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: F05-8460

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 Anzemet. 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: DOLASETRON
ANZEMET
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: 12/11/97 **ISR Number:** 3007644-2 **Report Type:** Direct **Company Report#:** **Age:** 49 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Vomiting Projectile		Anzemet	PS		ORAL	100 MG IV PRE-CHEMO	
			Norvasc	C				

Date: 01/06/98 **ISR Number:** 3018705-6 **Report Type:** Direct **Company Report#:** **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Pressure Decreased Bradycardia Dizziness Dyspnoea Urticaria	Health Professional	Anzemet Benadryl Zantac	PS C C		INTRAVENOUS	140 MG, IV	

Date: 01/07/98 **ISR Number:** 3017435-4 **Report Type:** Direct **Company Report#:** **Age:** 76 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased Cardiac Failure Congestive Feeling Abnormal Vomiting		Anzemet Mtx 5fu Crx	PS C C C		INTRAVENOUS	100MG IVP	

Date: 01/09/98 **ISR Number:** 3078061-4 **Report Type:** Periodic **Company Report#:** 199712259HMRI **Age:** 68 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	100 MG ONCE IV	1 DAY
			Normal Saline	C				

Date: 01/09/98 **ISR Number:** 3078072-9 **Report Type:** Periodic **Company Report#:** 199712262HMRI **Age:** 59 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	100 MG QD IV	3 DAY
			Normal Saline	C				

Date: 01/09/98 **ISR Number:** 3078075-4 **Report Type:** Periodic **Company Report#:** 199712264HMRI **Age:** 40 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Haemorrhage Injection Site Pain Pain	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	100 MG QD IV	
			Normal Saline	C				

Date: 01/09/98 **ISR Number:** 3078079-1 **Report Type:** Periodic **Company Report#:** 199712265HMRI **Age:** 54 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	100 MG IV	
			Normal Saline	C				

Date: 01/09/98 **ISR Number:** 3078083-3 **Report Type:** Periodic **Company Report#:** 199712268HMRI **Age:** 31 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	100 MG ONCE IV	
			Normal Saline	C				

Date: 01/09/98 **ISR Number:** 3078093-6 **Report Type:** Periodic **Company Report#:** 199712270HMRI **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	100 MG QD IV	
			Normal Saline	C				

Date: 01/09/98 **ISR Number:** 3078956-1 **Report Type:** Periodic **Company Report#:** 199712303HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain Vasospasm	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	IV	

Date: 01/09/98 **ISR Number:** 3078959-7 **Report Type:** Periodic **Company Report#:** 199712304HMRI **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	IV	

Date: 01/09/98 **ISR Number:** 3078963-9 **Report Type:** Periodic **Company Report#:** 199712415HMRI **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	100 MG ONCE IV	
			Glucose Injection	C				

Date: 02/05/98 **ISR Number:** 3023978-X **Report Type:** Expedited (15-Day) **Company Report#:** 199810301HPD **Age:** 74 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Decreased Bradycardia Loss Of Consciousness Syncope	Foreign Health Professional Other	Dolasetrone Uremitexan	PS C		INTRAVENOUS	100 MG ONCE IV	1 DAY

Date: 02/17/98 **ISR Number:** 3030486-9 **Report Type:** Expedited (15-Day) **Company Report#:** 199810301HPD **Age:** 74 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Foreign	Anemet	PS		INTRAVENOUS	100 MG ONCE IV	
	Hypotension	Health						
	Loss Of Consciousness	Professional	Uremitexan	C				
	Syncope							
	Vomiting							

Date: 03/20/98 **ISR Number:** 3057054-7 **Report Type:** Expedited (15-Day) **Company Report#:** 199810663HMRI **Age:** 60 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Eye Rolling	Health	Dolasetron	PS		INTRAVENOUS	100 MG ONCE IV	1 DAY
Required Intervention to Prevent Permanent Impairment/Damage	Hyperhidrosis	Professional						
	Malaise		Chemotherapy (Nos)	C				
	Pallor							
	Paraesthesia							
	Respiratory Arrest							
	Syncope Vasovagal							

Date: 03/20/98 **ISR Number:** 3057055-9 **Report Type:** Expedited (15-Day) **Company Report#:** 199810657HMRI **Age:** 60 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyspnoea	Health	Dolasetron	PS		INTRAVENOUS	200 MG ONCE IV	1 DAY
	Heart Rate Irregular	Professional						
	Hyperhidrosis		No Ingredient					
	Hypotension		Defined	C				
	Pallor							

Date: 03/30/98 **ISR Number:** 3059400-7 **Report Type:** Expedited (15-Day) **Company Report#:** 199810663HMRI **Age:** 60 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased	Health	Dolasetron	PS		INTRAVENOUS	100 MG ONCE IV	1 DAY
Required Intervention to Prevent Permanent Impairment/Damage	Eye Rolling	Professional						
	Hyperhidrosis		Chemotherapy (Nos)	C				
	Malaise							
	Pallor							
	Paraesthesia							
	Respiratory Arrest							
	Syncope Vasovagal							

Date: 04/08/98 **ISR Number:** 3061466-5 **Report Type:** Expedited (15-Day) **Company Report#:** 199810663HMRI **Age:** 60 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased	Health	Dolasetron	PS		INTRAVENOUS	1000 MG ONCE IV	1 DAY
Required Intervention to Prevent Permanent Impairment/Damage	Eye Rolling	Professional						
	Hyperhidrosis		No Ingredient					
	Malaise		Defined	C				
	Pallor							
	Paraesthesia							
	Respiratory Arrest							
	Syncope Vasovagal							

Date: 04/13/98 **ISR Number:** 3063696-5 **Report Type:** Expedited (15-Day) **Company Report#:** 199810657HMRI **Age:** 60 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Decreased	Health Professional	Dolasetron	PS		INTRAVENOUS	200 MG ONCE IV	1 DAY
	Dyspnoea							
	Heart Rate Irregular		Etoposide	C				
	Hyperhidrosis		Carboplatin	C				
	Leukopenia							
	Pallor							

Date: 05/07/98 **ISR Number:** 3074686-0 **Report Type:** Expedited (15-Day) **Company Report#:** 199811232HMRI **Age:** 53 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrioventricular Block First Degree	Health Professional	Dolasetron	PS		INTRAVENOUS	12.5 MG ONCE IV	1 DAY
	Bradycardia		Fentanyl	C				
			Desflurane	C				

Date: 06/01/98 **ISR Number:** 3088543-7 **Report Type:** Expedited (15-Day) **Company Report#:** 199810657HMRI **Age:** 60 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyspnoea	Health Professional	Dolasetron	PS		INTRAVENOUS	200 MG ONCE IV	1 DAY
	Heart Rate Irregular							
	Hyperhidrosis		Etoposide	C				
	Hypotension		Carboplatin	C				
	Pallor							

Date: 06/04/98 **ISR Number:** 3091101-1 **Report Type:** Expedited (15-Day) **Company Report#:** 199811232 HMRI **Age:** 53 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrioventricular Block First Degree	Health Professional	Dolasetron	PS		INTRAVENOUS	12.5 MG ONCE IV	
	Bradycardia		Vancomycin	C				
			Fentanyl	C				
			Desflurane	C				
			Estrogens Conjugated	C				
			Ibuprofen	C				
			Paracetamol	C				
			Carisoprodol	C				

Date: 06/15/98 **ISR Number:** 3094435-X **Report Type:** Expedited (15-Day) **Company Report#:** 199811740HMRI **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Bradycardia Respiratory Arrest Syncope	Health Professional	Dolasetron	PS		INTRAVENOUS	12.5 MG ONCE IV	1 DAY
			Glycopyrronium Bromide	SS		INTRAVENOUS	0.2 MG ONCE IV	1 DAY
			Diazac	SS		INTRAVENOUS	5 MG ONCE IV	1 DAY
			Diltiazem Hydrochloride	C				

Date: 06/24/98 **ISR Number:** 3098723-2 **Report Type:** Direct **Company Report#:** **Age:** 40 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Pain Palpitations Tachycardia		Anzemet	PS			12.5 FU Q 6	

Date: 06/29/98 **ISR Number:** 3099486-7 **Report Type:** Expedited (15-Day) **Company Report#:** 199811850HMRI **Age:** 37 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability Other	Abnormal Dreams Agitation Anxiety Depersonalisation Hallucination Headache Insomnia Movement Disorder Parkinson'S Disease Tic Tremor	Consumer Health Professional	Dolasetron (Anzemet) Solution For Injection Propofol Fentanyl Sevoflurane Succinylcholine Chloride	PS C C C C		INTRAVENOUS	12.5 MG ONCE IV	

Date: 06/30/98 **ISR Number:** 3101330-6 **Report Type:** Periodic **Company Report#:** 199810648HMRI **Age:** 64 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain Upper Dizziness Dysgeusia Eye Rolling Flushing Hypoaesthesia Hypotension Paraesthesia	Health Professional	Dolasetron (Anzemet) Methotrexate Dexamethasone Normal Saline	PS C C C		INTRAVENOUS	100 MG ONCE IVF	1 DAY

Date: 06/30/98 **ISR Number:** 3101332-X **Report Type:** Periodic **Company Report#:** 199810700HMRI **Age:** 57 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Discomfort Dyspnoea Hypertension Pain Restlessness	Health Professional	Dolasetron (Anzemet) Normal Saline Vinorelbine Ditartrate (Navelbine) Prochlorperazine Edisylate (Compazine) Cisapride (Propulside) Analgesics/Antirheum atics (Analgesics/Antirheu matics) No Ingredient Defined (Anxiolytics)	PS C C C C C C		INTRAVENOUS	100 MG ONCE IVB	

Date: 06/30/98 **ISR Number:** 3101334-3 **Report Type:** Periodic **Company Report#:** 199811807HMRI **Age:** 30 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block Second Degree	Health Professional	Dolasetron (Anzemet)	PS		INTRAVENOUS	12.5 MG ONCE IV	1 DAY
	Syncope		Propofol	C				
			Pentanyl	C				

Date: 07/08/98 **ISR Number:** 3252302-2 **Report Type:** Periodic **Company Report#:** 199711288HMRI **Age:** 24 MON **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Health Professional	Dolasetron (Anzemet) Tablets	PS		ORAL	ONCE PO	1 DAY

Date: 07/08/98 **ISR Number:** 3252304-6 **Report Type:** Periodic **Company Report#:** 199711307HMRI **Age:** 24 MON **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure No Adverse Drug Effect	Health Professional	Dolasetron (Anzemet) Tablets	PS		ORAL	ONCE PO	1 DAY

Date: 07/08/98 **ISR Number:** 3252306-X **Report Type:** Periodic **Company Report#:** 199811037HMRI **Age:** 39 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction	Health	Dolasetron (Anzemet)					
	Chest Discomfort	Professional	Tablets	PS		ORAL	100MG ONCE PO	1 DAY
	Dysgeusia		Taxol	SS		INTRAVENOUS	IV	1 DAY
	Dyspnoea		Ranitidine Hydrochloride	C				
	Erythema		Dexamethasone	C				
			Diphenhydramine	C				

Date: 07/15/98 **ISR Number:** 3105630-5 **Report Type:** Expedited (15-Day) **Company Report#:** 199811740HMRI **Age:** 63 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia	Health	Dolasetron	PS		INTRAVENOUS	12.5 MG ONCE IV	1 DAY
Hospitalization - Initial or Prolonged	Oxygen Saturation Decreased	Professional	Diazepam	SS		INTRAVENOUS	5 MG ONCE IV	1 DAY
	Respiratory Arrest		Glycopyrronium Bromide (Robinul)	SS		INTRAVENOUS	0.2 MG ONCE IV	1 DAY
	Syncope							
	Syncope Vasovagal		Levothyroxine Sodium (Synthroid)	C				
			Atenolol	C				
			Estrogens Conjugated (Premarin)	C				
			Hydrochlorothiazide	C				
			Triamterene (Dyazide)	C				
			Ranitidine Hydrochloride (Zantac)	C				

Date: 07/16/98 **ISR Number:** 3108584-0 **Report Type:** Direct **Company Report#:** **Age:** 33 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Muscle Rigidity Stridor Trismus		Anzemet	PS	Hoechst/Marion/Roussel		12.5 MG IV X1	

Date: 07/20/98 **ISR Number:** 3109627-0 **Report Type:** Direct **Company Report#:** **Age:** 43 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Heart Rate Increased		Anzemet	PS	Abbott	INTRAVENOUS	12.5 MG IV X 1	

Date: 07/31/98 **ISR Number:** 3110704-9 **Report Type:** Direct **Company Report#:** **Age:** 38 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Cyanosis Hypotension Oxygen Saturation Decreased		Anzemet	PS		INTRAVENOUS	12.5 MGM X 1 IVP	

Date: 08/03/98 **ISR Number:** 3112472-3 **Report Type:** Expedited (15-Day) **Company Report#:** 199812359HMRI **Age:** 43 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akinesia Pain	Health Professional	Dolasetron	PS		INTRAVENOUS	12.5 MG ONCE IV	1 DAY
			Midazolam Hydrochloride	C				
			Cefemetazole Sodium	C				
			Propofol	C				
			Neostigmine	C				
			Famotidine	C				
			Fentanyl	C				
			Glycopyrronium Bromide	C				

Date: 08/04/98 **ISR Number:** 3111678-7 **Report Type:** Direct **Company Report#:** **Age:** 69 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrioventricular Block Complete Bradycardia Syncope		Dolasetron	PS	Hoechst Marion Roussel	INTRAVENOUS	100MG IV X 1 DOSE	

Date: 08/10/98 **ISR Number:** 3117569-X **Report Type:** Expedited (15-Day) **Company Report#:** 199814001DDC **Age:** 69 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Dermatitis Pruritus Psoriasis	Foreign Study Health

Professional

Product	Role	Manufacturer	Route	Dose	Duration
Dolasetron	PS		ORAL	100 MG QD PO	
Lefaxin	C				
Ulcusan	C				

Date: 08/10/98 **ISR Number:** 3117570-6 **Report Type:** Expedited (15-Day) **Company Report#:** 199811850HMRI **Age:** 37 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Dreams	Consumer	Dolasetron	PS		INTRAVENOUS	12.5 MG ONCE IV	
	Agitation	Health						
	Anxiety	Professional	Propofol	C				
	Depersonalisation		Fentanyl	C				
	Enzyme Abnormality		Sevoflurane	C				
	Hallucination		Succinylcholine					
	Headache		Chloride	C				
	Insomnia							
	Metabolic Disorder							
	Muscle Twitching							
	Tic							
	Tremor							

Date: 08/13/98 **ISR Number:** 3116553-X **Report Type:** Expedited (15-Day) **Company Report#:** 199812444HMRI **Age:** 70 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardio-Respiratory Arrest	Health	Anzemet	PS		INTRAVENOUS	100 MG QR IV	
	Cyanosis	Professional	Gabapentin					
	Dyskinesia		(Neurotin)	C				
	Feeling Abnormal		Furosemide (Lasix)	C				
	Flushing		Fluorouracil (5-Fu)	C				
	Headache		Leucovorin	C				
	Hypotension		Taxol	C				
	Lethargy							
	Loss Of Consciousness							
	Pulse Absent							

Date: 08/19/98 **ISR Number:** 3118355-7 **Report Type:** Expedited (15-Day) **Company Report#:** 199812541HMRI **Age:** 69 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrioventricular Block Complete	Health	Dolasetron	PS		INTRAVENOUS	100 MG ONCE IV	
	Bradycardia	Professional						
	Nausea							
	Syncope							
	Vomiting							

Date: 09/10/98 **ISR Number:** 3128055-5 **Report Type:** Expedited (15-Day) **Company Report#:** 19981244HMRI **Age:** 70 YR **Gender:** Female **I/FU:** F

Outcome	PT
Hospitalization - Initial or Prolonged	Atrial Fibrillation
	Blood Culture Positive
	Blood Pressure Decreased

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Coma							
Cyanosis							
Dyskinesia							
Feeling Abnormal	Health	Dolasetron	PS		INTRAVENOUS	100 MG QW IV	190 DAY
Flushing	Professional	Gabapetin	C				
Headache		Furosemide	C				
Lethargy		Fluoruracil	C				
Loss Of Consciousness		Leucovorin	C				
Pulse Absent		Taxol	C				

Date: 09/14/98 **ISR Number:** 3128919-2 **Report Type:** Expedited (15-Day) **Company Report#:** 199812722HMRI **Age:** 44 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Health	Dolasetron	PS		INTRAVENOUS		
	Cardiac Enzymes Increased	Professional				BOLUS	12.5 MG ONCE	
	Drug Ineffective						IVB	1 DAY
	Feeling Hot		Cefotaxime Sodium					
	Nausea		(Claforan) Glucose	C				
	Pulmonary Oedema		Sodium Lactate,	C				
	Pulse Pressure Decreased		Potassium Chloride	C				
	Ventricular Fibrillation		Sodium Chloride	C				
	Ventricular Tachycardia		Amfebutamamone	C				
	Vomiting							

Date: 09/17/98 **ISR Number:** 3131004-7 **Report Type:** Direct **Company Report#:** **Age:** 44 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Anxiety		Anzemet(Dolasetron)	PS	Hoechst Marion			
Intervention to	Hypotension				Roussel	INTRAVENOUS	12.5MG ONCE	
Prevent Permanent	Hypoxia						IV	
Impairment/Damage	Nausea		Clafaron	C				
	Pulmonary Oedema		D5lr Iv	C		INTRAVENOUS		
	Pulse Pressure Decreased							
	Supraventricular Tachycardia							
	Tachypnoea							
	Ventricular Tachycardia							
	Vomiting							

Date: 09/28/98 **ISR Number:** 3136021-9 **Report Type:** Expedited (15-Day) **Company Report#:** 199812722HMRI **Age:** 44 YR **Gender:** Female **I/FU:** F

Outcome	PT
Other	Anxiety
	Blood Amylase Increased
	Cardiac Enzymes Increased
	Drug Interaction
	Feeling Hot
	Heart Rate Increased
	Hypotension
	Hypoxia
	Lipase Increased
	Myocardial Ischaemia
	Nausea
	Pulmonary Oedema
	Pulse Pressure Decreased

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Supraventricular Tachycardia Vomiting	Health Professional	Dolasetron	PS		INTRAVENOUS BOLUS	12.5 MG ONCE IVB	1 DAY
		Cefotaxime Sodium	C				
		Glucose	C				
		Sodium Lactate	C				
		Potassium Chloride	C				
		Sodium Chloride	C				
		Calcium Chloride Dihydrate	C				
		Amfebutamone	C				
		Beclometasone Dipropionate	C				
		Salbutamol	C				

Date: 10/06/98 **ISR Number:** 3252310-1 **Report Type:** Periodic **Company Report#:** 199712410HMRI **Age:** 58 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia Hypotension Pallor Speech Disorder Visual Disturbance Vomiting	Health Professional	Dolasetron (Anzemet) Solution For Injection	PS		INTRAVENOUS BOLUS	100 MG PRN IVB	2 DAY
			Codeine Phosphate, Paracetamol (Tylenol With Codeine)	C				
			Carboplatin	C				
			Etoposide	C				

Date: 10/06/98 **ISR Number:** 3252312-5 **Report Type:** Periodic **Company Report#:** 199812404HMRI **Age:** 33 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Bradycardia Ventricular Extrasystoles	Health Professional	Dolasetron (Anzemet)	PS		INTRAVENOUS	12.5 MG ONCE IV	1 DAY

Date: 10/13/98 **ISR Number:** 3142395-5 **Report Type:** Direct **Company Report#:** **Age:** 41 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Convulsion Dizziness Pulmonary Oedema Ventricular Tachycardia	Health Professional	Anzemet	PS		INTRAVENOUS	2.5 MG IV X 1	
			Versed	C		INTRAVENOUS		

Date: 10/22/98 **ISR Number:** 3144914-1 **Report Type:** Direct **Company Report#:** **Age:** **Gender:** Male **I/FU:** I

Outcome	PT
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Haemoglobin Decreased

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Haemorrhage Hypotension	Health Professional	Anzemet Famotidine Ferrous Sulfate Allopurinol Morphine Promethazine Captopril Warfarin Acetaminophen Amlodipine	PS C C C C C C C C C		INTRAVENOUS	12.5 MG IV X1	

Date: 10/28/98 **ISR Number:** 3147518-X **Report Type:** Expedited (15-Day) **Company Report#:** 199813209HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Cardiac Failure	Health Professional	Dolasetron	PS		INTRAVENOUS	IV	

Date: 10/29/98 **ISR Number:** 3148306-0 **Report Type:** Direct **Company Report#:** **Age:** 59 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Confusional State Delirium Disorientation		Anzemet Ultiva Lithium Prozac Prevacid Propulsid Versed Atropine	PS SS C C C C C C		INTRAVENOUS INTRAVENOUS	12.5MG IV 25MCG IV	

Date: 10/30/98 **ISR Number:** 3148961-5 **Report Type:** Expedited (15-Day) **Company Report#:** 199813228HMRI **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest	Health Professional	Dolasetron	PS				

Date: 11/03/98 **ISR Number:** 3151649-8 **Report Type:** Expedited (15-Day) **Company Report#:** 199813227HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Ventricular Tachycardia	Health Professional	Dolasetron	PS		INTRAVENOUS	ONCE IV	

Date: 11/04/98 **ISR Number:** 3151654-1 **Report Type:** Expedited (15-Day) **Company Report#:** 199813195HPD **Age:** 63 YR **Gender:** **I/FU:** I

Outcome	PT
Hospitalization - Initial or Prolonged	Angioneurotic Oedema Dermatitis Bullous Injection Site Pain

	Local Reaction Pruritus Purpura	**Report Source** Foreign Health Professional Other	**Product** Dolasetron Mesilate Decarbazin	**Role** PS C	**Manufacturer**	**Route** INTRAVENOUS	**Dose** IV	**Duration**

Date: 11/04/98 **ISR Number:** 3151658-9 **Report Type:** Expedited (15-Day) **Company Report#:** 199813240HMRI **Age:** **Gender:** **I/FU:** I

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Other	Ventricular Tachycardia	Health Professional	Dolasetron	PS				

Date: 11/06/98 **ISR Number:** 3152371-4 **Report Type:** Expedited (15-Day) **Company Report#:** 199813227HMRI **Age:** **Gender:** Male **I/FU:** I

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Other	Ventricular Tachycardia	Health Professional	Dolasetron	PS		INTRAVENOUS	ONCE IV	

Date: 11/06/98 **ISR Number:** 3152373-8 **Report Type:** Expedited (15-Day) **Company Report#:** 199813228HMRI **Age:** 54 YR **Gender:** Male **I/FU:** F

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Life-Threatening Hospitalization - Initial or Prolonged	Air Embolism Bradycardia Cardiac Arrest Ventricular Extrasystoles Ventricular Fibrillation	Health Professional	Dolasetron	PS		INTRAVENOUS	12.5 MG ONCE IV	1 DAY

Date: 11/10/98 **ISR Number:** 3154589-3 **Report Type:** Direct **Company Report#:** **Age:** 21 YR **Gender:** Female **I/FU:** I

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Life-Threatening	Hypotension		Anzemet	PS		INTRAVENOUS	12.5 MG ONCE IV NDC # 0088-1208-65	

Date: 12/03/98 **ISR Number:** 3166986-0 **Report Type:** Expedited (15-Day) **Company Report#:** 199813227HMRI **Age:** 53 YR **Gender:** Male **I/FU:** F

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Hospitalization - Initial or Prolonged	Anuria	Health Professional	Dolasetron (Anzemet)	PS		INTRAVENOUS	12.5MG ONCE IV	1 DAY
Other	Arrhythmia Blood Pressure Increased Electrocardiogram T Wave Inversion Feeling Abnormal Haematocrit Decreased Haemoglobin Decreased Heart Rate Increased Hypotension Nausea Ventricular Tachycardia		Droperidol Solution For Injection Midazolam Hydrochloride Ceftriaxone Sodium Propofol Lidocaine Fentanyl Vecuronium Bromide	SS C C C C C C		INTRAVENOUS	0.625MG ONCE IV	1 DAY

Oxygen	C
Ketorolac	
Tromethamine	C
Ondansetron	
Hydrochloride	C
Ephedrine	C
Glycopyrronium	
Bromide	C
Neostogmine	C
Nitrous Oxide	C
Sevofluranr	C
Sodium Amidotrizoate	C

Date: 12/03/98 **ISR Number:** 3166991-4 **Report Type:** Expedited (15-Day) **Company Report#:** 199813209HMRI **Age:** 35 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Ph Decreased	Health	Dolasetron (Anzemet)	PS		INTRAVENOUS	12.5 MG ONCE	
Hospitalization -	Bradycardia	Professional					IV	1 DAY
Initial or Prolonged	Cardiac Arrest		Metoclopramide	SS		INTRAVENOUS	10MG ONCE IV	1 DAY
	Cardiac Disorder		Fentanyl	C				
	Cardiac Failure		Lidocaine	C				
	Dermatitis		Propofol	C				
	Hypertension		Oxygen	C				
	Mitral Valve Incompetence		Glycopyrronium					
	Po2 Increased		Bromide	C				
	Pulse Absent		Nitrous Oxide	C				
	Tachycardia		Sevoflurane	C				
	Urticaria							

Date: 12/03/98 **ISR Number:** 3166996-3 **Report Type:** Expedited (15-Day) **Company Report#:** 199813228HMRI **Age:** 55 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Air Embolism	Health	Dolasetron (Anzemet)	PS		INTRAVENOUS	12.5MG ONCE	
Hospitalization -	Bradycardia	Professional					IV	1 DAY
Initial or Prolonged	Cardiac Arrest		Atenolol	C				
	Conduction Disorder		Midazolam	C				
	Nausea		Fentanyl	C				
	Pulmonary Oedema		Rocuronium	C				
	Tachycardia		Propofol	C				
	Ventricular Extrasystoles		Oxygen	C				
	Ventricular Fibrillation		Glycopyrronium					
	Ventricular Tachycardia		Bromide	C				
			Nitrous Oxide	C				
			Sevoflurane	C				
			Cefazolin	C				
			Neomycin Sulfate/Polymyxin B Sulfate	C				

Date: 12/17/98 **ISR Number:** 3171555-2 **Report Type:** Expedited (15-Day) **Company Report#:** 199813240HMRI **Age:** 41 YR **Gender:** Female **I/FU:** F

Outcome
Life-Threatening
Hospitalization -
Initial or Prolonged

Other

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Asthenia	Health	Dolasetron	PS		INTRAVENOUS	12.5 MG ONCE	
Blood Creatine Phosphokinase Mb Increased	Professional					IV	
Blood Ph Decreased		Midazolam Hydrochloride (Versed)	C				
Blood Potassium Decreased		Acetylsalicylic Acid (Aspirine)	C				
Dizziness							
Hypotension							
Hypoxia							
Pco2 Increased							
Pulmonary Oedema							
Syncope							
Ventricular Tachycardia							

Date: 12/18/98 **ISR Number:** 3171567-9 **Report Type:** Expedited (15-Day) **Company Report#:** 199813879HMR1 **Age:** 30 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Back Pain	Health	Dolasetron	PS		INTRAVENOUS	12.5 MG ONCE	
	Dyspnoea	Professional					IV	
	Hypertension		Midazolam Hydrochloride	C				
	Tachyarrhythmia		Famotidine	C				
	Ventricular Extrasystoles		Glycopyrronium Bromide	C				
	Ventricular Tachycardia							

Date: 12/18/98 **ISR Number:** 3171569-2 **Report Type:** Expedited (15-Day) **Company Report#:** 199813883HMRI **Age:** 40 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Back Pain	Health	Dolasetron	PS		INTRAVENOUS	12.5 MG ONCE	
	Electrocardiogram Abnormal	Professional					IV	
	Myocardial Ischaemia		Midazolam Hydrochloride (Versed)	C				

Date: 01/04/99 **ISR Number:** 3177323-X **Report Type:** Expedited (15-Day) **Company Report#:** 2954/11856 **Age:** 60 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotension	Foreign	Solu-Medrol Sterile Powder	PS		INTRAVENOUS	IV	
Other	Sedation	Consumer	Anzemet	SS		INTRAVENOUS	IV	
	Shock	Company Representative	Dacarbazine	SS				
			Clorazepate Potassium (Tranxene)	SS		INTRAVENOUS	IV	

Date: 01/07/99 **ISR Number:** 3178494-1 **Report Type:** Expedited (15-Day) **Company Report#:** 199812988RHF **Age:** 60 YR **Gender:** Female **I/FU:** I

Outcome	PT
Hospitalization - Initial or Prolonged	Hyperhidrosis
	Hypotension
	Sedation

Shock

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign	Dolasetron	PS		INTRAVENOUS	100 MG/DAY IV	1 DAY
	Dacarbazine	SS		INTRAVENOUS	1.6 G/DAY IV	1 DAY
	Methylprednisolone Sodium Succinate	SS				1 DAY
	Clorazepate Dipotassium	SS				1 DAY

Date: 01/11/99 **ISR Number:** 3193251-8 **Report Type:** Periodic **Company Report#:** 199812290HMRI **Age:** **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Health Professional	Anzemet	PS		INTRAVENOUS	12.5 MG IV	
	Gastrointestinal Pain		No Ingredient Defined (Anaesthetics)	C				

Date: 01/11/99 **ISR Number:** 3193252-X **Report Type:** Periodic **Company Report#:** 199813130HMRI **Age:** 30 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Tachycardia	Health Professional	Anzemet	PS			12.5 MG ONCE	
			Ephedrine Solution	SS			ONCE INJ	

Date: 01/11/99 **ISR Number:** 3193254-3 **Report Type:** Periodic **Company Report#:** 199813427HMRI **Age:** 79 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Health Professional	Anzemet	PS		INTRAVENOUS	IV	
	Electrocardiogram Abnormal		No Ingredient Defined (Anaesthetics)	C				
	Hypotension							

Date: 01/11/99 **ISR Number:** 3296056-2 **Report Type:** Periodic **Company Report#:** 199813108HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Breast Pain	Health Professional	Dolasetron (Anzemet) Tablets	PS				

Date: 01/11/99 **ISR Number:** 3296060-4 **Report Type:** Periodic **Company Report#:** 199812787HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Sedation	Health Professional	Dolasetron (Anzemet)	PS				
			Omeprazole (Prilosec)	SS				

Date: 01/11/99 **ISR Number:** 3296062-8 **Report Type:** Periodic **Company Report#:** 199812788HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pain In Extremity	Health Professional	Dolasetron (Anzemet)	PS				

Date: 01/11/99 **ISR Number:** 3296064-1 **Report Type:** Periodic **Company Report#:** 199812858HMRI **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Apathy Hostility Personality Disorder Stupor	Health Professional	Dolasetron (Anzemet)	PS		INTRAVENOUS	12.5 MG ONCE IV	

Date: 01/11/99 **ISR Number:** 3296066-5 **Report Type:** Periodic **Company Report#:** 199812935HMRI **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Bundle Branch Block	Health Professional	Delosetron (Anzemet)	PS		INTRAVENOUS	12.5 MG ONCE IV	1 DAY
			Atropine	C				
			Pyridostigmine	C				

Date: 01/11/99 **ISR Number:** 3296070-7 **Report Type:** Periodic **Company Report#:** 199813015HMRI **Age:** 62 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Face Oedema Injection Site Pain Pain Vasodilatation	Health Professional	Dolasetron (Anzemet) Solution For Injection	PS			100 MG ONCE INJ	1 DAY
			Dolasetron (Anzemet) Tablets	SS		ORAL	100 MG PO	
			Taxol	C				
			Taxol	C				
			Carboplatin	C				
			Carboplatin	C				
			Cimetidine (Tagamet)	C				
			Cimetidine (Tagamet)	C				
			Diphenydramine Hydrochloride (Benadryl)	C				
			Diphenhydramine Hydrochloride (Benadryl)	C				

Date: 01/11/99 **ISR Number:** 3296075-6 **Report Type:** Periodic **Company Report#:** 199813456HMRI **Age:** 74 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dizziness Injection Site Pain	Health Professional	Dolasetron (Anzemet)	PS		INTRAVENOUS	100 MG	
			Taxol	C				
			Doxorubicin (Adriamycin)	C				

Date: 01/11/99 **ISR Number:** 3296078-1 **Report Type:** Periodic **Company Report#:** 199813571HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pain	Health Professional	Dolasetron (Anzemet)	PS		INTRAVENOUS	IV	

Date: 01/11/99 **ISR Number:** 3296082-3 **Report Type:** Periodic **Company Report#:** 199813697HMRI **Age:** 29 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Extrapyramidal Disorder	Health Professional	Dolasetron (Anzemet)	PS		ORAL	12.5 MG/DAY PO	
	Sedation							
	Tremor		No Ingredient Defined					
			Anaesthetics)	C				

Date: 01/27/99 **ISR Number:** 3186604-5 **Report Type:** Expedited (15-Day) **Company Report#:** 199813227HMRI **Age:** 53 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anuria	Health Professional	Dolasetron (Anzemet) Solution For Injection	PS		INTRAVENOUS	12.5 MG ONCE IV	1 DAY
Other	Blood Pressure Decreased							
	Electrocardiogram Abnormal							
	Feeling Abnormal		Droperidol Solution For Injection	SS		INTRAVENOUS	0.625 MG ONCE IV	1 DAY
	Feeling Hot							
	Haematocrit Decreased							
	Haemoglobin Decreased							
	Ventricular Tachycardia							
			Midazolam Hydrochloride (Versed)	C				
			Ceftriaxone Sodium (Rocephin)	C				
			Lidocaine	C				
			Propofol	C				
			Fentanyl	C				
			(Norcuron)	C				
			Ocygen	C				
			Ketorolac Tromethamine (Toradol)	C				
			Ondansetron Hydrochloride (Zofran)	C				
			Ephedrine	C				
			Glycopyrronium Bromide (Robinul)	C				
			Neostigmine	C				
			Nitrous Oxide	C				
			Sevoflurane	C				
			Sodium Amidotrizoate (Hypaque)	C				

Date: 01/27/99 **ISR Number:** 3186608-2 **Report Type:** Expedited (15-Day) **Company Report#:** 199813209HMRI **Age:** 35 YR **Gender:** Male **I/FU:** F

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Anaphylactic Reaction	Health Professional	Dolasetron	PS		INTRAVENOUS	12.5 MG ONCE IV	
Atrioventricular Block							
Bradycardia		Metoclopramide	SS		INTRAVENOUS	10 MG ONCE IV	1 DAY
Cardiac Arrest		Fentanyl	C				1 DAY
Cardiac Failure		Lidocaine	C				
Dermatitis		Propofol	C				
Mitral Valve Incompetence		Oxygen	C				
Pulse Absent		Nitrous Oxide	C				
Tachycardia		Sevoflurane	C				
Urticaria		Midazolam Hydrochloride	C				

Date: 02/04/99 **ISR Number:** 3191835-4 **Report Type:** Expedited (15-Day) **Company Report#:** 199910257HMRI **Age:** 30 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Pain	Health Professional	Anzemet	PS			6 MG ONCE DAILY	
	Electrocardiogram St Segment Depression							
			Oxytocin	C				
			Morphine	C				

Date: 02/06/99 **ISR Number:** 4456658-4 **Report Type:** Direct **Company Report#:** USP 52066 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Anzemet	PS	Hoechst Marion Roussel		SOLUTION FOR INJECTION	

Date: 02/08/99 **ISR Number:** 3193679-6 **Report Type:** Expedited (15-Day) **Company Report#:** 199910286HMRI **Age:** 15 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Supraventricular Tachycardia	Health Professional	Anzemet	PS		INTRAVENOUS	12.5 MG ONCE IV	
			No Ingredient Defined (Anasthetics)	C				

Date: 02/12/99 **ISR Number:** 3197850-9 **Report Type:** Expedited (15-Day) **Company Report#:** 199910342HMRI **Age:** 45 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Increased	Health Professional	Dolasetron (Anzemet)	PS		INTRAVENOUS	12.5 MG ONCE IV	
	Chest Pain							
	Electrocardiogram Change							
	Heart Rate Increased							
	Hypertension							
	Myocardial Infarction							
	Tachycardia							

Date: 02/16/99 **ISR Number:** 3199336-4 **Report Type:** Expedited (15-Day) **Company Report#:** 2954/11856 **Age:** 60 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotension	Foreign	Solu-Medrol Sterile Powder (120 Mg)	PS		INTRAVENOUS	IV	
Other	Sedation	Consumer	Anzemet (100 Mg)	SS		INTRAVENOUS	IV	
	Shock	Company Representative	Dacarbazine	SS				
			Clorazepate Potassium (Tranxene) (40 Mg)	SS		INTRAVENOUS	IV	

Date: 02/16/99 **ISR Number:** 3199631-9 **Report Type:** Expedited (15-Day) **Company Report#:** 199812988RHF **Age:** 60 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradyphrenia	Foreign	Dolasetron (Anzemet)	PS		INTRAVENOUS	100 MG/DAY IV	1 DAY
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness		Dacarbazine	SS		INTRAVENOUS	1.6 G/DAY IV	1 DAY
	Hyperhidrosis		Methylprednisolone Sodium Succinate (Solu-Medrol)Powder For Injection	SS		INTRAVENOUS	120 MG/DAY IV	1 DAY
	Hypotension							
	Sedation							
	Shock		Clorazepate Dipotassium (Tranxene) Powder (Lyophilisate)	SS		INTRAVENOUS	40MG/DAY IV	1 DAY

Date: 02/19/99 **ISR Number:** 3203511-X **Report Type:** Expedited (15-Day) **Company Report#:** 199910545HMRI **Age:** 76 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Conduction Disorder	Health Professional	Dolasetron (Anzemet)	PS		INTRAVENOUS	128 MG IV	1 DAY
Other			Carboplatin	C				
			Taxol	C				
			Diphenyhydramine Hydrochloride (Benadryl)	C				
			Cimetidine (Tagamet)	C				
			No Ingredient Defined (All Other Therapeutic Products)	C				

Date: 03/01/99 **ISR Number:** 3208267-2 **Report Type:** Direct **Company Report#:** 52066 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Anzemet (Dolasetron Mesylate) Solution For Injection	PS	Hoechst Marion Roussel		INJECTION 12.5 MG; 0.625 MG (20 MG/ML)	

Date: 03/04/99 **ISR Number:** 3212931-9 **Report Type:** Expedited (15-Day) **Company Report#:** 199910257HMRI **Age:** 30 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Pain	Health	Dolasetron (Anzemet)	PS		INTRAVENOUS	6MG ONCE IV	
	Electrocardiogram St Segment Depression	Professional	Oxytocin	C				
			Morphine Sulfate	C				

Date: 03/08/99 **ISR Number:** 3214982-7 **Report Type:** Expedited (15-Day) **Company Report#:** 199910728HMRI **Age:** 16 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Cardiac Arrest Chest Pain Dyspnoea Loss Of Consciousness Respiratory Arrest	Health Professional	Dolasetron (Anzemet) Solution Nos	PS			25 MG 3X IV	2 DAY

Date: 03/11/99 **ISR Number:** 3217649-4 **Report Type:** Direct **Company Report#:** **Age:** 16 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrioventricular Block Cardiac Arrest	Health Professional	Anzemet	PS	Hoechst Marion Roussel	INTRAVENOUS	25MG IV Q2H PRN	3 DAY

Date: 03/15/99 **ISR Number:** 3218960-3 **Report Type:** Direct **Company Report#:** 52128 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Arrest Medication Error Motor Dysfunction		Anzemet (Dolasetron Mesylate) Epinephrine	PS	Hoechst Marion		AMPULE	
			Epinephrine	SS	American Regent		1 ML AMPULE	

Date: 03/15/99 **ISR Number:** 3221297-X **Report Type:** Expedited (15-Day) **Company Report#:** 199910825HMRI **Age:** 48 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hypertension Loss Of Consciousness Sinus Tachycardia Ventricular Fibrillation	Health Professional	Dolasetron (Anzemet) Boluses Oral Contraceptive Nos	PS C		INTRAVENOUS	20 MG ONCE IV	

Date: 03/19/99 **ISR Number:** 3223646-5 **Report Type:** Expedited (15-Day) **Company Report#:** 199910728HMRI **Age:** 16 YR **Gender:** Male **I/FU:** F

Outcome	PT
Life-Threatening Hospitalization - Initial or Prolonged	Apnoea Bradycardia Cardiac Arrest Chest Pain Coma Dyspnoea Loss Of Consciousness Nasopharyngitis Oxygen Saturation

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Decreased Paraesthesia Pulmonary Embolism Ventricular Extrasystoles	Health Professional	Dolasetron (Anzemet) Solution Nos	PS		INTRAVENOUS	25 MG 3X IV	2 DAY

Date: 03/19/99 **ISR Number:** 3223647-7 **Report Type:** Expedited (15-Day) **Company Report#:** 199910522RHF **Age:** 26 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Cardiac Arrest Condition Aggravated Drug Interaction Electrocardiogram Qrs Complex Abnormal Electrocardiogram St Segment Elevation Nausea Palpitations Ventricular Arrhythmia Ventricular Tachycardia Vomiting	Foreign Health Professional	Dolasetron (Anzemet) Solution For Injection	PS		INTRAVENOUS	200 MG/DAY IV	
			Fluorouracil Solution For Infusion	SS		INTRAVENOUS	700 MG/DAY IV	
			Fluorouracil Solution For Infusion	SS		INTRAVENOUS	3200 MG/DAY IV	
			Folic Acid	C				
			Tetracosactide	C				

Date: 03/19/99 **ISR Number:** 3223648-9 **Report Type:** Expedited (15-Day) **Company Report#:** 199910519RHF **Age:** 54 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Angina Pectoris Coronary Artery Disease Drug Interaction Drug Level Above Therapeutic Ejection Fraction Abnormal Electrocardiogram St Segment Elevation Hypokinesia Low Cardiac Output Syndrome Myocarditis Pulmonary Oedema	Foreign Health Professional	Dolasetron (Anzemet) Solution For Injection	PS		INTRAVENOUS	100 MG/DAY IV	
			Fluorouracil Solution For Infusion	SS		INTRAVENOUS	2800 MG/DAY IV	3 DAY
			Folic Acid	C				

Date: 03/19/99 **ISR Number:** 3223649-0 **Report Type:** Expedited (15-Day) **Company Report#:** 199910518RHF **Age:** 67 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angina Pectoris Chest Pain Drug Interaction	Foreign Health Professional	Dolasetron (Anzemet) Solution For Injection	PS		INTRAVENOUS	100 MG/DAY IV	
			Dolasetron (Anzemet) Solution For Injection	SS		INTRAVENOUS	10 MG/DAY IV	
			Fluorouracil Solution For Infusion	SS		INTRAVENOUS	2500 MG/DAY IV	
			Fluorouracil Solution For					

			Infusion	SS		INTRAVENOUS	700-700-0 MG IV
			Tetracosactide	C			
			Tetracosactide	C			
			Folic Acid	C			

Date: 03/24/99 **ISR Number:** 3311447-9 **Report Type:** Periodic **Company Report#:** 199813693HMRI **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia	Health	Dolasetron (Anzemet)	PS		ORAL	100 MG Q12H PO	
	Nausea	Professional						
	Sedation							

Date: 03/24/99 **ISR Number:** 3311450-9 **Report Type:** Periodic **Company Report#:** 199910030HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective	Health	Dolasetron (Anzemet)	PS				
		Professional						

Date: 03/25/99 **ISR Number:** 3226437-4 **Report Type:** Expedited (15-Day) **Company Report#:** 19991054HMRI **Age:** 76 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Conduction Disorder	Health	Dolasetron (Anzemet)	PS		INTRAVENOUS	128 MG IV	1 DAY
Other		Professional	Dolasetron (Anzemet)	SS		INTRAVENOUS	128 MG IV	1 DAY
			Dolasetron (Anzemet)	SS		INTRAVENOUS	128 MG IV	1 DAY
			Carboplatin	C				
			Taxol	C				
			Diphenhydramine Hydrochloride	C				
			Cimetidine	C				

Date: 03/25/99 **ISR Number:** 3226442-8 **Report Type:** Expedited (15-Day) **Company Report#:** 199910825HMRI **Age:** 48 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Health	Dolasetron (Anzemet)	PS		INTRAVENOUS	20 MG ONCE IV	
	Coma	Professional	Oral Contraceptive Nos	C				
	Hypertension							
	Ventricular Fibrillation							

Date: 04/02/99 **ISR Number:** 3232155-9 **Report Type:** Expedited (15-Day) **Company Report#:** 199911795DDC **Age:** 75 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cachexia	Foreign	Dolasetron Solution Nos	PS		INTRAVENOUS		1 DAY
	Dyspepsia	Health	Fluorouracil (5-Fu)	C				
	Nausea	Professional	Etoposide (Vepesid)	C				
	Vertigo	Other	Dexamethasone (Fortecortin)	C				
	Vomiting							

Date: 04/07/99 **ISR Number:** 3234571-8 **Report Type:** Expedited (15-Day) **Company Report#:** 199910522RHF **Age:** 26 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Cardiac Arrest Drug Interaction Electrocardiogram St Segment Elevation Palpitations Ventricular Tachycardia Vomiting	Foreign Health Professional Other	Dolasetron (Anzemet) Solution For Injection Fluorouracil Solution For Infusion Fluorouracil Solution For Infusion Folic Acid Tetracosactide (Synacthene Retard)	PS SS SS C C		INTRAVENOUS INTRAVENOUS INTRAVENOUS	200 MG/DAY 700 MG/DAY 3200 MG/DAY	

Date: 04/07/99 **ISR Number:** 3234572-X **Report Type:** Expedited (15-Day) **Company Report#:** 199910519RHF **Age:** 54 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Angina Pectoris Cardiac Disorder Cardiac Enzymes Increased Coronary Artery Occlusion Drug Interaction Ejection Fraction Abnormal Electrocardiogram St Segment Elevation Hypokinesia Low Cardiac Output Syndrome Myocarditis Pulmonary Oedema	Foreign Health Professional Other	Dolasetron (Anzemet) Solution For Injection Fluorouracil Solution For Infusion Folic Acid	PS SS C		INTRAVENOUS INTRAVENOUS	100 MG/DAY 2800 MG/DAY	 3 DAY

Date: 04/07/99 **ISR Number:** 3234573-1 **Report Type:** Expedited (15-Day) **Company Report#:** 199910518RHF **Age:** 67 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angina Pectoris Chest Pain Drug Interaction	Foreign Health Professional Other	Dolasetron (Anzemet) Solution For Injection Dolasetron (Anzemet) Solution For Injection Fluorouracil Solution Of Infusion Fluorouracil Solution For Infusion Tetracosactide (Synacthene) Tetracosactide (Synacthene) Folic Acid	PS SS SS SS C C C		INTRAVENOUS INTRAVENOUS INTRAVENOUS	100 MG/DAY 10 MG/DAY 2500 MG/DAY 700-7-0-MG	

Date: 04/07/99 **ISR Number:** 3234574-3 **Report Type:** Expedited (15-Day) **Company Report#:** 199910342HMRI **Age:** 45 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Pain	Health	Dolasetron (Anzemet)	PS		INTRAVENOUS	12.5 MG ONCE	
	Electrocardiogram Abnormal	Professional						
	Hypertension							
	Myocardial Infarction							
	Tachycardia							

Date: 04/09/99 **ISR Number:** 3236597-7 **Report Type:** Expedited (15-Day) **Company Report#:** 199911210HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Pain	Health	Dolasetron (Anzemet)					
	Clonic Convulsion	Professional	Solution Nos	PS		INTRAVENOUS	ONCE IV	
			Unknown Drug					
			(Unknown Drug)	C				

Date: 04/12/99 **ISR Number:** 3238183-1 **Report Type:** Expedited (15-Day) **Company Report#:** 199813228HMRI **Age:** 55 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Air Embolism	Health	Dolasetron (Anzemet)					
Hospitalization -	Atrioventricular Block	Professional	Solution For					
Initial or Prolonged	Bradycardia		Injection	PS		INTRAVENOUS	12.5 MG ONCE IV	1 DAY
	Cardiac Arrest							
	Dyspnoea		Atenolol	C				
	Pulmonary Oedema		Midazolam	C				
	Sinus Tachycardia		Fentanyl	C				
	Ventricular Extrasystoles		Rocuronium	C				
	Ventricular Fibrillation		Propofol	C				
	Ventricular Tachycardia		Oxygen	C				
			Glycopyrronium Bromide	C				
			Nitrous Oxide	C				
			Sevoflurane	C				
			Cefazolin	C				
			Neomycin Sulfate/Polymyxin B Sulfate	C				

Date: 04/12/99 **ISR Number:** 3240167-4 **Report Type:** Periodic **Company Report#:** 199813830HMRI **Age:** 68 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Arrhythmia	Health	Dolasetron (Anzemet)	PS		INTRAVENOUS	12.5 MG TWICE IV	1 DAY
Hospitalization -		Professional						
Initial or Prolonged			Midazolam Hydrochloride	C				
Other			Sufentanil Citrate	C				

Date: 04/12/99 **ISR Number:** 3240170-4 **Report Type:** Periodic **Company Report#:** 199910288HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Renal Failure Acute	Health Professional	Dolasetron (Anzemet)	PS		INTRAVENOUS	12.5MG IV	

Date: 04/12/99 **ISR Number:** 3240174-1 **Report Type:** Periodic **Company Report#:** 199910414HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Pain Electrocardiogram Abnormal	Health Professional	Dolasetron (Anzemet)	PS				

Date: 04/12/99 **ISR Number:** 3240177-7 **Report Type:** Periodic **Company Report#:** 199813427HMRI **Age:** 79 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia Electrocardiogram Abnormal Hypotension	Health Professional	Dolasetron (Anzemet) No Ingredient Defined (Anaesthetics)	PS C		INTRAVENOUS	IV	

Date: 04/12/99 **ISR Number:** 3325825-5 **Report Type:** Periodic **Company Report#:** 199813663HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Delirium	Health Professional	Dolasetron (Anzemet) Dexamethasone Metformin Hydrochloride	PS C C		INTRAVENOUS	IV	

Date: 04/12/99 **ISR Number:** 3325826-7 **Report Type:** Periodic **Company Report#:** 199813456HMRI **Age:** 74 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dizziness Injection Site Pain	Health Professional	Dolasetron (Anzemet) Dolasetron (Anzemet) Taxol Doxorubicin	PS SS C C		INTRAVENOUS INTRAVENOUS	100 MG IV 100 MG IV	

Date: 04/26/99 **ISR Number:** 3246396-8 **Report Type:** Direct **Company Report#:** **Age:** 48 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Pressure Fluctuation Cardiac Arrest Coma Convulsion Haemorrhagic Stroke Hypotension Hypoxic Encephalopathy Posture Abnormal Pupil Fixed Ventricular Fibrillation		Anzemet (Dolasetr) Cefuroxime Isofluorane Propofol Lidocaine Wyda	PS C C C C C	Hoechst Marion Roussel	INTRAVENOUS BOLUS	12.5MG ONCE IV BOLUSE	

Date: 04/26/99 **ISR Number:** 3246983-7 **Report Type:** Expedited (15-Day) **Company Report#:** 199812722HMRI **Age:** 44 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Health	Dolasetron (Anzemet) Solution For					
	Aspiration	Professional	Injection	PS		INTRAVENOUS BOLUS	12.5 MG ONCE IVB	1 DAY
	Blood Amylase Increased							
	Cardiac Enzymes Increased							
	Cholecystectomy							
	Feeling Hot		Cefotaxime Sodium	C				
	Hypotension		Glucose	C				
	Hypoxia		Sodium Lactate	C				
	Lipase Increased		Potassium Chloride	C				
	Pulmonary Oedema		Sodium Chloride	C				
	Pulse Pressure Decreased		Calcium Chloride					
	Supraventricular Tachycardia		Dihydrate	C				
	Ventricular Tachycardia		Amfebutamone Hydrochloride	C				
	Vomiting		Beclometasone Dipropionate	C				
			Salbutamol	C				

Date: 05/05/99 **ISR Number:** 3253979-8 **Report Type:** Expedited (15-Day) **Company Report#:** 199910518RHF **Age:** 67 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angina Pectoris	Foreign	Dolasetron (Anzemet) Solution For					
	Chest Pain	Health	Injection	PS		INTRAVENOUS	100 MG/DAY IV	
	Drug Interaction	Professional	Dolasetron (Anzemet) Solution For Injection	SS		INTRAVENOUS	10 MG/DAY IV	
			Fluorouracil Solution For Infusion	SS		INTRAVENOUS	700 MG/DAY IV	
			Fluorouracil Solution For Infusion	SS		INTRAVENOUS	2500 MG CYC IV	2 DAY
			Tetracosactide	C				
			Folic Acid	C				

Date: 05/05/99 **ISR Number:** 3253983-X **Report Type:** Expedited (15-Day) **Company Report#:** 199910522RHF **Age:** 26 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest	Foreign	Dolasetron (Anzemet) Solution For					
Hospitalization - Initial or Prolonged	Condition Aggravated	Health	Injection	PS		INTRAVENOUS	200 MG/DAY IV	
	Drug Interaction	Professional	Fluorouracil Solution For Infusion	SS		INTRATUMOR	3200 MG/DAY IV	2 DAY
	Electrocardiogram Qrs Complex Abnormal							
	Electrocardiogram St Segment Elevation							
	Palpitations		Folic Acid	C				
	Ventricular Tachycardia		Tetracosactide	C				
	Vomiting							

Date: 05/26/99 **ISR Number:** 3271083-X **Report Type:** Direct **Company Report#:** **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia		Anzemet 100mg Iv Inf					
Hospitalization -	Bronchospasm		Hoechst	PS	Hoechst	INTRAVENOUS	100MG IV	
Initial or Prolonged	Depressed Level Of						WEEKLY	
	Consciousness		Herceptin 21mg/Ml Iv					
	Heart Rate Decreased		Inf Genentech	SS	Genentech	INTRAVENOUS	150MG IV	
	Hypotension						WEEKLY	
	Lethargy		Ethyol 50mg/Ml Us					
	Sinus Bradycardia		Bioscience	SS	Us Bioscience	INTRAVENOUS	500MG IV	
							WEEKLY	

Date: 06/08/99 **ISR Number:** 3277893-7 **Report Type:** Expedited (15-Day) **Company Report#:** 199912418HMRI **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cardiovascular Disorder	Health	Dolasetron (Anzemet)	PS				
Initial or Prolonged		Professional	Unknown Drug					
			(Unknown Drug)	C				

Date: 06/09/99 **ISR Number:** 3279093-3 **Report Type:** Expedited (15-Day) **Company Report#:** ET99050007 **Age:** 76 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia	Health	Ethyol Soluble					
Hospitalization -	Blood Pressure Decreased	Professional	Powder	PS		INTRAVENOUS	500 MG	
Initial or Prolonged	Bronchospasm						INTRAVENOUS	
	Coma		Herceptin Injectable	SS		INTRAVENOUS	150 MG	
	Heart Rate Decreased						INTRAVENOUS	
	Hypotension		Dolasetron					
	Lethargy		Injectable	SS		INTRAVENOUS	100 MG	
	Loss Of Consciousness						INTRAVENOUS	
	Sinus Bradycardia		Glucophage	C				
			Norvasc	C				
			Zantac	C				
			Benadryl	C				
			Tylenol	C				
			Decadron	C				

Date: 06/10/99 **ISR Number:** 3281043-0 **Report Type:** Expedited (15-Day) **Company Report#:** 199912266HMRI **Age:** 53 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation	Health	Dolasetron (Anzemet)					
	Anaphylactic Reaction	Professional	Solution Nos	PS		INTRAVENOUS	12.5 MG IV	
	Angioneurotic Oedema		Gentamicin	C				
	Cyanosis		Famotidine	C				
	Oedema		Midazolam					
	Respiratory Distress		Hydrochloride	C				
	Restlessness		Metoclopramide	C				
	Tachycardia		Fentanyl	C				
			No Ingredient					
			Defined					
			(Anesthetics)	C				

Date: 06/10/99 **ISR Number:** 3281045-4 **Report Type:** Expedited (15-Day) **Company Report#:** 199912489HMRI **Age:** 76 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia	Health	Dolasetron (Anzemet)	PS		INTRAVENOUS	100 MG QW IV	28 WK
Hospitalization -	Bronchospasm	Professional	Herceptin Solution					
Initial or Prolonged	Depressed Level Of		For Infusion	SS		INTRAVENOUS	150 MG QW IV	28 WK
	Consciousness		Amifostine (Ethyol)					
	Hypotension		Solution For					
	Lethargy		Infusion	SS		INTRAVENOUS	500 MG QW IV	22 DAY
	Sinus Bradycardia							

Date: 06/10/99 **ISR Number:** 3281048-X **Report Type:** Expedited (15-Day) **Company Report#:** 199912419HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Atrioventricular Block	Health	Dolasetron (Anzemet)	PS				
Initial or Prolonged	Complete	Professional						

Date: 06/16/99 **ISR Number:** 3285076-X **Report Type:** Expedited (15-Day) **Company Report#:** 199910728HMRI **Age:** 16 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Apnoea	Health	Dolasetron Mesilate					
Initial or Prolonged	Bradycardia	Professional	(Anzemet) Solution					
	Cardiac Arrest		Nos	PS		INTRAVENOUS	25 MG 3X IV	2 DAY
	Coma							
	Dyspnoea							
	Feeling Abnormal							
	Loss Of Consciousness							
	Paraesthesia							
	Pulmonary Embolism							
	Ventricular Extrasystoles							

Date: 06/16/99 **ISR Number:** 3285081-3 **Report Type:** Expedited (15-Day) **Company Report#:** 199813227HMRI **Age:** 53 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anuria	Health	Dolasetron Mesilate					
Initial or Prolonged	Electrocardiogram	Professional	(Anzemet) Solution					
Other	Abnormal		For Injection	PS		INTRAVENOUS	12.5 MG ONCE IV	1 DAY
	Electrocardiogram Qrs							
	Complex Prolonged		Droperidol Solution					
	Feeling Abnormal		For Injection	SS		INTRAVENOUS	0.625 MG ONCE IV	1 DAY
	Feeling Hot							
	Haematocrit Decreased		Midazolam					
	Haemoglobin Decreased		Hydrochloride	C				
	Hypotension		Ceftriaxone Sodium	C				
	Nodal Arrhythmia		Propofol	C				
	Respiratory Rate		Lidocaine	C				
	Decreased		Fentanyl	C				
	Tachycardia		Vecuronium Bromide	C				
	Ventricular Tachycardia		Oxygen	C				
			Ketorolac					
			Tromethamine	C				
			Ondansetron					
			Hydrochloride	C				
			Ephedrine	C				
			Glycopyrronium					

			Bromide	C				
			Neostigmine	C				
			Nitrous Oxide	C				
			Sevoflurane	C				
			Sodium Amidotrizoate	C				

Date: 06/24/99 **ISR Number:** 3291338-2 **Report Type:** Expedited (15-Day) **Company Report#:** ET99050007 **Age:** 76 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia	Health	Ethyol Soluble					
Hospitalization - Initial or Prolonged	Blood Pressure Decreased	Professional	Powder	PS		INTRAVENOUS	500 MG INTRAVENOUS	
	Bronchospasm							
	Coma		Herceptin Injectable	SS		INTRAVENOUS	150 MG INTRAVENOUS	
	Heart Rate Decreased							
	Lethargy		Dolasetron					
	Loss Of Consciousness		Injectable	SS		INTRAVENOUS	100 MG INTRAVENOUS	
	Sinus Bradycardia							
			Glucophage	C				
			Tylenol	C				
			Zofran	C				
			Decadron	C				
			Benadryl	C				
			Norvasc	C				
			Zantac	C				

Date: 07/01/99 **ISR Number:** 3300283-5 **Report Type:** Periodic **Company Report#:** 199910414HMRI **Age:** **Gender:** **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Pain	Health	Dolasetron Mesilate					
	Electrocardiogram Abnormal	Professional	(Anzemet)	PS				

Date: 07/01/99 **ISR Number:** 3300286-0 **Report Type:** Periodic **Company Report#:** 199911284HMRI **Age:** 56 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Failure Acute	Health	Dolasetron Mesilate					
Other		Professional	(Anzemet) Solution					
			Nos	PS		INTRAVENOUS	12.5 MG ONCE IV	1 DAY
			No Ingrfedient Defined (Anaesthetics, General)	C				
			Quinapril Hydrochloride	C				

Date: 07/01/99 **ISR Number:** 3347183-2 **Report Type:** Periodic **Company Report#:** 199911299HMRI **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dry Mouth	Health	Dolasetron Mesilate					
	Nausea	Professional	(Anzemet) Tablets	PS		ORAL	300 MG PO	

Date: 07/01/99 **ISR Number:** 3347184-4 **Report Type:** Periodic **Company Report#:** 199911327HMRI **Age:** 68 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dizziness Sedation	Health Professional	Dolasetron Mesilate (Anzemet)	PS		ORAL	PO	

Date: 07/01/99 **ISR Number:** 3347185-6 **Report Type:** Periodic **Company Report#:** 199911757HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Coordination Abnormal	Health Professional	Dolasetron Mesilate (Anzemet)	PS				

Date: 07/01/99 **ISR Number:** 3347554-4 **Report Type:** Periodic **Company Report#:** 199911000HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Ventricular Extrasystoles	Health Professional	Dolasetron Mesilate (Anzemet)	PS				

Date: 07/01/99 **ISR Number:** 3347556-8 **Report Type:** Periodic **Company Report#:** 199911002HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Ventricular Extrasystoles	Health Professional	Dolasetron Mesilate (Anzemet0	PS				

Date: 07/01/99 **ISR Number:** 3347559-3 **Report Type:** Periodic **Company Report#:** 199911159HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	IV	

Date: 07/01/99 **ISR Number:** 3347560-X **Report Type:** Periodic **Company Report#:** 199911272HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	IV	

Date: 07/01/99 **ISR Number:** 3347564-7 **Report Type:** Periodic **Company Report#:** 199911273HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health Professional	Dolasetron Mesilate (Anzemet) Solution For Injection	PS			INJ	

Date: 07/01/99 **ISR Number:** 3347565-9 **Report Type:** Periodic **Company Report#:** 199912310HMRI **Age:** 39 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	100 MG IV	4 MON
			Vincristine	C				
			Dexamethasone	C				
			Cyclophosphamide	C				

Date: 07/01/99 **ISR Number:** 3347568-4 **Report Type:** Periodic **Company Report#:** 199912318HMRI **Age:** 58 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	100 MG IV	

Date: 07/01/99 **ISR Number:** 3347570-2 **Report Type:** Periodic **Company Report#:** 199912338HMRI **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Extrapyramidal Disorder		Dolasetron Mesilate (Anzemet) Solution					
			Nos	PS		INTRAVENOUS	100 MG IV	
			Dexamethasone	SS				

Date: 07/07/99 **ISR Number:** 3298668-9 **Report Type:** Expedited (15-Day) **Company Report#:** 199912419HMRI **Age:** **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block Complete	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	100 MG IV	30 MIN
	Cardiomegaly		Ranitidine Hydrochloride (Zantac)	C				
	Pulmonary Congestion		Amlodipine Besilate (Norvasc)	C				
			Doxorubicin	C				
			Cyclophosphamide	C				
			Trastuzumab (Herceptin)	C				
			Taxol	C				

Date: 07/14/99 **ISR Number:** 3303626-1 **Report Type:** Direct **Company Report#:** **Age:** 81 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Convulsion		Anzemet 100mg Hoechst Marion					
	Hypotension		Roussel	PS	Hoechst Marion Roused	INTRAVENOUS	1ST DOSE -IV	
	Pulse Absent		Gemzar 1300mg-Lilly	SS	Lilly	INTRAVENOUS	2ND WEEKLY DOSE IV	

Date: 08/18/99 **ISR Number:** 3329387-8 **Report Type:** Direct **Company Report#:** **Age:** 57 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cold Sweat		Camptosar	PS			240 MG IV 1ST DOSE	
	Hypertension							
	Muscle Twitching		Anzemet	SS			100 MG IV 1ST DOSE	
	Nausea							
	Visual Disturbance		Percodan Prn Pain	C				

Date: 08/30/99 **ISR Number:** 3338522-7 **Report Type:** Periodic **Company Report#:** 100143964-01-00 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health	Meperidine					
	Dyspnoea	Professional	Hydrochloride					
	Injection Site Reaction		Injection, Usp	PS		INTRAVENOUS	IV	
	Phlebitis		Dolasetron (Anzemet)	SS			INJECTION	

Date: 09/28/99 **ISR Number:** 3361718-5 **Report Type:** Expedited (15-Day) **Company Report#:** 199920665HPD **Age:** 56 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dyspnoea	Foreign	Anemet	PS		INTRAVENOUS	100 MG QD IV	1 DAY
Initial or Prolonged	Myocarditis	Study	Anemet Film-Coated					
Other	Pericarditis	Health	Tablets	SS		ORAL	200 MG QD PO	3 DAY
		Professional	5 Fu (Fluorouacil)	SS				4 DAY
			Novalgin	C				
			Dilanacin	C				
			Arelix Mite	C				

Date: 09/29/99 **ISR Number:** 3361528-9 **Report Type:** Periodic **Company Report#:** 199920651HMRI **Age:** 53 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Health	Dolasetron Mesilate					
	Dermatitis	Professional	(Anzemet) Solution					
	Dizziness		Nos	PS		INTRAVENOUS	100 MG ONCE	
	Hypotension						IV	1 DAY
	Nausea		Carboplatin	SS				
	Vasodilatation		Carboplatin	SS				1 DAY
	Vomiting		Carboplatin	SS			100 MG	

Date: 09/29/99 **ISR Number:** 3361532-0 **Report Type:** Periodic **Company Report#:** 199912810HMRI **Age:** 20 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Face Oedema	Consumer	Dolasetron Mesilate					
	Hypersensitivity		(Anzemet) Solution					
	Oedema Peripheral		Nos	PS		INTRAVENOUS	IV	1 DAY
	Tongue Oedema		Losartan Potassium	SS				
			Zolpidem Tartrate	C				
			Paroxetine					
			Hydrochloride	C				
			Nifedipine	C				
			Cyclophosphamide	C				
			Prednisone	C				

Date: 09/29/99 **ISR Number:** 3373517-9 **Report Type:** Periodic **Company Report#:** 199912310HMRI **Age:** 39 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	100 MG IV	4 DAY
			Vincristine	C				
			Dexamethasone (Decadron)	C				
			Doxorubicin (Adriamycin)	C				
			Cyclophosphamide (Cytoxan)	C				

Date: 09/29/99 **ISR Number:** 3373523-4 **Report Type:** Periodic **Company Report#:** 199912312HMRI **Age:** 59 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypotension	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	100 MG IV	
	Injection Site Pain		Dexamethasone (Decadron)	C				
	Syncope		Taxol	C				
			Carboplatin	C				

Date: 09/29/99 **ISR Number:** 3373525-8 **Report Type:** Periodic **Company Report#:** 199912315HMRI **Age:** 48 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	100 MG IV	
			Dexamethasone (Decadron)	C				
			No Ingredient Defined (All Other Therapeutic Products)	C				

Date: 09/29/99 **ISR Number:** 3373526-X **Report Type:** Periodic **Company Report#:** 199912316HMRI **Age:** 20 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	100 MG IV	
			Cyclophosphamide	C				
			Doxorubicin	C				
			Vincristine	C				
			Prednisone	C				

Date: 09/29/99 **ISR Number:** 3373527-1 **Report Type:** Periodic **Company Report#:** 199912318HMRI **Age:** 58 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	100 MG IV	
			Ondansetron Hydrochloride (Zofran)	C				

Date: 09/29/99 **ISR Number:** 3373528-3 **Report Type:** Periodic **Company Report#:** 199912843HMRI **Age:** 51 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dizziness	Health	Dolasetron Mesilate					
	Flushing	Professional	(Anzemet) Solution					
			Nos	PS		INTRAVENOUS	12.5 MG IV	

Date: 09/29/99 **ISR Number:** 3373529-5 **Report Type:** Periodic **Company Report#:** 199912844HMRI **Age:** 83 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Nausea	Health	Dolasetron Mesilate					
	Urticaria	Professional	(Anzemet)	PS		INTRAVENOUS	100 MG IV	1 DAY
			Doxorubicin					
			(Adriamycin)	SS				

Date: 09/29/99 **ISR Number:** 3373530-1 **Report Type:** Periodic **Company Report#:** 199912845HMRI **Age:** 41 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dizziness	Health	Dolasetron Mesilate					
	Hypoaesthesia	Professional	(Anzemet)	PS		INTRAVENOUS	100 MG IV	1 DAY
	Nervousness		Doxorubicin					
	Vasodilatation		(Adriamycin)	SS		INTRAVENOUS	57 MG/DAY IV	1 DAY
			Cyclophosphamide					
			(Cytoxan)	C				
			Dexamethasone					
			(Decadron)	C				

Date: 09/29/99 **ISR Number:** 3373531-3 **Report Type:** Periodic **Company Report#:** 199920632HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health	Dolasetron Mesilate					
		Professional	(Anzemet)	PS				

Date: 09/29/99 **ISR Number:** 3373532-5 **Report Type:** Periodic **Company Report#:** 199920779HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Pain	Health	Dolasetron Mesilate					
		Professional	(Anzemet)	PS		INTRAVENOUS	100 MG IV	

Date: 10/08/99 **ISR Number:** 3368594-5 **Report Type:** Expedited (15-Day) **Company Report#:** 830/20571 **Age:** 57 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cold Sweat	Health	Camptosar Injection					
Other	Muscle Twitching	Professional	(20 Mg/Ml)	PS		INTRAVENOUS	240 MG - 1DOSE; IV	
	Nausea	Other						
	Visual Disturbance		Anzemet	SS		INTRAVENOUS	100 MG/DAY; IV	
			Percodan	C				

Date: 10/26/99 **ISR Number:** 3382466-1 **Report Type:** Expedited (15-Day) **Company Report#:** 199921543HMRI **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hyponatraemia	Health	Dolasetron Mesilate					
Other	Inappropriate Antidiuretic Hormone Secretion	Professional	(Anzemet)	PS				
			Prochlorperazine Edisylate (Compazine)	C				
			Propofol (Diprivan)	C				
			Opioids (Nos)	C				
			Propofol	C				

Date: 11/02/99 **ISR Number:** 3388221-0 **Report Type:** Expedited (15-Day) **Company Report#:** 199921679HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health	Dolasetron Mesilate					
	Hypertension	Professional	(Anzemet)	PS				
	Tachycardia		Amifostine (Ethyol)	SS				
			No Ingredient Defined (All Other Therapeutic Products)	C				

Date: 12/02/99 **ISR Number:** 3413240-5 **Report Type:** Expedited (15-Day) **Company Report#:** 199921965HMRI **Age:** 42 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Health	Dolasetron Mesilate (Anzemet) Solution					
	Dyskinesia	Professional	For Infusion	PS		INTRAVENOUS	12.5 MG/KG ONCE IV	1 DAY
	Extrapyramidal Disorder							
	Respiratory Depression		No Ingredient Defined (Anaesthetics)	C				

Date: 12/09/99 **ISR Number:** 3418052-4 **Report Type:** Periodic **Company Report#:** 199921099HMRI **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrial Fibrillation	Health	Dolasetron Mesilate					
	Bradycardia	Professional	(Anzemet) Solution					
	Dizziness		For Injection	PS		INTRAVENOUS	100 MG IV	
	Hypotension		No Ingredient Defined (All Other Therapeutic Products)	C				

Date: 12/09/99 **ISR Number:** 3418054-8 **Report Type:** Periodic **Company Report#:** 199921730HMRI **Age:** 63 YR **Gender:** Female **I/FU:** I

Outcome	PT
Other	Chest Pain
	Dizziness
	Dyspnoea
	Headache
	Hypersensitivity

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hypoxia Vasodilatation	Health Professional	Dolasetron Mesilate (Anzemet) Solution For Injection	PS		INTRAVENOUS	140 MG ONCE IV	1 DAY
		Doxorubicin (Adriamycin)	C				
		Cyclophosphamide (Cytoxan)	C				
		Pravastatin Sodium (Pravachol)	C				

Date: 12/17/99 **ISR Number:** 3425038-2 **Report Type:** Expedited (15-Day) **Company Report#:** 199921965HMRI **Age:** 42 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia Extrapyramidal Disorder Post Procedural Complication Respiratory Depression Sedation	Health Professional	Dolasetron Mesilate (Anzemet) Solution For Infusion	PS		INTRAVENOUS	12.5 MG/KG, ONCE, IV	1 DAY
			(Anaesthetics)	C				
			(Corticosteroids, Plain)	C				

Date: 01/24/00 **ISR Number:** 3446143-0 **Report Type:** Direct **Company Report#:** **Age:** 18 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Difficulty In Walking Movement Disorder Tremor	Health Professional	Anzemet 12.5 Mg	PS		INTRAVENOUS	12.5MG IV	
			Morphine	C				
			Clindamycin	C				

Date: 01/28/00 **ISR Number:** 3447836-1 **Report Type:** Expedited (15-Day) **Company Report#:** 20001026HMRI **Age:** 41 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety Burning Sensation Chest Pain Cyanosis Drug Hypersensitivity Dyspnoea Palpitations Retinal Disorder Vitreous Floaters	Consumer	Dolasetron Mesilate (Anzemet) Solution For Injection	PS		INTRAVENOUS	ONCE IV	
			Estradiol (Estraderm Tts)	C				
			Lansoprazole (Prevacid)	C				

Date: 02/15/00 **ISR Number:** 3457467-5 **Report Type:** Direct **Company Report#:** **Age:** **Gender:** Female **I/FU:** I

Outcome	PT
Hospitalization - Initial or Prolonged	Dehydration Dizziness Fatigue Headache

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Mucosal Inflammation Neutropenia Pneumonia Refusal Of Treatment By Patient Vomiting	Health Professional	Taxotere (60 Mg/M2) Decadron (8 Mg) Decadron Adriamycin Anzemet	 PS SS SS SS				

Date: 02/16/00 **ISR Number:** 3458071-5 **Report Type:** Direct **Company Report#:** **Age:** 79 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Dizziness Headache Heart Rate Irregular Hypotension Pallor Pulse Absent Respiratory Arrest		Anzemet 100 Mg Iv Cyclophosphamide Mtx 5 Fu	PS C C C		INTRAVENOUS	100 MG IV	

Date: 03/02/00 **ISR Number:** 3469037-3 **Report Type:** Expedited (15-Day) **Company Report#:** 199921965HMRI **Age:** 42 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia Extrapyramidal Disorder Post Procedural Complication Respiratory Depression Sedation Vomiting	Health Professional	Dolasetron Mesilate (Anzemet) Solution For Injection No Ingredient Defined (Anaesthetics) No Ingredient Defined (Corticosteroids, Plain) Dexamethasone No Ingredient Defined (Muscle Relaxants, Peripherally Acting Agents) Fentanyl (Sublimaze) Midazolam Hydrochloride (Versed) Propofol	PS C C C C C C		INTRAVENOUS	12.5 MG/KG ONCE IV	1 DAY

Date: 03/30/00 **ISR Number:** 3482316-9 **Report Type:** Expedited (15-Day) **Company Report#:** 200011031HMRI **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal Exposure To Therapeutic Drugs Intra-Uterine Death	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	Q3H IV	4 MON

Date: 04/05/00 **ISR Number:** 3484238-6 **Report Type:** Periodic **Company Report#:** 199921977HMRI **Age:** 67 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Health	Dolasetron Mesilate					
	Stupor	Professional	(Anzemet)	PS		INTRAVENOUS	100 MG ONCE IV	
			Ace Inhibitors	C				
			No Ingredient Defined(All Other Therapeutic Products)	C				
			Glimepiride	C				

Date: 04/05/00 **ISR Number:** 3484239-8 **Report Type:** Periodic **Company Report#:** 200010626HMRI **Age:** 50 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Health	Dolasetron Mesilate					
	Anaphylactic Reaction	Professional	(Anzemet)	PS		INTRAVENOUS	100 MG Q3W IV	
	Diarrhoea		Fluorouracil (5-Fu)	C				
	Hypotension		Dexamethasone(Decadr on)	C				
	Shock		Methotrexate Sodium (Mtx)	C				
	Skin Discolouration		Taxol	C				
	Vasodilatation							

Date: 04/05/00 **ISR Number:** 3484240-4 **Report Type:** Periodic **Company Report#:** 200010983HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bronchospasm	Health	Dolasetron Mesilate					
		Professional	(Anzemet)	PS				

Date: 04/05/00 **ISR Number:** 3484241-6 **Report Type:** Periodic **Company Report#:** 199912312HMRI **Age:** 59 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension	Health	Dolasetron Mesilate					
	Injection Site Pain	Professional	(Anzemet)	PS		INTRAVENOUS	100 MG IV	1 DAY
	Syncope		Dexamthesone(Decadro n)	C				
			Taxol	C				
			Carboplatin	C				

Date: 04/05/00 **ISR Number:** 3484242-8 **Report Type:** Periodic **Company Report#:** 199920651HMRI **Age:** 53 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Health	Dolasetron Mesilate					
	Anaphylactic Reaction	Professional	(Anzemet) Solution					
	Dermatitis		For Injection	PS		INTRAVENOUS	100 MG ONCE IV	1 DAY
	Dizziness							
	Hypotension		Carboplatin	SS		INTRAVENOUS	100 MG ONCE IV	
	Vasodilatation							
	Vomiting		Carboplatin	SS			412 MG	1 DAY
			Carboplatin	SS			100 MG	

Date: 04/05/00 **ISR Number:** 3484243-X **Report Type:** Periodic **Company Report#:** 199921479HMRI **Age:** 10 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Ineffective	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	12.5 MG/KG IV	1 DAY
			Morphine Sulfate	C				
			Midazolam Hydrochloride(Versed)	C				

Date: 04/05/00 **ISR Number:** 3484244-1 **Report Type:** Periodic **Company Report#:** 199921488HMRI **Age:** 24 MON **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Ineffective	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	12.5 MG/KG IV	1 DAY
			Midazolam Hydrochloride9versed)	C				
			Pethidine Hydrochloride(Demerol)	C				
			Morphine	C				

Date: 04/05/00 **ISR Number:** 3484245-3 **Report Type:** Periodic **Company Report#:** 200010337HMRI **Age:** 78 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electrocardiogram Qt Prolonged	Health Professional	Dolasetron Mesilate (Anzemet)	PS			100 MG ONCE	
	Syncope		Atenolol (Tenormin)	SS				
			Allopurinol	C				
			Acetylsalicyclic Acid	C				
			No Ingredient Defined(All Other Therapeutic Products)	C				

Date: 04/05/00 **ISR Number:** 3487231-2 **Report Type:** Periodic **Company Report#:** 175/63165 **Age:** 41 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Health Professional	Adriamycin Pfs Sterile Solution	PS		INTRAVENOUS	57 MG/DAY; IV	
	Drug Interaction		Dolasetron (Anzemet)	SS		INTRAVENOUS	1 DOSE; IV	
	Feeling Hot		Decadron	C				
	Feeling Jittery		Cytoxan	C				
	Hypoaesthesia							
	Paraesthesia Oral							

Date: 04/05/00 **ISR Number:** 3487233-6 **Report Type:** Periodic **Company Report#:** 176/63165 **Age:** 83 YR **Gender:** Female **I/FU:** I

Outcome	PT
Other	Drug Interaction
	Nausea
	Pruritus

Urticaria

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional	Adriamycin Pfs Sterile Solution	PS		INTRAVENOUS	IV	
	Anzemet (Dolasetron)	SS		INTRAVENOUS	100 MG - 1 DOSE; IV	

Date: 04/05/00 **ISR Number:** 3556009-3 **Report Type:** Periodic **Company Report#:** 200010307HMRI **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pain	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	IV	

Date: 04/05/00 **ISR Number:** 3556010-X **Report Type:** Periodic **Company Report#:** 200010952HMRI **Age:** 45 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	100 MG/DAY IV	
	Headache		Fluoro-Uracil	C				
	Increased Appetite		Cyclophosphamide (Cytoxan)	C				
			Methotrexate	C				
			Paracetamol (Tylenol)	C				

Date: 04/05/00 **ISR Number:** 3556026-3 **Report Type:** Periodic **Company Report#:** 200010302HMRI **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypertrichosis	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc			
			Unknown Drug (Unknown Drug)	C				

Date: 04/11/00 **ISR Number:** 3486825-8 **Report Type:** Expedited (15-Day) **Company Report#:** 200011181HMRI **Age:** 53 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Health Professional	Dolasetron Mesilate (Anzemet) Solution For Injection	PS		INTRAVENOUS	100 MG ONCE IV	1 DAY
			Carboplatin	C				
			Dexamethasone (Decadron)	C				
			Phenytoin Sodium (Dilantin)	C				
			Cimetidine (Tagamet)	C				

Date: 04/12/00 **ISR Number:** 3487378-0 **Report Type:** Direct **Company Report#:** **Age:** 75 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arthralgia Chest Pain Injection Site Pain Neck Pain	Health Professional	Anzemet 100mg	PS		INTRAVENOUS	100 MG IV	

Date: 04/12/00 **ISR Number:** 3487825-4 **Report Type:** Expedited (15-Day) **Company Report#:** 200011179HMRI **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Dolasetron Mesilate (Anzemet) Solution For Injection	PS		INTRAVENOUS	100 MG ONCE IV	
			Fluorouracil	C				
			Irinotecan Hydrochloride	C				

Date: 04/17/00 **ISR Number:** 3488994-2 **Report Type:** Expedited (15-Day) **Company Report#:** 200011276HMRI **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Head Injury Pain Scar		Dolasetron Mesilate (Anzemet)	PS				
			Midazolam Hydrochloride (Versed)	SS				

Date: 04/21/00 **ISR Number:** 3490706-3 **Report Type:** Direct **Company Report#:** **Age:** 51 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Required Intervention to Prevent Permanent Impairment/Damage	Ventricular Arrhythmia Ventricular Extrasystoles Ventricular Tachycardia		Anzemet	PS		INTRAVENOUS	12.5 MG IV 5 MINUTES BEFORE EPISODE	
			General Anesthetic Consisting Of Propofol, Vecuronium, Forane / O2 / N20, Fentanyl(4	C				

Date: 06/02/00 **ISR Number:** 3507905-4 **Report Type:** Expedited (15-Day) **Company Report#:** 199921965HMRI **Age:** 42 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia Extrapyramidal Disorder Respiratory Depression Sedation	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	12.5 MG ONCE IV	1 DAY
			Dexamethasone	C				
			Fentanyl	C				
			Midazolam Hydrochloride	C				
			Propofol	C				

Date: 06/15/00 **ISR Number:** 3514436-4 **Report Type:** Expedited (15-Day) **Company Report#:** 200011732HMRI **Age:** 23 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Potassium Decreased	Consumer	Anzemet	PS	Aventis Pharmaceuticals Inc	ORAL	100 MG PRN PO	3 WK
	Chest Pain		Dolasetron Mesilate (Anzemet) Tablets	SS		ORAL	100 MG/DAY PO	3 WK
	Condition Aggravated							
	Headache							
	Nausea							
	Palpitations							
	Vomiting							
	Weight Decreased							

Date: 06/23/00 **ISR Number:** 3518906-4 **Report Type:** Expedited (15-Day) **Company Report#:** 200011918HMRI **Age:** 49 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Angina Pectoris	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS BOLUS	12.5 MG ONCE IVB	1 DAY
	Electrocardiogram St Segment Depression		(Prempro)	C				
	Myocardial Infarction		Vitamins Nos (Vitamins Nos)	C				

Date: 07/06/00 **ISR Number:** 3525669-5 **Report Type:** Expedited (15-Day) **Company Report#:** 199910519RHF **Age:** 54 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Angina Pectoris	Foreign	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	100 MG/DAY IV	
Hospitalization - Initial or Prolonged	Arteriogram Coronary Abnormal	Health Professional	Fluorouracil Solution For Infusion	SS		INTRAVENOUS	2800 MG/DAY IV	3 DAY
	Cardiac Disorder	Other	Folic Acid	C				
	Coronary Artery Disease							
	Drug Interaction							
	Ejection Fraction Abnormal							
	Electrocardiogram St Segment Elevation							
	Hypokinesia							
	Laboratory Test Abnormal							
	Low Cardiac Output Syndrome							
	Myocarditis							
	Pulmonary Oedema							

Date: 07/12/00 **ISR Number:** 3528115-0 **Report Type:** Periodic **Company Report#:** 199912810HMRI **Age:** 20 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Eyelid Oedema	Consumer	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	100 MG IV	1 DAY
	Face Oedema	Health Professional	Losartan Potassium (Cozaar)	SS		ORAL	50 MG QD PO	
	Hypersensitivity		Zolpidem Tartrate (Ambien)	C				
	Oedema Peripheral		Paroxetine Hydrochloride (Paxil)	C				
	Tongue Oedema							

			Nifedipine (Procardia)	C			
			Cyclophosphamide (Cytoxan)	C			
			Prednisone	C			

Date: 07/12/00 **ISR Number:** 3528116-2 **Report Type:** Periodic **Company Report#:** 200010337HMRI **Age:** 78 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electrocardiogram Qt Prolonged	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc		100 MG ONCE	
	Syncope		Atenolol (Tenormin)	SS				
			Allopurinol	C				
			Acetylsalicylic Acid (Asa)	C				
			Cyclophosphamide	C				

Date: 07/12/00 **ISR Number:** 3528117-4 **Report Type:** Periodic **Company Report#:** 200011321HMRI **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc			
			Topotecan Hydrochloride (Hycamtin)	C				
			Cisplatin	C				

Date: 07/12/00 **ISR Number:** 3579956-5 **Report Type:** Periodic **Company Report#:** 200011521HMRI **Age:** 49 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia	Consumer	Anzemet	PS	Aventis Pharmaceuticals Inc	ORAL	500 MG ONCE PO	1 DAY
	Dizziness							
	Hypotension							
	Vision Blurred		Dolasetron Mesilate (Anzemet) Tablet	SS		ORAL	500 MG ONCE PO	1 DAY
			Phenobarbital	C				
			Ergotamine Tartrate	C				
			Belladonna Alkaloids	C				
			Dexamethasone	C				
			Indometacin	C				
			Doxorubicin	C				
			Trastuzumab	C				
			Prochlorperazine	C				
			Taxol	C				

Date: 07/12/00 **ISR Number:** 3581444-7 **Report Type:** Periodic **Company Report#:** 200011044HMRI **Age:** 65 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Vitreous Floaters	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc		100 MG ONCE IVB	1 DAY
			Irinotecan					

			Hydrochloride	C				

Date: 07/14/00 **ISR Number:** 3530193-X **Report Type:** Expedited (15-Day) **Company Report#:** 200012094HMR1 **Age:** 44 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest	Health	Anzemet	PS	Aventis			
Hospitalization - Initial or Prolonged	Coma	Professional			Pharmaceuticals Inc		100 MG ONCE IVB	
	Convulsion							
	Pulse Absent		Torasemide (Demadex)	C				
	Respiratory Failure		Benazepril Hydrochloride (Lotrel)	C				
			Paroxetine Hydrochloride (Paxil)	C				
			Dexamethasone	C				
			Amlodipine	C				

Date: 08/02/00 **ISR Number:** 3540440-6 **Report Type:** Expedited (15-Day) **Company Report#:** 200020024US **Age:** 19 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrioventricular Block Complete	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc			

Date: 08/03/00 **ISR Number:** 3541319-6 **Report Type:** Expedited (15-Day) **Company Report#:** 200020025US **Age:** 22 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrioventricular Block	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc		5 MG/DAY	

Date: 08/03/00 **ISR Number:** 3541321-4 **Report Type:** Expedited (15-Day) **Company Report#:** 200020022US **Age:** 52 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Electrocardiogram Qt	Health	Anzemet	PS	Aventis			
Other	Corrected Interval Prolonged	Professional			Pharmaceuticals Inc		ONCE	
	Ventricular Tachycardia							

Date: 08/03/00 **ISR Number:** 3541332-9 **Report Type:** Expedited (15-Day) **Company Report#:** 200020038US **Age:** 25 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abortion Spontaneous	Health	Anzemet	PS	Aventis			
	Complications Of Maternal Exposure To Therapeutic	Professional			Pharmaceuticals Inc	INTRAVENOUS	12.5 MG Q4H IV	
	Drugs		Promethazine	C				
			Metoclopramide	C				
			Nutritional Supplement	C				

Date: 08/04/00 **ISR Number:** 3542995-4 **Report Type:** Expedited (15-Day) **Company Report#:** 200020022US **Age:** 52 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Electrocardiogram Qt	Health	Anzemet	PS	Aventis			
Other	Corrected Interval	Professional			Pharmaceuticals Inc		ONCE	
	Prolonged		Unknown Drug					
	Ventricular Tachycardia		(Unknown Drug)	C				

Date: 08/08/00 **ISR Number:** 3545313-0 **Report Type:** Expedited (15-Day) **Company Report#:** 200011276HMRI **Age:** 29 YR **Gender:** Male **I/FU:** F

Outcome	PT
Life-Threatening	Amnesia
Hospitalization -	Anaphylactic Shock
Initial or Prolonged	Angina Pectoris
Other	Anion Gap Increased
	Blood Creatine
	Phosphokinase Increased
	Blood Creatinine
	Increased
	Blood Lactate
	Dehydrogenase Increased
	Blood Urea Increased
	Bradycardia
	Brain Hypoxia
	Cardiac Disorder
	Cardio-Respiratory Arrest
	Cardiomegaly
	Chest Discomfort
	Chest Pain
	Coma
	Confusional State
	Dermatitis
	Dialysis
	Electrocardiogram St
	Segment Elevation
	Haematocrit Increased
	Head Injury
	Hyperhidrosis
	Hyperkalaemia
	Hypotension
	Lactic Acidosis
	Leukocytosis
	Metabolic Acidosis
	Myocardial Infarction
	Pain
	Pneumonia Aspiration
	Pneumonitis
	Po2 Increased
	Posturing
	Pupil Fixed
	Pupillary Light Reflex
	Tests Abnormal
	Pyrexia
	Renal Failure Acute
	Renal Impairment
	Respiratory Arrest
	Rhabdomyolysis
	Right Ventricular Failure
	Sinus Tachycardia

Ventricular Fibrillation

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	12.5 MG IV	
	Midazolam Hydrochloride (Versed)	SS		INTRAVENOUS	1 MG IV	
	Diazepam	C				

Date: 09/14/00 **ISR Number:** 3570906-4 **Report Type:** Direct **Company Report#:** **Age:** 31 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dystonia		Dolasetron	PS		INTRAVENOUS	12.5MG IV X 1	

Date: 10/03/00 **ISR Number:** 3586685-0 **Report Type:** Expedited (15-Day) **Company Report#:** 10536704 **Age:** 58 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	Chest Pain Cough Cryptogenic Organizing Pneumonia Cytomegalovirus Infection Dyspnoea Pulmonary Fibrosis	Foreign Health Professional Other	Vincrex	PS	Bristol Myers Squibb	INTRAVENOUS	16 INTERNATIONAL UNIT, 1/1 CYCLE IV	
			Mustine Hcl	SS		INTRAVENOUS	10 MILLIGRAM, 1/1 CYCLE IV; DURATION: 2 CYCLE	
			Vincristine Sulphate	SS		INTRAVENOUS	2 MILLIGRAM, IV; DURATION: 2 CYCLE	
			Procarbazine Hcl	SS		ORAL	150 MILLIGRAM, 7/1 CYCLE ORAL; DURATION: 2	
			Prednisolone	SS		ORAL	75 MILLIGRAM, 14/1 CYCLE ORAL; DURATION: 2 CYCLE	
			Doxorubicin Hcl	SS		INTRAVENOUS	50 MILLIGRAM, 1/1 CYCLE IV; DURATION: 2 CYCLE	
			Vinblastine Sulfate	SS		INTRAVENOUS	10 MILLIGRAM, 1/1 CYCLE IV; DURATION: 2 CYCLE	
			Dolasetron Mesylate	SS		ORAL	200 MILLIGRAM, 2/1 CYCLE ORAL	
			Filgrastim(Granulocyte Csf)	SS		SUBCUTANEOUS	480 MICROGRAM, SC	
			Verapamil (Verapamil Hcl)	C				
			Omeprazole					

			(Omeprazole)	C				

Date: 10/03/00 **ISR Number:** 3586963-5 **Report Type:** Expedited (15-Day) **Company Report#:** 200020714US **Age:** 42 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atrioventricular Block Complete	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc			
	Cardio-Respiratory Arrest		Midazolam Hydrochloride					
	Cardiovascular Disorder		(Versed)	C				
	Coronary Artery Occlusion		Anaesthetics	C				
	Cyanosis		Methotrexate	C				
	Myocardial Infarction							

Date: 10/11/00 **ISR Number:** 3592457-3 **Report Type:** Direct **Company Report#:** USP 53370 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Anzemet	PS	H. Marion Rousel			

Date: 10/16/00 **ISR Number:** 3596205-2 **Report Type:** Expedited (15-Day) **Company Report#:** 10536050 **Age:** 27 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Toxicity Fatigue	Foreign Health	Cisplatin	PS		INTRAVENOUS	100 MILIGRAMS 1/1 CYCLE IV	
	Lung Disorder Lung Infiltration	Professional Other	Platinol	SS	Bristol Myers Co	INTRAVENOUS	30 MILLIGRAM, 4/1 CYCLE IV	
	Pulmonary Function Test Abnormal		Etoposide	SS			40 MILLIGRAM 1/1 DAY	
			Dolasetron Mesylate	SS				
			Decadron (Dexamethasone)	C				
			Prochlorperazine (Prochlorperazine)	C				

Date: 10/24/00 **ISR Number:** 3601467-9 **Report Type:** Expedited (15-Day) **Company Report#:** 200021426US **Age:** 39 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chromaturia Dizziness Urinary Retention	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	ORAL	QD PO	5 DAY

Date: 10/26/00 **ISR Number:** 3602164-6 **Report Type:** Expedited (15-Day) **Company Report#:** 200021105US **Age:** 51 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Consumer	Anzemet	PS	Aventis Pharmaceuticals Inc		12.5 MG ONCE	1 DAY
	Heart Rate Increased							
	Increased Appetite		Levothyroxine Sodium (Synthroid)	C				
	Palpitations		Calcium Carbonate, Magnesium Trisilicate, Magnesium Carbonate (Tums)	C				
	Supraventricular Tachycardia							
	Therapeutic Response Unexpected							

			Metoprolol Succinate (Toprol Xl)	C				

Date: 11/03/00 **ISR Number:** 3606819-9 **Report Type:** Expedited (15-Day) **Company Report#:** 200021653US **Age:** 60 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Vasculitis	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	100 MG ONCE IV	1 DAY
			Doxorubicin	C				
			Vincristine	C				
			Cyclophosphamide	C				

Date: 11/03/00 **ISR Number:** 3606867-9 **Report Type:** Expedited (15-Day) **Company Report#:** 200021601US **Age:** 60 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Burning Sensation Haemorrhage Vasculitis	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	100 MG QD IV	
			Carboplatin	C				
			Etoposide	C				
			Promethazine Hydrochloride (Phenergan)	C				
			Dexamethasone (Decadron)	C				
			Unknown Drug (Unknown Drug)	C				

Date: 11/08/00 **ISR Number:** 3608915-9 **Report Type:** Expedited (15-Day) **Company Report#:** 200021402US **Age:** 48 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Angina Pectoris Atrial Fibrillation Blood Creatine Phosphokinase Mb Increased Cardiac Enzymes Increased Chest Discomfort Headache Hypoaesthesia Hypotension Pallor	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	12.5 MG ONCE IV	
			Cefazolin	C				
			Acetylsalicylic Acid (Aspirin)	C				
			Estrogen Nos	C				
			Cefalexin Monohydrate (Keflex)	C				

Date: 11/08/00 **ISR Number:** 3608990-1 **Report Type:** Expedited (15-Day) **Company Report#:** 200021426US **Age:** 39 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Chromaturia Dizziness Urinary Retention	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	ORAL	QD PO	5 DAY

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: 11/13/00 **ISR Number:** 3611117-3 **Report Type:** Periodic **Company Report#:** 200020707US **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypertension	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc			
			Taxol	C				

Date: 11/13/00 **ISR Number:** 3611119-7 **Report Type:** Periodic **Company Report#:** 200020716US **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypertension	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	UNKNOWN		
			Taxol	C				

Date: 11/13/00 **ISR Number:** 3611121-5 **Report Type:** Periodic **Company Report#:** 200020718US **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypertension	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	UNKNOWN		
			Taxol	C				

Date: 11/13/00 **ISR Number:** 3611123-9 **Report Type:** Periodic **Company Report#:** 200021257US **Age:** 58 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dizziness Postural	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	100 MG QD IV	3 DAY
Other	Electrocardiogram Abnormal		Fluorouracil (5-Fu)	C				
	Heart Rate Increased		Prednisone	C				
	Orthostatic Hypotension		Omeprazole (Prilosec)	C				
			Metoclopramide (Reglan)	C				

Trazodone	C	
Sertraline Hydrochloride (Zoloft)	C	

Date: 11/13/00 **ISR Number:** 3632129-X **Report Type:** Periodic **Company Report#:** 200020187US **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Nausea	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAMUSCULAR	IM	

Date: 11/13/00 **ISR Number:** 3632130-6 **Report Type:** Periodic **Company Report#:** 200012025HMRI **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Night Sweats Pollakiuria	Consumer	Anzemet	PS	Aventis Pharmaceuticals Inc			

Date: 11/13/00 **ISR Number:** 3632131-8 **Report Type:** Periodic **Company Report#:** 200020096US **Age:** 50 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Headache Pollakiuria	Consumer	Anzemet	PS	Aventis Pharmaceuticals Inc	ORAL	100 MG QD PO	
			Prochlorperazine Edisylate	C				
			Tolterodine L-Tartrate	C				
			Ranitidine Hydrochloride	C				
			Sertraline Hydrochloride	C				

Date: 11/20/00 **ISR Number:** 3614171-8 **Report Type:** Direct **Company Report#:** **Age:** 49 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Electrocardiogram St Segment Abnormal Vasospasm		Amzemet 12.5mg	PS		INTRAVENOUS	12.5MG IV X1 BEFORE END OF SURGERY	
			Robinul	SS			0.5MG (ROBINUL) X 2	
			Neostigmine 4-6mg	SS				
			Multivite	C				
			Ca++ Supp	C				
			Prempro	C				

Date: 12/06/00 **ISR Number:** 3628357-X **Report Type:** Expedited (15-Day) **Company Report#:** AUS002420(0) **Age:** 30 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pulmonary Fibrosis	Foreign Health Professional	Neupogen	PS		SUBCUTANEOUS	300 MCG, DAILY, SC	
			Bleomycin Sulfate	SS		INTRAVENOUS	15 KU, INTERMITTENT,	

					IV
Chlormethine Hydrochloride	SS			INTRAVENOUS	10 MG, ONE TIME DOSE, IV
Vincristine Sulfate	SS			INTRAVENOUS	2 MG, ONE TIME DOSEONE TIME DOSE, IV
Procarbazine Hydrochloride	SS				150 MG, DAILYDAILY
Doxorubicin Hydrochloride	SS			INTRAVENOUS	55 MG, ONE TIME DOSEONE TIME DOSE, IV
Vinblastine Sulfate	SS			INTRAVENOUS	10 MG, ONE TIME DOSEONE TIME DOSE, IV
Navoban	SS				5 MG, DAILYDAILY
Dolasetron Mesylate	SS				

Date: 12/11/00 **ISR Number:** 3626329-2 **Report Type:** Direct **Company Report#:** **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Anzemet (Dolasetron)	PS				

Date: 01/23/01 **ISR Number:** 3653724-8 **Report Type:** Expedited (15-Day) **Company Report#:** 200110343US **Age:** 70 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Metabolic Acidosis	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	IV	
			Cyclophosphamide	C				
			Doxorubicin	C				
			Prednisone	C				
			Vincristine	C				
			Allopurinol	C				
			Furosemide	C				
			Omeprazole	C				
			Doxazosin Mesilate	C				

Date: 01/23/01 **ISR Number:** 3653725-X **Report Type:** Expedited (15-Day) **Company Report#:** 200021601US **Age:** 60 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Burning Sensation	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	100 MG QD IV	0 MON
Other	Haemorrhagic Disorder		Carboplatin	C				
	Respiratory Disorder		Etoposide	C				
	Vasculitis		Promethazine Hydrochloride	C				
			Dexamethasone	C				

Date: 01/23/01 **ISR Number:** 3653726-1 **Report Type:** Expedited (15-Day) **Company Report#:** 200021653US **Age:** 60 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Respiratory Disorder	Health	Anzemet	PS	Aventis			
Hospitalization - Initial or Prolonged	Small Cell Lung Cancer Stage Unspecified	Professional			Pharmaceuticals Inc	INTRAVENOUS	100 MG ONCE IV	1 DAY
	Vasculitis		Doxorubicin	C				
			Vincristine	C				
			Cyclophosphamide	C				

Date: 01/23/01 **ISR Number:** 3653727-3 **Report Type:** Expedited (15-Day) **Company Report#:** 200110342US **Age:** 70 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Metabolic Acidosis	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	IV	

Date: 01/30/01 **ISR Number:** 3657661-4 **Report Type:** Expedited (15-Day) **Company Report#:** 2636 **Age:** 23 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dyspnoea Exertional		Bleomycin Sulfate	PS		INTRAVENOUS	IV	9 WK
	Hypoxia		Etoposide	SS				
	Pulmonary Function Test Abnormal		Cisplatin	SS				
			Anzemet	SS				
			Dexamethasone	SS				

Date: 03/01/01 **ISR Number:** 3672035-8 **Report Type:** Direct **Company Report#:** **Age:** 49 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Dizziness		Dolasetron 100mg Mmd	PS	Mmd	INTRAVENOUS BOLUS	100MG ONCE IV BOLUS	
	Hypotension							
			Gabapentin	C				
			Propranolol	C				
			Irbesartan	C				
			Effexor	C				
			Dicyclomine	C				
			Loperamide	C				
			Metronidazole	C				
			Kcl	C				

Date: 03/08/01 **ISR Number:** 3676747-1 **Report Type:** Expedited (15-Day) **Company Report#:** ETHYOL-01492 **Age:** 49 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysphonia	Health Professional	Ethyol	PS	Medimmune Oncology Inc	INTRAVENOUS	320 MG IV	
	Hypersensitivity					ORAL	100 MG PO	
	Laryngitis		Anzemet	SS				
	Odynophagia		Reglan	C				
	Pyrexia		Buspar	C				
	Radiation Injury		Xanax	C				
	Rash Generalised		Paxil	C				
			Synthroid	C				
			Centrum	C				
			Dilaudid	C				

			Radiation	C				

Date: 03/14/01 **ISR Number:** 3681133-4 **Report Type:** Expedited (15-Day) **Company Report#:** 200112032US **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Disorder Electrocardiogram Abnormal	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc			

Date: 03/15/01 **ISR Number:** 3682123-8 **Report Type:** Expedited (15-Day) **Company Report#:** 200112375GDDC **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia Loss Of Consciousness Rash Erythematous Urinary Incontinence	Foreign Health Professional Other	Anzemet Ifosfamide Cisplatin	PS C C	Aventis Pharmaceuticals Inc	INTRAVENOUS	IV	

Date: 03/15/01 **ISR Number:** 3682124-X **Report Type:** Expedited (15-Day) **Company Report#:** 200112371GDDC **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia Loss Of Consciousness Rash Erythematous Urinary Incontinence	Foreign Health Professional Other	Anzemet Ifosfamide Cisplatin	PS C C	Aventis Pharmaceuticals Inc	INTRAVENOUS	IV	

Date: 03/26/01 **ISR Number:** 3689432-7 **Report Type:** Direct **Company Report#:** **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective		Anzement 12.5mg Amp/Gruppo Lot A0001	PS	/Gruppo	INTRAVENOUS	12.5 MG/1X/IV	2 WK

Date: 03/27/01 **ISR Number:** 3690117-1 **Report Type:** Direct **Company Report#:** **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Anzemet / 12.5 Mg/ 0.625 Ml / Aventis	PS	Aventis	INTRAVENOUS BOLUS	12.5MG 1 TIME INTRAVENOUS BOLUS	
			Inapsine 2.5 Mg/1 Ml Taylor	SS	Taylor	INTRAVENOUS BOLUS	0.625 MG 1 TIME INTRAVENOUS BOLUS	

Date: 03/30/01 **ISR Number:** 3693233-3 **Report Type:** Expedited (15-Day) **Company Report#:** 199910728HMRI **Age:** 16 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia Cardio-Respiratory Arrest Coma Dyspnoea Loss Of Consciousness Paraesthesia Respiratory Arrest Ventricular Extrasystoles	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	25 MG 3X IV	2 DAY

Date: 04/12/01 **ISR Number:** 3703848-1 **Report Type:** Direct **Company Report#:** **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Anzemet 12.5 Mg/Ml Vial Aventis	PS	Aventis			

Date: 04/17/01 **ISR Number:** 3706354-3 **Report Type:** Direct **Company Report#:** **Age:** 30 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ventricular Tachycardia		Anzemet	PS		INTRAVENOUS	12.5 MG IV Q 6H	
			Zofran	C				
			Reglan	C				
			Prevacid	C				
			Phenergan	C				
			Simethisone	C				
			Tylenol	C				
			Sectal	C				

Date: 04/25/01 **ISR Number:** 3710855-1 **Report Type:** Direct **Company Report#:** **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Anzemet 12.5mg Aventis	PS	Aventis	INTRAVENOUS BOLUS	12.5MG QD /PRN IV BOLUS	

Date: 04/30/01 **ISR Number:** 3713023-2 **Report Type:** Direct **Company Report#:** **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Anzemet 12.5mg Aventis	PS	Aventiis			
			Inapsine 5mg/2ml Taylor	SS	Taylor			
			Digoxin 500 Mcg/2ml Elkins-Sinn	SS	Elkins-Sinn			

Date: 04/30/01 **ISR Number:** 3714239-1 **Report Type:** Direct **Company Report#:** **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Anzemet Solution For Injection	PS	Aventis Pharmaceuticals Inc			

Date: 05/18/01 **ISR Number:** 3725604-0 **Report Type:** Expedited (15-Day) **Company Report#:** 200113723US **Age:** **Gender:** Not Specified **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Failure Congestive Transient Ischaemic Attack	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc			

Date: 05/25/01 **ISR Number:** 3728945-6 **Report Type:** Expedited (15-Day) **Company Report#:** 200113723US **Age:** **Gender:** **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Failure Congestive Transient Ischaemic Attack	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc			

Date: 06/07/01 **ISR Number:** 3735971-X **Report Type:** Expedited (15-Day) **Company Report#:** 200011276HMRI **Age:** 29 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Other	Anaphylactic Shock Aortic Valve Incompetence Brain Hypoxia Cardiac Arrest Cardiac Disorder Chest Discomfort Coma Gaze Palsy Injury Myocardial Infarction Pneumonitis Renal Failure Acute Respiratory Arrest Rhabdomyolysis Sinus Tachycardia Skin Discolouration Tricuspid Valve Incompetence Ventricular Fibrillation Ventricular Hypertrophy		Anzemet Midazolam Hydrochloride (Versed) Diazepam (Valium) No Ingredient Defined (Antibiotics)	PS SS C C	Aventis Pharmaceuticals Inc	INTRAVENOUS INTRAVENOUS	12.5 MG IV 1 MG IV	

Date: 06/08/01 **ISR Number:** 3736280-5 **Report Type:** Expedited (15-Day) **Company Report#:** 200114053US **Age:** **Gender:** Female **I/FU:** I

Outcome	PT
Hospitalization - Initial or Prolonged	Chest Pain Cough Dyspnoea

Pyrexia

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer	Anzemet	PS	Aventis Pharmaceuticals Inc			

Date: 06/11/01 **ISR Number:** 3738341-3 **Report Type:** Expedited (15-Day) **Company Report#:** 200114071US **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Health	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	100 MG ONCE IV	1 DAY
	Convulsion	Professional						
	Extrapyramidal Disorder							
	Loss Of Consciousness		Diphenhydramine Hydrochloride (Benadryl)	C				
	Tachycardia		Cimetidine (Tagamet)	C				
			Dexamethasone (Decadron)	C				

Date: 06/13/01 **ISR Number:** 3739955-7 **Report Type:** Direct **Company Report#:** USP 54145 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Anzemet	PS	Aventis			

Date: 07/06/01 **ISR Number:** 3753557-8 **Report Type:** Direct **Company Report#:** **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Anzemet 12.5 Mg Inj. (Amps) (Aventis)	PS	Aventis	INTRAVENOUS	12.5MG IV	

Date: 07/11/01 **ISR Number:** 3756589-9 **Report Type:** Expedited (15-Day) **Company Report#:** 200113796DE **Age:** 61 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Haemorrhagic Stroke	Foreign	Anzemet	PS	Aventis Pharmaceuticals Inc	INTRAVENOUS	100 MG/DAY IV	1 WK
Life-Threatening	Leukopenia	Health						
Hospitalization - Initial or Prolonged	Pulmonary Haemorrhage	Professional	Mitoxantrone Hydrochloride (Novantron)	C				
	Sepsis	Other	Topotecan Hydrochloride (Hycamtin)	C				
	Thrombocytopenia		Cytarabine (Ara "Cell")	C				

Date: 07/13/01 **ISR Number:** 3758892-5 **Report Type:** Expedited (15-Day) **Company Report#:** 200114053US **Age:** 73 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Pneumonia	Consumer	Anzemet	PS	Aventis Pharmaceuticals Inc	ORAL	100 MG QD PO	4 DAY
Hospitalization - Initial or Prolonged	Pulmonary Embolism		Epoetin Alfa (Epogen)	C				

			Warfarin Sodium (Coumadine)	C			
			Alprazolam Xanax)	C			
			Ondansetron Hydrochloride (Zofran)	C			
			Docusate Calcium (Surfak)	C			

Date: 07/31/01 **ISR Number:** 3768446-2 **Report Type:** Expedited (15-Day) **Company Report#:** 200115173US **Age:** 53 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Difficulty In Walking Faecal Incontinence Hypoaesthesia Paraesthesia Urinary Incontinence	Consumer	Anzemet	PS	Aventis Pharmaceuticals Inc	ORAL	100 MG/DAY; PO	1 DAY
			Dolasetron Mesilate (Anzemet)	SS		INTRAVENOUS	ONCE; IV	1 DAY
			Ara-C	C				
			Prednisone	C				
			Amfebutamone Hydrochloride (Wellbutrin)	C				
			Fluoxetine Hydrochloride (Prozac)	C				
			Danazol	C				
			Folic Acid	C				
			Levothyroxine Sodium (Synthroid)	C				
			Gabapentin (Neurontin)	C				
			Omeprazole (Prilosec)	C				
			No Ingredient Defined (Vitamins)	C				

Date: 08/16/01 **ISR Number:** 3778877-2 **Report Type:** Expedited (15-Day) **Company Report#:** 200115173US **Age:** 53 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Difficulty In Walking Faecal Incontinence Hypoaesthesia Paraesthesia Urinary Incontinence	Consumer Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc	ORAL	100 MG/DAY/PO	1 DAY
			Dolasetron Mesilate (Anzemet)	SS		INTRAVENOUS	100 M/DAY IV	1 DAY
			Ara-C	C				
			Prednisone	C				
			Amfebutamone Hydrochloride (Wellbutrin)	C				
			Fluoxetine Hydrochloride (Prozac)	C				
			Danazol	C				
			Folic Acid	C				
			Levothyroxine Sodium (Synthroid)	C				
			Gabapentin (Neurontin)	C				

			Omeprazole (Prilosec)	C				
			Vitamins	C				

Date: 08/16/01 **ISR Number:** 3778987-X **Report Type:** Direct **Company Report#:** **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Anzemet Injection 12.5 Mg Amp	PS	Mfd By Aventis		INJECTION 12.5 MG AMP	

Date: 08/20/01 **ISR Number:** 3779864-0 **Report Type:** Direct **Company Report#:** USP 54279 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Anzemet	PS	Aventis Pharmaceuticals			

Date: 08/22/01 **ISR Number:** 3781927-0 **Report Type:** Direct **Company Report#:** **Age:** 56 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pain In Extremity		Anzemet (Dolasetron)	PS		INTRAVENOUS	100 MG IVP X 1	

Date: 08/23/01 **ISR Number:** 3782003-3 **Report Type:** Direct **Company Report#:** USP 54300 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Anzemet	PS	Abbott Hosp			

Date: 09/11/01 **ISR Number:** 3790999-9 **Report Type:** Expedited (15-Day) **Company Report#:** 200120152US **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haemorrhage	Health Professional	Dolasetron Mesilate (Anzemet)	PS				

Date: 09/11/01 **ISR Number:** 3791002-7 **Report Type:** Expedited (15-Day) **Company Report#:** 200120155US **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haemorrhage	Health Professional	Dolasetron Mesilate (Anzemet)	PS				

Date: 09/13/01 **ISR Number:** 3792649-4 **Report Type:** Direct **Company Report#:** USP 54375 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Inapsine (Droperidol)	PS	Taylor Pharm			
			Anzemet (Dolasetron Mesylate)	SS	Abbott			

Date: 10/29/01 **ISR Number:** 3816749-5 **Report Type:** Expedited (15-Day) **Company Report#:** 200115173US **Age:** 53 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Csf Test Abnormal Difficulty In Walking Faecal Incontinence Hypoaesthesia Paraesthesia Urinary Incontinence	Consumer Health Professional	Dolasetron Mesilate (Anzemet) Tablets Dolasetron Mesilate (Anzemet) Ara-C Prednisone Amfebutamone Hydrochloride (Wellbutrin) Fluoxetine Hydrochloride (Prozac) Danazol Folic Acid Levothyroxine Sodium (Synthroid) Gabapentin (Neurontin) Omeprazole (Prilosec) (Vitamins)	PS SS C C C C C C C C C C		ORAL INTRAVENOUS	100 MG/DAY PO 100 MG/DAY IV	1 DAY 1 DAY

Date: 11/13/01 **ISR Number:** 3825959-2 **Report Type:** Periodic **Company Report#:** 199813427HMRI **Age:** 79 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Other	Electrocardiogram Poor R-Wave Progression Hypotension Sinus Bradycardia	Health Professional	Dolasetron Mesilate (Anzemet) (Anaesthetics, General)	PS C		INTRAVENOUS	12.5 MG ONCE IV	1 DAY

Date: 11/13/01 **ISR Number:** 3825960-9 **Report Type:** Periodic **Company Report#:** 200114939US **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Failure	Health Professional	Dolasetron Mesilate (Anzemet) Cisplatin Ifosfamide Methylprednisolone Sodium Succinate (Solu-Medrol) Erythropoietin (Procrit)	PS C C C C		INTRAVENOUS	100 MG IV	

Date: 11/13/01 **ISR Number:** 3825961-0 **Report Type:** Periodic **Company Report#:** 200114938US **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Failure	Health Professional	Dolasetron Mesilate (Anzemet) Cisplatin Ifosfamide Methylprednisolone	PS C C		INTRAVENOUS	100 MG IV	

			Sodium Succinate (Solu-Medrol)	C				
			Erythropoietin (Procrit)	C				

Date: 11/13/01 **ISR Number:** 3825962-2 **Report Type:** Periodic **Company Report#:** 200114937US **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Failure	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	100 MG IV	
			Cisplatin	C				
			Ifosfamide	C				
			Methylprednisolone Sodium Succinate (Solu-Medrol)	C				
			Erythropoietin (Procrit)	C				

Date: 11/13/01 **ISR Number:** 3825963-4 **Report Type:** Periodic **Company Report#:** 200114936US **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Failure	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	100 MG IV	
			Cisplatin	C				
			Ifosfamide	C				
			Methylprednisolone Sodium Succinate (Solu-Medrol)	C				
			Erythropoietin (Procrit)	C				

Date: 11/13/01 **ISR Number:** 3825964-6 **Report Type:** Periodic **Company Report#:** 200114931US **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Failure	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	100 MG IV	
			Cisplatin	C				
			Ifosfamide	C				
			Methylprednisolone Sodium Succinate (Solu-Medrol)	C				
			Erythropoietin (Procrit)	C				

Date: 12/04/01 **ISR Number:** 3833065-6 **Report Type:** Direct **Company Report#:** **Age:** 54 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Body Temperature		Anzemet	PS				
Required Intervention to Prevent Permanent Impairment/Damage	Increased Chills Nausea Rash Erythematous Vomiting		Fludarabine	C				
			Cytoxan	C				

Date: 01/02/02 **ISR Number:** 3847424-9 **Report Type:** Expedited (15-Day) **Company Report#:** 20012362US **Age:** 70 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Health Professional	Dolasetron Mesilate (Anzemet) Solution For Injection	PS		INTRAVENOUS	100 MG ONCE IV	1 DAY
	Difficulty In Walking							
	Flushing							
	Mental Impairment							
	Nausea		Dolasetron Mesilate (Anzemet) Tablets No Ingredient Defined (Cardiovascular System)	SS		ORAL	100 MG QD PO	3 DAY
				C				

Date: 01/14/02 **ISR Number:** 3858817-8 **Report Type:** Expedited (15-Day) **Company Report#:** 200210379US **Age:** 71 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Health Professional	Dolasetron Mesilate (Anzemet) Solution For Injection	PS		INTRAVENOUS	100 MG ONCE IV	1 DAY
	Dysarthria							
	Staring							
			Acetylsalicylic Acid (Aspirin)	C				
			Dexamethasone (Decadron)	C				
			Finasteride (Proscar)	C				
			Simvastatin (Zocor)	C				
			Cisplatin	C				
			Etoposide	C				

Date: 02/06/02 **ISR Number:** 3865261-6 **Report Type:** Direct **Company Report#:** CTU 160962 **Age:** 25 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia		Dolasetron (Anzemet (R) Aventis) 100mg	PS	Aventis		100MG IV OR PO Q 24 HR	
			Methotrexate	C				
			Doxorubicin	C				
			Cyclophosphamide	C				
			Ativan	C				
			Omeprazole	C				
			Ceftaz	C				
			Fluconazole	C				

Date: 02/07/02 **ISR Number:** 3867074-8 **Report Type:** Expedited (15-Day) **Company Report#:** 200210379US **Age:** 71 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Health Professional	Dolasetron Mesilate (Anzemet) Solution For Injection	PS		INTRAVENOUS	100 MG ONCE IV	1 DAY
	Cerebrovascular Accident							
	Dysarthria							
	Staring							
			Acetylsalicylic Acid (Aspirin)	C				
			Dexamethasone					

			(Decadron)	C				
			Finasteride (Proscar)	C				
			Simvastatin (Zocor)	C				
			Cisplatin	C				
			Etoposide	C				

Date: 02/11/02 **ISR Number:** 3868665-0 **Report Type:** Expedited (15-Day) **Company Report#:** 200123632US **Age:** 70 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State Difficulty In Walking Flushing Mental Impairment	Health Professional	Dolasetron Mesilate (Anzement) Solution For Injection	PS		INTRAVENOUS	100 MG ONCE IV	1 DAY
			Dolasetron Mesilate (Anzemet) Tablets	SS		ORAL	100 MG QD PO	3 DAY
			Doxazosin Mesilate (Cardura0	C				
			Acetylsalicylic Acid (Aspirin)	C				
			Atenolol	C				
			Simvastatin (Zocor)	C				

Date: 02/12/02 **ISR Number:** 3869313-6 **Report Type:** Expedited (15-Day) **Company Report#:** 200123632US **Age:** 70 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Difficulty In Walking Flushing Mental Status Changes	Health Professional	Dolasetron Mesilate (Anzemet) Solution For Injection	PS		INTRAVENOUS	100 MG ONCE IV	1 DAY
			Dolasetron Mesilate (Anzemet) Tablets	SS		ORAL	100 MG QD PO	3 DAY
			Doxazosin Mesilate (Cardura)	C				
			Acetylsalicylic Acid (Aspirin)	C				
			Atenolol	C				
			Simvastatin (Zocor)	C				

Date: 02/12/02 **ISR Number:** 3869325-2 **Report Type:** Expedited (15-Day) **Company Report#:** 200210379US **Age:** 71 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Dysarthria Staring	Health Professional	Dolasetron Mesilate (Anzemet) Solution For Injection	PS		INTRAVENOUS	100 (4TH CYCLE) MG CYC IV	
			Acetylsalicylic Acid (Aspirin)	C				
			Dexamethasone (Decadron)	C				
			Finasteride (Proscar)	C				
			Simvastatin (Zocor)	C				
			Cisplatin	C				
			Etoposide	C				

Date: 03/25/02 **ISR Number:** 3888234-6 **Report Type:** Expedited (15-Day) **Company Report#:** 200212533US **Age:** 66 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Health	Dolasetron Mesilate (Anzemet)Solution For Injection	PS		INTRAVENOUS	100 MG ONCE IV	1 DAY
Other	Cerebrovascular Accident	Professional						
	Neuroleptic Malignant Syndrome							
	Visual Field Defect		Taxol	C				
			Carboplatin	C				
			Dexamethasone	C				
			Lorazepam (Ativan)	C				
			Diphenydramine	C				
			Insulin	C				

Date: 03/25/02 **ISR Number:** 3888940-3 **Report Type:** Expedited (15-Day) **Company Report#:** 200212461US **Age:** 37 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia	Consumer	Dolasetron Mesilate (Anzemet) Solution For Injection	PS		INTRAVENOUS	12.5 MG ONCE IV	1 DAY
	Condition Aggravated							
			Lansoprazole (Prevacid)	C				
			Clonazepam (Klonopin)	C				
			Methadone	C				
			Iron	C				

Date: 04/04/02 **ISR Number:** 3894768-0 **Report Type:** Direct **Company Report#:** CTU 164944 **Age:** 36 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia		Anzemet Injection	PS		INTRAVENOUS	12.5 MG IV X 1 DOSE	
	Somnolence							
			Prevacid	C				
			Klonopin	C				
			Fibercon	C				
			Multivitamin	C				

Date: 04/04/02 **ISR Number:** 3894800-4 **Report Type:** Direct **Company Report#:** CTU 164943 **Age:** 34 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation		Anzemet Injection	PS		INTRAVENOUS	12.5 MG IV X 1 DOSE	
	Akathisia							
	Anxiety		Prevacid	C				
	Dystonia		Klonopin	C				
	Emotional Distress							
	Movement Disorder							

Date: 04/19/02 **ISR Number:** 3909061-7 **Report Type:** Expedited (15-Day) **Company Report#:** AUS002420 **Age:** 30 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source
Other	Pulmonary Fibrosis	Foreign
		Health

Professional

Product	Role	Manufacturer	Route	Dose	Duration
Neupogen	PS			300 MCG, DAILY, SC	
Bleomycin Sulfate	SS		INTRAVENOUS	15 KU, INTERMITTENT, IV	
Chlormethine Hydrochloride	SS		INTRAVENOUS	10 MG, ONE TIME DOSE, IV	
Vincristine Sulfate	SS			2 MG, ONE TIME DOSE ONE TIME	
Procarbazine Hydrochloride	SS			150 MG, DAILY DAILY	
Doxorubicin Hydrochloride	SS			55 MG, ONE TIME DOSEONE TIME	
Vinblastine Sulfate	SS			10 MG, ONE TIME DOSEONE TIME	
Navoban	SS			5 MG, DAILY DAILY	
Dolasetron Mesylate	SS				

Date: 04/26/02 **ISR Number:** 3908348-1 **Report Type:** Expedited (15-Day) **Company Report#:** 200212461US **Age:** 37 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Agitation Akathisia Anxiety	Consumer

Product	Role	Manufacturer	Route	Dose	Duration
Dolasetron Mesilate (Anzemet)	PS			12.5MG ONCE	1 DAY
Dolasetron Mesilate (Anzemet) Solution For Injection	SS		INTRAVENOUS	12.5MG ONCE IV	1 DAY
Lansoprazole (Prevacid)	C				
Clonazepam (Klonopin)	C				
Methadone	C				
Fentanyl	C				
Ondansetron Hydrochloride (Zofran)	C				

Date: 05/09/02 **ISR Number:** 3915300-9 **Report Type:** Expedited (15-Day) **Company Report#:** 200212533US **Age:** 66 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged Other	Cerebrovascular Accident	Health Professional

Product	Role	Manufacturer	Route	Dose	Duration
Dolasetron Mesilate (Anzemet) Solution For Injection	PS		INTRAVENOUS	100 MG ONCE IV	1 DAY
Taxol	C				
Carboplatin	C				
Dexamethasone	C				

			Lorazepam (Ativan)	C				

Date: 05/20/02 **ISR Number:** 3919246-1 **Report Type:** Expedited (15-Day) **Company Report#:** 200214510US **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Health Professional	Dolasetron Mesilate (Anzemet) Solution For Injection	PS		INTRAVENOUS	100 MG IV	1 DAY
	Deafness		...	C				
	Disorientation		Dexamethasone	C				

Date: 05/29/02 **ISR Number:** 3926060-X **Report Type:** Expedited (15-Day) **Company Report#:** 001-0981-M0202662 **Age:** **Gender:** Unknown **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Health Professional Company Representative	Atorvastatin (Atorvastatin)	PS				
			Celecoxib	SS				
			Midazolam Hydrochloride	SS			2 MG	
			Fentanyl	SS			2 CC	
			Droperidol	SS			0.625	
			Dolasetron	SS			12.5	
			Propofol	SS			20 CC	
			Ketorolac Tromethamine	SS			60	

Date: 05/31/02 **ISR Number:** 3927349-0 **Report Type:** Expedited (15-Day) **Company Report#:** 2002AP01372 **Age:** 64 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Foreign	Atenolol	PS			50 MG DAILY	
	Malaise	Health Professional	Dolasetron Mesylate	SS			200 MG DAILY	
	Syncope	Other	Cosudex	SS			50 MG DAILY	
			Atacand	C				
			Chlotride	C				
			Omeprazole	C				
			Prednisolone	C				

Date: 06/03/02 **ISR Number:** 3928620-9 **Report Type:** Expedited (15-Day) **Company Report#:** 3654 **Age:** 26 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia		Cisplatin	PS		INTRAVENOUS	IV	1 DAY
	Drug Interaction		Homatropine Hydrobromide	SS		INTRAVENOUS	IV	1 DAY
	Hyperreflexia		Vinblastine Sulfate	SS		INTRAVENOUS	7.5 MG IV	
	Hypertonia		Mesna	SS		INTRAVENOUS	IV	
	Hypokalaemia		Dolasetron Mesilate	SS		INTRAVENOUS	100 MG ONCE IV	
	Hypophosphataemia		Dexamethasone	SS		INTRAVENOUS	8 MG ONCE IV	

Date: 06/28/02 **ISR Number:** 3941734-2 **Report Type:** Expedited (15-Day) **Company Report#:** 200214510US **Age:** 65 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Deafness Disorientation	Health Professional	Dolasetron Mesilate (Anzemet) Solution For Injection Dexamethasone	PS C		INTRAVENOUS	100 MG IV	1 DAY

Date: 07/19/02 **ISR Number:** 3951842-8 **Report Type:** Expedited (15-Day) **Company Report#:** A214487 **Age:** 49 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Agitation Disorientation Drug Interaction Euphoric Mood Serotonin Syndrome Suicidal Ideation	Literature Health Professional	Zoloft Tablets Anzemet(Dolasetron Mesylate)	PS SS			100.00 MG TOTAL:DAILY:UNKNOWN	

Date: 08/15/02 **ISR Number:** 3963713-1 **Report Type:** Expedited (15-Day) **Company Report#:** 200218113US **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Myocardial Infarction Torsade De Pointes	Health Professional	Dolasetron Mesilate (Anzemet) Sumatriptan (Imitrex)	PS C				

Date: 09/23/02 **ISR Number:** 3979813-6 **Report Type:** Expedited (15-Day) **Company Report#:** 200219210US **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased Febrile Neutropenia	Health Professional	Dolasetron Mesilate (Anzemet) Fluorouracil (5-Fu) Cyclophosphamide Epirubicin Lisinopril (Zestril) Hydrohlorothiazide	PS C C C C C				

Date: 09/25/02 **ISR Number:** 3982862-5 **Report Type:** Expedited (15-Day) **Company Report#:** 200219129US **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Cardiac Arrest Drug Ineffective	Health Professional	Dolasetron Mesilate (Anzemet) Solution For Injection Morphine Metoprolol Succinate (Toprol Xl)	PS C C		INTRAVENOUS	12.5 X 1 MG IV	1 DAY

Date: 09/30/02 **ISR Number:** 3983088-1 **Report Type:** Direct **Company Report#:** CTU 177544 **Age:** 59 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Urticaria		Anzimet 25mg/Ml	PS		INTRAVENOUS BOLUS	12.5MG ONCE IV BOLUS	

Date: 10/28/02 **ISR Number:** 4001464-8 **Report Type:** Expedited (15-Day) **Company Report#:** 200219129US **Age:** 73 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiac Arrest	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	12.5 X 1 MG IV	1 DAY
Other	Drug Ineffective		Morphine	C				
	Syncope Vasovagal		Metoprolol Succinate (Toprol Xl)	C				

Date: 11/25/02 **ISR Number:** 4014335-8 **Report Type:** Expedited (15-Day) **Company Report#:** US-BRISTOL-MYERS SQUIBB COMPANY-12111043 **Age:** 51 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Drug Interaction	Health Professional	Carboplatin	PS	Bristol-Myers Squibb Company	INTRAVENOUS	7 cycles were given	
Other	Grand Mal Convulsion		Tavegyl	C		INTRAVENOUS		
			Zantic	C		INTRAVENOUS		
			Fortecortin	C		INTRAVENOUS		
			Taxol	I	Bristol-Myers Squibb Company	INTRAVENOUS	7 cycles have been given	
			Anzemet	I		INTRAVENOUS		

Date: 11/27/02 **ISR Number:** 4015698-X **Report Type:** Direct **Company Report#:** USP 55358 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Diazepam	PS	Abbott Laboratories			
			Anzemet(Dolasetron Mesylate)	SS	Aventis Pharmaceuticals			

Date: 11/29/02 **ISR Number:** 4018394-8 **Report Type:** Expedited (15-Day) **Company Report#:** 200213735EU **Age:** 51 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Foreign	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	CYC IV	
	Drug Interaction	Other	Paclitaxel	SS		INTRAVENOUS	300 MG DAY IV	
			Carboplatin	C				
			Clemastine (Tavegyl)	C				
			Ranitidine	C				
			Dexamethasone	C				

Date: 12/16/02 **ISR Number:** 4026910-5 **Report Type:** Expedited (15-Day) **Company Report#:** 200221958US **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypoglycaemia Neutropenia	Health Professional	Dolasetron Mesilate (Anzemet) Tablets No Ingredient Defined (All Other Therapeutic Products)	PS C		ORAL	400 MG QD; PO	1 WK

Date: 01/08/03 **ISR Number:** 4040542-4 **Report Type:** Expedited (15-Day) **Company Report#:** 200222679US **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyspnoea Respiratory Arrest	Health Professional	Dolasetron Mesilate (Anzemet)	PS				

Date: 01/15/03 **ISR Number:** 4042256-3 **Report Type:** Direct **Company Report#:** CTU 184551 **Age:** 45 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Pressure Abnormal Cardio-Respiratory Arrest Convulsion Dizziness Feeling Hot Neck Pain Pulse Abnormal Ventricular Fibrillation		Cyclophosphamide 900 Mg Iv	PS		INTRAVENOUS	900 MG, 150 NS OVER 40 MIN IV, (11:25-12:05)	
			Dolasetron 100 Mg	SS			100 MG 100 NS WITH DEMETH, OVER 15 M (11:00-11:15)	
			Dexamethasone	SS		INTRAVENOUS	8 MG IV IN 100 NS WITH DOLASETRON OVER 15 MIN (11:00-11:15)	
			Toprol Xl	C				
			Hctz 25 Mg	C				
			Flexeril	C				
			Diclofenac	C				
			Vicodin	C				

Date: 01/31/03 **ISR Number:** 4051187-4 **Report Type:** Expedited (15-Day) **Company Report#:** 200221958US **Age:** **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypoglycaemia Neutropenia Overdose	Health Professional	Dolasetron Mesilate (Anzemet) Tablets No Ingredient Defined (All Other Therapeutic Products)	PS C		ORAL	400 MG QD PO	1 WK

Date: 02/07/03 **ISR Number:** 4054222-2 **Report Type:** Expedited (15-Day) **Company Report#:** 200310893GDDC **Age:** 5 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Parkinson'S Disease	Foreign Health Professional Other	Dolasetron Mesilate	PS		INTRAVENOUS	250 MG/DAY IV	1 DAY

Date: 02/20/03 **ISR Number:** 4061427-3 **Report Type:** Expedited (15-Day) **Company Report#:** 200310592FR **Age:** 71 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis	Foreign Other	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	CYC IV	1 DAY
			Cisplatin (Cisplatin "Qualimed")	SS		INTRAVENOUS	80 MG CYC IV	1 DAY
			Gemcitabine Hydrochloride (Gemzar)	SS		INTRAVENOUS	1250 MG CYC IV	1 DAY
			Nifedipine (Chronadalate)	C				
			Alizapride Hydrochloride (Plitican)	C				
			Trimetazidine Hydrochloride	C				

Date: 02/28/03 **ISR Number:** 4067811-6 **Report Type:** Expedited (15-Day) **Company Report#:** 200310893GDDC **Age:** 35 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Parkinson'S Disease	Foreign Health Professional Other	Dolasetron Mesilae (Zamanon)	PS		INTRAVENOUS	25 MG/DAY IV	1 DAY

Date: 03/05/03 **ISR Number:** 4068029-3 **Report Type:** Direct **Company Report#:** USP 55525 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Anzemet (Dolasetron Mesylate)	PS	Abbott Hosp			

Date: 03/07/03 **ISR Number:** 4072877-3 **Report Type:** Expedited (15-Day) **Company Report#:** 200310893GDDC **Age:** 35 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Extrapyramidal Disorder	Foreign Health Professional Other	Dolasetron Mesilate (Zamanon)	PS		INTRAVENOUS	12.5 MG/DAY IV	1 DAY

Date: 03/13/03 **ISR Number:** 4075562-7 **Report Type:** Expedited (15-Day) **Company Report#:** 200310886FR **Age:** 37 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis Neutropenia	Foreign Other	Dolasetron Mesilate (Anzemet) Cytarabine (Aracytine)	PS SS		INTRAVENOUS INTRAVENOUS	100 MG/DAY IV 400 MG/DAY IV	9 DAY 8 DAY

Date: 03/18/03 **ISR Number:** 4073567-3 **Report Type:** Expedited (15-Day) **Company Report#:** WAES 0303USA01197 **Age:** 46 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis Nausea Pancytopenia Pericardial Effusion Pleural Effusion Radiation Skin Injury		Decadron Tablets Taxotere Anzemet	PS SS SS	Merck & Co., Inc	ORAL INTRAVENOUS		8 WK

Date: 03/19/03 **ISR Number:** 4078553-5 **Report Type:** Expedited (15-Day) **Company Report#:** 200312126US **Age:** 17 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Myocardial Infarction Pulmonary Oedema Tachycardia Ventricular Hypokinesia	Health Professional	Dolasetron Mesilate (Anzemet) Solution For Injection General Anesthesia	PS C			INJ	1 DAY

Date: 03/19/03 **ISR Number:** 4078554-7 **Report Type:** Expedited (15-Day) **Company Report#:** 200311779US **Age:** 46 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pericardial Effusion Pleural Effusion	Health Professional	Docetaxel (Taxotere) Dolasetron Mesilate (Anzemet) Dexamethasone (Decadron) Doxorubicin Cyclosphosphamide Radiations Therapy Nos	PS SS SS C C C			55 MG QW	50 DAY

Date: 04/16/03 **ISR Number:** 4097323-5 **Report Type:** Expedited (15-Day) **Company Report#:** 2003009797 **Age:** **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Disability Other	Atrial Fibrillation Difficulty In Walking Drug Interaction Fatigue Lung Carcinoma Cell Type Unspecified Stage Iv Metastases To Central Nervous System Pneumonia	Consumer Health Professional	Tikosyn (Dofetilide) Paclitaxel (Paclitaxel) Dexamethasone (Dexamethasone) Cimetidine Dolasetron Mesilate (Dolasetron Mesilate) Levothyroxine Sodium	PS SS SS SS SS		ORAL	500 MCG (BID), ORAL 4 MG (BID)	

(Levothyroxine Sodium)	C	
Raloxifene Hydrochloride (Raloxifene Hydrochloride)	C	
Senokot-S (Docusate Sodium, Senna)	C	
Warfarin (Warfarin)	C	
Acetylsalicylic Acid (Acetylsalicylic Acid)	C	
Ascorbic Acid (Ascorbic Acid)	C	
Tocopherol (Tocopherol)	C	
Famotidine (Famotidine)	C	
Gabapentin (Gabapentin)	C	
Ditiazem Hydrochloride (Diltiazem Hydrochloride)	C	

Date: 04/25/03 **ISR Number:** 4097549-0 **Report Type:** Periodic **Company Report#:** US-BRISTOL-MYERS SQUIBB COMPANY-12175600 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Injury	Other	Taxol	PS	Bristol-Myers Squibb Company			
			Paraplatin	SS	Bristol-Myers Squibb Company			
			Platinol	SS	Bristol-Myers Squibb Company			
			Procrit	SS				
			Tissue Plasminogen Activator	SS				
			Zofran	SS				
			Anzemet	SS				

Date: 04/25/03 **ISR Number:** 4098090-1 **Report Type:** Expedited (15-Day) **Company Report#:** WAES 0303USA01197 **Age:** 46 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Pericardial Effusion Pleural Effusion		Decadron Tablets	PS	Merck & Co., Inc	ORAL		
			Taxotere	SS		INTRAVENOUS		8 WK
			Anzemet	SS				

Date: 05/14/03 **ISR Number:** 4113598-8 **Report Type:** Direct **Company Report#:** CTU 192981 **Age:** 68 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Systolic Increased Chest Pain Dysarthria Feeling Hot Pain		Taxotere (Aventis) (Diluent Polysorbale 80)	PS	Aventis	INTRAVENOUS	46 MG IVPB X 1	
			Anzemet (Aventis)	SS	Aventis	INTRAVENOUS	100 MG IV PUSH X 1	

Date: 06/11/03 **ISR Number:** 4128989-9 **Report Type:** Expedited (15-Day) **Company Report#:** 200315088US **Age:** 56 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardio-Respiratory Arrest	Health	Dolasetron Mesilate					
Other	Electrocardiogram Qt	Professional	(Anzemet)	PS				
	Prolonged		Carboplatin	SS				
	Loss Of Consciousness		Ranitidine Hydrochloride					
			(Zantac)	C				

Date: 06/11/03 **ISR Number:** 4128991-7 **Report Type:** Expedited (15-Day) **Company Report#:** 200315087US **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Health	Dolasetron Mesilate					
	Loss Of Consciousness	Professional	(Anzemet)	PS				
			Carboplatin	SS				

Date: 06/11/03 **ISR Number:** 4128992-9 **Report Type:** Expedited (15-Day) **Company Report#:** 200315086US **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardio-Respiratory Arrest	Health	Dolasetron Mesilate					
		Professional	(Anzemet)	PS				

Date: 06/11/03 **ISR Number:** 4128995-4 **Report Type:** Expedited (15-Day) **Company Report#:** 200315085US **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaphylactic Reaction	Health	Dolasetron Mesilate					
Other	Cardio-Respiratory Arrest	Professional	(Anzemet)	PS				
			Carboplatin	SS				

Date: 06/16/03 **ISR Number:** 4129386-2 **Report Type:** Direct **Company Report#:** CTU 195798 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Limb Injury		Anzemet 12.5mg					
	Medical Device Complication		Abbott Laboratories	PS	Abbott Laboratories	INTRAVENOUS BOLUS	12.5MG IV IV BOLUS	
	Pharmaceutical Product Complaint							

Date: 08/01/03 **ISR Number:** 4202868-0 **Report Type:** Periodic **Company Report#:** KDL031091 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Malignant Neoplasm Progression	Health Professional	Procrit	PS				
			Paclitaxel	SS		INTRAVENOUS	IV	
			Carboplatin	SS		INTRAVENOUS	IV	
			Cisplatin	SS		INTRAVENOUS	IV	
			Ondansetron Hydrochloride	SS		INTRAVENOUS	IV	
			Dolasetron Mesylate	SS		INTRAVENOUS	IV	

Date: 08/07/03 **ISR Number:** 4167268-0 **Report Type:** Expedited (15-Day) **Company Report#:** 200315085US **Age:** 44 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anxiety	Health	Dolasetron Mesilate					
Other	Cardio-Respiratory Arrest	Professional	(Anzemet)	PS			125 MG	
	Chest X-Ray Abnormal		Carboplatin	SS			394.41 MG Q3W	
	Coma		Gemcitabine Hydrochloride					
	Dyspnoea		(Gemzar)	C				
	Erythema		Dexamethasone					
	Granulocyte Count Decreased		(Hexadrol)	C				
	Haematocrit							
	Haemoglobin							
	Mean Cell Volume							
	Monocyte Count Increased							
	Pallor							
	Platelet Count							
	Vomiting							
	White Blood Cell Count							

Date: 08/07/03 **ISR Number:** 4167270-9 **Report Type:** Expedited (15-Day) **Company Report#:** 200315087US **Age:** 75 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatinine Increased	Health	Dolasetron Mesilate					
	Bradycardia	Professional	(Anzemet)	PS			125 MG	
	Cardio-Respiratory Arrest		Carboplatin	SS				
	Coma		Dexamethasone					
	Pleural Disorder		(Decadron)	C				
			Dexamethasone					
			(Hexadrol)	C				
			Diphenhydramine Hydrochloride	C				
			Ranitdine Hydrochloride					
			(Zantac)	C				
			Darbepoetin Alfa					
			(Aranesp)	C				
			Taxol	C				
			Granulocyte Macrophage Colony Stim Factor	C				
			Atenolol	C				
			Lisinopril (Zestril)	C				
			Morphine	C				
			Codeine Phosphate, Paracetamol (Tylenol W/Codeine No. 3)	C				
			Metoclopramide (Reglan)	C				

Date: 08/07/03 **ISR Number:** 4167272-2 **Report Type:** Expedited (15-Day) **Company Report#:** 200315086US **Age:** 57 YR **Gender:** Female **I/FU:** F

Outcome	PT
Life-Threatening	Cardio-Respiratory Arrest
Hospitalization - Initial or Prolonged	Haemodialysis
	Nausea
Other	Renal Tubular Necrosis

Respiratory Failure
Vomiting

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	150 MG IV	
	Dexamethasone (Hexadrol)	C				

Date: 08/07/03 **ISR Number:** 4167274-6 **Report Type:** Expedited (15-Day) **Company Report#:** 200315088US **Age:** 56 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alanine Aminotransferase	Health	Dolasetron Mesilate					
Life-Threatening	Aspartate	Professional	(Anzemet)	PS			240 MG	
Other	Aminotransferase		Carboplatin	SS				
	Asthenia		Ranitidine Hydrochloride					
	Blood Albumin		(Zantac)	C				
	Blood Alkaline Phosphatase		Dexamethasone (Hexadrol)	C				
	Blood Bilirubin		Diphenhydramine					
	Blood Calcium		Hydrochloride	C				
	Blood Chloride		Ranitidine Hydrochloride					
	Blood Creatinine		(Zantac)	C				
	Blood Glucose		Taxol	C				
	Blood Potassium		Darbopoetin Alfa					
	Blood Sodium		(Aranesp)	C				
	Blood Urea		Granolocyte Macrophage Colony					
	Cardio-Respiratory Arrest		Stim Factor	C				
	Coma		Dexamethasone (Decadron)	C				
	Electrocardiogram Qt Corrected Interval Prolonged							
	Excoriation							
	Fall							
	Haematocrit							
	Haemoglobin							
	Mean Cell Volume							
	Nausea							
	Neck Pain							
	Pain In Extremity							
	Pco2							
	Platelet Count							
	Pulse Absent							
	Skin Laceration							
	Weight Decreased							
	White Blood Cell Count							

Date: 08/13/03 **ISR Number:** 4167049-8 **Report Type:** Direct **Company Report#:** CTU 199922 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased		Anzemet	PS		INTRAVENOUS	100MG PREMED IV DRIP	
	Discomfort							
	Dizziness		Gemzar	SS		INTRAVENOUS DRIP	1870MG DAY 1 AND D IV DRIP	
	Hyperhidrosis							

Date: 08/20/03 **ISR Number:** 4172192-3 **Report Type:** Direct **Company Report#:** CTU 200267 **Age:** 51 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Grand Mal Convulsion		Dolasetron 20 Mg/Ml Aventis	PS	Aventis	INTRAVENOUS BOLUS	12.5 MG ONCE IV BOLUS	

Date: 09/02/03 **ISR Number:** 4178843-1 **Report Type:** Direct **Company Report#:** CTU 201089 **Age:** 47 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Apnoea Blood Pressure Abnormal Bradycardia Coma Post Procedural Complication		Dolasetron-Anzemet- Labetalol Furosemide Phenytoin	PS SS C C		INTRAVENOUS BOLUS INTRAVENOUS	12.5 MG 2 DOSES IV BOLUS 35 MG IV	

Date: 09/15/03 **ISR Number:** 4190996-8 **Report Type:** Expedited (15-Day) **Company Report#:** 200315085US **Age:** 44 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Other	Anaphylactic Reaction Cardio-Respiratory Arrest Chest X-Ray Abnormal Coma Haematocrit Haemoglobin Mean Cell Volume Monocyte Percentage Increased Platelet Count Vomiting White Blood Cell Count	Health Professional	Dolasetron Mesilate (Anzemet) Carboplatin Gemcitabine Hydrochloride (Gemzar) Dexamethasone (Hexadrol)	PS SS C C			125 MG 394.41 MG Q3W	

Date: 09/15/03 **ISR Number:** 4190997-X **Report Type:** Expedited (15-Day) **Company Report#:** 200315086US **Age:** 57 YR **Gender:** Female **I/FU:** F

Outcome	PT
Life-Threatening Hospitalization - Initial or Prolonged Other	Apnoea Blood Pressure Immeasurable Cardio-Respiratory Arrest Cyanosis Depressed Level Of Consciousness Haemodialysis Heart Rate Decreased Moaning Muscle Rigidity Oxygen Saturation Decreased Pallor Renal Failure Renal Tubular Necrosis Respiratory Failure

Vomiting

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	150 MG IV	
	Dexamethasone (Hexadrol)	C				

Date: 09/15/03 **ISR Number:** 4190999-3 **Report Type:** Expedited (15-Day) **Company Report#:** 200315087US **Age:** 72 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Apnoea	Health Professional	Dolasetron Mesilate (Anzemet)	PS			125 MG	
	Band Neutrophil Count		Carboplatin	SS				
	Blood Creatinine Increased		Dexamethasone (Decadron)	C				
	Bradycardia		Dexamethasone (Hexadrol)	C				
	Cardio-Respiratory Arrest		Diphenhydramine Hydrochloride	C				
	Circulatory Collapse		Ranitidine Hydrochloride (Zantac)	C				
	Coma		Darbepoetin Alfa (Aranesp)	C				
	Computerised Tomogram Abnormal		Taxol	C				
	Haematocrit		Granulocyte Macrophage Colony Stim Factor	C				
	Haemoglobin		Atenolol	C				
	Lymphocyte Count		Lisinopril (Zestril)	C				
	Mean Cell Volume		Morphine	C				
	Neutrophil Count		Codeine Phosphate, Paracetamol (Tylenol W/Codeine No. 3)	C				
	Platelet Count		Metoclopramide (Reglan)	C				
	White Blood Cell Count							

Date: 09/15/03 **ISR Number:** 4191002-1 **Report Type:** Expedited (15-Day) **Company Report#:** 200315088US **Age:** 56 YR **Gender:** Female **I/FU:** F

Outcome	PT
Death	Alanine Aminotransferase
Life-Threatening	Aspartate Aminotransferase
Other	Asthenia
	Blood Albumin
	Blood Alkaline Phosphatase
	Blood Bilirubin
	Blood Calcium
	Blood Chloride
	Blood Creatinine
	Blood Glucose
	Blood Potassium
	Blood Sodium
	Blood Urea
	Cardio-Respiratory Arrest

Coma							
Electrocardiogram Qt Prolonged	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Excoriation	Health	Dolasetron Mesilate					
Fall	Professional	(Anzemet)	PS			240 MG	
Haematocrit		Carboplatin	SS				
Haemoglobin		Ranitidine Hydrochloride					
Injury		(Zantac)	C				
Intentional Misuse		Dexamethasone					
Mean Cell Volume		(Hexadrol)	C				
Medication Error		Diphenhydramine					
Nausea		Hydrochloride	C				
Neck Pain		Ranitidine Hydrochloride					
Pain In Extremity		(Zantac)	C				
Pco2		Taxol	C				
Platelet Count		Darbeoetin Alfa					
Pulse Absent		(Aranesp)	C				
Skin Laceration		Granulocyte Macrophage Colony					
Urinary Incontinence		Stim Factor	C				
Weight Decreased		Dexamethasone					
White Blood Cell Count		(Decadron)	C				

Date: 09/26/03 **ISR Number:** 4195274-9 **Report Type:** Expedited (15-Day) **Company Report#:** FR-BRISTOL-MYERS SQUIBB COMPANY-12386876 **Age:** 69 YR **Gender:** Female **I/FU:** I

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Hospitalization - Initial or Prolonged	Hyponatraemia	Health Professional	Endoxan	PS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Doxorubicin Hcl	SS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Methylprednisolone	SS		INTRAVENOUS		
			Anzemet	SS		INTRAVENOUS		
			Vincristine	SS		INTRAVENOUS		
			Neupogen	SS		SUBCUTANEOUS		

Date: 10/01/03 **ISR Number:** 4205147-0 **Report Type:** Expedited (15-Day) **Company Report#:** 200313466FR **Age:** 69 YR **Gender:** Female **I/FU:** I

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Hospitalization - Initial or Prolonged	Hyponatraemia	Foreign Other	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	IV	1 DAY
			Cyclophosphamide (Endoxan)	SS		INTRAVENOUS	IV	1 DAY
			Methylprednisolone	SS		INTRAVENOUS	IV	1 DAY
			Vincristine	SS		INTRAVENOUS	IV	1 DAY
			Doxorubicin	SS		INTRAVENOUS	IV	1 DAY
			Filgrastim (Neupogen)	SS		SUBCUTANEOUS	SC	1 WK

Date: 10/16/03 **ISR Number:** 4211498-6 **Report Type:** Expedited (15-Day) **Company Report#:** UK047876 **Age:** 69 YR **Gender:** Female **I/FU:** I

Outcome	**PT**	**Report Source**
Hospitalization - Initial or Prolonged	Hyponatraemia	Foreign Health

Professional

Product	Role	Manufacturer	Route	Dose	Duration
Neupogen	PS		SUBCUTANEOUS	300 MCG, SC	
Dolasetron Mesylate	SS		INTRAVENOUS	IV	
Cyclophosphamide	SS		INTRAVENOUS	100 MG, IV	
Methylprednisolone	SS		INTRAVENOUS	120 MG, IV	
Vincristine Sulfate	SS		INTRAVENOUS	IV	
Doxorubicin Hydrochloride	SS		INTRAVENOUS	IV	

Date: 10/17/03 **ISR Number:** 4213681-2 **Report Type:** Direct **Company Report#:** CTU 204080 **Age:** 34 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Liver Function Test Abnormal		Cefazolin	PS		INTRAVENOUS	2G IV Q 8 HRS	
			Dolasetron	SS		INTRAVENOUS	12.5 MG IV X 1	
			Metoclopramide	C				

Date: 10/22/03 **ISR Number:** 4215431-2 **Report Type:** Direct **Company Report#:** CTU 204321 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Discomfort		Dexamethasone 10 Mg					
	Dyspnoea		Gensiasicor	PS	Gensiasicor	INTRAVENOUS	20 MG PREMED IV	
	Feeling Abnormal							
	Gastrooesophageal Reflux Disease		Anzemet 20 Mg/Ml Aventis	SS	Aventis	INTRAVENOUS	100 MG PREMED IV	
	Respiratory Rate Increased							

Date: 10/27/03 **ISR Number:** 4220883-8 **Report Type:** Expedited (15-Day) **Company Report#:** 200318967US **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypoaesthesia	Health Professional	Dolasetron Mesilate (Anzemet)	PS			ONCE	1 DAY
	Limb Injury							
	Pharmaceutical Product Complaint							
	Tendon Injury							

Date: 10/28/03 **ISR Number:** 4222645-4 **Report Type:** Expedited (15-Day) **Company Report#:** UK047876 **Age:** 69 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyponatraemia	Foreign Health Professional	Neupogen	PS		SUBCUTANEOUS	300 MCG, SC	
			Dolasetron Mesylate	SS		INTRAVENOUS	IV	
			Cyclophosphamide	SS		INTRAVENOUS	100 MG, IV	
			Methylprednisolone	SS		INTRAVENOUS	120 MG, IV	
			Vincristine Sulfate	SS		INTRAVENOUS	IV	
			Doxorubicin Hydrochloride	SS		INTRATUMOR	IV	

Date: 10/31/03 **ISR Number:** 4223953-3 **Report Type:** Direct **Company Report#:** CTU 204960 **Age:** 43 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Erythema		Anzemet 12.5mg	PS		INTRAVENOUS	12.5MG Q4PRN INTRAVENOUS	

Date: 11/07/03 **ISR Number:** 4234389-3 **Report Type:** Periodic **Company Report#:** 200313162US **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	12.5 MG, IV	
			Glycopyrrolate	C				
			Neostigmine	C				

Date: 11/07/03 **ISR Number:** 4234392-3 **Report Type:** Periodic **Company Report#:** 200310400US **Age:** 26 YR **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Bundle Branch Block Left	Health Professional	Dolasetron Mesilate (Anzemet)	PS			12.5 MG	1 DAY

Date: 11/07/03 **ISR Number:** 4234394-7 **Report Type:** Periodic **Company Report#:** 200220357US **Age:** 80 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Loss Of Consciousness	Health Professional	Dolasetron Mesilate (Anzemet)	PS			ONCE	1 DAY
			Xyotax	C				

Date: 11/07/03 **ISR Number:** 4234395-9 **Report Type:** Periodic **Company Report#:** 200310074US **Age:** 55 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypoglycaemia	Health Professional	Dolasetron Mesilate (Anzemet)	PS				1 DAY
	Hypotension		Dolasetron Mesilate (Anzemet)	SS				1 DAY
			Glipizide (Glucotrol)	SS		ORAL	PO	
			Verapamil	C				
			Promethazine Hydrochloride	C				
			Prochlorperazine Edisylate (Compazine)	C				
			Granisetron (Kytril)	C				
			Valdecoxib (Bextra)	C				
			Moxifloxacin Hydrochloride (Avelox)	C				
			Ranitidine Hydrochloride (Zantac)	C				
			Diphenhydramine Hydrochloride	C				
			Taxol	C				

Date: 11/07/03 **ISR Number:** 4234411-4 **Report Type:** Periodic **Company Report#:** 200220505US **Age:** 9 YR **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nausea Ventricular Extrasystoles	Health Professional	Dolasetron Mesilate (Anzemet)	PS		ORAL	10 MG PO	

Date: 11/14/03 **ISR Number:** 4236282-9 **Report Type:** Expedited (15-Day) **Company Report#:** 200318967US **Age:** 38 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Fall Head Injury Laceration Limb Injury Loss Of Consciousness Medical Device Complication Sensory Loss Tendon Injury	Health Professional	Dolasetron Mesilate (Anzemet) Fluoxetine (Sarafem)	PS C			ONCE	1 DAY

Date: 11/26/03 **ISR Number:** 4241974-1 **Report Type:** Expedited (15-Day) **Company Report#:** FR-BRISTOL-MYERS SQUIBB COMPANY-12443388 **Age:** 33 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pain In Extremity		Holoxan	PS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Uromitexan Inj	SS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Vepesid	SS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Anzemet	SS		INTRAVENOUS		
			Methyl-Gag	SS		INTRAVENOUS		
			Navelbine	SS		INTRAVENOUS		
			Neupogen	C				

Date: 12/19/03 **ISR Number:** 4255779-9 **Report Type:** Direct **Company Report#:** CTU 208488 **Age:** 17 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Heart Rate Increased Myocardial Infarction		Anzimet	PS				

Date: 12/23/03 **ISR Number:** 4258337-5 **Report Type:** Expedited (15-Day) **Company Report#:** 200320071US **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability Other	Accident Limb Injury Pharmaceutical Product Complaint	Health Professional	Dolasetron Mesilate (Anzemet)	PS				

Date: 12/24/03 **ISR Number:** 4257655-4 **Report Type:** Expedited (15-Day) **Company Report#:** US-BRISTOL-MYERS SQUIBB COMPANY-12458840 **Age:** 71 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Culture Positive Blood Pressure Decreased Discomfort Dizziness Escherichia Sepsis Febrile Neutropenia Hyperhidrosis Pancytopenia	Health Professional	Carboplatin	PS	Bristol-Myers Squibb Company		AUC=5 On day 1	
			Gemcitabine	SS		INTRAVENOUS	days 1 and 8 and in combination with carboplatin	
			Anzemet	SS		INTRAVENOUS		
			Dexamethasone	SS		INTRAVENOUS		

Date: 01/20/04 **ISR Number:** 4274628-6 **Report Type:** Direct **Company Report#:** CTU 210315 **Age:** 54 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Anxiety Feeling Abnormal Nightmare Suicidal Ideation Tremor		Anzemet	PS		ORAL	100 MG ONE DOSE ORAL	
			Dexamethasone	SS		ORAL	20 MG ONE DOSE ORAL	
			Cyclophosphamide	C				
			Doxirubicin	C				
			Compazine	C				
			Xanax	C				
			Antivert	C				
			Zantac	C				

Date: 02/10/04 **ISR Number:** 4292558-0 **Report Type:** Expedited (15-Day) **Company Report#:** 200410161US **Age:** 42 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged Other	Dyspnoea Platelet Count Decreased	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	100 MG ONCE IV	1 DAY
			Dolasetron Mesilate (Anzemet)	SS		INTRAVENOUS	100 MG ONCE IV	1 DAY
			Dolasetron Mesilate (Anzemet)	SS		INTRAVENOUS	100 MG ONCE IV	1 DAY
			Heparin Sodium (Heparin Flush)	C				
			Dexamethasone (Decadron)	C				
			Furosemide (Lasix)	C				
			Atropine	C				
			Irinotecan	C				
			Flourouracil	C				

Date: 02/20/04 **ISR Number:** 4299922-4 **Report Type:** Expedited (15-Day) **Company Report#:** 200411086US **Age:** **Gender:** Unknown **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation		Anzemet	PS	Aventis Pharmaceuticals Inc.	INTRAVENOUS	dose: NOT PROVIDED	

Date: 03/25/04 **ISR Number:** 4323066-6 **Report Type:** Expedited (15-Day) **Company Report#:** 200318967US **Age:** **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Fall		Anzemet	PS	Aventis Pharmaceuticals Inc.			
	Laceration							
	Loss Of Consciousness		Sarafem	C				
	Sensory Loss							
	Tendon Injury							

Date: 03/29/04 **ISR Number:** 4332230-1 **Report Type:** Expedited (15-Day) **Company Report#:** 2004-01110 **Age:** 53 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Impaired Healing	Literature	Dexamethasone (Watson Laboratories) (Dexamethasone)					
Required Intervention to Prevent Permanent Impairment/Damage	Osteonecrosis	Health Professional	Tablet	PS	Watson Laboratories			1095 DAY
			Docetaxel (Docetaxel)	SS			30 MG, 1/WEEK	
			Dolasetron Mesilate(Dolasetron Mesilate)	SS			50 MG, 1 WEEK	
			Pamidronate Disodium (Pamidronate Disodium)	SS			90 MG, 1/WEEK	

Date: 04/02/04 **ISR Number:** 4330393-5 **Report Type:** Expedited (15-Day) **Company Report#:** 200412300US **Age:** **Gender:** Unknown **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc.		dose: NOT PROVIDED	
Life-Threatening								

Date: 04/05/04 **ISR Number:** 4332953-4 **Report Type:** Direct **Company Report#:** CTU 215986 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaesthetic Complication		Anzemet (Dolasetron) 125 Mg /0.625 Ml					
	Coma		Aventis Pharm	PS	Aventis Pharm	INTRAVENOUS	12.5 MG X 1, IV	
	Encephalopathy							
	Extrapyramidal Disorder							
	Oculogyration							
	Opisthotonus							

Date: 04/13/04 **ISR Number:** 4337355-2 **Report Type:** Expedited (15-Day) **Company Report#:** 200318967US **Age:** **Gender:** Female **I/FU:** F

Outcome	PT
Other	Fall
	Hypoaesthesia
	Limb Injury
	Loss Of Consciousness
	Medical Device Complication
	Pain In Extremity

Skin Laceration Tendon Injury	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Anzemet	PS	Aventis Pharmaceuticals Inc.			
		Sarafem	C				

Date: 06/17/04 **ISR Number:** 4381019-6 **Report Type:** Direct **Company Report#:** USP 56610 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Demerol	PS	Abbott		INJECTABLE	
			Demerol	SS	Abbott		INJECTABLE	
			Demerol	SS	Abbott		INJECTABLE	
			Morphine Sulfate	SS	Abbott		INJECTABLE	
			Morphine Sulfate	SS	Abbott		INJECTABLE	
			Anzemet	SS	Aventis		INJECTABLE	

Date: 07/28/04 **ISR Number:** 4409925-4 **Report Type:** Direct **Company Report#:** USP 56767 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Anzemet	PS	Aventis		12.5 MG/0.625 MG INJECTABLE	
			Heparin	SS	Abbott		5000 UNITS/ 0.5 ML	

Date: 08/03/04 **ISR Number:** 4414078-2 **Report Type:** Expedited (15-Day) **Company Report#:** 200415684US **Age:** 28 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Caesarean Section Cervical Incompetence Drug Exposure During Pregnancy Premature Labour	Health Professional	Anzemet	PS	Aventis Pharmaceuticals Inc.			

Date: 09/21/04 **ISR Number:** 4454596-4 **Report Type:** Expedited (15-Day) **Company Report#:** 200418990GDDC **Age:** 23 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia		Anzemet	PS	Aventis Pharmaceuticals Inc.	INTRAVENOUS		
			Fentanyl	C				
			Morphine	C				
			Propofol	C				

Date: 11/01/04 **ISR Number:** 4518635-4 **Report Type:** Periodic **Company Report#:** 200318321US **Age:** 71 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased Dizziness Hyperhidrosis		Dolasetron	PS		INTRAVENOUS	100 MG ONCE IV	1 DAY
			Gemcitabine Hydrochloride	C				
			Dexamethasone	C				

Date: 11/01/04 **ISR Number:** 4518636-6 **Report Type:** Periodic **Company Report#:** 200413741US **Age:** 57 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction	Health Professional	Dolasetron Mesilate (Anzemet) Solution For Injection	PS		INTRAVENOUS	12.5 MG IV	

Date: 11/01/04 **ISR Number:** 4518637-8 **Report Type:** Periodic **Company Report#:** 200412525US **Age:** 73 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction	Health Professional	Dolasetron Mesilate (Anzemet)	PS			100 (PRIOR TO CHEMOTHERAPY) MG CYC	
	Blood Pressure Decreased							
	Pruritus							
	Swelling Face							
	Urticaria Generalised		Dexamethasone	C				
			Diphenhydramine Hydrochloride	C				
			Taxol	C				
			Carboplatin	C				

Date: 11/01/04 **ISR Number:** 4518638-X **Report Type:** Periodic **Company Report#:** 200411032US **Age:** **Gender:** Not Specified **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Health Professional	Dolasetron Mesilate (Anzemet)	PS				

Date: 11/01/04 **ISR Number:** 4518639-1 **Report Type:** Periodic **Company Report#:** 200411033US **Age:** **Gender:** Not Specified **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Health Professional	Dolasetron Mesilate (Anzemet)	PS				

Date: 11/01/04 **ISR Number:** 4518640-8 **Report Type:** Periodic **Company Report#:** 200411034US **Age:** **Gender:** Not Specified **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Health Professional	Dolasetron Mesilate (Anzemet)	PS				

Date: 11/01/04 **ISR Number:** 4518641-X **Report Type:** Periodic **Company Report#:** 200411035US **Age:** **Gender:** Not Specified **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Health Professional	Dolasetron Mesilate (Anzemet)	PS				

Date: 11/01/04 **ISR Number:** 4518642-1 **Report Type:** Periodic **Company Report#:** 200319846US **Age:** **Gender:** Male **I/FU:** I

Outcome
Hospitalization - Initial or Prolonged

Other

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Anaphylactic Reaction	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	100 MG IV	1 DAY
		Chemotherapy Nos	C				

Date: 11/01/04 **ISR Number:** 4518643-3 **Report Type:** Periodic **Company Report#:** 200319848US **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Anaphylactic Reaction	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	100 MG IV	1 DAY
			Chemotherapy Nos	C				

Date: 11/01/04 **ISR Number:** 4518644-5 **Report Type:** Periodic **Company Report#:** 200320513US **Age:** **Gender:** Not Specified **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Blood Amylase Increased Nausea Pancreatitis	Health Professional	Dolasetron Mesilate (Anzemet)	PS		INTRAVENOUS	100 MG ONE IV	1 DAY
			Doxorubicin (Adriamycin)	C				
			Cyclophosphamide (Cytoxan)	C				
			Fluorouracil	C				
			Dexamethasone	C				
			Metoclopramide (Reglan)	C				

Date: 11/08/04 **ISR Number:** 4495458-6 **Report Type:** Expedited (15-Day) **Company Report#:** 200318967US **Age:** **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Device Failure Fall Grip Strength Decreased Inflammation Loss Of Consciousness Movement Disorder Pain Sensory Loss Skin Laceration Tendon Injury		Anzemet	PS	Aventis Pharmaceuticals Inc.			
			Sarafem	C				

Date: 12/07/04 **ISR Number:** 4519858-0 **Report Type:** Expedited (15-Day) **Company Report#:** 200419083US **Age:** 61 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased Heart Rate Decreased Hyperhidrosis Shock Vomiting		Anzemet	PS	Aventis Pharmaceuticals Inc.			
			Carboplatin	C				
			Taxol	C				
			Benadryl /Old Form/	C			dose: UNK	
			Decadron	C			dose: UNK	
			Compazine	C			dose: UNK	

Date: 12/10/04 **ISR Number:** 4523126-0 **Report Type:** Expedited (15-Day) **Company Report#:** GB-JNJFOC-20041200657 **Age:** 67 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Reaction		Durogesic	PS		TRANSDERMAL		
Hospitalization - Initial or Prolonged			Morphine	SS		INTRAVENOUS		
			Dolasetron	SS		INTRAVENOUS		
			Propofol	SS		INTRAVENOUS		
			Betahistine	C		UNKNOWN		
			Mesalazine	C		UNKNOWN		
			Dothiepin	C		UNKNOWN		

Date: 12/15/04 **ISR Number:** 4527451-9 **Report Type:** Expedited (15-Day) **Company Report#:** 200419083US **Age:** **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Ineffective		Anzemet	PS	Aventis Pharmaceuticals Inc.			
	Heart Rate Decreased							
	Hyperhidrosis		Carboplatin	SS				
	Post Procedural Vomiting		Taxol	C				
	Shock		Benadryl /Old Form/	C			dose: UNK	
			Decadron	C			dose: UNK	
			Compazine	C			dose: UNK	

Date: 12/21/04 **ISR Number:** 4533268-1 **Report Type:** Expedited (15-Day) **Company Report#:** US-BRISTOL-MYERS SQUIBB COMPANY-12793154 **Age:** 61 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Shock		Carboplatin	PS	Bristol-Myers Squibb Company	INTRAVENOUS		1 DAY
			Anzemet	SS				1 DAY
			Taxol	C	Bristol-Myers Squibb Company	INTRAVENOUS		1 DAY
			Benadryl	C				1 DAY
			Decadron	C				1 DAY
			Compazine	C				1 DAY

Date: 01/20/05 **ISR Number:** 4556693-1 **Report Type:** Expedited (15-Day) **Company Report#:** 200419083US **Age:** **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Heart Rate Decreased		Anzemet	PS	Aventis Pharmaceuticals Inc.			
	Shock							
	Vomiting		Carboplatin	SS				
			Taxol	C				
			Benadryl /Old Form/	C			dose: UNK	
			Decadron	C			dose: UNK	
			Compazine	C			dose: UNK	

Date: 01/20/05 **ISR Number:** 4556756-0 **Report Type:** Expedited (15-Day) **Company Report#:** 200419083US **Age:** **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased		Anzemet	PS	Aventis Pharmaceuticals Inc.			
	Heart Rate Decreased							
	Hyperhidrosis		Carboplatin	SS				
	Shock		Taxol	C				
	Vomiting		Benadryl /Old Form/	C			dose: UNK	

			Decadron	C			dose: UNK	
			Compazine	C			dose: UNK	

Date: 01/21/05 **ISR Number:** 4558140-2 **Report Type:** Expedited (15-Day) **Company Report#:** 200510439GDDC **Age:** 56 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaesthetic Complication		Dolasetron	PS	Aventis Pharmaceuticals Inc.	INTRAVENOUS		
	Cardiac Cardiac Arrest		Valsartan	C		ORAL		
			Propofol	C				
			Fentanyl	C				
			Midazolam	C				

Date: 01/26/05 **ISR Number:** 4566507-1 **Report Type:** Direct **Company Report#:** CTU 238028 **Age:** 18 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Heart Rate Increased		Anzimet	PS				
	Myocardial Infarction							

Date: 02/17/05 **ISR Number:** 4590358-5 **Report Type:** Expedited (15-Day) **Company Report#:** 2005AP01005 **Age:** 30 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Convulsion	Foreign	Propofol	PS		INTRAVENOUS	1 G DAILY IV	
	Mental Status Changes	Health	Fentanyl	SS			200 UG DAILY	
	Postoperative	Professional	Paracoxib Sodium	SS			40 MG DAILY	
	Post Procedural Complication	Other	Tramadol Hydrochloride	SS			400 MG DAILY	
			Dolasetron Mesilate	SS			12.5 MG DAILY	

Date: 02/24/05 **ISR Number:** 4590242-7 **Report Type:** Expedited (15-Day) **Company Report#:** 200511219US **Age:** 18 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia		Anzemet	PS	Aventis Pharmaceuticals Inc.	INTRAVENOUS	dose: 12.5 X 1 DOSE	
	Idiosyncratic Drug Reaction							
	Post Procedural Complication		Propofol	C		INTRAVENOUS	dose: UNK	
			Anectine	C			dose: UNK	
			Ultane	C			dose: UNK	
			Oxygen	C			dose: UNK	
			Versed	C			dose: UNK	
			Fentanyl	C			dose: UNK	
			Marcaine	C			dose: UNK	

Date: 03/15/05 **ISR Number:** 4614244-7 **Report Type:** Expedited (15-Day) **Company Report#:** 05H-163-0292942-00 **Age:** 18 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia	Health Professional Company Representative	Bupivacaine Hcl Injection (Bupivacaine Hydrochloride) (Bupivacaine	PS			INJECTION	

		Propofol	SS			
		Suxamethonium Chloride	SS			
		Sevoflurane	SS			
		Dolasetron Mesilate	SS	INTRAVENOUS	CONTINUOUSLY 12.5 MG, ONCE, INTRAVENOUS	
		Oxygen	C			
		Midazolam Hydrochloride	C			
		Fentanyl	C			

Date: 03/21/05 **ISR Number:** 4613673-5 **Report Type:** Expedited (15-Day) **Company Report#:** 200511854US **Age:** 60 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma		Anzemet	PS	Aventis Pharmaceuticals Inc.	INTRAVENOUS		
	Tremor		Morphine	C				

Date: 03/28/05 **ISR Number:** 4620117-6 **Report Type:** Expedited (15-Day) **Company Report#:** 200511854US **Age:** 60 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma		Anzemet	PS	Aventis Pharmaceuticals Inc.	INTRAVENOUS		
	Depressed Level Of Consciousness		Morphine	C				
	Speech Disorder							
	Tremor							

Date: 04/06/05 **ISR Number:** 4627817-2 **Report Type:** Expedited (15-Day) **Company Report#:** 200511480GDDC **Age:** 45 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction		Anzemet	PS	Aventis Pharmaceuticals Inc.	INTRAVENOUS		
	Hypotension		Sevoflurane	SS				
	Supraventricular Tachycardia		Fentanyl	C		INTRAVENOUS		
			Propofol	C		INTRAVENOUS		
			Vecuronium Bromide	C		INTRAVENOUS		
			Isoflurane	C		RESPIRATORY (INHALATION)		

Date: 04/12/05 **ISR Number:** 4632815-9 **Report Type:** Expedited (15-Day) **Company Report#:** 200512786US **Age:** **Gender:** Unknown **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Compartment Syndrome		Anzemet	PS	Aventis Pharmaceuticals Inc.		dose: UNK	

Date: 05/05/05 **ISR Number:** 4653315-6 **Report Type:** Expedited (15-Day) **Company Report#:** 200510844DE **Age:** 68 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Petechiae		Anemet	PS	Aventis Pharmaceuticals Inc.	INTRAVENOUS		
	Thrombocytopenia							

			Oxaliplatin	C				
			5-Fu	C				
			Folinic Acid	C				

Date: 05/05/05 **ISR Number:** 4653322-3 **Report Type:** Expedited (15-Day) **Company Report#:** 200511219US **Age:** 18 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion		Anzemet	PS	Aventis Pharmaceuticals Inc.	INTRAVENOUS	dose: 12.5 X 1 DOSE	
	Dyskinesia		Propofol	C		INTRAVENOUS	dose: UNK	
			Anectine	C			dose: UNK	
			Ultane	C			dose: UNK	
			Oxygen	C			dose: UNK	
			Versed	C			dose: UNK	
			Fentanyl	C			dose: UNK	
			Marcaine	C			dose: UNK	

Date: 05/23/05 **ISR Number:** 4668150-2 **Report Type:** Expedited (15-Day) **Company Report#:** PHBS2005US02926 **Age:** 53 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bone Disorder		Pamidronate Disodium	PS		INTRAVENOUS	90 mg "per week"	
	Impaired Healing							
	Infection		Dexamethasone	SS		UNKNOWN	UNK, UNK	
	Oral Surgery		Docetaxel	SS		UNKNOWN	30 mg, QW	
	Osteonecrosis		Dolasetron Mesilate	SS		UNKNOWN	50 mg, QW	
	Tooth Extraction							
	Wound Debridement							

Date: 05/26/05 **ISR Number:** 4676533-X **Report Type:** Direct **Company Report#:** CTU 249675 **Age:** 28 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dystonia		Dolasetron	PS		INTRAVENOUS	12.5 MG IV	
			Tobramycin	C				
			Azithromycin	C				

Date: 06/16/05 **ISR Number:** 4691728-7 **Report Type:** Expedited (15-Day) **Company Report#:** 200514866US **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion		Anzemet	PS	Aventis Pharmaceuticals Inc.			
			Hydroxyzine	C			dose: UNK	

Date: 06/27/05 **ISR Number:** 4700529-2 **Report Type:** Direct **Company Report#:** CTU 251979 **Age:** 32 YR **Gender:** Male **I/FU:** I

Outcome	PT
Death	Cardio-Respiratory Arrest
	Loss Of Consciousness
	Nausea
	Retching
	Skin Discolouration

Ventricular Fibrillation

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Phenergan 25 Mg	PS		INTRAVENOUS	25 MG 1X INTRAVENOU	
	Anzemet 12.5 Mg	SS		INTRAVENOUS	12.5 1X INTRAVENOU	
	Lithium	C				
	Naltrexone	C				
	Avalide	C				
	Wellbutrin	C				

Date: 06/27/05 **ISR Number:** 4700565-6 **Report Type:** Direct **Company Report#:** CTU 251974 **Age:** 79 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia		Phenergan 25 Mg	PS		INTRAVENOUS	25 MG 1X INTRAVENOU	
	Cardiac Arrest							
	Electrocardiogram Abnormal		Anzemet 12.5 Mg	SS		INTRAVENOUS	12.5 MG 1 X INTRAVENOU	
	Encephalopathy		Lipitor	C				
	Hypotension		Diovan	C				
	Ischaemia		Dyazide	C				
	Tachycardia		Advair Diskus	C				
			Metoprolol	C				
			Neurontin	C				
			Insulin	C				
			Coumadin	C				
			Protonix	C				

Date: 07/15/05 **ISR Number:** 4717691-8 **Report Type:** Expedited (15-Day) **Company Report#:** 05H-163-0292942-00 **Age:** 18 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia	Health Professional Company Representative	Bupivacaine Hcl Injection (Bupivacaine Hydrochloride) (Bupivacaine	PS			INJECTION	
			Propofol	SS				
			Suxamethonium Chloride	SS				
			Sevoflurane	SS				
			Dolasetron Mesilate	SS		INTRAVENOUS	12.5 MG, ONCE, INTRAVENOUS	
			Oxygen	C				
			Midazolam Hydrochloride	C				
			Fentanyl	C				

Date: 07/21/05 **ISR Number:** 4720848-3 **Report Type:** Expedited (15-Day) **Company Report#:** 200312126US **Age:** 17 YR **Gender:** Female **I/FU:** F

Outcome	PT
Other	Acute Myocardial Infarction
	Arteriospasm Coronary

Cardiac Failure							
Ejection Fraction Decreased	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Electrocardiogram St Segment Depression		Anzemet	PS	Aventis Pharmaceuticals Inc.	PARENTERAL	dose: UNK	
Heart Rate Increased		Midazolam	C			dose: UNK	
Hypokinesia		Dexamethasone	C				
Oxygen Saturation Decreased		Lidocaine	C				
Pulmonary Oedema		Propofol	C				
Sinus Tachycardia		Fentanyl	C				
Tachycardia		Cisatracurium Besilate	C				
Troponin I Increased		Desflurane	C				
		Nitrous Oxide	C				

Date: 08/18/05 **ISR Number:** 4748042-0 **Report Type:** Expedited (15-Day) **Company Report#:** 200514866US **Age:** **Gender:** Female **I/FU:** F

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Other	Convulsion		Anzemet	PS	Aventis Pharmaceuticals Inc.			
			Hydroxyzine	C			dose: UNK	

Summary report for FOI selections:

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

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

Total number of reports: 398

From: 01-NOV-1997 To: Present