DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**
Center for Drug Evaluation and Research
Office of Regulatory Policy
Division of Information Disclosure Policy
5600 Fishers Lane, HFD-13
Rockville, Maryland 20857

August 24, 2005

In Response Refer to File: F05-8459

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

Dear Mr. Yablan,

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

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

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

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

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

Sincerely,
Harold D. Stepper
Paralegal Specialist
Office of Regulatory Policy
Division of Information Disclosure Policy, HFD-13

Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report
Selections for: GRANISETRON
KYTRIL
From: 01-NOV-1997 To: Present

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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date: 11/03/97 **ISR Number:** 3005490-7 **Report Type:** Direct **Company Report#:** **Age:** 64 YR **Gender:** Female **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Confusional State		Amifostine	PS		INTRAVENOUS	2220.4 MG X 1 IV	
	Hallucination							
	Muscle Twitching		Paclitaxel	SS				
			Dexamethasone	SS		INTRAVENOUS	20 MG IV	
			Kytril	SS				
			Carboplatin	SS				
			G-Csf	SS				

Date: 11/04/97 **ISR Number:** 100000148[illegible] **Report Type:** Expedited (15-Day) **Company Report#:** 97022699-1 **Age:** 67 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation	Health	Kytril (Granisetron)	PS	Smithkline Beecham	INTRAVENOUS	3 MILLIGRAMS	[illegible] DAY
	Headache	Professional	Cisplatin	C				
	Osteoarthritis		Digestive Enzyme Preparations	C				
	Pharyngitis		Doxazone Mesilate	C				
	Urinary Retention		Etoposide	C				
			Pirenzepine Hydrochloride	C				
			Trimebutine Trimaleate	C				

Date: 11/05/97 **ISR Number:** 100000162[illegible] **Report Type:** Expedited (15-Day) **Company Report#:** 97024889-1 **Age:** 68 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Health	Kytril	PS	Smithlike Beecham	ORAL		1 DAY
	Vomiting	Professional	Cisplatin	C				
			Fluorouracil	C				

Date: 11/19/97 **ISR Number:** 3001877-7 **Report Type:** Expedited (15-Day) **Company Report#:** 2715/11856 **Age:** 63 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angina Pectoris	Foreign	Solu-Medrol	PS		INTRAVENOUS	60MG/DAY;IV	
Other	Blood Creatine Phosphokinase Increased	Consumer Company	Fluorouracil	SS	Roche	INTRAVENOUS	1770 MG/DAY;IV	
	Blood Lactate Dehydrogenase Increased	Representative	Cisplatin	SS		INTRAVENOUS	177 MG/DAY;IV	
			Granisetron	SS		INTRAVENOUS	3MG/DAY;IV	

Date: 11/26/97 **ISR Number:** 3002921-3 **Report Type:** Expedited (15-Day) **Company Report#:** 97026862-1 **Age:** 49 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Laryngospasm		Kytril	PS	Smithkline Beecham	INTRAVENOUS	3MG	1 DAY
	Paraesthesia		Divina (Estradiol, Medroxyprogesterone)	C				
			Eloxatin (Oxaliplatine)	C				
			Lexomil (Bromazepam)	C				

	Solumedrol (Prednisolone)	C
	Soprol (Bisoprolol)	C

Date: 11/26/97 **ISR Number:** 3002922-5 **Report Type:** Expedited (15-Day) **Company Report#:** 97026863-1 **Age:** 65 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills		Kytril	PS	Smithkline Beecham	INTRAVENOUS	3MG	
	Disorientation		Ametycine (Mitomycine)	C				
	Hypertension		Holoxan (Ifosfamide)	C				
	Pyrexia		Uromitexan (Mesna)	C				
	Sedation							

Date: 11/26/97 **ISR Number:** 3003413-8 **Report Type:** Expedited (15-Day) **Company Report#:** 97014114-1 **Age:** 74 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaphylactic Shock	Health Professional	Kytril	PS	Smithkline Beecham	INTRAVENOUS	1 MILLIGRAMS INTRAVENOUS	30 SEC
Hospitalization - Initial or Prolonged	Brain Hypoxia		Kytril	SS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	1 DAY
	Cardio-Respiratory Arrest		Kytril	SS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	2 DAY
	Choking		Kytril	SS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	1 DAY
	Cough		Kytril	SS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	
	Encephalopathy		Kytril	SS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	1 DAY
	Fall		Kytril	SS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	1 DAY
	Myocardial Infarction		Kytril	SS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	1 DAY
	Rash Erythematous		Kytril	SS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	
	Respiratory Arrest		Kytril	SS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	1 DAY
			Kytril	SS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	1 DAY
			Kytril	SS	Smithkilne Beecham	INTRAVENOUS	INTRAVENOUS	2 DAY
			Kytril	SS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	2 DAY
			Cytoxan	C				
			Cytoxan	C				
			Cytoxan	C				
			Cytoxan	C				
			Cytoxan	C				
			Cytoxan	C				
			Cytoxan	C				
			Cytoxan	C				
			Oncovin	C				
			Oncovin	C				
			Oncovin	C				
			Oncovin	C				
			Oncovin	C				
			Oncovin	C				
			Oncovin	C				
			Oncovin	C				
			Fosamax	C				
			Zyloprim	C				
			Potassium	C				
			Vitamins	C				
			Bcnu	C				
			Bcnu	C				
			Bcnu	C				
			Aredia	C				
			Aredia	C				
			Aredia	C				
			Aredia	C				

			Aredia	C				
			Aredia	C				
			Aredia	C				
			Prednisone	C				

Date: 12/01/97 **ISR Number:** 3003437-0 **Report Type:** Expedited (15-Day) **Company Report#:** M067075 **Age:** 74 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaphylactic Reaction	Health	Cytoxan	PS		INTRAVENOUS	Q3W IV	
Life-Threatening	Cardiac Arrest	Professional	Kytril	SS		INTRAVENOUS	1 MG IV	
Hospitalization - Initial or Prolonged	Choking		Oncovin	C				
	Cough		Fosamax	C				
	Dyspnoea		Zyloprim	C				
	Encephalopathy		Potassium	C				
	Fall		Vitamins	C				
	Hypersensitivity							
	Respiratory Arrest							

Date: 12/05/97 **ISR Number:** 3007230-4 **Report Type:** Direct **Company Report#:** **Age:** 57 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination		Kytril	PS		INTRAVENOUS	1 MG IV; NDC# 0029-4149-01	
	Muscle Spasms		Adriamycin	C				
			Taxol	C				
			Benadryl	C				
			Zantac	C				
			Decadron	C				

Date: 12/09/97 **ISR Number:** 3004694-7 **Report Type:** Expedited (15-Day) **Company Report#:** M067075 **Age:** 74 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaphylactic Shock	Health	Cytoxan	PS		INTRAVENOUS	Q3W IV	6 MON
Life-Threatening	Cardiac Arrest	Professional	Kytril	SS		INTRAVENOUS	1 MG IV	
Hospitalization - Initial or Prolonged	Choking		Oncovin	C				
	Cough		Fosamax	C				
	Dyspnoea		Zyloprim	C				
	Encephalopathy		Potassium	C				
	Respiratory Arrest		Vitamins	C				

Date: 12/09/97 **ISR Number:** 3004934-4 **Report Type:** Expedited (15-Day) **Company Report#:** 2756/11856 **Age:** 49 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Interaction	Foreign	Solu-Medrol	PS		INTRAVENOUS	120 MG/DAY; IV	
Other	Potentiation	Consumer						
	Laryngospasm	Company	Oxaliplatine	SS		INTRAVENOUS	130MG/DAY IV	
	Paraesthesia	Representative	Granisetron	SS		INTRAVENOUS	3MG/DAY IV	
			Bisoprolol	C				
			Bromoxepam	C				
			Estradiol	C				
			Methylprogesterone	C				

Date: 12/15/97 **ISR Number:** 3008719-4 **Report Type:** Expedited (15-Day) **Company Report#:** 2756/11856 **Age:** 49 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Laryngospasm	Foreign	Solu-Medrol	PS		INTRAVENOUS	130 MG/SQ.M/DAY;IV	
Other	Paraesthesia	Consumer						
		Company						
		Representative	Oxaliplatine	SS		INTRAVENOUS	130 MG/DAY;IV	
			Granisetron	SS		INTRAVENOUS	3 MG/DAY;IV	
			Bisoprolol	C				
			Bromoxepam	C				
			Estradiol	C				
			Methylrogesterone	C				

Date: 12/22/97 **ISR Number:** 3013005-2 **Report Type:** Expedited (15-Day) **Company Report#:** 97028840-1 **Age:** 58 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Shock		Kytril	PS	Smithkline Beecham	INTRAVENOUS		1 DAY

Date: 12/22/97 **ISR Number:** 3013023-4 **Report Type:** Expedited (15-Day) **Company Report#:** 97027914-1 **Age:** 58 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atelectasis	Foreign	Kytril	PS		INTRAVENOUS		
	Drug Interaction	Health	Corancyl	C				
	Hypercapnia	Professional	Skenan	C				
	Hyperhidrosis		Sporanox	C				
	Hypotension							
	Lung Disorder							
	Sedation							
	Vomiting							

Date: 12/22/97 **ISR Number:** 3013027-1 **Report Type:** Expedited (15-Day) **Company Report#:** 97024749-1 **Age:** 72 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased	Health	Kytril	PS	Smithkline Beecham	INTRAVENOUS	2 MG IV	1 DAY
	Bradycardia	Professional	Metoclopramide	C				
	Chills		Pirenzepine Hydrochloride	C				
	Feeling Hot		Ringer-Lactate Solution	C				
	Hyperhidrosis							
	Hypotension							
	Pallor							
	Shock							
	Vomiting							

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

Outcome	PT
Death	Acidosis
Life-Threatening	Cholelithiasis
Hospitalization - Initial or Prolonged	Condition Aggravated
	Hepatic Failure
	Hepatitis C
	Hepatitis Fulminant

Hepatomegaly							
Hypotension							
Hypovolaemia	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Lymphadenopathy	Foreign	Carboplatin	PS		INTRAVENOUS	450 MG IV	1 DAY
Renal Atrophy	Health	Uft	SS		ORAL	200 MG PO	8 WK
Renal Impairment	Professional	Granisetron	SS		INTRAVENOUS	3-6 MG IV	3 DAY
Thrombocytopenia		Ondansetron	SS		INTRAVENOUS	4 MG IV	1 DAY
		Carbocysteine	C				
		Bromhexine	C				
		Roxithromycin	C				
		Levothyroxine Sodium	C				
		Triazolam	C				

Date: 01/13/98 **ISR Number:** 3095828-7 **Report Type:** Direct **Company Report#:** **Age:** 66 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Shock		Methotrexate	PS			65MG (40MG/M2)	
Hospitalization - Initial or Prolonged			Granisetron	SS				

Date: 01/14/98 **ISR Number:** 3016722-3 **Report Type:** Expedited (15-Day) **Company Report#:** 97029486-1 **Age:** 70 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukopenia	Health	Kytril	PS	Smithkline Beecham	ORAL	ORAL	5 DAY
	Thrombocytopenia	Professional	Cisplatin	C				
			Fluouracil	C				
			Furosemide	C				
			Mitomycin C	C				

Date: 01/14/98 **ISR Number:** 3016731-4 **Report Type:** Expedited (15-Day) **Company Report#:** 97028840-1 **Age:** 58 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaphylactic Shock		Kytril	PS	Smithkline Beecham	INTRAVENOUS		1 DAY
	Dermatitis							
	Hypotension							
	Injection Site Erythema							
	Malaise							
	Nausea							
	Syncope							

Date: 01/21/98 **ISR Number:** 3017659-6 **Report Type:** Expedited (15-Day) **Company Report#:** 97024749-1 **Age:** 72 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased	Health	Kytril	PS	Smithkline Beecham	INTRAVENOUS	2 MILLIGRAMS	1 DAY
	Chills	Professional	Metroclopramide	C				
	Feeling Hot		Pirenzepine Hydrochloride	C				
	Heart Rate Decreased		Ringer-Lactate Solution	C				
	Hyperhidrosis							
	Pallor							
	Shock							
	Vomiting							

Date: 02/09/98 **ISR Number:** 3026811-5 **Report Type:** Expedited (15-Day) **Company Report#:** 98002689-1 **Age:** 64 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Lactate Dehydrogenase Decreased Cough Neutrophilia Pharyngolaryngeal Pain	Health Professional	Kytril Carboplatin Tegafur-Uracil	PS C C	Smithkline Beecham	ORAL	1 MILLIGRAMS	23 DAY

Date: 02/09/98 **ISR Number:** 3026815-2 **Report Type:** Expedited (15-Day) **Company Report#:** 98003244-1 **Age:** 66 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ear Disorder Leukopenia	Health Professional	Kytril Carboplatin	PS C	Smithkline Beecham	ORAL		

Date: 02/11/98 **ISR Number:** 3027411-3 **Report Type:** Expedited (15-Day) **Company Report#:** 98002309-1 **Age:** 59 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Impairment	Foreign Health Professional	Kytril N/A Cisplatin Fluorouracil	PS SS C C	Smithkline Beecham	ORAL	2 MG	4 DAY

Date: 02/11/98 **ISR Number:** 3057206-6 **Report Type:** Expedited (15-Day) **Company Report#:** 98002309-1 **Age:** 59 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Failure Acute	Foreign Health Professional	Kytril Cisplatin Fluorouracil	PS C C	Smithkline Beecham	ORAL	2 MILLIGRAMS ORAL	4 DAY

Date: 02/12/98 **ISR Number:** 3028193-1 **Report Type:** Expedited (15-Day) **Company Report#:** 98003676-1 **Age:** 67 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Orthostatic Hypotension Syncope	Health Professional	Kytril Hytrin Compazine Stool Softener Cisplatin 5 Fu	PS C C C C C		ORAL	2 MILLIGRAMS DAILY ORAL	5 DAY

Date: 02/12/98 **ISR Number:** 3029343-3 **Report Type:** Expedited (15-Day) **Company Report#:** 98002689-1 **Age:** 62 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Lactate Dehydrogenase Decreased Cough Neutrophilia Pharyngolaryngeal Pain	Health Professional	Kytril Carboplatin Tegafur-Uracil	PS C C	Smithkline Beecham	ORAL	1 MILLIGRAMS	23 DAY

Date: 02/20/98 **ISR Number:** 3032608-2 **Report Type:** Expedited (15-Day) **Company Report#:** 98003980-1 **Age:** 65 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bone Marrow Depression Electrolyte Imbalance Hypoproteinaemia	Health Professional	Kytril Calcium Folinate Cisplatin Fluorouracil	PS C C C	Smithkline Beecham	ORAL	ORAL	2 DAY

Date: 02/26/98 **ISR Number:** 3037077-4 **Report Type:** Expedited (15-Day) **Company Report#:** 1997003295-1 **Age:** 75 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Shock	Foreign Health Professional	Kytril	PS	Smithkline Beecham	ORAL	3 MILLIGRAMS	1 DAY

Date: 03/04/98 **ISR Number:** 3040494-X **Report Type:** Expedited (15-Day) **Company Report#:** 1998005038-1 **Age:** 66 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukopenia Thrombocytopenia	Health Professional	Kytril Calcium Polystyrene Sulfonate Caarboplatin Frusemide Pirarubicin Hydrochloride	PS C C C C	Smithkline Beecham	ORAL	2 MG ORAL	6 DAY

Date: 03/05/98 **ISR Number:** 3047507-X **Report Type:** Expedited (15-Day) **Company Report#:** 1998000334-1 **Age:** 65 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Myelopathy Neutropenia Pneumonia Staphylococcal Infection	Health Professional	Kytril Cisplatin Epirubicin Hydrochloride Methotrexate Vinblastine Sulphate	PS C C C C	Smithkline Beecham	INTRAVENOUS	ORAL, INTRAVENOUS	5 DAY

Date: 03/19/98 **ISR Number:** 3057806-3 **Report Type:** Expedited (15-Day) **Company Report#:** 1998005895-1 **Age:** 85 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening Hospitalization - Initial or Prolonged	Bradypnoea Coma Hypercapnia Hypoventilation Loss Of Consciousness		Kytril Alpress (Prazosine) Endoxan (Cyclosphophamide) Isobar (Methylclothiazide, Triamterene) Isoptine (Verapamil)	PS C C C C	Smithkline Beecham	INTRAVENOUS	6 MILLIGRAMS	1 DAY

Date: 03/19/98 **ISR Number:** 3057808-7 **Report Type:** Expedited (15-Day) **Company Report#:** 1998006374-1 **Age:** 72 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukopenia Thrombocytopenia	Health Professional	Kytril	PS		INTRAVENOUS	3 MILLIGRAMS, INTRAVENOUS	1 DAY
			Cisplatin	C				
			Dexamethasone	C				
			Dexamethasone Sodium Phosphate	C				
			Mitomycin	C				
			Vindesine Sulfate	C				

Date: 03/24/98 **ISR Number:** 3067529-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1998006525-1 **Age:** 75 YR **Gender:** Male **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperkalaemia Leukopenia Renal Impairment Thrombocytopenia	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS	6 DAY
			Carboplatin	C				
			Dexamethasone	C				
			Dexamethasone Sodium Phosphate	C				
			Mitomycin	C				
			Vindesine Sulfate	C				

Date: 03/27/98 **ISR Number:** 3062119-X **Report Type:** Direct **Company Report#:** **Age:** 71 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Emotional Distress Hyperhidrosis Pallor Respiratory Distress		Kytril	PS	Smithkline Beecham	INTRAVENOUS	IV PUSH X / DOSE	

Date: 03/30/98 **ISR Number:** 3058178-0 **Report Type:** Expedited (15-Day) **Company Report#:** B036693 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Disability	Fibrosis Haemoglobin Decreased Pneumonia Red Blood Cell Count Decreased Thrombocytopenia	Foreign Health Professional	Cisplatin	PS		INTRAVENOUS	125 MG IV; 3 CYCLES	
			Granisetron	SS		INTRAVENOUS	3-6 MG IV; 4 CYCLES	
			Metoclopramide (Metoclopramide Hcl)	SS		INTRAVENOUS	30-10-30 MG IV; 4 CYCLES	
			Betamethasone (Bethamethasone)	SS		INTRAVENOUS	8 MG IV; 3 CYCLES	
			Uft (Tegafur Uracil)	SS		ORAL	600 MG PO; 3 CYCLES	

Date: 04/07/98 **ISR Number:** 3062380-1 **Report Type:** Expedited (15-Day) **Company Report#:** 1998007895-1 **Age:** 76 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthralgia		Kytril	PS	Smithkline Beecham	ORAL		
	Chest Pain		Cisplatine	C				
	Dyspnoea		Fluorouracile	C				
	Pain		Solu Medrol	C				
	Sensory Disturbance							

Date: 04/09/98 **ISR Number:** 3062253-4 **Report Type:** Expedited (15-Day) **Company Report#:** 1998007861-1 **Age:** 61 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperhidrosis		Granisetron	PS	Smithkline Beecham	INTRAVENOUS	1 MILLIGRAM	
	Hypotension							
	Tachycardia							

Date: 04/14/98 **ISR Number:** 3072767-9 **Report Type:** Direct **Company Report#:** **Age:** 40 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma		Kytril	PS		INTRAVENOUS	500MG X 1 IV	
	Convulsion		Tigan	SS		INTRAMUSCULAR	200MG IM Q 6H PRN	
	Cyanosis							
	Nausea		Ceftizoxine	C				
	Vomiting		Netronio	C				
			Prozac	C				
			Benadryl	C				

Date: 04/27/98 **ISR Number:** 3070693-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1998009669-1 **Age:** 50 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hiccups	Health Professional	Kytril	PS	Smithkline Beecham	INTRAVENOUS	3 MILLIGRAMS	
			Endoxan	C				
			Vebesine	C				

Date: 05/05/98 **ISR Number:** 3073708-0 **Report Type:** Expedited (15-Day) **Company Report#:** 1998010945-1 **Age:** 62 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	2 MG ORAL; 3MG IV	5 DAY
	Eczema							
	Leukopenia		Calcium Folinate	C				
	Stomatitis		Fluorouracil	C				

Date: 05/05/98 **ISR Number:** 3073722-5 **Report Type:** Expedited (15-Day) **Company Report#:** 1998010951-1 **Age:** 59 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukopenia	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	SEE TEXT**	
	Stomatitis		Carboplatin	C				
	Thrombocytopenia		Etoposide	C				

Date: 05/11/98 **ISR Number:** 3075193-1 **Report Type:** Expedited (15-Day) **Company Report#:** 1998011996-1 **Age:** 46 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Foreign	Kytril	PS	Smithkline Beecham	INTRAVENOUS	3 MILLIGRAMS	2 DAY
	Metabolic Encephalopathy		Azantac	C				
	Sedation		Debridat	C				
			Eldisine	C				
			Holoxan	C				
			Lasilix	C				
			Potassium Chlorure	C				
			Sectral	C				
			Solupred	C				
			Ulcar	C				
			Uromitexan	C				

Date: 05/11/98 **ISR Number:** 3075200-6 **Report Type:** Expedited (15-Day) **Company Report#:** 1998011174-1 **Age:** 67 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactoid Reaction	Health	Kytril	PS		ORAL	3 MILLIGRAMS	4 DAY
Other	Dyspnoea	Professional	Blood Transfusion	C				
			Cytarabine	C				
			Daunorubicin	C				
			Etoposide	C				

Date: 05/15/98 **ISR Number:** 3079312-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1988006654-1 **Age:** 46 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Health	Kytril	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS	
	Depression	Professional					ORAL	
	Suicidal Ideation		Beclazone	C				
			Corsodly	C				
			Cyclophosphamide	C				
			Fluorouracil	C				
			Maxolon	C				
			Methotrexate	C				
			Xanax	C				

Date: 05/28/98 **ISR Number:** 3083732-X **Report Type:** Expedited (15-Day) **Company Report#:** 1998012842-1 **Age:** 63 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Back Pain		Kytril	PS	Smithkline Beechem	INTRAVENOUS	3 MG	
Hospitalization - Initial or Prolonged	Blood Amylase Increased						INTRAVENOUS	3 DAY
	Nausea		Cisplatyl	C				
	Pancreatitis Acute		Holoxan	C				
	Sepsis		Vepeside	C				

Date: 05/28/98 **ISR Number:** 3084850-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1998012706-1 **Age:** 60 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Potassium Decreased	Foreign	Granisetron	PS	Smithkline Beecham	INTRAVENOUS	1 MILLIGRAM	
	Cardio-Respiratory Arrest						INTRAVENOUS	1 DAY
	Grand Mal Convulsion		Calcichew	C				
			Domperidone	C				

			Enalapril	C				
			Ferrogard	C				
			Furasemide	C				
			Gastrocote	C				

Date: 06/15/98 **ISR Number:** 3094569-X **Report Type:** Expedited (15-Day) **Company Report#:** 1998003295-1 **Age:** 75 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Decreased	Health	Kytril	PS	Smithkline Beecham	INTRAVENOUS	3 MILLIGRAMS	1 DAY
	Chest Pain	Professional	Cisplatin	C				
	Dermatitis		Cyclophosphamide	C				
	Flushing							
	Shock							

Date: 06/15/98 **ISR Number:** 3094613-X **Report Type:** Expedited (15-Day) **Company Report#:** 1998013722-1 **Age:** 50 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction	Literature	Granisetron	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	
	Dyspnoea		Carboplatin	C				
	Hypotension		Glucosaline	C				
	Loss Of Consciousness		Methylprednisolone	C				
	Pruritus		Paclitaxel	C				

Date: 06/15/98 **ISR Number:** 3094620-7 **Report Type:** Expedited (15-Day) **Company Report#:** 1998011174-1 **Age:** 67 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactoid Reaction	Health	Kytril	PS	Smithkline Beecham	INTRAVENOUS	3 MILLIGRAMS	
Hospitalization -	Cyanosis	Professional					INTRAVENOUS	4 DAY
Initial or Prolonged	Dyspnoea		Blood Transfusion	C				
Other			Cefoperazone Sodium-Sulbactam Sodium	C				
			Daunorubicin Hydrochloride	C				
			Endocitabine	C				
			Etoposide	C				

Date: 06/15/98 **ISR Number:** 3094992-3 **Report Type:** Expedited (15-Day) **Company Report#:** 1998014443-1 **Age:** 60 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hepatic Enzyme Increased	Health	Kytril	PS		INTRAVENOUS	12 MILLIGRAMS	
Initial or Prolonged	Hepatic Trauma	Professional					INTRAVENOUS	
	Prothrombin Time Ratio Decreased		Raniplex	C				
			Temegic	C				
			Flagyl	C				
			Forene	C				
			Oflocet	C				
			Primperan	C				
			Pro-Dafalgan	C				

Date: 06/15/98 **ISR Number:** 3094996-0 **Report Type:** Expedited (15-Day) **Company Report#:** 1998006525-1 **Age:** 75 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperkalaemia	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS ORAL	
	Leukopenia							
	Renal Impairment		Carboplatin	C				
	Thrombocytopenia		Dexamethason	C				
			Dexamethason Sodium Phosphate	C				
			Vindesine Sulfate	C				

Date: 06/16/98 **ISR Number:** 3094572-X **Report Type:** Expedited (15-Day) **Company Report#:** 1998002689-1 **Age:** 62 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Lactate Dehydrogenase Decreased	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	1 MILLIGRAMS ORAL	23 DAY
	Cough		Carboplatin	C				
	Neutrophilia		Hot Water Extracts Of Mycobacterium Tuberculosis	C				
	Pharyngolaryngeal Pain		Tegafur-Uracil	C				
			Vitamin A	C				

Date: 06/16/98 **ISR Number:** 3094574-3 **Report Type:** Expedited (15-Day) **Company Report#:** 1998013719-1 **Age:** 40 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Leukopenia	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS ORAL	2 DAY
			Cyclophosphamide	C				
			Epirubicin Hydrochloride	C				
			Fluorouracil	C				
			Medroxyprogesterone Acetate	C				
			Ondansetron Hydrochloride	C				

Date: 06/17/98 **ISR Number:** 3094566-4 **Report Type:** Expedited (15-Day) **Company Report#:** 1998014647-1 **Age:** 42 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Liver Function Test Abnormal		Kytril	PS	Smithkline Beecham	INTRAVENOUS	3 MILLIGRAMS	
			Gemzar	C				

Date: 06/19/98 **ISR Number:** 3096808-8 **Report Type:** Expedited (15-Day) **Company Report#:** 199811081RHF **Age:** 63 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuropathy Peripheral	Foreign Other	Furosemide	PS		INTRAVENOUS	40 MG QD IV	1 DAY
			Ifosfamide	SS		INTRAVENOUS	5250 MG IV	1 DAY
			Cisplatin	SS		INTRAVENOUS	140 MG IV	1 DAY
			Vinorelbine Ditartrate	SS		INTRAVENOUS	43.7 MG IV	1 DAY
			Granisetron	SS		INTRAVENOUS	3 MG IV	1 DAY

Date: 06/23/98 **ISR Number:** 3097335-4 **Report Type:** Direct **Company Report#:** **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Bradycardia Hypotension	Health Professional	Kytril	PS		ORAL	2 MG PO D1-3 CHEMO	

Date: 06/25/98 **ISR Number:** 3098538-5 **Report Type:** Expedited (15-Day) **Company Report#:** 100867 **Age:** 74 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated Hypokalaemia Hyponatraemia	Foreign Health Professional Other	Bactrim Forte	PS		ORAL	960 MG 1 X PER DAY ORAL	
			Bactrim	SS		INTRAVENOUS	2 DOSE FORM 1 X PER DAY INTRAVENOUS	
			Atacand	SS		ORAL	16 MG 1 X PER DAY ORAL	
			Anafranil	SS			25 MG 1 X PER DAY	
			Haldol	SS		ORAL	2 DROP 3 X PER DAY ORAL	
			Paspertin	SS		INTRAVENOUS	30 MG DAILY 1 X PER CONTINUOUS INTRAVENOUS	
			Minalgin	SS		INTRAVENOUS	10 MG DAILY 1 X PER DAY CONTINUOUS INTRAVENOUS	
			Kytril	SS		INTRAVENOUS	1 MG 2 X PER DAY INTRAVENOUS	
			Pethidin	SS		INTRAVENOUS	100 MG DAILY 1 X PER DAY CONTINUOUS INTRAVENOUS	
			Antra	C				
			Marcoumar	C				
			Tramadolor	C				
			Treuphadol	C				
			Halcion	C				
			Collunosol-N	C				

Date: 06/26/98 **ISR Number:** 3099891-9 **Report Type:** Expedited (15-Day) **Company Report#:** 1998015330-1 **Age:** 63 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuropathy Peripheral		Kytril	PS	Smithkline Beecham	INTRAVENOUS	3 MILLIGRAMS INTRAVENOUS	1 DAY
			Cisplatine	C				
			Holoxan	C				
			Lasilix	C				
			Navelbine	C				

Date: 06/30/98 **ISR Number:** 3100246-9 **Report Type:** Expedited (15-Day) **Company Report#:** 1998014443-1 **Age:** 50 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Depressed Level Of Consciousness	Health Professional	Kytril (Granisetron)	PS	Smithkline Beecham	INTRAVENOUS	12 MILLIGRAMS	
Hospitalization - Initial or Prolonged	Hepatic Enzyme Increased						INTRAVENOUS	9 DAY
Other	Hepatitis		Ciflox (Ciprofloxacine)	C				
	Prothrombin Level Decreased		Flagyl (Metronidazole)	C				
			Forene	C				
			Primperan (Metoclopramide)	C				
			Pro-Dafalgan (Propacetamol)	C				
			Raniplex (Rantidine)	C				
			Temgesic (Buprenorphine)	C				

Date: 07/02/98 **ISR Number:** 3101644-X **Report Type:** Expedited (15-Day) **Company Report#:** B039474 **Age:** 66 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea	Foreign Health Professional	Glucophage	PS		ORAL	1700 MG QD ORAL	
			Primperan (Metoclopramide Hcl)	SS		OTHER	INJECTION	
			Daonil (Glyburide)	SS		ORAL	1.25 MG QD ORAL	
			Renitec (Enalapril Maleate)	SS		ORAL	ORAL	
			Granisetron	SS		INTRAVENOUS	IV	
			Elvorine (Calcium Levofolinate)	SS		UNKNOWN	UNKNOWN	
			5-Fl (Fluorouracil)	SS		UNKNOWN	UNKNOWN	

Date: 07/08/98 **ISR Number:** 3103177-3 **Report Type:** Expedited (15-Day) **Company Report#:** 1998015937-1 **Age:** 23 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthralgia	Foreign Health Professional	Kytril	PS	Smithkline Beecham	INTRAMUSCULAR	5 MILLIGRAMS	
							INTRAMUSCULAR	288 DAY
			Cortancyl	C				
			Endoxan	C				
			Mesna	C				
			Mopral	C				

Date: 07/10/98 **ISR Number:** 3103830-1 **Report Type:** Expedited (15-Day) **Company Report#:** 1997027914-1 **Age:** 58 YR **Gender:** Female **I/FU:** F

Outcome	PT
Death	Atelectasis
Hospitalization - Initial or Prolonged	Hypercapnia
	Hyperhidrosis
	Hypotension
	Lung Disorder
	Mucous Membrane Disorder
	Respiratory Failure
	Sedation

Vomiting

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health	Kytril	PS		INTRAVENOUS	3 MILLIGRAMS	
Professional	Cortancyl	C				
	Skenan	C				
	Sporanox	C				

Date: 07/17/98 **ISR Number:** 3106264-9 **Report Type:** Expedited (15-Day) **Company Report#:** FR02-09188 **Age:** 55 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dermatitis	Foreign	Taxotere	PS		INTRAVENOUS	MONTHLY IV	
Initial or Prolonged	Eczema	Health	Dexamethasone	SS		ORAL	MONTHLY PO	
	Mouth Ulceration	Professional	Kytril	SS		INTRAVENOUS	MONTHLY IV	

Date: 07/24/98 **ISR Number:** 3108921-7 **Report Type:** Expedited (15-Day) **Company Report#:** 19980159371 **Age:** 23 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Arthralgia		Kytril	PS	Smithkline Beecham	INTRAMUSCULAR	5 MILLIGRAMS	1 DAY
Initial or Prolonged	Arthropathy		Cortancyl	C				
	Bone Infection		Endoxan	C				
	Infarction		Mesna	C				
	Mixed Connective Tissue Disease		Mopral	C				
	Myalgia							
	Necrosis							
	Pain							
	Sacroiliitis							

Date: 07/30/98 **ISR Number:** 3112765-X **Report Type:** Expedited (15-Day) **Company Report#:** 1998018696-1 **Age:** 61 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Alkaline		Kytril	PS		INTRAVENOUS	INTRAVENOUS	3 DAY
Initial or Prolonged	Phosphatase Increased		Dogmatil	C				
	Rhabdomyolysis		Endoxan	C				
			Farmorubicine	C				
			Fluorouracil	C				
			Mopral	C				

Date: 07/30/98 **ISR Number:** 3112766-1 **Report Type:** Expedited (15-Day) **Company Report#:** 1998018721-1 **Age:** 55 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dermatitis		Kytril	PS		INTRAVENOUS	3 MILLIGRAM INTRAVENOUS	
Initial or Prolonged	Dermatitis Bullous							
	Eczema		Dexamethasone	C				
	Mouth Ulceration		Taxotere	C				
	Rash Pustular							

Date: 08/03/98 **ISR Number:** 3112283-9 **Report Type:** Expedited (15-Day) **Company Report#:** 199807299-2 **Age:** 63 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bone Marrow Depression	Health	Kytril	PS	Smithkilne Beecham	ORAL	3 MILLIGRAMS	
Hospitalization - Initial or Prolonged	Haemoglobin Decreased	Professional	Actrapid	C				
	Leukopenia		Hycamtin	C				
	Pyrexia		Solumedrol	C				
	Sepsis							
	Thrombocytopenia							

Date: 08/10/98 **ISR Number:** 3114853-0 **Report Type:** Expedited (15-Day) **Company Report#:** 1998019249-1 **Age:** 54 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aspartate	Health	Kytril	PS	Smithkline Beecham	ORAL	ORAL	5 DAY
	Aminotransferase	Professional	Docetaxel Hydrate	C				
	Increased		Fadrozole					
	Blood Lactate		Hydrochloride					
	Dehydrogenase Increased		Hydrate	C				
	Leukopenia		Medroxyprogesterone					
			Acetate	C				
			Ramosetron					
			Hydrochloride	C				
			Toremifene Citrate	C				

Date: 08/10/98 **ISR Number:** 3116713-8 **Report Type:** Expedited (15-Day) **Company Report#:** 1998019570-1 **Age:** 48 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haemoglobin Decreased	Health	Kytril	PS		INTRAVENOUS	3 MILLIGRAMS	
	Leukopenia	Professional					INTRAVENOUS	1 DAY
	Neutropenia		Docetaxal Hydrate	C				
			Teprenone	C				

Date: 08/11/98 **ISR Number:** 3115401-1 **Report Type:** Expedited (15-Day) **Company Report#:** 1998019252-1 **Age:** 75 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia	Health	Kytril	PS	Smithkline Beecham	ORAL	ORAL	5 DAY
	Leukopenia	Professional	Azasetron					
	Thrombocytopenia		Hydrochloride	C				
			Cyclophosphamide	C				
			Fluorouracil	C				
			Pirarubicin					
			Hydrochloride	C				
			Toremifene Citrate	C				

Date: 08/13/98 **ISR Number:** 3116706-0 **Report Type:** Expedited (15-Day) **Company Report#:** 1998019365-1 **Age:** 64 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Leukopenia	Health	Kytril	PS			INTRAVENOUS	
		Professional					ORAL	
			Docetaxal Hydrate	C				
			Hydrocortisone					
			Sodium Succinate	C				

Date: 08/13/98 **ISR Number:** 3116710-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1998019366-1 **Age:** 46 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Health	Kytril	PS			INTRAVENOUS	
	Leukopenia	Professional					ORAL	
	Neutropenia		Docetaxel Hydrate	C				
			Goserlin Acetate	C				

Date: 08/25/98 **ISR Number:** 3121759-X **Report Type:** Expedited (15-Day) **Company Report#:** 1998019283-1 **Age:** 65 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Condition Aggravated	Health	Kytril	PS	Smithkline Beecham	INTRAVENOUS	9 MILLIGRAMS	
	Drug Ineffective	Professional					INTRAVENOUS	2 DAY
	Dyskinesia		Laroxyl					
	Nausea		(Amitriptyline)	C				
	Vipoma		Pro-Dafalgan					
	Vomiting		(Proparacetamol)	C				
			Sandostatine					
			(Octreotide)	C				
			Zophren					
			(Ondansetron)	C				

Date: 09/01/98 **ISR Number:** 3124864-7 **Report Type:** Expedited (15-Day) **Company Report#:** 1998021278-1 **Age:** 74 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cystitis Haemorrhagic		Kytril	PS	Smithkline Beecham	INTRAVENOUS	3 MILLIGRAMS	
			Paraplatine					
			(Carboplatine)	C				
			Vepeside (Etoposide)	C				

Date: 09/15/98 **ISR Number:** 3130223-3 **Report Type:** Expedited (15-Day) **Company Report#:** 1998019570-1 **Age:** 48 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haemoglobin Decreased	Health	Kytril	PS	Smithkline Beecham	INTRAVENOUS	3 MILLIGRAMS	
	Leukopenia	Professional					INTRAVENOUS;	
	Neutropenia						ORAL	3 DAY
			Docetaxal Hydrate	C				
			Teprenone	C				

Date: 09/23/98 **ISR Number:** 3134338-5 **Report Type:** Expedited (15-Day) **Company Report#:** 199801443-1 **Age:** 50 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hepatitis	Health	Kytril	PS	Smithkline Beecham	INTRAVENOUS	12 MILLIGRAMS	
Hospitalization - Initial or Prolonged	Liver Function Test	Professional					INTRAVENOUS	9 DAY
	Abnormal		Ciflox	C				
	Prothrombin Level		Flagyl	C				
	Abnormal		Forene	C				
			Primperan	C				
			Pro-Dafalgan	C				
			Raniplex	C				
			Temgesic	C				

Date: 09/30/98 **ISR Number:** 3136497-7 **Report Type:** Expedited (15-Day) **Company Report#:** 1998023379-1 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	ORAL	3 DAY
			Calcium Folinate	C				
			Cisplatin	C				
			Fluorouracil	C				
			Metoclopramide	C				

Date: 10/09/98 **ISR Number:** 3141211-5 **Report Type:** Expedited (15-Day) **Company Report#:** 1998023939-1 **Age:** 61 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS	
	Hepatic Function Abnormal						ORAL	4 DAY
	Jaundice		Azasetron Hydrochloride	C				
			Doxorubicin Hydrochloride	C				
			Fluorouracil	C				
			Heparin	C				

Date: 10/14/98 **ISR Number:** 3141280-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1998024401-1 **Age:** 57 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness		Kytril	PS	Smithkline Beecham	INTRAVENOUS	3 MILLIGRAMS INTRAVENOUS	
	Dyskinesia		Cyclophosphamide	C				

Date: 10/14/98 **ISR Number:** 3141282-6 **Report Type:** Expedited (15-Day) **Company Report#:** 1998023379-1 **Age:** 53 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	ORAL	3 DAY
	Hyperacusis		Calcium Folinate	C				
			Cisplatin	C				
			Fluorouracil	C				
			Metoclopramide	C				

Date: 10/14/98 **ISR Number:** 3141288-7 **Report Type:** Expedited (15-Day) **Company Report#:** 1998024217-1 **Age:** 62 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	4 MILLIGRAMS	
	Leukopenia						ORAL	4 DAY
	Thrombocytopenia		Cyclophosphamide	C				
			Doxorubicin Hydrochloride	C				
			Loxoprofen Sodium	C				
			Roxatidine Acetate Hydrochloride	C				
			Teprenone	C				
			Vincristine Sulfate	C				

Date: 10/14/98 **ISR Number:** 3141290-5 **Report Type:** Expedited (15-Day) **Company Report#:** 1998020255-1 **Age:** 47 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hypotension	Health Professional	Kytril	PS		INTRAVENOUS	3 MILLIGRAMS INTRAVENOUS AND ORAL	
Hospitalization - Initial or Prolonged			Cyclophosphamide	C				
			Fluorouracil	C				
			Methotrexate	C				

Date: 10/21/98 **ISR Number:** 3144496-4 **Report Type:** Expedited (15-Day) **Company Report#:** 1998024401-1 **Age:** 57 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Reaction		Kytril	PS	Smithkline Beecham	INTRAVENOUS	3MILLIGRAMS INTRAVENOUS	
Hospitalization - Initial or Prolonged	Blood Pressure Decreased							
	Coma		Cyclophosphamide	C				
	Depressed Level Of Consciousness							
	Dyskinesia							

Date: 10/29/98 **ISR Number:** 3149583-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1998025290-1 **Age:** 52 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Headache		Kytril (Granisetron)	PS	Smithkline Beecham	ORAL	ORAL	3 DAY
	Leukopenia		Carboplatin	C				
	Peritoneal Disorder		Dexamethasone	C				
			Diphenhydramine	C				
			Docetaxel Hydrate	C				
			Ranitidine Hydrochloride	C				

Date: 11/02/98 **ISR Number:** 3155937-0 **Report Type:** Expedited (15-Day) **Company Report#:** 1998026016-1 **Age:** 68 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Faecal Incontinence	Health Professional	Kytril	PS		ORAL	2 MILLIGRAMS ORAL	4 DAY
	Fall		Carboplatin	C				
	Leukopenia		Dexamethasone Acetate	C				
	Sepsis		Dephenhydramine Tannate	C				
	Thrombocytopenia		Docetaxel Hydrate	C				
			Rantidine Hydrochloride	C				

Date: 11/16/98 **ISR Number:** 3158351-7 **Report Type:** Expedited (15-Day) **Company Report#:** 1998026763-1 **Age:** 73 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukopenia	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS, ORAL	10 DAY
			Fluorouracil	C				

Date: 11/16/98 **ISR Number:** 3158353-0 **Report Type:** Expedited (15-Day) **Company Report#:** 1998027068-1 **Age:** 81 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neutropenia Thrombocytopenia	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS ORAL	5 DAY
			Cisplatin	C				
			Fluorouracil	C				

Date: 11/17/98 **ISR Number:** 3162312-1 **Report Type:** Expedited (15-Day) **Company Report#:** 1998026814-1 **Age:** 52 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Bowel Sounds Abnormal Fistula Ileus Paralytic Metastases To Bone	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS	5 DAY
			Cefotiam Hydrochloride	C				
			Cisplatin	C				
			Famotidine	C				
			Irinotecan Hydrochloride (Irinotecan)	C				
			Metoclpramide	C				
			Ondanesetron Hydrochloride (Ondansetron)	C				
			Sodium Bicarbonate	C				

Date: 11/24/98 **ISR Number:** 3162313-3 **Report Type:** Expedited (15-Day) **Company Report#:** 1998026883-1 **Age:** 65 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dysthymic Disorder Myocardial Infarction	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS	1 DAY
			Cisplatin	C				
			Famotidine	C				
			Furosemide	C				
			Irinotecan Hydrochloride	C				
			Sodium Bicarbonate	C				

Date: 12/10/98 **ISR Number:** 3169074-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1998029008-1 **Age:** 70 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Leukopenia Thrombocytopenia	Health Professional	Kytril (Granisetron) Smithkline Beecham	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS ORAL	6 DAY
			Domperidone	C				
			Furosemide	C				
			Irinotecan Hydrochloride	C				
			Nedaplatin	C				
			Ramosetron Hydrochloride	C				

Date: 12/10/98 **ISR Number:** 3169076-6 **Report Type:** Expedited (15-Day) **Company Report#:** 1998028717-1 **Age:** 75 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Clostridium Colitis Diarrhoea	Health Professional	Kytril (Granisetron) Smithkline Beecham	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS ORAL	2 DAY
			Ceftazidime	C				
			Nedaplatin	C				
			Piperacillin Sodium	C				

Date: 12/10/98 **ISR Number:** 3169120-6 **Report Type:** Expedited (15-Day) **Company Report#:** 1998026814-1 **Age:** 52 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Breath Sounds Decreased	Health	Kytril (Granisetron)	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS	
Hospitalization - Initial or Prolonged	Condition Aggravated	Professional					ORAL	5 DAY
	Ileus Paralytic		Cefotiam					
	Metastases To Bone		Hydrochloride	C				
	Metastatic Neoplasm		Cisplatin	C				
	Vesical Fistula		Famotidine	C				
			Irinotecan					
			Hydrochloride	C				
			Metoclopramide	C				
			Ondanesetron					
			Hydrochloride	C				
			Sodium Bicarbonate	C				

Date: 12/10/98 **ISR Number:** 3169148-6 **Report Type:** Expedited (15-Day) **Company Report#:** 1998028689-1 **Age:** 66 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bone Marrow Depression	Health	Kytril	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS	
	C-Reactive Protein	Professional					ORAL	3 DAY
	Increased		Betamethasone	C				
	Hepatic Function Abnormal		Carboplatin	C				
	Pyrexia		Etopside	C				

Date: 12/10/98 **ISR Number:** 3169211-X **Report Type:** Expedited (15-Day) **Company Report#:** 1998025290-1 **Age:** 52 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Ascites		Kytril					
Hospitalization - Initial or Prolonged	Headache		(Granisetron)	PS	Smithkline Beecham	ORAL	ORAL	3 DAY
	Leukopenia		Carboplatin	C				
			Dexamethasone	C				
			Diphenhydramine	C				
			Docetaxel Hydrate	C				
			Ranitidine					
			Hydrochlkoride	C				

Date: 12/10/98 **ISR Number:** 3169212-1 **Report Type:** Expedited (15-Day) **Company Report#:** 1998028707-1 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Flushing	Health Professional	Kytril (Granisetron)	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	12 DAY
			Cisplatin	C				
			Picibanil	C				

			Tegafur	C				

Date: 12/14/98 **ISR Number:** 3171324-3 **Report Type:** Expedited (15-Day) **Company Report#:** 1998029976-1 **Age:** 64 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Gastric Ulcer Haemorrhage Haematemesis Metastasis	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	4 MG ORAL/ CONTINUOUS INTRAVENOUS	5 DAY
			Cisplatin	C				
			Dexamethasone	C				
			Furosemide	C				
			Vindesine Sulphate	C				

Date: 12/15/98 **ISR Number:** 3171295-X **Report Type:** Expedited (15-Day) **Company Report#:** 1998029816-1 **Age:** 73 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Neutropenia	Health Professional	Kytril	PS	Smithkline Beecham	INTRAVENOUS	3 MILLIGRAMS	
			Carboplatiin	C				
			Dexamethasone	C				
			Paclitaxel (Taxol)	C				
			Ranitidine Hydrochloride	C				

Date: 12/15/98 **ISR Number:** 3171337-1 **Report Type:** Expedited (15-Day) **Company Report#:** 1998029817-1 **Age:** 50 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Liver Function Test Abnormal Thrombocytopenia	Health Professional	Kytril	PS	Smithkline Beecham	INTRAVENOUS	CONTINUOUS INTRAVENOUS; 2 MILLIGRAMS; ORAL	6 DAY
			Bleomycin Sulphate	C				
			Cisplatin	C				
			Dexamethasone	C				
			Droperidol	C				
			Etopside	C				
			Fosfomycine	C				
			Furosemide	C				
			Ranitidine Hydrochloride	C				

Date: 12/17/98 **ISR Number:** 3171566-7 **Report Type:** Expedited (15-Day) **Company Report#:** 1998029549-1 **Age:** 61 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Thrombocytopenia	Health Professional	Kytril	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	6 DAY
			Cisplatin	C				
			Fluorouracil	C				
			Fosfomycin	C				

Date: 12/17/98 **ISR Number:** 3171570-9 **Report Type:** Expedited (15-Day) **Company Report#:** 1998029542-1 **Age:** 50 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neutropenia	Health	Kytril	PS	Smithkline Beecham	INTRAVENOUS	CONTINUOUS	
	Thrombocytopenia	Professional					INTRAVENOUS	
			Carboplatin	C				
			Dexamethasone	C				
			Diphenhydramine	C				
			Mirimostim	C				
			Paclitaxel	C				
			Ranitidine Hydrochloride	C				

Date: 12/17/98 **ISR Number:** 3172351-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1998030065-1 **Age:** 50 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Function Abnormal	Foreign	Kytril	PS	Smitkline Beecham		2 MG ORAL	5 DAY
	Liver Function Test Abnormal	Health Professional	Carboplatin	C				
			Dexamethasone	C				
			Paclitaxel	C				
			Phosphomycin	C				

Date: 12/17/98 **ISR Number:** 3172352-4 **Report Type:** Expedited (15-Day) **Company Report#:** 1998030087-1 **Age:** 46 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Function Abnormal	Health Professional	Kytril	PS			2 MG ORAL	5 DAY
			Carboplatin	C				
			Dexamethasone	C				
			Paclitaxel	C				

Date: 12/21/98 **ISR Number:** 3172665-6 **Report Type:** Expedited (15-Day) **Company Report#:** 1998030010-1 **Age:** 70 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Function Abnormal	Health Professional	Kytril	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	5 DAY
	Leukopenia Thrombocytopenia		Kytril	SS	Smithkline Beecham	ORAL	ORAL	2 DAY
			Cisplatin	C				
			Diltiazem Hydrochloride	C				
			Etoposide	C				
			Lansoprazole	C				
			Theophylline	C				
			Triazolam	C				

Date: 12/23/98 **ISR Number:** 3176382-8 **Report Type:** Expedited (15-Day) **Company Report#:** 1998028707-1 **Age:** 75 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Hypersensitivity	Health Professional	Kytril	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	12 DAY
	Pruritus		Cisplatin	C				
	Rash Erythematous		Picibanil	C				
			Tegafur	C				

Date: 01/05/99 **ISR Number:** 3178125-0 **Report Type:** Expedited (15-Day) **Company Report#:** 1998030855-1 **Age:** 50 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthralgia		Kytril	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	8 DAY
	Blood Bilirubin Increased		Amlor	C				
	Hepatitis		Antilymphocitic Serum	C				
	Pyrexia		Debridat	C				
	Sepsis		Imovane	C				
	Serum Sickness		Lasilix	C				
			Neoral	C				
			Neupogen	C				
			Polaramine	C				
			Pro-Dafalgan	C				
			Solu-Medrol	C				
			Sorbitol	C				

Date: 01/13/99 **ISR Number:** 3183650-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1998028717-1 **Age:** 75 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Clostridium Colitis	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	2 MG, ORAL	2 DAY
	Diarrhoea		Ceftazidime	C				
			Nedaplatin	C				
			Piperacillin Sodium	C				

Date: 01/19/99 **ISR Number:** 3181951-5 **Report Type:** Expedited (15-Day) **Company Report#:** 1999000154-1 **Age:** 65 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Attention Deficit/Hyperactivity Disorder	Health Professional	Granisetron	PS	Smithkline Beecham			1 DAY
	Balance Disorder		Prochlorperazine	C				
	Coordination Abnormal							
	Drug Effect Decreased							
	Hyporeflexia							
	Tremor							

Date: 01/19/99 **ISR Number:** 3181952-7 **Report Type:** Expedited (15-Day) **Company Report#:** 1999000038-1 **Age:** 56 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Thrombocytopenia	Health Professional	Granisetron	PS	Smithkline Beecham	INTRAVENOUS	2 MILLIGRAMS	6 DAY
			Ascorbic Acid	C				
			Carboplatin	C				
			Cisplatin	C				

Date: 01/19/99 **ISR Number:** 3182332-0 **Report Type:** Expedited (15-Day) **Company Report#:** 1999000049-1 **Age:** 34 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Chloride Decreased	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	ORAL	6 DAY
	Blood Potassium Decreased		Ascorbic Acid	C				
	Blood Sodium Decreased		Cisplatin	C				
	Electrolyte Imbalance		Epirubicin	C				
	Leukopenia							

Date: 01/29/99 **ISR Number:** 3188597-3 **Report Type:** Expedited (15-Day) **Company Report#:** F/99/00039/SIM03 **Age:** 50 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	Hepatitis Cholestatic Liver Function Test Abnormal		Neoral Pro Dafalgan Kytril Solu-Medrol Neupogen	PS SS SS C C		ORAL INTRAVENOUS	ORAL 6 G INTRAVENOUS	

Date: 02/09/99 **ISR Number:** 3194441-0 **Report Type:** Expedited (15-Day) **Company Report#:** 1268/11153 **Age:** 55 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Neutropenia	Foreign Consumer Company Representative	Medrol Tablets (4 Mg) Pamidronique Acid (Aredia) 30 Mg Docetaxel (Taxotere) (80 Mg) Granisetron (Kytril) Paroxetene Fluticasone Levothyroxine Loflazepate Ethyl	PS SS SS SS C C C C		ORAL INTRAVENOUS INTRAVENOUS INTRAVENOUS	16 MG-3Q1DY; ORAL 30 MG-3Q1DY;IV 80 MG-2Q1DY; IV IV	

Date: 02/12/99 **ISR Number:** 3198098-4 **Report Type:** Expedited (15-Day) **Company Report#:** 1999002898-1 **Age:** 38 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium Depressed Level Of Consciousness Dizziness Mydriasis Visual Disturbance	Health Professional	Kytril (Granisetron) Smithkline Beecham Cisplatin Huscode (Dihydrocodeine Phosphate) Metoclopramide Morphine Sulphate	PS C C C C	Smithkline Beecham	INTRAVENOUS		1 DAY

Date: 02/22/99 **ISR Number:** 3205267-3 **Report Type:** Expedited (15-Day) **Company Report#:** 1999003277-1 **Age:** 58 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Blood Creatinine Increased Blood Potassium Increased Blood Urea Increased Haemodialysis Oliguria Renal Failure Acute	Health Professional	Kytril (Granisetron) Smithkline Beecham	PS	Smithkline Beecham	ORAL	ORAL	3 DAY

Date: 03/01/99 **ISR Number:** 3417473-3 **Report Type:** Periodic **Company Report#:** M080279 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Reaction	Health Professional	Taxol	PS	Bristol Myers Squibb Co Pharmaceutical Research Institute	INTRAVENOUS	337 MG IV CONTINUING 1 CYCLES	
			Benadryl	SS		INTRAVENOUS	50MG IV I CYCLES	
			Tagamet	SS		INTRAVENOUS	300MG IV 1 CYCLES	
			Kytril	SS		INTRAVENOUS	1 MG IV 1 CYCLES	
			Decadron	SS		INTRAVENOUS	20 MG IV 1 CYCLES	

Date: 03/01/99 **ISR Number:** 3440159-6 **Report Type:** Periodic **Company Report#:** 1998007051-1 **Age:** 9 MON **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Crying	Health Professional	Kytril Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	200 MICROGRAMS 1.0 DAILY INTRAVENOUS	1 DAY
	Flushing		Kytril Smithkline Beecham	SS	Smithkline Beecham		1.0 DAILY	1 DAY
			Kytril Smithkline Beecham	SS	Smithkline Beecham		1.0 DAILY	1 DAY
			Etoposide	C				
			Normal Saline	C				

Date: 03/01/99 **ISR Number:** 3440161-4 **Report Type:** Periodic **Company Report#:** 1998007052-1 **Age:** 14 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Feeling Jittery	Health Professional	Kytril Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	1.0 DAILY INTRAVENOUS	1 DAY
	Flushing							
	Hyperhidrosis							
	Retching		Kytril Smithkline Beecham	SS	Smithkline Beecham			
			Vincristine	C				
			Methotrexate	C				

Date: 03/01/99 **ISR Number:** 3440164-X **Report Type:** Periodic **Company Report#:** 1998007054-1 **Age:** 10 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anxiety	Health Professional	Kytril Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	1 MILLIGRAMS 1.0 DAILY INTRAVENOUS	1 DAY
	Feeling Jittery							
	Flushing							
	Nausea							
	Vomiting		Kytril Smithkline Beecham	SS	Smithkline Beecham			
			Kytril Smithkline Beecham	SS	Smithkline Beecham			
			Kytril Smithkline					

			Beecham	SS	Smithkline Beecham			1	DAY
			Methotrexate	C					
			Vincristine	C					

Date: 03/01/99 **ISR Number:** 3440168-7 **Report Type:** Periodic **Company Report#:** 1998009318-1 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Migraine	Health Professional	Kytril Smithkline Beecham	PS	Smithkline Beecham			
			Kytril Smithkline Beecham	SS	Smithkline Beecham	INTRAVENOUS	100 MICROGRAMS INTRAVENOUS	
			Kytril Smithkline Beecham	C	Smithkline Beecham	INTRAVENOUS	100 MICROGRAMS 1.0 DAILY INTRAVENOUS	
			Cytoxan (Cyclophosphamide)	C				
			Methotrexate	C				
			5fu (Fluorouracil)	C				

Date: 03/01/99 **ISR Number:** 3440170-5 **Report Type:** Periodic **Company Report#:** 1998010930-1 **Age:** 50 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anxiety	Health Professional	Kytril Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	1 DAY
	Blood Pressure Increased		Kytril Smithkline Beecham	SS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	1 DAY
	Dyspnoea		Doxorubicin	C				
	Tremor		Cyclophosphamide	C				
			Coumadin (Warfarin)	C				
			Septra (Sulfamethoxazole/Trimetho)	C				
			Mexiletine	C				
			Pepcid (Famotidine)	C				

Date: 03/01/99 **ISR Number:** 3440181-X **Report Type:** Periodic **Company Report#:** 1998010964-1 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective	Consumer	Kytril Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	1 MILLIGRAMS 1.0 DAILY INTRAVENOUS	7 DAY
	Nausea		Adriamycin (Doxorubicin)	C				

Date: 03/01/99 **ISR Number:** 3440184-5 **Report Type:** Periodic **Company Report#:** 1998022122-1 **Age:** 52 YR **Gender:** Female **I/FU:** I

Outcome	PT
	Micturition Urgency
	Pain

Urinary Retention

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional	Kytril Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	1 MILLIGRAMS INTRAVENOUS	
	Kytril Smithkline Beecham	SS	Smithkline Beecham	ORAL	1 MILLIGRAMS 2.0 DAILY ORAL	3 DAY
	Taxol	C				
	Carboplatin	C				
	Benadryl (Diphenhydramine)	C				
	Tagamet (Cimetidine)	C				
	Compazine (Prochlorperazine)	C				
	Ativan (Lorazepam)	C				
	Ms Contin (Morphine Sulfate)	C				
	Decadron (Dexamethasone)	C				
	Gemzar (Gemcitabine Hydrochloride)	C				
	Zofran (Ondansetron Hydrochloride)	C				
	Duragesic Patch (Fentanyl Citrate)	C				

Date: 03/01/99 **ISR Number:** 3440195-X **Report Type:** Periodic **Company Report#:** 1998022131-1 **Age:** 47 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dermatitis Urticaria	Health Professional	Kytril Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	6 DAY
			Kytril Smithkline Beecham	SS	Smithkline Beecham	ORAL	ORAL	6 DAY
			Premarin (Estrogens Conjugated)	C				
			Taxol	C				
			Carboplatin	C				
			Senokot S (Ducusate Sodium And Senna)	C				

Date: 03/01/99 **ISR Number:** 3440197-3 **Report Type:** Periodic **Company Report#:** 1998023611-1 **Age:** 52 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Palmar-Plantar Erythrodysaesthesia Syndrome	Consumer	Kytril Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	1.0 DAILY INTRAVENOUS	5 DAY
			Carboplatin	C				

Date: 03/01/99 **ISR Number:** 3440209-7 **Report Type:** Periodic **Company Report#:** 1998028466-1 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	International Normalised Ratio Increased	Health Professional	Kytril Smithkline Beecham	PS	Smithkline Beecham			
			Coumadin (Warfarin Sodium)	C				
			Decadron (Dexamethasone)	C				
			Vincristine	C				
			Bcnu (Carmustine)	C				
			Cyclophosphamide	C				

Date: 03/02/99 **ISR Number:** 3210325-3 **Report Type:** Expedited (15-Day) **Company Report#:** 1998030065-1 **Age:** 50 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Function Abnormal	Health	Kytril (Granisetron)					
	Liver Function Test Abnormal	Professional	Smithkline Beecham	PS		INTRAVENOUS	2 MILLIGRAMS INTRAVENOUS	5 DAY
			Carboplatin	C				
			Dexamethasone	C				
			Paclitaxel	C				
			Phosphomycin	C				

Date: 03/02/99 **ISR Number:** 3210329-0 **Report Type:** Expedited (15-Day) **Company Report#:** 1998030087-1 **Age:** 46 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Function Abnormal	Health	Kytril	PS		INTRAVENOUS	2 MILLIGRAMS CONTINUOUS	
	Liver Function Test Abnormal	Professional					INTRAVENOUS	5 DAY
			Carboplatin	C				
			Dexamethasone	C				
			Paclitaxel	C				

Date: 03/02/99 **ISR Number:** 3218788-4 **Report Type:** Direct **Company Report#:** **Age:** 3 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated		Vincristine	PS				
	Decreased Appetite		Doxorubicin (Iv)	SS		INTRAVENOUS		
	Deep Vein Thrombosis		Actinomycin-D (Iv)	SS		INTRAVENOUS		
	Feeling Cold		Kytril (Iv)	SS		INTRAVENOUS	IV	
	Vomiting		Bactrim (Po)	SS		ORAL		
			Fluconazole (Iv)	SS		INTRAVENOUS		
			Zantac (Iv)	SS		INTRAVENOUS		
			Reglan (Iv)	SS		INTRAVENOUS		
			Morphine Sulfate (Iv)	SS		INTRAVENOUS		
			Fentanyl (Iv)	SS		INTRAVENOUS		

Date: 03/16/99 **ISR Number:** 3223101-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1999003277-1 **Age:** 58 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Blood Creatinine Increased Blood Potassium Increased Blood Urea Increased Haemodialysis Oliguria Renal Failure Acute	Health Professional	Kytril	PS	Smithkline Beecham	ORAL	ORAL	3 DAY

Date: 03/16/99 **ISR Number:** 3223118-8 **Report Type:** Expedited (15-Day) **Company Report#:** 1999000049-1 **Age:** 34 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Electrolyte Imbalance Leukopenia	Health Professional	Kytril (Granisetron)					
			Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	2 DAY
			Ascorbic Acid	C				
			Cisplatin	C				
			Epirubicin	C				

Date: 03/16/99 **ISR Number:** 3223124-3 **Report Type:** Expedited (15-Day) **Company Report#:** 1999000038-1 **Age:** 56 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Thrombocytopenia	Health Professional	Kytril (Granisetron)					
			Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	2 DAY
			Ascorbic Acid	C				
			Carboplatin	C				
			Cisplatin	C				

Date: 03/19/99 **ISR Number:** 3223653-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1999000154-1 **Age:** 65 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Condition Aggravated Coordination Abnormal Dizziness Gait Disturbance Hyperreflexia Hyporeflexia Nervousness Retching Tremor Vomiting	Health Professional	Granisetron	PS	Smithkline Beecham			1 DAY
			Ci-994 (Developmental)	C				
			Cprochlorperazine	C				

Date: 03/19/99 **ISR Number:** 3223749-5 **Report Type:** Direct **Company Report#:** **Age:** 44 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cystitis Nausea Pain Pancreatitis Vomiting		Irinotecan (Cpt 11)	PS		INTRAVENOUS	232 MG IV XT1 ; CYCLE 1 PO 1ST TX)	
			Decadron	SS		INTRAVENOUS	10MG IV	
			Kytril	SS		ORAL	1MG PO	
			Vicodin	C				

			Durageaic	C				
			Morphine	C				

Date: 04/16/99 **ISR Number:** 3241770-8 **Report Type:** Expedited (15-Day) **Company Report#:** 1998028689-1 **Age:** 66 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bone Marrow Depression	Health	Kytril (Granisetron)	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS	
	C-Reactive Protein Increased	Professional					ORAL	3 DAY
	Hepatic Function Abnormal		Betamethasone	C				
	Pyrexia		Carboplatin	C				
			Etopside	C				

Date: 04/27/99 **ISR Number:** 3247403-9 **Report Type:** Expedited (15-Day) **Company Report#:** 99-01534 **Age:** 44 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cystitis	Study	Camptosar	PS		INTRAVENOUS	232 MILLIGRAMS; ONE DOSE ONLY; INTRAVENOUS	
	Nausea	Health						
	Pain	Professional						
	Pancreatitis							
	Vomiting		Decadron	SS		INTRAVENOUS	10 MILLIGRAMS; ONE DOSE ONLY; INTRAVENOUS	
			Kytril	SS		ORAL	1 MILLIGRAMS; ONE DOSE ONLY; ORAL	
			Vicodin	C				
			Duragesic Patch	C				

Date: 04/29/99 **ISR Number:** 3249690-X **Report Type:** Expedited (15-Day) **Company Report#:** 1999008197-1 **Age:** 71 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bone Marrow Depression		Kytril (Granisetron) Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS		5 DAY
	Diarrhoea		Cisplatyl	C				
	Dyspepsia		Dermoval	C				
	Gastritis		Di Antalvic	C				
	Hepatic Failure		Doliprane	C				
	Infectious Mononucleosis		Fluoro-Uracil	C				
	Liver Function Test Abnormal		Gaviscon	C				
	Mucosal Inflammation							
	Oesophageal Ulcer							
	Sepsis							
	Vomiting							

Date: 05/04/99 **ISR Number:** 3253287-5 **Report Type:** Expedited (15-Day) **Company Report#:** 1999009113-1 **Age:** 48 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hypertension	Health	Kytril (Granisetron)					
	Loss Of Consciousness	Professional	Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	3 MILLIGRAMS INTRAVENOUS	1 DAY
	Nervous System Disorder							

			Docetaxel Hydrate	C				

Date: 05/07/99 **ISR Number:** 3256568-4 **Report Type:** Expedited (15-Day) **Company Report#:** B045808 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased	Foreign Study Health Professional Other	Ifomide (Ifosfamide)	PS		INTRAVENOUS	2 G/DAY IV	4 DAY
			Nedaplatin	SS		INTRAVENOUS	100 MG/DAY IV	1 DAY
	Blood Creatinine Increased		Bleomycin Hcl	SS		INTRAVENOUS	5 MG/DAY IV	5 DAY
			Granisetron (Granisetron Hcl)	SS		INTRAVENOUS	3 MG/DAY IV	3 DAY
	Blood Lactate Dehydrogenase Increased		Uromitexan	C				
			Lenograstim	C				
	Bone Marrow Depression		Cefminox Sodium	C				
	Endotoxic Shock							
	Hypotension							
	Leukopenia							
	Nausea							
	Pyrexia							
	Renal Failure							
	Sepsis							
	Thrombocytopenia							

Date: 05/07/99 **ISR Number:** 3256705-1 **Report Type:** Expedited (15-Day) **Company Report#:** 1999008197-1 **Age:** 71 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bone Marrow Depression		Kytril (Granisetron) Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	5 DAY
	Condition Aggravated		Cisplatyl (Cisplatine)	C				
	Diarrhoea		Dermoval (Clobetasol)	C				
	Dyspepsia		Di Antalvic (Paracetamol, Dextropropoxyphene)	C				
	Gastritis		Doliprane (Paracetamol)	C				
	Hepatic Failure		Fluoro-Uracil	C				
	Hepatitis		Gaviscon	C				
	Infectious Mononucleosis		Imovane (Zopiclone)	C				
	Liver Function Test Abnormal		Loxen (Nicardipine)	C				
	Mucosal Inflammation		Pevaryl (Econazole)	C				
	Oesophageal Ulcer		Primperan (Metoclopramide)	C				
	Sepsis		Smecta (Diosmectite)	C				
	Vomiting		...	C				

Date: 06/08/99 **ISR Number:** 3277930-X **Report Type:** Expedited (15-Day) **Company Report#:** 1999012005-1 **Age:** 72 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Anaemia Pyrexia Renal Impairment	Health Professional	Kytril (Granisetron) Smithkline Beecham	PS	Smithkline Beecham	ORAL	ORAL	4 DAY
			Cisplatin	C				
			Fluorouracil	C				

Date: 06/22/99 **ISR Number:** 3289114-X **Report Type:** Expedited (15-Day) **Company Report#:** 1999013301-1 **Age:** 40 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Discomfort Dyspnoea Laryngeal Oedema Oedema Pyrexia Urticaria		Kytril (Granisetron) Smithkline Beecham Eloxatine Solumedrol	 PS C C	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	1 DAY

Date: 07/06/99 **ISR Number:** 3297733-X **Report Type:** Expedited (15-Day) **Company Report#:** 1999014595-1 **Age:** 53 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening	Coma Convulsion Hyponatraemia Inappropriate Antidiuretic Hormone Secretion		Kytril (Granisetron) Smithkline Beecham Adriblastine Endoxan Vincristine	 PS C C C	Smithkline Beecham	INTRAVENOUS	6 MILLIGRAMS INTRAVENOUS	 4 DAY

Date: 07/06/99 **ISR Number:** 3298279-5 **Report Type:** Expedited (15-Day) **Company Report#:** 1999014712-1 **Age:** 40 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Hypersensitivity Laryngeal Oedema Pyrexia Urticaria	Health Professional	Kytril (Granisetron) Smithkline Beecham Eloxatin Solu-Medrol	 PS C C	Smithkline Beecham	INTRAVENOUS		1 DAY

Date: 07/09/99 **ISR Number:** 3300593-1 **Report Type:** Expedited (15-Day) **Company Report#:** 1999012005-1 **Age:** 72 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Anaemia Condition Aggravated Pyrexia Renal Impairment	Foreign Health Professional	Kytril (Granisetron) Smithkline Beecham Cisplatin Fluorouracil	 PS C C	Smithkline Beecham	ORAL	ORAL	4 DAY

Date: 07/13/99 **ISR Number:** 3302474-6 **Report Type:** Expedited (15-Day) **Company Report#:** 278/50467 **Age:** 53 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening	Coma Convulsion Hyponatraemia Inappropriate Antidiuretic Hormone Secretion	Foreign Health Professional Company Representative	Adriamycin Rdf Endoxan Vincristine Kytril	PS SS SS SS		INTRAVENOUS	60 MG/DAY; IV 400 MG/DAY 1.4 MG/DAY 3 MG-2Q1DY	

Date: 07/16/99 **ISR Number:** 3305648-3 **Report Type:** Expedited (15-Day) **Company Report#:** 1999015932-1 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haemolytic Uraemic Syndrome		Granisetron	PS	Smithkline Beecham			
			Aciclovir	C				
			Cyclophosphamide	C				
			Dexamethasone Sodium Phosphate	C				

Date: 08/09/99 **ISR Number:** 3328648-6 **Report Type:** Expedited (15-Day) **Company Report#:** 1999-07-1367 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Health Professional Company Representative	Intron A (Interferon Alfa-2b Recombinant) Injectable	PS				
	Diarrhoea Haemorrhagic		Motrin	SS			PRN	
	Enterocolitis Haemorrhagic		Kytril	SS				
			Senokot	C				

Date: 08/26/99 **ISR Number:** 3336508-X **Report Type:** Expedited (15-Day) **Company Report#:** 1999-07-1367 **Age:** 44 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Health Professional Company Representative	Intron A (Interferon Alfa-2b Recombinant) Injectable	PS		INTRAVENOUS	40 MU 5XWK* INTRAVENOUS	
Other	Constipation		Motrin Tablets	SS		ORAL	400 MG QID ORAL	
	Diarrhoea Haemorrhagic		Kytril	SS				
	Enterocolitis Haemorrhagic		Senokot	C				
	Fatigue		Tylenol	C				
	Nausea							
	Oral Intake Reduced							
	Orthostatic Hypotension							
	Platelet Count Decreased							
	Vomiting							

Date: 09/01/99 **ISR Number:** 3339229-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1999020607-1 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Health Professional	Kytril Smithkline Beecham	PS	Smithkline Beecham			
Other	Constipation		Intron A	C				
	Diarrhoea Haemorrhagic		Motrin	C				
	Enterocolitis Haemorrhagic							
	Platelet Count Decreased							

Date: 09/01/99 **ISR Number:** 3339315-7 **Report Type:** Expedited (15-Day) **Company Report#:** 1999020846-1 **Age:** 78 YR **Gender:** Male **I/FU:** I

Outcome	PT
Life-Threatening	Bradycardia
Hospitalization - Initial or Prolonged	Chest Pain
	Depressed Level Of Consciousness
	Heart Rate Decreased
	Hypotension

Nausea

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional	Kytril (Granisetron) Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS		
	Azulene Sulfonate	C				
	Betamethasone	C				
	Ranitidine Hydrochloride	C				
	Sodium / L-Glutamine	C				
	Sucralfate	C				

Date: 09/01/99 **ISR Number:** 3339337-6 **Report Type:** Expedited (15-Day) **Company Report#:** 1999021790-1 **Age:** 66 YR **Gender:** Female **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neutropenia	Health Professional	Kytril (Granisetron) Smithkline Beecham	PS	Smithkline Beecham	ORAL	ORAL	7 DAY
	Platelet Count Decreased		Carboplatin	C				
	Red Blood Cell Count Decreased		Herbal Medicine	C				
			Paclitaxel	C				

Date: 09/03/99 **ISR Number:** 3341175-5 **Report Type:** Expedited (15-Day) **Company Report#:** 1999021792-1 **Age:** 57 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neutropenia	Health Professional	Kytril (Granisetron) Smithkline Beecham	PS	Smithkline Beecham	ORAL	ORAL	7 DAY
			Carboplatin	C				
			Herbal Medicine (Nos)	C				
			Methylprednisolone Sodium Succinate	C				
			Metoclopramide	C				
			Paclitaxel	C				

Date: 09/07/99 **ISR Number:** 3342274-4 **Report Type:** Expedited (15-Day) **Company Report#:** 76/74166 **Age:** 61 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angina Pectoris	Foreign Literature	Etoposide Injection (Mfr Unk)	PS		INTRAVENOUS	100 MG/SQ.M DAY IV	
Other	Atrioventricular Block Complete	Health Professional	Cisplatin	SS		INTRAVENOUS	80 MG/SQ.M DAY IV	
	Blood Pressure Systolic Decreased	Company Representative	Granisetron	SS		INTRAVENOUS	3 MG/DAY IV	
	Chest Pain		Ondansetron	SS		ORAL	4 MG/DAY ORAL	
	Electrocardiogram St Segment Abnormal							
	Heart Rate Decreased							
	Hyperhidrosis							
	Syncope							

Date: 09/08/99 **ISR Number:** 3344377-7 **Report Type:** Expedited (15-Day) **Company Report#:** 1999021539-1 **Age:** 58 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Enzyme Increased Liver Disorder		Kytril (Granisetron) Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	3 MILLIGRAMS; INTRAVENOUS	1 DAY
			Cisplatine	C				
			Largactil	C				
			Plitican	C				

Date: 09/14/99 **ISR Number:** 3347355-7 **Report Type:** Expedited (15-Day) **Company Report#:** B0070487A **Age:** 50 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Anaphylactic Shock Heart Rate Decreased Loss Of Consciousness	Foreign Health Professional Company Representative	Zantac Injection (Ranitidine Hydrochloride)	PS		INTRAVENOUS	INTRAVENOUS	
			Granisetron Infusion (Gramisetron)	SS		INTRAVENOUS	INTRAVENOUS INFUSION	

Date: 09/20/99 **ISR Number:** 3352515-5 **Report Type:** Expedited (15-Day) **Company Report#:** 1999020846-1 **Age:** 78 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening Hospitalization - Initial or Prolonged	Bradycardia Chest Pain Depressed Level Of Consciousness Hypotension Nausea	Health Professional	Kytril (Granisetron)	PS	Smithkline Beecham	INTRAVENOUS		1 DAY
			Azulene Sulfonate	C				
			Betamethasone	C				
			Ranitidine Hydrochloride	C				
			Sodium/L-Glutame	C				
			Sucralfate	C				

Date: 09/29/99 **ISR Number:** 3360942-5 **Report Type:** Expedited (15-Day) **Company Report#:** B0070487A **Age:** 50 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Disability	Anaphylactic Shock Anaphylactoid Reaction Chest Pain Erythema Flushing Heart Rate Decreased Hyperhidrosis Loss Of Consciousness Nausea Vomiting	Foreign Health Professional	Zantac (Formulation Unknown) (Ranitidine Hydrochloride)	PS			SEE TEXT	
			Zantac Injection (Ranitidine Hydrochloride)	SS		INTRAVENOUS	INTRAVENOUS	
			Kytril (Formulation Unknown) (Kytril)	SS			SEE TEXT	
			Granisetron Infusion (Granisetron)	SS		INTRAVENOUS	INTRAVENOUS INFUSION	
			Vitamin B Complex	SS				
			Cancer Chemotherapy	C				
			Dexamethasone	C				
			Diphenydramine	C				

Date: 10/14/99 **ISR Number:** 3372973-X **Report Type:** Expedited (15-Day) **Company Report#:** 1999026056-1 **Age:** 58 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Pyrexia	Health Professional	Kytril (Granisetron) Smithkline Beecham Zinostatin Stimalameras	 PS C	Smithkline Beecham	ORAL	ORAL	7 DAY

Date: 10/18/99 **ISR Number:** 3374911-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1999026037-1 **Age:** 69 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills Hypotension Pyrexia	Health Professional	Kytril (Granisetron) Cefdinir Dialysis (Nos) Famotidine Furosemide Lactulose Zinostain Stimalamer	PS C C C C C C	Smithkline Beecham	ORAL		7 DAY

Date: 10/22/99 **ISR Number:** 3379419-6 **Report Type:** Expedited (15-Day) **Company Report#:** B0070487A **Age:** 50 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability Other	Anaphylactic Shock Anaphylactoid Reaction Anoxia Blood Pressure Decreased Chest Pain Encephalopathy Erythema Faecal Incontinence Heart Rate Decreased Hyperhidrosis Loss Of Consciousness Nervous System Disorder Urinary Incontinence Vomiting	Foreign Health Professional	Zantac (Formulation Unknown) (Ranitidine Hydrochloride) Zantac Injection (Ranitidine Hydrochloride) Kytril (Formulation Unknown) (Kytril) Granisetron Infusion (Granisetron) Cancer Chemotherapy Dexamethasone Diphenhydraomine Vitamin B Complex	PS SS SS SS C C C C		INTRAVENOUS INTRAVENOUS	SEE TEXT INTRAVENOUS SEE TEXT INTRAVENOUS INFUSION	

Date: 11/09/99 **ISR Number:** 3391871-9 **Report Type:** Expedited (15-Day) **Company Report#:** 1999026055-1 **Age:** 70 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Haemorrhage Haemorrhagic Diathesis Hepatic Function Abnormal Pyrexia	Health Professional	Kytril (Granisetron) Smithkline Beecham Furosemide Potassium Carenoate Spironolactone Zinostatin Stimalamer	 PS C C C C	Smithkline Beecham	ORAL	ORAL	7 DAY

Date: 11/16/99 **ISR Number:** 3399101-9 **Report Type:** Expedited (15-Day) **Company Report#:** 1999028582-1 **Age:** 60 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaemia	Health	Kytril (Granisetron)					
	Blood Pressure Decreased	Professional	Smithkline Beecham	PS	Smithkline Beecham	ORAL	20 MILLIGRAMS	
	Chest Pain						ORAL	4 DAY
	Dyspnoea		Cisplatin	C				
	Faeces Discoloured		Fluorouracil	C				
	Gastrointestinal							
	Haemorrhage							

Date: 11/18/99 **ISR Number:** 3402665-X **Report Type:** Expedited (15-Day) **Company Report#:** 1999029693-1 **Age:** 69 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatinine	Study	Kytril (Granisetron)					
	Increased	Health	Smithkline Beecham	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS	
	Blood Urea Increased	Professional					ORAL (SEE	
	Condition Aggravated						IMAGE)	5 DAY
	Renal Impairment		Calcium Folinate	C				
			Cisplatin	C				
			Fluorouracil	C				

Date: 11/18/99 **ISR Number:** 3402672-7 **Report Type:** Expedited (15-Day) **Company Report#:** 1999026055-1 **Age:** 70 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Haemorrhage		Kytril (Granisetron)					
Hospitalization -	Hepatic Function Abnormal		Smithkline Beecham	PS	Smithkline Beecham	ORAL	ORAL	7 DAY
Initial or Prolonged	Pyrexia		Furosemide	C				
	Red Blood Cell Count		Potassium Canrenoate	C				
	Increased		Spironolactone	C				
	Thrombocythaemia		Zinostatin					
	White Blood Cell Count		Stimalamer	C				
	Increased							

Date: 11/29/99 **ISR Number:** 3409793-3 **Report Type:** Expedited (15-Day) **Company Report#:** 1999029375-1 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Leukopenia	Study	Kytril (Granisetron)					
	Thrombocytopenia	Health	Smithkline Beecham	PS	Smithkline Beecham	INTRAMUSCULAR	2 MILLIGRAMS,	
		Professional					INTRAMUSCULAR	DAY
			Carboplatin	C				
			Etoposide	C				

Date: 11/29/99 **ISR Number:** 3409798-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1999029916-1 **Age:** 74 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chills	Foreign	Kytril					
Initial or Prolonged	Hypertension	Health	(Granisetron)	PS	Smithkline Beecham			1 DAY
	Loss Of Consciousness	Professional	5-Fluoro Uracile	C				
	Tachycardia	Other	Calcium Folinate	C				
			Diamicron					
			(Gliclazide)	C				
			Minipress					

			(Prazosine)	C				
			Oxaliplatine	C				

Date: 11/30/99 **ISR Number:** 3411366-3 **Report Type:** Expedited (15-Day) **Company Report#:** 1999030358-1 **Age:** 45 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased	Health Professional	Kytril	PS	Smithkline Beehcam	INTRAVENOUS	1 MILLIGRAMS 1.0 DAILY	1 DAY
	Dizziness							
	Hypotension		Decadron (Dexamethasone)	C				
			Navelbine (Vinorelbine Tartrate)	C				

Date: 12/02/99 **ISR Number:** 3415237-8 **Report Type:** Expedited (15-Day) **Company Report#:** 1999031000-1 **Age:** 55 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pancytopenia	Study	Kytril (Granisetron)					
		Health Professional	Smithkline Beecham	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS 4 MILLIGRAMS 2 MILLIGRAMS	2 DAY
			Carboplatin	C				
			Cyclophosphamide	C				
			Pirarubisin Hydrochloride	C				

Date: 12/03/99 **ISR Number:** 3413382-4 **Report Type:** Expedited (15-Day) **Company Report#:** 1999029693-1 **Age:** 69 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatine Increased	Foreign	Kytril (Granisetron)					
	Blood Urea Increased	Study	Smithkline Beecham	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS ORAL	5 DAY
	Renal Impairment	Health Professional	Kytril (Granisetron)					
		Other	Smithkline Beecham	SS	Smithkline Beecham	INTRAVENOUS	3 MILLIGRAMS INTRAVENOUS	1 DAY
			Calcium Folinate	C				
			Cisplatin	C				
			Fluorouracil	C				

Date: 12/07/99 **ISR Number:** 3415566-8 **Report Type:** Expedited (15-Day) **Company Report#:** 1999031021-1 **Age:** 37 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Leukopenia	Study	Kytril (Granisetron)					
		Health Professional	Smithkline Beecham	PS	Smithkline Beecham	ORAL	ORAL	
			Cisplatin	C				
			Cyclophosphamide	C				
			Pirarubicin Hydrochloride	C				

Date: 12/14/99 **ISR Number:** 3421373-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1999030989-1 **Age:** 57 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anaemia	Study	43694a (Granisetron)					
	Haemoglobin Decreased	Health	Smithkline Beecham	PS	Smithkline Beecham	ORAL	ORAL	1 DAY
	Leukopenia	Professional	Carboplatin	C				
	Thrombocytopenia		Cyclophospamide	C				
			Pirarubicin Hydrochloride	C				

Date: 12/21/99 **ISR Number:** 3427163-9 **Report Type:** Expedited (15-Day) **Company Report#:** 1999030989-1 **Age:** 57 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pancytopenia	Study	4369a (Granisetron)					
		Health	Smithkline Beecham	PS	Smithkline Beecham	ORAL	ORAL	1 DAY
		Professional	Carboplatin	C				
			Cyclophosphamide	C				
			Pirarubicin Hydrochloride	C				

Date: 12/21/99 **ISR Number:** 3427165-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1999030358-1 **Age:** 45 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	Blood Pressure Decreased	Health	Kytril Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	1 MILLIGRAMS 1.0 DAILY INTRAVENOUS	1 DAY
	Dizziness	Professional						
	Hypotension							
			Decadron (Dexamethasone)	C				
			Navelbine (Vinorelbine Tartrate)	C				

Date: 12/21/99 **ISR Number:** 3427196-2 **Report Type:** Expedited (15-Day) **Company Report#:** 1999031982-1 **Age:** 30 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Supraventricular Tachycardia	Foreign	Kytril	PS	Smithkline Beecham	INTRAVENOUS	1 MILLIGRAMS INTRAVENOUS	1 DAY
		Other						
			Diclofenac	C				
			Fragmin (Dalteparin)	C				
			Morphine	C				
			Paracetamol	C				

Date: 12/21/99 **ISR Number:** 3434965-1 **Report Type:** Expedited (15-Day) **Company Report#:** 1999032302-1 **Age:** 70 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Leukopenia	Health	Kytril (Granisetron)					
	Thrombocytopenia	Professional	Smithkline Beecham	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS ORAL	6 DAY
			5fu	C				
			Cisplatin	C				
			Furosemide	C				

Date: 12/29/99 **ISR Number:** 3435340-6 **Report Type:** Expedited (15-Day) **Company Report#:** 1999031000-1 **Age:** 55 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaemia	Study	Kytril (Granisetron)					
	Haemoglobin Decreased	Health	Smithkline Beecham	PS	Smithkline Beecham	ORAL	SEE IMAGE	
	Leukopenia	Professional					ORAL	2 DAY
	Thrombocytopenia		Carboplatin	C				
			Cyclophosphamide	C				
			Pirarubisin Hydrochloride	C				

Date: 12/29/99 **ISR Number:** 3439224-9 **Report Type:** Expedited (15-Day) **Company Report#:** 1999032686-1 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactoid Reaction	Health	Kytril (Granisetron)					
	Erythema	Professional	Smithkline Beecham	PS			3 MILLIGRAMS	510 DAY
	Pruritus		Cisplatin	C				
			Tegafur Uracil	C				

Date: 01/05/00 **ISR Number:** 3441759-X **Report Type:** Expedited (15-Day) **Company Report#:** 1999020607-1 **Age:** 44 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation	Health	Kytril Smithkline					
Other	Diarrhoea Haemorrhagic	Professional	Beecham	PS	Smithkline Beecham	ORAL	2 MILLIGRAMS; 1.0 DAILY	
	Enterocolitis Haemorrhagic						ORAL	6 DAY
	Muscle Spasms		Intron A (Interferon Alfa-2b Recombinant)	C				
	Platelet Count Decreased		Intron A (Interferon Alfa-2b Recombinant)	C				
			Motrin (Ibuprofen)	C				
			Acetaminophen	C				

Date: 01/07/00 **ISR Number:** 3443480-0 **Report Type:** Expedited (15-Day) **Company Report#:** 1999033740-1 **Age:** 45 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukopenia	Study	43694a (Granisetron)					
		Health Professional	Smithkline Beecham	PS	Smithkline Beecham	ORAL	3 MILLIGRAM INTRAVENOUS/2 MILLIGRAMS ORAL	4 DAY
			Carboplatin	C				

Date: 01/07/00 **ISR Number:** 3443490-3 **Report Type:** Expedited (15-Day) **Company Report#:** 1999033590-1 **Age:** 57 YR **Gender:** Female **I/FU:** I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Bilirubin Increased
	Blood Lactate Dehydrogenase Increased
	Chest Pain
	Condition Aggravated
	Drug Hypersensitivity
	Dyspnoea

	Flushing Haematocrit Decreased Haemoglobin Decreased Haemolysis Hypoxia Muscle Spasms Pulmonary Embolism Sepsis	Report Source Health Professional	Product Kytril Smithkline Beecham Kytril Smithkline Beecham	Role PS SS	Manufacturer Smithkline Beecham Smithkline Beecham	Route INTRACAVERNOUS INTRAVENOUS	Dose INTRAVENOUS INTRAVENOUS	Duration 1 DAY 1 DAY

Date: 01/13/00 **ISR Number:** 3445431-1 **Report Type:** Expedited (15-Day) **Company Report#:** 1999033736-1 **Age:** 63 YR **Gender:** Male **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Vomiting	Health Professional	Kytril (Granisetron) Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	6 MILLIGRAMS ; 3 MILLIGRAMS INTRAVENOUS	2 DAY
			Bifidobacterium	C				
			Digestive Enzyme Preparations (Nos)	C				
			Fluorouracil	C				
			Ilinotecan	C				
			Stomachis & Digestives (Nos)	C				
			Urapidil	C				

Date: 01/18/00 **ISR Number:** 3444872-6 **Report Type:** Expedited (15-Day) **Company Report#:** WAES 99120258 **Age:** 45 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Dizziness Hypotension	Health Professional	Inj Decadron (Dexamethasone 21-Phosphate Disodium	PS		UNKNOWN	UNKNOWN	
			Kytril 1 Mg	SS		INTRAVENOUS	UNKNOWN IV	
			Navelbine	C				

Date: 02/08/00 **ISR Number:** 3454678-X **Report Type:** Expedited (15-Day) **Company Report#:** 1999033740-1 **Age:** 45 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukopenia	Study Health Professional	43694a (Granisetron) Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	2MG/3MG INTRAVENOUS; ORAL	4 DAY
			Carboplatin	C				

Date: 02/08/00 **ISR Number:** 3456192-4 **Report Type:** Expedited (15-Day) **Company Report#:** 1999029916-1 **Age:** 74 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills Hypertension Loss Of Consciousness Tachycardia	Health Professional	Kytril (Granisetron) Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	1 DAY
			5-Fluoro Uracile	C				
			Calcium Folinate	C				
			Diamiscron					

			(Gliclazide)	C				
			Minipress (Prazosine)	C				
			Oxaliplatine	C				

Date: 02/11/00 **ISR Number:** 3456882-3 **Report Type:** Expedited (15-Day) **Company Report#:** 1999033590-1 **Age:** 57 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia Blood Bilirubin Increased Blood Lactate Dehydrogenase Increased Chest Pain Drug Hypersensitivity Dyspnoea Flushing Haemolysis Hypoxia Muscle Spasms Pulmonary Embolism Rectal Haemorrhage	Health Professional	Kytril Smithkline Beecham Dexamethasone Ondansetron	PS C C	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	1 DAY

Date: 02/14/00 **ISR Number:** 3457961-7 **Report Type:** Expedited (15-Day) **Company Report#:** 10264430 **Age:** 78 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Confusional State Diarrhoea Electroencephalogram Abnormal Epilepsy Hypotension Pyrexia Sedation Skin Discolouration Speech Disorder	Foreign Health Professional	Holoxan (Ifosfamide)	PS		INTRAVENOUS	2175 MILLIGRAM, 1/1 DAY IV	
			Vepeside-Sandoz (Etoposide)	SS		INTRAVENOUS	145 MILLIGRAM, 1/1 DAY IV	
			Mesna	SS		INTRAVENOUS	2400 MILLIGRAM, 1/1 DAY IV	
			Kytril (Granisetron Hcl)	SS		INTRAVENOUS	1/1 DAY IV	
			Imovane	C				
			Xanax	C				
			Diffu-K (Potassium Supplements	C				

Date: 03/03/00 **ISR Number:** 3468941-X **Report Type:** Expedited (15-Day) **Company Report#:** 10287688 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening Other	Convulsion Loss Of Consciousness	Foreign Literature Health Professional Other	Briplatin (Cisplatin)	PS		INTRAVENOUS	100 MILLIGRAM ,1/1 DAY IV	
			Taxotere (Docetaxel)	SS		INTRAVENOUS	100 MILLIGRAM, 1/1 DAY IV	
			Primperan (Metoclopramide Hcl)	SS		INTRAVENOUS	20 MILLIGRAMS , 1/1 DAY IV	
			Droleptan (Droperidol)	SS		INTRAVENOUS	.5 MILLIGRAM	

					, 1/1 DAY IV
Kytril (Granisetron Hcl)	SS		INTRAVENOUS	6 MILLIGRAM ,1/1 DAY IV	
Decadron (Dexamethasone)	SS		INTRAVENOUS	.2 MILLIGRAMS , 1/1 DAY IV	
Polaramine (Chlorpheniramine Maleate)	SS		INTRAVENOUS	10 MILLIGRAM ,1/1 DAY IV	

Date: 03/08/00 **ISR Number:** 3472344-1 **Report Type:** Expedited (15-Day) **Company Report#:** 1999033732-1 **Age:** 57 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukopenia	Study Health Professional	43694a (Granisetron) Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	3 MILLIGRAMS, INTRAVENOUS	1 DAY
			43694a (Granisetron Smithkline Beecham)	SS	Smithkline Beecham	ORAL	2 MILLIGRAMS, ORAL	5 DAY
			Carboplatin	C				
			Paclitaxel	C				

Date: 03/13/00 **ISR Number:** 3474991-X **Report Type:** Expedited (15-Day) **Company Report#:** 1999033529-1 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Induced Condition Aggravated Drug Effect Decreased Nausea	Health Professional	Kytril Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	500 MICROGRAMS INTRAVENOUS	4 DAY

Date: 03/20/00 **ISR Number:** 3478162-2 **Report Type:** Expedited (15-Day) **Company Report#:** 2000007398-1 **Age:** 75 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Blood Amylase Increased Lipase Increased Pancreatitis Acute	Health Professional	Kytril	PS	Smithkline Beecham			1 DAY
			Lasix (Furosemide)	C				
			Nitrates	C				
			Insulin	C				
			Avandia (Rosigltazone)	C				
			Carboplatinum	C				
			Etoposide	C				
			Dexamethasone	C				
			Asa (Acetylsalicylic Acid)	C				
			Gemfibrozil	C				

Date: 04/11/00 **ISR Number:** 3488133-8 **Report Type:** Expedited (15-Day) **Company Report#:** 2000009353-1 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain Lower Flatulence Ileus Paralytic

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Rectal Tenesmus Vomiting	Health Professional	Kytril (Granisetron) Smithkline Beecham Aclarubicin Hydrochloride Cytarabine Filgrastim	 PS C C C	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	

Date: 04/11/00 **ISR Number:** 3488135-1 **Report Type:** Expedited (15-Day) **Company Report#:** 2000009144-1 **Age:** 1 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension Cyst Diarrhoea Gastrointestinal Disorder Ileus Paralytic Metastases To Central Nervous System Oral Intake Reduced Vomiting	Health Professional	Kytril (Granisetron) Smithkline Beecham Cyclophosphamide Mesna Pirarubicin Prednisolone Sodium Succinate Vincristin	 PS C C C C C		INTRAVENOUS	INTRAVENOUS	

Date: 07/24/00 **ISR Number:** 3534849-4 **Report Type:** Expedited (15-Day) **Company Report#:** 2000020229-1 **Age:** 55 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Diarrhoea Nausea Oesophagitis Pyrexia	Foreign	Kytril Taxotere (Docetaxel)	PS C	Smithkline Beecham Pharmaceuticals			

Date: 07/27/00 **ISR Number:** 3538400-4 **Report Type:** Expedited (15-Day) **Company Report#:** 2000021714-1 **Age:** 45 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Ineffective		Kytril 5-Fluorouracil Eloxatine Elvorine Solu-Medrol	PS C C C C	Smithkline Beecham Pharmaceuticals	INTRAVENOUS	3 MILLIGRAMS INTRAVENOUS	 3 DAY

Date: 08/14/00 **ISR Number:** 3550381-6 **Report Type:** Expedited (15-Day) **Company Report#:** 2000023333-1 **Age:** 63 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Discomfort Malaise Oedema	Foreign Other	Kytril Cisplatyl (Cisplatine) Levothyrox (Levothyroxine) Tamofene (Tamoxifene)	PS C C C	Smithkline Beecham Pharmaceuticals	INTRAVENOUS	IV	

			Vepeside (Etoposide)	C				

Date: 08/21/00 **ISR Number:** 3554467-1 **Report Type:** Expedited (15-Day) **Company Report#:** 2000024292-1 **Age:** 31 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Ammonia Increased	Health	Kytril	PS	Smithkline Beecham			
Hospitalization -	Cardiac Arrest	Professional			Pharmaceuticals	INTRAVENOUS	1 MILLIGRAMS	
Initial or Prolonged	Dialysis						INTRAVENOUS	
	Hepatic Encephalopathy		Diprivan	C				
	Hepatic Enzyme Increased		Lidocaine	C				
	Hepatic Failure		N2o	C				
	Hepatic Necrosis		Sevoflurane	C				
	Renal Failure		Xefo	C				
	Reye'S Syndrome							

Date: 08/28/00 **ISR Number:** 3560276-X **Report Type:** Expedited (15-Day) **Company Report#:** 2000020229-1 **Age:** 55 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Diarrhoea		Kytril	PS	Smithkline Beecham			
Hospitalization -	Nausea				Pharmaceuticals			
Initial or Prolonged	Oesophagitis		Taxotere (Docetaxel)	C				
	Pyrexia							

Date: 08/28/00 **ISR Number:** 3560575-1 **Report Type:** Expedited (15-Day) **Company Report#:** 2000024292-1 **Age:** 31 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Ammonia Increased	Foreign	Kytril	PS	Smithkline Beecham			
Hospitalization -	Cardiac Arrest	Health			Pharmaceuticals	INTRAVENOUS	1 MILLIGRAMS	1 DAY
Initial or Prolonged	Dialysis	Professional	Cortisone (Flexase)	C				
	Hepatic Enzyme Increased	Other	Diprivan (Propofol)	C				
	Hepatic Failure		Lidocaine	C				
	Hepatic Necrosis		Morphine	C				
	Renal Failure		N2o	C				
	Reye'S Syndrome		Remefentanil	C				
			Sevoflurane	C				
			Xefo (Lornoxicam)	C				

Date: 09/11/00 **ISR Number:** 3570017-8 **Report Type:** Expedited (15-Day) **Company Report#:** 2000024292-1 **Age:** 31 YR **Gender:** **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Ammonia Increased	Health	Kytril	PS	Smithkline Beecham			
Hospitalization -	Cardiac Arrest	Professional			Pharmaceuticals	INTRAVENOUS	1 MG IV	1 DAY
Initial or Prolonged	Dialysis							
	Hepatic Encephalopathy							
	Hepatic Enzyme Increased							
	Hepatic Failure							
	Hepatic Necrosis							
	Renal Failure							
	Reye'S Syndrome							

Date: 10/02/00 **ISR Number:** 3585498-3 **Report Type:** Expedited (15-Day) **Company Report#:** 2000028020-1 **Age:** 48 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angioneurotic Oedema Dyspnoea	Health Professional	Kytril	PS	Smithkline Beecham Pharmaceuticals	ORAL		2 DAY
			5-Fluorouracile	C				
			Endoxan					
			(Epirubicine)	C				
			Farmorubicine (Epirubicine)	C				
			Xanax (Alprazolam)	C				
			Zophren (Ondansetron)	C				

Date: 10/02/00 **ISR Number:** 3585499-5 **Report Type:** Expedited (15-Day) **Company Report#:** 2000027782-1 **Age:** 26 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angioneurotic Oedema Dyspnoea		Kytril	PS	Smithkline Beecham Pharmaceuticals	INTRAVENOUS		1 DAY

Date: 10/23/00 **ISR Number:** 3600499-4 **Report Type:** Expedited (15-Day) **Company Report#:** 2000029956-1 **Age:** 49 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability Other	Stevens-Johnson Syndrome		Kytril	PS	Smithkline Beecham Pharmaceuticals	ORAL	4 MILLIGRAMS ORAL	5 DAY
			Cetirizine	C				
			Cyclizine	C				
			Danthron/Docusate	C				
			Diazepam	C				
			Fluconazole	C				
			Haloperidol	C				
			Leucovorin	C				
			Methotrimeprazine	C				
			Metolocpramide	C				
			Morphine	C				
			Naproxen	C				
			Omeprazole	C				
			Phenytoin	C				
			Senna	C				
			Temazepam	C				

Date: 10/25/00 **ISR Number:** 3601417-5 **Report Type:** Expedited (15-Day) **Company Report#:** 10574119 **Age:** 49 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Haemolytic Uraemic Syndrome Renal Failure Acute Thrombocytopenia	Foreign Health Professional Other	Ifex	PS	Bristol Myers Squibb Co Pharmaceutical Research Institute	INTRAVENOUS	5400MG, IV	
			Efferalgan Codeine	SS		INTRAVENOUS	5400 MILLIGRAM, IV	
			Cisplatyl (Cisplatin)	SS		INTRAVENOUS	180 MILLIGRAM, IV	
			Kytril (Granisetron Hcl)	SS				

Ametycine (Mitomycin)	SS		INTRAVENOUS	10 MILLIGRAM, IV	
Solu-Medrol (Methylprednisolone)	C		INTRAVENOUS	120 MILLIGRAM, IV	

Date: 11/09/00 **ISR Number:** 3608939-1 **Report 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 21 DAYS	
	Facial Palsy							
	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: 11/14/00 **ISR Number:** 3611363-9 **Report Type:** Expedited (15-Day) **Company Report#:** 2000028020-1 **Age:** 48 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angioneurotic Oedema	Health Professional	Kytril (Granisetron)	PS	Smithkline Beecham Pharmaceuticals	ORAL		2 DAY
	Dyspnoea		5-Fluorouracile	C				
	Face Oedema		Endoxan (Epirubicine)	C				
	Oropharyngeal Swelling		Farmorubicine (Epirubicine)	C				
	Skin Test Positive		Xanax (Alprazolam)	C				
			Zophren (Ondansetron)	C				

Date: 11/14/00 **ISR Number:** 3611522-5 **Report Type:** Expedited (15-Day) **Company Report#:** 2000031417-1 **Age:** 24 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia		Kytril	PS	Smithkline Beecham Pharmaceuticals	INTRAVENOUS		1 DAY
	Hypotension							
	Loss Of Consciousness		Heparine	C				
	Pyrexia		Kidrolase (Asparaginase)	C				
	Shock							
	Tachycardia							
	Urticaria							
	Vomiting							

Date: 11/20/00 **ISR Number:** 3614871-X **Report Type:** Expedited (15-Day) **Company Report#:** 801#3#2000-04052 (000) **Age:** 72 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Bullous	Health Professional	Cyclophosphamide	PS	Asta Medica Inc		I.V.	
	Henoch-Schonlein Purpura		Solu-Medrol (Methylprdnisolone Sodium	SS		INTRAVENOUS	I.V.	
	Pyrexia		Etoposide (Etoposide)	SS		INTRAVENOUS	I.V.	
	Skin Necrosis		Cisplatin (Cisplatin)	SS		INTRAVENOUS	I.V.	
			Adriamycin (Doxorubicin)	SS		INTRAVENOUS	I.V.	
			Kytril (Granisetron)	SS		INTRAVENOUS	I.V.	

Date: 11/20/00 **ISR Number:** 3615206-9 **Report Type:** Expedited (15-Day) **Company Report#:** 10604056 **Age:** 72 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Bullous	Foreign	Cytoxan	PS	Bristol Myers Squibb Co Pharmaceutical			
	Henoch-Schonlein Purpura	Health Professional			Research Institute	INTRAVENOUS	IV	
	Pyrexia	Other	Cisplastin For Inj (Cisplatin)	SS		INTRAVENOUS	IV	
	Skin Necrosis		Vepesid Inj (Etoposide)	SS		INTRAVENOUS	IV	
			Adriamycin (Doxorubicin Hcl)	SS		INTRAVENOUS	IV	
			Solu-Medrol (Methylprednisolone)	SS		INTRAVENOUS	IV	
			Kytril (Granisetron Hcl)	SS		INTRAVENOUS	IV	

Date: 11/21/00 **ISR Number:** 3615805-4 **Report Type:** Expedited (15-Day) **Company Report#:** 2000031417-1 **Age:** 24 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaphylactic Shock		Kytril	PS	Smithkline Beecham Pharmaceuticals	INTRAVENOUS		1 DAY
	Bradycardia							
	Heart Rate Increased		Heparine	C				
	Hypotension		Kidrolase (Asparaginase)	C				
	Loss Of Consciousness							
	Pyrexia							
	Tachycardia							
	Urticaria							
	Vomiting							

Date: 11/21/00 **ISR Number:** 3616641-5 **Report Type:** Expedited (15-Day) **Company Report#:** 2000031417-1 **Age:** 24 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaphylactic Shock		Kytril	PS	Smithkline Beecham Pharmaceuticals	INTRAVENOUS		1 DAY
	Hypotension							
	Loss Of Consciousness		Heparine	C				
	Pyrexia		Kidrolase	C				
	Tachycardia							
	Urticaria							
	Vomiting							

Date: 11/27/00 **ISR Number:** 3617188-2 **Report Type:** Expedited (15-Day) **Company Report#:** 2000033445-1 **Age:** 72 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Bullous		Kytril	PS	Smithkline Beecham Pharmaceuticals	INTRAVENOUS		
	Henoch-Schonlein Purpura							
	Pyrexia		Adriamycine	C				
	Skin Necrosis		Cisplatine	C				
			Endoxan (Cyclophosphamide)	C				
			...	C				
			Etoposide	C				
			Solumedrol (Methylprednisolone)	C				

Date: 12/06/00 **ISR Number:** 3624041-7 **Report Type:** Expedited (15-Day) **Company Report#:** 2000031417-1 **Age:** 24 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaphylactic Shock	Foreign	Kytril	PS	Smithkline Beecham Pharmaceuticals	INTRAVENOUS	INTRAVENOUS	1 DAY
	Bradycardia	Health Professional Other						
	Hypotension		Heparine	C				
	Loss Of Consciousness		Kidrolase (Asparaginase)	C				
	Pyrexia							
	Tachycardia							
	Urticaria							
	Vomiting							

Date: 12/18/00 **ISR Number:** 3633659-7 **Report Type:** Expedited (15-Day) **Company Report#:** 2000034986-1 **Age:** 77 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Albumin Decreased	Health Professional	Kytril	PS	Smithkline Beecham Pharmaceuticals	INTRAVENOUS	3 MG, IV	30 MIN
Other	Blood Pressure Systolic Increased		Cefozopran Hydrochloride (Firstcin)	C				
	Coma		Theophylline (Theolong)	C				
	Heart Rate Increased							
	Protein Total Decreased							
	Ventricular Extrasystoles							

Date: 01/26/01 **ISR Number:** 3656048-8 **Report Type:** Expedited (15-Day) **Company Report#:** 2000034570-1 **Age:** 69 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Health Professional	Kytril	PS	Hoffmann La Roche Inc	INTRAVENOUS	3 MILLIGRAMS	5 DAY
	Aspartate Aminotransferase Increased		Cyclophosphamide (Endoxan)	C				
	Blood Lactate Dehydrogenase Increased		Doxorubicin Hydrochloride (Adriacin)	C				
	Gamma-Glutamyltransferase Increased		Prednisone	C				
	Hypersensitivity		Vincristine Sulphate (Oncovin)	C				

Date: 02/06/01 **ISR Number:** 3661198-6 **Report Type:** Expedited (15-Day) **Company Report#:** 2001002219-1 **Age:** 39 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Shock	Foreign Other	Kytril	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	1 DAY

Date: 02/15/01 **ISR Number:** 3666481-6 **Report Type:** Expedited (15-Day) **Company Report#:** 10705879 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Vision Blurred Visual Field Defect	Foreign Health Professional Other	Cyclophosphamide Inj(Cyclophosphamide)	PS		INTRAVENOUS	2.2 GRAM, 1/1 CYCLE IV	
			Uromitexan(Mesna)	SS		INTRAVENOUS	1.6 GRAM, 1/1 CYCLE IV	
			Uromitexan(Mesna)	SS		ORAL	1.6 GRAM, 1/1 CYCLE ORAL	
			Kevatril (Granisetron Hcl)	SS		INTRAVENOUS	1 MILLIGRAM, 4/2 CYCLE IV	
			Fortecortin(Dexamethasone)	SS		INTRAVENOUS	8 MILLIGRAM, IV	
			Natulan(Procarbazine Hcl)	SS		ORAL	175 MILLIGRAMS, 4/2 CYCLE ORAL	
			Decortin (Prednisone)	SS		ORAL	80 MILLIGRAMS, 14/1 CYCLE ORAL	
			Zantic(Ranitidine Hcl)	SS		ORAL	300 MILLIGRAMS, ORAL	
			Kalinor-Retard P(Potassium Chloride)	SS		ORAL	4 DOSAGE FORM, ORAL	
			Doxorubicin(Doxorubicin Hcl)	SS		INTRAVENOUS	62 MILLIGRAM, 1/1 CYCLE IV	
			Etoposide	SS		INTRAVENOUS	350 MILLIGRAM, 3/1 CYCLE IV	
			Vincristine (Vincristine)	C				
			Bleomycin(Bleomycin)	C				
			Neupogen(Granulocyte Csf)	C				

Date: 02/15/01 **ISR Number:** 3666953-4 **Report Type:** Expedited (15-Day) **Company Report#:** 2001002219-1 **Age:** 39 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Blood Pressure Decreased Hyperhidrosis Hypovolaemic Shock Pallor		Kytril Smithkline Beecham	PS	Smithkline Beecham	INTRAVENOUS	1.0 DAILY INTRAVENOUS	1 DAY

Date: 02/16/01 **ISR Number:** 3666725-0 **Report Type:** Expedited (15-Day) **Company Report#:** 005#3#2001-16618 (000) **Age:** 39 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Vision Blurred Visual Field Defect	Foreign Health Professional Other	Cyclophosphamide(Cyclophosphamide)	PS	Asta Medica Ag	INTRAVENOUS	2.2G	
			Uromitexan (Mesna)	SS		INTRAVENOUS	1.6 G IV/PO	
			Kevatril (Granisetron Hydrochloride)	SS		INTRAVENOUS	1 MG	
			Fortecortin (Dexamethasone)	SS		INTRAVENOUS	8 MG	
			Natulan (Procarbazine Hydrochloride)	SS		ORAL	175 MG	
			Decortin (Prednisone)	SS		ORAL	80 MG	
			Zantic (Ranitidine Hydrochloride)	SS		ORAL	300 MG	
			Kalinor Retard (Potassium Chloride)	SS		ORAL	4 DOS F	
			Doxorubicin	SS		INTRAVENOUS	62 MG	
			Etoposide	SS		INTRAVENOUS	350 MG	
			Vincristine	C				
			Cyclophosphamide	C	Asta Medica Inc			
			Neupogen (Filgrastim)	C				

Date: 02/20/01 **ISR Number:** 3668369-3 **Report Type:** Expedited (15-Day) **Company Report#:** 2001003642-1 **Age:** 60 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Uveitis	Health Professional	Kytril	PS	Hoffmann La Roche Inc	ORAL	1.0 DAILY ORAL	22 DAY
			Taxotere (Docetaxel)	C				
			Adriamycin (Doxorubicin Hydrochloride)	C				

Date: 02/27/01 **ISR Number:** 3671250-7 **Report Type:** Expedited (15-Day) **Company Report#:** 2001045210FR **Age:** 47 YR **Gender:** Female **I/FU:** I

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain Chills Hypotension Pyrexia Suffocation Feeling

Vomiting

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign	Solu-Medrol	PS	Pharmacia And Upjohn Co	INTRAVENOUS	IV	
Health Professional	5-Fu (Fluorouracil)					
Other	5-Fu(Fluorouracil)	SS		INTRAVENOUS	IV	
	Elvorine (Calcium Levofolinate)	SS		INTRAVENOUS	IV	
	Campto (Irinotecan Hydrochloride)	SS		INTRAVENOUS	IV	
	Kytril (Ganisetron)	SS		INTRAVENOUS		

Date: 02/28/01 **ISR Number:** 3670714-X **Report Type:** Expedited (15-Day) **Company Report#:** WAES 01028121 **Age:** 71 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Myocardial Infarction		Decadron Phosphate	PS	Merck & Co., Inc	INTRAVENOUS		1 DAY
	Pulmonary Oedema		Irinotecan Hydrochloride	SS		INTRAVENOUS DRIP		1 DAY
			Granisetron	SS		INTRAVENOUS DRIP		1 DAY
			Iron (Unspecified)	C				

Date: 03/02/01 **ISR Number:** 3672919-0 **Report Type:** Expedited (15-Day) **Company Report#:** WAES 01028121 **Age:** 71 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Myocardial Infarction	Foreign	Decadron	PS	Merck And Co Inc	INTRAVENOUS	4 MG, IV	1 DAY
	Pulmonary Oedema	Health Professional	Inj Irinotecan Hydrohloride	SS		INTRAVENOUS	140 MG, IV	1 DAY
			Inj Granisetron	SS		INTRAVENOUS	1.5 MG, IV	1 DAY
			Iron (Unspecified)	C				

Date: 03/07/01 **ISR Number:** 3675581-6 **Report Type:** Expedited (15-Day) **Company Report#:** 2001005172-1 **Age:** 69 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Angina Pectoris	Foreign	Kytril	PS	Hoffmann La Roche Inc	INTRAVENOUS	3 MILLIGRAMS, INTRAVENOUS	1 DAY
	Erythema	Health Professional						
	Oedema							
	Respiratory Distress	Other	Methylprednisolone Sodium Succinate (Sol-Medrol)	C				
	Tachycardia							
	White Blood Cell Count Decreased							

Date: 03/07/01 **ISR Number:** 3675602-0 **Report Type:** Expedited (15-Day) **Company Report#:** 2001004531-1 **Age:** 71 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Myocardial Infarction	Foreign	Kytril	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	1 DAY
	Pulmonary Oedema	Health Professional	Campto (Irinotecan)	C				
	Sinus Arrhythmia		Decadron (Desametasone)	C				
			Ferlixit (Iron)	C				

Date: 03/07/01 **ISR Number:** 3675628-7 **Report Type:** Expedited (15-Day) **Company Report#:** 2001005172-1 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Shock	Foreign Health Professional Other	Kytril	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	

Date: 03/07/01 **ISR Number:** 3675633-0 **Report Type:** Expedited (15-Day) **Company Report#:** 2001004720-1 **Age:** 47 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Chills Hypotension Pyrexia Suffocation Feeling Vomiting	Foreign	Kytril	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	1 DAY
			Kytrel	SS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	
			Solumedrol (Methylprednisolone)	C				
			Solumedrol (Methylprednisolone)	C				
			Campto (Irinotecan)	C				
			Campto (Irinotecan)	C				
			5-Fluorouracile (Fluorouracil)	C				
			5-Fluorouracile (Vluorouracil)	C				
			5-Fluorouracile (Fluorouracil)	C				
			Elvorine (Calcium Levofolinate)	C				
			Elvorine (Calcium Levofolinate)	C				

Date: 03/12/01 **ISR Number:** 3680876-6 **Report Type:** Expedited (15-Day) **Company Report#:** 2001004720-1 **Age:** 47 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Hypotension Pyrexia Suffocation Feeling Vomiting	Foreign	Kytril	PS	Hoffmann La Roche Inc	INTRAVENOUS	INTRAVENOUS	1 DAY
			Solumedrol (Methylprednisolone)	C				
			Campto (Irinotecan)	C				
			5-Fluorouracile (Fluorouflacil)	C				
			Elvorine (Calcium Evofolinate)	C				

Date: 03/13/01 **ISR Number:** 3682623-0 **Report Type:** Expedited (15-Day) **Company Report#:** 2001005906-1 **Age:** 50 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aplasia Haemoglobin Decreased Neutrophil Count Decreased Pancytopenia Platelet Count Decreased Pyrexia	Foreign Health Professional	Kytril	PS	Smithkline Beecham	INTRAVENOUS	INTRAVENOUS	1 DAY
			Hycamtin (Topotecan)	C				

Date: 03/16/01 **ISR Number:** 3683612-2 **Report Type:** Expedited (15-Day) **Company Report#:** 2001047410IT **Age:** 72 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Myocardial Infarction Pulmonary Oedema	Foreign Health Professional Other	Camptosar Granisetron(Granisetron) Dexamethasone (Dexamethasone) Ferlixit (Benzyl Alcohol, Saccharin Sodium, Ferrous Gluconate)	PS SS SS SS	Pharmacia And Upjohn Co		140 MG, DURATION 2 DAYS 0 HRS	

Date: 03/21/01 **ISR Number:** 3687279-9 **Report Type:** Expedited (15-Day) **Company Report#:** 1999013301-1 **Age:** 40 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Discomfort Dyspnoea Hypersensitivity Laryngeal Oedema Pyrexia Urticaria	Foreign Health Professional	Kytril Solumedrol(Methylprednisolone) Eloxatine(Oxaliplatine)	PS C C	Smithkline Beecham Pharmaceuticals	INTRAVENOUS	INTRAVENOUS	1 DAY

Date: 03/21/01 **ISR Number:** 3687355-0 **Report Type:** Expedited (15-Day) **Company Report#:** 1999014712-1 **Age:** 40 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Hypersensitivity Laryngeal Oedema Pyrexia Urticaria	Health Professional	Kytril Solu-Medrol (Methylprednisolone Sodium Succinate) Eloxatin (Oxaliplatin)	PS C C	Hoffmann La Roche Inc	INTRAVENOUS	INTRAVENOUS	1 DAY

Date: 03/23/01 **ISR Number:** 3689137-2 **Report Type:** Expedited (15-Day) **Company Report#:** ETHYOL-01524 **Age:** 72 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrial Fibrillation Cardiac Disorder Chronic Obstructive Airways Disease Exacerbated Dyspnoea Hypoxia Pneumonia Bacterial Productive Cough	Study Health Professional	Ethyol Kytril Radiation Taxol Carboplatin Decadron Compazine	PS SS C C C C C	Medimmune Oncology Inc	INTRAVENOUS ORAL	376 MG UNK IV 1 MG Q24HR PO	

Date: 04/10/01 **ISR Number:** 3702271-3 **Report Type:** Expedited (15-Day) **Company Report#:** 2001005172-1 **Age:** 69 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Angina Pectoris	Foreign	Kytril	PS	Hoffmann La Roche Inc	INTRAVENOUS	3 MILLIGRAMS INTRAVENOUS	1 DAY
	Erythema	Health Professional						
	Oedema							
	Respiratory Distress	Other	Methylprednisolone Sodium Succinate (Solu-Medrol)	C				
	Tachycardia							
	White Blood Cell Count Increased		Epirubicin Hydrochloride (Farmorubicin)	C				
			Cyclophosphamide (Endoxan)	C				

Date: 04/10/01 **ISR Number:** 3702275-0 **Report Type:** Expedited (15-Day) **Company Report#:** 2000034570-1 **Age:** 65 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Foreign	Kytril	PS	Hoffmann La Roche Inc	INTRAVENOUS	INTRAVENOUS	5 DAY
	Aspartate Aminotransferase Increased	Health Professional	Cyclophosphamide (Endoxan)	C				
	Blood Lactate Dehydrogenase Increased	Other	Doxorubicin Hydrochloride (Adriacin)	C				
	Hepatic Function Abnormal		Vincristine Sulphate (Oncovin)	C				
	Liver Disorder		Prednisone (Prednisone)	C				

Date: 04/16/01 **ISR Number:** 3705459-0 **Report Type:** Expedited (15-Day) **Company Report#:** 2001051817FR **Age:** 80 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atrioventricular Block Complete	Foreign	Xanax	PS	Pharmacia And Upjohn Co	ORAL	0.5 MG, QD, ORAL	
	Bone Marrow Depression	Health Professional						
	Pyrexia	Other	Vogalene (Metopimazine)	SS		ORAL	ORAL	
			Taxol (Paclitaxel)	SS		INTRAVENOUS	IV	
			Paraplatine (Carboplatin)	SS		INTRAVENOUS	IV	
			Kytril (Granisetron)	SS		INTRAVENOUS	3 MG, QD, IV	
			Ranitidine (Ranitidine)	SS		INTRAVENOUS	2ML, QD, IV	

Date: 04/18/01 **ISR Number:** 3707673-7 **Report Type:** Expedited (15-Day) **Company Report#:** 2001009121-1 **Age:** 49 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Haematocrit Decreased	Health Professional	Kytril	PS	Hoffmann La Roche Inc	INTRAVENOUS	1 MILLIGRAM 1.0 DAILY INTRAVENOUS	1 DAY
	Infection							
	Pyrexia							
	Rash Papular							
	Rash Pustular							
	Stevens-Johnson Syndrome							

Date: 04/23/01 **ISR Number:** 3709194-4 **Report Type:** Expedited (15-Day) **Company Report#:** 10792885 **Age:** 80 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Atrioventricular Block Complete Bone Marrow Depression Pyrexia	Foreign Health Professional Other	Taxol	PS	Bristol Myers Squibb Co Pharmaceutical Research Institute	INTRAVENOUS	IV	
			Paraplatine (Carboplatin)	SS				
			Xanax (Alprazolam)	SS				
			Vogalene (Metopimazine)	SS				
			Kytril (Granisetron Hcl)	SS				
			Ranitidine Hcl	SS				

Date: 04/23/01 **ISR Number:** 3709548-6 **Report Type:** Expedited (15-Day) **Company Report#:** 2001009121-1 **Age:** 49 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Haematocrit Decreased Pyrexia Rash Papular Rash Pustular	Health Professional	Kytril	PS	Hoffmann La Roche Inc	INTRAVENOUS	1 MILLIGRAMS 1.0 DAILY INTRAVENOUS	1 DAY

Date: 04/26/01 **ISR Number:** 3711398-1 **Report Type:** Expedited (15-Day) **Company Report#:** 10705879 **Age:** . **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Accommodation Disorder Visual Acuity Reduced Visual Field Defect	Foreign Health Professional Other	Cytoxan	PS	Bristol Myers Squibb Co Pharmaceutical Research Institute	INTRAVENOUS	2.2 GRAM 1/1 CYCLE IV	
			Uromitexan (Mesna)	SS		INTRAVENOUS	1.6 GRAM 1/1 CYCLE IV	
			Urometixan (Mesna)	SS		ORAL	1.6 GRAM 1/1 CYCLE ORAL	
			Kevatril (Granisetron Hcl)	SS		INTRAVENOUS	1 MILLIGRAM 4/2 CYCLE IV	
			Fortecortin (Dexamethasone)	SS		INTRAVENOUS	8 MILLIGRAM IV	
			Natulan (Procarbazine Hcl)	SS		ORAL	175 MILLIGRAM 4/2 CYCLE ORAL	
			Decortin (Prednisone)	SS		ORAL	80 MILLIGRAM 14/1 CYCLE ORAL	
			Zantic (Ranitidine Hcl)	SS		ORAL	300 MILLIGRAM ORAL	
			Kalinor-Retard P (Potassium Chloride)	SS		ORAL	4 DOSAGE FORM ORAL	
			Doxorubicin (Doxorubicin Hcl)	SS		INTRAVENOUS	62 MILLIGRAM 1/1 CYCLE IV	

			Etoposide	SS		INTRAVENOUS	350 MILLIGRAM 3/1 CYCLE IV
			Vincristine (Vincristine)	C			
			Bleomycin (Bleomycin)	C			
			Neupogen (Granulocyte Csf)	C			

Date: 05/07/01 **ISR Number:** 3718970-3 **Report Type:** Expedited (15-Day) **Company Report#:** 2001010573-1 **Age:** 80 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aplastic Anaemia	Foreign	Kytril	PS	Hoffmann La Roche Inc	INTRAVENOUS	INTRAVENOUS	1 DAY
	Atrioventricular Block Complete	Health Professional	Xanax (Alprazolam)	C				
	Cholestasis		Vogalene (Metopimazine)	C				
	Platelet Count Decreased		Taxol (Paclitaxel)	C				
	Pyrexia		Paraplatine (Carboplatin)	C				
	Thrombocythaemia		Azantac (Ranitidine)	C				
	White Blood Cell Count Increased							

Date: 05/07/01 **ISR Number:** 3718972-7 **Report Type:** Expedited (15-Day) **Company Report#:** 2001010628-1 **Age:** 65 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills	Foreign	Kytril	PS	Hoffmann La Roche Inc	INTRAVENOUS	INTRAVENOUS	
	Chromaturia	Health Professional Other	Irinotecan + Folinic Acid (Folfiri)	C				
	Haemolysis		Methylprednisolone (Solumedrol)	C				
	Thrombocytopenia							

Date: 05/21/01 **ISR Number:** 3726766-1 **Report Type:** Expedited (15-Day) **Company Report#:** 10574119 **Age:** 49 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Haemolytic Uraemic Syndrome	Foreign Health Professional	Ifex	PS	Bristol Myers Squibb Co Pharmaceutical Research Institute	INTRAVENOUS	5400 MILLIGRAM, IV	
	Renal Failure Acute		Efferalgan Codeine (Acetaminophen + Codeine Phosphate)	SS		ORAL	ORAL	
	Thrombocytopenia		Solu-Medrol (Methylprednisolone)	SS		INTRAVENOUS	120 MILLIGRAM, IV	
			Cisplatyl (Cisplatin)	SS		INTRAVENOUS	180 MILLIGRAM, IV	
			Ametycine (Mitomycin)	SS		INTRAVENOUS	10 MILLIGRAM IV	
			Kytril (Granisetron Hcl)	SS				

Date: 05/23/01 **ISR Number:** 3727316-6 **Report Type:** Expedited (15-Day) **Company Report#:** B0107833A **Age:** 80 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atrioventricular Block Complete		Azantac	PS	Glaxo Wellcome	INTRAVENOUS	50MG Per day	1 DAY
	Bone Marrow Depression		Xanax	SS		ORAL	.5MG Per day	
	Haemoglobin Decreased		Vogalene	SS		ORAL		
	Neutropenia		Taxol	SS		INTRAVENOUS		3 DAY
	Platelet Count Decreased		Kytril	SS		INTRAVENOUS	3MG Per day	1 DAY
	Pyrexia		Paraplatine	SS		INTRAVENOUS		3 DAY
	White Blood Cell Count Decreased							

Date: 05/25/01 **ISR Number:** 3729032-3 **Report Type:** Expedited (15-Day) **Company Report#:** 2001009121-1 **Age:** 49 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea	Health Professional	Kytril	PS	Hoffmann La Roche Inc	INTRAVENOUS	1 MILLIGRAMS 1.0 DAILY	
Other	Drug Hypersensitivity						INTRAVENOUS	1 DAY
	Pyrexia							
	Rash Generalised							
	Rash Papular							
	Rash Pustular							

Date: 05/25/01 **ISR Number:** 3729432-1 **Report Type:** Expedited (15-Day) **Company Report#:** B0107833A **Age:** 80 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atrioventricular Block Complete	Foreign	Zantac	PS	Glaxo Wellcome Inc	INTRAVENOUS	50 MG PER DAY INTRAVENOUS	
	Bone Marrow Depression		Alprazolam (Alprazolam)	SS		ORAL	.5 MG PER DAY ORAL	
	Neutropenia		Metopimazine (Metopimazine)	SS		ORAL	ORAL	
	Platelet Count Decreased		Paclitaxel (Paclitaxel)	SS		INTRAVENOUS	INTRAVENOUS	
	Pyrexia		Granisetron Hydrochloride (Granisetron Hydrochloride)	SS		INTRAVENOUS	3 MG PER DAY INTRAVENOUS	
			Carboplatin (Carboplatin)	SS		INTRAVENOUS	INTRAVENOUS	

Date: 05/31/01 **ISR Number:** 3731297-9 **Report Type:** Expedited (15-Day) **Company Report#:** 2001013024-1 **Age:** 68 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypersensitivity	Health Professional	Kytril	PS	Hoffmann La Roche Inc	INTRAVENOUS	1 MILLIGRAMS 1.0 DAILY	
Other	Hypotension						INTRAVENOUS	1 DAY
	Palpitations							
	Subclavian Artery Embolism		Cisplatin	C				
	Transient Ischaemic Attack		Mannitol	C				
			Anzemet (Dolasetron Mesylate)	C				
			Zofran (Ondansetron					

			Hydrochloride)	C				
			Florinef (Fludrocortisone Acetate)	C				
			Reglan (Metroclopramide)	C				
			Baby Aspirin	C				
			Compazine (Prochlorperazine)	C				
			Magnesium	C				
			Potassium	C				

Date: 06/05/01 **ISR Number:** 3733979-1 **Report Type:** Expedited (15-Day) **Company Report#:** 10853588 **Age:** 36 MON **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Shock Arrhythmia	Foreign Health Professional Other	Vepesid Kytril (Granisetron Hcl)	PS SS	Bristol Myers Squibb Co	INTRAVENOUS	IV	

Date: 06/08/01 **ISR Number:** 3738243-2 **Report Type:** Expedited (15-Day) **Company Report#:** 2001010673-1 **Age:** 80 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aplastic Anaemia Atrioventricular Block Blood Alkaline Phosphatase Increased Blood Lactate Dehydrogenase Increased Cholestasis Gamma-Glutamyltransferase Increased Neutrophil Count Decreased Pyrexia White Blood Cell Count Increased	Foreign Health Professional	Kytril Xanax (Alprazolam) Vogalene (Metopimazine) Taxol (Paclitaxel) Paraplatine (Carboplatin) Azantac (Ranitidine)	PS C C C C C	Hoffmann La Roche Inc	INTRAVENOUS	INTRAVENOUS	1 DAY

Date: 06/18/01 **ISR Number:** 3741660-8 **Report Type:** Expedited (15-Day) **Company Report#:** ATO-01-0004 **Age:** 70 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Anxiety Bundle Branch Block Right	Health Professional	Trisenox Kytril (Granisetron Hydrochloride)	PS SS	Cell Therapeutics Inc	INTRAVENOUS	0.20 MG/KG, IVI 1 IN 1 D	

Date: 06/21/01 **ISR Number:** 3743992-6 **Report Type:** Expedited (15-Day) **Company Report#:** 2001010628-1 **Age:** 62 YR **Gender:** Male **I/FU:** F

Outcome	PT
Hospitalization - Initial or Prolonged	Chills Chromaturia Erythema Haemolysis

Thrombocytopenia

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health	Kytril	PS	Hoffmann La Roche Inc	INTRAVENOUS	1 VIALS INTRAVENOUS	1 DAY
Professional	Irinotecan + Folinic Acid (Folfiri)	C				
Other	Methylprednisolone (Solumedrol)	C				

Date: 06/27/01 **ISR Number:** 3749907-9 **Report Type:** Expedited (15-Day) **Company Report#:** 10853588 **Age:** 36 MON **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Shock	Foreign	Vepesid	PS	Bristol Myers Squibb Co	INTRAVENOUS	IV	
Other	Arrhythmia	Health Professional Other	Kytril (Granisetron Hcl)	SS				

Date: 07/02/01 **ISR Number:** 3751360-6 **Report Type:** Expedited (15-Day) **Company Report#:** 2001014689-1 **Age:** 56 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Foreign	Kytril	PS	Hoffmann La Roche Inc	ORAL	1 MILLIGRAMS 1.0 DAILY ORAL	2 DAY
Other	Blood Sodium Decreased							
	Circulatory Collapse							
	Feeling Abnormal		Diclofenac	C				
	Hyperhidrosis		Ranitidine	C				
	Panic Attack		Warfarin	C				
	Psychotic Disorder		Dexamethasone	C				
	Renal Impairment		Metoclopramide	C				
	Vision Blurred							
	Vomiting							

Date: 07/05/01 **ISR Number:** 3753699-7 **Report Type:** Expedited (15-Day) **Company Report#:** 2001010628-1 **Age:** 62 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Autoimmune Disorder	Foreign	Kytril	PS	Hoffmann La Roche Inc	INTRAVENOUS	1 VIALS INTRAVENOUS	1 DAY
	Back Pain	Health Professional Other						
	Chills		Oxaliplatine	C				
	Dermatitis Exfoliative		Methylprednisolone (Solumedrol)	C				
	Haematuria		Calcium Levofolinate	C				
	Haemolysis		5 Fu	C				
	Hepatic Function Abnormal							
	Hypersensitivity							
	Inflammation							
	Nephritis Interstitial							
	Platelet Count Decreased							
	Pyrexia							

Date: 07/10/01 **ISR Number:** 3756295-0 **Report Type:** Expedited (15-Day) **Company Report#:** 2001015644-1 **Age:** 11 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arterial Occlusive	Literature	Granisetron	PS	Smithkline Beecham			
Other	Disease	Health	Fentanyl	C				
	Delirium	Professional	Antibacterial	C				
	Hepatic Failure	Other	Antifungal	C				
	Renal Failure		Antiviral	C				
	Serotonin Syndrome		Cyclosporine	C				
	Vein Disorder		Hydromorphone	C				

Date: 07/10/01 **ISR Number:** 3756296-2 **Report Type:** Expedited (15-Day) **Company Report#:** 2001015644-1 **Age:** 11 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Angiopathy	Health	Granisetron	PS	Smithkline Beecham			
Other	Anxiety	Professional						
	Clonic Convulsion							
	Confusional State							
	Constricted Affect							
	Coordination Abnormal							
	Delirium							
	Disturbance In Attention							
	Dysphoria							
	Eye Disorder							
	Feeling Jittery							
	Hallucination							
	Hepatic Failure							
	Irritability							
	Renal Failure							
	Serotonin Syndrome							
	Venous Occlusion							

Date: 08/08/01 **ISR Number:** 3773259-1 **Report Type:** Expedited (15-Day) **Company Report#:** ETHYOL-01524 **Age:** 72 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Atrial Fibrillation	Study	Ethyol	PS	Medimmune Oncology			
Initial or Prolonged	Chronic Obstructive	Health			Inc	INTRAVENOUS	376 MG UNK IV	
	Airways Disease	Professional	Kytril	SS		ORAL	1 MG Q24HR PO	
	Exacerbated		Radiation	C				
	Cough		Taxol	C				
	Dyspnoea		Carboplatin	C				
	Hypoxia		Decadron	C				
	Pneumonia Bacterial		Compazine	C				
	Ventricular Arrhythmia		...	C				

Date: 08/23/01 **ISR Number:** 3782364-5 **Report Type:** Expedited (15-Day) **Company Report#:** 2001013428-1 **Age:** 54 YR **Gender:** Female **I/FU:** I

Outcome	PT
Other	Abdominal Pain
	Alopecia
	Blood Glucose Increased
	Blood Lactate
	Dehydrogenase Increased
	Blood Pressure Increased
	Blood Urea Increased

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Decreased Appetite Drug Ineffective Dry Mouth Dysphonia Eating Disorder Fatigue Haematocrit Decreased Haemoglobin Decreased Heart Rate Increased Hepatomegaly Lymphadenopathy Lymphocyte Count Decreased Lymphocyte Count Increased Mean Cell Volume Decreased Monocyte Count Decreased Neutrophil Count Decreased Neutrophil Count Increased Oral Candidiasis Oral Soft Tissue Disorder Swelling White Blood Cell Count Decreased White Blood Cell Count Increased	Consumer Health Professional	Kytril Roche Monopril (Fosinopril Sodium) Cytoxan (Cyclophosphamide) Adriamycin (Doxorubicin Hydrochloride) Vincristine Prednisone Benadryl (Diphenhydramine Hydrochloride) Rituxan (Rituximab) Anzemet (Dolasetron Mesylate) Tylenol (Acetaminophen)	PS C C C C C C C C		ORAL	1 MILLIGRAMS 2.0 DAILY ORAL	9 DAY

Date: 08/29/01 **ISR Number:** 3785764-2 **Report Type:** Expedited (15-Day) **Company Report#:** 2001068403FR **Age:** 47 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Chills Hypotension Pyrexia Suffocation Feeling Vomiting	Foreign Health Professional Other	Camptosar (Irinotecan) Solution, Sterile Solu-Medrol (Methylprednisolone) Powder, Sterile Fluorouracil (Fluorouracil) Kytril(Granisetron) Elvorine (Calcium Levofolinate)	PS SS SS SS SS		INTRAVENOUS INTRAVENOUS INTRAVENOUS INTRAVENOUS	IV IV IV 3 MG/3 ML, IV	

Date: 09/12/01 **ISR Number:** 3792951-6 **Report Type:** Expedited (15-Day) **Company Report#:** 10968162 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Shock	Foreign Health Professional Company Representative Other	Vepesid Inj (Etoposide) Kytril (Granisetron Hcl)	PS SS		INTRAVENOUS INTRAVENOUS	500 MG/M2, IV 3 MILLIGRAM, IV	

Date: 09/21/01 **ISR Number:** 3797623-X **Report Type:** Expedited (15-Day) **Company Report#:** 10946747 **Age:** **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aplasia Pure Red Cell	Foreign	Vepesid Inj (Etoposide)	PS		INTRAVENOUS	150 MILLIGRAM, IV	
		Health Professional	Randa (Cisplatin)	SS		INTRAVENOUS	120 MILLIGRAM, IV	
		Company Representative	Fildesin (Vindesine Sulfate)	SS		INTRAVENOUS	3 MILLIGRAM, IV	
		Other	Lasix (Furosemide)	SS		INTRAVENOUS	20 MILLIGRAM, IV	
			Kytril (Granisetron Hcl)	SS		INTRAVENOUS	3 MILLIGRAM, IV	
			Decadron (Dexamethasone)	SS		INTRAVENOUS	8 MILLIGRAM, IV	

Date: 09/25/01 **ISR Number:** 3797757-X **Report Type:** Expedited (15-Day) **Company Report#:** 268588 **Age:** 48 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Intestinal Obstruction		Granisetron Hydrochloride	PS	Roche			
			Carboplatin	SS			CYCLICAL REGIME. START OF CYCLE FOUR 31 MAY 2001.	
			Paclitaxel	SS			CYCLICAL REGIME. START OF CYCLE FOUR 31 MAY 2001.	
			Dexamethason	C				
			Tavegil	C				
			Ronatic	C				

Date: 10/02/01 **ISR Number:** 3804017-7 **Report Type:** Expedited (15-Day) **Company Report#:** 268588 **Age:** 48 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Intestinal Obstruction	Foreign Study	Granisetron Hydrochloride (Granisetron Hydrochloride)	PS		INTRAVENOUS	1.5 MG DAILY INTRAVENOUS	
		Health Professional	Carboplatin (Carboplatin)	SS		INTRAVENOUS	508.55 MG DAILY INTRAVENOUS	
			Paclitaxel (Paclitaxel)	SS		INTRAVENOUS	288.75 MG DAILY INTRAVENOUS	
			Dexamethason (Dexamethasone)	C				

			Tavegil (Clemastine Or Clemastine Fumarate)	C				
			Ronatic (Chlorpheniramine Maleate/Phenylephrine Hydrochloride/Pyrila	C				

Date: 10/23/01 **ISR Number:** 3812019-X **Report Type:** Expedited (15-Day) **Company Report#:** 300032 **Age:** 77 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aplasia		Kytril	PS	Roche			142 DAY
	Cardiac Failure		Diffu-K	SS				146 DAY
	Cardiomegaly		Vindesine Sulfate	SS			THE PATIENT RECEIVED 6 COURSES.	115 DAY
	Cardiomyopathy							
	Heart Rate Increased							
	Lactic Acidosis		Solupred	SS				146 DAY
	Pyrexia		Endoxan Asta	SS			THE PATIENT RECEIVED 6 COURSES.	142 DAY
	Shock							
			Adriblastine	SS			THE PATIENT RECEIVED 6 COURSES. DOSAGE=270 MG/M2.	142 DAY
			Previscan	C				

Date: 10/23/01 **ISR Number:** 3812021-8 **Report Type:** Expedited (15-Day) **Company Report#:** 270050 **Age:** 72 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Circulatory Collapse		Granisetron Hydrochloride	PS	Roche			1 DAY
	Facial Bones Fracture		Gemcitabine	SS				
	Skull Fracture		Navelbine	SS				
	Syncope		L-Thyroxin	C				
			Timonil	C				
			Serevent	C				
			Atrovent	C				
			Itrop	C				
			Dulcolax	C				
			Fraxiparin	C				

Date: 10/25/01 **ISR Number:** 3814649-8 **Report Type:** Expedited (15-Day) **Company Report#:** 300032 **Age:** 77 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aplasia	Foreign	Kytril (Granisetron)	PS		INTRAVENOUS	INTRAVENOUS	
	Cardiac Failure	Other	Diffu-K (Potassium Chloride)	SS		ORAL	2 DOSE FORM DAILY ORAL	
	Cardiomegaly							
	Cardiomyopathy							
	Haemodialysis		Vindesine Sulfate (Vindesine Sulfate)	SS		INTRAVENOUS	INTRAVENOUS	
	Lactic Acidosis							
	Pyrexia							
	Shock		Solupred (Prednisolone Sodium Metasulfobenzoate)	SS		ORAL	ORAL	

Endoxan Asta (Cyclophosphamide)	SS		INTRAVENOUS	INTRAVENOUS		
Adriblastine (Doxorubicin Hydrochloride)	SS		INTRAVENOUS	INTRAVENOUS		
Previscan (Fluindione)	C					

Date: 10/25/01 **ISR Number:** 3815477-X **Report Type:** Expedited (15-Day) **Company Report#:** 270050 **Age:** 72 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Circulatory Collapse	Foreign	Granisetron Hydrochloride (Granisetron Hydrochloride)	PS			1 PER ONE DOSE	
	Facial Bones Fracture	Study	Gemcitabine (Gemcitabine)	SS				
	Non-Small Cell Lung Cancer	Health Professional	Navelbine (Vinorelbine Tartrate)	SS				
	Skull Fracture		L-Thyroxin (Levothyroxine Sodium)	C				
	Syncope		Timonil (Carbamazepine)	C				
			Serevent (Salmeterol Xinafoate)	C				
			Atrovent (Ipratropium Bromide)	C				
			Itrop (Ipratropium Bromide)	C				
			Dulcolax (Bisacodyl)	C				
			Fraxiparin (Nadroparin Calcium)	C				

Date: 12/04/01 **ISR Number:** 3833476-9 **Report Type:** Expedited (15-Day) **Company Report#:** 302472 **Age:** 11 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatic Failure		Granisetron Hydrochloride	PS	Roche			
	Renal Failure		Fentanyl	SS	Roche			
	Serotonin Syndrome		Antibiotics	C				
			Cyclosporine	C				

Date: 12/07/01 **ISR Number:** 3837736-7 **Report Type:** Expedited (15-Day) **Company Report#:** 302472 **Age:** 11 YR **Gender:** Female **I/FU:** I

Outcome	PT
Other	Anxiety
	Clonic Convulsion
	Confusional State
	Constricted Affect
	Coordination Abnormal
	Delirium

Disturbance In Attention							
Dysphoria							
Hallucination, Visual	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Hepatic Failure	Literature	Granisetron					
Irritability	Health	Hydrochloride	PS				
Renal Failure Chronic	Professional	Fentanyl (Fentanyl					
Serotonin Syndrome		Citrate)	SS		INTRAVENOUS	INTRAVENOUS	
Tremor		Antibiotics					
Venoocclusive Liver		(Antibiotic Nos)	C				
Disease		Cyclosporine					
		(Cyclosporine)	C				

Date: 12/12/01 **ISR Number:** 3837328-X **Report Type:** Expedited (15-Day) **Company Report#:** 302472 **Age:** 11 YR **Gender:** Female **I/FU:** I

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Other	Serotonin Syndrome		Granisetron					
			Hydrochloride	PS	Roche			
			Fentanyl	SS	Roche			
			Antibiotics	C				
			Cyclosporine	C				

Date: 12/12/01 **ISR Number:** 3839430-5 **Report Type:** Expedited (15-Day) **Company Report#:** 20010648403FR **Age:** 47 YR **Gender:** Female **I/FU:** F

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
	Abdominal Pain	Foreign	Camptosar					
	Hypotension	Health	(Irinotecan)					
	Pyrexia	Professional	Solution, Sterile	PS		INTRAVENOUS	SEE IMAGE	
	Suffocation Feeling	Other	Solu-Medrol					
	Vomiting		(Methylprednisolone)	SS		INTRAVENOUS	IV	
			Fluorouracil					
			(Fluorouracil)	SS		INTRAVENOUS	SEE IMAGE	
			Kytril (Granisetron)	SS		INTRAVENOUS	3 MG/3 ML, IV	
			Elvorine (Calcium					
			Levofolinate)	SS				

Date: 12/12/01 **ISR Number:** 3839438-X **Report Type:** Expedited (15-Day) **Company Report#:** 2001045210FR **Age:** 47 YR **Gender:** Female **I/FU:** F

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Hospitalization -	Abdominal Pain	Foreign	Solu-Medrol					
Initial or Prolonged	Chills	Health	(Methylprednisolone)					
	Hypotension	Professional	Powder, Sterile	PS		INTRAVENOUS	IV	
	Pyrexia	Other	5-Fu (Fluorouracil)	SS		INTRAVENOUS	IV	
	Suffocation Feeling		Elvorine (Calcium					
	Vomiting		Levofolinate)	SS		INTRAVENOUS	SEE IMAGE	
			Camptosar					
			(Irinotecan)					
			Solution, Sterile	SS		INTRAVENOUS	SEE IMAGE	
			Kytril (Granisetron)	SS		INTRAVENOUS	SEE IMAGE	

Date: 12/14/01 **ISR Number:** 3839164-7 **Report Type:** Expedited (15-Day) **Company Report#:** 303279 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Full Blood Count Decreased		Kytril	PS	Roche			5 DAY
			Adriacin	SS				3 DAY
			Ifomide	SS				5 DAY
			Solita-T3 Injection	C				6 DAY
			Meylon	C				6 DAY
			Uromitexan	C				5 DAY

Date: 12/14/01 **ISR Number:** 3839652-3 **Report Type:** Expedited (15-Day) **Company Report#:** 302472 **Age:** 11 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatic Failure Renal Failure Serotonin Syndrome Venoocclusive Disease	Literature Health Professional	Granisetron Hydrochloride (Granisetron Hydrochloride)	PS				
			Fentanyl (Fentanyl Citrate)	SS		INTRAVENOUS		
			Antibiotics (Antibiotic Nos)	C				
			Cyclosporine (Cyclosporine)	C				

Date: 12/18/01 **ISR Number:** 3841132-6 **Report Type:** Expedited (15-Day) **Company Report#:** 303279 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haemoglobin Increased Platelet Count Decreased White Blood Cell Count Decreased	Foreign Study Health Professional	Kytril (Granisetron)	PS		INTRAVENOUS DRIP	0.4 MG DAILY INTRAVENOUS DRIP	
			Adriacin (Doxorubicin Hydrochloride)	SS		INTRAVENOUS	10 MG DAILY INTRAVENOUS	
			Ifomide (Ifosfamide)	SS		INTRAVENOUS	1000 MG DAILY INTRAVENOUS	
			Solita-T3 Injection (Potassium Chloride/Sodium Chloride/Sodium Lactate)	C				
			Meylon (Sodium Bicarbonate)	C				
			Uromitexan (Mesna)	C				

Date: 12/21/01 **ISR Number:** 3842631-3 **Report Type:** Expedited (15-Day) **Company Report#:** 303534 **Age:** 74 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Tremor		Kytril	PS	Roche		3MG/3ML	1 DAY
			Tegeline	SS				1 DAY
			Eldisine	SS				1 DAY
			Endoxan	SS				1 DAY
			Adriblastine	SS				1 DAY

Date: 12/21/01 **ISR Number:** 3842913-5 **Report Type:** Expedited (15-Day) **Company Report#:** US-BRISTOL-MYERS SQUIBB COMPANY-11635729 **Age:** 74 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Exacerbated Tremor		Endoxan	PS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Adriblastine	SS		INTRAVENOUS		
			Eldisine	SS		INTRAVENOUS		
			Kytril	SS		INTRAVENOUS		
			Tegeline	SS		INTRAVENOUS	10g/200 ml	
			Chloraminophene	C				

Date: 12/27/01 **ISR Number:** 3845864-5 **Report Type:** Expedited (15-Day) **Company Report#:** 303534 **Age:** 74 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Tremor	Foreign Other	Kytril (Granisetron)	PS		INTRAVENOUS	1 MG/ML INTRAVENOUS	
			Tegeline (Globulin, Immune)	SS		INTRAVENOUS	1 DOSE FORM INTRAVENOUS	
			Eldisine (Vindesine Sulfate)	SS		INTRAVENOUS	6 MG INTRAVENOUS	
			Endoxan (Cyclophosphamide)	SS		INTRAVENOUS	INTRAVENOUS	
			Adriblastine (Doxorubicin Hydrochloride)	SS		INTRAVENOUS	47 MG INTRAVENOUS	

Date: 12/27/01 **ISR Number:** 3846187-0 **Report Type:** Expedited (15-Day) **Company Report#:** 801#3#2001-18688 (000) **Age:** 74 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Tremor	Foreign Health Professional	Endoxan (Cyclophosphamide)	PS		INTRAVENOUS	INTRAVENOUS	1 DAY
			Adriblastine (Doxorubicin Hydrochloride)	SS		INTRAVENOUS	47 MG I.V.	
			Eldisine (Vindesine Sulfate)	SS		INTRAVENOUS	6 MG I.V.	
			Tegeline (Human Immunoglobulin)	SS		INTRAVENOUS	10 G I.V.	
			Kytril (Granisetron)	SS		INTRAVENOUS	3 MG I.V.	

Date: 01/03/02 **ISR Number:** 3849066-8 **Report Type:** Expedited (15-Day) **Company Report#:** 2001086667FR **Age:** 74 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cough Dyspnoea Hypogammaglobulinaemia Lymphadenopathy Tremor	Foreign Health Professional Other	Adriamycine(Doxorubicin Hydrochloride) Solution, Sterile	PS		INTRAVENOUS	47 MG, QD, IV	
			Endoxan (Cyclophosphamide)	SS		INTRAVENOUS	IV	
			Eldisine (Vindesine Sulfate)	SS		INTRAVENOUS	6 MG, IV	
			Normal Human Immunoglobulin	SS		INTRAVENOUS	10 G/200 ML,	

			Kytril (Granisetron)	SS		INTRAVENOUS	IV 3 MG/3 ML, IV

Date: 01/22/02 **ISR Number:** 3855221-3 **Report Type:** Expedited (15-Day) **Company 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. 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: 01/23/02 **ISR Number:** 3856134-3 **Report Type:** Expedited (15-Day) **Company 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: 01/23/02 **ISR Number:** 3856160-4 **Report Type:** Expedited (15-Day) **Company Report#:** 302678 **Age:** 14 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Intestinal Obstruction		Granisetron Hydrochloride	PS	Roche			16 DAY
			Oncovin	SS				15 DAY
			Leunase	C			INTERVAL: 5 TIMES/ 5-14 NOVEMBER.	10 DAY
			Daunomycin	C				7 DAY
			Endoxan	C				1 DAY

Date: 01/23/02 **ISR Number:** 3859633-3 **Report Type:** Expedited (15-Day) **Company 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: 01/24/02 **ISR Number:** 3860256-0 **Report Type:** Expedited (15-Day) **Company 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)	PS		INTRAVENOUS	INTRAVENOUS	
			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: 01/25/02 **ISR Number:** 3860073-1 **Report Type:** Expedited (15-Day) **Company Report#:** 302678 **Age:** 14 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain Upper Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Bilirubin Increased Haemoglobin Decreased Intestinal Obstruction Platelet Count Decreased Tenderness White Blood Cell Count Decreased	Foreign Study Health Professional	Granisetron Hydrochloride (Granisetron Hydrochloride0	PS		INTRAVENOUS DRIP	3 MG DAILY INTRAVENOUS DRIP	
			Oncovin (Vincristine)	SS		INTRAVENOUS	2 MG DAILY INTRAVENOUS	
			Leunase (Asparaginase)	C				
			Daunomycin (Daunorubicin Hydrochloride)	C				
			Endoxan (Cyclophosphamide)	C				

Date: 01/28/02 **ISR Number:** 3861442-6 **Report Type:** Expedited (15-Day) **Company 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 INTRAVENOUS	
			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				

Date: 01/29/02 **ISR Number:** 3860872-6 **Report Type:** Expedited (15-Day) **Company Report#:** B0133033A **Age:** 47 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased		Zophren	PS	Glaxo Wellcome	INTRAVENOUS	24MG per day	1 DAY
	Aspartate Aminotransferase Increased		Solumedrol	SS		INTRAVENOUS		1 DAY
	Blood Alkaline Phosphatase Increased		Cisplatin	SS		INTRAVENOUS	80MGM2 per day	
	Gamma-Glutamyltransferase Increased		Metoclopramide	SS		INTRAVENOUS	60MG per day	1 DAY
	Infectious Mononucleosis		Kytril	SS	Glaxo Wellcome	ORAL	4MG per day	5 DAY
	Liver Function Test Abnormal		Cetornan	C		UNKNOWN		
			Di-Antalvic	C		UNKNOWN		
			Eprex	C		UNKNOWN	4285.7IU per day	
			Forlax	C		UNKNOWN		
			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: 01/29/02 **ISR Number:** 3860875-1 **Report Type:** Expedited (15-Day) **Company 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: 01/31/02 **ISR Number:** 3860645-4 **Report Type:** Expedited (15-Day) **Company Report#:** 305343 **Age:** 69 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation Dehydration Vomiting		Kytril	PS	Roche			3 DAY
			Capecitabine	SS	Roche		14 DAYS TREATMENT FOLLOWED BY ONE WEEKS REST	
			Irinotecan	SS				
			Dexamethasone	C				5 DAY
			Metoclopramide	C				5 DAY

Date: 01/31/02 **ISR Number:** 3860649-1 **Report Type:** Expedited (15-Day) **Company Report#:** 305343 **Age:** 69 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation Dehydration Vomiting		Kytril	PS	Roche			3 DAY
			Capecitabine	SS	Roche		14 DAYS TREATMENT FOLLOWED BY ONE WEEKS REST	
			Irinotecan	SS				
			Dexamethasone	C				5 DAY
			Metoclopramide	C				5 DAY

Date: 01/31/02 **ISR Number:** 3862949-8 **Report Type:** Expedited (15-Day) **Company Report#:** 305343 **Age:** 69 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation Dehydration Vomiting	Foreign Study Health Professional	Kytril (Granisetron)	PS				
			Capecitabine (Capecitabine)	SS		ORAL	3300 MG DAILY ORAL	
			Irinotecan (Irinotecan Hydrochloride)	SS		INTRAVENOUS	415MG 1 PER 3 WEEK INTRAVENOUS	
			Dexamethasone (Dexamethasone)	C				
			Metoclopramide (Metoclopramide Hydrochloride)	C				

Date: 01/31/02 **ISR Number:** 3862953-X **Report Type:** Expedited (15-Day) **Company Report#:** 305343 **Age:** 69 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation Dehydration Vomiting	Foreign Study Health Professional	Kytril (Granisetron)	PS				
			Capecitabine (Capecitabine)	SS		ORAL	3300 MG DAILY ORAL	
			Irinotecan (Irinotecan Hydrochloride)	SS		INTRAVENOUS	415 MG 1 PER 3 WEEK	

			Dexamethasone (Dexamethasone)	C		INTRAVENOUS		
			Metoclopramide (Metoclopramide Hydrochloride)	C				

Date: 02/20/02 **ISR Number:** 3870847-9 **Report Type:** Expedited (15-Day) **Company Report#:** 303279 **Age:** 15 MON **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Platelet Count Decreased		Granisetron Hydrochloride	PS	Roche			5 DAY
			Adriacin	SS				3 DAY
			Ifomide	SS				5 DAY
			Solita-T3 Injection	C				6 DAY
			Meylon	C				6 DAY
			Uromitexan	C				5 DAY

Date: 02/22/02 **ISR Number:** 3874650-5 **Report Type:** Expedited (15-Day) **Company Report#:** 303279 **Age:** 15 MON **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haemoglobin Decreased Platelet Count Decreased White Blood Cell Count Decreased	Foreign Study Health Professional	Granisetron Hydrochloride (Granisetron Hydrochloride)	PS		INTRAVENOUS DRIP	0.4 MG DAILY INTRAVENOUS DRIP	
			Adriacin (Doxorubicin Hydrochloride)	SS		INTRAVENOUS	10 MG DAILY INTRAVENOUS	
			Ifomide (Ifosfamide)	SS		INTRAVENOUS	1000 MG DAILY INTRAVENOUS	
			Solita-T3 Injection (Potassium Chloride/Sodium Chloride/Sodium Lactate)	C				
			Meylon (Sodium Bicarbonate)	C				
			Uromitexan (Mesna)	C				

Date: 02/22/02 **ISR Number:** 3875278-3 **Report Type:** Expedited (15-Day) **Company 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: 02/25/02 **ISR Number:** 3873015-X **Report Type:** Expedited (15-Day) **Company Report#:** US-BRISTOL-MYERS SQUIBB COMPANY-11727757 **Age:** 59 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Shock		Paraplatin	PS	Bristol-Myers Squibb Company	INTRAPERITONEAL		
			Kytril	SS		INTRAVENOUS		

Date: 02/27/02 **ISR Number:** 3874075-2 **Report Type:** Expedited (15-Day) **Company Report#:** 306099 **Age:** 75 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Body Temperature Increased		Kytril	PS	Roche			5 DAY
	Ileus Paralytic		Randa	SS				4 DAY
	Metastases To Gastrointestinal Tract		Taxol	SS	Roche			1 DAY
	Peritonitis		Leukoprol	C				7 DAY

Date: 02/28/02 **ISR Number:** 3878191-0 **Report Type:** Expedited (15-Day) **Company Report#:** 306099 **Age:** 75 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ileus Paralytic	Foreign	Kytril (Granisetron)					
	Intestinal Obstruction	Health	3 Mg	PS		INTRAVENOUS	3 MG INTRAVENOUS	
	Metastases To Gastrointestinal Tract	Professional	Randa (Cisplatin)	SS		INTRAVENOUS DRIP	20 MG INTRAVENOUS DRIP	
	Peritonitis		Taxol (Paclitaxel)	SS		INTRAVENOUS DRIP	210 MG INTRAVENOUS DRIP	
			Leukoprol (Mirimostim)	C				

Date: 03/08/02 **ISR Number:** 3879815-4 **Report Type:** Expedited (15-Day) **Company Report#:** US-BRISTOL-MYERS SQUIBB COMPANY-11746070 **Age:** 42 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coordination Abnormal		Cisplatin	PS	Bristol-Myers Squibb Company	INTRAVENOUS		
	Dizziness		Kytril	SS				

Date: 04/17/02 **ISR Number:** 3900587-9 **Report Type:** Expedited (15-Day) **Company Report#:** 310629 **Age:** 61 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bronchospasm		Kytril	PS	Roche			1 DAY
	Hypertension		Taxotere	SS				1 DAY
	Rash		Solumedrol	SS				1 DAY

Date: 04/17/02 **ISR Number:** 3902331-8 **Report Type:** Expedited (15-Day) **Company Report#:** 310629 **Age:** 61 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bronchospasm	Foreign	Kytril (Granisetron)	PS		INTRAVENOUS	INTRAVENOUS	
	Hypertension	Other	Taxotere (Docetaxel)	SS		INTRAVENOUS	190 MG INTRAVENOUS	
	Rash							
	Rash Generalised		Solumedrol (Methylprednisolone Sodium Succinate) 120 Mg/2ml	SS		INTRAVENOUS	120 MG/ML INTRAVENOUS	

Date: 04/22/02 **ISR Number:** 3903749-X **Report Type:** Expedited (15-Day) **Company Report#:** 304844 **Age:** 38 YR **Gender:** Female **I/FU:** F

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. 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: 04/23/02 **ISR Number:** 3906154-5 **Report Type:** Expedited (15-Day) **Company Report#:** 304844 **Age:** 38 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis	Foreign	Kytril (Granisetron)	PS		INTRAVENOUS	INTRAVENOUS	
		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: 05/01/02 **ISR Number:** 3909252-5 **Report Type:** Expedited (15-Day) **Company 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: 05/07/02 **ISR Number:** 3914100-3 **Report Type:** Periodic **Company Report#:** 11669462 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error	Health	Carboplatin	PS				
	Neoplasm Malignant	Professional	Gemzar (Gemcitabine					
		Company	Hcl)	SS				
		Representative	Kytril (Granisetron					
		Other	Hcl0	SS				
			Decadron					
			(Dexamethasone)	SS				

Date: 06/10/02 **ISR Number:** 3930039-1 **Report Type:** Expedited (15-Day) **Company Report#:** 305343 **Age:** 69 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Constipation	Health	Kytril	PS	Roche			1 DAY
Initial or Prolonged	Dehydration	Professional	Capecitabine	SS	Roche		14 DAYS TREATMENT FOLLOWED BY ONE WEEKS REST	
	Vomiting		Irinotecan	SS				
			Dexamethasone	C				5 DAY
			Primperan	C				7 DAY
			Atenolol	C			STARTED PRE-STUDY.	
			Phosphate	C				3 DAY
			Nacl	C				2 DAY

Date: 06/13/02 **ISR Number:** 3934133-0 **Report Type:** Expedited (15-Day) **Company Report#:** 305343 **Age:** 69 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Constipation	Foreign	Kytril (Granisetron)	PS		INTRAVENOUS	3 MG DAILY INTRAVENOUS	
Initial or Prolonged	Dehydration	Study						
	Vomiting	Health	Capecitabine					
		Professional	(Capecitabine)	SS		ORAL	3300 MG DAILY ORAL	
			Irinotecan (Irinotecan Hydrochloride)	SS		INTRAVENOUS	415 MG 1 PER 3 WEEK INTRAVENOUS	
			Dexamethasone (Dexamethasone)	C				
			Primperan (Metoclopramide Hydrochloride)	C				
			Atenolol (Atenolol)	C				
			Phosphate (Phosphate					

		Nos)	C	
		Nacl (Sodium Chloride)	C	

Date: 06/19/02 **ISR Number:** 3938222-6 **Report Type:** Expedited (15-Day) **Company Report#:** US-BRISTOL-MYERS SQUIBB COMPANY-11669462 **Age:** **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Other	Medication Error		Carboplatin	PS	Bristol-Myers Squibb Company			
			Gemzar	SS				
			Kytril	SS				
			Decadron	SS				

Date: 06/26/02 **ISR Number:** 3940480-9 **Report Type:** Expedited (15-Day) **Company Report#:** 2002111750FR **Age:** 77 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis Conjunctivitis Bacterial Dermatitis Bullous Procedural Complication Pyrexia Rash Erythematous Stomatitis Toxic Epidermal Necrolysis Urinary Tract Infection	Foreign Health Professional Other	Solu-Medrol(Methylprednisolone) Powder, Sterile	PS		INTRAVENOUS	IV	
			Kytril(Granisetron)	SS		INTRAVENOUS	IV	
			Taxotere(Docetaxel)	SS		INTRAVENOUS	IV	

Date: 06/27/02 **ISR Number:** 3940036-8 **Report Type:** Expedited (15-Day) **Company Report#:** 315648 **Age:** 77 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis Conjunctivitis Bacterial Dermatitis Bullous Dermatitis Exfoliative Pain Pyrexia Skin Fissures Stomatitis Toxic Epidermal Necrolysis Urinary Tract Infection		Kytril	PS	Roche			39 DAY
			Solumedrol	SS				39 DAY
			Taxotere	SS				39 DAY

Date: 07/01/02 **ISR Number:** 3943115-4 **Report Type:** Expedited (15-Day) **Company Report#:** 315648 **Age:** 77 YR **Gender:** Female **I/FU:** I

Outcome	PT
Hospitalization - Initial or Prolonged	Agranulocytosis Conjunctivitis Bacterial Dermatitis Bullous Dermatitis Exfoliative Pain Pyrexia Radiation Skin Injury Rash Erythematous Stomatitis

	Toxic Epidermal Necrolysis Urinary Tract Infection	**Report Source** Foreign Other	**Product** Kytril (Granisetron) Solumedrol (Methylprednisolone Sodium Succinate) Taxotere (Docetaxel)	**Role** PS SS SS	**Manufacturer**	**Route** INTRAVENOUS INTRAVENOUS INTRAVENOUS	**Dose** INTRAVENOUS INTRAVENOUS INTRAVENOUS	**Duration**

Date: 07/08/02 **ISR Number:** 3944354-9 **Report Type:** Expedited (15-Day) **Company Report#:** 315648 **Age:** 77 YR **Gender:** Female **I/FU:** F

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Hospitalization - Initial or Prolonged	Agranulocytosis Dermatitis Bullous Dermatitis Exfoliative Pyrexia Stomatitis Toxic Epidermal Necrolysis	Consumer	Kytril Solumedrol Taxotere	PS SS SS	Roche			39 DAY 39 DAY 39 DAY

Date: 07/17/02 **ISR Number:** 3949552-6 **Report Type:** Expedited (15-Day) **Company Report#:** 316987 **Age:** **Gender:** Female **I/FU:** I

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Hospitalization - Initial or Prolonged	Autoimmune Thrombocytopenia Chills Gingival Bleeding Haemorrhage Purpura Thrombocytopenia	Health Professional	Kytril Solumedrol Oxaliplatine 5-Fu	PS SS SS SS	Roche			

Date: 07/25/02 **ISR Number:** 3953196-X **Report Type:** Expedited (15-Day) **Company Report#:** 316912 **Age:** **Gender:** Female **I/FU:** F

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Hospitalization - Initial or Prolonged	Erythema Multiforme		Kytril Piroxicam Ranitine Co-Codamol Metoclopramide Propofol Temazepam Glycopyrronium	PS C C C C C C C	Roche			

Date: 07/31/02 **ISR Number:** 3955753-3 **Report Type:** Expedited (15-Day) **Company Report#:** 317667 **Age:** 65 YR **Gender:** Male **I/FU:** I

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Hospitalization - Initial or Prolonged	Cardiac Arrest		Kytril Heparin	PS C	Roche			

Date: 08/30/02 **ISR Number:** 3968524-9 **Report Type:** Expedited (15-Day) **Company Report#:** US-BRISTOL-MYERS SQUIBB COMPANY-12012944 **Age:** 60 YR **Gender:** Male **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia Crepitations Dilatation Ventricular Ejection Fraction Decreased Myocardial Infarction Ventricular Hypokinesia Ventricular Tachycardia	Health Professional	Taxol Inj 30 Mg/5 Ml	PS	Bristol-Myers Squibb Company	INTRAVENOUS	1st dose on 7-Jun-02	8 DAY
			Cisplatin	SS	Bristol-Myers Squibb Company	INTRAVENOUS	1ST DOSE ON 01JUL02	8 DAY
			Etoposide	SS	Bristol-Myers Squibb Company	INTRAVENOUS	Concentration = 100mg/5mL	
			Carboplatine Teva	SS		INTRAVENOUS	1st and 2nd doses on 7- and 14-Jun-02	15 DAY
			Solu-Medrol	SS		INTRAVENOUS		32 DAY
			Kytril	SS		INTRAVENOUS		32 DAY

Date: 09/05/02 **ISR Number:** 3972607-7 **Report Type:** Expedited (15-Day) **Company Report#:** 2002121778FR **Age:** 60 YR **Gender:** Male **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dizziness Lung Crepitation Myocardial Infarction Syncope Ventricular Tachycardia	Foreign Health Professional Other	Solu-Medrol (Methylprednisolone) Powder, Sterile	PS		INTRAVENOUS	IV	
			Cisplatin (Cisplatin)	SS		INTRAVENOUS	IV	
			Taxol (Paclitaxel)	SS		INTRAVENOUS	IV	
			Etoposide (Etoposide)	SS		INTRAVENOUS	IV	
			Kytril (Granisetron)	SS		INTRAVENOUS	IV	
			Carboplatin (Carboplatin)	SS		INTRAVENOUS	IV	

Date: 09/11/02 **ISR Number:** 3973440-2 **Report Type:** Expedited (15-Day) **Company Report#:** 317667 **Age:** 65 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Shock Cardiac Arrest	Health Professional	Kytril	PS	Roche			
			Heparin	C				
			Aracytine	C				

Date: 10/03/02 **ISR Number:** 3987068-1 **Report Type:** Expedited (15-Day) **Company Report#:** 2002125321FR **Age:** 60 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia Crepitations Dilatation Ventricular Myocardial Infarction Sinus Tachycardia Ventricular Tachycardia	Foreign Health Professional Other	Etoposide (Etoposide) Solution, Sterile	PS		INTRAVENOUS	100 MG, IV	
			Cisplatin (Cisplatin)	SS		INTRAVENOUS	200 MG, QD DAYS, 1,8, IV	
			Taxol (Paclitaxel)	SS		INTRAVENOUS	84 MG, QD, DAYS, 7,14, IV	
			Carboplatin (Carboplatin)	SS		INTRAVENOUS	900 MG, QD,	

							DAYS, 7,14,21, IV	
			Solu-Medrol (Methylprednisolone) Powder, Sterile	SS		INTRAVENOUS	IV	
			Kytril (Granisetron)	SS		INTRAVENOUS	15 MG, QD, IV	

Date: 10/07/02 **ISR Number:** 3989161-6 **Report Type:** Expedited (15-Day) **Company Report#:** 2002125321FR **Age:** 60 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia	Foreign	Etoposide (Etoposide) Solution, Sterile	PS		INTRAVENOUS	100 MG, IV	
	Crepitations	Health	Cisplatin (Cisplatin)	SS		INTRAVENOUS	200 MG, QD DAYS 1,8, IV	
	Dilatation Ventricular	Professional	Taxol (Paclitaxel)	SS		INTRAVENOUS	84 MG, QD, DAYS 7,14, IV	
	Myocardial Infarction	Other	Carboplatin (Carboplatin)	SS		INTRAVENOUS	900 MG, QD, DAYS 7, 14, 21, IV	
	Sinus Tachycardia		Solu-Medrol (Methylprednisolone) Powder, Sterile	SS		INTRAVENOUS	IV	
	Syncope		Kytril (Granisetron)	SS		INTRAVENOUS	15 MG, QD, IV	
	Ventricular Hypokinesia							
	Ventricular Tachycardia							

Date: 10/07/02 **ISR Number:** 3989556-0 **Report Type:** Expedited (15-Day) **Company Report#:** 2002121778FR **Age:** 60 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Crepitations	Foreign	Solu-Medrol (Methylprednisolone) Powder, Sterile	PS		INTRAVENOUS	IV	
	Dizziness	Health	Cisplatin (Cisplatin)	SS		INTRAVENOUS	IV	
	Syncope	Professional	Taxol (Paclitaxel)	SS		INTRAVENOUS	IV	
	Ventricular Tachycardia	Other	Etoposide (Etoposide)	SS		INTRAVENOUS	IV	
			Kytril (Granisetron)	SS		INTRAVENOUS	IV	
			Carboplatin (Carboplatin)	SS		INTRAVENOUS	IV	

Date: 10/29/02 **ISR Number:** 3999060-1 **Report Type:** Expedited (15-Day) **Company Report#:** WAES 0210USA02388 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Shock	Health Professional	Decadron (Dexamethasone Sodium Phosphate)	PS	Merck & Co., Inc			
			Ranitidine Hydrochloride	SS				
			Granisetron Hydrochloride	SS				

Date: 11/01/02 **ISR Number:** 4001387-4 **Report Type:** Expedited (15-Day) **Company Report#:** 323871 **Age:** 72 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased	Health	Kytril	PS	Roche			60 DAY
	Cyanosis	Professional	Zantac	SS				60 DAY
	Depressed Level Of Consciousness		Decadron	C				60 DAY
	Heart Rate Abnormal		Chemotherapy	C				
	Hypoaesthesia		Taxol	C			DOSAGE REPORTED AS 70MG/BODY	
	Hypoventilation							
	Nausea							
	Shock							

Date: 11/06/02 **ISR Number:** 4004647-6 **Report Type:** Expedited (15-Day) **Company Report#:** B0283969A **Age:** **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Shock		Zantac	PS	Glaxo Wellcome	INTRAVENOUS	200MG per day	
Other			Dexamethasone	SS		UNKNOWN		
			Granisetron Hydrochloride	SS	Glaxo Wellcome	UNKNOWN		

Date: 12/04/02 **ISR Number:** 4018753-3 **Report Type:** Expedited (15-Day) **Company Report#:** B0282226A **Age:** 38 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Apnoea	Health	Melphalan	PS	Glaxo Wellcome	INTRAVENOUS	60MGM2 per day	3 DAY
	Blood Pressure Fluctuation	Professional	Zovirax	SS	Glaxo Wellcome	ORAL	1G per day	42 DAY
	Loss Of Consciousness		Metoclopramide	SS	Glaxo Wellcome	INTRAVENOUS	10MG per day	1 DAY
			Furosemide	SS	Glaxo Wellcome	INTRAVENOUS	20MG per day	3 DAY
			Granisetron	SS	Glaxo Wellcome	INTRAVENOUS	6MG per day	3 DAY
			Famotidine	SS		ORAL	40MG per day	
			Fluconazole	SS		ORAL	200MG per day	59 DAY
			Levofloxacin	SS		ORAL	300MG per day	29 DAY
			Sulfamethoxazole + Trimethoprim	SS	Glaxo Wellcome		3TAB per day	50 DAY
			Sodium Bicarbonate	SS		INTRAVENOUS	100ML per day	7 DAY
			Polypharmacy	C				
			Allopurinol	C	Glaxo Wellcome			

Date: 12/12/02 **ISR Number:** 4021695-0 **Report Type:** Expedited (15-Day) **Company Report#:** B0283969A **Age:** 72 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Shock	Health	Zantac	PS	Glaxo Wellcome	INTRAVENOUS	100MG per day	57 DAY
Other	Blood Pressure Decreased	Professional	Dexamethasone Sodium Phosphate	SS		INTRAVENOUS	4MG per day	1 DAY
	Cyanosis		Granisetron Hydrochloride	SS	Glaxo Wellcome	INTRAVENOUS	1UNIT per day	1 DAY
	Heart Rate Decreased		Sodium Chloride	C	Glaxo Wellcome	INTRAVENOUS	100ML Unknown	
	Loss Of Consciousness							
	Nausea							

Date: 12/27/02 **ISR Number:** 4035031-7 **Report Type:** Expedited (15-Day) **Company Report#:** 2002CG01923 **Age:** 64 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Myocardial Infarction	Foreign	Mopral	PS				
	Myocardial Ischaemia	Health Professional	Fluorouracil	SS		INTRAVENOUS	4800 MG DAILY IV	
		Other	Eloxatine	SS		INTRAVENOUS	200 MG DAILY IV	
			Elvorine	SS		INTRAVENOUS	400 MG DAILY IV	
			Kytril	SS		INTRAVENOUS	2 DF DAILY IV	

Date: 01/02/03 **ISR Number:** 4039700-4 **Report Type:** Expedited (15-Day) **Company Report#:** 2002CG01923 **Age:** 64 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Myocardial Infarction	Foreign	Mopral	PS				
		Health Professional	Fluorouracil	SS		INTRAVENOUS	4800 MG DAILY IV	
		Other	Eloxatine	SS		INTRAVENOUS	200 MG DAILY IV	
			Elvorine	SS		INTRAVENOUS	400 MG DAILY IV	
			Kytril	SS		INTRAVENOUS	2 DF DAILY IV	

Date: 01/03/03 **ISR Number:** 4039235-9 **Report Type:** Expedited (15-Day) **Company Report#:** A02200202158 **Age:** 64 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Myocardial Ischaemia	Health Professional	Eloxatine - (Oxaliplatin) - Powder - 5 Mg/Ml	PS		INTRAVENOUS	200 MG DISC	1 DAY
			(Fluorouracil) - Solution	SS		INTRAVENOUS	4800 MG DISC	1 DAY
			Elvorine - (Calcium Levofolinate) - Powder - 100 Mg	SS			400 MG DISC	1 DAY
			Kytril - (Granisetron) - Solution - 1 Mg/Ml	SS		INTRAVENOUS	6 MG DISC	1 DAY
			Mopral - (Omeprazole) - Powder - 40 Mg	SS				

Date: 01/06/03 **ISR Number:** 4039512-1 **Report Type:** Expedited (15-Day) **Company Report#:** 316912 **Age:** **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	Erythema Multiforme	Foreign Health Professional	Kytril (Granisetron)	PS				
			Piroxicam (Piroxicam)	C				
			Ranitine (Ranitidine)	C				
			Co-Codamol (Acetaminophen/Codeine Phosphate)	C				
			Metoclopramide (Metoclopramide					

			Hydrochloride)	C				
			Propofol (Propofol)	C				
			Temazepam (Temazepam)	C				
			Glycopyrronium (Glycopyrrolate)	C				

Date: 01/06/03 **ISR Number:** 4039951-9 **Report Type:** Expedited (15-Day) **Company Report#:** 306099 **Age:** 75 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Diastolic Decreased	Foreign	Kytril (Granisetron)					
	Blood Pressure Systolic Increased	Health Professional	3 Mg	PS		INTRAVENOUS	3 MG INTRAVENOUS	
	Body Temperature Increased		Randa(Cisplatin)	SS		INTRAVENOUS DRIP	20 MG INTRAVENOUS DRIP	
	C-Reactive Protein Increased		Taxol (Paclitaxel)	SS		INTRAVENOUS DRIP	210 MG INTRAVENOUS DRIP	
	Ileus Paralytic							
	Metastases To Gastrointestinal Tract							
	Nausea		Leukoprol (Mirimostim)	C				
	Peritonitis							

Date: 01/08/03 **ISR Number:** 4040686-7 **Report Type:** Expedited (15-Day) **Company Report#:** 323871 **Age:** 72 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alanine Aminotransferase Increased	Foreign Health Professional	Kytril (Granisetron)	PS		INTRAVENOUS DRIP	3 MG DAILY INTRAVENOUS DRIP	
	Blood Creatinine Decreased							
	Blood Potassium Increased		Zantac (Ranitidine)	SS		INTRAVENOUS DRIP	100 MG DAILY INTRAVENOUS DRIP	
	Depressed Level Of Consciousness							
	Drug Hypersensitivity							
	Heart Rate Decreased		Decadron (Dexamethasone)	C				
	Hypoaesthesia		Taxol (Paclitaxel)	C				
	Lymphocyte Count Decreased							
	Nausea							
	Platelet Count Increased							
	Pulse Absent							
	Red Blood Cell Count Decreased							
	Shock							
	White Blood Cell Count Increased							

Date: 01/13/03 **ISR Number:** 4042387-8 **Report Type:** Expedited (15-Day) **Company Report#:** 328468 **Age:** 64 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Myocardial Ischaemia	Foreign Health Professional	Kytril (Granisetron)	PS		INTRAVENOUS	2 DOSE FORM DAILY INTRAVENOUS	
		Other	Mopral (Omeprazole) 40 Mg	SS		INTRAVENOUS	INTRAVENOUS	

Elvorine (Leucovorin Calcium) 100 Mg	SS		INTRAVENOUS	400 MG INTRAVENOUS	
Eloxatine (Oxaliplatin) 100 Mg	SS		INTRAVENOUS	200 MG INTRAVENOUS	
Fluoro-Uracil (Fluorouracil)	SS		INTRAVENOUS	4800 MG INTRAVENOUS	

Date: 02/13/03 **ISR Number:** 4057702-9 **Report Type:** Expedited (15-Day) **Company Report#:** 330988 **Age:** 27 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthma	Foreign Health Professional	Kytril (Granisetron)	PS				
			Becotide (Beclomethasone Dipropionate)	C				
			Ventolin (Albuterol Or Albuterol Sulfate)	C				
			Ibuprofen (Ibuprofen)	C				

Date: 02/14/03 **ISR Number:** 4056070-6 **Report Type:** Expedited (15-Day) **Company Report#:** JP-GLAXOSMITHKLINE-B0289581A **Age:** 59 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Shock	Health Professional	Zantac	PS	Glaxosmithkline	INTRAVENOUS	50MG per day	1 DAY
	Blood Pressure Decreased		Dexamethasone Sodium Phosphate	SS		INTRAVENOUS	4MG per day	1 DAY
	Erythema		Granisetron Hydrochloride	SS	Glaxosmithkline	INTRAVENOUS	3MG per day	1 DAY
	Flushing		Isotonic Sodium Chloride	C	Glaxosmithkline	INTRAVENOUS	100ML per day	1 DAY
	Haematocrit Decreased							
	Haemoglobin Decreased							
	Headache							
	Heart Rate Increased							
	Hyperhidrosis							
	Incontinence							
	Nausea							
	Vomiting							

Date: 02/27/03 **ISR Number:** 4084782-7 **Report Type:** Periodic **Company Report#:** 318705 **Age:** 20 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Pressure Decreased	Health Professional	Kytril (Granisetron) 1mg/Ml	PS		INTRAVENOUS	0.6MG 1 PER 2 HOUR INTRAVENOUS	
	Blood Pressure Fluctuation							
	Blood Pressure Increased							
	Disease Progression		Fentanyl (Fentanyl Citrate)	C				
	Dyspnoea		Dexamethasone (Dexamethasone)	C				
	Headache							
	Neoplasm Malignant							
	Rash Macular							
	Tachycardia							

Date: 02/27/03 **ISR Number:** 4084783-9 **Report Type:** Periodic **Company Report#:** 318905 **Age:** 70 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Rash	Health Professional	Kytril (Granisetron) 1 Mg	PS		INTRAVENOUS	INTRAVENOUS	
			Kytril (Granisetron) 1mg	SS		ORAL	ORAL	

Date: 03/18/03 **ISR Number:** 4079935-8 **Report Type:** Expedited (15-Day) **Company Report#:** US030847 **Age:** 40 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea	Health Professional	Neulasta (Neulasta - Prefilled Syringe)	PS		SUBCUTANEOUS	6 MG, EVERY 3 WEEKS, SC	
	Hypoxia		Doxorubicin Hydrochloride	SS				
			Docetaxel	SS				
			Cyclophosphamide	SS				
			Granisetron Hcl	SS				
			Dexamethasone	SS				

Date: 03/24/03 **ISR Number:** 4082971-9 **Report Type:** Expedited (15-Day) **Company Report#:** 333966 **Age:** 22 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia	Foreign Study	Granisetron Hydrochloride (Granisetron Hydrochloride)	PS		INTRAVENOUS DRIP	3 MG 2 PER DAY INTRAVENOUS DRIP	
	Pneumonia							
	Renal Disorder	Health Professional						
	Respiratory Failure							
	Stomatitis							
			Methotrexate (Methotrexate)	SS		OTHER	15 MG DAILY OTHER	
			Ciclosporin (Cyclosporine)	SS				
			Cytarabine (Cytarabine)	C				
			Prednisone (Prednisone)	C				
			Cyclophosphamide (Cyclophosphamide)	C				
			Morphine Hydrochloride (Morphine Hydrochloride)	C				
			Lasix (Furosemide)	C				
			Ciprofloxacin (Ciprofloxacin)	C				
			Firstcin (Cefozopran)	C				
			Diamox (Acetazolamide)	C				

Date: 03/24/03 **ISR Number:** 4082972-0 **Report Type:** Expedited (15-Day) **Company Report#:** 334137 **Age:** 13 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Foreign	Kytril (Granisetron)	PS		RECTAL	3 MG DAILY RECTAL	
	Hepatic Failure	Health						
	Stomatitis	Professional	Vincristine Sulfate (Vincristine)	C				
			Ifosfamide (Ifosfamide)	C				
			Mtx (Methotrexate)	C				
			Etoposide (Etoposide)	C				
			Ara-C (Cytarabine Hydrochloride)	C				

Date: 03/27/03 **ISR Number:** 4079562-2 **Report Type:** Expedited (15-Day) **Company Report#:** US-GLAXOSMITHKLINE-A0401594A **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Supraventricular Tachycardia		Zofran	PS	Glaxosmithkline			
			Kytril	SS	Glaxosmithkline			

Date: 03/28/03 **ISR Number:** 4080503-2 **Report Type:** Expedited (15-Day) **Company Report#:** WAES 0303USA02285 **Age:** 40 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea		Decadron (Dexamethasone Sodium Phosphate)	PS	Merck & Co., Inc			43 DAY
	Hypoxia		Neulasta	SS		SUBCUTANEOUS		23 DAY
			Adriamycin	SS				43 DAY
			Taxotere	SS				43 DAY
			Cyclophosphamide	SS				43 DAY
			Kytril	SS				43 DAY

Date: 04/02/03 **ISR Number:** 4083545-6 **Report Type:** Expedited (15-Day) **Company Report#:** JP-ROCHE-333966 **Age:** 22 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia	Health	Granisetron Hydrochloride	PS	Roche	INTRAVENOUS DRIP		1 DAY
	C-Reactive Protein Increased	Professional	Granisetron Hydrochloride	SS	Roche	INTRAVENOUS DRIP		2 DAY
	Malignant Mediastinal Neoplasm		Methotrexate	SS		OTHER		1 DAY
	Pneumonia		Ciclosporin	SS		INTRAVENOUS		7 DAY
	Pneumonitis		Ciclosporin	SS		INTRAVENOUS		4 DAY
	Renal Disorder		Cytarabine	C		OTHER		1 DAY
	Renal Failure		Prednisone	C		OTHER		1 DAY
	Respiratory Failure		Cyclophosphamide	C		INTRAVENOUS		2 DAY
	Stomatitis		Morphine Hydrochloride	C		INTRAVENOUS		6 DAY
			Lasix	C		INTRAVENOUS		3 DAY
			Ciprofloxacin	C		INTRAVENOUS		4 DAY
			Firstcin	C		INTRAVENOUS		2 DAY
			Diamox	C		INTRAVENOUS		1 DAY

Date: 04/02/03 **ISR Number:** 4088019-4 **Report Type:** Expedited (15-Day) **Company Report#:** 2003153054US **Age:** 40 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Hypoxia White Blood Cell Count Increased	Health Professional	Adriamycin Pfs (Doxorubicin Hydrochloride) Solution, Sterile	PS			CYCLE 3.	
			Neosar (Cyclophosphamide) Powder, Sterile	SS			CYCLE 3.	
			Neulasta (Neulasta - Prefilled Syringue)	SS		SUBCUTANEOUS	6 MG, EVERY 3 WEEKS, SUBCUTANEOUS	
			Taxotere (Docetaxel)	SS			CYCLE 3.	
			Kytril (Granisetron)	SS				
			Decadron (Dexamethasone)	SS				

Date: 04/03/03 **ISR Number:** 4084328-3 **Report Type:** Expedited (15-Day) **Company 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 Vomiting		Granisetron Hydrochloride	PS	Roche	INTRAVENOUS		6 DAY
			Zofran	SS		INTRAVENOUS		8 DAY
			Vincristin	C		INTRAVENOUS		
			Methotrexate	C		INTRAVENOUS		
			Oncaspar	C		INTRAMUSCULAR		

Date: 04/03/03 **ISR Number:** 4084332-5 **Report Type:** Expedited (15-Day) **Company Report#:** JP-ROCHE-333966 **Age:** 22 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening	Arrhythmia Pneumonia Renal Disorder Stomatitis		Granisetron Hydrochloride	PS	Roche	INTRAVENOUS DRIP		1 DAY
			Granisetron Hydrochloride	SS	Roche	INTRAVENOUS DRIP		2 DAY
			Methotrexate	SS		OTHER		1 DAY
			Ciclosporin	SS		INTRAVENOUS		7 DAY
			Ciclosporin	SS		INTRAVENOUS		4 DAY
			Cytarabine	C		OTHER		1 DAY
			Prednisone	C		OTHER		1 DAY
			Cyclophosphamide	C		INTRAVENOUS		2 DAY
			Morphine Hydrochloride	C		INTRAVENOUS		6 DAY
			Lasix	C		INTRAVENOUS		3 DAY
			Ciprofloxacin	C		INTRAVENOUS		4 DAY
			Firstcin	C		INTRAVENOUS		2 DAY
			Diamox	C		INTRAVENOUS		1 DAY

Date: 04/08/03 **ISR Number:** 4086486-3 **Report Type:** Expedited (15-Day) **Company Report#:** US-GLAXOSMITHKLINE-A0401594A **Age:** 5 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Supraventricular Tachycardia		Zofran	PS	Glaxosmithkline			
			Kytril	SS	Glaxosmithkline			

Date: 04/28/03 **ISR Number:** 4098476-5 **Report Type:** Expedited (15-Day) **Company Report#:** US-BRISTOL-MYERS SQUIBB COMPANY-12243572 **Age:** 40 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Hypoxia		Cytoxan	PS	Bristol-Myers Squibb Company			
			Adriamycin	SS				
			Taxotere	SS				
			Neulasta	SS		SUBCUTANEOUS		
			Kytril	SS				
			Decadron	SS				

Date: 05/07/03 **ISR Number:** 4107494-X **Report Type:** Direct **Company Report#:** CTU 192451 **Age:** 63 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Chest Pain		Kytril 1mg/Ml Roche	PS	Roche	INTRAVENOUS	1MG IV-SS WEEKLY	
			Gemzar 1 Gram Vials Lilly	SS	Lilly	INTRAVENOUS	2375ML IV-SS WEEKLY	
			Dexamethasone	C				

Date: 05/19/03 **ISR Number:** 4110684-3 **Report Type:** Expedited (15-Day) **Company Report#:** JP-BRISTOL-MYERS SQUIBB COMPANY-12270377 **Age:** 38 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaphylactic Shock		Paraplatin	PS	Bristol-Myers Squibb Company	INTRAVENOUS		1 DAY
			Kytril	SS		INTRAVENOUS		
			Docetaxel	C		INTRAVENOUS		

Date: 05/19/03 **ISR Number:** 4111182-3 **Report Type:** Periodic **Company Report#:** US-BRISTOL-MYERS SQUIBB COMPANY-11974201 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction Headache		Cytoxan	PS	Bristol-Myers Squibb Company			
			Adriamycin Rdf	SS				
			Kytril	SS				
			Solu-Medrol	SS				

Date: 05/19/03 **ISR Number:** 4111193-8 **Report Type:** Periodic **Company Report#:** US-BRISTOL-MYERS SQUIBB COMPANY-12027900 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction Headache		Cytoxan	PS	Bristol-Myers Squibb Company			
			Adriamycin Rdf	SS				
			Kytril	SS				

			Solu-Medrol	SS				

Date: 05/27/03 **ISR Number:** 4118100-2 **Report Type:** Expedited (15-Day) **Company Report#:** 081-9033-M0100001 **Age:** 74 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angina Pectoris Atrioventricular Block Complete Blood Pressure Decreased Bradycardia Cardioactive Drug Level Increased Condition Aggravated Dizziness Renal Impairment	Foreign Health Professional	Norvasc (Amlodipine)	PS		ORAL	5 MG (DAILY), ORAL	
			Herbesser R (Diltiazem Hydrochloride)	SS		ORAL	200 MG (DAILY), ORAL	
			Artist (Carvedilol)	SS		ORAL	10 MG (DAILY), ORAL	
			Sigmart (Nicorandil)	SS		ORAL	15 MG (DAILY), ORAL	
			Bayaspirin (Acetylsalicylic Acid)	SS		ORAL	100 MG (DAILY), ORAL	
			5 Fu (Fluorouracil)	SS		INTRAVENOUS	500 MG (DAILY), INTRAVENOUS	
			Cisplatin (Cisplatin)	SS		INTRAVENOUS	10 MG (DAILY), INTRAVENOUS	
			Kaytril (Granisetron Hydrochloride)	SS		INTRAVENOUS	3 MG (DAILY), INTRAVENOUS	
			Ciprofloxacin (Ciprofloxacin)	SS				
			Isosorbide Mononitrate (Isosorbide Mononitrate)	C				
			Famotidine (Famotidine)	C				
			Plaunotol (Plaunotol)	C				

Date: 06/05/03 **ISR Number:** 4122854-9 **Report Type:** Expedited (15-Day) **Company Report#:** JP-BRISTOL-MYERS SQUIBB COMPANY-12270377 **Age:** 38 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaphylactoid Reaction		Paraplatin	PS	Bristol-Myers Squibb Company	INTRAVENOUS		1 DAY
			Kytril	SS		INTRAVENOUS		
			Docetaxel	C		INTRAVENOUS		

Date: 06/30/03 **ISR Number:** 4148564-X **Report Type:** Periodic **Company Report#:** 2003012317 **Age:** 55 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Feeling Abnormal Leukopenia Pyrexia Skin Lesion	Health Professional	Zoloft (Sertraline)	PS		ORAL	200 MG (DAILY), ORAL	
			Granisetron (Granisetron)	SS				

Trazodone (Trazodone)	C
Ibuprofen (Ibuprofen)	C
Docusate (Docusate)	C
Prochlorperazine Edisylate (Prochlorperazine Edisylate)	C

Date: 07/02/03 **ISR Number:** 4139918-6 **Report Type:** Expedited (15-Day) **Company Report#:** TW-ROCHE-340784 **Age:** 61 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Gastritis	Health Professional	Kytril	PS	Roche	UNKNOWN		
			Epoetin Beta	SS	Roche	SUBCUTANEOUS		
			Docetaxel	C		SUBCUTANEOUS		
			Vitamin B Complex	C				
			Kolantyl	C				

Date: 07/11/03 **ISR Number:** 4190112-2 **Report Type:** Periodic **Company Report#:** 200312770US **Age:** 40 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea	Health Professional	Docetaxel (Taxotere)	PS				1 DAY
	Hypoxia		Doxorubicin	SS				1 DAY
	White Blood Cell Count Increased		Cyclophosphamide	SS				1 DAY
			Granisetron Hydrochloride	SS				
			Dexamethasone	SS				
			Neulasta	C				

Date: 07/11/03 **ISR Number:** 4194561-8 **Report Type:** Periodic **Company Report#:** 200312762US **Age:** 40 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea	Health Professional	Docetaxel (Taxotere)	PS				1 DAY
	Hypoxia		Doxorubicin	SS				1 DAY
	White Blood Cell Count Increased		Cyclophosphamide	SS				1 DAY
			Granisetron Hydrochloride	SS				
			Dexamethasone	SS				
			Neulasta	C				

Date: 07/15/03 **ISR Number:** 4147078-0 **Report Type:** Expedited (15-Day) **Company Report#:** JP-GLAXOSMITHKLINE-A0404662A **Age:** 60 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Function Abnormal	Consumer	Navelbine	PS	Glaxosmithkline	INTRAVENOUS	32MG Per day	8 DAY
	Liver Function Test Abnormal		Randa	SS		INTRAVENOUS	126MG Per day	1 DAY
			Kytril	SS	Glaxosmithkline	INTRAVENOUS	3MG Per day	8 DAY
			Ms Contin	C	Glaxosmithkline			
			Sennoside	C	Glaxosmithkline			
			Pantosin	C				
			Decadron	C				8 DAY
			Radiation	C				
			Magnesium Oxide	C				

			Alloid G	C				
			Urso	C				

Date: 07/28/03 **ISR Number:** 4155377-1 **Report Type:** Expedited (15-Day) **Company Report#:** JP-ROCHE-342994 **Age:** 14 MON **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased		Kytril	PS	Roche	INTRAVENOUS		57 DAY
	Chills		Chemotherapy	C				
	Dyspnoea							
	Pyrexia							

Date: 08/07/03 **ISR Number:** 4163381-2 **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-343928 **Age:** 72 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chest Pain		Kytril	PS	Roche	INTRAVENOUS		
Initial or Prolonged	Lethargy		Kytril	SS	Roche	INTRAVENOUS		1 DAY
			Decadron	C		INTRAVENOUS		1 DAY

Date: 08/18/03 **ISR Number:** 4169524-9 **Report Type:** Expedited (15-Day) **Company Report#:** GB-BRISTOL-MYERS SQUIBB COMPANY-12357257 **Age:** 50 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Lymphadenopathy		Cyclophosphamide	PS	Bristol-Myers Squibb			
Initial or Prolonged	Pancreatitis Acute				Company	ORAL		
			Fludarabine	SS		ORAL		
			Granisetron	SS		ORAL		
			Co-Trimoxazole	SS		ORAL		
			Allopurinol	C		ORAL		

Date: 09/02/03 **ISR Number:** 4176950-0 **Report Type:** Expedited (15-Day) **Company Report#:** TW-ROCHE-340784 **Age:** 61 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Aspartate		Kytril	PS	Roche	UNKNOWN		
Initial or Prolonged	Aminotransferase		Epoetin Beta	SS	Roche	SUBCUTANEOUS		
	Increased		Docetaxel	SS	Roche	INTRAVENOUS	DOSING	
	Blood Urea Decreased						REGIMEN	
	Cellulitis						REPORTED AS	
	Gastritis						115 MG Q3S.	106 DAY
	Haemoglobin Decreased		Vitamin B Complex	C				
	Skin Exfoliation		Kolantyl	C				
			Furosemide	C				17 DAY
			Potassium Chloride	C				17 DAY
			Diclofenac Sr	C				17 DAY
			Vitamin B6	C				17 DAY
			Cyprohepatadine	C				3 DAY
			Celecoxib	C				3 DAY

Date: 09/10/03 **ISR Number:** 4183087-3 **Report Type:** Expedited (15-Day) **Company Report#:** JP-ROCHE-342994 **Age:** 14 MON **Gender:** Male **I/FU:** F

Outcome	PT
Life-Threatening	Blood Alkaline Phosphatase Decreased

	Blood Creatinine Decreased Blood Pressure Decreased C-Reactive Protein Increased Chills Dyspnoea Haematocrit Decreased Haemoglobin Decreased Heart Rate Increased Irritability Peripheral Coldness Protein Total Decreased Pyrexia Red Blood Cell Count Decreased Tachypnoea White Blood Cell Count Decreased	**Report Source**	**Product** Kytril Chemotherapy Oncovin Cylocide Predonine Fungizone Baktar	**Role** PS C C C C C C	**Manufacturer** Roche	**Route** INTRAVENOUS INTRAVENOUS DRIP INTRAVENOUS DRIP ORAL ORAL ORAL	**Dose**	**Duration** 57 DAY 1 DAY 2 DAY 22 DAY 98 DAY 3 DAY

Date: 09/30/03 **ISR Number:** 4197603-9 **Report Type:** Expedited (15-Day) **Company Report#:** JP-ROCHE-342994 **Age:** 14 MON **Gender:** Male **I/FU:** F

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Life-Threatening	Anaphylactoid Reaction Blood Alkaline Phosphatase Decreased Blood Calcium Decreased Blood Creatinine Decreased Blood Pressure Decreased C-Reactive Protein Increased Chills Crying Dyspnoea Haematocrit Decreased Haemoglobin Decreased Heart Rate Increased Irritability Protein Total Decreased Red Blood Cell Count Decreased Respiratory Rate Increased Rhinorrhoea Sepsis White Blood Cell Count Decreased		Kytril Kytril Chemotherapy Oncovin Cylocide Predonine Fungizone Baktar	PS SS C C C C C C	Roche Roche	INTRAVENOUS INTRAVENOUS INTRAVENOUS DRIP INTRAVENOUS DRIP ORAL ORAL ORAL		1 DAY 1 DAY 1 DAY 2 DAY 22 DAY 98 DAY 3 DAY

Date: 10/06/03 **ISR Number:** 4201960-4 **Report Type:** Expedited (15-Day) **Company Report#:** TW-ROCHE-340784 **Age:** 61 YR **Gender:** Female **I/FU:** F

Outcome	**PT**
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased Blood Urea Decreased Cellulitis

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Gastritis		Kytril	PS	Roche	UNKNOWN		
Haemoglobin Decreased		Docetaxel	SS	Roche	INTRAVENOUS	DOSING REGIMEN REPORTED AS 115 MG Q3S.	106 DAY
		Epoetin Beta	C	Roche	SUBCUTANEOUS		
		Vitamin B Complex	C				
		Kolantyl	C				
		Furosemide	C				17 DAY
		Potassium Chloride	C				17 DAY
		Diclofenac Sr	C				17 DAY
		Vitamin B6	C				17 DAY
		Cyprohepatadine	C				3 DAY
		Celecoxib	C				3 DAY

Date: 10/16/03 **ISR Number:** 4209958-7 **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-343928 **Age:** 72 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Pain		Kytril	PS	Roche	INTRAVENOUS		1 DAY
	Deep Vein Thrombosis		Kytril	SS	Roche	INTRAVENOUS		1 DAY
	Haematoma		Kytril	SS	Roche	INTRAVENOUS		1 DAY
	Lethargy		Decadron	C		INTRAVENOUS		1 DAY
	Pulmonary Embolism							

Date: 10/27/03 **ISR Number:** 4218608-5 **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-349784 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Decreased		Kytril	PS	Roche	INTRAVENOUS		
	Dyspnoea		Decadron	C		INTRAVENOUS		
	Erythema		Benadryl	C		INTRAVENOUS		
	Pruritus							

Date: 12/01/03 **ISR Number:** 4243247-X **Report Type:** Expedited (15-Day) **Company Report#:** DE-ROCHE-350744 **Age:** 53 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills		Kevatril	PS	Roche	INTRAVENOUS		
	Diarrhoea Haemorrhagic		Capecitabine	SS	Roche	ORAL	ACTUAL DOSE RECEIVED = 3500 MG. INTERMITTENT THERAPY GIVEN	16 DAY
	Nausea							
	Paraesthesia							
	Paraesthesia Oral							
	Pyrexia							
	Rectal Stenosis		Capecitabine	SS	Roche	ORAL		
	Tachypnoea		Oxaliplatin	SS	Roche	INTRAVENOUS	ACTUAL DOSE RECEIVED = 250 MG.	
	Vomiting							
			Dexamethasone	SS		ORAL		

Date: 12/01/03 **ISR Number:** 4243436-4 **Report Type:** Expedited (15-Day) **Company Report#:** JP-GLAXOSMITHKLINE-B0311341A **Age:** 68 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	139 DAY
			Granisetron	SS	Glaxosmithkline	INTRAVENOUS	3MG Per day	139 DAY
			Dexamethasone	C		INTRAVENOUS		1 DAY
			Sodium Chloride Solution	C	Glaxosmithkline			

Date: 12/16/03 **ISR Number:** 4252277-3 **Report Type:** Expedited (15-Day) **Company Report#:** DE-ROCHE-353826 **Age:** 49 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaemia	Health	Interferon Alfa-2a	PS	Roche	UNKNOWN		
Hospitalization -	Cachexia	Professional	Granisetron Hydrochloride	SS	Roche	UNKNOWN		
Initial or Prolonged	Cardiac Failure		Vinblastin	SS		UNKNOWN		
	Cold Sweat		Gemzar	SS		UNKNOWN		
	Drug Toxicity		Dexa	SS		UNKNOWN		
			Zometa	SS		UNKNOWN		

Date: 12/17/03 **ISR Number:** 4253562-1 **Report Type:** Expedited (15-Day) **Company Report#:** DE-ROCHE-353826 **Age:** 49 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaemia	Health	Interferon Alfa-2a	PS	Roche	UNKNOWN		
Hospitalization -	Cachexia	Professional	Granisetron Hydrochloride	SS	Roche	UNKNOWN		
Initial or Prolonged	Cardiovascular Disorder		Vinblastin	SS		UNKNOWN		
	Cold Sweat		Gemzar	SS		UNKNOWN		
	Drug Toxicity		Dexa	SS		UNKNOWN		
	Shock		Zometa	SS		UNKNOWN		

Date: 01/13/04 **ISR Number:** 4269462-7 **Report Type:** Expedited (15-Day) **Company Report#:** FR-ROCHE-355362 **Age:** 34 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Osteonecrosis		Kytril	PS	Roche	INTRAVENOUS	ONE VIAL GIVEN DAILY ON DAYS 1 - 5 OF CYCLIC THERAPY.	46 DAY
			Bleomycine	SS		INTRAVENOUS	INTERMITTENT THERAPY GIVEN ON DAYS 1, 7 AND 15.	46 DAY
			Solu Medrol	SS		INTRAVENOUS	INTERMITTENT THERAPY GIVEN FROM DAY 1 -5.	46 DAY
			Vepeside	SS		INTRAVENOUS	GIVEN DAILY FROM DAY 1 - 5.	46 DAY
			Cisplatine	SS		INTRAVENOUS	GIVEN ON DAYS 1- 5.	46 DAY

Date: 01/15/04 **ISR Number:** 4274056-3 **Report Type:** Expedited (15-Day) **Company Report#:** 2004193697FR **Age:** 34 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Osteonecrosis	Foreign	Solu-Medrol (Methylprednisolone)					
		Health Professional	Powder, Sterile	PS		INTRAVENOUS	SEE IMAGE	
		Other	Cisplatin (Cisplatin)	SS		INTRAVENOUS	SEE IMAGE	
			Bleomycin (Bleomycin)	SS		INTRAVENOUS	SEE IMAGE	
			Vepesid (Etoposide)	SS		INTRAVENOUS	SEE IMAGE	
			Kytril (Granisetron)	SS		INTRAVENOUS	1 DF, IV	

Date: 02/06/04 **ISR Number:** 4286783-2 **Report Type:** Expedited (15-Day) **Company Report#:** DE-ROCHE-353826 **Age:** 49 YR **Gender:** Male **I/FU:** F

Outcome	PT
Death	Alpha 1 Globulin Increased
Hospitalization - Initial or Prolonged	Alpha 2 Globulin Increased
	Anaemia
	Beta Globulin Abnormal
	Blood Albumin Decreased
	Blood Alkaline Phosphatase Increased
	Blood Cholinesterase Decreased
	Bowel Sounds Abnormal
	Bundle Branch Block Right
	Cachexia
	Cardiovascular Disorder
	Cold Sweat
	Drug Toxicity
	Dyspnoea
	Electrocardiogram Repolarisation Abnormality
	Gamma-Glutamyltransferase Increased
	General Physical Condition Abnormal
	Immunoglobulins Increased
	Ischaemia
	Metastases To Bone
	Metastases To Lung
	Metastases To Nervous System
	Metastases To The Mediastinum
	Muscular Weakness
	Neoplasm Progression
	Neutrophil Count Increased
	Oesophageal Disorder
	Pneumonia
	Prothrombin Time Shortened
	Qrs Axis Abnormal
	Reticulocyte Count

Decreased
Tachycardia

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional	Interferon Alfa-2a	PS	Roche	UNKNOWN		
	Granisetron Hydrochloride	SS	Roche	UNKNOWN		
	Vinblastin	SS		UNKNOWN		
	Gemzar	SS		UNKNOWN		
	Dexa	SS		UNKNOWN		
	Zometa	SS		UNKNOWN		
	Morphine	C				

Date: 02/09/04 **ISR Number:** 4289971-4 **Report Type:** Expedited (15-Day) **Company Report#:** DE-ROCHE-357741 **Age:** 60 YR **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthralgia	Consumer	Kevatril	PS	Roche	INTRAVENOUS		
	Myalgia		Taxotere	SS		INTRAVENOUS		
	Oedema Peripheral		Fortecortin	SS		INTRAVENOUS	ROUTE IS REPORTED AS IV/ ORAL. DOSING REGIMEN IS	3 DAY
	Parainfluenzae Virus Infection		Paspertin	SS		ORAL		4 DAY
	Pyrexia		Berodual	C				
	Thrombophlebitis		Berotec	C				
			Imap	C				
			Pantozol	C				

Date: 02/23/04 **ISR Number:** 4302036-8 **Report Type:** Expedited (15-Day) **Company Report#:** FR-ROCHE-355362 **Age:** 34 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Osteonecrosis		Kytril	PS	Roche	INTRAVENOUS	ONE VIAL GIVEN DAILY ON DAYS 1 - 5 OF CYCLIC THERAPY.	46 DAY
			Bleomycine	SS		INTRAVENOUS	INTERMITTENT THERAPY GIVEN ON DAYS 1, 7 AND 15.	46 DAY
			Solu Medrol	SS		INTRAVENOUS	INTERMITTENT THERAPY GIVEN FROM DAY 1 -5.	46 DAY
			Vepeside	SS		INTRAVENOUS	GIVEN DAILY FROM DAY 1 - 5.	46 DAY
			Cisplatine	SS		INTRAVENOUS	GIVEN ON DAYS 1- 5.	46 DAY

Date: 02/23/04 **ISR Number:** 4303411-8 **Report Type:** Expedited (15-Day) **Company Report#:** 2004195147DE **Age:** 60 YR **Gender:** Female **I/FU:** F

Outcome	PT
Hospitalization - Initial or Prolonged	Arthralgia
	Myalgia

Nasopharyngitis
Oedema Peripheral
Rheumatoid Arthritis
Thrombophlebitis

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Study Health Professional Other	Comparator-Docetaxel (Comparator-Docetaxel) Injection	PS		INTRAVENOUS	75 MG/M2, DAILY, CYCLIC, IV	
	Comparator - Dexamethasone (Dexamethasone) Injection	SS		INTRAVENOUS	8MG, IV, IV	
	Comparator - Dexamethasone (Dexamethasone, Dexamethasone) Tablet	SS		ORAL	8 MG, ORAL, ORAL	
	Kevatril (Granisetron Hydrochloride)	SS		INTRAVENOUS	3 MG, QD, IV	
	Paspertin (Metoclopramide Hydrochloride)	SS		ORAL	40 MG, QID, ORAL	
	Pantozol (Pantoprazole Sodium)	C				
	Imap (Fluspirilene)	C				
	Begodural	C				

Date: 02/27/04 **ISR Number:** 4308988-4 **Report Type:** Expedited (15-Day) **Company Report#:** 2004193697FR **Age:** 34 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Osteonecrosis	Foreign Health Professional Other	Solu-Medrol (Methylprednisolone) Powder, Sterile	PS		INTRAVENOUS	SEE IMAGE	
			Cisplatin (Cisplatin)	SS		INTRAVENOUS	SEE IMAGE	
			Bleomycin (Bleomycin)	SS		INTRAVENOUS	SEE IMAGE	
			Vepesid (Etoposide)	SS		INTRAVENOUS	SEE IMAGE	
			Kytril (Granisetron)	SS		INTRAVENOUS	1 DF, IV	

Date: 03/01/04 **ISR Number:** 4308489-3 **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-359775 **Age:** 52 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Laryngeal Cancer		Kytril	PS	Roche	UNKNOWN		

Date: 03/02/04 **ISR Number:** 4311179-4 **Report Type:** Direct **Company Report#:** CTU 213586 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Bradycardia		Kytril 1 Mg Roche	PS	Roche	ORAL	1 MG DAILY ORAL	
			Fluconazole	C				

Gatifloxacin	C
Acyclovir	C
Allopurinol	C
Dexamethasone	C
Medroxyprogesterone	C

Date: 03/05/04 **ISR Number:** 4313375-9 **Report Type:** Direct **Company Report#:** CTU 213950 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Pruritus Rash		Kytril	PS		INTRAVENOUS	1 MG IV	

Date: 03/08/04 **ISR Number:** 4313492-3 **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-360234 **Age:** 65 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Myocardial Infarction		Kytril	PS	Roche	UNKNOWN		

Date: 03/24/04 **ISR Number:** 4325501-6 **Report Type:** Expedited (15-Day) **Company Report#:** 2004204331JP **Age:** 72 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium	Foreign Health Professional Other	Camptosar(Irinotecan) Solution, Sterile	PS		INTRAVENOUS DRIP	80 MG, IV DRIP	
			Randa(Cisplatin)	SS		INTRAVENOUS DRIP	IV DRIP	
			Kytril(Granisetron)	SS				

Date: 04/09/04 **ISR Number:** 4335639-5 **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-363445 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bronchospasm		Kytril	PS	Roche	INTRAVENOUS		

Date: 04/19/04 **ISR Number:** 4341086-2 **Report Type:** Expedited (15-Day) **Company Report#:** FR-ROCHE-363963 **Age:** 64 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Hepatitis Hepatitis Cholestatic		Kytril	PS	Roche	INTRAVENOUS	CYCLE	57 DAY
			Muphoran	SS		INTRAVENOUS	CYCLE	57 DAY
			Kytril	C		ORAL	CYCLE	

Date: 04/22/04 **ISR Number:** 4343974-X **Report Type:** Expedited (15-Day) **Company Report#:** FR-ROCHE-363963 **Age:** 64 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Consumer	Kytril	PS	Roche	ORAL	CYCLE	57 DAY
	Aspartate Aminotransferase Increased		Kytril	SS	Roche	INTRAVENOUS	CYCLE	57 DAY
	Hepatitis		Muphoran	SS		INTRAVENOUS	CYCLE	57 DAY
	Hepatitis Cholestatic							

Date: 05/11/04 **ISR Number:** 4356076-3 **Report Type:** Periodic **Company Report#:** US-BRISTOL-MYERS SQUIBB COMPANY-12279592 **Age:** 42 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Migraine		Doxorubicin Hcl	PS	Bristol-Myers Squibb Company			
			Cyclophosphamide	SS	Bristol-Myers Squibb Company			
			Neulasta	SS		SUBCUTANEOUS		
			Granisetron Hcl	SS				
			Dexamethasone	SS				

Date: 06/02/04 **ISR Number:** 4372362-5 **Report Type:** Expedited (15-Day) **Company Report#:** 2004204331JP **Age:** 72 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour	Foreign	Camptosar (Irinotecan)					
	Amnesia	Health	Solution, Sterile	PS		INTRAVENOUS DRIP	80 MG, IV DRIP	
	Blood Pressure Systolic Increased	Professional	Randa (Cisplatin)	SS		INTRAVENOUS DRIP	80 MG, IV DRIP	
	Body Temperature Increased	Other	Kytril (Granisetron)	SS		INTRAVENOUS DRIP	3 MG, IV DRIP	
	Delirium		Tenormin (Atenolol)	SS		ORAL	25 MG, ORAL	
	Depressed Level Of Consciousness		Norvasc (Amlodipine Besilate)	SS		ORAL	5 MG, ORAL	
	Restlessness		Blopress (Candesartan Cilexetil)	SS		ORAL	8 MG, ORAL	
	Tremor		Decadron	C				
	Urinary Incontinence							

Date: 06/08/04 **ISR Number:** 4372832-X **Report Type:** Expedited (15-Day) **Company Report#:** GB-BRISTOL-MYERS SQUIBB COMPANY-12357257 **Age:** 50 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pancreatitis Acute	Health Professional	Cyclophosphamide	PS	Bristol-Myers Squibb Company	ORAL		
			Fludarabine	SS		ORAL		
			Granisetron	SS		ORAL		
			Co-Trimoxazole	SS		ORAL		
			Allopurinol	C		ORAL		

Date: 06/09/04 **ISR Number:** 4374935-2 **Report Type:** Expedited (15-Day) **Company Report#:** GB-BRISTOL-MYERS SQUIBB COMPANY-12349288 **Age:** 50 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Lymphadenopathy Pancreatitis Acute		Cyclophosphamide	PS	Bristol-Myers Squibb Company	ORAL		
			Fludarabine	SS		ORAL		
			Granisetron	SS		ORAL		
			Co-Trimoxazol	SS		ORAL		
			Allopurinol	C				

Date: 06/10/04 **ISR Number:** 4378624-X **Report Type:** Expedited (15-Day) **Company Report#:** 2004AP02925 **Age:** 72 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium Depressed Level Of Consciousness Hypoacusis Memory Impairment Tremor Urinary Incontinence	Foreign Health Professional Other	Tenormin	PS			25 MG DAILY PO	
			Camptosar	SS			80 MG DAILY IVD	
			Randa	SS			80 MG DAILY IVD	
			Kytril	SS			3 MG DAILY IVD	
			Norvasc	SS			5 MG DAILY PO	
			Blopress	SS			8 MG DAILY PO	

Date: 06/21/04 **ISR Number:** 4384424-7 **Report Type:** Expedited (15-Day) **Company Report#:** 2004204331JP **Age:** 72 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Amnesia Blood Pressure Increased Body Temperature Increased Delirium Depressed Level Of Consciousness Hyperhidrosis Hypoacusis Restlessness Tremor Urinary Incontinence	Foreign Health Professional	Camptosar (Irinotecan) Solution, Sterile	PS		INTRAVENOUS DRIP	80 MG, UNK, IV DRIP	
			Randa (Cisplatin)	SS		INTRAVENOUS DRIP	80 MG, UNK, IV DRIP	
			Kytril (Granisetron)	SS		INTRAVENOUS DRIP	3 MG, UNK, IV DRIP	
			Atenolol (Atenolol, Atenolol) Tablet	SS		ORAL	25 MG, UNK, ORAL	
			Norvasc (Amlodipine Besilate)	SS		ORAL	5 MG, UNK, ORAL	
			Blopress (Candesartan Cilexetil)	SS		ORAL	8 MG, UNK, ORAL	
			Decadron	C				

Date: 06/23/04 **ISR Number:** 4386565-7 **Report Type:** Expedited (15-Day) **Company Report#:** 2004218807JP **Age:** 3 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Pancytopenia Streptococcal Sepsis	Foreign Literature

		Health Professional Other	Product	Role	Manufacturer	Route	Dose	Duration
			Cytosar (Cytarabine) Powder, Sterile	PS		INTRAVENOUS DRIP	2400 MG, QD, IV DRIP	
			Methotrexate (Methotrexate) Solution, Sterile	SS			12.5 MG, QD	
			Solu-Cortef (Hydrocortisone) Powder, Sterile	SS			25 MG, QD	
			L-Asparaginase (Asparaginase)	SS		INTRAVENOUS DRIP	6000 U, QD, IV DRIP	
			Granisetron Hydrochloride	SS				
			Methylprednisolone Sodium Succinate (Methylprednisolone Sodium Succinate)	C				

Date: 07/23/04 **ISR Number:** 4405350-0 **Report Type:** Expedited (15-Day) **Company Report#:** JP-BRISTOL-MYERS SQUIBB COMPANY-12648861 **Age:** 10 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Pulmonary Fibrosis		Endoxan	PS	Bristol-Myers Squibb Company	INTRAVENOUS		1091 DAY
			Uromitexan	SS	Bristol-Myers Squibb Company	INTRAVENOUS		1091 DAY
			Oncovin	SS		INTRAVENOUS		1091 DAY
			Randa	SS		INTRAVENOUS		1091 DAY
			Kytril	SS		INTRAVENOUS		1091 DAY

Date: 08/05/04 **ISR Number:** 4416578-8 **Report Type:** Expedited (15-Day) **Company Report#:** JP-BRISTOL-MYERS SQUIBB COMPANY-12648861 **Age:** 10 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Pulmonary Fibrosis	Health Professional	Endoxan	PS	Bristol-Myers Squibb Company	INTRAVENOUS		1091 DAY
			Uromitexan	SS	Bristol-Myers Squibb Company	INTRAVENOUS		1091 DAY
			Oncovin	SS		INTRAVENOUS		1091 DAY
			Randa	SS		INTRAVENOUS		1091 DAY
			Kytril	SS		INTRAVENOUS		1091 DAY

Date: 08/13/04 **ISR Number:** 4425135-9 **Report Type:** Expedited (15-Day) **Company Report#:** US-AMGEN-US084356 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypersensitivity Oropharyngeal Swelling Throat Tightness		Neulasta - Prefilled Syringe	PS		SUBCUTANEOUS		
			Kytril	SS				
			Adriamycin	C				
			Cytoxan	C				

Date: 08/13/04 **ISR Number:** 4425471-6 **Report Type:** Expedited (15-Day) **Company Report#:** JP-ROCHE-377253 **Age:** 70 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Arrhythmia		Kytril	PS	Roche	INTRAVENOUS		
	Cardioplegia		Briplatin	C				
	Shock		Saxizon	C				

Date: 08/19/04 **ISR Number:** 4431801-1 **Report Type:** Expedited (15-Day) **Company Report#:** 104959ISR **Age:** 40 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea	Health Professional	Carboplatin	PS		INTRAVENOUS	40 MILLIGRAM; INTRAVENOUS (NOS)	1 DAY
	Hyperhidrosis							
	Pain							
	Paraesthesia		Fluorouracil	SS		INTRAVENOUS	80 MILLIGRAM, INTRAVENOUS (NOS)	1 DAY
	Syncope							
	Vomiting		Alizapride Hydrochloride	SS		INTRAVENOUS	NI; INTRAVENOUS NOS	1 DAY
			Granisetron	SS		INTRAVENOUS	NI; INTRAVENOUS NOS	

Date: 08/23/04 **ISR Number:** 4430893-3 **Report Type:** Expedited (15-Day) **Company Report#:** DE-ROCHE-375868 **Age:** 66 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation	Health Professional	Kevatril	PS	Roche	ORAL		
	Intestinal Obstruction		Kevatril	SS	Roche	ORAL		1 DAY
			Investigational Drug	SS		UNKNOWN	STUDY DRUG: PTK787/ZK2225 84 VS PLACEBO.	
			Morphine	SS		UNKNOWN		
			Oxaliplatin	C				
			5-Fu	C				
			Leucovorin	C				

Date: 08/24/04 **ISR Number:** 4433273-X **Report Type:** Expedited (15-Day) **Company Report#:** DRON00204002739 **Age:** 51 YR **Gender:** Male **I/FU:** I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Glucose Increased
	Blood Magnesium Decreased
	Blood Sodium Decreased
	Confusional State
	Contusion
	Convulsion
	Eye Injury
	Face Injury
	Fall
	Gastrointestinal Haemorrhage
	Haemolytic Anaemia
	Liver Transplant Rejection

Mental Status Changes
Metabolic Encephalopathy
Nausea
Pancytopenia
Vomiting

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional	Marinol (Dronabinol)	PS		ORAL	DAILY PO	
	Aranesp (Aranesp)	SS		SUBCUTANEOUS	200 IU QD SC	
	Kytril (Granisetron)	SS		INTRAVENOUS	1 MG QD IV	
	Oxycontin (Oxycodone Hydrochloride)	SS		ORAL	20 MG BID PO	
	Neurontin (Gabapentin)	SS		ORAL	DAILY PO	
	Aricept (Donepezil Hydrochloride)	SS		ORAL	DAILY PO	
	Morphine Sulfate (Morphine Sulfate)	C				
	Chlorpromazine (Chlorpromazine)	C				
	Oxycodone (Oxycodone)	C				
	Prograf (Prograf)	C				
	Protonix (Protonix)	C				
	Prandin "Kuhn" (Deflazacort)	C				
	Zoloft (Sertraline Hydrochloride)	C				
	Glipizide (Glipizide)	C				
	Procardia (Nifedipine)	C				
	Magnesium (Magnesium)	C				
	Levaquin (Levofloxacin)	C				
	Pentamidine (Pentamidine)	C				
	Pericolace (Pericolace)	C				
	Dulcolax (Bisacodyl)	C				
	Asa (Acetylsalicylic Acid)	C				
	Lasix (Lasix)	C				
	Leukine (Sargramostim)	C				
	Dexamethasone (Dexamethasone)	C				
	Adriamycin (Doxorubicin)	C				
	Cisplatinum (Cisplatin)	C				
	Senecot (Senecot)	C				
	Inderal (Inderal)	C				
	Multivitamins (Multivitamins)	C				
	Insulin (Insulin)	C				
	Aldactone (Aldactone)	C				
	Megace (Megace)	C				

Date: 08/27/04 **ISR Number:** 4435177-5 **Report Type:** Expedited (15-Day) **Company Report#:** GB-ROCHE-378163 **Age:** 62 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Arrest		Kytril	PS	Roche	INTRAVENOUS		
			Midazolam	C		UNKNOWN		

Date: 08/30/04 **ISR Number:** 4439646-3 **Report Type:** Expedited (15-Day) **Company Report#:** USA-2004-0016457 **Age:** 51 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Glucose Increased Blood Magnesium Decreased Blood Sodium Decreased Confusional State Contusion Convulsion Eye Disorder Face Injury Fall Mental Status Changes Nausea Pancytopenia Vomiting	Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS			20 MG, QL2H	
			Oxyir Capsules 5 Mg(Oxycodone Hydrochloride, Oxycodone Hydrochloride) Ir	SS			5 MG, Q4H	
			Aranesp(Darbepoetin)	SS				
			Kytril(Granisetron)	SS		INTRAVENOUS	1 MG, INTRAVENOUS	
			Prograft(Tacrolimus)	SS			2 MG; 4 MG	
			Protonix(Pantoprazole)	SS			40 MG, DAILY	
			Acetylsalicylic Acid(Acetylsalicylic Acid)	SS			81 MG, DAILY	
			Gabapentin(Gabapentin)	SS				
			Magnesium(Magnesium)	SS			400 MG	
			Senokot(Senna Fruit)	SS				
			Donepezil(Donepezil)	SS				
			Inderal(Propranolol Hydrochloride)	SS				
			Dronabinol(Dronabinol)	SS				
			Megace(Megestrol Acetate)	SS				
			Insulin(Insulin)	SS				
			Aldactone(Spironolactone)	SS				
			Ambien(Zolpidem Tartrate)	SS				
			Chlorpromazine(Chlorpromazine)	C				
			Glipizide(Glipizide)	C				
			Procardia	C				
			Pentamidine(Pentamidine)	C				
			Peri-Colace (Sennoside A+B, Docusate Sodium) Tablet	C				
			Dulcolax	C				
			Dexamethasone(Dexamethasone)	C				
			Cis-Platinum(Cisplatin)	C				
			Zoloft(Sertraline					

			Hydrochloride)	C				
			Leukine(Sargramostim)	C				
			Adriamycin(Doxorubicin)	C				

Date: 08/31/04 **ISR Number:** 4437964-6 **Report Type:** Expedited (15-Day) **Company Report#:** DE-ROCHE-375868 **Age:** 66 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation	Health Professional	Kevatril	PS	Roche	ORAL		
	Intestinal Obstruction		Kevatril	SS	Roche	ORAL		1 DAY
			Investigational Drug	SS		UNKNOWN	STUDY DRUG: PTK787/ZK222584 VS PLACEBO.	
			Morphine	SS		UNKNOWN		
			Oxaliplatin	C				
			5-Fu	C				
			Leucovorin	C				

Date: 08/31/04 **ISR Number:** 4439240-4 **Report Type:** Expedited (15-Day) **Company Report#:** 2004057138 **Age:** 51 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Consumer	Neurontin (Gabapentin)	PS				
Other	Contusion	Health Professional	Aricept (Donepezil Hydrochloride)	SS				
	Convulsion		Oxycodone Hydrochloride (Oxycodone Hydrochloride)	SS			40 MG (20 MG, 2 IN 1 D)	
	Eye Injury		Darbepoetin Alfa (Darbepoetin Alfa)	SS		SUBCUTANEOUS	(200 MCG), SUBCUTANEOUS	
	Fall		Dronabinol (Dronabinol)	SS				
	Mental Status Changes		Granisetron (Granisetron)	SS			1 MG (1 MG, 1 IN 1 D)	
	Nausea		Zolpidem Tartrate (Zolpidem Tartrate)	C				
	Pancytopenia		Sertraline Hydrochloride	C				
	Soft Tissue Disorder		Glipizide (Glipizide)	C				
	Swelling		Nifedipine (Nifedipine)	C				
	Vomiting		Magnesium (Magnesium)	C				
			Levofloxacin (Levofloxacin)	C				
			Pentamidine (Pentamidine)	C				
			Bisacodyl (Bisacodyl)	C				
			Acetylsalicylic Aicd (Acetylsalicylic					

Acid)	C
Furosemide (Furosemide)	C
Sargramostim (Sargramostim)	C
Dexamethasone (Dexamethasone)	C
Granisetron (Granisetron)	C
Morphine Sulfate (Morphine Sulfate)	C
Chlorpromazine (Chlorpromazine)	C
Tacrolimus (Tacrolimus)	C
Pantoprazole (Pantoprazole)	C
Doxorubicin (Doxorubicin)	C
Cisplatin (Cisplatin)	C
Deflazacort (Deflazacort)	C
Senna Fruit (Senna Fruit)	C
Propranolol Hydrochloride (Propranolol Hydrochloride)	C
Multivitamins (Ascorbic Acid, Ergocalciferol, Folic Acid, Nicotinamide,	C
Insulin (Insulin)	C
Spironolactone (Spironolactone)	C
Megestroll Acetate (Megestrol Acetate)	C
Repaglinide (Repaglinide)	C

Date: 09/01/04 **ISR Number:** 4439042-9 **Report Type:** Expedited (15-Day) **Company Report#:** FR-BRISTOL-MYERS SQUIBB COMPANY-12683827 **Age:** 49 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intestinal Obstruction		Carboplatin	PS	Bristol-Myers Squibb Company	INTRAVENOUS	cycle 2: 12-May-2004, cycle 3: 26-May2004.	
			Paclitaxel	SS	Bristol-Myers Squibb Company	INTRAVENOUS	cycle 2: 12-May-2004, cycle 3: 26-May2004.	
			Polaramine	SS		INTRAVENOUS		
			Methylprednisolone	SS		INTRAVENOUS		
			Kytril	SS		INTRAVENOUS		

Date: 09/02/04 **ISR Number:** 4444227-1 **Report Type:** Expedited (15-Day) **Company Report#:** A03200402800 **Age:** 51 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Health Professional	Ambien - Zolpidem Tartrate - Tablet	PS		ORAL	ORAL	
	Confusional State		Aranesp - Darbepoetin Alfa - Solution	SS		SUBCUTANEOUS	SUBCUTANEOUS	
	Contusion		Marinol - Dronabinol	SS				
	Convulsion		Kytril - Granisetron - Solution -1 Mg	SS		INTRAVENOUS	1 MG QD - INTRAVENOUS NOS	
	Face Injury		Oxycontin - Oxycodone Hydrochloride - 20 Mg	SS			20 MG Q12HR	
	Fall		Neurontin - Gabapentin	SS				
	Fatigue		Aricept - Donepezil Hydrochloride	SS				
	Gastrointestinal Haemorrhage		Morphine Sulfate	C				
	Haemolytic Anaemia		Chlorpromazine	C				
	Liver Transplant Rejection		Oxycodone	C				
	Metabolic Encephalopathy		Tacrolimus	C				
	Pancytopenia		Pantoprazole	C				
	Swelling		Deflazacort	C				
			Sertraline Hydrochloride	C				
			Glipizide	C				
			Nifedipine	C				
			Magnesium	C				
			Levofloxacin	C				
			Pentamidine	C				
			Peri-Colace	C				
			Bisacodyl	C				
			Acetylsalicylic Acid	C				
			Furosemide	C				
			Sargramostim	C				
			Dexamethasone	C				
			Doxorubicin	C				
			Cisplatin	C				
			Senna Fruit	C				
			Propranolol Hydrochloride	C				
			Multivitamins	C				
			Insulin	C				
			Spironolactone	C				
			Megestrol Acetate	C				

Date: 09/03/04 **ISR Number:** 4440191-X **Report Type:** Expedited (15-Day) **Company Report#:** FR-ROCHE-378555 **Age:** 49 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intestinal Obstruction	Consumer	Kytril	PS	Roche	INTRAVENOUS		1 DAY
			Paclitaxel	SS		INTRAVENOUS		1 DAY
			Carboplatine	SS		INTRAVENOUS		1 DAY
			Methylprednisolone	SS		INTRAVENOUS	"A DOSE OF 1"	1 DAY
			Polaramine	SS		INTRAVENOUS	"A DOSE OF 5"	1 DAY

Date: 09/08/04 **ISR Number:** 4443661-3 **Report Type:** Expedited (15-Day) **Company Report#:** JP-GLAXOSMITHKLINE-B0340349A **Age:** 73 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaphylactic Shock		Zantac	PS	Glaxosmithkline	INTRAVENOUS	50MG Per day	18 WK
	Cough		Kytril	SS	Glaxosmithkline	INTRAVENOUS	3MG Per day	18 WK
	Depressed Level Of Consciousness		Decadron	SS		INTRAVENOUS	12MG Per day	18 WK
	Feeling Abnormal		Restamin	C	Glaxosmithkline	ORAL		18 WK
	Hot Flush		Taxol	C		INTRAVENOUS	100MG Per day	120 DAY
	Vomiting							

Date: 09/09/04 **ISR Number:** 4444935-2 **Report Type:** Expedited (15-Day) **Company Report#:** DE-ROCHE-375868 **Age:** 66 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation	Health Professional	Granisetron Hydrochloride	PS	Roche	ORAL		
	Intestinal Obstruction		Granisetron Hydrochloride	SS	Roche	ORAL		1 DAY
			Investigational Drug	SS		UNKNOWN	STUDY DRUG: PTK787/ZK2225 84 VS PLACEBO.	
			Morphine	SS		UNKNOWN		
			Oxaliplatin	C				
			5-Fu	C				
			Leucovorin	C				

Date: 09/10/04 **ISR Number:** 4449121-8 **Report Type:** Expedited (15-Day) **Company Report#:** 2004230236FR **Age:** 49 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intestinal Obstruction	Foreign Health Professional Other	Solu-Medrol (Methylprednisolone) Powder, Sterile	PS		INTRAVENOUS	120 MG, SINGLE, IV SEE IMAGE	
			Polaramine (Dexchlorpheniramine Maleate)	SS		INTRAVENOUS	5 MG, SINGLE, IV	
			Carboplatin (Carboplatin) Solut	SS		INTRAVENOUS	3 MG, SINGLE, IV	
			Clitaxel (Paclitaxel) Solution, Sterile	SS		INTRAVENOUS	SINGLE, IV	
			Eumetic (Granisetron Hhydrochloride) Solution, Sterile	SS		INTRAVENOUS	3 MG, SINGLE, IV	
			.	C				
			.	C				
			.	C				
			.	C				
			.	C				
			.	C				
			.	C				
			.	C				

Date: 09/15/04 **ISR Number:** 4450267-9 **Report Type:** Expedited (15-Day) **Company Report#:** USA-2004-0016457 **Age:** 51 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Health Professional Other	Oxycontin Tablets (Oxycondone Hydrochloride) Cr Tablet	PS			20 MG, Q12H	
	Blood Glucose Increased		Oxyir Capsules 5mg (Oxycodone Hydrochloride, (Oxycodone Hydrochloride) Ir	SS			5 MG, Q4H	
	Blood Magnesium Decreased		Aranesp (Darbepoetin)	SS				
	Blood Sodium Decreased		Kytril (Granisetron)	SS		INTRAVENOUS	1 MG, INTRAVENOUS	
	Confusional State		Prograf (Tacrolimus)	SS			SEE IMAGE	
	Contusion		Protonil (Pantoprazole)	SS			40 MG DAILY	
	Convulsion		Acetylsalicylic Acid (Acetylsalicylic Acid)	SS			81 MG, DAILY	
	Face Injury		Gabapentin (Gabapentin)	SS				
	Fall		Magnesium (Magnesium)	SS			400 MG	
	Fatigue		Senokot (Sennoside A+B)	SS				
	Mental Status Changes		Donepezil (Donepezil)	SS				
	Nausea		Inderal (Propranolol Hydrochloride)	SS				
	Pancytopenia		Dronabinol (Dronabinol)	SS				
	Swelling		Megace (Megestrol Acetate)	SS				
	Vomiting		Insulin (Insulin)	SS				
			Aldactone (Spironolactone)	SS				
			Ambien (Zolpidem Tartrate)	SS				
			Chlorpromazine (Chlorpromazine)	C				
			Glipizide (Glipizide)	C				
			Procardia	C				
			Pentamidine (Pentamidine)	C				
			Peri-Colace (Sennoside A+B, Docusate Sodium)	C				
			Dulcolax	C				
			Dexamethasone (Dexamethasone)	C				
			Cis-Platinum (Cisplatin)	C				
			Zoloft (Sertraline Hydrochloride)	C				
			Leukine (Sargramostim)	C				
			Adriamycin					

			(Doxorubicin)	C				

Date: 09/17/04 **ISR Number:** 4452316-0 **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-380104 **Age:** 51 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia		Granisetron					
Initial or Prolonged	Convulsion		Hydrochloride	PS	Roche	UNKNOWN		1 DAY
	Fall		Darbepoetin Alfa	SS		SUBCUTANEOUS		
	Fatigue		Dronabinol	SS		UNKNOWN		
	Gastrointestinal		Oxycodone	SS		UNKNOWN		31 DAY
	Haemorrhage		Gabapentin	SS		UNKNOWN		
	Haemolytic Anaemia		Donepezil					
	Head Injury		Hydrochloride	SS		UNKNOWN		
	Liver Transplant		Zolpidem Tartrate	SS		UNKNOWN		
	Rejection		Morphine Sulfate	C				55 DAY
	Mental Status Changes		Chlorpromazine	C				
	Metabolic Encephalopathy		Oxyir	C				
	Nausea		Tacrolimus	C				
	Neuropathy		Pantoprazole	C				
	Pancytopenia		Prandin	C				
	Swelling		Sertraline					
	Tremor		Hydrochloride	C				
	Vomiting		Glipizide	C				
			Nifedipine	C				
			Magnesium	C				
			Levofloxacine	C				8 DAY
			Pentamidine	C				
			Pericolace	C				
			Bisacodyl	C				
			Acetylsalicylic Acid	C				
			Frusemide	C		INTRAVENOUS		1 DAY
			Sargamostim	C		SUBCUTANEOUS		6 DAY
			Dexamethasone	C		INTRAVENOUS		1 DAY
			Doxorubicin	C				
			Cisplatin	C				
			Senna Fruit	C				
			Propranolol	C				
			Multivitamins	C				
			Insulin	C				
			Spironolactone	C				
			Megestrol Acetate	C				

Date: 09/17/04 **ISR Number:** 4452830-8 **Report Type:** Expedited (15-Day) **Company Report#:** 2004057138 **Age:** 51 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia	Consumer	Neurontin					
Initial or Prolonged	Confusional State	Health	(Gabapentin)	PS				
Other	Contusion	Professional	Aricept (Donepezil					
	Convulsion		Hydrochloride)					
	Fall		(Donepezil)	SS				
	Fatigue		Oxycodone					
	Mental Status Changes		Hydrochloride					
	Nausea		(Oxycodone					
	Pancytopenia		Hydrochloride)	SS			40 MG (20 MG	
	Skull X-Ray Abnormal						, 2 IN 1 D)	
	Swelling		Darbepoetin Alfa					
	Vomiting		(Darbepoetin Alfa)	SS		SUBCUTANEOUS	(200 MCG), SUBCUTANEOUS	

Dronabinol (Dronabinol)	SS	
Granisetron (Granisetron)	SS	1 MG (1 MG, 1 IN 1 D)
Zolpidem Tartrate (Zolpidem Tartrate)	C	
Sertraline Hydrochloride(Sertraline Hydrochloride)	C	
Glipizide (Glipizide)	C	
Nifedipine (Nifedipine)	C	
Magenesium (Magnesium)	C	
Levofloxacin (Levofloxacin)	C	
Pentamidine (Pentamidine)	C	
Peri-Colace (Casanthranol, Docusate Sodium)	C	
Bisacodyl (Bisacodyl)	C	
Acetylsalicylic Acid (Acetylsalicylic Acid)	C	
Furosemide (Furosemide)	C	
Sargramostim (Sargramostim)	C	
Dexamethasone (Dexamethasone)	C	
Granisetron (Granisetron)	C	
Morphine Sulfate (Morphine Sulfate)	C	
Chlorpromazine (Chlorpromazine)	C	
Tacrolimus (Tacrolimus)	C	
Pantoprazole (Pantoprazole)	C	
Doxorubicin (Doxorubicin)	C	
Cisplatin(Cisplatin)	C	
Deflazacort (Deflazacort)	C	
Senna Fruit (Sena Fruit)	C	
Propranolol Hydrochloride (Propranolol Hydrochloride)	C	
Multivitamins (Ascorbic Acid, Ergoclaciferol, Folic Acid, Nicotinamide,	C	
Insulin (Insulin)	C	

			Spironolactone (Spironolactone)	C				
			Megestrol Acetate (Megestrol Acetate)	C				
			Repaglinide (Repaglinide)	C				

Date: 09/20/04 **ISR Number:** 4453840-7 **Report Type:** Expedited (15-Day) **Company Report#:** FR-ROCHE-380528 **Age:** 53 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Angioneurotic Oedema		Kytril	PS	Roche	UNKNOWN		
	Urticaria		5-Fluorouracil	C				

Date: 09/21/04 **ISR Number:** 4454926-3 **Report Type:** Expedited (15-Day) **Company Report#:** FR-ROCHE-378555 **Age:** 49 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intestinal Obstruction		Kytril	PS	Roche	INTRAVENOUS		1 DAY
			Paclitaxel	SS		INTRAVENOUS		1 DAY
			Paclitaxel	SS		INTRAVENOUS		1 DAY
			Paclitaxel	SS		INTRAVENOUS		1 DAY
			Carboplatine	SS		INTRAVENOUS		1 DAY
			Carboplatine	SS		INTRAVENOUS		1 DAY
			Carboplatine	SS		INTRAVENOUS		1 DAY
			Methylprednisolone	SS		INTRAVENOUS		1 DAY
			Methylprednisolone	SS		INTRAVENOUS		1 DAY
			Methylprednisolone	SS		INTRAVENOUS		1 DAY
			Polaramine	SS		INTRAVENOUS		1 DAY
			Polaramine	SS		INTRAVENOUS		1 DAY
			Polaramine	SS		INTRAVENOUS		1 DAY

Date: 09/21/04 **ISR Number:** 4481626-6 **Report Type:** Periodic **Company Report#:** 167-20785-04060472(0) **Age:** 72 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Constipation	Foreign	Thalidomide - Pharmion (Thalidomide) (Capsules)	PS	Pharmion	ORAL	100 MG, QD, ORAL; 50 MG, QD, ORAL	
Hospitalization - Initial or Prolonged	Death	Study	Granisetron (Granisetron)	SS		INTRAVENOUS	1 MG, QD, INTRAVENOUS	
	Disease Progression	Health Professional	Gemcitabine (Gemcitabine) (Unknown)	SS				
	Dyspnoea	Other	Carboplatin (Carboplatin) (Unknown)	SS				
	Pleural Effusion		Manevac (Manevac)	C				
			Maxalon (Metoclopramide Hydrochloride)	C				
			Coversyl (Perindopril)	C				

Date: 09/27/04 **ISR Number:** 4461606-7 **Report Type:** Direct **Company Report#:** CTU 228120 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dystonia		Kytril	PS		INTRAVENOUS	0.1 MG IV PRN	
	Grip Strength Decreased							

Date: 09/28/04 **ISR Number:** 4461248-3 **Report Type:** Expedited (15-Day) **Company Report#:** FR-ROCHE-378555 **Age:** 49 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intestinal Obstruction		Kytril	PS	Roche	INTRAVENOUS		1 DAY
			Taxol	SS		INTRAVENOUS		1 DAY
			Taxol	SS		INTRAVENOUS		1 DAY
			Taxol	SS		INTRAVENOUS		1 DAY
			Carboplatine	SS		INTRAVENOUS		1 DAY
			Carboplatine	SS		INTRAVENOUS		1 DAY
			Carboplatine	SS		INTRAVENOUS		1 DAY
			Methylprednisolone	SS		INTRAVENOUS	MARKETED BY MERCK LABO9RATORY.	1 DAY
			Methylprednisolone	SS		INTRAVENOUS		1 DAY
			Methylprednisolone	SS		INTRAVENOUS		1 DAY
			Polaramine	SS		INTRAVENOUS		1 DAY
			Polaramine	SS		INTRAVENOUS		1 DAY
			Polaramine	SS		INTRAVENOUS		1 DAY

Date: 09/28/04 **ISR Number:** 4464806-5 **Report Type:** Direct **Company Report#:** CTU 228149 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dystonia		Kytril	PS		INTRAVENOUS	0.1 MG IV PRN	
	Grip Strength Decreased							

Date: 10/15/04 **ISR Number:** 4475449-1 **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-382568 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion		Kytril	PS	Roche	UNKNOWN		
			Demerol	SS		ORAL		

Date: 10/15/04 **ISR Number:** 4479026-8 **Report Type:** Expedited (15-Day) **Company Report#:** 104959ISR **Age:** 40 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Hypersensitivity	Health Professional	Carboplatin	PS		INTRAVENOUS	40 MILLIGRAM	
	Dyspnoea						INTRAVENOUS NOS	1 DAY
	Hyperhidrosis							
	Infusion Related Reaction		Fluorouracil	SS		INTRAVENOUS	80 MILLIGRAM	
	Pain						INTRAVENOUS	
	Paraesthesia						NOS	1 DAY
	Syncope		Alizapride					
	Vomiting		Hydrochloride	SS		INTRAVENOUS	INTRAVENOUS NOS	1 DAY
			Granisetron	SS		INTRAVENOUS	INTRAVENOUS NOS	1 DAY

Date: 10/27/04 **ISR Number:** 4486980-7 **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-383879 **Age:** 41 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia		Kytril	PS	Roche	UNKNOWN		
	Chest Discomfort		Taxol	C		INTRAVENOUS		
	Chills		Decadron	C				
	Dyspnoea		Benadryl	C				
	Flushing		Pepcid	C				
	Musculoskeletal Stiffness							
	Nausea							
	Oxygen Saturation Decreased							
	Tremor							
	Urinary Incontinence							

Date: 10/28/04 **ISR Number:** 4488120-7 **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-384077 **Age:** 45 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant		Kytril	PS	Roche	UNKNOWN		

Date: 11/02/04 **ISR Number:** 4494448-7 **Report Type:** Expedited (15-Day) **Company Report#:** 2004IC000341 **Age:** 73 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Foreign	5-Fluorouracil					
	Cerebral Haemorrhage	Health	(Fluorouracil)	PS		INTRAVENOUS	937 MG; INTRAVENOUS	
	Hepatic Neoplasm Malignant	Professional	Calcium Levofolinate (Calcium					
	Metastases To Abdominal Cavity		Levofolinate)	SS		INTRAVENOUS	400 MG; INTRAVENOUS	
	Metastases To Lung		Kytril (Granisetron)	SS		INTRAVENOUS	1 DF; INTRAVENOUS	
	Pain In Extremity		Firstcin (Cefozopran					
	Renal Mass		Hydrochloride)	SS		INTRAVENOUS	4 GM; INTRAVENOUS	
			Uniphyl (Theophylline)	SS		ORAL	200 MG; ORAL	
			Omepral (Omeprazole)	SS		ORAL	20 MG; ORAL	
			Allopurinol (Allopurinol)	SS		ORAL	100 MG; ORAL	
			Lac B (Lactobacillus Bifidus, Lyophilized)	SS		ORAL	3 GM; ORAL	
			Myslee (Zolpidem Tartrate)	SS		ORAL	10 MG; ORAL	
			Depas (Etizolam)	SS		ORAL	0.5 MG; ORAL	
			Herbal Extracts Nos (Herbal Extracts Nos)	SS		ORAL	ORAL	
			Lepetan (Buprenorphine Hydrochloride)	SS		RECTAL	RECTAL	

Date: 11/17/04 **ISR Number:** 4503166-8 **Report Type:** Expedited (15-Day) **Company Report#:** JP-MERCK-0411USA02460 **Age:** 50 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Shock		Decadron Tablets	PS	Merck & Co., Inc	ORAL		1 DAY
			Zantac	SS		PARENTERAL		1 DAY
			Kytril	SS		PARENTERAL		1 DAY
			Lactec	C		INTRAVENOUS DRIP		

Date: 11/19/04 **ISR Number:** 4505766-8 **Report Type:** Expedited (15-Day) **Company Report#:** JP-GLAXOSMITHKLINE-B0356810A **Age:** 50 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactoid Reaction		Zantac	PS	Glaxosmithkline	INTRAVENOUS	50MG Per day	0 DAY
	Hypotension		Kytril	SS	Glaxosmithkline	INTRAVENOUS	3MG Per day	0 DAY
			Decadron	SS		INTRAVENOUS	8MG Per day	0 DAY
			Lactec	C		INTRAVENOUS	100ML Per day	0 DAY

Date: 11/19/04 **ISR Number:** 4506181-3 **Report Type:** Expedited (15-Day) **Company Report#:** JP-MERCK-0411USA02460 **Age:** 50 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Shock Unresponsive To Verbal Stimuli	Health Professional	Decadron Tablets	PS	Merck & Co., Inc	ORAL		1 DAY
			Zantac	SS		PARENTERAL		1 DAY
			Kytril	SS		PARENTERAL		1 DAY
			Lactec	C		INTRAVENOUS DRIP		
			Sodium Chloride	C		INTRAVENOUS		

Date: 11/23/04 **ISR Number:** 4507626-5 **Report Type:** Expedited (15-Day) **Company Report#:** JP-BRISTOL-MYERS SQUIBB COMPANY-12770061 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaphylactic Shock		Briplatin	PS	Bristol-Myers Squibb Company	INTRAVENOUS DRIP	initiated therapy: 05-Aug-2003	323 DAY
Hospitalization - Initial or Prolonged	Hypoxic Encephalopathy							
	Pulse Absent							
			Kytril	SS		INTRAVENOUS DRIP		323 DAY
			Saxizon	SS		INTRAVENOUS DRIP		323 DAY
			Ts-1	SS		ORAL		350 DAY
			Bayaspirin	C		ORAL		
			Pletaal	C		ORAL		
			Aldactone-A	C		ORAL		
			Diovan	C		ORAL		
			Sigmart	C		ORAL		
			Artist	C		ORAL		
			Mexitil	C		ORAL		
			Lendormin	C		ORAL		

Date: 11/29/04 **ISR Number:** 4512311-X **Report Type:** Expedited (15-Day) **Company Report#:** JP-GLAXOSMITHKLINE-B0356810A **Age:** 50 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactoid Reaction		Zantac	PS	Glaxosmithkline	INTRAVENOUS	50MG Per day	0 DAY
	Defaecation Urgency		Kytril	SS	Glaxosmithkline	INTRAVENOUS	3MG Per day	0 DAY
	Depressed Level Of Consciousness		Decadron	SS		INTRAVENOUS	8MG Per day	0 DAY
	Face Oedema		Lactec Isotonic Sodium	C		INTRAVENOUS	100ML Per day	0 DAY
	Hypoaesthesia		Chloride	C	Glaxosmithkline	INTRAVENOUS	100ML Per day	1 DAY
	Hypotension							
	Nausea							
	Pallor							
	Pulse Pressure Decreased							
	Vomiting							

Date: 12/01/04 **ISR Number:** 4515198-4 **Report Type:** Expedited (15-Day) **Company 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 dose	1 DAY
	Hyperhidrosis							
	Hypotension		Vena	C	Glaxosmithkline	ORAL	3TAB Weekly	
	Nausea		Decadron	C		INTRAVENOUS	8MG Per day	
	Vomiting		Isotonic Sodium Chloride	C	Glaxosmithkline	INTRAVENOUS		
			Taxol	C				

Date: 12/10/04 **ISR Number:** 4523558-0 **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-388424 **Age:** 22 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest		Kytril	PS	Roche	UNKNOWN		1 DAY

Date: 12/21/04 **ISR Number:** 4533383-2 **Report Type:** Expedited (15-Day) **Company Report#:** JP-BRISTOL-MYERS SQUIBB COMPANY-12648861 **Age:** 10 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Body Temperature Decreased		Endoxan	PS	Bristol-Myers Squibb Company	INTRAVENOUS		1091 DAY
	Pericardial Effusion		Uromitexan	SS	Bristol-Myers Squibb Company	INTRAVENOUS		1091 DAY
	Pleural Effusion							
	Pleural Fibrosis		Oncovin	SS		INTRAVENOUS		1091 DAY
	Pulmonary Fibrosis		Randa	SS		INTRAVENOUS		1091 DAY
	Shock		Kytril	SS		INTRAVENOUS		1091 DAY

Date: 12/29/04 **ISR Number:** 4540944-3 **Report Type:** Expedited (15-Day) **Company Report#:** FR-GLAXOSMITHKLINE-B0362704A **Age:** 49 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain		Azantac	PS	Glaxosmithkline	INTRAVENOUS	25MG per day	1 DAY
	Dyspepsia		Taxol	SS		INTRAVENOUS	120MG per day	1 DAY
	Glossodynia		Paraplatine	SS		INTRAVENOUS	150MG per day	1 DAY
	Tachycardia		Kytril	SS	Glaxosmithkline	INTRAVENOUS	3MG per day	1 DAY
			Polaramine	SS		INTRAMUSCULAR	5MG per day	1 DAY
			Solumedrol	SS		INTRAVENOUS	20MG per day	1 DAY

Date: 01/10/05 **ISR Number:** 4556013-2 **Report Type:** Periodic **Company Report#:** A03200403494 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Demerol	PS			UNIT DOSE	
			Kytril - Granisetron - Unit Dose	SS				

Date: 01/14/05 **ISR Number:** 4552398-1 **Report Type:** Periodic **Company Report#:** US-GLAXOSMITHKLINE-A0508350A **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction		Imitrex	PS	Glaxosmithkline	UNKNOWN		
			Kytril	SS	Glaxosmithkline			

Date: 01/14/05 **ISR Number:** 4553018-2 **Report Type:** Expedited (15-Day) **Company Report#:** FR-BRISTOL-MYERS SQUIBB COMPANY-12814232 **Age:** 49 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 Drug Tolerance Decreased Dyspepsia Glossodynia Tachycardia		Taxol	PS	Bristol-Myers Squibb Company	INTRAVENOUS	6 mg/ml concentrate solution for infusion	1 DAY
			Carboplatin	SS	Bristol-Myers Squibb Company	INTRAVENOUS	50 mg solution for perfusion	1 DAY
			Kytril	SS		INTRAVENOUS		1 DAY
			Polaramine	SS		INTRAMUSCULAR		1 DAY
			Solu-Medrol	SS		INTRAVENOUS		1 DAY
			Azantac	SS		INTRAVENOUS		1 DAY

Date: 01/18/05 **ISR Number:** 4555843-0 **Report Type:** Periodic **Company Report#:** A001-002-006183 **Age:** 51 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	Convulsion Mental Status Changes	Health Professional	Aricept (Donepezil Hydrochloride)	PS		ORAL	ORAL	
			Aranesp (Darbepoetin Alfa)	SS		SUBCUTANEOUS	200 MCG, SUBCUTANEOUS	
			Marinol (Dronabinol)	SS				
			Kytril (Granisetron)	SS		INTRAVENOUS	INTRAVENOUS (NOT	
			Oxycontin (Oxycodone Hydrochloride)	SS			20 MG, 1 IN 12 HR	
			Neurontin (Gabapentin)	SS				
			Ambien (Zolpidem Tartrate)	SS				
			Oxy Ir (Oxycodone Hydrochloride)	SS			5 MG, 1 IN 4 HR	
			Morphine Sulfate	C				
			Chlorpromazine	C				
			Prograf (Tacrolimus)	C				
			Protonix					

(Pantoprazole)	C
Prandin (Repaglinide)	C
Zoloft (Sertraline Hydrochloride)	C
Glipizide	C
Procardia (Nifedipine)	C
Magnesium	C
Levaquin (Levofloxacin)	C
Pentamidine	C
Peri-Colace	C
Dulcolax (Bisacodyl)	C
Baby Aspirin (Acetylsalicylic Acid)	C
Dexamethasone	C
Adriamycin	C
Cisplatinum	C
Senokot (Senna Fruit)	C
Inderal (Propranolol Hydrochloride)	C
Multivitamins	C
Insulin	C
Aldactone (Spironolactone)	C
Megace (Megestrol Acetate)	C

Date: 01/24/05 **ISR Number:** 4559274-9 **Report Type:** Expedited (15-Day) **Company Report#:** FR-ROCHE-392640 **Age:** 54 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anoxia		Kytril	PS	Roche	INTRAVENOUS		1 DAY
	Chills		Gemzar	SS		INTRAVENOUS		70 DAY
	Cough							
	Cyanosis							
	Dyspnoea							
	General Physical Health Deterioration							
	Hyperhidrosis							
	Hypoxia							
	Lymphangitis							
	Pyrexia							
	Tachypnoea							

Date: 01/25/05 **ISR Number:** 4563090-1 **Report Type:** Expedited (15-Day) **Company Report#:** 2005015505 **Age:** 49 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Foreign	Solu-Medrol (Methylprednisolone Sodium Succinate)	PS		INTRAVENOUS	20 MG (20 MG, 1 IN 1 D), INTRAVENOUS	
	Burning Sensation	Health Professional						
	Dyspepsia							
	Tachycardia							
			Dexchlorpheniramne Maleate (Dexchlorpheniramine					

Maleate)	SS		INTRAMUSCULAR	5 MG (5 MG, 1 IN 1 D), INTRAMUSCULAR	
Clitaxel (Paclitaxel)	SS		INTRAVENOUS	120 MG (120 MG, 1 IN 1 D), INTRAVENOUS	
Ranitidine (Ranitidine Hydrochloride)	SS		INTRAVENOUS	25 MG (25 MG, 1 IN 1 D), INTRAVENOUS	
Carboplatin (Caraboplatin)	SS		INTRAVENOUS	150 MG (150 MG, 1 IN 1 D), INTRAVNEOUS	
Eumetic (Granisetron Hdyrochloride)	SS		INTRAVENOUS	3 MG (3 MG, 1 IN 1 D), INTRAVENOS	

Date: 01/28/05 **ISR Number:** 4563370-X **Report Type:** Periodic **Company Report#:** US-GLAXOSMITHKLINE-A0501961A **Age:** 49 YR **Gender:** Female **I/FU:** I

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

Date: 02/10/05 **ISR Number:** 4577057-0 **Report Type:** Expedited (15-Day) **Company Report#:** FR-SANOFI-SYNTHELABO-A02200500273 **Age:** 76 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dialysis		Eloxatine	PS		INTRAVENOUS		1 DAY
	Renal Failure Acute		Kytril	SS		INTRAVENOUS		
			Elvorine	SS		INTRAVENOUS		
			Fluorouracil Dakota Pharm	SS		INTRAVENOUS		

Date: 02/15/05 **ISR Number:** 4582840-1 **Report Type:** Expedited (15-Day) **Company Report#:** FR-ROCHE-394646 **Age:** 50 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Angioneurotic Oedema		Kytril	PS	Roche	INTRAVENOUS	DOSE REPORTED AS 1 DOSE/CYCLE	
	Myocardial Ischaemia							
	Shock							

Date: 02/15/05 **ISR Number:** 4582851-6 **Report Type:** Expedited (15-Day) **Company Report#:** FR-ROCHE-394891 **Age:** 76 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Renal Failure Acute		Kytril	PS	Roche	INTRAVENOUS		
			Fluorouracil	SS		INTRAVENOUS		
			Eloxatine	SS		INTRAVENOUS		
			Elvorine	SS		INTRAVENOUS		

Date: 02/23/05 **ISR Number:** 4589654-7 **Report Type:** Expedited (15-Day) **Company Report#:** FR-ROCHE-391539 **Age:** 51 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaphylactic Shock		Kytril	PS	Roche	INTRAVENOUS		
	Hypersensitivity		Kytril	SS	Roche	INTRAVENOUS		1 DAY
	Hypotension							
	Loss Of Consciousness							
	Myocardial Ischaemia							

Date: 02/25/05 **ISR Number:** 4591318-0 **Report Type:** Expedited (15-Day) **Company Report#:** FR-ROCHE-395684 **Age:** 68 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea		Kytril	PS	Roche	INTRAVENOUS		223 DAY
	Haemodialysis		Gemzar	SS		INTRAVENOUS		223 DAY
	Hypertension		Methylprednisolone	SS		INTRAVENOUS		223 DAY
	Oedema Peripheral							
	Renal Failure Acute							
	Respiratory Distress							

Date: 02/25/05 **ISR Number:** 4591322-2 **Report Type:** Expedited (15-Day) **Company Report#:** JP-ROCHE-395943 **Age:** 40 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction		Kytril	PS	Roche	INTRAVENOUS DRIP		
	Vomiting		Paxil	SS		ORAL		
			Cisplatin	SS		INTRAVENOUS DRIP		

Date: 02/25/05 **ISR Number:** 4596128-6 **Report Type:** Expedited (15-Day) **Company Report#:** A001-OCT-3720 **Age:** 51 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Contusion	Study	Aricept (Donepezil Hydrochloride)	PS				
	Face Injury	Health	Marinol (Dronabinol)	SS				
	Fall	Professional	Kytril (Granisetron)	SS		INTRAVENOUS	1 IN 1 D, INTRAVENOUS	
	Mental Status Changes		Oxycontin (Oxycodone Hydrochloride)	SS			1 IN 12 HR	
			Neurontin (Gabapentin)	SS				
			Ambien (Zolpidem Tartrate)	SS				
			Aranesp (Darbepoetin Alfa)	C				
			Morphine Sulfate					

(Morphine Sulfate)	C
Chlorpromazine (Chlorpromazine)	C
Oxy Ir (Oxycodone Hydrochloride)	C
Prograf (Tacrolimus)	C
Protonix (Pantoprazole)	C
Prandin (Repaglinide)	C
Zoloft (Sertraline Hydrochloride)	C
Glipizide (Glipizide)	C
Procardia (Nifedipine)	C
Magnesium (Magnesium)	C
Levaquin (Levofloxacin)	C
Pentamidine (Pentamidine)	C
Pericolace (Peri-Colace)	C
Dulcolax Suppository (Bisacodyl)	C
Baby Aspirin (Acetylsalicylic Acid)	C
Lasix (Furosemide)	C
Leukine (Sargramostim	C
Dexamethasone (Dexamethasone)	C
Adriamycin (Doxorubicin)	C
Cisplatinum (Cisplatin)	C
Senekot (Senna Fruit)	C
Inderal (Propranolol Hydrochloride)	C
Multivitamins (Multivitamins)	C
Insulin (Insulin)	C
Aldactone (Spironolactone)	C
Megace (Megestrol Acetate)	C

Date: 02/28/05 **ISR Number:** 4592757-4 **Report Type:** Expedited (15-Day) **Company Report#:** US-SOLVAY-00204002739 **Age:** 18935 DY **Gender:** Male **I/FU:** F

Outcome	PT
Death	Anaemia
Hospitalization - Initial or Prolonged	Confusional State
	Convulsion
	Face Injury
	Fall
	Hepatic Neoplasm Malignant

Mental Status Changes
Nausea
Pancytopenia
Vomiting

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Marinol	PS		ORAL	Daily Dose: unk.	
	Aranesp	SS		SUBCUTANEOUS	Daily Dose: 200 iu.	
	Oxycontin	SS		ORAL	Daily Dose: 40 mg.	31 DAY
	Aricept	SS		ORAL	Daily Dose: unk.	
	Neurontin	SS		ORAL	Daily Dose: unk.	
	Kytril	SS		INTRAVENOUS	Daily Dose: 1 mg.	1 DAY
	Morphine Sulfate	C		UNKNOWN	Daily Dose: 15 mg. Frequency:As needed	55 DAY
	Zoloft	C		ORAL	Daily Dose: 100 mg.	
	Procardia	C		ORAL	Daily Dose: 120 mg.	
	Dexamethasone	C		INTRAVENOUS	Daily Dose: 10 mg. Frequency:Once	1 DAY
	Leukine	C		SUBCUTANEOUS	Daily Dose: 500 mg.	7 DAY
	Lasix	C		INTRAVENOUS	Daily Dose: 40 mg. Frequency:Once	1 DAY
	Asa	C		ORAL	Daily Dose: 81 mg.	
	Dulcolax	C		RECTAL	Daily Dose: 5 mg. Frequency:As needed	
	Pericolace	C		UNKNOWN	Daily Dose: 2 DF.	
	Pentamidine	C		RESPIRATORY (INHALATION)	Daily Dose: unk.	
	Levaquin	C		ORAL	Daily Dose: 500 mg.	8 DAY
	Magnesium	C		ORAL	Daily Dose: 800 mg.	
	Darbepoetin Alfa	C		SUBCUTANEOUS	Daily dose: unknown	87 DAY
	Megace	C		ORAL	Daily Dose: unk.	
	Aldactone	C		ORAL	Daily Dose: unk.	
	Insulin	C		UNKNOWN	Daily Dose: unk.	
	Multivitamins	C		UNKNOWN	Daily Dose: unk.	
	Inderal	C		ORAL	Daily Dose: unk.	
	Senecot	C		UNKNOWN	Daily Dose:	

Cisplatinum	C	SUBCUTANEOUS	unk. Daily Dose: unk.	
Adriamycin	C	SUBCUTANEOUS	Daily Dose: unk.	
Glipizide	C	ORAL	Daily Dose: 500 mg.	
Prandin	C	ORAL	Daily Dose: 0.1 mg.	
Protonix	C	UNKNOWN	Daily Dose: 40 mg.	
Prograf	C	UNKNOWN	Daily Dose: 8 mg.	
Chlorpromazine	C	UNKNOWN	Daily Dose: 25 mg. Frequency:As needed	
Prograf	C	UNKNOWN	Daily Dose: 4 mg.	
Oxycodone	C	ORAL	Daily Dose: 30 mg.	

Date: 02/28/05 **ISR Number:** 4592838-5 **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-388424 **Age:** 22 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia Cardiac Arrest Ventricular Extrasystoles Ventricular Fibrillation		Kytril	PS	Roche	INTRAVENOUS		1 DAY

Date: 02/28/05 **ISR Number:** 4610652-9 **Report Type:** Periodic **Company Report#:** 374438 **Age:** 64 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant	Health Professional	Kytril (Granisetron)	PS		INTRAVENOUS	INTRAVENOUS	

Date: 03/11/05 **ISR Number:** 4605874-7 **Report Type:** Expedited (15-Day) **Company Report#:** PHBS2005JP02931 **Age:** 68 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Leukaemia		Glivec	PS	Novartis Sector: Pharma	ORAL	400 mg/day	8640 MIN
	Bradycardia		Prednisolone	SS		ORAL	30 mg/d	17280 MIN
	Cardio-Respiratory Arrest		Kytril	SS			1 DF/d	17280 MIN
	Electrocardiogram Qrs		Oncovin	SS			2 mg/d	1440 MIN
	Complex Prolonged		Daunomycin	SS			35 mg/d	2880 MIN
	Fatigue		Daunomycin	SS			35 mg/d	2880 MIN
	Haematemesis		Sunrabin	SS			250 mg/d	15840 MIN
	Nausea		Leukerin	SS		ORAL	100 mg/d	17280 MIN
	Oedema Peripheral		Micardis	SS		ORAL	40 mg/d	10080 MIN
	Urine Output Decreased		Sepamit - Slow Release	SS		ORAL	10 mg/d	11520 MIN
	Weight Increased		Itorol	SS		ORAL	40 mg/d	
			Novorapid	SS		SUBCUTANEOUS		
			Novorapid	SS		SUBCUTANEOUS		
			Baktar	SS		ORAL	4 DF/d	1440 MIN
			Baktar	SS		ORAL	4 DF/d	1440 MIN

Magnesium Oxide	SS	ORAL	2 g/d	8640 MIN
Gran	SS	SUBCUTANEOUS	150 ug/d	7200 MIN
Decadron	SS		40 mg/d	5760 MIN
Marzulene S	SS	ORAL	2 g/d	27360 MIN
Acecol	SS	ORAL	2 mg/d	7200 MIN
Acecol	SS	ORAL	4 mg/d	23040 MIN
Salobel	SS	ORAL	100 mg/d	23040 MIN
Itrizole	SS	ORAL	200 mg/d	24480 MIN
Pyrinazin	SS	ORAL	1.2 g/d	12960 MIN
Myslee	SS			31680 MIN
Omepral	SS		40 mg/d	
Adona (Ac-17)	SS		100 mg/d	
Hanp	SS	INTRAVENOUS	UNK, UNK	
Catabon	SS	INTRAVENOUS	72 ml/d	
Albumin Human	SS	INTRAVENOUS	2.5-5 g/d	
Lasix	SS	INTRAVENOUS	20-80 mg/d	20160 MIN
Hyper-Cvad	SS			

Date: 03/11/05 **ISR Number:** 4606031-0 **Report Type:** Expedited (15-Day) **Company Report#:** FR-ROCHE-397179 **Age:** 51 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aplasia Lymphangioleiomyomatosis Myeloid Leukaemia		Kytril	PS	Roche	INTRAVENOUS	DOSAGE REGIMEN REPORTED AS 6 DOSES TOTAL.	102 DAY
			Methylprednisolone	SS		INTRAVENOUS	DOSAGE REGIMEN REPORTED AS 6 DOSES TOTAL.	102 DAY
			Cardioxane	SS		INTRAVENOUS	DOSAGE REGIMEN REPORTED AS 6 DOSES TOTAL.	102 DAY
			Primperan	SS		INTRAVENOUS	DOSAGE REGIMEN REPORTED AS 6 DOSES TOTAL.	102 DAY
			Endoxan	SS		INTRAVENOUS	DOSAGE REGIMEN REPORTED AS 6 DOSES TOTAL.	102 DAY
			Unknown Study Drug	SS		INTRAVENOUS	DRUG NAME REPORTED AS EPIADRIAMYCIN E. DOSAGE REGIMEN	102 DAY

Date: 03/18/05 **ISR Number:** 4612576-X **Report Type:** Expedited (15-Day) **Company Report#:** DE-BRISTOL-MYERS SQUIBB COMPANY-12891685 **Age:** 78 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation Diarrhoea Proctalgia Proctitis		Cisplatin	PS	Bristol-Myers Squibb Company	PARENTERAL		
			Pemetrexed Disodium	SS		PARENTERAL		
			Kevatril	SS		INTRAVENOUS		2 DAY
			Vitamin B12	C				
			Lafol	C				
			Dexamethasone	C				

Enalapril	C			
Glucophage	C	Bristol-Myers Squibb Company		
L-Thyroxine	C		Dose: 100 ug	

Date: 03/29/05 **ISR Number:** 4621873-3 **Report Type:** Expedited (15-Day) **Company Report#:** TR-SANOFI-SYNTHELABO-A01200501677 **Age:** 56 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Grand Mal Convulsion		Oxaliplatin	PS		INTRAVENOUS		1 DAY
			Fluorouracil	SS		INTRAVENOUS		2 DAY
			Granisetron	SS		INTRAVENOUS		1 DAY
			Folinic Acid	C		INTRAVENOUS		

Date: 04/04/05 **ISR Number:** 4626132-0 **Report Type:** Expedited (15-Day) **Company Report#:** PHBS2005JP02931 **Age:** 68 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Leukaemia		Glivec	PS	Novartis Sector: Pharma	ORAL	400 mg/day	8640 MIN
	Aspiration		Prednisolone	SS		ORAL	30 mg/d	17280 MIN
	Blood Pressure Systolic Increased		Kytril	SS			1 DF/d	17280 MIN
	Bradycardia		Oncovin	SS			2 mg/d	1440 MIN
	Cardio-Respiratory Arrest		Daunomycin	SS			35 mg/d	2880 MIN
	Cardiovascular Disorder		Daunomycin	SS			35 mg/d	2880 MIN
	Electrocardiogram Qrs Complex Prolonged		Sunrabin	SS			250 mg/d	15840 MIN
	Fall		Leukerin	SS		ORAL	100 mg/d	17280 MIN
	Fatigue		Micardis	SS		ORAL	40 mg/d	10080 MIN
	Gastrointestinal Haemorrhage		Sepamit - Slow Release	SS		ORAL	10 mg/d	11520 MIN
	Haematemesis		Itorol	SS		ORAL	40 mg/d	
	Head Injury		Novorapid	SS		SUBCUTANEOUS		
	Nausea		Novorapid	SS		SUBCUTANEOUS		
	Oedema Peripheral		Baktar	SS		ORAL	4 DF/d	1440 MIN
	Platelet Count Decreased		Baktar	SS		ORAL	4 DF/d	1440 MIN
	Pulmonary Haemorrhage		Magnesium Oxide	SS		ORAL	2 g/d	8640 MIN
	Pulse Absent		Gran	SS		SUBCUTANEOUS	150 ug/d	7200 MIN
	Respiratory Rate Decreased		Decadron	SS			40 mg/d	5760 MIN
	Therapy Non-Responder		Marzulene S	SS		ORAL	2 g/d	27360 MIN
	Unresponsive To Verbal Stimuli		Acecol	SS		ORAL	2 mg/d	7200 MIN
	Urinary Incontinence		Acecol	SS		ORAL	4 mg/d	23040 MIN
	Urine Output Decreased		Salobel	SS		ORAL	100 mg/d	23040 MIN
	Weight Decreased		Itrizole	SS		ORAL	200 mg/d	24480 MIN
	Weight Increased		Pyrinazin	SS		ORAL	1.2 g/d	12960 MIN
			Myslee	SS				31680 MIN
			Omepral	SS			40 mg/d	
			Adona (Ac-17)	SS			100 mg/d	
			Hanp	SS		INTRAVENOUS	UNK, UNK	
			Catabon	SS		INTRAVENOUS	72 ml/d	
			Albumin Human	SS		INTRAVENOUS	2.5-5 g/d	
			Lasix	SS		INTRAVENOUS	20-80 mg/d	20160 MIN
			Hyper-Cvad	SS				

Date: 04/08/05 **ISR Number:** 4630817-X **Report Type:** Expedited (15-Day) **Company Report#:** FR-ROCHE-400863 **Age:** 75 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Rectal Haemorrhage		Kytril	PS	Roche	UNKNOWN		
	Thrombocytopenia		Solu-Medrol	SS		UNKNOWN		
			Fluorouracil	C				
			Oxaliplatin	C				
			Leucovorin	C				
			Irinotecan	C				

Date: 04/15/05 **ISR Number:** 4636424-7 **Report Type:** Expedited (15-Day) **Company Report#:** CA-ROCHE-400862 **Age:** 77 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatic Failure		Kytril	PS	Roche	UNKNOWN		
	Pleural Effusion		Carboplatin	C		INTRAVENOUS		
	Small Intestinal		Taxol	C		INTRAVENOUS		
	Obstruction		Pariet	C		ORAL		
			Levothyroxine	C		ORAL		

Date: 04/18/05 **ISR Number:** 4639296-X **Report Type:** Expedited (15-Day) **Company Report#:** USA-2004-0016457 **Age:** 51 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS			20 MG, Q12H	
	Blood Glucose Increased		Oxyir Capsules 5 Mg (Oxycodone Hydrochloride, Oxycodone Hydrochloride)	SS			5 MG, Q4H	
	Blood Magnesium Decreased		Aranesp (Darbepoetin)	SS				
	Blood Sodium Decreased		Kytril (Granisetron)	SS		INTRAVENOUS	1 MG, INTRAVENOUS	
	Brain Oedema		Prograf (Tacrolimus)	SS			SEE IMAGE	
	Confusional State		Protonix (Pantoprazole)	SS			40 MG, DAILY	
	Contusion		Acetylsalicylic Acid (Acetylsalicylic Acid)	SS			81 MG, DAILY	
	Fall		Gabapentin (Gabapentin)	SS				
	Fatigue		Magnesium (Magnesium)	SS			400 MG	
	Injury		Donepezil (Donepezil)	SS				
	Mental Status Changes		Inderal (Propranolol Hydrochloride)	SS				
	Nausea		Dronabinol (Dronabinol)	SS				
	Pancytopenia		Megace (Megestrol Acetate)	SS				
	Reticulocyte Count Increased		Insulin (Insulin)	SS				
	Vomiting		Aldactone (Spironolactone)	SS				

Ambien (Zolpidem Tartrate)	SS
Senokot (Sennoside A+B)	C
Chlorpromazine (Chlorpromazine)	C
Glipizide (Glipizide)	C
Procardia	C
Pentamidine (Pentamidine)	C
Peri-Colace (Sennoside A+B, Docusate Sodium) Tablet	C
Dulcolax	C
Dexamethasone (Dexamethasone)	C
Cis-Platinum (Cisplatin)	C
Zoloft (Sertraline Hydrochloride)	C
Leukine (Sargramostim)	C
Adriamycin (Doxorubicin)	C

Date: 04/29/05 **ISR Number:** 4648319-3 **Report Type:** Expedited (15-Day) **Company Report#:** CA-ROCHE-401304 **Age:** 45 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Eye Pain		Kytril	PS	Roche	OTHER	ROUTE: IV/PO.	21 DAY
	Photophobia		5 Fu	SS		INTRAVENOUS		32 DAY
	Vision Blurred		Stemetil	SS		ORAL		37 DAY
			Leucovorin	C		INTRAVENOUS		32 DAY

Date: 05/09/05 **ISR Number:** 4656163-6 **Report Type:** Expedited (15-Day) **Company Report#:** FR-ROCHE-403724 **Age:** 51 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Myeloid Leukaemia		Kytril	PS	Roche	INTRAVENOUS		93 DAY
	Bone Marrow Depression		Cardioxane	SS		INTRAVENOUS		102 DAY
			Endoxan	SS		UNKNOWN		102 DAY
			Primperan	SS		UNKNOWN		102 DAY
			Methylprednisolone	SS		UNKNOWN		102 DAY
			4'-Epiadriamycin	SS		UNKNOWN		

Date: 05/10/05 **ISR Number:** 4657548-4 **Report Type:** Expedited (15-Day) **Company Report#:** JP-BRISTOL-MYERS SQUIBB COMPANY-12949327 **Age:** 70 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea		Maxipime	PS	Bristol-Myers Squibb Company	INTRAVENOUS		4 DAY
	Lung Disorder		Gemzar	SS		INTRAVENOUS		1 DAY
	Pulmonary Oedema		Kytril	SS		INTRAVENOUS		1 DAY
			Mucodyne	C		ORAL		
			Opso	C		ORAL		

Date: 05/13/05 **ISR Number:** 4661752-9 **Report Type:** Expedited (15-Day) **Company Report#:** JP-ROCHE-404255 **Age:** 69 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiomegaly		Kytril	PS	Roche	INTRAVENOUS		
	Dyspnoea		Gemzar	SS		INTRAVENOUS		
	Lung Disorder		Maxipime	SS		INTRAVENOUS		4 DAY
	Pulmonary Haemorrhage		Mucodyne	C		ORAL		
	Pulmonary Oedema		Morphine Hydrochloride	C		ORAL		

Date: 05/23/05 **ISR Number:** 4669493-9 **Report Type:** Expedited (15-Day) **Company Report#:** JP-ROCHE-404255 **Age:** 69 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Disseminated		Kytril	PS	Roche	INTRAVENOUS		1 DAY
Hospitalization - Initial or Prolonged	Intravascular Coagulation		Gemzar	SS		INTRAVENOUS		1 DAY
	Liver Disorder		Maxipime	SS		INTRAVENOUS		4 DAY
	Lung Disorder		Mucodyne	C		ORAL	FORM REPORTED AS ORAL FORMULATION.	
	Pulmonary Oedema							
	Respiratory Failure							
			Morphine Hydrochloride	C		ORAL		

Date: 05/26/05 **ISR Number:** 4674526-X **Report Type:** Expedited (15-Day) **Company Report#:** JP-ROCHE-404255 **Age:** 69 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiomegaly		Kytril	PS	Roche	INTRAVENOUS		1 DAY
Hospitalization - Initial or Prolonged	Disseminated		Gemzar	SS		INTRAVENOUS		1 DAY
	Intravascular Coagulation		Maxipime	SS		INTRAVENOUS		4 DAY
	Liver Disorder		Mucodyne	C		ORAL	FORM REPORTED AS ORAL FORMULATION.	
	Lung Disorder							
	Pulmonary Oedema							
	Respiratory Failure							
			Morphine Hydrochloride	C		ORAL		
			Picibanil	C				

Date: 05/31/05 **ISR Number:** 4677314-3 **Report Type:** Expedited (15-Day) **Company Report#:** 200511035DE **Age:** 32 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Stress Disorder		Docetaxel	PS	Aventis Pharmaceuticals Inc.			
			Cyclophosphamid	SS				
			Adriamycin	SS				
			Fortecortin	SS				
			Kevatril	SS				
			Uromitexan	SS				

Date: 06/06/05 **ISR Number:** 4682446-X **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-380104 **Age:** 51 YR **Gender:** Male **I/FU:** F

Outcome	PT
Hospitalization - Initial or Prolonged	Anaemia
	Convulsion
	Disease Progression
	Gastrointestinal

Haemorrhage							
Haemolytic Anaemia							
Liver Transplant							
Rejection	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Mental Status Changes		Granisetron					
Metabolic Encephalopathy		Hydrochloride	PS	Roche	INTRAVENOUS		1 DAY
Nausea		Darbepoetin Alfa	SS		SUBCUTANEOUS		87 DAY
Pancytopenia		Dronabinol	SS		UNKNOWN		
Vomiting		Oxycodone	SS		UNKNOWN		31 DAY
		Gabapentin	SS		UNKNOWN		
		Donepezil					
		Hydrochloride	SS		UNKNOWN		
		Zolpidem Tartrate	SS		UNKNOWN		
		Morphine Sulfate	C				55 DAY
		Chlorpromazine	C				
		Oxyir	C				
		Tacrolimus	C				
		Pantoprazole	C				
		Prandin	C				
		Sertraline					
		Hydrochloride	C				
		Glipizide	C				
		Nifedipine	C				
		Magnesium	C				
		Levofloxacine	C				8 DAY
		Pentamidine	C				
		Pericolace	C				
		Bisacodyl	C				
		Acetylsalicylic Acid	C				
		Frusemide	C		INTRAVENOUS		1 DAY
		Sargamostim	C		SUBCUTANEOUS		6 DAY
		Dexamethasone	C		INTRAVENOUS		1 DAY
		Doxorubicin	C				
		Cisplatin	C				
		Senna Fruit	C				
		Propranolol	C				
		Multivitamins	C				
		Insulin	C				
		Spironolactone	C				
		Megestrol Acetate	C				

Date: 06/17/05 **ISR Number:** 4695051-6 **Report Type:** Expedited (15-Day) **Company Report#:** 081-9033-M0100001 **Age:** 74 YR **Gender:** Male **I/FU:** F

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Hospitalization - Initial or Prolonged	Atrioventricular Block Complete	Foreign Health	Norvasc (Amlodipine)	PS		ORAL	5 MG (DAILY), ORAL	
	Blood Pressure Decreased	Professional	Diltiazem Hydrochloride (Diltiazem					
	Bradycardia		Hydrochloride)	SS		ORAL	200 MG (DAILY), ORAL	
	Dizziness		Artist (Carvedilol)	SS		ORAL	10 MG (DAILY), ORAL	
	Malaise		Sigmart (Nicorandil)	SS		ORAL	15 MG (DAILY), ORAL	
	Renal Impairment		Bayaspirin (Acetylsalicylic Acid)	SS		ORAL	100 MG (DAILY), ORAL	
			Fluorouracil					

			(Fluorouracil)	SS		INTRAVENOUS	500 MG (DAILY), INTRAVENOUS	
			Cisplatin (Cisplatin)	SS		INTRAVENOUS	10 MG (DAILY), INTRAVENOUS	
			Granisetron (Granisetron Hydrochloride)	SS		INTRAVENOUS	3 MG (DAILY), INTRAVENOUS	
			Ciprofloxacin (Ciprofloxacin)	SS				
			Isosorbide Mononitrate (Isosorbide Mononitrate)	C				
			Famotidine (Famotidine)	C				
			Plaunotol (Plaunotol)	C				

Date: 06/20/05 **ISR Number:** 4696103-7 **Report Type:** Expedited (15-Day) **Company Report#:** 200510266BYL **Age:** 70 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Respiratory Failure	Foreign	Ciproxan-I.V. 300 (Ciprofloxacin)	PS		INTRAVENOUS DRIP	300 MG, QD, INTRAVENOUS DRIP	
	Dyspnoea	Health Professional	Maxipime (Cefepime Hydrochloride)	SS		INTRAVENOUS DRIP	2 G, TOTAL DAILY, INTRAVENOUS DRIP	
	Lung Disorder	Other	Gemzar (Gemcitabine Hydrochloride)	SS		INTRAVENOUS DRIP	1500 MG, QD, INTRAVENOUS DRIP	
			Kytril (Granisetron)	SS		INTRAVENOUS DRIP	3 MG, QD, INTRAVENOUS DRIP	
			Picibanil	C				

Date: 06/23/05 **ISR Number:** 4699642-8 **Report Type:** Expedited (15-Day) **Company Report#:** 200510266BYL **Age:** 70 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Respiratory Failure	Foreign	Ciproxan-I.V.300 (Ciprofloxacin Lactate)	PS		INTRAVENOUS DRIP	300 MG, QD, INTRAVENOUS DRIP	
	Disseminated Intravascular Coagulation	Health Professional	Maxipime (Cefepime Hydrochloride)	SS		INTRAVENOUS		
	Lung Disorder	Other						

						DRIP	2 G, TOTAL DAILY, INTRAVENOUS DRIP	
			Gemzar (Gemcitabine Hydrochloride)	SS		INTRAVENOUS DRIP	1500 MG, QD, INTRAVENOUS DRIP	
			Kytril (Granisetron)	SS		INTRAVENOUS DRIP	3 MG, QD, INTRAVENOUS DRIP	
			Picibanil	C				

Date: 06/30/05 **ISR Number:** 4704784-4 **Report Type:** Expedited (15-Day) **Company Report#:** 200510266BYL **Age:** 70 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Respiratory Failure Disseminated Intravascular Coagulation Dyspnoea Lung Disorder	Foreign Health Professional Other	Ciproxan-I.V. 300 (Ciprofloxacin Lactate)	PS		INTRAVENOUS DRIP	300 MG, QD, INTRAVENOUS DRIP	
			Maxipime (Cefepime Hydrochloride)	SS		INTRAVENOUS DRIP	2 G, TOTAL DAILY, INTRAVENOUS DRIP	
			Gemzar (Gemcitabine Hydrochloride)	SS		INTRAVENOUS DRIP	1500 MG, QD, INTRAVENOUS DRIP	
			Kytril (Granisetron)	SS		INTRAVENOUS DRIP	3 MG, QD, INTRAVENOUS DRIP	
			Picibanil	C				

Date: 07/08/05 **ISR Number:** 4709923-7 **Report Type:** Expedited (15-Day) **Company Report#:** IE-ROCHE-407181 **Age:** 43 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Localised Infection Parotid Gland Enlargement Swelling Face		Kytril	PS	Roche	UNKNOWN		1 DAY
			Kytril	SS	Roche	UNKNOWN		
			Dexamethasone	C		INTRAVENOUS		1 DAY
			Doxorubicin	C		INTRAVENOUS		1 DAY
			Cyclophosphamide	C		INTRAVENOUS		1 DAY

Date: 07/11/05 **ISR Number:** 4710514-2 **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-409123 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Grand Mal Convulsion		Kytril	PS	Roche	UNKNOWN		
			Kytril	SS	Roche	UNKNOWN		

Date: 07/15/05 **ISR Number:** 4715211-5 **Report Type:** Expedited (15-Day) **Company Report#:** IE-ROCHE-407181 **Age:** 43 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Sialoadenitis		Kytril	PS	Roche	ORAL		1 DAY
	Swelling Face		Kytril	SS	Roche	ORAL		
			Dexamethasone	C		INTRAVENOUS		1 DAY
			Doxorubicin	C		INTRAVENOUS		1 DAY
			Cyclophosphamide	C		INTRAVENOUS		1 DAY

Date: 07/15/05 **ISR Number:** 4715230-9 **Report Type:** Expedited (15-Day) **Company Report#:** AU-ROCHE-409696 **Age:** 47 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Erythema		Kytril	PS	Roche	INTRAVENOUS		1 DAY
	Infusion Related Reaction							
	Infusion Site Burning							
	Injection Site Irritation							
	Pruritus							
	Urticaria							

Date: 07/19/05 **ISR Number:** 4719234-1 **Report Type:** Direct **Company Report#:** CTU 253570 **Age:** 42 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pain Of Skin		Docetaxel (Taxotere)	PS		INTRAVENOUS	180 MG IV Q 2 WEEKS	
	Rash							
	Skin Exfoliation		Kytril 1mg	SS			1MG	
			Decadron 20 Mg Iv	SS		INTRAVENOUS	20 MG	
			Ambien	C				
			Paxil	C				
			Coreg	C				
			Zyrtec	C				
			Zestril	C				

Summary report for FOI selections:

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

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

Total number of reports: 475

From: 01-NOV-1997 To: Present