pain		Lotronex	PS	Glaxosmithkline	ORAL	1MG Twice per	
	Constipation						day	
	Diarrhoea		Zofran	SS	Glaxosmithkline		UNKNOWN	4MG Unknown
	Drug Ineffective							

Date:11/22/04ISR Number: 4506809-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0339667A
Age:48 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Erythema		Zophren	PS	Glaxosmithkline		INTRAVENOUS	8MG per day
Initial or Prolonged	Eyelid Oedema		Cisplatine	SS			INTRAVENOUS	140MG per day
	Face Oedema		Gemzar	SS			INTRAVENOUS	2200MG per

day

			Neurontin	C		ORAL

3UNIT per day

			Inexium	C		ORAL

1UNIT per day

			Aspegic	C		ORAL

250MG per day

Plitican	C
Solumedrol	C

UNKNOWN

UNKNOWN

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/22/04ISR Number: 4509037-5Report Type:Direct Company Report #CTU 232541
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma		Levofloxacin	PS			500 MG	
	Ventricular Extrasystoles		Ondansetrone Po	SS			8 MG	
	Ventricular Tachycardia		Promethazine	SS			25 MG	

Date:11/22/04ISR Number: 4510753-XReport Type:Expedited (15-DaCompany Report #FR-2004-034824
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema Multiforme	Foreign Other	Fludara (Fludarabine Phosphate) Ampule	PS		INTRAVENOUS	INTRAVENOUS	
			Endoxan (Cyclophosphamide) Ampule	SS		INTRAVENOUS	INTRAVENOUS	
			Primperan (Metoclopramide)	SS		ORAL	ORAL	
			Zophren (Ondansetron Hydrochloride)	SS		INTRAVENOUS	INTRAVENOUS	

Date:11/22/04ISR Number: 4511296-XReport Type:Expedited (15-DaCompany Report #12754727
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Foreign Body Aspiration	Foreign Health	Naltrexone (Naltrexone Hcl)	PS		ORAL	ORAL	
		Professional	Diazepam	SS		ORAL	10 MILLIGRAM	
		Other					ORAL	

			Heminevrin (Chlormethiazole Edisylate)	SS	ORAL
ORAL					
			Omeprazole	SS	ORAL
20 MILLIGRAM					
1 DAY ORAL					
			Clonidine	SS	ORAL
.1 MILLIGRAM					
ORAL					
			Lorazepam	SS	ORAL
2.5 MILLIGRAM					
ORAL					
			Temazepam	SS	ORAL
20 MILLIGRAM					
ORAL					
			Rohypnol (Flunitrazepam)	SS	ORAL
1 MILLIGRAM					
ORAL					
			Chlorpromazine	SS	ORAL
50 MILLIGRAM					
ORAL					
			Octreotide (Octreotide Acetate)	SS	
SUBCUTANEOUS	100 MICROGRAM				
1/12 HOUR SC					
			Metoclopramide (Metoclopramide Hcl)	SS	
SUBCUTANEOUS	10 MILLIGRAM				
1/8 HOUR SC					
			Buccastem (Prochlorperazine Maleate)	SS	ORAL
ORAL					
			Buscopan (Hyoscine Butylbromide)	SS	ORAL
10 MILLIGRAM					
ORAL					
			Acupan (Nefopam Hcl)	SS	ORAL
ORAL					
			Voltarol (Diclofenac		

			Sodium)	SS		ORAL	25 MILLIGRAM 3/1 DAY ORAL
			Zofran (Ondansetron Hcl)	SS		ORAL	8 MILLIGRAM ORAL

Date:11/23/04ISR Number: 4507616-2Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12769998
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Cystitis Haemorrhagic		Endoxan	PS	Bristol-Myers Squibb Company	INTRAVENOUS	1 DAY
			Uromitexan	SS	Bristol-Myers Squibb Company	INTRAVENOUS	1 DAY
			Zophren	SS		INTRAVENOUS	1 DAY
			Sandoglobulin	SS		INTRAVENOUS	1 DAY

Date:11/23/04ISR Number: 4512083-9Report Type:Expedited (15-DaCompany Report #A02200403139
Age:63 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Supraventricular Tachycardia	Foreign Health Professional Other	Stilnox - (Zolpidem) - Tablet - 10 Mg	PS		ORAL	15 MG OD
			Solu-Medrol - (Methylprednisolone Sodium Succinate) - Powder	SS		INTRAVENOUS	60 MG QD
			Mopral - (Omeprazole) - Capsule - 20 Mg	SS		ORAL	20 MG OD
			Zophren -				

			(Ondansetron Hydrochloride) - Solution	SS			
INTRAVENOUS	1 UNIT OD						
			Taxotere - (Docetaxel) - Solution	SS			
INTRAVENOUS	132 MG OTHER						
			Seresta - (Oxazepam) - Tablet - 50 Mg	SS			ORAL
50 MG OD							

Date:11/24/04ISR Number: 4510417-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0517258A
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Death	Health	Zofran	PS	Glaxosmithkline	
UNKNOWN						
		Professional	Unknown	SS		

Date:11/24/04ISR Number: 4510466-4Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0357014A
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Dermatitis Bullous	Consumer	Zophren	PS	Glaxosmithkline	
INTRAVENOUS	5 DAY					
Initial or Prolonged	Erythema Multiforme		Endoxan	SS		
INTRAVENOUS	5 DAY					
	Self-Medication		Fludara	SS		
INTRAVENOUS	5 DAY					
			Primperan	SS	Glaxosmithkline	ORAL
16 DAY						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/24/04ISR Number: 4510469-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0357051A
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cystitis Haemorrhagic	Consumer	Zophren	PS	Glaxosmithkline	INTRAVENOUS	1MG per day	1 DAY
Initial or Prolonged			Endoxan	SS		INTRAVENOUS	800MG per day	1 DAY
			Uromitexan	SS		INTRAVENOUS	800MG per day	1 DAY
			Sandoglobulin	SS	Glaxosmithkline	INTRAVENOUS	60G per day	1 DAY

Date:11/24/04ISR Number: 4510478-0Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0357373A
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bundle Branch Block Right	Consumer	Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG	
	Cardiac Arrest					cumulative		
	Cardiogenic Shock					dose	2	DAY
	Chest Pain		Fluorouracil	SS		INTRAVENOUS	1.8MGM2 per	
	Electrocardiogram St					day	2	DAY
	Segment Elevation		Levothyrox	C	Glaxosmithkline	UNKNOWN		
	Hyperhidrosis		Lexomil	C		UNKNOWN		
	Ill-Defined Disorder		Lovenox	C		UNKNOWN		
	Loss Of Consciousness		Physiotens	C		UNKNOWN		
	Malaise							
	Pulmonary Hypertension							
	Respiratory Arrest							

Date:11/24/04ISR Number: 4512413-8Report Type:Expedited (15-DaCompany Report #M2004-1695
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Foreign Body Aspiration	Foreign	Chlorpromazine	PS		ORAL	50 MG PRN,	
		Other					ORAL	
			Clonidine	SS		ORAL	0.1 MG, PRN,	
							ORAL	
			Omeprazole (Omeprazole)	SS		ORAL	20 MG DAILY	
							ORAL	
			Temazepam (Temazepam)	SS			20 MG PRN	
			Voltarol (Diclofenac)	SS			25 MG TID	
			Diazepam (Diazepam)	SS			10 MG PRN	
			Heminevrin (Clomethiazole)	SS				
			Lorazepam (Lorazepam)	SS			2.5 MG PRN	
			Rohypnol (Flunitrazepam)	SS			1 MG PRN	
			Metoclopramide (Metoclopramide)	SS			10 MG Q8H	
			Buccastem (Prochlorperazine)	SS				
			Buscopan (Hyoscine)	SS			10 MG, PRN	
			Naltrexone (Naltrexone)	SS				
			Acupan (Nefopam Hydrochloride)	SS				
			Zofran (Ondansetron)	SS			8 MG, PRN	
			Octreotide (Octreotide)	SS			100MCG Q12H	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/26/04ISR Number: 4515092-9Report Type:Expedited (15-DaCompany Report #DSA_25395_2004
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration	Foreign	Ativan	PS		ORAL	2.5 MG PRN PO	
	Vomiting	Health	Voltarol	SS		ORAL	25 MG TID PO	
		Professional	Acupan	SS		ORAL	DF PO	
		Other	Buccastem	SS		ORAL	DF PO	
			Buscopan	SS		ORAL	10 MG PRN PO	
			Chlorpromazine	SS		ORAL	50 MG PRN PO	
			Clonidine	SS		ORAL	1 MG PRN PO	
			Diazepam	SS		ORAL	10 MG PRN PO	
			Heminevrin	SS		ORAL	DF PO	
			Metoclopramide	SS			SUBCUTANEOUS	10 MG Q8HR SC
			Naltrexone	SS		ORAL	DF PO	
			Octreotide	SS			SUBCUTANEOUS	100 MCG Q12HR SC
			Omeprazole	SS		ORAL	20 MG PO	
			Rohypnol	SS		ORAL	1 MG PRN PO	
			Temazepam	SS		ORAL	20 MG PRN PO	
			Zofran	SS		ORAL	8 MG PRN PO	

Date:11/29/04ISR Number: 4512318-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0357374A
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death		Bundle Branch Block Right		Zophren	PS	Glaxosmithkline	
INTRAVENOUS		2 DAY					
		Cardiac Arrest		Fluorouracil	SS		
INTRAVENOUS	1.8GM2	per					
		Cardio-Respiratory Arrest					
day	2 DAY						
		Cardiogenic Shock		Levothyrox	C	Glaxosmithkline	
UNKNOWN							
		Chest Pain		Lexomil	C		
UNKNOWN							
		Circulatory Collapse		Lovenox	C		
UNKNOWN							
		Electrocardiogram St		Physiotens	C		
UNKNOWN							
		Segment Elevation					
		Hyperhidrosis					
		Ill-Defined Disorder					
		Loss Of Consciousness					
		Malaise					
		Pulmonary Embolism					
		Respiratory Arrest					

Date:11/29/04ISR Number: 4512330-3Report Type:Expedited (15-DaCompany Report #M24752
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State		Zofran	PS	Glaxosmithkline			
UNKNOWN								
	Dystonia		Propofol	SS				
UNKNOWN								
	Muscle Rigidity		Dynastat	SS				
UNKNOWN							40MG	Unknown

Date:11/29/04ISR Number: 4515668-9Report Type:Expedited (15-DaCompany Report #12754727
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Foreign Body Aspiration	Health Professional	Naltrexone (Naltrexone Hcl)	PS		ORAL		
ORAL								
		Other	Diazepam	SS		ORAL	10	MILLIGRAM
ORAL								
			Omeprazole	SS		ORAL	20	MILLIGRAM

			Lorazepam	SS	ORAL
2.5 MILLIGRAM					
ORAL					
			Rohypnol (Flunitrazepam)	SS	ORAL
1 MILLIGRAM					
ORAL					
			Octreotide (Octreotide Acetate)	SS	
SUBCUTANEOUS	100 MICROGRAM				
1/12 HOUR SC					
			Buccastem (Prochlorperazine Maleate)	SS	ORAL
ORAL					
			Acupan (Nefopam Hcl)	SS	ORAL
ORAL					
			Zofran (Ondansetron Hcl)	SS	ORAL
8 MILLIGRAM					
ORAL					
			Voltarol (Diclofenac Sodium)	SS	ORAL
25 MILLIGRAM					
3/1 DAY ORAL					
			Buscopan (Hyoscine Butylbromide)	SS	ORAL
10 MILLIGRAM					
ORAL					
			Metoclopramide (Metoclopramide Hcl)	SS	
SUBCUTANEOUS	10 MILLIGRAM				
1/8 HOUR SC					
			Chlorpromazine	SS	ORAL
50 MILLIGRAM					
ORAL					
			Temazepam	SS	ORAL
20 MILLIGRAM					

ORAL

			Clonidine	SS	ORAL
.1 MILLIGRAM					
ORAL					
			Heminevrin (Chlormethiazole Edisylate)	C	ORAL
ORAL					

Date:11/30/04ISR Number: 4512947-6Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12775680
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Arthralgia		Endoxan	PS	Bristol-Myers Squibb Company	
	Myalgia					
INTRAVENOUS -interrupted						
	Pancytopenia		Zophren	SS		
INTRAVENOUS - interrupted						
			Fludara	SS		
INTRAVENOUS -interrupted						
			Mabthera	SS		
INTRAVENOUS -interrupted						

Date:12/01/04ISR Number: 4515198-4Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0349721A
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Anaphylactic Shock		Zantac	PS	Glaxosmithkline	
INTRAVENOUS 50MG Per day 1 DAY						
	Cold Sweat		Zofran	SS	Glaxosmithkline	
INTRAVENOUS 1 DAY						
	Feeling Abnormal		Kytril	SS	Glaxosmithkline	
INTRAVENOUS 3MG Single						
	Hyperhidrosis					
dose 1 DAY						
	Hypotension		Vena	C	Glaxosmithkline	ORAL
3TAB Weekly						
	Nausea		Decadron	C		
INTRAVENOUS 8MG Per day						
	Vomiting		Isotonic Sodium Chloride	C	Glaxosmithkline	
INTRAVENOUS						
			Taxol	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/01/04ISR Number: 4515207-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0357373A
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bundle Branch Block Right		Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG	
	Cardiac Arrest						cumulative	
	Cardiogenic Shock						dose	2 DAY
	Chest Pain		Fluorouracil	SS		INTRAVENOUS	1.8MGM2 per	
	Circulatory Collapse						day	2 DAY
	Electrocardiogram St		Levothyrox	C	Glaxosmithkline	UNKNOWN		
	Segment Elevation		Lexomil	C		UNKNOWN		
	Hyperhidrosis		Lovenox	C		UNKNOWN		
	Ill-Defined Disorder		Physiotens	C		UNKNOWN		
	Loss Of Consciousness							
	Malaise							
	Pulmonary Hypertension							
	Respiratory Arrest							
	Therapy Non-Responder							

Date:12/01/04ISR Number: 4515208-4Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0357374A
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bundle Branch Block Right		Zophren	PS	Glaxosmithkline	INTRAVENOUS	2 DAY	
	Cardiac Arrest		Fluorouracil	SS		INTRAVENOUS	1.8GM2 per	
	Cardio-Respiratory Arrest						day	2 DAY
	Cardiogenic Shock		Levothyrox	C	Glaxosmithkline	UNKNOWN		
	Chest Pain		Lexomil	C		UNKNOWN		

	Electrocardiogram St		Lovenox	C		
UNKNOWN						
	Segment Elevation		Physiotens	C		
UNKNOWN						
	Hyperhidrosis					
	Ill-Defined Disorder					
	Loss Of Consciousness					
	Malaise					
	Pulmonary Embolism					
	Pulmonary Hypertension					
	Respiratory Arrest					

Date:12/01/04ISR Number: 4515219-9Report Type:Expedited (15-DaCompany Report #M24747
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Confusional State		Zofran	PS	Glaxosmithkline	
UNKNOWN						
	Dystonia		Propofol	SS		
UNKNOWN						
	Muscle Rigidity		Dynastat	SS		
UNKNOWN	40MG Unknown					

Date:12/01/04ISR Number: 4515221-7Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0358120A
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Atrioventricular Block		Zophren	PS	Glaxosmithkline	
INTRAVENOUS	8MG Per day 1 DAY					
Initial or Prolonged	Complete		Carboplatine	SS		
INTRAVENOUS	510MG Per day 1 DAY					
	Syncope		Tranxene	SS		
INTRAVENOUS	20MG Per day 1 DAY					
			Ranitidine	SS	Glaxosmithkline	
INTRAVENOUS	100MG Per day 1 DAY					
			Solumedrol	SS		
INTRAVENOUS	80MG Per day 1 DAY					
			Taxol	SS		
INTRAVENOUS	234MG Per day 1 DAY					
			Becotide	C	Glaxosmithkline	
RESPIRATORY						
(INHALATION)						
			Lexomil	C		
UNKNOWN	.25UNIT Three					

times per day

			Dafalgan	C	Glaxosmithkline	
UNKNOWN	6UNIT per day					
			Smecta	C		
UNKNOWN	3UNIT per day					
			Stilnox	C		
UNKNOWN	1UNIT per day					
			Imodium	C		
UNKNOWN						
			Polaramine	C		
INTRAVENOUS	1 DAY					

Date:12/01/04ISR Number: 4515222-9Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0358227A
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Arthralgia		Zophren	PS	Glaxosmithkline	
INTRAVENOUS 8MG Cyclic						
	Blood Disorder		Endoxan	SS		
INTRAVENOUS 430MG Cyclic						
	Mobility Decreased		Fludara	SS		
INTRAVENOUS 43MG Cyclic						
	Myalgia		Rituximab	SS		
INTRAVENOUS 650MG Cyclic						
	Pain In Extremity					

Date:12/01/04ISR Number: 4519039-0Report Type:Expedited (15-DaCompany Report #2004-11-1262
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Blood Pressure Systolic Decreased	Foreign	Temodal (Temozolomide)			
	Circulatory Collapse	Health Professional	Capsules Like			
	Exanthem		Temodar	PS		ORAL
SEE IMAGE						
			Zofran (Ondansetron)			
			Tablets	SS		ORAL
4 MG QD ORAL						

Date:12/02/04ISR Number: 4516850-7Report Type:Expedited (15-DaCompany Report #M24750
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State		Zofran	PS	Glaxosmithkline		UNKNOWN	
	Dystonia		Propofol	SS			UNKNOWN	
	Muscle Rigidity		Dynastat	SS			UNKNOWN	40MG Per day

Date:12/03/04ISR Number: 4518078-3Report Type:Expedited (15-DaCompany Report #M24749
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State		Zofran	PS	Glaxosmithkline		UNKNOWN	
	Dystonia		Propofol	SS			UNKNOWN	
	Muscle Rigidity		Dynastat	SS			UNKNOWN	40MG per day

Date:12/03/04ISR Number: 4518081-3Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0358427A
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depressed Level Of Consciousness Medication Error Prothrombin Time Prolonged		Zophren	PS	Glaxosmithkline		UNKNOWN	

Date:12/06/04ISR Number: 4519335-7Report Type:Expedited (15-DaCompany Report #2004-11-1262
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Circulatory Collapse		Zofran	PS	Glaxosmithkline	ORAL	4MG Per day	
Initial or Prolonged	Exanthem		Temozolomide	SS		ORAL	285MG Per day	97 DAY

Date:12/09/04ISR Number: 4521740-XReport Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12784971
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Colitis Ischaemic		Endoxan	PS	Bristol-Myers Squibb Company			
Initial or Prolonged								
INTRAVENOUS								1 DAY
			Farmorubicin	SS				
INTRAVENOUS								1 DAY
			Fluorouracil	SS				
INTRAVENOUS								1 DAY
			Zophren	SS				
INTRAVENOUS								
			Soludecadron	SS				
INTRAVENOUS								

Date:12/10/04ISR Number: 4523702-5Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0358728A
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain		Zophren	PS	Glaxosmithkline			
INTRAVENOUS								
Initial or Prolonged	Colitis Ischaemic		Farmorubicine	SS				
INTRAVENOUS							117MG per day	
	Rectal Haemorrhage		Soludecadron	SS				
INTRAVENOUS								
			Fluorouracil	SS				
INTRAVENOUS							588MG per day	
			Endoxan	SS				
INTRAVENOUS							588MG per day	

Date:12/14/04ISR Number: 4526661-4Report Type:Expedited (15-DaCompany Report #M24747
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State		Zofran	PS	Glaxosmithkline	UNKNOWN		
	Dystonia		Propofol	SS		UNKNOWN		
	Muscle Rigidity		Dynastat	SS		UNKNOWN	40MG	Unknown

Date:12/14/04ISR Number: 4526662-6Report Type:Expedited (15-DaCompany Report #M24750
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State		Zofran	PS	Glaxosmithkline	UNKNOWN		
	Dystonia		Propofol	SS		UNKNOWN		
	Muscle Rigidity		Dynastat	SS		UNKNOWN	40MG	Per day

Date:12/14/04ISR Number: 4526664-XReport Type:Expedited (15-DaCompany Report #M24749
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State		Zofran	PS	Glaxosmithkline	UNKNOWN		
	Dystonia		Propofol	SS		UNKNOWN		
	Muscle Rigidity		Dynastat	SS		UNKNOWN	40MG	per day

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/17/04ISR Number: 4529904-6Report Type:Expedited (15-DaCompany Report #GB-ABBOTT-04P-167-0282539-00
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia		Sevoflurane Liquid For Inhalation	PS				
	Pruritus		Ondansetron	SS				
	Rash Macular		Propofol	SS				
	Unevaluable Event		Diamorphine	SS				

Date:12/17/04ISR Number: 4530716-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0358120A
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Atrioventricular Block		Zophren	PS	Glaxosmithkline			
INTRAVENOUS							8MG Per day	1 DAY
Initial or Prolonged	Atrioventricular Block		Carboplatine	SS				
INTRAVENOUS							510MG Per day	1 DAY
	Complete		Tranxene	SS				
INTRAVENOUS							20MG Per day	1 DAY
	Syncope		Ranitidine	SS	Glaxosmithkline			
INTRAVENOUS							100MG Per day	1 DAY
			Solumedrol	SS				
INTRAVENOUS							80MG Per day	1 DAY
			Taxol	SS				
INTRAVENOUS							234MG Per day	1 DAY
			Becotide	C	Glaxosmithkline			
RESPIRATORY								
(INHALATION)								
			Lexomil	C				
UNKNOWN							.25UNIT Three	
times per day								
			Dafalgan	C	Glaxosmithkline			
UNKNOWN							6UNIT per day	
			Smecta	C				
UNKNOWN							3UNIT per day	
			Stilnox	C				
UNKNOWN							1UNIT per day	
			Imodium	C				
UNKNOWN								

			Polaramine	C		
INTRAVENOUS	1 DAY					

Date:12/22/04ISR Number: 4538566-3Report Type:Expedited (15-DaCompany Report #A02200403139
Age:63 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Supraventricular Tachycardia	Foreign Health	Stilnox (Zolpidem)	PS		ORAL
15 MG OD ORAL						
		Professional Other	Solu-Medrol (Methylprednisolone Sodium Succinate)	SS		
INTRAVENOUS	60 MG QD					
INTRAVENOUS						
NOS	1 DAY					
			Mopral - (Omeprazole)	SS		ORAL
20 MG OD ORAL						
			Zophren - (Ondansetron Hydrochloride)	SS		
INTRAVENOUS	1 UNIT OD					
INTRAVENOUS						
NOS	1 DAY					
			Taxotere - (Docetaxel)	SS		
INTRAVENOUS	132 MG OTHER					
INTRAVENOUS						
NOS	1 DAY					
			Seresta (Oxazepam)	SS		ORAL
50 MG OD ORAL						

Date:12/22/04ISR Number: 4538662-0Report Type:Expedited (15-DaCompany Report #WAES 0411USA00716
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Arrest	Foreign	Tab Decadron Tablets					
	Duodenitis	Study	(Dexamethasone)	PS		ORAL	SEE IMAGE	3 DAY
	Haematemesis	Other	Cap Placebo	SS		ORAL	3 DAY	
	Hiatus Hernia		Tab Dexamethasone	SS		ORAL	8 MG/HS	3 DAY
	Hypokalaemia		Cap Ondansetron	SS		ORAL	8 MG/BID	3 DAY
	Oesophagitis		Inj Cisplatin	SS			INTRAVENOUS	70 MG/M[2] 1 DAY
	Ventricular Arrhythmia		Inj Docetaxel	SS			25 MG/M[2]	1 DAY
	Vomiting		Inj Ondansetron	SS			INTRAVENOUS	32 MG/1X 1 DAY
			Furosemide	C				
			Lactulose	C				
			Metoprolol Succinate	C				
			Mirtazapine	C				
			Nadroparin	C				
			Oxazepam	C				
			Polyethylene Glycol	C				

Date:12/27/04ISR Number: 4541819-6Report Type:Expedited (15-DaCompany Report #211055
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Pulmonary Fibrosis	Foreign	Mabthera					
		Health	(Rituximab)	PS			INTRAVENOUS	750 MG,
		Professional					INTRAVENOUS	
		Other	Zophren (Ondansetron Hydrochloride)	SS				
			Adriblastine (Doxorubicin, Doxorubicin					

	Hydrochloride)	SS
100 MG		
	Aracytin (Cytarabine)	SS
4000 MG		
	Oncovin (Vincristine Sulfate)	SS
	Cisplatyl (Cisplatin)	SS
200 MG		
	Endoxan (Cyclophosphamide)	SS
60 MG		
	Dexamethasone (Dexamethasone)	C
	Solu-Medrol (Methylprednisolone Sodium Succinate)	C
	Cortancyl (Prednisone)	C
	Neulasta (Pegfilgrastim)	C
	Fasturtec (Rasburicase)	C
	Paracetamol (Acetaminophen)	C
	Polaramine (Dexchlorpheniramine Maleate)	C
	Celectol	

(Celiprolol Hydrochloride)	C
Triatec (Ramipril)	C
Permixon (Saw Palmetto)	C
Dysalfa (Terazsin Hydrochloride)	C
Aspegic (Aspirin Dl-Lysine)	C

Date:12/29/04ISR Number: 4540916-9Report Type:Expedited (15-DaCompany Report #CA-GLAXOSMITHKLINE-B0347475A
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Drug Exposure During Pregnancy Pulmonary Valve Stenosis		Ondansetron	PS	Glaxosmithkline			

Date:12/29/04ISR Number: 4540917-0Report Type:Expedited (15-DaCompany Report #CA-GLAXOSMITHKLINE-B0347476A
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Drug Exposure During Pregnancy Duodenal Atresia		Ondansetron	PS	Glaxosmithkline			

Date:12/29/04ISR Number: 4540939-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0362645A
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Acute Pulmonary Oedema		Zophren	PS	Glaxosmithkline			
INTRAVENOUS	8MG per day	42	DAY					
Initial or Prolonged	Cough		Solumedrol	SS				
INTRAVENOUS	120MG per day	42	DAY					
	Dyspnoea		Gemzar	SS				
INTRAVENOUS	1900MG per							

Hypocapnia
day 42 DAY
Hypoxia Nisisco C ORAL
Pulmonary Oedema Hemigoxine Nativelle C Glaxosmithkline ORAL
.125MG per

day

Amlor C ORAL
10MG Per day

Vasten C ORAL
Kardegic C ORAL
Insulin C
Previscan C
Lasilix C Glaxosmithkline

Date:12/29/04ISR Number: 4540942-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0362672A
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Arterial Thrombosis Limb		Zophren	PS	Glaxosmithkline			
INTRAVENOUS								5 DAY
Initial or Prolonged	Injection Site Erythema		Solumedrol	SS				
INTRAVENOUS								5 DAY
	Injection Site Thrombosis		Primperan	SS	Glaxosmithkline			
INTRAVENOUS								5 DAY
	Neutropenia		Cisplatine	SS				
INTRAVENOUS							220MG per day	1 DAY
	Renal Failure		Fluorouracil	SS				
INTRAVENOUS							2200MG per	
day								5 DAY
			Mopral	C	Glaxosmithkline			
UNKNOWN								
			Stilnox	C				
UNKNOWN								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/03/05ISR Number: 4543233-6Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12760971
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block Syncope		Taxol	PS	Bristol-Myers Squibb Company	INTRAVENOUS	1	DAY
Other			Carboplatin	SS	Bristol-Myers Squibb Company	INTRAVENOUS	1	DAY
			Tranxene	SS		INTRAVENOUS	1	DAY
			Ranitidine	SS		INTRAVENOUS	1	DAY
			Zophren	SS		INTRAVENOUS	1	DAY
			Solu-Medrol	SS		INTRAVENOUS	1	DAY
			Stilnox	C				
			Lexomil	C				
			Dafalgan	C				
			Smecta	C				
			Becotide	C				
			Imodium	C				

Date:01/03/05ISR Number: 4545567-8Report Type:Expedited (15-DaCompany Report #F01200401878
Age:66 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Constipation Dehydration Haematochezia Hepatic Cirrhosis Hepatic Failure Hepatorenal Syndrome Hepatotoxicity Ileus	Study Health Professional	Oxaliplatin - Solution - 85 Mg/M2 Gemcitabine - Solution - 1000	PS		INTRAVENOUS INTRAVENOUS	85 MG/M2 Q2W - NOS	ON DAYS 2 AND 16

Neoplasm Progression Mg/M2 SS
INTRAVENOUS 1000 MG/M2
Pyrexia
DAYS 2 AND 16
Renal Failure
Q4W -
Small Intestinal
INTRAVENOUS
Obstruction
NOS
Weight Decreased Avastatin - Solution
- SS
INTRAVENOUS 10 MG/KG DAYS

1 ABD 15 Q2W

- INTRAVENOUS

NOS

Ondansetron Hcl SS
Pantoprazole Sodium C
Prochlorperazine
Edisylate C
Lorazepam C
Diltiazem C
Hydrochlorothiazide C

Date:01/05/05ISR Number: 4545015-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0363105A
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chills		Zophren	PS	Glaxosmithkline			
INTRAVENOUS	24MG per day	1	DAY					
Initial or Prolonged	Pyrexia		Polaramine	SS				
INTRAVENOUS	5MG per day	1	DAY					
	Renal Failure		Gemzar	SS				
INTRAVENOUS	1900MG per							
day		1	DAY					
			Fluorouracil	SS				
INTRAVENOUS	3800MG							
cumulative								
dose		2	DAY					

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Freedom Of Information (FOI) Report

Date:01/06/05ISR Number: 4546527-3Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0363118A
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Nausea		Zophren	PS	Glaxosmithkline			
INTRAVENOUS							1	DAY
Initial or Prolonged	Rash		Temozolomide	SS				
UNKNOWN							1UNIT per day	1 DAY
	Vasodilation	Procedure	Depakine Chrono	C		ORAL	1000MG per day	
	Vomiting							
			Prozac	C			UNKNOWN	
			Efferalgan	C	Glaxosmithkline		UNKNOWN	
			Mopral	C	Glaxosmithkline		UNKNOWN	
			Gaviscon	C	Glaxosmithkline		UNKNOWN	
			Spasfon	C			UNKNOWN	
			Solumedrol	C			UNKNOWN	
			Radiotherapy	C				

Date:01/10/05ISR Number: 4549054-2Report Type:Expedited (15-DaCompany Report #FR-MERCK-0501FRA00015
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Interstitial Lung Disease		Cosmegen	PS	Merck & Co., Inc			
INTRAVENOUS							92	DAY
Initial or Prolonged			Etoposide	SS				
INTRAVENOUS							92	DAY
			Ondansetron Hydrochloride	SS				
INTRAVENOUS							92	DAY

Date:01/10/05ISR Number: 4551238-4Report Type:Expedited (15-DaCompany Report #2004-12-1360
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Gastrointestinal Disorder Nausea Vasodilatation Vomiting	Foreign Health Professional Other	Temodal (Temozolomide) Capsules (Like Temodar)	PS		ORAL	ORAL	
			Zophren (Ondansetron) Injectable	SS			INTRAVENOUS	INTRAVENOUS
			Depakine Chrono (Sodium Valproate)	C				
			Prozac	C				
			Efferalgan (Paracetamol)	C				
			Mopral (Omeprazole)	C				
			Gaviscon	C				
			Spasfon	C				

Date:01/11/05ISR Number: 4549661-7Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0363379A
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia Dystonia Intentional Self-Injury Tremor		Ondansetron	PS	Glaxosmithkline		INTRAVENOUS	
			Thyroxine	C	Glaxosmithkline	ORAL		
			Diclofenac	C		ORAL		
			Codeine	C			UNKNOWN	

Date:01/11/05ISR Number: 4551466-8Report Type:Expedited (15-DaCompany Report #2005002083
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Colitis Ischaemic Rectal Haemorrhage	Foreign Health Professional	Epirubicin Hydrochloride (Epirubicin Hydrochloride)	PS		INTRAVENOUS	117 MG,	INTRAVENOUS
			Fluorouracil (Fluorouracil)	SS		INTRAVENOUS	588 MG,	INTRAVENOUS
			Cyclophosphamide (Cyclophosphamide)	SS		INTRAVENOUS	588 MG,	INTRAVENOUS
			Dexamethasone (Dexamethasone)	SS		INTRAVENOUS	(20 MG),	INTRAVENOUS
			Ondansetron (Ondansetron)	SS		INTRAVENOUS	(2 MG/ML),	INTRAVENOUS

Date:01/11/05ISR Number: 4551604-7Report Type:Expedited (15-DaCompany Report #2004AL001121
Age:63 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Supraventricular Tachycardia	Foreign Health Professional Other	Serax (Oxazepam) Tablets, 15 Mg (Alpharma) (Serax (Oxazepam) Tablets, 15 Mg (Alpharma)	PS	Alpharma	ORAL	50 MG;QD;PO	

			Mopral (<Null>)	SS		ORAL
20 MG;QD;PO						
			Solu-Medrol	SS		
INTRAVENOUS	60 MG;QD;IV					
			Zolpidem	SS		ORAL
QD;PO						
			Taxotere	SS		
132 MG;QD;						
			Zophren	SS		
QD;IV						

Date:01/12/05ISR Number: 4550444-2Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0363587A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Ileus Paralytic		Zofran	PS	Glaxosmithkline	ORAL	8MG Twice per	
							day	25 DAY
			Docetaxel	C				
INTRAVENOUS	150MG per day	16 DAY						
			Paracetamol	C	Glaxosmithkline	ORAL	500MG per day	

Date:01/14/05ISR Number: 4554478-3Report Type:Expedited (15-DaCompany Report #PHFR2004GB04138
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration	Foreign	Voltarol (Diclofenac					
	Drug Withdrawal Syndrome	Health	Sodium)	PS		ORAL	25 MG, TID,	
		Professional					ORAL	
		Other	Octreotide (Octreotide Acetate)	SS				
SUBCUTANEOUS	100 UG Q12H,							
SUBCUTANEOUS								
			Heminevrin (Clomethiazole Edisilate)	SS		ORAL		
ORAL								

		Omeprazol (Ngx) (Omeprazole)	SS	ORAL
20 MG/DAY, ORAL				
		Clonidine (Ngx) (Clonidine Hydrochloride)	SS	ORAL
0.1 MG, PRN, ORAL				
		Diazepam (Ngx) (Diazepam)	SS	ORAL
10 MG, PRN, ORAL				
		Lorazepam (Ngx) (Lorazepam)	SS	ORAL
2.5 MG, PRN, ORAL				
		Temazepam (Ngx) (Temazepam)	SS	ORAL
20 MG, PRN, ORAL				
		Rohypnol (Flunitrazepam)	SS	ORAL
1 MG, PRN, ORAL				
		Chlorpromazine (Chlorpromazine)	SS	ORAL
50 MG, PRN, ORAL				
		Metoclopramide (Metoclopramide)	SS	
SUBCUTANEOUS	10 MG Q8H, SUBCUTANEOUS			
		Buccastem (Prochlorperazine Maleate)	SS	ORAL
ORAL				
		Buscopan (Hyoscine		

				Butylbromide)	SS		ORAL
10 MG, PRN,							
ORAL							
				Naltrexone (Naltrexone)	SS		ORAL
ORAL							
				Acupan (Nefopam Hydrochloride)	SS		ORAL
ORAL							
				Zofran (Ondansetron Hydrochloride)	SS		ORAL
8 MG, PRN,							
ORAL							

Date:01/14/05ISR Number: 4556647-5Report Type:Expedited (15-DaCompany Report #2005CG00085
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Alveolitis	Foreign	Mopral	PS		
Hospitalization -	Anaemia	Health	Largactil	SS		
Initial or Prolonged	Bronchoalveolar Lavage	Professional	Largactil	SS		
	Abnormal	Other	Largactil	SS		
	Chest X-Ray Abnormal		Vepeside	SS		
INTRAVENOUS 170 MG DAILY						
	Creatinine Renal					
IV						
	Clearance Decreased		Vepeside	SS		
INTRAVENOUS 170 MG DAILY						
	Depressed Level Of					
IV						
	Consciousness		Vepeside	SS		
INTRAVENOUS 170 MG DAILY						
	General Physical Health					
IV						
	Deterioration		Cisplatin "Qualimde"	SS	Qualimed	
INTRAVENOUS 50 MG DAILY						
	Leukocytosis					
IV						
	Pneumonia		Cisplatin "Qualimed"	SS	Qualimed	
INTRAVENOUS 50 MG DAILY						
	Septic Shock					
IV						
	Vomiting		Cisplatin "Qualimed"	SS	Qualimed	
INTRAVENOUS 50 MG DAILY						
IV						
			Lexomil	SS		

			Zophren	SS
INTRAVENOUS	16 MG T1WK IV			
			Zophren	SS
INTRAVENOUS	16 MG T1WK IV			
			Zophren	SS
INTRAVENOUS	16 MG T1WK IV			
			Calcium Carbonate W/Colecalciferol	SS
			Solupred	SS
			Solupred	SS
			Solupred	SS
			Solupred	SS
			Stilnox/Fra/	SS
			Primperan	SS
			Primperan	SS
			Primperan	SS
			Solu-Medrol	SS
			Solu-Medrol	SS
			Solu-Medrol	SS
			Deroxat	SS
			Durogesic	SS
			Actiskenan	SS

Date:01/18/05ISR Number: 4554303-0Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0363677A
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chest X-Ray Abnormal		Zophren	PS	Glaxosmithkline			
INTRAVENOUS	8MG Monthly							
Initial or Prolonged	General Physical Health		Cosmegen	SS				
INTRAVENOUS	1.42G Monthly							
	Deterioration		Vepeside	SS				
INTRAVENOUS	200MG Monthly							
	Hypoxia							
	Interstitial Lung Disease							
	Lung Disorder							
	Pyrexia							
	Respiratory Distress							

Date:01/18/05ISR Number: 4554308-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0364005A
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chest Discomfort		Augmentin	PS	Glaxosmithkline			
UNKNOWN								3 DAY
Initial or Prolonged	Lung Infection		Zophren	SS	Glaxosmithkline			
INTRAVENOUS							8MG Weekly	1 DAY
	Pruritus		Solumedrol	SS				
INTRAVENOUS							60MG Weekly	1 DAY
	Pyrexia		Cisplatine	SS				
INTRAVENOUS							45MG Weekly	1 DAY
	Rash		Taxotere	SS				
INTRAVENOUS							37MG Weekly	1 DAY
	Rash Maculo-Papular		Etoposide	SS				
1 DAY								
			Radiotherapy	C				

Date:01/18/05ISR Number: 4554774-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0364025A
Age:45 YR Gender:Female I/FU:I

Outcome	PT
Death	Alveolitis
Hospitalization -	Anaemia
Initial or Prolonged	Blood Creatinine Decreased
	Bronchoalveolar Lavage Abnormal
	C-Reactive Protein Increased
	Chest X-Ray Abnormal

	Cough						
	Creatinine Renal Clearance Decreased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Depressed Level Of Consciousness		Zophren	PS	Glaxosmithkline	ORAL	8MG Cyclic
	General Physical Health		Largactil	SS		ORAL	
			Vepeside	SS			INTRAVENOUS 170MG Cyclic
	Deterioration		Mopral	SS	Glaxosmithkline	ORAL	
	Inflammation		Cisplatine	SS			INTRAVENOUS 50MG Cyclic
	Lung Consolidation		Lexomil	SS		ORAL	3 MON
	Lung Disorder		Primperan	C	Glaxosmithkline		UNKNOWN
	Neutrophilia		Solumedrol	C			UNKNOWN
	Pyrexia		Deroxat	C	Glaxosmithkline		UNKNOWN 3 MON
	Septic Shock		Stilnox	C			UNKNOWN
	Vomiting		Densical D3	C			UNKNOWN 4 MON
			Solupred	C	Glaxosmithkline		UNKNOWN
			Durogesic	C			UNKNOWN
			Actiskenan	C	Glaxosmithkline		UNKNOWN
			Atarax	C			UNKNOWN

Date:01/21/05ISR Number: 4558787-3Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0340937A
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Abdominal Pain		Zophren	PS	Glaxosmithkline		UNKNOWN
Initial or Prolonged	Antinuclear Antibody		Neurontin	SS		ORAL	8 WK
	Positive		Taxotere	SS			INTRAVENOUS 110MG Cyclic

	Aphthous Stomatitis		Caelyx	SS		
INTRAVENOUS	70MG Cyclic					
	Catheter Site Infection		Becilan	C		ORAL
250MG Three						
	Diarrhoea					
times per day						
	Erythema					
	Nikolsky'S Sign					
	Oedema Peripheral					
	Pain					
	Pain In Extremity					
	Pyrexia					
	Rash Erythematous					
	Skin Exfoliation					
	Staphylococcal Infection					
	Stevens-Johnson Syndrome					

Date:01/21/05ISR Number: 4558804-0Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0364280A
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Chloroma		Ondansetron	PS	Glaxosmithkline	ORAL
8MG Three						
times per day	7 MON					
			Doxepin	C		
UNKNOWN	100MG Per day					

Date:01/21/05ISR Number: 4561317-3Report Type:Expedited (15-DaCompany Report #9664
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Feeling Hot		Carboplatin	PS		
INTRAVENOUS	500 MG FREQ					
Initial or Prolonged	Hyperhidrosis					
UNK; IV						
	Hypotension		Dexamethasone	SS		
INTRAVENOUS	NI; IV					
	Malaise		Paclitaxel	SS		
INTRAVENOUS	175 MG/M2					
	Shock					
FREQ UNK; IV						
			Ranitidine	SS		
INTRAVENOUS	50 MG FREQ					

UNK; IV			Dexchlorpheniramine	SS		
UNKNOWN	5 MG FREQ					
UNK, UNK			Ondansetron	SS		
NI; UNK			Cyclophosphamide	C		

Date:01/24/05ISR Number: 4559313-5Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040800636
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Acute Generalised	Health	Caelyx	PS		INTRAVENOUS		
Initial or Prolonged	Exanthematous Pustulosis	Professional	Becilan	SS		OROPHARINGEAL		
	Antinuclear Antibody		Neurontin	SS		OROPHARINGEAL		
	Positive		Neurontin	SS		OROPHARINGEAL		
	Aphthous Stomatitis		Neurontin	SS		OROPHARINGEAL		
	Nausea		Taxotere	SS		INTRAVENOUS		
	Skin Infection		Radiation Therapy	SS				
	Stevens-Johnson Syndrome		Zophren	SS				
	Vomiting							

Date:01/24/05ISR Number: 4559535-3Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0541638A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acrochordon		Zofran	PS	Glaxosmithkline			
	Ankyloglossia Congenital							

Date:01/24/05ISR Number: 4559538-9Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0364814A
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chloroma		Ondansetron	PS	Glaxosmithkline	ORAL	8MG Three	
	Myelodysplastic Syndrome						times per day	7 MON
			Doxepin	C			UNKNOWN	100MG Per day

Date:01/24/05ISR Number: 4562673-2Report Type:Expedited (15-DaCompany Report #2005015418
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arterial Thrombosis Limb	Foreign	Solu-Medrol (Methylprednisolone Sodium Succinate)	PS			220 MG (220 MG, 1 IN 1 D)	
	Injection Site Erythema	Health Professional	Cisplatin	SS			2.2 GRAM (2.2 GRAM, 1 IN 1	
	Injection Site Thrombosis	Other	Metoclopramide	SS				
	Neutropenia		Fluorouracil	SS				
	Renal Failure		Zophren (Ondansetron Hydrochloride)	SS				
			Omeprazole	C				
			Zolpidem	C				

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Freedom Of Information (FOI) Report

Date:01/25/05ISR Number: 4560171-3Report Type:Expedited (15-DaCompany Report #200412840FR
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Antinuclear Antibody Positive Blood Potassium Decreased Blood Sodium Decreased Clostridial Infection Diarrhoea Enterobacter Infection Erythema Multiforme Haemoglobin Decreased Inflammation Muscle Spasms Red Blood Cell Count Decreased Staphylococcal Infection Stevens-Johnson Syndrome Systemic Lupus Erythematosus Toxic Skin Eruption White Blood Cell Count Decreased		Taxotere Zophren Neurontin Caelyx Becilan	PS SS SS SS C	Aventis Pharmaceuticals Inc.	ORAL	INTRAVENOUS Dose unit: units	

Date:01/25/05ISR Number: 4560547-4Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0364819A
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Subileus		Topotecan Gemcitabine	PS SS	Glaxosmithkline	INTRAVENOUS INTRAVENOUS	4MG per day 1600MG per day	1 DAY 1 DAY
			Zophren	SS	Glaxosmithkline	UNKNOWN		

			Lipanthyl	C		
UNKNOWN						
			Esberiven	C		
UNKNOWN						
			Praxilene	C		
UNKNOWN						
			Previscan	C		
UNKNOWN						
			Plitican	C		
UNKNOWN						

Date:01/25/05ISR Number: 4563273-0Report Type:Expedited (15-DaCompany Report #2005015491
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Pulmonary Oedema Cardiac Failure Cough	Foreign Health Professional	Solu-Medrol (Methylprednisolone Sodium Succinate)	PS		INTRAVENOUS	120 MG (WEEKLY), INTRAVENOUS	
	Hypocapnia Hypoxia		Ondansetron (Ondansetron)	SS		INTRAVENOUS	INTRAVENOUS	
			Gemcitabine (Gemcitabine)	SS		INTRAVENOUS	1.9 GRAM (WEEKLY), INTRAVENOUS	
			Hydrochlorothiazide (Hydrochlorothiazide)	C				
			Digoxin (Digoxin)	C				
			Amlodipine					

			(Amlodipine)	C		
			Fluindione (Fluindione)	C		
			Pravastatin (Pravastatin)	C		
			Acetylsalicylate Lysine (Acetylsalicylate Lysine)	C		
			Insulin Human (Insulin Human)	C		

Date:01/25/05ISR Number: 4569038-8Report Type:Direct Company Report #CTU 237875
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Convulsion		Zofran 4mg Glaxosmithkline	PS	Glaxosmithkline	INTRAVENOUS	4MG	Q8H
			Protonix	C		INTRAVENOUS		
			Reglan	C				

Date:01/27/05ISR Number: 4567556-XReport Type:Expedited (15-DaCompany Report #2005-01-1289
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pruritus Rash Maculo-Papular	Foreign Health Professional	Temodal (Temozolomide) Like Temodar Capsules	PS		ORAL	350 MG	ORAL;
SEE IMAGE		Other						
			Ondansetron	SS				
			Ethinyl Estradiol/Gestodene Oral	C				
			Fluoxetine	C				
			Alprazolam Oral	C				
			Omeprazole	C				

Date:01/27/05ISR Number: 4575291-7Report Type:Direct Company Report #CTU 238320
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dysarthria		Zofran 2 Mg Iv	PS		INTRAVENOUS	2 MG IV Q 8 HRS PRN	
	Dyskinesia							
			Hydromorphone	C				
			Pca	C				
			Ancef	C				

Date:01/28/05ISR Number: 4564363-9Report Type:Expedited (15-DaCompany Report #CA-GLAXOSMITHKLINE-B0347474A
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Drug Exposure During Pregnancy		Ondansetron	PS	Glaxosmithkline			
	Urinary Tract Disorder							

Date:01/31/05ISR Number: 4565524-5Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0365833A
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Eosinophilia		Augmentin	PS	Glaxosmithkline	ORAL		
	Laryngeal Oedema		Folinic Acid	SS	Glaxosmithkline	INTRAVENOUS	75MG per day	
	Leukocytoclastic Vasculitis		Aracytine	SS		INTRAVENOUS	179MG per day	
	Oedema		Methotrexate	SS		INTRAVENOUS		
	Pruritus		Rituximab	SS		INTRAVENOUS		
	Rash		Zophren	SS	Glaxosmithkline	UNKNOWN		
	Rash Papular		Cyclophosphamide	C		UNKNOWN		
	Rash Vesicular		Epirubicine	C		UNKNOWN		
	Weight Increased		Vindesine	C		UNKNOWN		
			Prednisone	C		UNKNOWN		
			Oflocet	C		UNKNOWN		
			Inexium	C		UNKNOWN		
			Imovane	C		UNKNOWN		
			Spasfon	C		UNKNOWN		
			Gaviscon	C	Glaxosmithkline	UNKNOWN		
			Di Antalvic	C		UNKNOWN		
			Xanax	C		UNKNOWN		
			Pyostacine	C		UNKNOWN		
			Solumedrol	C		UNKNOWN		

Date:02/01/05ISR Number: 4567152-4Report Type:Expedited (15-DaCompany Report #FR-SANOFISYNTHELABO-D01200401745
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	General Physical Health		Sr57746 Or Placebo	PS		ORAL	50	DAY
Life-Threatening	Deterioration		Fluorouracil	SS		INTRAVENOUS	400 mg/m2 as IV bolus then 600 mg/m2 as 22 hours continuous	2 DAY
	Leukopenia					INTRAVENOUS		2 HR
	Neutropenia		Oxaliplatin	SS		INTRAVENOUS	200 mg/m2 as 2 hours infusion on D1-D2 Q2W	2 DAY
	Pneumonia		Leucovorin	SS		UNKNOWN	UNK	30 DAY
	Pyrexia					UNKNOWN	UNK	16 DAY
			Zophren	SS		UNKNOWN	UNK	4 DAY
			Maltofer	C		UNKNOWN	UNK	
			Noroxine	C		UNKNOWN	UNK	16 DAY
			Forlax	C		UNKNOWN	UNK	30 DAY
			Granocyte	C		UNKNOWN	UNK	30 DAY
			Primperan	C		UNKNOWN	UNK	8 DAY
			Solumedrol	C		UNKNOWN	UNK	
			Furandotoine	C		UNKNOWN	UNK	2 WK
			Aranesp	C		UNKNOWN	UNK	4 YR
			Tardyferon	C		UNKNOWN	UNK	1 MON
			Imovane	C		UNKNOWN	UNK	
			Lactulose	C		UNKNOWN	UNK	
			Kardegic	C				
			Mopral	C				

UNKNOWN	UNK
UNKNOWN	UNK
UNKNOWN	UNK
UNKNOWN	UNK

Nitriderm	C
Spironolactone	C
Pritor	C
Sectral	C

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Freedom Of Information (FOI) Report

Date:02/04/05ISR Number: 4570605-6Report Type:Expedited (15-DaCompany Report #SGB1-2005-00005
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	4MG Cyclic	UNKNOWN
	Dizziness		Metoclopramide	SS	Glaxosmithkline			UNKNOWN
	Dyspnoea		Zometa	SS				
	Feeling Cold		Epirubicin	C				UNKNOWN
	Headache							
	Oedema Peripheral							
	Oral Candidiasis							
	Pain In Extremity							
	Photosensitivity Reaction							

Date:02/04/05ISR Number: 4576154-3Report Type:Expedited (15-DaCompany Report #2005015491
Age:72 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Pulmonary Oedema	Foreign Health Professional	Solu-Medrol (Methylprednisolone Sodium Succinate)	PS		INTRAVENOUS	120 MG (WEEKLY),	INTRAVENOUS
	Cardiac Failure							
	Cough							
	Dyspnoea							
	Hypocapnia							
	Hypoxia							
			Ondansetron (Ondansetron)	SS		INTRAVENOUS	INTRAVENOUS	
			Gemcitabine Hydrochloride (Gemcitabine Hydrochloride)	SS		INTRAVENOUS	1.9 GRAM (WEEKLY),	INTRAVENOUS

Hydrochlorothiazide (Hydrochlorothiazide)	C
Digoxin (Digoxin)	C
Amlodipine Besilate (Amlodipine Besilate)	C
Flundione (Flundione)	C
Pravastatin (Pravastatin)	C
Acetylsalicylate Lysine (Acetylsalicylate Lysine)	C
Insulin Human (Insulin Human)	C
Co-Diovan (Hydrochlorothiazde, Valsartan)	C

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Freedom Of Information (FOI) Report

Date:02/04/05ISR Number: 4576166-XReport Type:Expedited (15-DaCompany Report #2005019587
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Pyrexia Rash Generalised Rash Maculo-Papular Rash Pruritic	Foreign Health Professional	Solu-Medrol (Methylprednisolone Sodium Succinate)	PS			60 MG (CYCLIC	INTERVAL: EVERY
			Ondansetron Hydrochloride	SS			8 MG (CYCLIC	INTERVAL: EVERY
			Cisplatin	SS			45 MG (CYCLIC	INTERVAL: EVERY
			Docetaxel	C				
			Hyzaar (Hydrochlorothiazide, Losartan Potassium)	C				
			Theophylline	C				
			Beclometasone Dipropionate	C				
			Salbutamol W/Ipratropium	C				
			Pravastatin Sodium	C				
			Trimetazidine Hydrochloride	C				
			Levocetirizine Dihydrochloride	C				
			Guethural (Guethol Carbonate, Urea)	C				
			Colchicine	C				
			Clavulin					

	(Amoxicillin Trihydrate, Clavulanate Potassium)	C

Date:02/04/05ISR Number: 4576190-7Report Type:Expedited (15-DaCompany Report #2004056277
Age:51 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain
	Abdominal Rigidity
	Acute Generalised Exanthematous Pustulosis
	Antinuclear Antibody Positive
	Aphthous Stomatitis
	Blood Albumin Decreased
	Blood Chloride Decreased
	Blood Creatinine Decreased
	Blood Creatinine Increased
	Blood Glucose Increased
	Blood Potassium Decreased

		Blood Urea Decreased Catheter Related Infection					
Dose	Duration	Clostridial Infection Dermatitis Bullous Diarrhoea Enterobacter Infection General Physical Health Deterioration Nausea Oedema Peripheral Pain In Extremity Pco2 Decreased Protein Total Decreased Staphylococcal Infection Stevens-Johnson Syndrome Vomiting	Report Source	Product	Role	Manufacturer	Route
100 MG (100 MG, 1 IN 1 D), ORAL			Foreign Health Professional	Neurontin (Gabapentin)	PS		ORAL
750 MG (250 MG, 3 IN 1 D),				Pyridoxine Hydrochloride (Pyridoxine Hydrochloride)	SS		
				Ondansetron Hydrochloride (Ondansetron Hydrochloride)	SS		
INTRAVENOUS	110 MG (110 MG, 1 IN 3 WK),			Docetaxel (Docetaxel)	SS		
INTRAVENOUS				Doxorubicin Hydrochloride (Doxorubicin Hydrochloride)	SS		
INTRAVENOUS	70 MG (70 MG, 1 IN 3 WK),						
INTRAVENOUS							

Date:02/08/05ISR Number: 4575106-7Report Type:Expedited (15-DaCompany Report #PHFR2005GB00747
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dizziness		Zometa	PS	Novartis Sector: Pharma	INTRAVENOUS	4 mg every 2	weeks
	Dyspnoea							
	Feeling Cold							
	Headache		Metoclopramide	SS				UNKNOWN
	Oedema Peripheral		Ondansetron	SS				UNKNOWN
	Oral Candidiasis		Epirubicin	C				UNKNOWN
	Pain In Extremity							
	Photosensitivity Reaction							

Date:02/09/05ISR Number: 4575468-0Report Type:Expedited (15-DaCompany Report #200510416FR
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hepatic Failure		Lovenox	PS	Aventis Pharmaceuticals Inc.	SUBCUTANEOUS		
Hospitalization - Initial or Prolonged	Hepatitis							
	Hepatitis Cholestatic		Cisplatine	SS		INTRAVENOUS		
			Ketek	SS	Aventis Pharmaceuticals Inc.	ORAL		
			Mopral	SS		INTRAVENOUS		
			Zophren	SS		INTRAVENOUS		
			Gemzar	SS		INTRAVENOUS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/09/05ISR Number: 4577818-8Report Type:Expedited (15-DaCompany Report #B0369183A
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Confusional State Dyskinesia Dystonia Encephalopathy Grimacing Haematocrit Decreased Peritoneal Haemorrhage Saccadic Eye Movement Tonic Clonic Movements	Literature Health Professional	Zofran (Formulation Unknown) (Ondansetron Hydrochloride)	PS		INTRAVENOUS	4 MG/ UNKNOWN/ INTRAVENOUS	

Date:02/09/05ISR Number: 4578125-XReport Type:Expedited (15-DaCompany Report #212007
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Eosinophilia Hepatitis B Laryngeal Oedema Neutropenia Pruritus Staphylococcal Infection Toxic Skin Eruption Vasculitis Viral Infection Weight Increased	Foreign Health Professional Other	Mabthera (Rituximab) Conc For Solution For Infusion Methotrexate (Methotrexate) Zophren (Ondansetron Hydrochloride) Augmentin (Amoxacillin, Clavulanate Potassium) Aracytine (Cytarabine) Acide Folinique(Leucovorin Calcium) Cyclophosphamide (Cyclophospamide) Epirubicin Hydrochloride(Epirub	PS SS SS SS SS C		ORAL	INTRAVENOUS	INTRAVENOUS 3 G QD ORAL

icin Hydrochloride)	C
Vindesine (Vindesine)	C
Prednisone (Prednisone)	C
Inexium (Esomeprazole Magnesium)	C
Imovane (Zopiclone)	C
Spasfon (Phloroglucinol, Trimethylphlorglucinol)	C
Gaviscon (Gastrointestinal Drug Nos)	C
Di-Antalvic (Acetaminophen, Propoxyphene Hydrochloride)	C
Xanax (Alprazolam)	C
Augmentin (Amoxicillin,	

Clavulanate Potassium)	C
Oflocet (Ofloxacin)	C
Pyostacine (Pristinamycin)	C
Solu-Medrol (Methylprednisolone Sodium Succinate)	C

Date:02/09/05ISR Number: 4604896-XReport Type:Direct Company Report #CTU 242461
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Chills Extrapyramidal Disorder Muscle Spasms Pain Post Procedural Complication		Zofran	PS		INTRAVENOUS	4 MG IV	

Date:02/10/05ISR Number: 4577101-0Report Type:Expedited (15-DaCompany Report #GB-ROCHE-391917
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration		Diazepam	PS	Roche	ORAL	REGIMEN	REPORTED AS PRN
			Rohypnol	SS	Roche	ORAL	REGIMEN	REPORTED AS PRN
			Heminevrin	SS		ORAL		
			Omeprazole	SS		ORAL		
			Clonidine	SS		ORAL	REGIMEN	

RPEORTED AS				
PRN				
	Lorazepam	SS		ORAL
REGIMEN				
REPORTED AS				
PRN				
	Temazepam	SS	Roche	ORAL
REGIMEN				
REPORTED AS				
PRN				
	Chlorpromazine	SS		ORAL
REGIMEN				
REPORTED PRN				
	Octreotide	SS		
SUBCUTANEOUS				
	Metoclopramide	SS		
SUBCUTANEOUS				
	Buccastem	SS		ORAL
	Buscopan	SS		ORAL
REGIMEN				
REPORTED AS				
PRN				
	Naltrexone	SS		ORAL
	Acupan	SS		ORAL
	Voltarol	SS	Roche	ORAL
	Zofran	SS		ORAL
REGIMEN				
REPORTED AS				
PRN				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/10/05ISR Number: 4577373-2Report Type:Expedited (15-DaCompany Report #2004-12-1365
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chills		Zophren	PS	Glaxosmithkline			
INTRAVENOUS							24MG Per day	1 DAY
Initial or Prolonged	Pyrexia		Polaramine	SS				
INTRAVENOUS							5MG Per day	1 DAY
	Renal Failure		Gemzar	SS				
INTRAVENOUS							1900MG Per	
day							1 DAY	
			Fluorouracil	SS				
INTRAVENOUS							3800MG Per	
day							2 DAY	

Date:02/14/05ISR Number: 4580259-0Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0369726A
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hepatic Failure		Zophren	PS	Glaxosmithkline			
INTRAVENOUS								
	Hepatitis Cholestatic		Cisplatine	SS				
INTRAVENOUS							160MG Cyclic	1 DAY
	Hepatocellular Damage		Mopral	SS	Glaxosmithkline			
INTRAVENOUS							40MG Cyclic	1 DAY
			Lovenox	SS				
SUBCUTANEOUS							40MG Per day	17 DAY
			Gemzar	SS				
INTRAVENOUS							2000MG Per	
day							1 DAY	
			Ketek	SS		ORAL		
800MG Per day							16 DAY	
			Surbronc	C	Glaxosmithkline			
UNKNOWN							16 DAY	
			Medrol	C				
UNKNOWN							17 DAY	
			Ethyol	C				
INTRAVENOUS							1500MG Per	
day							1 DAY	

			Primperan	C	Glaxosmithkline	
INTRAVENOUS	2AMP per day	1 DAY				

Date:02/15/05ISR Number: 4582797-3Report Type:Expedited (15-DaCompany Report #2004-12-1365
Age:59 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Chills		Zophren	PS	Glaxosmithkline	
INTRAVENOUS	24MG Per day	1 DAY				
Initial or Prolonged	Pyrexia		Polaramine	SS		
INTRAVENOUS	5MG Per day	1 DAY				
	Renal Failure		Gemzar	SS		
INTRAVENOUS	1900MG Per					
day	1 DAY					
			Fluorouracil	SS		
INTRAVENOUS	3800MG Per					
day	2 DAY					

Date:02/16/05ISR Number: 4588341-9Report Type:Expedited (15-DaCompany Report #2005AP01022
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Required	Rash Maculo-Papular	Foreign	Propofol	PS		
Intervention to		Health	Keflin	SS		
Prevent Permanent		Professional	Fentanyl	SS		
Impairment/Damage		Other	Lignocaine	SS		
			Cephalothin	SS		
			Dexamethasone	SS		
			Ondansetron Hydrochloride Dihydrate	SS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/16/05ISR Number: 4589530-XReport Type:Expedited (15-DaCompany Report #2005008102
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block Complete Syncope	Foreign Health Professional	Solu-Medrol (Methylprednisolone Sodium Succinate)	PS		INTRAVENOUS	80 MG (40 MG/2 ML TWICE A DAY),	
			Carboplatine (Carboplatin)	SS		INTRAVENOUS	510 MG (DAILY),	
			Tranxene (Clorazepate Dipotassium)	SS		INTRAVENOUS	20 MG (20 MG/2 ML DAILY),	
			Ranitidine (Ranitidine Hydrochloride)	SS		INTRAVENOUS	100 MG (DAILY),	
			Ondansetron Hydrochloride (Ondansetron Hydrochloride)	SS		INTRAVENOUS	8 MG (2 MG/ML FOUR TIMES A	

DAY),			
INTRAVENOUS			
		Paclitaxel (Paclitaxel)	SS
INTRAVENOUS	234 MG (30		
MG/5 ML			
DAILY),			
INTRAVENOUS			
		Dexchlorpheniramine Maleate (Dexchlorpheniramine Maleate)	C
		Zolpidem (Zolpidem)	C
		Bromazepam (Bromazepam)	C
		Paracetamol (Paracetamol)	C
		Smectite (Smectite)	C
		Beclometasone Dipropionate (Beclometasone Dipropionate)	C
		Loperamide Hydrochloride (Loperamide Hydrochloride)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/17/05ISR Number: 4590087-8Report Type:Expedited (15-DaCompany Report #211055
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Pulmonary Fibrosis	Foreign Health Professional Other	Mabthera (Rituximab)	PS		INTRAVENOUS	750 MG,	INTRAVENOUS
			Zophren (Ondansetron Hydrochloride)	SS				
			Adriablastine (Doxorubicin, Doxorubicin Hydrochloride)	SS			100 MG	
			Aracytin (Cytarabine)	SS			4000 MG	
			Oncovin (Vincristine Sulfate)	SS				
			Cisplatyl (Cisplatin)	SS			200 MG	
			Endoxan (Cyclophosphamide)	C			60 MG	
			Dexamethasone (Dexamethasone)	C				
			Solu-Medrol (Methylprednisolone Sodium Succinate)	C				
			Cortancyl (Prednisone)	C				
			Neulasta (Pegfilgrastim)	C				
			Fasturtec (Rasburicase)	C				
			Paracetamol (Acetaminophen)	C				
			Polaramine (Dexchlorpheniramine Maleate)	C				

Celectol (Celiprolol Hydrochloride)	C
Triatec (Ramipril)	C
Permixon (Saw Palmetto)	C
Dysalfa (Terazosin Hydrochloride)	C
Aspegic (Aspirin Dl-Lysine)	C

Date:02/18/05ISR Number: 4587246-7Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0370746A
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthralgia		Zophren	PS	Glaxosmithkline	ORAL	1UNIT Cyclic	1 DAY
	Chest Pain		Solupred	SS	Glaxosmithkline	ORAL	1UNIT Cyclic	1 DAY
	Dyspnoea		Taxol	SS		INTRAVENOUS		1 DAY
			Carboplatine	SS		INTRAVENOUS		1 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/18/05ISR Number: 4590284-1Report Type:Direct Company Report #CTU 240799
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acidosis		Ceftriaxone 2 Gm Iv					
Other	Body Temperature		Daily/Roche	PS	Roche			
INTRAVENOUS	2 GM DAY IV							
	Increased		Enoxaparin	SS				
	Dehydration		Gabapentin	SS				
	Haemolytic Anaemia		Ondansetron	SS				
	Heart Rate Increased		Apap	SS				
	Intervertebral Discitis		Hydroxyzine	SS				
	Multi-Organ Failure		Clonidine	SS				
	Renal Failure		Percocet-10	SS				
	Respiratory Failure							
	Sepsis							

Date:02/22/05ISR Number: 4588545-5Report Type:Expedited (15-DaCompany Report #200510416FR
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alpha 2 Globulin		Lovenox	PS	Aventis			
Hospitalization -	Increased				Pharmaceuticals Inc.			
SUBCUTANEOUS								
Initial or Prolonged	Encephalopathy		Cisplatine	SS				
INTRAVENOUS								
	Hepatic Failure		Ketek	SS	Aventis			
	Hepatitis				Pharmaceuticals Inc.	ORAL		
	Hepatitis Cholestatic		Mopral	SS				
INTRAVENOUS								
	Hypergammaglobulinaemia		Zophren	SS				
INTRAVENOUS								
	Infection		Gemzar	SS				
INTRAVENOUS								
	Shock							

Date:02/22/05ISR Number: 4588860-5Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0364005A
Age:69 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Chest Discomfort		Zophren	PS	Glaxosmithkline
INTRAVENOUS	8MG Weekly	1 DAY			
Initial or Prolonged	Lung Infection		Augmentin	SS	Glaxosmithkline
UNKNOWN		3 DAY			
	Pruritus		Solumedrol	SS	
INTRAVENOUS	60MG Weekly	1 DAY			
	Pyrexia		Cisplatine	SS	
INTRAVENOUS	45MG Weekly	1 DAY			
	Rash		Taxotere	SS	
INTRAVENOUS	37MG Weekly	1 DAY			
	Rash Maculo-Papular		Etoposide	SS	
1 DAY					
			Radiotherapy	C	

Date:02/22/05ISR Number: 4591125-9Report Type:Expedited (15-DaCompany Report #2005-125212-NL
Age:82 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Aphasia
Initial or Prolonged	Aspartate
	Aminotransferase
	Increased
	Blood Creatinine
	Increased
	Blood Lactate
	Dehydrogenase Increased
	C-Reactive Protein
	Increased
	Disorientation
	Pneumonia
	Sluggishness

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	White Blood Cell Count Increased							
		Health	Mirtazapine	PS		ORAL	15 MG QD ORAL	1 DAY
		Professional	Ondansetron Hydrochloride	SS		ORAL	2 MG QD ORAL	
			Acetylsalicylic Acid	C				
			Pantoprazole Sodium	C				
			Metoclopramide Hydrochloride	C				
			Delix Plus	C				
			Amlodipine	C				
			Belch Zak Mite	C				
			Torsemide	C				
			Citalopram Hydrobromide	C				
			Tiotropium Bromide	C				
			Symbicort /Can/	C				
			Fentanyl	C				
			Movicol	C				

Date:02/22/05ISR Number: 4592781-1Report Type:Expedited (15-DaCompany Report #10212
Age:6 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Aspartate Aminotransferase Increased	Foreign Study	Methotrexate	PS		SUBCUTANEOUS	15 MG WEEKLY	
SC	1215 DAY		Naproxen	SS		ORAL	175 MG BID PO	
			Ondansetron	SS		ORAL	PO	
			Etanercept	SS		SUBCUTANEOUS	10 MG 2/WK SC	

Date:02/28/05ISR Number: 4592938-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0369726A
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cytolytic Hepatitis		Zophren	PS	Glaxosmithkline	INTRAVENOUS		
	Hepatic Failure		Cisplatine	SS		INTRAVENOUS	160MG Cyclic	1 DAY
	Hepatocellular Damage		Mopral	SS	Glaxosmithkline	INTRAVENOUS	40MG Cyclic	1 DAY
			Lovenox	SS		SUBCUTANEOUS	40MG Per day	17 DAY
			Gemzar	SS		INTRAVENOUS	2000MG Per day	1 DAY
			Ketek	SS		ORAL	800MG Per day	16 DAY
			Surbronc	C	Glaxosmithkline	UNKNOWN		16 DAY
			Medrol	C		UNKNOWN		17 DAY
			Ethyol	C		INTRAVENOUS	1500MG Per day	1 DAY
			Primperan	C	Glaxosmithkline	INTRAVENOUS	2AMP per day	1 DAY

Date:02/28/05ISR Number: 4592944-5Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0372070A
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia		Zophren	PS	Glaxosmithkline	INTRAVENOUS	2MG Twice per day	6 DAY
Hospitalization - Initial or Prolonged	Drug Interaction							
	Drug Tolerance Decreased		Rivotril	SS		INTRAVENOUS	1UNIT Twice per day	6 DAY
	Headache							
			Mopral	C	Glaxosmithkline	UNKNOWN		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/02/05ISR Number: 4596717-9Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0364280A
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chloroma		Ondansetron	PS	Glaxosmithkline	ORAL	8MG Three times per day	7 MON
			Doxepin	C			UNKNOWN	100MG Per day

Date:03/02/05ISR Number: 4596718-0Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0364814A
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chloroma		Ondansetron	PS	Glaxosmithkline	ORAL	8MG Three times per day	7 MON
	Myelodysplastic Syndrome							
			Doxepin	C			UNKNOWN	100MG Per day

Date:03/03/05ISR Number: 4597632-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0547006A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Drug Exposure During Pregnancy		Zofran	PS	Glaxosmithkline			
	Finger Deformity							

Date:03/04/05ISR Number: 4599744-0Report Type:Direct Company Report #CTU 242088
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anxiety		Zofran	PS			INTRAVENOUS	X1

Initial or Prolonged	Dysphagia					
INTRAVENOU						
	Dystonia		Effexor Xr	C		
	Intermittent Claudication		Vicodin	C		
	Joint Stiffness					
	Restlessness					
	Trismus					

Date:03/11/05ISR Number: 4605960-1Report Type:Expedited (15-DaCompany Report #CL-GLAXOSMITHKLINE-A0549211A
Age:1 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia		Zofran	PS	Glaxosmithkline			
INTRAVENOUS								
Other	Respiratory Depression					BOLUS	2MG Single	
dose	1	DAY						

Date:03/15/05ISR Number: 4613631-0Report Type:Expedited (15-DaCompany Report #5025
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaphylactic Reaction	Foreign	Midazolam	PS			3 MG ONCE	
Hospitalization -	Angioneurotic Oedema	Health	Fentanyl	SS				
Initial or Prolonged	Cardiac Arrest	Professional	Ondansetron	SS			4 MG ONCE	
	Electrocardiogram St	Other	Propofol	SS			200 MG TOTAL	
	Segment Depression		Lignocaine	SS				
			Rocuronium Bromide	SS				
			Irbesartan	C				
			Indapamide Hemihydrate	C				

Pravastatin Sodium	C
Betahistine	C
Piroxicam	C
Oxygen	C

Date:03/15/05ISR Number: 4613643-7Report Type:Expedited (15-DaCompany Report #5249
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hyperthermia Malignant	Foreign	Midazolam	PS			2.5 MG	1 DAY
	Neuroleptic Malignant	Health	Fentanyl	SS			100 MICROGRAM	1 DAY
	Syndrome	Professional	Propofol	SS			200 MG	1 DAY
		Other	Cefazolin Sodium	SS			1 G	3 DAY
			Morphine Sulfate	SS			8 MG	3 DAY
			Ondansetron Hydrochloride	SS			4 MG	1 DAY

Date:03/15/05ISR Number: 4614130-2Report Type:Expedited (15-DaCompany Report #B0373048A
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression	Study Literature Health Professional	Zofran Unspecified Injectable (Ondansetron Hydrochloride)	PS		INTRAVENOUS	.1 MG/KG/ SINGLE DOSE/INTRAVEN OUS	

Date:03/16/05ISR Number: 4610106-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0504921A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation		Compazine	PS	Glaxosmithkline		UNKNOWN	
	Tremor		Zofran	SS	Glaxosmithkline	ORAL	8MG Variable	
							dose	
			Zofran	SS	Glaxosmithkline	ORAL	8MG Variable	
							dose	

Date:03/17/05ISR Number: 4611540-4Report Type:Expedited (15-DaCompany Report #FR-ROCHE-397493
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia		Rivotril	PS	Roche		INTRAVENOUS	6 DAY
	Drug Interaction		Zophren	I			INTRAVENOUS	6 DAY
	Drug Intolerance		Zophren	I			INTRAVENOUS	
	Headache							

Date:03/17/05ISR Number: 4611582-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0549007A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Spontaneous		Zofran	PS	Glaxosmithkline		INTRAVENOUS	DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/17/05ISR Number: 4611592-1Report Type:Expedited (15-DaCompany Report #AU-GLAXOSMITHKLINE-B0372952A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysgeusia		Zofran	PS	Glaxosmithkline	ORAL	4MG At night	
	Feeling Abnormal		Nexium	C		ORAL	40MG per day	
	Nausea		Citalopram Hydrobromide	C		ORAL	20MG per day	
	Pharmaceutical Product							
	Complaint							

Date:03/21/05ISR Number: 4613609-7Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12894572
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aphasia		Etopophos For Inj	PS	Bristol-Myers Squibb			
Other	Bone Marrow Depression				Company		3	DAY
	Coma		Cisplatine Dakota	SS			3	DAY
	Personality Change		Adriblastine	SS				
	Speech Disorder		Gemzar	SS				
			Vincristine	SS				
			Solu-Medrol	SS				
			Zophren	SS				
			Plavix	C	Regulatory Health Authority South Africa			
			Zocor	C				
			Combivent	C				

Date:03/22/05ISR Number: 4615171-1Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0375005A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase		Zophren	PS	Glaxosmithkline		INTRAVENOUS	

Initial or Prolonged	Increased		Largactil	SS			
INTRAVENOUS							
	Aspartate		Primperan	SS	Glaxosmithkline		
INTRAVENOUS							
	Aminotransferase		Solumedrol	SS			
INTRAVENOUS							
	Increased		Navelbine	SS	Glaxosmithkline		
INTRAVENOUS	55MG Cyclic	1 DAY					
	Gamma-Glutamyltransferase		Cisplatine	SS			
INTRAVENOUS	220MG Cyclic	1 DAY					
	Increased		Tranxene	SS			ORAL
20MG per day	7 DAY						
	White Blood Cell Count Decreased						

Date:03/23/05ISR Number: 4618477-5Report Type:Expedited (15-DaCompany Report #212007
Age:56 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Eosinophilia	Foreign	Mabthera (Rituximab)			
Initial or Prolonged	Hepatitis B	Health	Conc For Solution			
	Laryngeal Oedema	Professional	For Infusion	PS		
INTRAVENOUS	INTRAVENOUS					
	Neutropenia	Other	Methotrexate			
	Pruritus		(Methotrexate)	SS		
INTRAVENOUS						
	Pyrexia		Zophren (Ondansetron			
	Staphylococcal Infection		Hydrochloride)	SS		
INTRAVENOUS	INTRAVENOUS					
	Toxic Skin Eruption		Augmentin			
	Vasculitis		(Amoxicillin,			
	Viral Infection		Clavulanate			
	Weight Increased		Potassium)	SS		ORAL
3 G, QD, ORAL						
			Aracytine			
			(Cytarabine)	SS		
INTRAVENOUS	0, 179 MG,					

QD,			
INTRAVENOUS			
		Acide Folinique (Leucovorin Calcium)	SS
INTRAVENOUS	0, 75 MG, QD,		
INTRAVENOUS			
		Epirubicin (Epirubicin Hydrochloride)	C
		Vindesine (Vindesine)	C
		Prednisone (Prednisone)	C
		Inexium (Esomeprazole Magnesium)	C
		Imovane (Zopiclone)	C
		Spasfon (Phloroglucinol, Trimethylphlorogluci nol)	C
		Gaviscon (Unk Ingredients) (Gastrointestinal Drug Nos)	C
		Di-Antalvic (Acetaminophen, Propoxyphene Hydrochloride)	C
		Xanax (Alprazolam)	C
		Augmentin (Amoxicillin, Clavulanate Potassium)	C
		Oflocet (Ofloxacin)	C
		Pyostacine (Pristinamycin)	C
		Solu-Medrol Methylprednisolone Sodium Succinate)	C
		Cyclophosphamide	C

Date:03/24/05ISR Number: 4617844-3Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0328132A
Age:44 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blister		Zophren	PS	Glaxosmithkline	ORAL	5 WK	
	Epidermal Necrosis		Acuilix	SS		ORAL	22 YR	
	Erythema		Noctran	SS		ORAL	5 WK	
	Inflammation		Ethyol	SS		INTRAVENOUS	5 WK	
	Mucosal Erosion							
	Oral Pain							
	Pyrexia							
	Rash							
	Stevens-Johnson Syndrome							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/24/05ISR Number: 4620077-8Report Type:Expedited (15-DaCompany Report #2005045334
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abnormal Behaviour Agnosia Aphasia Aplasia Coma Speech Disorder Vitamin B1 Deficiency	Foreign Health Professional Other	Doxorubicin Hydrochloride Powder, Sterile	PS			62 MG (62 MG, DAY 1, CYCLIC)	
			Solu-Medrol (Methylprednisolone Sodium Succinate)	SS		INTRAVENOUS	71 MG (71 MG, DAY 1-DAY 5, CYCLIC)	
			Cisplatin (Cisplatin)	SS			58 MG (58 MG, DAY 1-DAY 3, CYCLIC)	
			Etoposide (Etoposide)	SS			180 MG (180 MG, DAY 1-DAY 3, CYCLIC)	
			Vincristine (Vincristine)	SS			2 MG (2 MG, DAY 1, CYCLIC)	
			Gemcitabine Hydrochloride					

				(Gemcitabine Hydrochloride)	SS		
INTRAVENOUS	1786 MG (1786 MG, DAY 1, CYCLIC)						
				Ondansetron Hydrochloride	SS		
INTRAVENOUS	8 MG (8 MG, DAY 1-DAY 3, CYCLIC						
				Clopidogrel Sulfate	C		
				Simvastatin (Simvastatin)	C		
				Combivent (Ipratropium Bromide, Salbutamol Sulfate)	C		
RESPIRATORY (INHALATION)							

Date:03/25/05ISR Number: 4620997-4Report Type:Expedited (15-DaCompany Report #05H-056-0294744-00
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrial Fibrillation	Foreign	Pentothal Injection					
	Bradycardia	Health	(Thiopental Sodium)					
	Cardiac Arrest	Professional	(Thiopental Sodium)	PS		INTRAVENOUS	500 MG,	
	Post Procedural Nausea	Other				INTRAVENOUS		
	Torsade De Pointes		Suxamethonium	SS		INTRAVENOUS	100 MG,	
	Ventricular Hypokinesia					INTRAVENOUS		
			Desflurane	SS		RESPIRATORY (INHALATION)	INHALATION	
			Sufentanil	SS		INTRAVENOUS	60, "LAST IV	

FLUSH AT

11:00 PM",

INTRAVENOUS

				Ropivacaine	SS		

7.5

MILLIGRAM/MIL

LILITERS, 15

ML, NOT

REPORTED

				Ondansetron	SS		

INTRAVENOUS INTRAVENOUS

Date:03/25/05ISR Number: 4621046-4Report Type:Expedited (15-DaCompany Report #2005046980
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Health Professional	Solu-Medrol (Methylprednisolone Sodium Soccinate)	PS				
INTRAVENOUS	INTRAVENOUS							
	Aminotransferase Increased		Chlorpromazine (Chlorpromazine)	SS				
INTRAVENOUS	INTRAVENOUS							
	Asthenia		Metoclopramide					
	Gamma-Glutamyltransferase		(Metoclopramide)	SS				
INTRAVENOUS	INTRAVENOUS							
	Increased		Vinorelbine (Vinorelbine)	SS				
INTRAVENOUS	(CYCLICAL),							
INTRAVENOUS			Cisplatin (Cisplatin)	SS				
INTRAVENOUS	(CYCLICAL),							
INTRAVENOUS			Ondansetron Hydrochloride					

			(Ondansetron Hydrochloride)	SS			
INTRAVENOUS	INTRAVENOUS						
			Clorazepate Dipotassium (Clorazepate Dipotassium)	C			

Date:03/28/05ISR Number: 4621210-4Report Type:Expedited (15-DaCompany Report #2005015418
Age:64 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arterial Thrombosis Limb Injection Site Erythema Injection Site Thrombosis Neutropenia Phlebothrombosis Renal Failure	Foreign Health Professional Other	Solu-Medrol (Methylprednisolone Sodium Succinate)	PS			220 MG (220 MG, 1 IN 1 D)	
			Cisplatin	SS			2.2 GRAM (2.2 GRAM, 1 IN 1	
			Metoclopramide	SS				
			Fluorouracil	SS				
			Zophren (Ondansetron Hydrochloride)	SS				
			Omeprazole	C				
			Zolpidem	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/28/05ISR Number: 4621556-XReport Type:Expedited (15-DaCompany Report #6190
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Erythema Multiforme	Literature	Vancomycin	PS			1 G BID	3 DAY
	General Physical Health Deterioration Shock Toxic Epidermal Necrolysis	Health Professional	Acyclovir	SS				
			Etoposide	SS				
			Gentamicin	SS				
			Fluconazole	SS				
			Ceftazidime	SS				
			Imipenem	SS				
			Idarubicin Ara-C	SS				
			Ondansetron	SS				

Date:03/30/05ISR Number: 4622855-8Report Type:Expedited (15-DaCompany Report #AT-GLAXOSMITHKLINE-B0375218A
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mucosal Inflammation		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	32MG Single	
							dose	1 DAY
			Gw679769	SS	Glaxosmithkline	ORAL	100MG per day	3 DAY
			Dexamethasone	SS		ORAL	12MG per day	4 DAY
			Nexium	C		ORAL		
			Voltaren	C	Glaxosmithkline	ORAL		

Date:03/30/05ISR Number: 4622858-3Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0375739A
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia		Zophren	PS	Glaxosmithkline	INTRAVENOUS		
Hospitalization - Initial or Prolonged	Shock Torsade De Pointes		Celocurine	SS	Glaxosmithkline	INTRAVENOUS	100MG	cumulative

Ventricular Fibrillation
dose
Ventricular Hypokinesia Pentothal SS
INTRAVENOUS 500MG
cumulative
dose
Suprane SS
RESPIRATORY
(INHALATION) 210 MIN
Sufenta SS
INTRAVENOUS 60MCG
cumulative
dose
Naropeine SS
INTRAVENOUS 112.5MG
cumulative
dose

Date:04/01/05ISR Number: 4625338-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0551986A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion		Zofran	PS	Glaxosmithkline			
UNKNOWN								
Initial or Prolonged	Delusion							

Date:04/04/05ISR Number: 4628624-7Report Type:Expedited (15-DaCompany Report #20050300062
Age:36 YR Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Bradycardia
	Cardiac Arrest

Torsade De Pointes
Ventricular Fibrillation

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Health Professional Other	Suprane (Desflurane)	PS	Baxter	INTRAVENOUS	100 MG	ONCE
	Celocurine (Suxamethonium)	SS		IV		
	Pentothal (Thiopental)	SS	Abbott	INTRAVENOUS	500 MG	ONCE
	Sufenta (Sufentanil)	SS		IV		
	Naropeine (Ropivacaine)	SS		15 ML	ONCE	
	Zophren (Ondansetron)	SS				

Date:04/05/05ISR Number: 4627140-6Report Type:Expedited (15-DaCompany Report #MX-GLAXOSMITHKLINE-A0552392A
Age:10 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Mouth		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Three times per day	3 DAY
	Hallucination, Auditory							
	Headache							
	Vision Blurred							

Date:04/05/05ISR Number: 4627160-1Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0376424A
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Dreams		Zophren	PS	Glaxosmithkline	ORAL	8MG per day	12 DAY
Initial or Prolonged	Cognitive Disorder		Zovirax	SS	Glaxosmithkline	INTRAVENOUS	2250MG per day	6 DAY
	Confusional State							
	Disorientation		Polaramin	SS		INTRAVENOUS	15MG per day	12 DAY
	Hallucination, Visual		Mopral	SS	Glaxosmithkline	ORAL	20MG Per day	14 DAY
	Hypersomnia		Primperan	SS	Glaxosmithkline	INTRAVENOUS	60MG per day	
	Incoherent		Neurontin	SS		ORAL	4	DAY
	Metabolic Encephalopathy		Fraxodi	C	Glaxosmithkline	SUBCUTANEOUS		
	Psychomotor Retardation		Fungizone	C		UNKNOWN		
	Retrograde Amnesia		Chemotherapy	C		UNKNOWN		

Date:04/05/05ISR Number: 4629011-8Report Type:Direct Company Report #CTU 245275
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Akathisia		Zofran	PS		INTRAVENOUS	4 MG ONCE	
	Anxiety					INTRANVENOUS		
	Flushing							

Date:04/06/05ISR Number: 4628123-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0376167A
Age:58 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Abdominal Pain
	Anaphylactic Shock

	Depressed Level Of Consciousness					
	Feeling Cold	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Hypotension		Alkeran	PS	Glaxosmithkline	
INTRAVENOUS	325MG Cyclic 1 DAY					
	Pruritus		Zophren	SS	Glaxosmithkline	
INTRAVENOUS	8MG Cyclic 1 DAY					
	Rash					
	Swelling					
	Tongue Oedema					

Date:04/08/05ISR Number: 4633284-5Report Type:Expedited (15-DaCompany Report #2005CG00637
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Abnormal Dreams	Foreign	Mopral	PS		ORAL
20 MG QD PO						
Initial or Prolonged	Confusional State	Health	Polaramine	SS		
INTRAVENOUS	15 MG QD IV					
	Decreased Activity	Professional	Primperan	SS		
INTRAVENOUS	60 MG QD IV					
	Disorientation	Other	Zovirax Glaxo			
	Hallucination, Visual		Wellcome	SS	Glaxo Wellcome	
INTRAVENOUS	2250 MG QD IV					
	Hypersomnia		Neurontin	SS		ORAL
300 MG QD PO						
	Incoherent		Neurontin	SS		ORAL
400 MG QD PO						
	Metabolic Encephalopathy		Neurontin	SS		ORAL
200 MG QD PO						
	Retrograde Amnesia		Zophren	SS		
8 MG QD						
	Somnolence		Fraxodi	C		
			Fungizone	C		

Date:04/12/05ISR Number: 4633140-2Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0376898A
Age:37 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Disability Dystonia Zofran PS Glaxosmithkline
INTRAVENOUS 4MG Single
Hyperventilation
dose 1 DAY
Paracetamol C Glaxosmithkline
UNKNOWN

Date:04/14/05ISR Number: 4635166-1Report Type:Expedited (15-DaCompany Report #AT-GLAXOSMITHKLINE-B0376428A
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Fatigue		Ondansetron	PS	Glaxosmithkline	ORAL	8MG Per day	3 DAY
Initial or Prolonged			Gw679769	SS	Glaxosmithkline	ORAL	150MG per day	1 DAY
			Taxotere	SS			INTRAVENOUS	1 DAY
			Dexamethasone	SS			INTRAVENOUS	8MG Single
							dose	1 DAY

Date:04/20/05ISR Number: 4642488-7Report Type:Direct Company Report #CTU 246685
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dystonia		Zofran	PS	Glaxo			
INTRAVENOUS	4MG PUSH							
Initial or Prolonged								
INTRAVENOUS								

Date:04/22/05ISR Number: 4642384-5Report Type:Expedited (15-DaCompany Report #AT-GLAXOSMITHKLINE-B0375218A
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Mucosal Inflammation		Ondansetron	PS	Glaxosmithkline			
INTRAVENOUS	32MG Single							
Initial or Prolonged								
dose	1 DAY							

					Gw679769	SS	Glaxosmithkline	ORAL
100MG per day	3	DAY						
					Dexamethasone	SS		ORAL
12MG per day	4	DAY						
					Nexium	C		ORAL
					Voltaren	C	Glaxosmithkline	ORAL

Date:04/26/05ISR Number: 4645219-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0363118A
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Nausea		Zophren	PS	Glaxosmithkline	
INTRAVENOUS	1 DAY					
Initial or Prolonged	Rash		Temozolomide	SS		
UNKNOWN	1UNIT per day 1 DAY					
	Vomiting		Depakine Chrono	C		ORAL
1000MG per						
day						
			Prozac	C		
UNKNOWN						
			Efferalgan	C	Glaxosmithkline	
UNKNOWN						
			Mopral	C	Glaxosmithkline	
UNKNOWN						
			Gaviscon	C	Glaxosmithkline	
UNKNOWN						
			Spasfon	C		
UNKNOWN						
			Solumedrol	C		
UNKNOWN						
			Radiotherapy	C		

Date:04/27/05ISR Number: 4646067-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0442611A
Age:14 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Drug Ineffective		Zofran	PS	Glaxosmithkline	
INTRAVENOUS	5 DAY					
	Headache		Sodium Bicarbonate	SS		
INTRAVENOUS						

Nausea		Methotrexate	C		
Vomiting		Leucovorin	C	Glaxosmithkline	
		Vincristine	C		
		Prednisone	C		
		Doxorubicin	C		
		Cytoxan	C		

Date:04/27/05ISR Number: 4646068-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0501953A
Age:78 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pruritus		Zofran	PS	Glaxosmithkline	INTRAVENOUS		
			Chemotherapy	C				

Date:04/27/05ISR Number: 4646069-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0502173A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypoxia		Zofran	PS	Glaxosmithkline	UNKNOWN		

Date:04/27/05ISR Number: 4646070-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0502994A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Extravasation		Zofran	PS	Glaxosmithkline	INTRAVENOUS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/27/05ISR Number: 4646071-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0503140A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Nausea		Zofran	PS	Glaxosmithkline		8MG Three times per day	

Date:04/27/05ISR Number: 4646072-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0503529A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Headache		Zofran	PS	Glaxosmithkline	INTRAVENOUS	32MG Single dose	
			Chemotherapy	C				

Date:04/27/05ISR Number: 4646073-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0505469A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Infusion Site Reaction		Zofran	PS	Glaxosmithkline	INTRAVENOUS	32MG Per day	

Date:04/27/05ISR Number: 4646075-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0506009A
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	INTRAVENOUS	32MG Single dose	1 DAY
			Zofran	SS	Glaxosmithkline	ORAL	8MG Twice per	

day 4 DAY

			Ambien	C	
			Protonix	C	

Date:04/27/05ISR Number: 4646076-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0506799A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During		Zofran	PS	Glaxosmithkline			DAY
	Pregnancy		Phenergan	C	Glaxosmithkline			
	Nausea							
	Weight Decreased							

Date:04/27/05ISR Number: 4646077-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0507249A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During		Zofran	PS	Glaxosmithkline	INTRATHECAL	4MG Single	
	Pregnancy						dose	0 DAY
	Vomiting		Unknown	C				

Date:04/27/05ISR Number: 4646078-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0507568A
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Phlebitis		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Per day	0 DAY
			Morphine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/27/05ISR Number: 4646079-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0507599A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Chills		Zofran	PS	Glaxosmithkline	INTRAVENOUS		
	Malaise		Methadone	C	Glaxosmithkline			
	Paraesthesia							

Date:04/27/05ISR Number: 4646080-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0507600A
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Oculogyration		Zofran	PS	Glaxosmithkline	INTRAVENOUS	32MG	See dosage text
			Decadron	C		INTRAVENOUS	16MG	Single dose

Date:04/27/05ISR Number: 4646081-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0507689A
Age:11 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Headache		Zofran	PS	Glaxosmithkline	INTRAVENOUS	17MG	Single
			Benadryl	C	Glaxosmithkline			
			Tylenol	C	Glaxosmithkline			

dose 0 DAY

Date:04/27/05ISR Number: 4646082-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0508960A
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Dyskinesia		Zofran	PS	Glaxosmithkline	
INTRAVENOUS 4MG Single						
Initial or Prolonged dose	Dystonia					
Other	Extrapyramidal Disorder		Vioxx	C		
			Protonix	C		
			Fosamax	C		
			Voltaren	C	Glaxosmithkline	
OPHTHALMIC						

Date:04/27/05ISR Number: 4646083-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0510327A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Dizziness		Zofran	PS	Glaxosmithkline	
			Meclizine	SS		
			Scopolamine Patch	SS		
TRANSDERMAL						
			Phenergan	C	Glaxosmithkline	
			Compazine	C	Glaxosmithkline	
			Antivert	C		

Date:04/27/05ISR Number: 4646084-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0514876A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Injection Site Reaction		Zofran	PS	Glaxosmithkline	
INTRAVENOUS 4MG Unknown						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/27/05ISR Number: 4646085-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0515532A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypoaesthesia		Zofran	PS	Glaxosmithkline			

Date:04/27/05ISR Number: 4646086-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0517828A
Age:3 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation		Zofran	PS	Glaxosmithkline	INTRAVENOUS		
	Difficulty In Walking		Antibiotic	C				
	Dyskinesia							
	Dystonia							
	Fall							
	Joint Stiffness							
	Musculoskeletal Stiffness							

Date:04/27/05ISR Number: 4646087-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0518225A
Age:53 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	INTRAVENOUS	8MG As required	
	Feeling Of Relaxation							
			Hyperalimentation	C				
			Dilaudid	C				
			Duragesic	C				
			Valium	C				

Date:04/27/05ISR Number: 4646088-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0518966A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Drug Ineffective		Zofran	PS	Glaxosmithkline	
UNKNOWN						

Date:04/27/05ISR Number: 4646089-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0521552A
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline			
INTRAVENOUS							100MG	See
	Medication Error							
dosage text							0	DAY
	No Adverse Effect		Zofran	SS	Glaxosmithkline	ORAL		
	Overdose							

Date:04/27/05ISR Number: 4646090-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0522152A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion		Zofran	PS	Glaxosmithkline			
INTRAVENOUS								
Initial or Prolonged	Hypersensitivity							
Other								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/27/05ISR Number: 4646091-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0526610A
Age:2 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation		Zofran	PS	Glaxosmithkline	INTRAVENOUS		

Date:04/27/05ISR Number: 4646092-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0527576A
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	INTRAVENOUS		

Date:04/27/05ISR Number: 4646093-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0528381A
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Chills		Zofran	PS	Glaxosmithkline	INTRAVENOUS	0	DAY
	Dyskinesia		Dilaudid	SS				
	Hypoaesthesia		Percocet	C				
	Paraesthesia		Vistaril	C				

Date:04/27/05ISR Number: 4646094-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0529117A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Electrocardiogram Change		Zofran	PS	Glaxosmithkline	UNKNOWN		

Date:04/27/05ISR Number: 4646095-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0529203A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Anxiety		Zofran	PS	Glaxosmithkline	
UNKNOWN						

Date:04/27/05ISR Number: 4646096-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0530907A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Infusion Site Reaction		Zofran	PS	Glaxosmithkline	
INTRAVENOUS	4MG Single					
	Injection Site Swelling					
dose	0 DAY					
			Diprivan	C		
			Fentanyl	C		
			Lidocaine	C		
			Zemuron	C		

Date:04/27/05ISR Number: 4646097-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0531531A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Injection Site Erythema		Zofran	PS	Glaxosmithkline	
INTRAVENOUS	0 DAY					
	Injection Site Reaction					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/27/05ISR Number: 4646098-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0532054A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Rash		Zofran	PS	Glaxosmithkline			

Date:04/27/05ISR Number: 4646099-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0540287A
Age:57 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Urticaria		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Single dose	0 DAY
			Diprivan	SS				

Date:04/27/05ISR Number: 4646100-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0540799A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Exposure During Pregnancy Venous Occlusion		Zofran	PS	Glaxosmithkline	INTRAVENOUS		

Date:04/27/05ISR Number: 4646101-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0541754A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Per day	
	Vomiting		Methotrexate	C				

Date:04/27/05ISR Number: 4646102-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0541755A
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline			
INTRAVENOUS	4MG Per day							
	Pharmaceutical Product		Methotrexate	C				
	Complaint							
	Vomiting							

Date:04/27/05ISR Number: 4646103-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0548220A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Migraine		Zofran	PS	Glaxosmithkline			
INTRAVENOUS	32MG Unknown							
			No Concurrent Medication	C				

Date:04/27/05ISR Number: 4646106-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0373629A
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation		Zofran	PS	Glaxosmithkline	ORAL	8MG Per day	
	Drug Exposure During Pregnancy		Benadryl	C	Glaxosmithkline			
	Drug Ineffective							
	Nausea							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/27/05ISR Number: 4646107-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0500853A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL	8MG	Unknown

Date:04/27/05ISR Number: 4646108-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0503454A
Age:25 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During Pregnancy		Zofran	PS	Glaxosmithkline	ORAL	4MG As required	2 WK
	Drug Ineffective		Phenergan	C	Glaxosmithkline			

Date:04/27/05ISR Number: 4646109-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0505941A
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During Pregnancy		Zofran	PS	Glaxosmithkline	ORAL	4MG As required	6 WK
	Pharyngeal Oedema							

Date:04/27/05ISR Number: 4646110-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0508093A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Vomiting		Zofran	PS	Glaxosmithkline	ORAL		

Date:04/27/05ISR Number: 4646111-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0508642A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Galactorrhoea		Zofran	PS	Glaxosmithkline	ORAL	4MG Twice per day	2 YR

Date:04/27/05ISR Number: 4646112-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0508944A
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Eye Swelling		Zofran	PS	Glaxosmithkline	ORAL	4MG As required	1 DAY
			Unknown Medication	C				

Date:04/27/05ISR Number: 4646113-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0509662A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Palpitations		Zofran	PS	Glaxosmithkline	ORAL	4MG As required	
			Azithromycin	C				
			Oral Contraceptive	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/27/05ISR Number: 4646114-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0510921A
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Screen Positive		Zofran	PS	Glaxosmithkline	ORAL	4MG Variable	
dose								9 DAY
			Promethazine	C				
			Neurontin	C				
			Lamictal	C	Glaxosmithkline			
			Risperdal	C				

Date:04/27/05ISR Number: 4646115-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0514144A
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During		Zofran	PS	Glaxosmithkline	ORAL	4MG Twice per	
	Pregnancy							
day								4 DAY
	Irritability		No Concurrent					
	Rash		Medication	C				

Date:04/27/05ISR Number: 4646116-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0515872A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Rash		Zofran	PS	Glaxosmithkline	ORAL	3	DAY
			No Concurrent					
			Medication	C				

Date:04/27/05ISR Number: 4646117-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0516538A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Vomiting		Zofran	PS	Glaxosmithkline	ORAL

WK

Date:04/27/05ISR Number: 4646118-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0519381A
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Arthralgia		Zofran	PS	Glaxosmithkline	ORAL
8MG Three						
times per day 10 DAY						
			Fosamax	C		
UNKNOWN						
			Dexamethasone	C		ORAL
4MG Three						
times per day						
			Ferrous Gluconate	C		ORAL
324MG Per day						
			Promethazine	C		ORAL
25U As						
required						
			Ibuprofen	C	Glaxosmithkline	ORAL
600MG Four						
times per day						
			Taxol	C		

Date:04/27/05ISR Number: 4646119-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0519403A
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Hypovolaemia		Zofran	PS	Glaxosmithkline	ORAL
24MG Per day 5 YR						
	Orthostatic Hypotension		Celexa	SS		
			Ativan	C		

				Benadryl	C	Glaxosmithkline	
				Anafranil	C		
				Chronulac	C		
				Zocor	C		
				Axid	C		

Date:04/27/05ISR Number: 4646120-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0519548A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation		Zofran	PS	Glaxosmithkline	ORAL		
			Prozac	SS				

Date:04/27/05ISR Number: 4646121-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0522788A
Age:79 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Pressure Increased		Zofran	PS	Glaxosmithkline	ORAL	4MG Single	
	Burning Sensation						dose	1 DAY
	Dry Mouth		Oxygen	C				
	Immobile							
	Nausea							
	Panic Reaction							

Date:04/27/05ISR Number: 4646122-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0524730A
Age:34 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During		Zofran	PS	Glaxosmithkline	ORAL	8MG Per day	6 DAY
	Pregnancy		Loratadine	C				
	Drug Ineffective		Vitamins	C				
			Folic Acid	C				

Date:04/27/05ISR Number: 4646123-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0525236A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abdominal Distension		Zofran	PS	Glaxosmithkline	ORAL	2MG Twice per	
	Constipation						day	10 WK
	Drug Exposure During Pregnancy		No Concurrent Medication	C				

Date:04/27/05ISR Number: 4646124-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0531764A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Vomiting		Zofran	PS	Glaxosmithkline	ORAL	4MG Unknown	1 DAY
			Vicodin	SS			UNKNOWN	
			Prednison	C				
			Antibiotic	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/27/05ISR Number: 4646125-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0533600A
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL	4MG Six times	per day
			No Concurrent Medication	C				

Date:04/27/05ISR Number: 4646126-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0533618A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL	8MG Three	times per day
			Compazine	C	Glaxosmithkline			
			Lorazepam	C				

Date:04/27/05ISR Number: 4646127-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0534133A
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During		Zofran	PS	Glaxosmithkline	ORAL	8MG Three	
	Pregnancy							
	Drug Ineffective						times per day	1 WK

Date:04/27/05ISR Number: 4646128-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0537599A
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Insomnia		Zofran	PS	Glaxosmithkline	ORAL
1TAB Twice per day	1 WK					
			Chemotherapy	C		
UNKNOWN						

Date:04/27/05ISR Number: 4646129-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0542442A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Abdominal Pain		Zofran	PS	Glaxosmithkline	ORAL
1	DAY					
	Drug Exposure During Pregnancy		Prenatal Vitamins	C		
	Metrorrhagia					

Date:04/27/05ISR Number: 4646135-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0511614A
Age:31 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL
8MG Four times per day	3 YR					
			Ivig	C	Glaxosmithkline	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/27/05ISR Number: 4646136-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0513624A
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During		Zofran	PS	Glaxosmithkline	ORAL	4MG As	
	Pregnancy						required	
	Nausea		Pepcid	C				
	Vomiting		Multivitamin	C				
			Zofran	C	Glaxosmithkline	INTRAVENOUS		

Date:04/27/05ISR Number: 4646137-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0514522A
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL	8MG Three times per day	1 YR

Date:04/27/05ISR Number: 4646138-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0515761A
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During		Zofran	PS	Glaxosmithkline	ORAL	4MG Six times	
	Pregnancy						per day	2 MON
	Headache							

Date:04/27/05ISR Number: 4646139-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0516240A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL
4MCG Unknown						

Date:04/27/05ISR Number: 4646140-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0523475A
Age:31 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Drug Exposure During		Zofran	PS	Glaxosmithkline	ORAL
8MG Twice per						
	Pregnancy					
day						
	Nausea		Zofran	SS	Glaxosmithkline	ORAL
8MG Twice per						
	Vomiting					
day						
			Prenatal Vitamin	C		

Date:04/27/05ISR Number: 4646141-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0527591A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Drug Exposure During		Zofran	PS	Glaxosmithkline	ORAL
	Pregnancy		No Concurrent			
	Drug Ineffective		Medication	C		

Date:04/27/05ISR Number: 4646142-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0528376A
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Drug Exposure During		Zofran	PS	Glaxosmithkline	ORAL
8MG Twice per						
	Pregnancy					
day						
	Vomiting					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/27/05ISR Number: 4646143-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0529008A
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Glucose Decreased		Zofran	PS	Glaxosmithkline	ORAL	4MG Four	
	Feeling Jittery						times per day	
			Insulin	C				
			Glucophage	C				
			Oxycontin	C				

Date:04/27/05ISR Number: 4646144-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0531311A
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During		Zofran	PS	Glaxosmithkline	ORAL	8MG Twice per	
	Pregnancy						day	1 WK
	Pruritus Generalised		Prenatal Vitamins	C				
	Rash Generalised		Pulmicort	C				
			Singulair	C				
			Tilade	C				

Date:04/27/05ISR Number: 4646145-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0531731A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL	8MG Unknown	
			No Concurrent Medication	C				

Date:04/27/05ISR Number: 4646146-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0537114A
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Zofran	PS	Glaxosmithkline	ORAL	2	WK
	Nausea		Xanax	C				
	Vomiting		Methadone	C	Glaxosmithkline			
			Heart Medication	C				

Date:04/27/05ISR Number: 4646147-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0538443A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During Pregnancy Therapeutic Response Decreased		Zofran	PS	Glaxosmithkline	ORAL		

Date:04/27/05ISR Number: 4646148-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0540926A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During Pregnancy Drug Ineffective Dysgeusia Nausea		Zofran	PS	Glaxosmithkline	OTHER		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/27/05ISR Number: 4646149-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0540937A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During		Zofran	PS	Glaxosmithkline	ORAL	4MG	Unknown 1 WK
	Pregnancy		No Concurrent					
	Nausea		Medication	C				

Date:04/27/05ISR Number: 4646150-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0544959A
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During		Zofran	PS	Glaxosmithkline	ORAL	4MG	Three
	Pregnancy						times per day	1 DAY
	Drug Ineffective		Prenatal Vitamins	C				

Date:04/27/05ISR Number: 4646151-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0547392A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Back Pain		Zofran	PS	Glaxosmithkline	ORAL	8MG	Three
							times per day	1 YR
			Lamictal	C	Glaxosmithkline			

Date:04/28/05ISR Number: 4647261-1Report Type:Expedited (15-DaCompany Report #200510416FR
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alpha 2 Globulin		Lovenox	PS	Aventis			
Hospitalization -	Increased				Pharmaceuticals Inc.			
SUBCUTANEOUS								

Initial or Prolonged	Hepatic Encephalopathy		Cisplatine	SS		
INTRAVENOUS						
	Hepatic Failure		Ketek	SS	Aventis Pharmaceuticals Inc.	ORAL
	Hepatitis					
	Hepatitis Cholestatic		Mopral	SS		
INTRAVENOUS						
	Hepatocellular Damage		Zophren	SS		
INTRAVENOUS						
	Hypergammaglobulinaemia		Gemzar	SS		
INTRAVENOUS						
	Septic Shock					
	Sleep Disorder					

Date:04/29/05ISR Number: 4649089-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0555108A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Blood Amino Acid Level Increased		Zofran	PS	Glaxosmithkline	
	Drug Exposure During Pregnancy					

Date:04/29/05ISR Number: 4649096-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0555581A
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Atrial Fibrillation		Zofran	PS	Glaxosmithkline	
SUBLINGUAL 8MG Unknown						
Initial or Prolonged			Chemotherapy	C		
Other			Radiation Treatment	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/29/05ISR Number: 4649105-0Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0348937A
Age:31 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaphylactic Shock		Zophren	PS	Glaxosmithkline	INTRAVENOUS		
	Cough		Plitican	SS		INTRAVENOUS		
	Dysphonia		Latex	SS		UNKNOWN		
	Eyelid Oedema		Betadine	SS		UNKNOWN		
	Face Oedema							
	Generalised Erythema							

Date:04/29/05ISR Number: 4649115-3Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0369726A
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cytolytic Hepatitis		Zophren	PS	Glaxosmithkline	INTRAVENOUS		
	Eosinophil Count		Cisplatine	SS		INTRAVENOUS	160MG Cyclic	1 DAY
	Decreased		Mopral	SS	Glaxosmithkline	INTRAVENOUS	40MG Cyclic	1 DAY
	Eosinophilia		Lovenox	SS		SUBCUTANEOUS	40MG Per day	17 DAY
	Hepatic Encephalopathy		Gemzar	SS		INTRAVENOUS	2000MG Per day	1 DAY
	Hepatic Failure							
	Hepatocellular Damage		Ketek	SS		ORAL	800MG Per day	16 DAY
	Jaundice		Surbronc	C	Glaxosmithkline	UNKNOWN		16 DAY
	Sleep Disorder		Medrol	C		UNKNOWN		17 DAY
			Ethyol	C		INTRAVENOUS	1500MG Per day	1 DAY
			Primperan	C	Glaxosmithkline	INTRAVENOUS	2AMP per day	1 DAY

Date:05/03/05ISR Number: 4653164-9Report Type:Direct Company Report #CTU 247665
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Congenital Anomaly In Offspring Drug Exposure During Pregnancy Finger Deformity		Zofran	PS		INJECTED		

Date:05/05/05ISR Number: 4653452-6Report Type:Expedited (15-DaCompany Report #CA-GLAXOSMITHKLINE-A0556287A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction Blood Pressure Decreased Drug Exposure During Pregnancy Erythema Throat Tightness		Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Single dose	

Date:05/05/05ISR Number: 4655655-3Report Type:Expedited (15-DaCompany Report #KII-2005-0016341
Age:27 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased
Other	Aspartate Aminotransferase Increased

	Blood Creatine Phosphokinase Increased Blood Creatine Phosphokinase Mb Increased Blood Pressure Decreased Body Temperature Increased Confusional State Dysarthria Intentional Misuse Multiple Drug Overdose Prothrombin Time Prolonged Somnolence	Report Source Study Health Professional Other	Product Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet Tylenol Pm (Diphenhydramine) Ondansetron (Ondansetron) Zolpidem (Zolpidem) Cyclobenzaprine (Cyclobenzaprine) Ssri ()	Role PS SS SS SS SS	Manufacturer	Route ORAL ORAL ORAL ORAL ORAL ORAL
Dose	Duration						
SEE TEXT, ORAL 4 MG, SEE TEXT, ORAL SEE TEXT							

Date:05/11/05ISR Number: 4658477-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0379844A
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Subileus		Zophren Solupred Skenan Efferalgan Codeine Gemzar Carboplatine	PS SS SS SS SS SS	Glaxosmithkline Glaxosmithkline	ORAL ORAL ORAL ORAL
6 DAY 6 DAY						
INTRAVENOUS INTRAVENOUS	1 DAY 1 DAY					

Date:05/12/05ISR Number: 4660467-0Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0379752A
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction		Cefuroxime Sodium	PS	Glaxosmithkline		UNKNOWN	
	Drug Interaction		Suxamethonium	SS	Glaxosmithkline		UNKNOWN	
	Hypotension		Ondansetron	SS	Glaxosmithkline		UNKNOWN	
	Procedural Complication		Atracurium	SS	Glaxosmithkline		UNKNOWN	
			Cymbalta	SS		ORAL	40MG Unknown	
			Fentanyl	SS			UNKNOWN	
			Desflurane	SS			UNKNOWN	
			Propofol	SS			UNKNOWN	

Date:05/13/05ISR Number: 4661418-5Report Type:Expedited (15-DaCompany Report #CA-GLAXOSMITHKLINE-A0557810A
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bone Marrow Depression		Zofran	PS	Glaxosmithkline	ORAL	8MG Twice per day	4 MON
	Contusion							
	Leukopenia		Temozolomide	SS		ORAL	380MG Per day	4 MON
	Neutropenia							
	Pruritus							
	Rash							
	Thrombocytopenia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/13/05ISR Number: 4661419-7Report Type:Expedited (15-DaCompany Report #CA-GLAXOSMITHKLINE-A0557817A
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haemoglobin Decreased		Zofran	PS	Glaxosmithkline	ORAL	8MG Twice per	
	Leukopenia							
day								2 MON
	Neutropenia		Temozolomide	SS		ORAL	320MG Per day	
	Rash							
	Thrombocytopenia							

Date:05/13/05ISR Number: 4661790-6Report Type:Expedited (15-DaCompany Report #2005GB00856
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction		Propofol	PS	Zeneca Pharmaceutical		INTRAVENOUS	
	Drug Interaction							
	Procedural Hypotension		Duloxetine Hydrochloride	SS		ORAL		
			Ondansetron	I			UNKNOWN	
			Fentanyl	I			UNKNOWN	
			Suxamethonium	I			UNKNOWN	
			Atracurium	I			UNKNOWN	
			Desflurane	I			UNKNOWN	
			Cefuroxime	I			UNKNOWN	

Date:05/13/05ISR Number: 4661879-1Report Type:Expedited (15-DaCompany Report #AU-MERCK-0505AUS00082
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Life-Threatening	Anxiety		Emend	PS	Merck & Co., Inc	ORAL	
YR							
	Hypotension		Cisplatin	SS			
PARENTERAL	15	DAY					
	Pyrexia		Emend	SS	Merck & Co., Inc	ORAL	
YR							
	Rash		Ondansetron	SS			
UNKNOWN	15	DAY					
			Ondansetron	SS			
UNKNOWN	15	DAY					
			Dexamethasone	SS			
UNKNOWN							

Date:05/16/05ISR Number: 4663717-XReport Type:Expedited (15-DaCompany Report #200414329BCC
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Exposure During	Consumer	Rid Shampoo	PS				
TRANSPLACENTAL	TRANSPLACENTA							
Initial or Prolonged	Pregnancy	Health						
L								
	Jaundice Neonatal	Professional	Nix (Permethrin)	SS				
	Premature Baby	Other	Zofran (Ondansetron					
	Reticulocyte Count		Hydrochloride)	SS				
	Increased		Meclizine	SS				
			Prenatal Vitamins	C				

Date:05/16/05ISR Number: 4664278-1Report Type:Expedited (15-DaCompany Report #11000
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anaphylactic Reaction	Foreign	Fentanyl	PS				
	Drug Interaction	Health	Propofol	SS				
	Procedural Hypotension	Professional	Suxamethasone	SS				
		Other	Atracurium	SS				
			Cefuroxime	SS				
			Duloxetine					

			Hydrochloride	SS		ORAL	PO
			Ondansetron	SS			
			Desflurane	SS			

Date:05/17/05ISR Number: 4663513-3Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0558772A
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cerebrovascular Accident		Zofran	PS	Glaxosmithkline	ORAL	8MG Per day	
			No Concurrent Medication	C				

Date:05/17/05ISR Number: 4663529-7Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0376424A
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Dreams		Zophren	PS	Glaxosmithkline	ORAL	8MG per day	12 DAY
Initial or Prolonged	Cognitive Disorder		Zovirax	SS	Glaxosmithkline		INTRAVENOUS	2250MG per day	6 DAY
	Confusional State							
	Disorientation		Polaramin	SS			INTRAVENOUS	15MG per day	12 DAY
	Hallucination, Visual		Mopral	SS	Glaxosmithkline	ORAL	20MG Per day	14 DAY
	Hypersomnia		Primperan	SS	Glaxosmithkline		INTRAVENOUS	60MG per day	
	Incoherent		Neurontin	SS		ORAL	4 DAY	
	Metabolic Encephalopathy		Fraxodi	C	Glaxosmithkline		SUBCUTANEOUS	
	Psychomotor Retardation		Fungizone	C			UNKNOWN	
	Retrograde Amnesia		Chemotherapy	C			UNKNOWN	

Date:05/17/05ISR Number: 4663544-3Report Type:Expedited (15-DaCompany Report #CH-GLAXOSMITHKLINE-B0380858A
Age:15 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Augmentin	PS	Glaxosmithkline	INTRAVENOUS	1.2MG Three times per day	4 DAY
	Procedural Site Reaction		Zofran	SS	Glaxosmithkline	INTRAVENOUS	4MG As required	5 DAY
			Perfalgan	C	Glaxosmithkline	INTRAVENOUS	1G Four times per day	3 DAY

Date:05/19/05ISR Number: 4666101-8Report Type:Expedited (15-DaCompany Report #BE-GLAXOSMITHKLINE-B0380963A
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Haemorrhage		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	4MG Single dose	
			Placebo	SS	Glaxosmithkline	ORAL	1	DAY

Date:05/19/05ISR Number: 4666109-2Report Type:Expedited (15-DaCompany Report #ES-GLAXOSMITHKLINE-B0381455A
Age:78 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrioventricular Block		Zofran	PS	Glaxosmithkline	ORAL	1	DAY
Hospitalization - Initial or Prolonged			Irinotecan Hydrochloride	SS				
UNKNOWN		1 DAY						
			Atropine	C			1	DAY
			Dexamethasone	C			1	DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/20/05ISR Number: 4667751-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0558429A
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Atelectasis		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	4MG Single	
Initial or Prolonged	Chest Pain							
dose							1	MIN
Other	Unwanted Awareness During		Gw597599	SS	Glaxosmithkline	INTRAVENOUS	18MG Single	
	Anaesthesia							
dose							15	MIN
			Placebo	SS	Glaxosmithkline	ORAL		
			Estradiol Patch	C		TOPICAL		
			Prevacid	C		ORAL		
			Percocet	C		ORAL		
			Fentanyl	C		INTRAVENOUS	25MCG As	
required							3	DAY
			Midazolam	C		1MG Single		
dose								
			Rocuronium	C				
			Fentanyl	C				
			Propofol	C				
			Sevoflurane	C				
			Cephazolin	C	Glaxosmithkline			
			Clonidin	C				

Date:05/20/05ISR Number: 4667761-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0559031B
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Exposure During		Zofran	PS	Glaxosmithkline			
4	DAY							
	Pregnancy		Reglan	SS	Glaxosmithkline			
4	DAY							
	Drug Interaction							

Date:05/20/05ISR Number: 4667783-7Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0380869A
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest X-Ray Abnormal		Zophren	PS	Glaxosmithkline	INTRAVENOUS		1 DAY
	Crepitations		Deticene	SS		INTRAVENOUS	380MG Cyclic	1 DAY
	Pyrexia		Tranxene	SS		ORAL	1	DAY

Date:05/20/05ISR Number: 4669538-6Report Type:Expedited (15-DaCompany Report #2005073375
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Exposure During Pregnancy	Health Professional	Meclizine (Meclizine)	PS		TRANSPLACENTAL	PLACENTAL	
	Jaundice Neonatal		Permethrin (Permethrin)	SS		TRANSPLACENTAL	PLACENTAL	
	Premature Baby							
	Reticulocyte Count Increased		A-200 Pyrinate (Piperonyl Butoxide, Pyrethrum Extract)	SS		TRANSPLACENTAL	PLACENTAL	
			Ondansetron Hydrochloride (Ondansetron Hydrochloride)	SS		TRANSPLACENTAL	PLACENTAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/20/05ISR Number: 4669539-8Report Type:Expedited (15-DaCompany Report #2005074999
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Exposure During Pregnancy Premature Labour Premature Rupture Of Membranes	Health Professional	Meclizine (Meclizine) Permethrin (Permethrin) A-200 Pyrinate (Piperonyl Butoxide, Pyrethrum Extract) Ondansetron Hydrochloride (Ondansetron Hydrochloride) Prenatal Vitamns (Ascorbic Acid, Biotin, Minerals Nos, Nicotinic Acid, Retinol,Tocopherol,V	PS SS SS SS C				

Date:05/23/05ISR Number: 4668930-3Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12894572
Age:59 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening Hospitalization - Initial or Prolonged Other	Acute Respiratory Distress Syndrome Aphasia Bone Marrow Depression Coma Personality Change Shock Speech Disorder		Etopophos For Inj Cisplatine Dakota Adriblastine Gemzar Vincristine Solu-Medrol Zophren Plavix Zocor Combivent	PS SS SS SS SS SS SS C C C	Bristol-Myers Squibb Company Regulatory Health Authority South Africa		3 DAY 3 DAY	

Date:05/23/05ISR Number: 4668983-2Report Type:Expedited (15-DaCompany Report #BE-GLAXOSMITHKLINE-B0380833A
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Haemorrhage		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	4MG per day	
Other	Shock Haemorrhagic		Gw679769	SS	Glaxosmithkline	ORAL	100MG per day	

Date:05/23/05ISR Number: 4668985-6Report Type:Expedited (15-DaCompany Report #AT-GLAXOSMITHKLINE-B0380957A
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain		Ondansetron	PS	Glaxosmithkline	ORAL	8MG Twice per day	
	Ileus							
	Vomiting		Gw679769	SS	Glaxosmithkline	ORAL	100MG Per day	
			Durogesic	SS				
			Dexamethasone	SS		INTRAVENOUS	8MG Single dose	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/24/05ISR Number: 4672598-XReport Type:Expedited (15-DaCompany Report #BE-GLAXOSMITHKLINE-B0380963A
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Haemorrhage		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	4MG Single	
			Placebo	SS	Glaxosmithkline	ORAL	dose	1 DAY

Date:05/24/05ISR Number: 4674528-3Report Type:Expedited (15-DaCompany Report #20050500125
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death Neonatal	Consumer	Reglan (Metoclopramide)					
Life-Threatening	Drug Exposure During Pregnancy		Baxter	PS	Baxter			
	Foetal Heart Rate Abnormal		Zofran (Ondansetron)	SS				
	Stillbirth							

Date:05/27/05ISR Number: 4676395-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0548259A
Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Convulsion		Wellbutrin Xl	PS	Glaxosmithkline	ORAL	450MG Per day	
Other			Ativan	SS		ORAL	1MG Twice per day	
			Remeron	SS		ORAL	7.5MG Per day	
			Zofran	SS	Glaxosmithkline	ORAL	8MG As required	
			Seroquel	SS		ORAL	150MG At	

night

			Prozac	SS		
UNKNOWN	100MG Per day					

Date:05/31/05ISR Number: 4677482-3Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12980314
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hand-Foot-And-Mouth Disease		Glucophage	PS	Bristol-Myers Squibb Company	ORAL		
	Toxic Epidermal Necrolysis		Previscan	SS		ORAL		
	Vomiting		Stilnox	SS		ORAL		
			Zophren	SS		ORAL		
			Xeloda	SS		ORAL		

23-Feb-2005

to

08-Mar-2005,

then

16-Mar-2004

Date:05/31/05ISR Number: 4679326-2Report Type:Expedited (15-DaCompany Report #B0375739A
Age:36 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrial Fibrillation	Foreign	Zofran Injection					
Hospitalization - Initial or Prolonged	Bradycardia		(Ondansetron Hydrochloride)	PS				
	Cardiac Arrest					INTRAVENOUS	4 MG/ DOSE/INTRAVEN OUS	SINGLE
	Torsade De Pointes							
	Ventricular Fibrillation							
	Ventricular Hypokinesia		Suxamethonium	C				

Thiopentone Sodium	C
Desflurane	C
Sufentanil Citrate	C
Ropivaciane Hcl	C
Paroxetine Hydrochloride)	C
Acamprosate	C

Date:05/31/05ISR Number: 4679677-1Report Type:Expedited (15-DaCompany Report #ACC000043
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Flutter	Consumer	Reglan	PS		INTRAVENOUS	INTRAVENOUS	
	Drug Exposure During Pregnancy Intra-Uterine Death Neonatal Disorder		Zofran	SS		INTRAVENOUS	INTRAVENOUS	

Date:05/31/05ISR Number: 4679988-XReport Type:Expedited (15-DaCompany Report #B0381591A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hyperglycaemia	Foreign Study Health Professional	Zofran (Ondansetron Hydrocloride)	PS		INTRAVENOUS	4 MG / SINGLE DOSE /	INTRAVENOUS
			Gw679769 (Gw679769)	SS		ORAL	150 MG / SINGLE DOSE /	ORAL

Date:05/31/05ISR Number: 4680058-5Report Type:Expedited (15-DaCompany Report #2005075038
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrioventricular Block	Foreign	Irinotecan Hydrochloride Solution, Sterile (Irinotecan Hydrochloride)	PS		INTRAVENOUS	INTRAVENOUS	
Hospitalization - Initial or Prolonged		Health Professional	Zofran (Ondansetron Hydrochloride)	SS		ORAL	24 GRAM (24 GRAM,),	ORAL
			Atropine "Braun" (Atropine Sulfate)	C				
			Dexamethasone (Dexamethasone)	C				

Date:06/02/05ISR Number: 4679380-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0382108A
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hand-Foot-And-Mouth Disease Toxic Epidermal Necrolysis Vomiting		Zophren	PS	Glaxosmithkline	ORAL	1	DAY
			Glucophage	SS		ORAL	850MG Twice per day	
			Previscan	SS		ORAL	5MG per day	
			Stilnox	SS		ORAL	1UNIT per day	
			Xeloda	SS		ORAL	6UNIT per day	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/02/05ISR Number: 4679482-6Report Type:Expedited (15-DaCompany Report #FR-SANOFI-SYNTHELABO-A02200501351
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Palmar-Plantar Erythrodysaesthesia Syndrome Toxic Epidermal Necrolysis		Stilnox	PS		ORAL	1	DAY
			Glucophage	SS		ORAL		
			Previscan	SS		ORAL		
			Zophren	SS		ORAL		
			Xeloda	SS		ORAL	6 DF	14 DAY
	Vomiting		Xeloda	SS		ORAL	6 DF	17 DAY

Date:06/02/05ISR Number: 4680000-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0558429A
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atelectasis		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	4MG Single dose	1 MIN
	Chest Pain							
Other	Unwanted Awareness During Anaesthesia		Gw597599	SS	Glaxosmithkline	INTRAVENOUS	18MG Single dose	15 MIN
			Placebo	SS	Glaxosmithkline	ORAL		
			Estradiol Patch	C		TOPICAL		
			Prevacid	C		ORAL		
			Percocet	C		ORAL		
			Fentanyl	C		INTRAVENOUS	25MCG As required	3 DAY
			Midazolam	C		1MG Single dose		
			Rocuronium	C				
			Fentanyl	C				
			Propofol	C				
			Cephazolin	C	Glaxosmithkline			

			Clonidin	C		
INTRAVENOUS						
			Fentanyl	C		
INTRAVENOUS						
			Remifentanil	C	Glaxosmithkline	
INTRAVENOUS						

Date:06/02/05ISR Number: 4682428-8Report Type:Direct Company Report #CTU 250154
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Drug Exposure During		Zofran	4mg	PS		ORAL	ORAL, AS	
	Pregnancy								
DIRECTED									
	Dyspepsia								
	Vomiting								

Date:06/03/05ISR Number: 4681064-7Report Type:Expedited (15-DaCompany Report #CA-GLAXOSMITHKLINE-A0556287A
Age:34 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Anaphylactic Reaction
	Blood Pressure Decreased
Other	Drug Exposure During
	Pregnancy
	Dysphonia
	Erythema
	Eyelid Oedema
	Face Oedema
	Hypotension
	Pharyngeal Oedema
	Pruritus

Throat Tightness

		Report Source	Product	Role	Manufacturer	Route	Dose	Duration
			Zofran	PS	Glaxosmithkline	INTRAVENOUS	4MG Single dose	
			Demerol	C		INTRAVENOUS		

Date:06/06/05ISR Number: 4682662-7Report Type:Expedited (15-DaCompany Report #CZ-GLAXOSMITHKLINE-B0381555A
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	32MG Single dose	1 DAY
			Blinded Trial Medication	SS	Glaxosmithkline	ORAL	4	DAY
			Navelbine	SS	Glaxosmithkline	INTRAVENOUS	40MG per day	22 DAY

Date:06/06/05ISR Number: 4682666-4Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0382312A
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hot Flush		Ondansetron	PS	Glaxosmithkline	ORAL	16MG Per day	2 DAY
	Respiratory Tract Congestion		Gw679769	SS	Glaxosmithkline	ORAL	150MG Per day	2 DAY
			Dexamethasone	SS		INTRAVENOUS	8MG Single dose	1 DAY
	Wheezing							

Date:06/09/05ISR Number: 4686244-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0375572A
Age:67 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dystonia		Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG Cyclic	DAY
Initial or Prolonged	Muscle Contracture		Primperan	C	Glaxosmithkline	INTRAVENOUS	100MG Cyclic	HR
	Trismus		Cisplatyl	C		INTRAVENOUS	200MG Cyclic	24 HR
			Vp16	C		INTRAVENOUS	200MG Cyclic	48 HR
			Methylprednisolone	C		INTRAVENOUS	240MG Cyclic	

Date:06/09/05ISR Number: 4686263-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0383170A
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Myocardial Infarction		Zophren	PS	Glaxosmithkline	UNKNOWN		
			Taxotere	SS		UNKNOWN		

Date:06/10/05ISR Number: 4687492-8Report Type:Expedited (15-DaCompany Report #PHEH2003US11704
Age:44 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Abdominal Distension
Initial or Prolonged	Abdominal Pain Lower
Other	Anorexia
	Asthenia
	C-Reactive Protein Increased
	Colitis Ischaemic
	Diarrhoea Haemorrhagic
	Drug Ineffective

	Drug Intolerance Dyschezia Erythema	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Gastrointestinal Motility Disorder		Zelnorm	PS	Novartis Sector: Pharma	ORAL	6 mg, BID 405 DAY
	Haematochezia		Ondansetron	SS			UNK, PRN
	Haemorrhoids		Celexa	C			
	Impaired Gastric Emptying		Klonopin	C			
	Inflammatory Bowel Disease		Miralax	C			
			Docusate	C			
	Intestinal Functional Disorder		Citalopram	C			
			Milk Of Magnesia	C			
	Leukocytosis		Promethazine	C			UNK, PRN
	Malaise		Prevacid	C			
	Mucosal Inflammation		Omeprazole	C			
	Mucosal Ulceration		Alprazolam	C			
	Nausea Oedema Mucosal Red Blood Cell Sedimentation Rate Increased Weight Decreased						

Date:06/10/05ISR Number: 4687906-3Report Type:Expedited (15-DaCompany Report #BR-GLAXOSMITHKLINE-A0561688A
Age:3 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Death		Zofran	PS	Glaxosmithkline	ORAL	4MG Unknown

Date:06/10/05ISR Number: 4687937-3Report Type:Expedited (15-DaCompany Report #NL-GLAXOSMITHKLINE-B0382976A
Age:71 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Nausea		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	32MG Single

Initial or Prolonged dose	Pain						
	DAY						
				Blinded Trial Medication	SS	Glaxosmithkline	
INTRAVENOUS	4	DAY					
				Cisplatin	SS		
INTRAVENOUS							
				Vinorelbine	SS	Glaxosmithkline	
INTRAVENOUS							

Date:06/10/05ISR Number: 4687941-5Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0383051A
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation		Ondansetron Hydrochloride	PS	Glaxosmithkline	ORAL	4MG Per day	3 DAY
	Nausea							
	Urinary Tract Infection		Cyclizine	SS	Glaxosmithkline			1 DAY
	Vomiting		Epirubicin	SS				
INTRAVENOUS		1 DAY						
			Zoledronic Acid	C				
INTRAVENOUS		22 DAY						
			Cephalexin	C	Glaxosmithkline			8 DAY

Date:06/10/05ISR Number: 4688064-1Report Type:Expedited (15-DaCompany Report #FR-ROCHE-406415
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Toxic Epidermal		Xeloda	PS	Roche	ORAL		14 DAY
Initial or Prolonged	Necrolysis		Xeloda	SS	Roche	ORAL		14 DAY

		Glucophage	SS	Roche	ORAL
		Zophren	SS		ORAL
1 DAY					
		Stilnox	SS		ORAL
		Previscan	SS		ORAL

Date:06/13/05ISR Number: 4688837-5Report Type:Expedited (15-DaCompany Report #CZ-GLAXOSMITHKLINE-B0381555A
Age:72 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Constipation		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	32MG Single	
Initial or Prolonged								
dose							1	DAY
			Navelbine	SS	Glaxosmithkline	INTRAVENOUS	40MG per day	22 DAY
			Blinded Trial Medication	C	Glaxosmithkline	ORAL		
4 DAY								

Date:06/13/05ISR Number: 4688847-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0383535A
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Aphonia		Zophren	PS	Glaxosmithkline	INTRAVENOUS	1AMP Single	
Initial or Prolonged	Dyspnoea							
dose							1	DAY
	Face Oedema		Perfalgan	SS	Glaxosmithkline	INTRAVENOUS	1G Single	
dose							1	DAY
			Profenid	C		INTRAVENOUS	200MG Single	
dose							1	DAY

Date:06/15/05ISR Number: 4690652-3Report Type:Expedited (15-DaCompany Report #NL-GLAXOSMITHKLINE-B0382976A
Age:71 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Nausea Pain Vomiting		Ondansetron Blinded Trial Medication Cisplatin Vinorelbine	PS SS C C	Glaxosmithkline Glaxosmithkline	INTRAVENOUS INTRAVENOUS INTRAVENOUS INTRAVENOUS	32MG Single dose 4	DAY DAY

Date:06/15/05ISR Number: 4690657-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0383785A
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hot Flush Hyperhidrosis Hypertensive Crisis Pruritus Generalised		Zophren Eloxatine Solumedrol	PS SS C	Glaxosmithkline	INTRAVENOUS INTRAVENOUS INTRAVENOUS	8MG Cyclic 120MG Cyclic	

Date:06/15/05ISR Number: 4690667-5Report Type:Expedited (15-DaCompany Report #HK-GLAXOSMITHKLINE-B0384192A
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Loss Of Consciousness Ventricular Tachycardia		Zofran	PS	Glaxosmithkline	UNKNOWN	4MG Per day	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/17/05ISR Number: 4692748-9Report Type:Expedited (15-DaCompany Report #SK-GLAXOSMITHKLINE-B0384082A
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Febrile Neutropenia		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	32MG Single	
Hospitalization -								
dose							1	DAY
Initial or Prolonged			Blinded Trial Medication	SS	Glaxosmithkline	INTRAVENOUS		4 DAY
			Navelbine	SS	Glaxosmithkline	INTRAVENOUS	48MG per day	1 DAY
			Cisplatin	SS		INTRAVENOUS	113MG per day	1 DAY

Date:06/20/05ISR Number: 4694677-3Report Type:Expedited (15-DaCompany Report #2005-0137
Age:81 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased		Raniplex	PS	Glaxosmithkline	INTRAVENOUS	300MG Per day	15 MIN
Hospitalization -	Cardio-Respiratory Arrest		Zophren	SS	Glaxosmithkline	INTRAVENOUS	8MG Per day	15 MIN
Initial or Prolonged	Heart Rate Decreased		Solumedrol	SS		INTRAVENOUS	8MG Per day	15 MIN
	Hypersensitivity							
	Loss Of Consciousness							
	Malaise							
	Oxygen Saturation Decreased							
	Vomiting							

Date:06/20/05ISR Number: 4697328-7Report Type:Expedited (15-DaCompany Report #2005086962
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased	Foreign	Solu-Medrol					
	Cardio-Respiratory Arrest	Health	(Methylprednisolone					

		Dizziness	Professional	Sodiuim Succinate)	PS		
INTRAVENOUS	80 MG (40 MG,	Heart Rate Decreased					
2 IN 1 D),		Malaise					
INTRAVENOUS		Oxygen Saturation Decreased		Raniplex (Ranitidine)	SS		
INTRAVENOUS	300 MG(50 MG,	Vomiting					
15 MIN),							
INTRAVENOUS				Zophren (Ondansetron Hydrochloride)	SS		
INTRAVENOUS	8 MG (8 MG,						
15 MIN),							
INTRAVENOUS							

Date:06/22/05ISR Number: 4696903-3Report Type:Expedited (15-DaCompany Report #AU-JNJFOC-20050603846
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased		Tramadol Hydrochloride	PS				
UNKNOWN								
	C-Reactive Protein		Parecoxib Sodium	SS				
UNKNOWN								
	Increased		Cephalothin Sodium	SS				
UNKNOWN								
	Nephritis Interstitial		Panadeine	SS				
UNKNOWN								
	White Blood Cell Count		Panadeine	SS				
UNKNOWN								
	Increased		Nurofen	SS				
UNKNOWN								
			Zofran	SS				
UNKNOWN								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/22/05ISR Number: 4697235-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0384662A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrioventricular Block		Zophren	PS	Glaxosmithkline	ORAL		
	Loss Of Consciousness		Ethambutol	C				
UNKNOWN								
			Para-Aminosalicylic	C				
UNKNOWN							2G Twice per	
day								
			Capreomycin	C				
UNKNOWN								

Date:06/23/05ISR Number: 4698143-0Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0547006A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Drug Exposure During Pregnancy		Zofran	PS	Glaxosmithkline			
	Finger Deformity							

Date:06/23/05ISR Number: 4698197-1Report Type:Expedited (15-DaCompany Report #US-MERCK-0506USA02386
Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dyspnoea		Emend	PS	Merck & Co., Inc	ORAL		
1 DAY								
Initial or Prolonged	Hypotension		Emend	SS	Merck & Co., Inc	ORAL		
	Infusion Related Reaction		Decadron Tablets	SS		ORAL		
	Pruritus		Ondansetron	SS				
UNKNOWN								
			Methotrexate	SS				
UNKNOWN								

Date:06/24/05ISR Number: 4699299-6Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0563895A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Lice Infestation		Zofran	PS	Glaxosmithkline	UNKNOWN		
	Normal Delivery		Rid	C		TOPICAL		
	Premature Labour		Meclizine	C		UNKNOWN		
			Permethrin	C	Glaxosmithkline	TOPICAL		

Date:06/24/05ISR Number: 4699300-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0563895B
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Bilirubin Increased		Zofran	PS	Glaxosmithkline			
	Drug Exposure During Pregnancy		Rid	C				
			Meclizine	C				
	Jaundice		Permethrin	C	Glaxosmithkline			
	Jaundice Neonatal		Hepatitis B Vaccine	C	Glaxosmithkline		1	DAY
	Premature Baby							
	Reticulocyte Count Increased							

Date:06/28/05ISR Number: 4701153-8Report Type:Expedited (15-DaCompany Report #S0502759
Age:61 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Myocardial Infarction		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS		
			Dexamethasone	SS		INTRAVENOUS		
			Irinotecan	SS		INTRAVENOUS	250MG	Per day

				Fluorouracil		SS	
INTRAVENOUS							
				Calcium Folinate		SS	Glaxosmithkline
INTRAVENOUS							

Date:06/29/05ISR Number: 4703905-7Report Type:Direct Company Report #CTU 252221
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product		Role	Manufacturer	Route
Dose	Duration						
Required	Dyspnoea		Ondansetron	4mg	PS		
INTRAVENOUS	4MG ONCE						
Intervention to	Dystonia						
INTRAVENOU							
Prevent Permanent			Diphenhydramine				
Impairment/Damage			25mg		SS		
INTRAVENOUS	25MG ONCE						
INTRAVENOU							
			Dilaudid		C		

Date:06/30/05ISR Number: 4704399-8Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0382312A
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product		Role	Manufacturer	Route
Dose	Duration						
Other	Hot Flush		Ondansetron		PS	Glaxosmithkline	ORAL
16MG Per day	2 DAY						
	Hypersensitivity		Gw679769		SS	Glaxosmithkline	ORAL
150MG Per day	2 DAY						
	Respiratory Tract		Dexamethasone		SS		
INTRAVENOUS	8MG Single						
	Congestion						
dose	1 DAY						
	Wheezing		Epirubicin		C		

Date:06/30/05ISR Number: 4704403-7Report Type:Expedited (15-DaCompany Report #2005-0137
Age:81 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product		Role	Manufacturer	Route
Dose	Duration						

Life-Threatening Anaphylactic Shock Raniplex PS Glaxosmithkline
INTRAVENOUS 300MG Per day 15 MIN
Hospitalization - Blood Pressure Decreased Zophren SS Glaxosmithkline
INTRAVENOUS 8MG Per day 15 MIN
Initial or Prolonged Cardio-Respiratory Arrest Solumedrol SS
INTRAVENOUS 80MG Per day 15 MIN
Drug Hypersensitivity
Heart Rate Decreased
Loss Of Consciousness
Malaise
Oxygen Saturation
Decreased
Vomiting

Date:06/30/05ISR Number: 4704405-0Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0384662A
Age: Gender:Male I/FU:F

Outcome PT Report Source Product Role Manufacturer Route
Dose Duration
Other Atrioventricular Block Zophren PS Glaxosmithkline ORAL
Atrioventricular Block Linezolide SS
UNKNOWN
Second Degree Capreomycin SS
UNKNOWN
Loss Of Consciousness Para-Aminosalicylic SS
UNKNOWN 2G Twice per
day
Ethambutol C
UNKNOWN

Date:06/30/05ISR Number: 4704412-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0385597A
Age:61 YR Gender:Female I/FU:I

Outcome PT
Hospitalization - Incorrect Route Of Drug
Initial or Prolonged Administration

Pleural Effusion

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
			Zophren	PS	Glaxosmithkline	
INTRAVENOUS	1 DAY					
			Azantac	SS	Glaxosmithkline	
INTRAVENOUS	1 DAY					
			Aracytine	SS		
INTRAVENOUS	1 DAY					
			Solumedrol	SS		
INTRAVENOUS	1 DAY					
			Zavedos	SS		
INTRAVENOUS	1 DAY					
			Acupan	SS		
INTRAVENOUS	1 DAY					

Date:07/05/05ISR Number: 4706479-XReport Type:Expedited (15-DaCompany Report #HK-GLAXOSMITHKLINE-B0384192A
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Electrocardiogram Qt		Zofran	PS	Glaxosmithkline	
UNKNOWN	4MG Per day					
Hospitalization -	Prolonged					
Initial or Prolonged	Loss Of Consciousness					
	Syncope					
	Ventricular Extrasystoles					
	Ventricular Tachycardia					

Date:07/06/05ISR Number: 4708601-8Report Type:Expedited (15-DaCompany Report #2005-130056-NL
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Myocardial Infarction	Foreign	Dexamethasone	PS		
INTRAVENOUS	DF					
Initial or Prolonged						
INTRAVENOUS						
(NOS)						
			Irinotecan	SS		
INTRAVENOUS	250 MG					

INTRAVENOUS

(NOS)

		Fluorouracil	SS
INTRAVENOUS	DF		
INTRAVENOUS			
(NOS)			
		Calcium Folinate	SS
INTRAVENOUS	DF		
INTRAVENOUS			
(NOS)			
		Ondansetron	SS
INTRAVENOUS	DF		
INTRAVENOUS			
(NOS)			

Date:07/07/05ISR Number: 4708539-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0386343A
Age:34 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Abdominal Distension
Hospitalization - Initial or Prolonged	Abdominal Pain Upper
	Anuria
	Ascites
	Brain Oedema
	Budd-Chiari Syndrome
	Diarrhoea
	Haematochezia
	Hepatic Encephalopathy
	Hepatic Failure
	Hepatic Vein Thrombosis
	Hepatocellular Damage
	Hepatorenal Syndrome

	Loss Of Consciousness Malaise Metabolic Acidosis	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Oliguria		Zophren	PS	Glaxosmithkline		
INTRAVENOUS	8MG Cyclic Pleural Effusion		Adriablastin	SS			
INTRAVENOUS	20MGM2 per Portal Vein Thrombosis						day
	Shock		Holoxan	SS			
INTRAVENOUS	2.5GM2 per Sinus Tachycardia						day
	Thrombocytopenia		Uromitexan	SS			
INTRAVENOUS	2.5GM2 per Vomiting						day
			Soludecadron	SS			
INTRAVENOUS	20MG per day					6 DAY	
			Deticene	SS			
INTRAVENOUS	300MGM2 per						day
			Solumedrol	C			
INTRAVENOUS	60MG See						dosage text
						24 DAY	
			Largactil	C			
INTRAVENOUS	.5UNIT per						day
						1 DAY	
			Aranesp	C			
INTRAVENOUS	150MG Weekly						
			Neulasta	C			
SUBCUTANEOUS	6MG See						dosage text

Date:07/08/05ISR Number: 4711067-5Report Type:Expedited (15-DaCompany Report #2005093261
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Toxic Epidermal	Foreign	Solu-Medrol				

Initial or Prolonged	Necrolysis	Health Professional	(Methylprednisolone Sodium Succinate)	PS			
INTRAVENOUS	80 MG,						
INTRAVENOUS							
			Metoclopramide (Metoclopramide)	SS			ORAL
1 DOSE FORM,							
ORAL							
			Cisplatin (Cisplatin)	SS			
INTRAVENOUS	50 MG,						
INTRAVENOUS							
			Zophren (Ondansetron Hydrochloride)	SS			ORAL
8 MG, ORAL							
			Ethyol (Amifostine)	SS			
INTRAVENOUS	400 MG,						
INTRAVENOUS							

Date:07/08/05ISR Number: 4711074-2Report Type:Expedited (15-DaCompany Report #2005094696
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Shock	Foreign	Solu-Medrol					
Hospitalization -	Cardio-Respiratory Arrest	Health	(Methylprednisolone					
Initial or Prolonged	Hypersensitivity	Professional	Sodium Succinate)	PS				
INTRAVENOUS	80 MG (1 D),							
INTRAVENOUS								
			Ranitidine (Ranitidine Hydrochloride)	SS				
INTRAVENOUS	300 MG (1 D),							
INTRAVENOUS								
			Ondansetron (Ondansetron Hydrochloride)	SS				
INTRAVENOUS	8 MG (1 D),							
INTRAVENOUS								

Date:07/08/05ISR Number: 4711087-0Report Type:Expedited (15-DaCompany Report #2005082131
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Chest Wall Pain Pleural Effusion	Foreign Health Professional	Idarubicin Hydrochloride Solution, Sterile (Idarubicin Hydrochloride)	PS		INTRAVENOUS	1.5 GRAM (15 MG, CYCLIC),	
			Cytarabine (Cytarabine)	SS		INTRAVENOUS	1.5 GRAM (1500 MG, CYCLIC),	
			Methylprednisolone Acetate Suspension, Sterile (Methylprednisolone Acetate)	SS		INTRAVENOUS	INTRAVENOUS	
			Ondansetron (Ondansetron)	SS		INTRAVENOUS	INTRAVENOUS	
			Ranitidine Hydrochloride (Ranitidine Hydrochloride)	SS		INTRAVENOUS	100 MG,	
			Nefopam (Nefopam)	SS		INTRAVENOUS	INTRAVENOUS	

Date:07/11/05ISR Number: 4710867-5Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0383535A
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Aphonia		Zophren	PS	Glaxosmithkline	INTRAVENOUS	1AMP	Single
Initial or Prolonged	Bronchospasm							
dose							1	DAY
	Dyspnoea		Perfalgan	C	Glaxosmithkline	INTRAVENOUS	1G	Single
	Face Oedema							
dose							1	DAY
	Laryngeal Oedema		Profenid	C		INTRAVENOUS	200MG	Single
	Oxygen Saturation							
dose							1	DAY
	Decreased							

Date:07/11/05ISR Number: 4713605-5Report Type:Expedited (15-DaCompany Report #2005094755
Age:34 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Anaemia
Hospitalization -	Ascites
Initial or Prolonged	Brain Oedema
	Budd-Chiari Syndrome
	Cytolytic Hepatitis
	Diarrhoea Haemorrhagic
	Hepatic Encephalopathy
	Hepatic Failure
	Hepatorenal Syndrome
	Liver Transplant
	Loss Of Consciousness
	Metabolic Acidosis
	Neutropenia
	Pleural Effusion

		Portal Vein Thrombosis Shock Sinus Tachycardia Thrombocytopenia Vomiting	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
INTRAVENOUS	20 MG/M2 (1 IN 1 D),		Foreign Health Professional	Adriblastine (Doxorubicin Hydrochloride)	PS		
INTRAVENOUS				Ifosfamide (Ifosfamide)	SS		
INTRAVENOUS	2.5 MG/M2 (CYCLICAL),						
INTRAVENOUS				Mesna (Mesna)	SS		
INTRAVENOUS	25 MG/M2 (CYCLICAL),						
INTRAVENOUS				Dexamethasone (Dexamethasone)	SS		
INTRAVENOUS	20 MG (20 MG, 1 IN 1 D),						
INTRAVENOUS				Solu-Medrol (Methylprednisone Sodium Succinate)	SS		
INTRAVENOUS	60 MG (CYCLICAL),						
INTRAVENOUS				Dacarbazine (Dacarbazine)	SS		
INTRAVENOUS	300 MG/M2 (CYCLICAL),						
INTRAVENOUS							

				Ondansetron (Ondansetron)	SS		
INTRAVENOUS	16 MG (8 MG, 2 IN 1D), INTRAVENOUS						
				Chlorpromazine (Chlorpromazine)	SS		
INTRAVENOUS	INTRAVENOUS						
				Darbepoetin Alfa (Darbepoetin Alfa)	SS		
INTRAVENOUS	150 MG (1 WK), INTRAVENOUS						
				Pegfilgrastim (Pegfilgrastim)	SS		
SUBCUTANEOUS	6 MG (1 IN 1 D), SUBCUTANEOUS						

Date:07/12/05ISR Number: 4712360-2Report Type:Expedited (15-DaCompany Report #B0386188A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electrocardiogram Qt Corrected Interval Prolonged	Foreign Study Literature Health Professional	Zofran (Ondansetron Hydrochloride)	PS		INTRAVENOUS	4 MG/INTRAVENOUS	

Date:07/13/05ISR Number: 4714231-4Report Type:Direct Company Report #CTU 253153
Age:39 YR Gender:Female I/FU:I

Outcome	PT
Death	Drug Exposure During Pregnancy

Foetal Distress Syndrome
Intra-Uterine Death

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Zofran	PS				
	Reglan	SS				

Date:07/14/05ISR Number: 4714396-4Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0386343A
Age:34 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abdominal Distension		Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG Cyclic	
Hospitalization -	Abdominal Pain Upper		Adriablastin	SS		INTRAVENOUS	20MGM2 per	
Initial or Prolonged	Anuria							day
	Ascites		Holoxan	SS		INTRAVENOUS	2.5GM2 per	
	Brain Oedema							day
	Budd-Chiari Syndrome		Uromitexan	SS		INTRAVENOUS	2.5GM2 per	
	Diarrhoea							day
	Haematochezia		Deticene	SS		INTRAVENOUS	300MGM2 per	
	Hepatic Encephalopathy							day
	Hepatic Failure		Soludecadron	C		INTRAVENOUS	20MG per day	6 DAY
	Hepatic Vein Thrombosis		Solumedrol	C		INTRAVENOUS	60MG See	
	Hepatocellular Damage							dosage text
24 DAY								
	Hepatorenal Syndrome		Largactil	C		INTRAVENOUS	.5UNIT per	
	Loss Of Consciousness							day
1 DAY								
	Malaise		Aranesp	C		INTRAVENOUS	150MG Weekly	
	Metabolic Acidosis		Neulasta	C		SUBCUTANEOUS	6MG See	

	Oliguria					
dosage text						
	Pleural Effusion		Corticosteroid	C		
INTRAVENOUS	3 DAY					
	Portal Vein Thrombosis					
	Shock					
	Sinus Tachycardia					
	Thrombocytopenia					
	Vomiting					

Date:07/15/05ISR Number: 4717171-XReport Type:Expedited (15-DaCompany Report #2005-DE-02563GD
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Anxiety	Literature	Trazodone (Trazodone			
Initial or Prolonged	Blood Pressure Increased		Hydrochloride) (Nr)	PS		
150 MG						
Other	Drug Toxicity		Hydromorphone			
	Heart Rate Increased		(Hydromorphone (Nr)			
	Hot Flush		(Hydromorphone)	SS		
SUBCUTANEOUS 750 MG	(SEE					
	Hyperhidrosis					
TEXT, EVERY 4						
	Hypoaesthesia Oral					
HOURS), SC						
	Palpitations		Citalopram			
	Panic Attack		(Citalopram			
	Serotonin Syndrome		Hydrobromide) (Nr)	SS		
40 MG (NR,						
	Tremor					
ONCE DAILY)						
			Linezolid			
			(Linezolid) (Nr)	SS		ORAL
1200 MG (NR,						
TWICE DAILY)						
PO 10 DAY						
			Olanzapine			
			(Olanzapine) (Nr)	SS		
2.5 MG (NR,						
ONCE DAILY)						
			Ondansetron			
			(Ondansetron) (Nr)	SS		
8 MG AS						
NEEDED (NR)						

Senna (Senna Alexandrina)	SS
Clonazepam (Clonazepam)	C
Pantoprazole (Pantoprazole)	C
Metformin (Metformin)	C
Sodium Docusate (Docusate Sodium)	C
Perindopril (Perindopril)	C
Furosemide (Furosemide)	C

Date:07/18/05ISR Number: 4716018-5Report Type:Expedited (15-DaCompany Report #AU-GLAXOSMITHKLINE-B0387896A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder		Zofran	PS	Glaxosmithkline			
UNKNOWN								
	Tremor		Prochlorperazine	C	Glaxosmithkline			

Date:07/19/05ISR Number: 4717153-8Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0387499A
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dyskinesia		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	4MG per day	1 DAY
			Cyclizine	C	Glaxosmithkline	INTRAVENOUS	50MG per day	0 DAY
			Paracetamol	C	Glaxosmithkline	INTRAVENOUS	1G per day	0 DAY
			Dihydrocodeine	C		INTRAVENOUS	60MG per day	0 DAY

Date:07/20/05ISR Number: 4718632-XReport Type:Expedited (15-DaCompany Report #SE-GLAXOSMITHKLINE-B0387436A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Systolic		Zofran	PS	Glaxosmithkline	INTRAVENOUS		
	Increased		Morphine	C		INTRAMUSCULAR		
	Dysarthria		Atropin	C				
	Dyspnoea		Selokeen	C				
	General Physical Health Deterioration		Norvasc	C				
	Hypertension		Zopiclone	C				
	Movement Disorder							
	Muscle Twitching							
	Pharmaceutical Product Complaint							

Date:07/26/05ISR Number: 4724763-0Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0387707A
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dyskinesia		Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	4MG	Unknown 1 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/27/05ISR Number: 4725978-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0388324A
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Generalised Exanthematous Pustulosis Toxic Skin Eruption		Zophren	PS	Glaxosmithkline	ORAL		
			Mopral	SS	Glaxosmithkline	ORAL		
			Hypnovel	C			INTRAVENOUS	1 DAY
			Diprivan	C			INTRAVENOUS	1 DAY
			Paracetamol	C	Glaxosmithkline	ORAL		
			Sufenta	C			INTRAVENOUS	1 DAY

Date:07/28/05ISR Number: 4727196-6Report Type:Expedited (15-DaCompany Report #2005CG01284
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Generalised Exanthematous Pustulosis		Mopral	PS		ORAL		
			Zophren	SS		ORAL		
			Diprivan	C			INTRAVENOUS	
			Hypnovel	C			INTRAVENOUS	
			Sufenta	C			INTRAVENOUS	
			Paracetamol	C		ORAL		

Date:07/29/05ISR Number: 4729051-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0546949A
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Imitrex	PS	Glaxosmithkline	ORAL	50MG Three times per day	12 YR
	Nausea							
	Therapeutic Response		Zofran	SS	Glaxosmithkline			
	Unexpected		Bextra	C				
			Inhalers	C				

Date:08/01/05ISR Number: 4730192-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0388282A
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blister		Zophren	PS	Glaxosmithkline	ORAL	8MG Cyclic	29 DAY
	Pruritus		Primperan	SS	Glaxosmithkline	ORAL	1UNIT Cyclic	7 DAY
	Pyrexia		Solumedrol	SS		INTRAVENOUS	80MG Cyclic	29 DAY
	Rash Maculo-Papular		Cisplatine	SS		INTRAVENOUS	50MG Cyclic	29 DAY
	Skin Disorder		Ethyol	SS		INTRAVENOUS	400MG Cyclic	32 DAY
	Toxic Epidermal Necrolysis							

Date:08/03/05ISR Number: 4732497-1Report Type:Expedited (15-DaCompany Report #CA-GLAXOSMITHKLINE-A0567297A
Age:52 YR Gender:Female I/FU:F

Outcome	PT
Life-Threatening	Crepitations
Hospitalization - Initial or Prolonged	Dyspnoea
	Electrocardiogram St Segment Depression
	Laryngospasm
	Oxygen Saturation Decreased
	Pulmonary Oedema
	Venous Pressure Jugular Increased

Wheezing

		Report Source	Product	Role	Manufacturer	Route	Dose	Duration
			Ondansetron	PS	Glaxosmithkline	INTRAVENOUS	4MG Single	dose	5 MIN
			Gw679769	SS	Glaxosmithkline	ORAL	50MG Single	dose	1 DAY
			Morphine	C		INTRAVENOUS	20MG As	required	1 DAY

Date:08/03/05ISR Number: 4734086-1Report Type:Direct Company Report #CTU 255357
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest		Ondansetron	PS		INTRAVENOUS	32MG ONCE	
	Cough					INTRAVENOUS		
	Dyspnoea		Diphenhydramine	SS		INTRAVENOUS	50 ONCE	
	Infusion Related Reaction					INTRAVENOUS		
	Oxygen Saturation Decreased							
	Tremor							

Date:08/04/05ISR Number: 4734768-1Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0388784A
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiomyopathy		Zophren 8 Mg	PS	Glaxosmithkline	INTRAVENOUS		
			Deticene	SS		ORAL		

				Zoloft	C		
UNKNOWN							
				Paracetamol + Tramadol	C		
UNKNOWN							

Date:08/04/05ISR Number: 4734783-8Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0047203A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatic Enzyme Increased		Zofran	PS	Glaxosmithkline			
UNKNOWN								
	Pancreatic Enzymes		Oxaliplatin	SS				
UNKNOWN								
	Increased		Xeloda	SS				
UNKNOWN								

Date:08/04/05ISR Number: 4738759-6Report Type:Expedited (15-DaCompany Report #2005088980
Age:26 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Amyloidosis	Foreign	Zyvoxid (Linezolid)	PS		ORAL	600 MG (600	
Initial or Prolonged	Anaemia	Health					MG, DAILY),	
Other	Arrhythmia	Professional					ORAL	
	Atrioventricular Block Second Degree		Para-Aminosalicyliqu e Acid (Aminosalicylic					
	Dizziness							
	Loss Of Consciousness		Acid)	SS		ORAL	10 GRAM	
	Mitochondrial Toxicity						(DAILY), ORAL	
	Nausea		Ethambutol					
	Syncope		(Ethambutol)	SS		ORAL	1500 MG	
	Vertigo						(DAILY), ORAL	
	Vomiting		Ondansetron (Ondansetron0	SS		ORAL	ORAL	

			Capreomycin (Capreomycin)	SS		
INTRAVENOUS	1 GRAM (TID),					
INTRAVENOUS						
			Ondansetron(Ondanset ron)	C		
			Pyrazinamide (Pyrazinamide)	C		
			Sodium(Aminosalicyla te Sodium)	C		

Date:08/05/05ISR Number: 4735973-0Report Type:Expedited (15-DaCompany Report #US-MERCK-0506USA02386
Age:15 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dyspnoea		Emend	PS	Merck & Co., Inc	ORAL		
1 DAY								
Initial or Prolonged	Hypotension		Emend	SS	Merck & Co., Inc	ORAL		
	Pruritus		Decadron Tablets	SS		ORAL		
			Ondansetron	SS				
UNKNOWN								
			Methotrexate	SS				
UNKNOWN								

Date:08/08/05ISR Number: 4738199-XReport Type:Direct Company Report #USP 57285
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Intercepted Medication		Zofran	PS	Glaxosmithkine			
INJECTABLE								
	Error		Fentanyl Citrate	SS	Abbott			
	Medication Error							

Date:08/11/05ISR Number: 4742811-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0569537A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Dyskinesia		Zofran	PS	Glaxosmithkline	
INTRAVENOUS						
Initial or Prolonged	Panic Attack					

Date:08/12/05ISR Number: 4743743-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0385597A
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chest Wall Pain		Zophren	PS	Glaxosmithkline			
INTRAVENOUS								1 DAY
Initial or Prolonged	Dyspnoea		Azantac	SS	Glaxosmithkline			
INTRAVENOUS								1 DAY
	Incorrect Route Of Drug		Aracytine	SS				
INTRAVENOUS							1.5G	
	Administration							
cumulative								
	Pleural Effusion							
dose								1 HR
			Solumedrol	SS				
INTRAVENOUS								1 DAY
			Zavedos	SS				
INTRAVENOUS							15MG	
cumulative								
dose								15 MIN
			Acupan	SS				
INTRAVENOUS								1 DAY

Date:08/12/05ISR Number: 4743747-XReport Type:Expedited (15-DaCompany Report #AU-GLAXOSMITHKLINE-B0387896A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder		Zofran	PS	Glaxosmithkline			
UNKNOWN								
	Tremor		Prochlorperazine	C	Glaxosmithkline			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/12/05ISR Number: 4743748-1Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0388324A
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Generalised Exanthematous Pustulosis Toxic Skin Eruption		Zophren	PS	Glaxosmithkline	ORAL		
			Mopral	SS	Glaxosmithkline	ORAL		
			Hypnovel	C			INTRAVENOUS	1 DAY
			Diprivan	C			INTRAVENOUS	1 DAY
			Paracetamol	C	Glaxosmithkline	ORAL		
			Sufenta	C			INTRAVENOUS	1 DAY

Date:08/15/05ISR Number: 4744859-7Report Type:Expedited (15-DaCompany Report #ES-GLAXOSMITHKLINE-B0390216A
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Chest Pain		Zofran	PS	Glaxosmithkline		INTRAVENOUS	8MG per day 1 DAY
	Dyspnoea		Cyclophosphamide	SS			INTRAVENOUS	800MG per day 1 DAY
	Erythema		Methotrexate	SS			INTRAVENOUS	50MG per day 1 DAY
	Hypersensitivity		Dexamethasone	SS			INTRAVENOUS	12MG per day 1 DAY

Date:08/15/05ISR Number: 4744867-6Report Type:Expedited (15-DaCompany Report #ES-GLAXOSMITHKLINE-B0390265A
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abdominal Pain		Zofran	PS	Glaxosmithkline		INTRAVENOUS	8MG per day 1 DAY
Hospitalization - Initial or Prolonged	Electrocardiogram Change		Ranitidine	SS	Glaxosmithkline		INTRAVENOUS	50MG per day 1 DAY
	Hyperhidrosis		Fortecortin	SS			INTRAVENOUS	20MG per day 1 DAY
	Hypotension							

Date:08/16/05ISR Number: 4745941-0Report Type:Expedited (15-DaCompany Report #IE-GLAXOSMITHKLINE-B0389861A
Age:35 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Accidental Exposure		Zofran	PS	Glaxosmithkline	UNKNOWN	2MGML	Unknown
Other	Discomfort							
	Eye Disorder							
	Eye Penetration							
	Foreign Body In Eye							
	Medication Error							
	Pain							
	Pharmaceutical Product							
	Complaint							

Date:08/18/05ISR Number: 4748066-3Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0388282A
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blister		Zophren	PS	Glaxosmithkline	ORAL	8MG Cyclic	29 DAY
Initial or Prolonged	Pruritus		Primperan	SS	Glaxosmithkline	ORAL	1UNIT Cyclic	7 DAY
	Pyrexia		Solumedrol	SS		INTRAVENOUS	80MG Cyclic	29 DAY
	Rash Maculo-Papular		Cisplatine	SS		INTRAVENOUS	50MG Cyclic	29 DAY
	Skin Disorder		Ethyol	SS		INTRAVENOUS	400MG Cyclic	32 DAY
	Toxic Epidermal Necrolysis							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Summary report for FOI selections:

Selection by inexact search of active ingredient: ONDANSETRON%

Selection by inexact search of Tradename/Verbatim: ZOFRAN%

Total number of reports: 1,536

From: 01-NOV-1997 To: Present