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: F05-8455

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 Marinol. 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: DRONABINOL
MARINOL
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: 03/27/98 **ISR Number:** 3060679-6 **Report Type:** Expedited (15-Day) **Company Report#:** 18651-008 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Condition Aggravated Convulsion	Health Professional	Marinol (Dronabinol)	PS		ORAL	10 MG, BID, PO	3 WK

Date: 04/28/98 **ISR Number:** 3072102-6 **Report Type:** Direct **Company Report#:** **Age:** 68 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Embolism		Megace	PS			800 MG BID QD	
			Marinol	SS			2.5 MG BID QD	

Date: 04/29/98 **ISR Number:** 3073328-8 **Report Type:** Direct **Company Report#:** **Age:** 68 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Embolism	Other	Megace	PS		ORAL	800 MG BID QD	
	Prothrombin Time Prolonged		Marinol	SS		ORAL	2.5MG BID QD	

Date: 09/16/98 **ISR Number:** 3240006-1 **Report Type:** Periodic **Company Report#:** 18651-007 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Increased Rebound Hypertension	Health Professional	Marinol (Dronabinol) Capsules	PS	Roxane Laboratories			

Date: 05/06/99 **ISR Number:** 3255101-0 **Report Type:** Direct **Company Report#:** **Age:** 46 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Gastrointestinal Haemorrhage Hepatic Cirrhosis Portal Hypertension Varices Oesophageal		Marinol (Dronabinol)/Placebo ; Roxane	PS		ORAL	2.5MG PO TID/0MG POTED	
			Combivir	C				
			Wellbutan	C				
			Septra	C				
			Testostexane	C				
			Mvi	C				
			Vitamin E	C				
			Nelfinavir	C				
			Acyclovir	C				
			Prozac	C				

Date: 07/27/99 **ISR Number:** 3325507-X **Report Type:** Periodic **Company Report#:** 18651-009 **Age:** 90 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotonia	Consumer	Marinol (Dronabinol) Capsules, 5 Mg-Roxane					

			Laboratories, Inc.	PS	Roxane Laboratories, Inc.	ORAL	5 MG QD PO
			Vasotec	C			
			Zaroxolyn	C			
			Zantac	C			
			Lanoxin	C			
			Xalatan	C			
			Trusopt Drops	C			

Date: 07/27/99 **ISR Number:** 3325512-3 **Report Type:** Periodic **Company Report#:** 18651-010 **Age:** 64 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination	Consumer	Marinol (Dronabinol) Capsules, 5 Mg-Roxane Laboratories, Inc.	PS	Roxane Laboratories, Inc.	ORAL	5MG PO HS	
			Prilosec	C				
			Amor Thyroid Tablets	C				
			Courmadin	C				
			Prednisone	C				
			Potassium	C				
			Reglan	C				
			Megestrol	C				
			Zoloft	C				
			Heart Medication	C				

Date: 07/27/99 **ISR Number:** 3325517-2 **Report Type:** Periodic **Company Report#:** 18651-011 **Age:** 61 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyspnoea	Consumer	Marinol (Dronabinol) Capsules, 2.5mg-Roxane Laboratories, Inc.	PS	Roxane Laboratories, Inc.	ORAL	2.5MG BID PO	
			Percocet	C				

Date: 07/27/99 **ISR Number:** 3325526-3 **Report Type:** Periodic **Company Report#:** 18651-012 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Psychotic Disorder	Consumer	Marinol (Dronabinol) Capsules Roxane Laboratories, Inc.	PS	Roxane Laboratories, Inc.			

Date: 08/05/99 **ISR Number:** 3322255-7 **Report Type:** Direct **Company Report#:** **Age:** 61 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Oral Intake Reduced Pleural Effusion		Megace 800mg Po Daily	PS		ORAL	800MG PO DAILY	
			Marinol 2.5mg Po Bid	SS				

Date: 08/27/99 **ISR Number:** 3336534-0 **Report Type:** Expedited (15-Day) **Company Report#:** 10077584 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Study	Taxol Inj					
	Dehydration	Health	(Paclitaxel)	PS		INTRAVENOUS	284 MG 1/1 DAY IV	
	Diarrhoea	Professional						
	Dysphagia		Carboplat Inj					
	Fluid Overload		(Carboplatin)	SS		INTRAVENOUS	120 MG 1/1 DAY IV	
	Mental Impairment							
	Nausea		Decadron					
	Pain		(Dexamethasone)	SS			20 MG	
	Vomiting		Scopolamine	SS				
			Marinol (Tetrahydrocannabinol)	SS				
			Lopressor	C				
			Monopril	C				
			A.S.A.	C				
			Duragesic	C				
			Nph	C				
			Reglan	C				
			Humibid L.A.	C				
			Compazine	C				

Date: 10/26/99 **ISR Number:** 3384276-8 **Report Type:** Periodic **Company Report#:** 9941785 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Headache	Consumer	Viagra Tablets	PS				
			Marinol	SS				

Date: 07/07/00 **ISR Number:** 3528170-8 **Report Type:** Periodic **Company Report#:** 18651-013 **Age:** 32 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia	Consumer	Marinol	PS	Unimed Inc		1.5 MG DAILY 1 MOS, 10 MG DILY 2ND MONTH	1 MON
	Hypotension							
			Valium 5-10mg Daily,Cuprimine Tid	C				

Date: 07/07/00 **ISR Number:** 3528175-7 **Report Type:** Periodic **Company Report#:** 18651-016 **Age:** 61 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health Professional	Marinol	PS	Unimed Inc	ORAL	5MG, TID,PO	
			Bactrim Ds	C				
			Zerit	C				
			Viramune	C				
			Prilosec	C				
			Lorazepam	C				
			Lipitor	C				
			Glucotrol	C				

Date: 07/07/00 **ISR Number:** 3528177-0 **Report Type:** Periodic **Company Report#:** 18651-017 **Age:** 31 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorectal Disorder	Consumer	Marinol	PS	Unimed Inc		5MG, FOR 2, Q 4-8 HRS. PM	
	Constipation	Health						
	Diarrhoea	Professional	Oxycontin	SS			1 OR 2 Q4-6 HRS.PM	
	Hyperhidrosis	Other						
	Migraine		Benefix (Fctor 1x					
	Nausea		Anticoagulant					
	Vomiting		Factor)	C				

Date: 07/17/00 **ISR Number:** 3531022-0 **Report Type:** Expedited (15-Day) **Company Report#:** 200416 **Age:** 55 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blister	Foreign	Ms Contin	PS	Purdue Frederick Co	ORAL	800 MG QD PO	
	Dermatitis	Health	Marinol (Dronabinol)	SS				
	Skin Ulcer	Professional	Musaril (Tetrazepam)	C				
		Company	Melleril					
		Representative	(Thioridazine)	C				

Date: 12/13/00 **ISR Number:** 3627211-7 **Report Type:** Direct **Company Report#:** **Age:** 45 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Murder		Dronabinol	PS				
Required			Fluconazole	C				
Intervention to			Morphine	C				
Prevent Permanent			Lorazepam	C				
Impairment/Damage			Ondansetron	C				
			Promethazine	C				
			Prochlorperazine	C				
			Lorazepam	C				
			Haloperidol	C				

Date: 12/15/00 **ISR Number:** 3631582-5 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00200006511 **Age:** 82 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Study	Marinol	PS	Unimed Inc	ORAL	5 MG BID PO	
	Blood Pressure Systolic Increased	Health	Exelon (Rivastigmine					
		Professional	Tartrate)	SS		ORAL	4.5 MG BID PO	
	Chest Pain		Zoloft (Sertraline					
	Gastritis		Hydrochloride)	C				
	Hypersomnia							
	Medication Error							
	Oedema							
	Tremor							
	Vomiting							

Date: 12/15/00 **ISR Number:** 3631584-9 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00200006572 **Age:** 79 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure Congestive	Study	Marinol	PS	Unimed Inc	ORAL	5 MG BID PO	
		Health	Toprol Xl					
		Professional	(Metoprolol					

Succinate)	C
Lasix (Furosemide)	C
Digoxin (Digoxin)	C
Coumadin (Warfarin Sodium)	C
Amiodarone (Amiodarone)	C
Synthroid (Levothyroxine Sodium)	C
Buspar (Buspirone Hydrochloride)	C
Nitro Patch (Glyceryl Trinitrate)	C
Asendin (Amoxapine)	C
Risperdal (Risperidone)	C

Date: 01/05/01 **ISR Number:** 3642824-4 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00200006747 **Age:** 70 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Chest Pain	Study	Marinol	PS	Unimed Inc	ORAL	5 MG BID PO,	
Hospitalization - Initial or Prolonged	Myocardial Infarction	Health Professional					2.5 MG BID PO	
	Myocardial Ischaemia		Norvasc (Amlodipine Besilate)	C				
	Nausea		Cardura (Doxazosin Mesilate)	C				
	Vomiting		Exelon (Rivastigmine Tartrate)	C				
			Aricept (Donepezil Hydrochloride)	C				
			Risperdal (Risperidone)	C				

Date: 01/05/01 **ISR Number:** 3642827-X **Report Type:** Expedited (15-Day) **Company Report#:** DRON00200006695 **Age:** 92 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Femur Fracture	Study	Marinol	PS	Unimed Inc	ORAL	2.5 MG BID PO	
		Health Professional						

Date: 01/12/01 **ISR Number:** 3647338-3 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00200006511 **Age:** 82 YR **Gender:** Male **I/FU:** F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain Upper
	Asthenia
	Blood Glucose Increased
	Blood Pressure Systolic Increased
	Chest Pain
	Convulsion
	Gastritis
	Hypersomnia
	Medication Error
	Oedema

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Pallor							
Pancreatitis							
Tremor	Study	Marinol	PS	Unimed Inc	ORAL	SEE IMAGE	
Vomiting	Health	Exelon (Rivastigmine					
	Professional	Tartrate)	SS		ORAL	4.5 MG BID PO	
		Zoloft	C				
		Pepcid	C				

Date: 01/16/01 **ISR Number:** 3648820-5 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00200006695 **Age:** 92 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Fall	Study	Marinol	PS	Unimed Inc	ORAL	2.5 MG BID PO	
Initial or Prolonged	Femur Fracture	Health						
	Insomnia	Professional						
	Oedema Peripheral							

Date: 01/18/01 **ISR Number:** 3651010-3 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00200006747 **Age:** 70 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abnormal Behaviour	Study	Marinol	PS	Unimed Inc	ORAL	5MG, 2.5MG	
Hospitalization -	Myocardial Infarction	Health					BID PO	
Initial or Prolonged		Professional	Norvasc	C				
			Cardura	C				
			Exelon	C				
			Aricept	C				
			Risperdal	C				
			Nitro-Dur	C				
			Ecotrin	C				

Date: 01/26/01 **ISR Number:** 3656012-9 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00200006695 **Age:** 92 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Fall	Study	Marinol	PS	Unimed Inc	ORAL	2.5 MG BID PO	
Initial or Prolonged	Femur Fracture	Health	Duragesic (Fentanyl)	C				
		Professional	Restoril (Temazepam)	C				
			Dyazide ()	C				

Date: 01/26/01 **ISR Number:** 3656016-6 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00200006511 **Age:** 82 YR **Gender:** Male **I/FU:** F

Outcome	PT
Hospitalization -	Abdominal Pain Upper
Initial or Prolonged	Asthenia
	Blood Glucose Increased
	Blood Pressure Increased
	Chest Pain
	Convulsion
	Gastritis
	Gastrooesophageal Reflux
	Disease
	Hypersomnia
	Leukocytosis
	Medication Error

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Nausea Oedema Pallor Pancreatitis Tremor Vomiting	Study Health Professional	Marinol Exelon (Rivastigmine Tartrate) Zoloft (Sertraline Hydrochloride) Pepcid (Famotidine) Exelon (Rivastigmine Tartrate)	PS SS C C C	Unimed Inc	ORAL ORAL	5 MG BID PO, 5 MG DAILY PO 4.5 MG BID PO, 1.5 MG BID PO	

Date: 01/31/01 **ISR Number:** 3658304-6 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00201000231 **Age:** 62 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Impairment	Study Health Professional	Marinol Detrol (Tolterodine L-Tartrate) Zyprexa (Olanzapine) Exelon	PS C C C	Unimed Inc	ORAL	2.5 MG BID PO	

Date: 02/20/01 **ISR Number:** 3668361-9 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00200006747 **Age:** 70 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Abnormal Behaviour Aggression Atrial Fibrillation Cardiac Disorder Dementia Ejection Fraction Abnormal Hypokinesia Mitral Valve Incompetence Myocardial Infarction Vomiting	Study Health Professional	Marinol Norvasc (Amlodipine Besilate) Cardura (Doxazosin Mesilate) Exelon (Rivastigmine Tartrate) Aricept (Donepezil Hydrochloride) Risperdal (Risperidone) Nitro-Dur (Glyceryl Trinitrate) Ecotrin (Acetylsalicylic Acid)	PS C C C C C C C	Unimed Inc	ORAL	5 MG BID PO, 2.5 MG BID PO, 2.5 MG BID PO	

Date: 02/21/01 **ISR Number:** 3668923-9 **Report Type:** Periodic **Company Report#:** PHEH2000US11513 **Age:** 81 YR **Gender:** Male **I/FU:** I

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Asthenia Chest Pain Nausea Oedema

	Overdose Sedation Tremor Vomiting	Report Source Health Professional	Product Exelon	Role PS	Manufacturer Novartis Pharmaceuticals Corp	Route ORAL	Dose 4.5 MG, BID, ORAL	Duration
			Marinol (Dronabinol)	SS				41 DAY
			Zoloft (Sertraline Hydrochloride)	C				
			Compazine (Prochlorperazine Edisylate)	C				

Date: 05/21/01 **ISR Number:** 3727116-7 **Report Type:** Periodic **Company Report#:** PHEH2000US11513 **Age:** 81 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Asthenia Chest Pain Nausea Oedema Overdose Sedation Tremor Vomiting	Health Professional	Exelon	PS	Novartis Pharmaceuticals Corp	ORAL	4.5 MG; 1.5 MG, BID, ORAL	
			Marinol (Dronabinol)	SS				41 DAY
			Zoloft (Sertraline Hydrochloride)	C				
			Compazine (Prochlorperazine Edisylate)	C				

Date: 05/28/01 **ISR Number:** 3728938-9 **Report Type:** Direct **Company Report#:** **Age:** 23 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyskinesia Eye Movement Disorder		Marinol, 5mg, Unlimited Pharmaceutical	PS	Unlimited Pharmaceutical	ORAL	5MG, TID, ORAL	

Date: 06/12/01 **ISR Number:** 3757303-3 **Report Type:** Periodic **Company Report#:** DRON00201000333 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Emotional Disorder Malaise Nausea	Consumer	Marinol	PS	Unimed Inc	ORAL	DAILY PO	

Date: 07/12/01 **ISR Number:** 3757300-8 **Report Type:** Periodic **Company Report#:** DRON00201000622 **Age:** 39 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Headache	Consumer	Marinol	PS	Unimed Inc	ORAL	5 MG DAILY PO	

Date: 07/12/01 **ISR Number:** 3757301-X **Report Type:** Periodic **Company Report#:** DRON00201000634 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Consumer	Marinol	PS	Unimed Inc	ORAL	DAILY PO	
			Sulfamethoxazole (Sulfamethoxazole)	C				
			Hyzaar	C				

Date: 07/12/01 **ISR Number:** 3757302-1 **Report Type:** Periodic **Company Report#:** DRON00201000117 **Age:** 38 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Mydriasis	Consumer	Marinol	PS	Unimed Inc	ORAL	5 MG QD PO, 2.5 MG PRN PO	
	Nervousness							
	Pupillary Disorder		Paxil (Paroxetine Hydrochloride)	C				
	Sedation		Crixivan (Indinavir Sulfate)	C				
	Tachycardia		Combivir	C				
	Thinking Abnormal		Bactrim Ds	C				
			Afrin	C				

Date: 07/12/01 **ISR Number:** 3757309-4 **Report Type:** Periodic **Company Report#:** DRON00201000407 **Age:** 38 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Effect Increased	Health Professional	Marinol	PS	Unimed Inc	ORAL	5 MG TID PO	
	Euphoric Mood		Lorazepam (Lorazepam)	C				
			Hydrocodone W/Acetaminophen	C				
			Erythromycin (Erythromycin)	C				
			Loperamide (Loperamide)	C				
			Metoclopramide (Metoclopramide)	C				
			Celebrex (Celecoxib)	C				
			Zoloft (Sertraline Hydrochloride)	C				
			Folic Acid (Folic Acid)	C				
			Standard Solution	C				
			Metronidazole (Metronidazole)	C				
			Duragesic (Fentanyl)	C				
			Calcium With Vitamin D	C				
			Tetracycline (Tetracycline)	C				
			Protonix	C				
			Aciphex	C				
			Flomax (Morniflumate)	C				
			Ketorolac (Ketorolac)	C				
			Clindamycin (Clindamycin)	C				

Date: 07/12/01 **ISR Number:** 3757314-8 **Report Type:** Periodic **Company Report#:** DRON00201000633 **Age:** 50 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Skin Discolouration	Consumer	Marinol	PS	Unimed Inc	ORAL	10 MG BID PO	
			Zoloft (Sertraline Hydrochloride)	C				
			Klonopin (Clonazepam)	C				

Date: 07/12/01 **ISR Number:** 3757319-7 **Report Type:** Periodic **Company Report#:** DRON00201001512 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health Professional	Marinol	PS	Unimed Inc	ORAL	DAILY PO	

Date: 07/12/01 **ISR Number:** 3757324-0 **Report Type:** Periodic **Company Report#:** DRON00201001644 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyspepsia	Health Professional	Marinol	PS	Unimed Inc	ORAL	DAILY PO	

Date: 07/12/01 **ISR Number:** 3757329-X **Report Type:** Periodic **Company Report#:** DRON00201001675 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness Therapeutic Response Unexpected	Consumer	Marinol	PS	Unimed Inc	ORAL	10 MG BID PO, 5 MG BID PO	

Date: 07/12/01 **ISR Number:** 3757349-5 **Report Type:** Periodic **Company Report#:** DRON00201002225 **Age:** 88 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia Dizziness Speech Disorder	Consumer	Marinol	PS	Unimed Inc	ORAL	10 MG QD PO	
			Betapace (Sotalol Hydrochloride)	C				
			Warfarin (Warfarin)	C				

Date: 07/12/01 **ISR Number:** 3757371-9 **Report Type:** Periodic **Company Report#:** DRON00201002525 **Age:** 9 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia Depression Emotional Disorder Personality Disorder	Health Professional	Marinol	PS	Unimed Inc	ORAL	5 G DAILY PO	
			Viracept (Nelfinavir Mesilate)	C				
			Cytovene (Ganciclovir Sodium)	C				
			Epivir (Lamivudine)	C				
			Fortovase (Saquinavir)	C				
			Videx (Didanosine)	C				
			Bactrim (Bactrim)	C				
			Imodium (Loperamide Hydrochloride)	C				

			Zerit (Stavudine)	C				
			(Azithromycin)	C				

Date: 08/14/01 **ISR Number:** 3777366-9 **Report Type:** Expedited (15-Day) **Company Report#:** BLND00201003509 **Age:** 45 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation	Foreign	Marinol	PS	Unimed Inc	ORAL	10 DAILY PO	
	Intestinal Obstruction	Health	Baclofen	C				
	Vomiting	Professional	Tizanidine	C				
			Amitriptyline	C				
			Clonazepam	C				
			Oxybutynin	C				
			Spasmonal (Alverine Citrate)	C				
			Rabeprazole	C				

Date: 10/11/01 **ISR Number:** 3807590-8 **Report Type:** Direct **Company Report#:** **Age:** 87 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hallucination		Dronabinol	PS				

Date: 10/22/01 **ISR Number:** 3812656-2 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00201000256 **Age:** 79 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Study	Compassia					
	Anaemia	Health	(Dronabinol)	PS		ORAL	2.5 MG BID PO	
	Blood Creatine Phosphokinase Increased	Professional	Synthroid (Levothyroxine Sodium)	C				
	Blood Thyroid Stimulating Hormone Increased							

Date: 10/22/01 **ISR Number:** 3812711-7 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00201001964 **Age:** 88 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atrophy	Study	Marinol (Dronabinol)	PS		ORAL	5 MG BID PO	
Hospitalization - Initial or Prolonged	Brain Herniation	Health	Enalapril					
	Fall	Professional	(Enalapril)	C				
	Haemorrhagic Stroke		Coumadin (Warfarin Sodium)	C				
	Head Injury		Prinivil					
	Nervous System Disorder		(Lisinopril)	C				
	Pulse Absent		Lasix (Furosemide)	C				
			Mevacor (Lovastatin)	C				
			Pepcid (Famotidine)	C				
			Xanax (Alprazolam)	C				
			Valium (Diazepam)	C				

Date: 12/10/01 **ISR Number:** 3838041-5 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00201004844 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose Hypotension Medication Error Paralysis Syncope	Health Professional	Marinol (Dronabinol) Methadone (Methadone) Clonapin (Clonazepam)	PS C C		ORAL	30MG ONCE PO	

Date: 01/14/02 **ISR Number:** 3852002-1 **Report Type:** Direct **Company Report#:** CTU 159045 **Age:** 87 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hallucination		Dronabinol	PS				

Date: 02/06/02 **ISR Number:** 3865731-0 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00202000353 **Age:** 93 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall Hip Fracture	Study Health Professional	Marinol (Dronabinol) Multivitamins ()	PS C		ORAL	2.5 MG BID PO	

Date: 07/25/02 **ISR Number:** 3954143-7 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00201003602 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety Disorientation Hyperventilation Medication Error Nausea Sexual Abuse	Consumer	Marinol (Dronabinol)	PS		ORAL	DAILY PO	

Date: 09/17/02 **ISR Number:** 3977332-4 **Report Type:** Expedited (15-Day) **Company Report#:** PHNU2002DE03089 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Muscle Spasticity	Foreign Health Professional Other	Lioresal(Baclofen) Tablet Dronabinol (Dronabinol)	PS SS		ORAL	ORAL	

Date: 11/14/02 **ISR Number:** 4009970-7 **Report Type:** Direct **Company Report#:** CTU 180964 **Age:** 59 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium Mental Status Changes Renal Failure Acute		Marinol	PS		ORAL	5MG ORAL	

Date: 12/10/02 **ISR Number:** 4024891-1 **Report Type:** Expedited (15-Day) **Company Report#:** PHNU2002DE03089 **Age:** **Gender:** Unknown **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Foreign	Lioresal (Baclofen)					
	Muscle Spasticity	Health Professional	Tablet	PS		ORAL	ORAL	
		Other	Dronabinol (Dronabinol)	SS			CHANGING DOSAGE	
			Mydocalm "Strathmann" (Tolperisone Hydrochloride)	C				
			Sirdalud	C				
			Benzodiazepines	C				

Date: 02/21/03 **ISR Number:** 4059171-1 **Report Type:** Direct **Company Report#:** CTU 187090 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Status Changes		Dronabinol 2.5 Mg	PS		ORAL	2.5 MG BID ORAL	
			Asa	C				
			Calcium	C				
			Docusate	C				
			Erythromycin	C				
			Fluoxetine	C				
			Gabapentin	C				
			Hydralazine	C				
			Insulin	C				
			Lisinopril	C				
			Metoprolol	C				
			Nephrocap	C				
			Pyridoxine	C				
			Rabeprazole	C				
			Simvastatin	C				
			Sodium Bicarbonate	C				
			Clonidine Patch	C				

Date: 04/22/03 **ISR Number:** 4100581-1 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00203000912 **Age:** 50 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Health Professional	Marinol (Dronabinol)	PS		ORAL	2.5 MG TID PO	
	Contusion		Oxycontin (Oxycodone Hydrochloride)	C				
	Fall		Wellbutrin (Amfebutamone Hydrochloride)	C				
	Haemorrhagic Stroke		Msir (Morphine Sulfate)	C				
	Metastases To Central Nervous System							
	Speech Disorder							

Date: 06/18/03 **ISR Number:** 4132616-4 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00203000912 **Age:** 50 YR **Gender:** Female **I/FU:** F

Outcome	PT
Death	Cerebellar Infarction
Hospitalization - Initial or Prolonged	Cerebral Artery Occlusion
	Cerebral Ischaemia

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Contusion Demyelination Eye Swelling Fall Metastases To Spine Nerve Root Compression Spinal Compression Fracture	Health Professional	Marinol (Dronabinol) Oxycontin (Oxycodone Hydrochloride) Wellbutrin (Amfebutamone Hydrochloride) Msir (Morphine Sulfate) Ativan (Lorazepam) Ambien (Zolpidem Tartrate) Lidoderm (Lidoderm) Vioxx (Rofecoxib)	PS C C C C C C C		ORAL	5 MG DAILY PO	

Date: 06/18/03 **ISR Number:** 4132622-X **Report Type:** Expedited (15-Day) **Company Report#:** DRON00203001454 **Age:** 70 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Health Professional Company Representative	Marinol (Dronabinol) Topamax (Topiramate) Lamictal (Lamotrigine)	PS C C		ORAL	2.5 MG BID PO	

Date: 06/18/03 **ISR Number:** 4132624-3 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00203001453 **Age:** 49 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Convulsion	Health Professional Company Representative	Marinol (Dronabinol) Elavil (Amitriptyline Hydrochloride) Dilantin (Phenytoin Sodium) Unknown Hiv Medications (Unknown Hiv Medications)	PS C C C		ORAL	2.5 MG BID PO	

Date: 06/27/03 **ISR Number:** 4139163-4 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00203001281 **Age:** 51 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia Hypoaesthesia Mobility Decreased	Health Professional Company Representative	Marinol (Dronabinol) Keppra (Levetiracetam) Decadron (Dexamethasone) Pepcid (Famotidine) Sulfasalazin (Sulfasalazine)	PS C C C C		ORAL	5 MG DAILY PO	

Date: 06/30/03 **ISR Number:** 4139652-2 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00203001595 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pituitary Tumour Benign	Consumer	Marinol (Dronabinol)	PS		ORAL	DAILY PO	
			Elavil (Amitriptyline Hydrochloride)	C				
			Klonopin (Clonazepam)	C				

Date: 07/15/03 **ISR Number:** 4149082-5 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00201000636 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Marinol (Dronabinol)	PS		ORAL	2.5 MG BID; PO	

Date: 07/25/03 **ISR Number:** 4157631-6 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00203001454 **Age:** 70 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Health Professional	Marinol (Dronabinol)	PS		ORAL	2.5 MG BID PO	
		Company Representative	Topamax (Topiramate)	C				
			Lamictal (Lamotrigine)	C				
			Trileptal (Oxcarbazepine)	C				
			Prevacid (Lansoprazole)	C				
			Zoloft (Sertraline Hydrochloride)	C				
			Bactrim	C				
			Azithromycin (Azithromycin)	C				
			Vasotec (Enalapril Maleate)	C				
			Daraprim (Pyrimethamine)	C				
			Leucovorin (Leucovorin)	C				

Date: 07/25/03 **ISR Number:** 4157633-X **Report Type:** Expedited (15-Day) **Company Report#:** DRON00203001453 **Age:** 49 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Health Professional	Marinol (Dronabinol)	PS		ORAL	2.5 MG BID PO	
	Convulsion	Company Representative	Elavil (Amitriptyline Hydrochloride)	C				
	Drug Interaction		Dilantin (Phenytoin Sodium)	C				
	Drug Screen Positive		Unknown Hiv Medications (Unknown Hiv Medications)	C				
	Respiratory Depression		Norvir (Ritonavir)	C				
			Fortovase (Saquinavir)	C				
			Ziagen (Abacavir)	C				

Epivir (Lamivudine)	C		
Daraprim (Pyrimethamine)	C		
Leucovorin (Leucovorin)	C		
Aldactone (Spironolactone)	C		
Duragesic Patches (Fentanyl)	C		
Percocet (Percocet)	C		

Date: 07/30/03 **ISR Number:** 4164677-0 **Report Type:** Periodic **Company Report#:** DRON00202002202 **Age:** 37 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abortion Spontaneous	Consumer	Marinol (Dronabinol)	PS		ORAL	5 MG TID PO	

Date: 08/04/03 **ISR Number:** 4163796-2 **Report Type:** Expedited (15-Day) **Company Report#:** 2003012192 **Age:** 73 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dizziness	Consumer	Tikosyn (Dofetilide)	PS			1000 MCG (BID)	
Other	Drug Interaction	Health Professional	Dronabinol (Dronabinol)	SS			2.5 MG (PRN)	
			Stavudine (Stavudine)	C				
			Lamivudine (Lamivudine)	C				
			Nevirapine (Nevirapine)	C				
			Losartan Potassium (Losartan Potassium)	C				
			Carvedilol (Carvedilol)	C				
			Furosemide (Furosemide)	C				
			Potassium (Potassium)	C				
			Warfarin (Warfarin)	C				
			Loperamide (Loperamide)	C				
			Ipratropium Bromide (Ipratropium Bromide)	C				
			Salmetetrol Xinafoate (Salmeterol Xinafoate)	C				

Date: 09/11/03 **ISR Number:** 4200786-5 **Report Type:** Periodic **Company Report#:** 2003164678US **Age:** 37 YR **Gender:** Male **I/FU:** I

Outcome	PT
Hospitalization - Initial or Prolonged	Asthenia
	Difficulty In Walking
	Flushing

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Muscle Twitching Myalgia Nausea Renal Failure Acute Somnolence Vomiting	Health Professional	Bextra (Valdecoxib) Tablet	PS		ORAL	UNK, UNK; ORAL	
		Celebrex (Celecoxib, Celecoxib) Capsule	SS		UNKNOWN	UNK, UNK, UNK	
		Viread (Tenofovir)	SS		UNKNOWN	300 UNK, UNK, UNK	
		Fortovase (Saquinavir)	SS		UNKNOWN	UNK, UNK, UNK	
		Zerit (Stavudine)	SS			UNK, UNK, UNK	
		Kaletra (Lopinavir/Ritonavir)	SS		UNKNOWN	UNK, UNK, UNK	
		Phenergan (Promethazine)	SS		UNKNOWN	UNK, UNK, UNK	
		Ambien (Zolpidem Tartrate)	SS		UNKNOWN	UNK, UNK, UNK	
		Ensure (Vitamins Nos)	SS		UNKNOWN	UNK, UNK, UNK	
		Tricor (Fenofibrate)	SS		UNKNOWN	UNK, UNK, UNK	
		Dulcolax (Bisacodyl)	SS		UNKNOWN	UNK, UNK, UNK	
		Marinol (Dronabinol)	SS			UNK, UNK, UNK	
		Soma (Carisoprodol)	SS		UNKNOWN	UNK, UNK, UNK	
		Bactrim Ds (Sulfamethoxazole Trimethoprim)	SS		UNKNOWN	UNK, UNK, UNK	
		Biaxin (Clarithromycin)	SS		UNKNOWN	UNK, UNK, UNK	
		Protonix ( )	SS		UNKNOWN	UNK, UNK, UNK	
		Oxandrin (Oxlandrolone)	SS		UNKNOWN	UNK, UNK, UNK	
		Neurontin (Gabapentin)	SS		UNKNOWN	UNK, UNK, UNK	
		Colchicine (Colchicine)	SS		UNKNOWN	UNK, UNK, UNK	

Date: 09/30/03 **ISR Number:** 4202995-8 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00203002664 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypersomnia	Health Professional Company Representative	Marinol (Dronabinol)	PS		ORAL	5 MG TID PO	

Date: 10/29/03 **ISR Number:** 4223679-6 **Report Type:** Expedited (15-Day) **Company Report#:** KII-2003-0004100 **Age:** 51 YR **Gender:** Female **I/FU:** I

Outcome	PT
Hospitalization - Initial or Prolonged Other	Abnormal Behaviour Agitation Blood Ph Increased Delusion Depressed Level Of Consciousness Hypotonia

	Multiple Drug Overdose Somnolence Toxicologic Test Abnormal	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
		Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS				
			Duragesic(Fentanyl)	SS				
			Marinol(Dronabinol)	SS				
			Benzodiazepine Derivatives()	SS				
			Tricyclic Antidepressants()	SS				

Date: 02/26/04 **ISR Number:** 4307912-8 **Report Type:** Periodic **Company Report#:** 2003164678US **Age:** 37 YR **Gender:** Male **I/FU:** I

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Hospitalization - Initial or Prolonged	Asthenia Difficulty In Walking Flushing Muscle Twitching Myalgia Nausea Renal Failure Acute Somnolence Vomiting	Health Professional	Bextra (Valdecoxib) Tablet	PS		ORAL	UNK, UNK; ORAL	
			Celebrex (Celecoxib, Celecoxib)Capsule	SS		UNKNOWN	UNK, UNK, UNK	
			Viread (Tenofovir)	SS		UNKNOWN	300 UNK, UNK, UNK	
			Fortovase (Saquinavir)	SS		UNKNOWN	UNK, UNK, UNK	
			Zerit (Stavudine)	SS		UNKNOWN	UNK, UNK, UNK	
			Kaletra (Lopinavir/Ritonavir)	SS		UNKNOWN	UNK, UNK, UNK	
			Phenergan (Promethazine)	SS		UNKNOWN	UNK, UNK, UNK	
			Ambien (Zolpidem Tartrate)	SS		UNKNOWN	UNK, UNK, UNK	
			Ensure (Vitamins Nos)	SS		UNKNOWN	UNK, UNK, UNK	
			Tricor (Fenofibrate)	SS		UNKNOWN	UNK, UNK, UNK	
			Dulcolax (Bisacodyl)	SS		UNKNOWN	UNK, UNK, UNK	
			Marinol (Dronabinol)	SS		UNKNOWN	UNK, UNK, UNK	
			Somac (Carisoprodol)	SS		UNKNOWN	UNK, UNK, UNK	
			Bactrim Ds (Sulfamethoxazole, Trimethoprium)	SS		UNKNOWN	UNK, UNK, UNK	
			Biaxin (Clarithromycin)	SS		UNKNOWN	UNK, UNK, UNK	
			Protonix	SS		UNKNOWN	UNK, UNK, UNK	
			Oxandrin (Oxandrolone)	SS		UNKNOWN	UNK, UNK, UNK	
			Neurontin (Gabapentin)	SS		UNKNOWN	UNK, UNK, UNK	
			Colchicine (Colchicine)	SS		UNKNOWN	UNK, UNK, UNK	

Date: 07/16/04 **ISR Number:** 4406642-1 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00204002327 **Age:** 50 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Circulatory Collapse	Foreign	Marinol (Dronabinol)	PS		ORAL	2.5 MG BID, PO	
	Confusional State	Study						
	Somnolence	Health	Amitripytline					
	Speech Disorder	Professional	(Amitriptyline)	SS		ORAL	200 MG DAILY PO	
		Other	Baclofen (Baclofen)	SS		ORAL	70 MG DAILY PO	
			Tizanidine (Tizanidine)	SS		ORAL	32 MG DAILY PO	

Date: 07/19/04 **ISR Number:** 4402771-7 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00204000324 **Age:** 58 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Diastolic Decreased	Study	Marinol (Marinol)	PS		ORAL	2.5 MG BID PO, SEE IMAGE	
	Dizziness	Health Professional	Ondansetron					
	Fatigue		(Ondansetron)	SS		INTRAVENOUS	16 MG DAILY IV, SEE IMAGE	
	Feeling Abnormal							
	Nausea		Dexamethasone					
	Oral Intake Reduced		(Dexamethasone)	SS		ORAL	20 MG DAILY PO	
	Syncope		Vitamin C	C				
			Glucosamine	C				
			Calcium	C				
			Folic Acid	C				
			Centrum	C				
			Lisinopril	C				
			Hydrochlorothiazide	C				
			Vitamin E	C				
			Aspirine (Acetylsalicylic Acid)	C				

Date: 07/19/04 **ISR Number:** 4402773-0 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00204001114 **Age:** 64 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Study	Marinol (Dronabinol)	PS		ORAL	2 DF DAILY PO	
	Chest Pain	Health Professional	Ondansetron (Ondansetron)	SS		INTRAVENOUS	16 MG ONCE IV	
	Febrile Neutropenia		Dexamethasone					
	Gastrooesophageal Reflux Disease		(Dexamethasone)	SS		ORAL	20 MG ONCE PO	
	Muscle Spasms		Carboplatin (Carboplatin)	SS		INTRAVENOUS	465 MG ONCE IV	
	Pancytopenia							
	White Blood Cell Count Increased		Gemzar (Gemcitabine Hydrochloride)	SS		INTRAVENOUS	1830 MG ONCE IV, 1830 MG ONCE IV	
			Verapamil	C				
			Glucotrol (Glipizide)	C				
			Lisinopril	C				

Date: 07/19/04 **ISR Number:** 4403798-1 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00204001047 **Age:** 53 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Pain Headache	Study Health Professional	Marinol (Dronabinol) Ondansetron (Ondansetron) Dexamethasone (Dexamethasone)	PS SS SS		ORAL INTRAVENOUS ORAL	2.5 MG BID PO 16 MG ONCE IV 20 MG DAILY PO	

Date: 07/23/04 **ISR Number:** 4408644-8 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00204002336 **Age:** 49 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Multiple Sclerosis Relapse Urinary Tract Infection	Foreign Study Health Professional Other	Marinol (Marinol) Baclofen (Baclofen) Propranolol Prozac (Fluoxetine Hydrochloride) Quinine Sulfate Zopiclone Tolterodine	PS C C C C C C		ORAL	8 DF DAILY PO	

Date: 07/23/04 **ISR Number:** 4409729-2 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00204002000 **Age:** 75 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia Biopsy Bone Marrow Abnormal Nausea Pneumonia Klebsiella Pneumonitis Sepsis Vomiting	Study Health Professional	Marinol (Dronabinol) Dexamethasone (Dexamethasone) Ondansetron (Ondansetron) Fosinopril (Fosinopril) Adalat (Nifedipine) Metformin (Metformin) Terazosin (Terazosin)	PS SS SS C C C C		ORAL ORAL INTRAVENOUS	2.5 MG BID PO, 2.5 MG QID PO 20 MG ONCE PO 16 MG ONCE IV	

Date: 08/05/04 **ISR Number:** 4423253-2 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00204001047 **Age:** 53 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Potassium Decreased Chest Pain Glycosylated Haemoglobin Increased Haemoglobin Decreased Headache	Study Health Professional	Marinol (Dronabinol) Ondansetron (Ondansetron) Dexamethasone (Dexamethasone) Ultracet (Tramadol) Novolin (Insulin)	PS SS SS C C		ORAL INTRAVENOUS ORAL	2.5 MG BID PO 16 MG ONCE IV 20 MG DAILY PO	

Date: 08/17/04 **ISR Number:** 4431000-3 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00204001047 **Age:** 53 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Back Pain Blood Potassium Decreased Chest Pain Glycosylated Haemoglobin Increased Haemoglobin Decreased Headache Myocardial Infarction Prothrombin Time Prolonged	Study Health Professional	Marinol (Dronabinol) Ondansetron (Ondansetron) Dexamethasone (Dexamethasone) Ultracet (Tramadol) Novolin (Insulin)	PS SS SS C C		ORAL INTRAVENOUS ORAL	2.5 MG BID PO 16 MG ONCE IV 20 MG DAILY PO	

Date: 08/24/04 **ISR Number:** 4433273-X **Report Type:** Expedited (15-Day) **Company Report#:** DRON00204002739 **Age:** 51 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Glucose Increased Blood Magnesium Decreased Blood Sodium Decreased Confusional State Contusion Convulsion Eye Injury Face Injury Fall Gastrointestinal Haemorrhage Haemolytic Anaemia Liver Transplant Rejection Mental Status Changes Metabolic Encephalopathy Nausea Pancytopenia Vomiting	Health Professional	Marinol (Dronabinol) Aranesp (Aranesp) Kytril (Granisetron) Oxycontin (Oxycodone Hydrochloride) Neurontin (Gabapentin) Aricept (Donepezil Hydrochloride) Morphine Sulfate (Morphine Sulfate) Chlorpromazine (Chlorpromazine) Oxycodone (Oxycodone) Prograf (Prograf) Protonix (Protonix) Prandin "Kuhn" (Deflazacort) Zoloft (Sertraline Hydrochloride) Glipizide (Glipizide) Procardia (Nifedipine) Magnesium (Magnesium) Levaquin (Levofloxacin) Pentamidine (Pentamidine) Pericolace (Pericolace) Dulcolax (Bisacodyl) Asa (Acetylsalicylic Acid) Lasix (Lasix) Leukine (Sargramostim) Dexamethasone (Dexamethasone) Adriamycin	PS SS SS SS SS C C C C C C C C C C C C C C C C C		ORAL SUBCUTANEOUS INTRAVENOUS ORAL ORAL ORAL	DAILY PO 200 IU QD SC 1 MG QD IV 20 MG BID PO DAILY PO DAILY PO	

(Doxorubicin)	C
Cisplatinum (Cisplatin)	C
Senecot (Senecot)	C
Inderal (Inderal)	C
Multivitamins (Multivitamins)	C
Insulin (Insulin)	C
Aldactone (Aldactone)	C
Megace (Megace)	C

Date: 08/30/04 **ISR Number:** 4439646-3 **Report Type:** Expedited (15-Day) **Company Report#:** USA-2004-0016457 **Age:** 51 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Glucose Increased	Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS			20 MG, QL2H	
	Blood Magnesium Decreased	Other	Oxyir Capsules 5 Mg(Oxycodone Hydrochloride, Oxycodone Hydrochloride) Ir	SS			5 MG, Q4H	
	Blood Sodium Decreased		Aranesp(Darbepoetin)	SS				
	Confusional State		Kytril(Granisetron)	SS		INTRAVENOUS	1 MG, INTRAVENOUS	
	Contusion		Prograft(Tacrolimus)	SS			2 MG; 4 MG	
	Convulsion		Protonix(Pantoprazole)	SS			40 MG, DAILY	
	Eye Disorder		Acetylsalicylic Acid(Acetylsalicylic Acid)	SS			81 MG, DAILY	
	Face Injury		Gabapentin(Gabapentin)	SS				
	Fall		Magnesium(Magnesium)	SS			400 MG	
	Mental Status Changes		Senokot(Senna Fruit)	SS				
	Nausea		Donepezil(Donepezil)	SS				
	Pancytopenia		Inderal(Propranolol Hydrochloride)	SS				
	Vomiting		Dronabinol(Dronabinol)	SS				
			Megace(Megestrol Acetate)	SS				
			Insulin(Insulin)	SS				
			Aldactone(Spironolactone)	SS				
			Ambien(Zolpidem Tartrate)	SS				
			Chlorpromazine(Chlorpromazine)	C				
			Glipizide(Glipizide)	C				
			Procardia	C				
			Pentamidine(Pentamidine)	C				
			Peri-Colace (Sennoside A+B, Docusate Sodium) Tablet	C				
			Dulcolax	C				

			Dexamethasone(Dexamethasone)	C				
			Cis-Platinum(Cisplatin)	C				
			Zoloft(Sertraline Hydrochloride)	C				
			Leukine(Sargramostim)	C				
			Adriamycin(Doxorubicin)	C				

Date: 08/31/04 **ISR Number:** 4439240-4 **Report Type:** Expedited (15-Day) **Company Report#:** 2004057138 **Age:** 51 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Consumer	Neurontin (Gabapentin)	PS				
Other	Contusion	Health Professional	Aricept (Donepezil Hydrochloride)	SS				
	Convulsion		Oxycodone Hydrochloride (Oxycodone Hydrochloride)	SS			40 MG (20 MG, 2 IN 1 D)	
	Eye Injury		Darbepoetin Alfa (Darbepoetin Alfa)	SS		SUBCUTANEOUS	(200 MCG), SUBCUTANEOUS	
	Fall		Dronabinol (Dronabinol)	SS				
	Mental Status Changes		Granisetron (Granisetron)	SS			1 MG (1 MG, 1 IN 1 D)	
	Nausea		Zolpidem Tartrate (Zolpidem Tartrate)	C				
	Pancytopenia		Sertraline Hydrochloride	C				
	Soft Tissue Disorder		Glipizide (Glipizide)	C				
	Swelling		Nifedipine (Nifedipine)	C				
	Vomiting		Magnesium (Magnesium)	C				
			Levofloxacin (Levofloxacin)	C				
			Pentamidine (Pentamidine)	C				
			Bisacodyl (Bisacodyl)	C				
			Acetylsalicylic Aicd (Acetylsalicylic Acid)	C				
			Furosemide (Furosemide)	C				
			Sargramostim (Sargramostim)	C				
			Dexamethasone (Dexamethasone)	C				
			Granisetron (Granisetron)	C				
			Morphine Sulfate					

(Morphine Sulfate)	C
Chlorpromazine (Chlorpromazine)	C
Tacrolimus (Tacrolimus)	C
Pantoprazole (Pantoprazole)	C
Doxorubicin (Doxorubicin)	C
Cisplatin (Cisplatin)	C
Deflazacort (Deflazacort)	C
Senna Fruit (Senna Fruit)	C
Propranolol Hydrochloride (Propranolol Hydrochloride)	C
Multivitamins (Ascorbic Acid, Ergocalciferol, Folic Acid, Nicotinamide,	C
Insulin (Insulin)	C
Spironolactone (Spironolactone)	C
Megestroll Acetate (Megestrol Acetate)	C
Repaglinide (Repaglinide)	C

Date: 09/02/04 **ISR Number:** 4444227-1 **Report Type:** Expedited (15-Day) **Company Report#:** A03200402800 **Age:** 51 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Health Professional	Ambien - Zolpidem Tartrate - Tablet	PS		ORAL	ORAL	
	Confusional State		Aranesp - Darbepoetin Alfa - Solution	SS		SUBCUTANEOUS	SUBCUTANEOUS	
	Contusion		Marinol - Dronabinol	SS				
	Convulsion		Kytril - Granisetron - Solution -1 Mg	SS		INTRAVENOUS	1 MG QD - INTRAVENOUS NOS	
	Face Injury							
	Fall							
	Fatigue							
	Gastrointestinal Haemorrhage							
	Haemolytic Anaemia							
	Liver Transplant Rejection		Oxycontin - Oxycodone Hydrochloride - 20 Mg	SS			20 MG Q12HR	
	Metabolic Encephalopathy		Neurontin - Gabapentin	SS				
	Pancytopenia		Aricept - Donepezil Hydrochloride	SS				
	Swelling		Morphine Sulfate	C				
			Chlorpromazine	C				
			Oxycodone	C				
			Tacrolimus	C				
			Pantoprazole	C				
			Deflazacort	C				
			Sertraline					

Hydrochloride	C
Glipizide	C
Nifedipine	C
Magnesium	C
Levofloxacin	C
Pentamidine	C
Peri-Colace	C
Bisacodyl	C
Acetylsalicylic Acid	C
Furosemide	C
Sargramostim	C
Dexamethasone	C
Doxorubicin	C
Cisplatin	C
Senna Fruit	C
Propranolol Hydrochloride	C
Multivitamins	C
Insulin	C
Spironolactone	C
Megestrol Acetate	C

Date: 09/15/04 **ISR Number:** 4450267-9 **Report Type:** Expedited (15-Day) **Company Report#:** USA-2004-0016457 **Age:** 51 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Blood Glucose Increased Blood Magnesium Decreased Blood Sodium Decreased Confusional State Contusion Convulsion Face Injury Fall Fatigue Mental Status Changes Nausea Pancytopenia Swelling Vomiting	Health Professional Other	Oxycontin Tablets (Oxycondone Hydrochloride) Cr Tablet	PS			20 MG, Q12H	
			Oxyir Capsules 5mg (Oxycodone Hydrochloride, (Oxycodone Hydrochloride) Ir	SS			5 MG, Q4H	
			Aranesp (Darbepoetin)	SS				
			Kytril (Granisetron)	SS		INTRAVENOUS	1 MG, INTRAVENOUS	
			Prograf (Tacrolimus)	SS			SEE IMAGE	
			Protonil (Pantoprazole)	SS			40 MG DAILY	
			Acetylsalicylic Acid (Acetylsalicylic Acid)	SS			81 MG, DAILY	
			Gabapentin (Gabapentin)	SS				
			Magnesium (Magnesium)	SS			400 MG	
			Senokot (Sennoside A+B)	SS				
			Donepezil (Donepezil)	SS				
			Inderal (Propranolol Hydrochloride)	SS				
			Dronabinol (Dronabinol)	SS				
			Megace (Megestrol Acetate)	SS				
			Insulin (Insulin)	SS				
			Aldactone					

	(Spironolactone)	SS
	Ambien (Zolpidem Tartrate)	SS
	Chlorpromazine (Chlorpromazine)	C
	Glipizide (Glipizide)	C
	Procardia	C
	Pentamidine (Pentamidine)	C
	Peri-Colace (Sennoside A+B, Docusate Sodium)	C
	Dulcolax	C
	Dexamethasone (Dexamethasone)	C
	Cis-Platinum (Cisplatin)	C
	Zoloft (Sertraline Hydrochloride)	C
	Leukine (Sargramostim)	C
	Adriamycin (Doxorubicin)	C

Date: 09/17/04 **ISR Number:** 4452316-0 **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-380104 **Age:** 51 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia		Granisetron Hydrochloride	PS	Roche	UNKNOWN		1 DAY
	Convulsion		Darbepoetin Alfa	SS		SUBCUTANEOUS		
	Fall		Dronabinol	SS		UNKNOWN		
	Fatigue		Oxycodone	SS		UNKNOWN		31 DAY
	Gastrointestinal		Gabapentin	SS		UNKNOWN		
	Haemorrhage		Donepezil Hydrochloride	SS		UNKNOWN		
	Haemolytic Anaemia		Zolpidem Tartrate	SS		UNKNOWN		
	Head Injury		Morphine Sulfate	C				55 DAY
	Liver Transplant		Chlorpromazine	C				
	Rejection		Oxyir	C				
	Mental Status Changes		Tacrolimus	C				
	Metabolic Encephalopathy		Pantoprazole	C				
	Nausea		Prandin	C				
	Neuropathy		Sertraline Hydrochloride	C				
	Pancytopenia		Glipizide	C				
	Swelling		Nifedipine	C				
	Tremor		Magnesium	C				
	Vomiting		Levofloxacine	C				8 DAY
			Pentamidine	C				
			Pericolace	C				
			Bisacodyl	C				
			Acetylsalicylic Acid	C				
			Frusemide	C		INTRAVENOUS		1 DAY
			Sargamostim	C		SUBCUTANEOUS		6 DAY
			Dexamethasone	C		INTRAVENOUS		1 DAY
			Doxorubicin	C				
			Cisplatin	C				
			Senna Fruit	C				
			Propranolol	C				

			Multivitamins	C				
			Insulin	C				
			Spironolactone	C				
			Megestrol Acetate	C				

Date: 09/17/04 **ISR Number:** 4452830-8 **Report Type:** Expedited (15-Day) **Company Report#:** 2004057138 **Age:** 51 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Asthenia Confusional State Contusion Convulsion Fall Fatigue Mental Status Changes Nausea Pancytopenia Skull X-Ray Abnormal Swelling Vomiting	Consumer Health Professional	Neurontin (Gabapentin)	PS				
			Aricept (Donepezil Hydrochloride) (Donepezil)	SS				
			Oxycodone Hydrochloride (Oxycodone Hydrochloride)	SS			40 MG (20 MG , 2 IN 1 D)	
			Darbepoetin Alfa (Darbepoetin Alfa)	SS		SUBCUTANEOUS	(200 MCG), SUBCUTANEOUS	
			Dronabinol (Dronabinol)	SS				
			Granisetron (Granisetron)	SS			1 MG (1 MG, 1 IN 1 D)	
			Zolpidem Tartrate (Zolpidem Tartrate)	C				
			Sertraline Hydrochloride(Sertraline Hydrochloride)	C				
			Glipizide (Glipizide)	C				
			Nifedipine (Nifedipine)	C				
			Magenesium (Magnesium)	C				
			Levofloxacin (Levofloxacin)	C				
			Pentamidine (Pentamidine)	C				
			Peri-Colace (Casanthranol, Docusate Sodium)	C				
			Bisacodyl (Bisacodyl)	C				
			Acetylsalicylic Acid (Acetylsalicylic Acid)	C				
			Furosemide (Furosemide)	C				
			Sargramostim (Sargramostim)	C				
			Dexamethasone (Dexamethasone)	C				
			Granisetron (Granisetron)	C				
			Morphine Sulfate (Morphine Sulfate)	C				

Chlorpromazine (Chlorpromazine)	C
Tacrolimus (Tacrolimus)	C
Pantoprazole (Pantoprazole)	C
Doxorubicin (Doxorubicin)	C
Cisplatin(Cisplatin)	C
Deflazacort (Deflazacort)	C
Senna Fruit (Sena Fruit)	C
Propranolol Hydrochloride (Propranolol Hydrochloride)	C
Multivitamins (Ascorbic Acid, Ergoclaciferol, Folic Acid, Nicotinamide,	C
Insulin (Insulin)	C
Spironolactone (Spironolactone)	C
Megestrol Acetate (Megestrol Acetate)	C
Repaglinide (Repaglinide)	C

Date: 10/25/04 **ISR Number:** 4483544-6 **Report Type:** Expedited (15-Day) **Company Report#:** US-SOLVAY-00204003714 **Age:** 778 MON **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration Drug Ineffective Electrolyte Imbalance		Marinol	PS		ORAL		4 DAY

Date: 10/26/04 **ISR Number:** 4485744-8 **Report Type:** Expedited (15-Day) **Company Report#:** US-SOLVAY-00204003752 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Marinol	PS		ORAL	Daily dose: unknown	

Date: 10/29/04 **ISR Number:** 4488958-6 **Report Type:** Expedited (15-Day) **Company Report#:** US-SOLVAY-00204003714 **Age:** 778 MON **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration Drug Ineffective Electrolyte Imbalance	Consumer	Marinol	PS		ORAL		4 DAY

Date: 11/08/04 **ISR Number:** 4495435-5 **Report Type:** Expedited (15-Day) **Company Report#:** US-SOLVAY-00204003858 **Age:** 28526 DY **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration Nausea Vomiting		Marinol	PS		ORAL	Daily dose: 2.5 milligram(s) ONCE	1 DAY
			Chemotherapy	C		UNKNOWN	Daily dose: unknown	
			Nifedipine	C		ORAL	Daily dose: 1 dosage form	
			Atenolol	C		ORAL	Daily dose: 1 dosage form	
			Simvastin	C		ORAL	Daily dose: 1 dosage form	

Date: 11/09/04 **ISR Number:** 4501424-4 **Report Type:** Expedited (15-Day) **Company Report#:** DRON00204003858 **Age:** 78 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration Nausea Vomiting	Consumer	Marinol (Dronabinol)	PS		ORAL	2.5 MILLIGRAM (S) QD ORAL	
			Chemotherapy (Chemotherapy)	C				
			Nifedipine (Nifedipine)	C				
			Atenolol (Atenolol)	C				
			Simvastatin (Simvastatin)	C				

Date: 11/30/04 **ISR Number:** 4513142-7 **Report Type:** Expedited (15-Day) **Company Report#:** US-SOLVAY-00204003714 **Age:** 787 MON **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration Drug Ineffective Electrolyte Imbalance Full Blood Count Abnormal		Marinol	PS		ORAL	Daily dose: 2.5 milligram(s)	4 DAY
			Ambien	C		ORAL	Daily dose: 10 milligram(s)	
			Klonopin	C		ORAL	Daily dose: 1 milligram(s)	61 DAY
			Ativan	C		ORAL	Daily dose: 3 milligram(s)	
			Metoprolol	C		ORAL	Daily dose: 50 milligram(s)	

Date: 12/16/04 **ISR Number:** 4528499-0 **Report Type:** Expedited (15-Day) **Company Report#:** US-SOLVAY-00204004363 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Pain Cyclic Vomiting Syndrome		Marinol	PS		ORAL	Daily dose: 25 milligram(s)	29 DAY
			Opiods	C		UNKNOWN	Daily dose: unknown	

Date: 01/18/05 **ISR Number:** 4554376-5 **Report Type:** Expedited (15-Day) **Company Report#:** US-SOLVAY-00204004363 **Age:** **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Chest Pain Cyclic Vomiting Syndrome		Marinol	PS		ORAL	Daily dose: 25 milligram(s)	29 DAY
			Opiods	C		UNKNOWN	Daily dose: unknown	

Date: 01/18/05 **ISR Number:** 4555843-0 **Report Type:** Periodic **Company Report#:** A001-002-006183 **Age:** 51 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Convulsion Mental Status Changes	Health Professional	Aricept (Donepezil Hydrochloride)	PS		ORAL	ORAL	
			Aranesp (Darbepoetin Alfa)	SS		SUBCUTANEOUS	200 MCG, SUBCUTANEOUS	
			Marinol (Dronabinol)	SS				
			Kytril (Granisetron)	SS		INTRAVENOUS	INTRAVENOUS (NOT	
			Oxycontin (Oxycodone Hydrochloride)	SS			20 MG, 1 IN 12 HR	
			Neurontin (Gabapentin)	SS				
			Ambien (Zolpidem Tartrate)	SS				
			Oxy Ir (Oxycodone Hydrochloride)	SS			5 MG, 1 IN 4 HR	
			Morphine Sulfate	C				
			Chlorpromazine	C				
			Prograf (Tacrolimus)	C				
			Protonix (Pantoprazole)	C				
			Prandin (Repaglinide)	C				
			Zoloft (Sertraline Hydrochloride)	C				
			Glipizide	C				
			Procardia (Nifedipine)	C				
			Magnesium	C				
			Levaquin (Levofloxacin)	C				
			Pentamidine	C				
			Peri-Colace	C				
			Dulcolax (Bisacodyl)	C				
			Baby Aspirin (Acetylsalicylic Acid)	C				
			Dexamethasone	C				
			Adriamycin	C				
			Cisplatinum	C				
			Senokot (Senna Fruit)	C				
			Inderal (Propranolol Hydrochloride)	C				
			Multivitamins	C				

			Insulin	C				
			Aldactone (Spironolactone)	C				
			Megace (Megestrol Acetate)	C				

Date: 02/25/05 **ISR Number:** 4596128-6 **Report Type:** Expedited (15-Day) **Company Report#:** A001-OCT-3720 **Age:** 51 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Contusion	Study	Aricept (Donepezil Hydrochloride)	PS				
	Face Injury	Health	Marinol (Dronabinol)	SS				
	Fall	Professional	Kytril (Granisetron)	SS		INTRAVENOUS	1 IN 1 D, INTRAVENOUS	
	Mental Status Changes		Oxycontin (Oxycodone Hydrochloride)	SS			1 IN 12 HR	
			Neurontin (Gabapentin)	SS				
			Ambien (Zolpidem Tartrate)	SS				
			Aranesp (Darbepoetin Alfa)	C				
			Morphine Sulfate (Morphine Sulfate)	C				
			Chlorpromazine (Chlorpromazine)	C				
			Oxy Ir (Oxycodone Hydrochloride)	C				
			Prograf (Tacrolimus)	C				
			Protonix (Pantoprazole)	C				
			Prandin (Repaglinide)	C				
			Zoloft (Sertraline Hydrochloride)	C				
			Glipizide (Glipizide)	C				
			Procardia (Nifedipine)	C				
			Magnesium (Magnesium)	C				
			Levaquin (Levofloxacin)	C				
			Pentamidine (Pentamidine)	C				
			Pericolace (Peri-Colace)	C				
			Dulcolax Suppository (Bisacodyl)	C				
			Baby Aspirin (Acetylsalicylic Acid)	C				
			Lasix (Furosemide)	C				
			Leukine (Sargramostim	C				
			Dexamethasone (Dexamethasone)	C				
			Adriamycin (Doxorubicin)	C				

Cisplatinum (Cisplatin)	C
Senekot (Senna Fruit)	C
Inderal (Propranolol Hydrochloride)	C
Multivitamins (Multivitamins)	C
Insulin (Insulin)	C
Aldactone (Spironolactone)	C
Megace (Megestrol Acetate)	C

Date: 02/28/05 **ISR Number:** 4592757-4 **Report Type:** Expedited (15-Day) **Company Report#:** US-SOLVAY-00204002739 **Age:** 18935 DY **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaemia		Marinol	PS		ORAL	Daily Dose: unk.	
Hospitalization - Initial or Prolonged	Confusional State							
	Convulsion		Aranesp	SS		SUBCUTANEOUS	Daily Dose: 200 iu.	
	Face Injury							
	Fall		Oxycontin	SS		ORAL	Daily Dose: 40 mg.	31 DAY
	Hepatic Neoplasm							
	Malignant		Aricept	SS		ORAL	Daily Dose: unk.	
	Mental Status Changes							
	Nausea		Neurontin	SS		ORAL	Daily Dose: unk.	
	Pancytopenia							
	Vomiting		Kytril	SS		INTRAVENOUS	Daily Dose: 1 mg.	1 DAY
			Morphine Sulfate	C		UNKNOWN	Daily Dose: 15 mg. Frequency:As needed	55 DAY
			Zoloft	C		ORAL	Daily Dose: 100 mg.	
			Procardia	C		ORAL	Daily Dose: 120 mg.	
			Dexamethasone	C		INTRAVENOUS	Daily Dose: 10 mg. Frequency:Once	1 DAY
			Leukine	C		SUBCUTANEOUS	Daily Dose: 500 mg.	7 DAY
			Lasix	C		INTRAVENOUS	Daily Dose: 40 mg. Frequency:Once	1 DAY
			Asa	C		ORAL	Daily Dose: 81 mg.	
			Dulcolax	C		RECTAL	Daily Dose: 5 mg. Frequency:As needed	
			Pericolace	C		UNKNOWN	Daily Dose: 2 DF.	
			Pentamidine	C		RESPIRATORY (INHALATION)	Daily Dose: unk.	
			Levaquin	C		ORAL	Daily Dose:	

Magnesium	C	ORAL	500 mg. Daily Dose: 800 mg.	8	DAY
Darbepoetin Alfa	C	SUBCUTANEOUS	Daily dose: unknown	87	DAY
Megace	C	ORAL	Daily Dose: unk.		
Aldactone	C	ORAL	Daily Dose: unk.		
Insulin	C	UNKNOWN	Daily Dose: unk.		
Multivitamins	C	UNKNOWN	Daily Dose: unk.		
Inderal	C	ORAL	Daily Dose: unk.		
Senecot	C	UNKNOWN	Daily Dose: unk.		
Cisplatinum	C	SUBCUTANEOUS	Daily Dose: unk.		
Adriamycin	C	SUBCUTANEOUS	Daily Dose: unk.		
Glipizide	C	ORAL	Daily Dose: 500 mg.		
Prandin	C	ORAL	Daily Dose: 0.1 mg.		
Protonix	C	UNKNOWN	Daily Dose: 40 mg.		
Prograf	C	UNKNOWN	Daily Dose: 8 mg.		
Chlorpromazine	C	UNKNOWN	Daily Dose: 25 mg. Frequency:As needed		
Prograf	C	UNKNOWN	Daily Dose: 4 mg.		
Oxycodone	C	ORAL	Daily Dose: 30 mg.		

Date: 03/02/05 **ISR Number:** 4598320-3 **Report Type:** Expedited (15-Day) **Company Report#:** USA-2004-0016457 **Age:** 51 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia Asthenia Blood Glucose Increased Blood Sodium Decreased Confusional State Contusion Eye Injury Fall Fatigue Mental Status Changes Nausea Pancytopenia Vomiting	Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS			20 MG, Q12H,	
			Oxyir Capsules 5mg (Oxycodone Hdyrochloride, Oxycodone Hydrochloride)Ir	SS			5 MG, Q4H,	
			Aranesp (Darbepoetin)	SS				
			Protonix (Pantoprozole)	SS			40 MG DAILY	
			Gabapentin (Gabapentin)	SS				
			Donepezil	SS				
			Dronabinol (Dronabinol)	SS				
			Insulin (Inslin)	SS				

Ambien (Zolpidem Tartrate)	SS			
Senokot(Sennosidea+B)	SS			
Aldactone (Spironolactone)	SS			
Megacet (Megestrol Acetate)	SS			
Inderal (Propranolol Hydrochloride)	SS			
Magnesium (Magnesium)	SS			400 MG
Acetylsalicylic Acid (Acetylsalicylic Acid)	SS			81 MG DAILY
Prograf (Tarcolimus)	SS			SEE IMAGE
Kytril (Granisetron)	C		INTRAVENOUS	1 MG, INTRAVENOUS
Chlorpromazine (Chlorpromazine)	C			
Glipizide (Glipizide)	C			
Procardia	C			
Pentamidine (Pentamidine)	C			
Peri-Colace (Sennodide A+B, Docusate Sodium)	C			
Dulcolax	C			
Dexamethasone (Dexamethasone)	C			
Cis-Platium (Cisplatin)	C			
Zoloft (Sertraline Hydrochloride)	C			
Leukine (Sargramostim)	C			
Adriamycin (Doxorubicin)	C			

Date: 03/08/05 **ISR Number:** 4604328-1 **Report Type:** Expedited (15-Day) **Company Report#:** 2005035080 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anal Fissure Constipation Haemorrhoids Rectal Haemorrhage	Literature Health Professional	Camptosar (Irinotecan Hydrochloride)	PS		INTRAVENOUS	16 MG (CYCLIC), INTRAVENOUS	
			Methadone Hydrochloride (Methadone Hydrochloride)	SS		ORAL	7.5 MG (3 IN 1 D), ORAL	
			Temozolomide (Temozolomide)	SS		ORAL	160 MG (CYCLIC), ORAL	
			Dronabinol (Dronabinol)	SS		ORAL	5 MG (2 IN 1	

								D), ORAL
			Gabapentin (Gabapentin)	C				
			Modafinil (Modafinil)	C				

Date: 04/18/05 **ISR Number:** 4639296-X **Report Type:** Expedited (15-Day) **Company Report#:** USA-2004-0016457 **Age:** 51 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride) Cr					
	Blood Glucose Increased	Other	Tablet	PS			20 MG, Q12H	
	Blood Magnesium Decreased		Oxyir Capsules 5 Mg (Oxycodone Hydrochloride, Oxycodone					
	Blood Sodium Decreased		Hydrochloride)	SS			5 MG, Q4H	
	Brain Oedema		Aranesp (Darbepoetin)	SS				
	Confusional State		Kytril (Granisetron)	SS		INTRAVENOUS	1 MG, INTRAVENOUS	
	Contusion		Prograf (Tacrolimus)	SS			SEE IMAGE	
	Fall		Protonix (Pantoprazole)	SS			40 MG, DAILY	
	Fatigue		Acetylsalicylic Acid (Acetylsalicylic Acid)	SS			81 MG, DAILY	
	Injury		Gabapentin (Gabapentin)	SS				
	Mental Status Changes		Magnesium (Magnesium)	SS			400 MG	
	Nausea		Donepezil (Donepezil)	SS				
	Pancytopenia		Inderal (Propranolol Hydrochloride)	SS				
	Reticulocyte Count Increased		Dronabinol (Dronabinol)	SS				
	Vomiting		Megace (Megestrol Acetate)	SS				
			Insulin (Insulin)	SS				
			Aldactone (Spironolactone)	SS				
			Ambien (Zolpidem Tartrate)	SS				
			Senokot (Sennoside A+B)	C				
			Chlorpromazine (Chlorpromazine)	C				
			Glipizide (Glipizide)	C				
			Procardia	C				
			Pentamidine (Pentamidine)	C				
			Peri-Colace (Sennoside A+B, Docusate Sodium) Tablet	C				
			Dulcolax	C				

Dexamethasone (Dexamethasone)	C	
Cis-Platinum (Cisplatin)	C	
Zoloft (Sertraline Hydrochloride)	C	
Leukine (Sargramostim)	C	
Adriamycin (Doxorubicin)	C	

Date: 05/23/05 **ISR Number:** 4673229-5 **Report Type:** Direct **Company Report#:** CTU 249270 **Age:** 66 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Agitation		Zyvox	PS		INTRAVENOUS	600 MG IV Q 12 H	
	Diarrhoea							
	Hypertension		Paxil	SS			25 QD	
	Mydriasis		Marinol	SS			25 DC BID	
	Serotonin Syndrome							
	Tremor							

Date: 06/06/05 **ISR Number:** 4682446-X **Report Type:** Expedited (15-Day) **Company Report#:** US-ROCHE-380104 **Age:** 51 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia		Granisetron Hydrochloride	PS	Roche	INTRAVENOUS		1 DAY
	Convulsion		Darbepoetin Alfa	SS		SUBCUTANEOUS		87 DAY
	Disease Progression		Dronabinol	SS		UNKNOWN		
	Gastrointestinal		Oxycodone	SS		UNKNOWN		31 DAY
	Haemorrhage		Gabapentin	SS		UNKNOWN		
	Haemolytic Anaemia		Donepezil Hydrochloride	SS		UNKNOWN		
	Liver Transplant		Zolpidem Tartrate	SS		UNKNOWN		
	Rejection		Morphine Sulfate	C				55 DAY
	Mental Status Changes		Chlorpromazine	C				
	Metabolic Encephalopathy		Oxyir	C				
	Nausea		Tacrolimus	C				
	Pancytopenia		Pantoprazole	C				
	Vomiting		Prandin	C				
			Sertraline Hydrochloride	C				
			Glipizide	C				
			Nifedipine	C				
			Magnesium	C				
			Levofloxacine	C				8 DAY
			Pentamidine	C				
			Pericolace	C				
			Bisacodyl	C				
			Acetylsalicylic Acid	C				
			Frusemide	C		INTRAVENOUS		1 DAY
			Sargamostim	C		SUBCUTANEOUS		6 DAY
			Dexamethasone	C		INTRAVENOUS		1 DAY
			Doxorubicin	C				
			Cisplatin	C				
			Senna Fruit	C				
			Propranolol	C				
			Multivitamins	C				

Insulin	C
Spironolactone	C
Megestrol Acetate	C

Date: 06/20/05 **ISR Number:** 4694272-6 **Report Type:** Expedited (15-Day) **Company Report#:** US-SOLVAY-00205001930 **Age:** 758 MON **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Ineffective		Marinol	PS		ORAL	Daily dose: 5 milligram(s)	
	Intestinal Obstruction		Topotecan	C		INTRAVENOUS	5 DAYS WEEK/EVERY 3 WEEKS	
			Toprol Xl	C		ORAL	Daily dose: unknown	
			Synthroid	C		ORAL	Daily dose: unknown	
			Zelnorm	C		ORAL	Daily dose: unknown	
			Reglan	C		ORAL	Daily dose: unknown	
			Coumadin	C		ORAL	Daily dose: unknown	
			Wellbutrin	C		ORAL	Daily dose: unknown	
			Ativan	C		ORAL	Daily dose: unknown	
			Zofran	C		ORAL	Daily dose: unknown	
			Phenergan	C		UNKNOWN	Daily dose: unknown	
			Protonix	C		ORAL	Daily dose: unknown	
			Tpn	C		INTRAVENOUS	Daily dose: unknown	

Date: 07/22/05 **ISR Number:** 4724979-3 **Report Type:** Direct **Company Report#:** CTU 254051 **Age:** 50 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Status Changes		Dronabinol	PS				

Summary report for FOI selections:

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

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

Total number of reports: 102

From: 01-NOV-1997 To: Present