Date: 07/28/1999 **ISR Number:** 3312756-X **Report Type:** Expedited (15-Day) **Company Report Number:** 205994 **Age:** 75 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Bilirubin Increased	Foreign	Tasmar (Tolcapone)	PS				
	Condition Aggravated	Health Professional	Madopar Dr	C				
	Liver Function Tests Nos Abnormal		Parlodel	C				
	Stress Symptoms		Deanxit	C				

Date: 07/13/1999 **ISR Number:** 3315065-8 **Report Type:** Expedited (15-Day) **Company Report Number:** USA010108 **Age:** 32 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Aspartate Aminotransferase Increased	Health Professional	Vicodin	PS		ORAL		
	Completed Suicide	Other	Accutane	SS				
	Hepatic Failure							
	Mental Impairment Nos							
	Multi-Organ Failure							
	Non-Accidental Overdose							

Date: 08/02/1999 **ISR Number:** 3315944-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 205976 **Age:** 74 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Apraxia	Foreign	Tasmar (Tolcapone)	PS		ORAL		
	Extrapyramidal Disorder Nec	Health Professional	Madopar	C				
	Insomnia Nec		Aspirin Cardio	C				
	Liver Function Tests Nos Abnormal		Eltroxin	C				
	Muscle Rigidity		Fosamax	C				
	Oedema Peripheral		Sirdalud	C				
	Restless Leg Syndrome		Venoruton	C				
	Varicose Veins Nos		Paragar	C				
			Calcium D Sauter	C				

Date: 07/30/1999 **ISR Number:** 3316272-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 206552 **Age:** 19 YR **Gender:** Not Specified

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Pressure Abnormal	Health Professional	Accutane Capsules (Isotretinoin) 40mg	PS		ORAL		
	Cardiovascular Disorder Nos							
	Mental Disorder Nec							
	Neurological Disorder Nos							
	Social Avoidant Behaviour							
	Stress Symptoms							
	Valvular Heart Disease Nos							

FDA - Adverse Event Reporting System (AERS)
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Date: 08/04/1999 **ISR Number:** 3318970-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 207602 **Age:** 19 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Headache Nos	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
	Hypertension Nos							
	Stress Symptoms							

Date: 08/06/1999 **ISR Number:** 3321055-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 207951 **Age:** 70 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Insomnia Nec	Health Professional	Tasmar (Tolcapone)	PS		ORAL		
	Liver Function Tests Nos Abnormal		Mirapex	C				
			Estrogen	C				
			Triamterene	C				
			Tylenol	C				
			Symmetrel	C				

Date: 08/10/1999 **ISR Number:** 3322533-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 211956 **Age:** 14 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Abdominal Pain Upper	Other	Accutane Capsules (Isotretinoin) 40mg	PS		ORAL		
	Blood In Stool		Prevacid	C				
	Dry Skin		Vitamins	C				
	Fatigue		(Multivitamin Nos)	C				
	Gastritis Nos							
	Hypersomnia							
	Hyperventilation							
	Proctalgia							

Date: 08/10/1999 **ISR Number:** 3322541-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 201521 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Brain Neoplasm Nos	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
	Condition Aggravated							
	Conjunctivitis Nec							
	Eye Discharge							
	Hallucination, Auditory							
	Obsessive-Compulsive Disorder							
	Palpitations							
	Red Eye							
	Schizophrenia Nos							
	Stress Symptoms							

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Date: 08/10/1999 **ISR Number:** 3322748-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 211463 **Age:** 27 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Cervical Carcinoma Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Depression Nec	Other						
	Dry Skin							
	Hysterectomy Nos							
	Lip Dry							

Date: 08/12/1999 **ISR Number:** 3324919-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 212616 **Age:** 83 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Blindness Nec	Health Professional	Tasmar (Tolcapone) 200mg	PS		ORAL		
	Reading Disorder		Sertraline (Sertraline Hydrochloride)	C				
	Retinal Vein Thrombosis		Lisinopril (Lisinopril)	C				
	Vision Blurred		Sinemet Cr (Carbidopa/Levodopa)	C				
			Aspirin (Aspirin)	C				
			Folic Acid (Folic Acid)	C				

Date: 08/13/1999 **ISR Number:** 3325599-8 **Report Type:** Expedited (15-Day) **Company Report Number:** F/99/01924/PLO **Age:** 78 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Confusion	Foreign	Parlodel (Bromocriptine Mesilate)	PS		ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Disorientation	Other	Tasmar (Tolcapone)	SS		ORAL		
	Drug Interaction Nos		Sinemet	C				
	Hallucination Nos		Lasilix	C				
			Renitec	C				
			Nitriderm	C				
			Kardegic	C				

Date: 08/17/1999 **ISR Number:** 3327683-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 212643 **Age:** 27 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blindness Transient	Other	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
	Dizziness (Exc Vertigo)							
	Heart Rate Increased							
	Oxygen Saturation Decreased							
	Palpitations							
	Syncope							
	Visual Disturbance Nos							

Date: 08/24/1999 **ISR Number:** 3333397-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 213055 **Age:** 26 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Tenderness	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Anorexia		Birth Control Pills	C				
	Anxiety Nec							
	Arthralgia							
	Chest Pain							
	Depression Nec							
	Dizziness (Exc Vertigo)							
	Dyspnoea Nos							
	Liver Tenderness							
	Loose Stools							
	Myalgia							
	Nausea							
	Palpitations							
	Supraventricular Tachycardia							
	Tachycardia Nos							
	Weight Decreased							

Date: 08/25/1999 **ISR Number:** 3335345-X **Report Type:** Expedited (15-Day) **Company Report Number:** 213286 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Acne Nos	Other						
	Dermatitis Nos							
	Diarrhoea Nos							
	Granuloma Nos							
	Insomnia Nec							
	Malaise							
	Meconium Increased							
	Nasal Congestion							
	Parity							
	Pyrexia							
	Rhinorrhoea							
	Seborrhoea							
	Skin Warm							
	Sneezing							
	Umbilical Cord Around Neck							
	Upper Respiratory Tract Infection Nos							

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Date: 08/25/1999 **ISR Number:** 3335349-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 112672 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alpha 1 Foetoprotein Increased	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Appetite Decreased		Oral Contraceptive Pill	C				
	Candida Nos							
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Conjunctivitis Nec							
	Cough							
	Crying							
	Diarrhoea Nos							
	Ecchymosis							
	Faecal Abnormality Nos							
	Feeding Problem In Newborn							
	Foetal Distress Syndrome							
	Haematoma Nos							
	Heart Rate Increased							
	Jaundice Neonatal							
	Nasal Congestion							
	Respiratory Disorder Nos Neonatal							
	Shoulder Dystocia							
	Torticollis							
	Upper Respiratory Tract Infection Nos							

Date: 08/26/1999 **ISR Number:** 3335362-X **Report Type:** Expedited (15-Day) **Company Report Number:** 207100 **Age:** 77 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Condition Aggravated	Foreign	Tasmar (Tolcapone)	PS				
	Fatigue	Health Professional	Sinemet Cr	C				
	Liver Function Tests Nos Abnormal		Madopar Liq	C				
	Parkinsonism Aggravated							
	Pruritus							
	Restlessness							
	Sleep Disorder Nos							
	Transaminase Nos Increased							
	Tremor Nec							
	Weakness							

Date: 08/26/1999 **ISR Number:** 3335369-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 213108 **Age:** 35 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Foreign	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Angioneurotic Oedema	Health Professional	Arthrotec (Diclofenac Sodium/Misoprostol)	SS		ORAL		
	Arthralgia		Prednisone	C				
	Bronchospasm Nos							
	Chest Pain							
	Chest Tightness							
	Dysphagia							
	Dyspnoea Nos							
	Gastroenteritis Nos							
	Hypoaesthesia							
	Insomnia Nec							
	Joint Swelling							
	Myalgia							
	Pain In Limb							
	Pleural Rub							
	Pruritus							
	Rash Maculo-Papular							
	Sore Throat Nos							
	Urticaria Nos							
	Vomiting Nos							

Date: 08/26/1999 **ISR Number:** 3335375-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 109655 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Appetite Decreased	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Blood Pressure Decreased							
	Bradycardia Foetal							
	Caesarean Section							
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Cough							
	Diarrhoea Neonatal							
	Disorder Neonatal Nos							
	Dyspepsia							
	Failed Induction Of Labour							
	Feeding Problem In Newborn							
	Injection Site Erythema							
	Injection Site Inflammation							
	Irritability							
	Nasal Congestion							
	Nasopharyngitis							

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Date: 08/31/1999 **ISR Number:** 3338395-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 213780 **Age:** 51 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Constipation	Consumer	Tasmar (Tolcapone)	PS		ORAL		
	Depression Nec		Norvasc	C				
	Drooling		Synthroid	C				
	Dyspnoea Nos		Miacalcin	C				
	Dystonia		Sinemet	C				
	Eating Disorder Nec							
	Liver Function Tests Nos Abnormal							
	Oedema Lower Limb							
	Pain In Jaw							
	Posture Abnormal							
	Sedation							
	Weight Decreased							

Date: 08/30/1999 **ISR Number:** 3338941-9 **Report Type:** Periodic **Company Report Number:** 202278 **Age:** 83 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Appetite Decreased	Other	Tasmar (Tolcapone) 200 Mg	PS		ORAL		
	Condition Aggravated		Sinemet Cr (Carbidopa/Levodopa)	C				
	Constipation		Levodopa-Carbidopa (Carbidopa/Levodopa)	C				
	Depression Aggravated		Parlodel (Bromocriptine Mesylate)	C				
	Dizziness (Exc Vertigo)		Bumetanide (Bumetanide)	C				
	Headache Nos		K Dur (Potassium Chloride)	C				
	Nervousness		Atenolol (Atenolol)	C				
	Oedema Lower Limb		Norvasc (Amlodipne Besylate)	C				
	Weakness		Zestril (Lisinopril)	C				
			Lorazepam (Lorazepam)	C				
			Amaryl (Glimepiride)	C				

Date: 08/30/1999 **ISR Number:** 3338945-6 **Report Type:** Periodic **Company Report Number:** 207769 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dyskinesia Nec	Health Professional	Tasmar (Tolcapone)	PS		ORAL		
	Mania		Sinemet (Carbidopa/Levodopa)	SS		ORAL		
	Sleep Disorder Nos							

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Date: 08/30/1999 **ISR Number:** 3338946-8 **Report Type:** Periodic **Company Report Number:** 209145 **Age:** 81 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Difficulty In Walking	Other	Tasmar (Tolcapone)	PS		ORAL		
	Disorientation							
	Fall							
	Fatigue							
	Lethargy							
	Malaise							
	Parkinson'S Disease Aggravated							
	Urine Discolouration							

Date: 09/01/1999 **ISR Number:** 3339145-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 213286 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Acne Nos	Other						
	Choking							
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Cough							
	Diarrhoea Neonatal							
	Insomnia Nec							
	Malaise							
	Meconium Increased							
	Nasal Congestion							
	Premature Labour							
	Premature Rupture Of Membranes							
	Pyrexia							
	Respiratory Disorder Nos Neonatal							
	Rhinorrhoea							
	Seborrhoea							
	Sneezing							
	Sputum Increased							
	Umbilical Cord Around Neck							
	Upper Respiratory Tract Infection Nos							

Date: 09/03/1999 **ISR Number:** 3341866-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 212571 **Age:** 60 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aggression	Foreign	Tasmar (Tolcapone)	PS				
	Back Pain	Health Professional	Madopar	C				
	Blood Bilirubin Increased							

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Date: 09/08/1999 **ISR Number:** 3343168-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 205301 **Age:** 17 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Ankylosing Spondylitis	Health Professional	Accutane Capsules(Isotretinoin)	PS		ORAL		
	Antinuclear Factor Positive							
	Arthralgia							
	Depression Nec							
	Dermatitis Nos							
	Dry Skin							
	Erythrocyte Sedimentation Rate Increased							
	Fatigue							
	Herpes Simplex							
	Joint Stiffness							
	Joint Swelling							
	Juvenile Rheumatoid Arthritis							
	Nausea							
	Polyarthritis Acute							
	Pyrexia							
	Sore Throat Nos							
	Synovitis							
	Tenderness Nos							
	Upper Respiratory Tract Infection Nos							
	Weight Decreased							

Date: 09/08/1999 **ISR Number:** 3343170-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 214251 **Age:** 19 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Anxiety Nec	Other						
	Appetite Decreased							
	Arthralgia							
	Clamminess							
	Depression Nec							
	Dizziness (Exc Vertigo)							
	Feeling Cold							
	Head Injury							
	Lip Dry							
	Myalgia							
	Nausea							
	Panic Attack							
	Suicidal Ideation							
	Weight Decreased							

Date: 09/08/1999 **ISR Number:** 3343367-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 214389 **Age:** 37 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Arrhythmia Nos	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
	Chest Tightness		Insulin	C				
	Cyst Nos							
	Dermatitis Nos							
	Dyspnoea Nos							
	Herpes Zoster							
	Palpitations							

Date: 09/08/1999 **ISR Number:** 3343421-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 214256 **Age:** 33 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Cellulitis	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Mood Alteration Nos							

Date: 09/09/1999 **ISR Number:** 3344275-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 208428 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Agitation Neonatal	Health Professional	Accutane	PS		TRANSPLACENTAL		
	Apgar Score Low	Other	Birth Control Pills	C				
	Blood Bilirubin Increased		Dura-Vent	C				
	Complications Of Maternal Exposure To Therapuetic Drugs		Amoxil	C				
	Disorder Foetal Nos		Macrobid	C				
	Feeding Problem In Newborn		Tylenol	C				
	Flatulence							
	Foetal Movements Decreased							
	Gastro-Oesophageal Reflux Disease							
	Heart Rate Decreased							
	Infantile Colic							
	Infarction Nos							
	Jaundice Neonatal							
	Neonatal Respiratory Distress Syndrome							
	Oligohydramnios							
	Oral Candidiasis							
	Placental Disorder Nos							
	Regurgitation Of Food							
	Umbilical Cord Around Neck							
	Vomiting Neonatal							

Date: 09/09/1999 **ISR Number:** 3344295-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 205994 **Age:** 75 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Bilirubin Increased	Foreign	Tasmar (Tolcapone)	PS				
	Liver Function Tests Nos Abnormal	Health Professional	Madopar Dr	C				
	Somatisation Disorder		Parlodel	C				
			Deanxit	C				
			Selipran	C				
			Cortison	C				
			Aspirin Cardio	C				
			Temesta	C				

Date: 09/10/1999 **ISR Number:** 3345418-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 112379 **Age:** 15 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Aggravated	Foreign	Roaccutane (Isotretinoin))	PS		ORAL		
	Dry Mouth	Health Professional	Lysanxia (Prazepam)	C				
	Epistaxis		Anafranil (Clomipramine Hydrochloride)	C				
	Lip Dry		Hept-A-Myal (Heptaminol Hydrochloride)	C				
	Non-Accidental Overdose		Anafranil (Clomipramine Hydrochloride)	C				
	Postural Hypotension							
	Rash Erythematous							
	Suicide Attempt							
	Vomiting Nos							

Date: 09/20/1999 **ISR Number:** 3352434-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 207894 **Age:** 36 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Acne Aggravated		Loestrin	C				
	Arthralgia		Paxil	C				
	Back Pain							
	Chest Pain							
	Depressed Mood							
	Depression Nec							
	Dermatitis Exfoliative Nos							
	Dry Skin							
	Fatigue							
	Hypertriglyceridaemia							
	Irritability							
	Kidney Infection Nos							
	Lip Dry							
	Myalgia							

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Date: 09/20/1999 **ISR Number:** 3352438-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 214774 **Age:** 19 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Anorexia	Health Professional	Accutane Capsules (Isotretinoin) 100 Mg	PS		ORAL		
Hospitalization - Initial or Prolonged	Diabetes Mellitus Insulin-Dependent							
Disability	Diabetic Ketoacidosis							
	Hyperglycaemia Nos							
	Hyperphagia							
	Polydipsia							
	Polyuria							
	Weakness							

Date: 09/21/1999 **ISR Number:** 3353900-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 208428 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Abdominal Pain Nos	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Apgar Score Low	Other	Birth Control Pills	C				
	Blood Bilirubin Increased		Dura-Vent	C				
	Bradycardia Foetal		Amoxil	C				
	Caesarean Section		Macrobid	C				
	Candida Nos		Tylenol	C				
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Flatulence							
	Foetal Movements Decreased							
	Gastro-Oesophageal Reflux Disease							
	Irritability							
	Jaundice Neonatal							
	Joint Disorder Nos							
	Neonatal Respiratory Distress Syndrome							
	Oligohydramnios							
	Premature Baby							
	Regurgitation Of Food							
	Umbilical Cord Around Neck							
	Vomiting Neonatal							
	Vomiting Projectile							

Date: 09/22/1999 **ISR Number:** 3354851-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 215487 **Age:** 60 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Upper	Foreign	Tasmar (Tolcapone)	PS				
	Constipation	Health Professional	Madopar	C				
	Irritable Bowel Syndrome							

Date: 09/22/1999 **ISR Number:** 3354982-X **Report Type:** Expedited (15-Day) **Company Report Number:** 215637 **Age:** 19 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation	Foreign	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Delirium	Health Professional	Baclofen	C				
	Delusion Nos		Clonidine	C				

Date: 09/22/1999 **ISR Number:** 3354985-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 215403 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Ataxia Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Convulsions Nos							
	Dysarthria							
	Headache Nos							
	Intracranial Haemangioma							
	Vomiting Nos							

Date: 09/23/1999 **ISR Number:** 3356716-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 204535 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Accidental Exposure	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
Congenital Anomaly	Calcinosis		Retin A Cream	C				
	Congenital Auricle Absence		Prenatal Vitamins	C				
	Dysphasia							
	Eyelid Function Disorder Nos							
	Mental Retardation Severity Unspecified							
	Pregnancy Nos							
	Speech Disorder Nec							
	Strabismus Congenital							

Date: 09/23/1999 **ISR Number:** 3357546-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 208050 **Age:** 38 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Acid Fast Stain Positive	Foreign	Roaccutane (Isotretinoin)	PS		ORAL		
	Alopecia	Health Professional						
	Anaemia Nos	Other						
	Condition Aggravated							
	Cough							
	Depression Nec							
	Dry Mouth							
	Epistaxis							
	Haemoglobin Decreased							
	Hiv Test Positive							
	Leucopenia Nos							

Date: 09/28/1999 **ISR Number:** 3361731-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 860102175001 **Age:** 43 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Alopecia	Literature	Isotretinoin Oral (Isotretinoin)	PS		ORAL		
Life-Threatening	Cheilitis	Health Professional						
Hospitalization - Initial or Prolonged	Condition Aggravated							
Required Intervention to Prevent Permanent Impairment/Damage	Corneal Disorder Nos							
	Corneal Ulcer Nec							
	Depression Nec							
	Dry Eye Nec							
	Haemorrhage Nos							
	Headache Nos							
	Pituitary Tumour Benign Nos							
	Skin Disorder Nos							
	Vascular Disorder Nos							

Date: 09/28/1999 **ISR Number:** 3361734-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 208428 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Abdominal Pain Nos	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Apgar Score Low	Other	Birth Control Pills (Oral Contraceptive Nos)	C				
	Blood Bilirubin Increased		Dura-Vent (Guaifenesin/Phenylpropanolamine Hydrochloride)	C				
	Candida Nos		Amoxil	C				
	Complications Of Maternal Exposure To Therapuetic Drugs		Macrobid	C				
	Congenital Hip Dislocation		Tylenol	C				
	Crying							
	Flatulence							
	Foetal Movements Decreased							
	Gastro-Oesophageal Reflux Disease							
	Heart Rate Decreased							
	Irritability							
	Jaundice Nos							
	Joint Disorder Nos							
	Neonatal Respiratory Distress Syndrome							
	Oligohydramnios							
	Placental Disorder Nos							
	Umbilical Cord Around Neck							
	Vomiting Nos							

Date: 09/30/1999 **ISR Number:** 3361789-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 216188 **Age:** **Gender:** Unknown

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec Ectopic Pregnancy Insomnia Nec Pregnancy Nos	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 10/04/1999 **ISR Number:** 3363690-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 215119 **Age:** 39 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Blindness Nec Confusion Headache Nos Nausea Sweating Increased	Consumer Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 10/04/1999 **ISR Number:** 3363699-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 83462 **Age:** 21 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide Dry Skin Lip Dry	Foreign Health Professional Other	Roaccutane (Isotretinoin) Flixotide (Fluticasone Propionate)	PS C		ORAL		

Date: 10/04/1999 **ISR Number:** 3363707-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 216188 **Age:** **Gender:**

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec Ectopic Pregnancy Insomnia Nec Pregnancy Nos	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 10/04/1999 **ISR Number:** 3363794-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 216399 **Age:** 36 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Diabetes Mellitus Nos Dyspnoea Nos Eye Pain Granuloma Nos Headache Nos Hemiparesis Hypertension Nos Palpitations Parotid Gland Enlargement Visual Disturbance Nos	Consumer Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

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Date: 10/04/1999 **ISR Number:** 3363873-X **Report Type:** Expedited (15-Day) **Company Report Number:** 213108 **Age:** 35 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Foreign	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Angioneurotic Oedema	Health Professional	Arthrotec (Diclofenac Sodium/Misoprostol)	SS		ORAL		
	Arthralgia		Prednisone (Prednisone)	C				
	Bronchospasm Nos							
	Chest Pain							
	Dysphagia							
	Eosinophilia (Exc Pulmonary)							
	Gastroenteritis Nos							
	Hypoaesthesia							
	Hyponatraemia							
	Insomnia Nec							
	Joint Swelling							
	Leucocytosis Nos							
	Liver Function Tests Nos Abnormal							
	Oedema Upper Limb							
	Pain In Limb							
	Pleural Rub							
	Sore Throat Nos							
	Urticaria Nos							
	Vomiting Nos							

Date: 10/04/1999 **ISR Number:** 3364014-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 72038 **Age:** 32 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec	Foreign	Roaccutane (Isotretinoin)	PS		ORAL		
	Chest Pain	Health Professional	Vitamin A (Vitamin A)	SS		ORAL		
	Crying	Other						
	Depression Nec							
	Diarrhoea Nos							
	Gingival Bleeding							
	Hallucination Nos							
	Headache Nos							
	Hypothalamo-Pituitary Disorders Nec							
	Irritability							
	Menstruation Irregular							
	Nervousness							
	Polycystic Ovaries							
	Salivary Hypersecretion							
	Social Avoident Behaviour							

Date: 10/12/1999 **ISR Number:** 3368636-7 **Report Type:** Direct **Company Report Number:** **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Abdominal Pain Upper		Accutane 10mg Roche	PS	Roche	ORAL		
Hospitalization - Initial or Prolonged	Aphasia		Claritan	C				
Disability	Convulsions Nos		Omnicef	C				
Other	Dizziness (Exc Vertigo)							
Required Intervention to Prevent Permanent Impairment/Damage	Dysarthria							
	Dyspnoea Exertional							
	Dyspnoea Nos							
	Fall							
	Fatigue							
	Gasping							
	Headache Nos							
	Hypoglycaemia Nos							
	Miosis							
	Sensation Of Pressure Nos							
	Sleep Disorder Nos							
	Spinal Compression Fracture							
	Toothache							
	Visual Disturbance Nos							

Date: 10/08/1999 **ISR Number:** 3369019-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 213808 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Anal Disorder Nos	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Anorexia							
	Blood Bilirubin Increased							
	Blood Triglycerides Increased							
	Depression Nec							
	Diarrhoea Nos							
	Dry Mouth							
	Dry Skin							
	Dry Throat							
	Gastritis Nos							
	Gilbert'S Syndrome							
	Lip Dry							
	Mucosal Dryness Nos							
	Nutritional Support							
	Oesophageal Reflux							
	Parent-Child Problem							
	Urethral Disorder Nos							
	Vomiting Nos							
	Weakness							

Date: 10/08/1999 **ISR Number:** 3369153-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 75403 **Age:** 17 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Angioneurotic Oedema	Foreign	Roaccutane (Isotretinoin) 20 Mg	PS		ORAL		
	Back Pain	Literature	Roaccutane Gel (Isotretinoin) .05%	SS		TOPICAL		
	Blister	Health Professional	Diane 35 (Cyproterone Acetate/Ethinyl Estradiol)	C				
	Burning Sensation Nos	Other	Eryfluid (Erythromycin)	C				
	Dermatitis Bullous		Eclaran (Benzoyl Peroxide)	C				
	Drug Hypersensitivity		Concomitant Drug Unk (Generic Component(S) Unknown)	C				
	Face Oedema							
	Headache Nos							
	Influenza Like Illness							
	Insomnia Nec							
	Myalgia							
	Mycoplasma Infection Nos							
	Pruritus							

Date: 10/08/1999 **ISR Number:** 3369162-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 213686 **Age:** 30 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Cerebrovascular Arteriovenous Malformation (Exc Haemorrhagic)	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
	Cerebrovascular Disorder Nos							
	Hypoaesthesia							
	Memory Impairment							
	Paraesthesia Nec							
	Visual Disturbance Nos							

Date: 10/08/1999 **ISR Number:** 3369232-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 216377 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Delusion Nos	Health Professional	Accutane (Isotretinoin)	PS		ORAL		
	Insomnia Nec	Other						
	Mood Alteration Nos							
	Paranoia							
	Psychotic Disorder Nos							
	Suicidal Ideation							

Date: 10/13/1999 **ISR Number:** 3371538-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 214389 **Age:** 37 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Arrhythmia Nos	Health Professional	Accutane Capsules (Isotretinoin) 40mg	PS		ORAL		
	Chest Tightness		Insulin (Insulin)	C				
	Dermatitis Nos							
	Dyspnoea Nos							

Date: 10/13/1999 **ISR Number:** 3371540-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 214251 **Age:** 19 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Anxiety Nec	Other						
	Appetite Decreased							
	Arthralgia							
	Clumminess							
	Depression Nec							
	Dizziness (Exc Vertigo)							
	Head Injury							
	Insomnia Nec							
	Lip Dry							
	Myalgia							
	Nausea							
	Panic Attack							
	Relationship Breakdown							
	Suicidal Ideation							
	Weight Decreased							

Date: 10/13/1999 **ISR Number:** 3371685-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 202838 **Age:** 69 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos	Foreign	Tasmar (Tolcapone)	PS				
	Appetite Decreased	Health Professional	Madopar (Benserazide/Levodopa)	C				
	Atelectasis		Madopar Hbs (Benserazide/Levodopa)	C				
	Blood Potassium Decreased							
	Bundle Branch Block Right							
	C-Reactive Protein Increased							
	Fatigue							
	Hypotension							
	Influenza							
	Liver Function Tests Nos Abnormal							
	Loose Stools							
	Mental Impairment Nos							
	Pulmonary Congestion							
	Pulse Absent							
	Pyelonephritis Nos							
	Pyrexia							
	Renal Angle Tenderness							
	Renal Cyst Nos							
	Spinal Osteoarthritis							
	Urinary Tract Infection Nos							

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Date: 10/14/1999 **ISR Number:** 3372795-X **Report Type:** Expedited (15-Day) **Company Report Number:** 216377 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Anger Blood Pressure Fluctuation Bradycardia Nos Delusion Nos Educational Problem Fatigue Hallucination, Visual Headache Nos Insomnia Nec Mood Alteration Nos Nausea Overdose Nos Paranoia Psychotic Disorder Nos Stress Symptoms Suicidal Ideation	Health Professional Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 10/14/1999 **ISR Number:** 3372800-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 215202 **Age:** 1 WK **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Congenital Anomaly	Balance Impaired Nos Complications Of Maternal Exposure To Therapuetic Drugs Congenital Musculoskeletal Abnormality Nos Congenital Oral Malformation Nos Developmental Delay Nos Hypotonia Miosis Movement Disorder Nos Muscle Weakness Pregnancy Nos Pupils Unequal Sensory Disturbance Nos Speech Disorder (Developmental) Visual Disturbance Nos	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 10/14/1999 **ISR Number:** 3372802-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 217126 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Aggravated Schizophrenia Nos	Foreign Health Professional	Roaccutane (Isotretinoin)	PS		ORAL		

Date: 10/19/1999 **ISR Number:** 3376077-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 215202 **Age:** 1 WK **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Congenital Anomaly	Balance Impaired Nos Complications Of Maternal Exposure To Therapuetic Drugs Coordination Abnormal Nos Developmental Delay Nos Eye Movement Disorder Nos Gastrointestinal Malformation Nos Hypotonia Miosis Multiple Congenital Abnormalities Muscle Weakness Neurological Disorder Nos Opisthotonus Pupils Unequal Sensory Disturbance Nos Speech Disorder (Developmental) Visual Disturbance Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 10/19/1999 **ISR Number:** 3376172-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 217309 **Age:** 40 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Mania Paranoia	Foreign Health Professional	Roaccutane (Isotretinoin)	PS		ORAL		

Date: 10/19/1999 **ISR Number:** 3376185-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 211956 **Age:** 14 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Abdominal Pain Upper Blood In Stool Chest Pain Dry Skin Fatigue Gastritis Nos Hypersomnia	Other	Accutane Capsules (Isotretinoin) 40 Mg Prevacid (Lansoprazole) Vitamins (Multivitamin Nos)	PS C C		ORAL		

Date: 10/21/1999 **ISR Number:** 3378758-2 **Report Type:** Direct **Company Report Number:** **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Delusion Nos	Health Professional	Accutane	PS		ORAL		
	Mental Disorder Nec							
	Suicidal Ideation							

Date: 10/21/1999 **ISR Number:** 3378804-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 213780 **Age:** 51 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Back Pain	Consumer	Tasmar (Tolcapone)	PS		ORAL		
	Constipation	Health Professional	Sinemet (Carbidopa/Levodopa) 275 Mg	SS		ORAL		
	Depression Nec		Norvasc (Amlodipine Besylate)	C				
	Drooling		Synthroid (Levothyroxine Sodium)	C				
	Drug Interaction Nos		Miacalcin (Salcatonin)	C				
	Dysphagia							
	Dyspnoea Nos							
	Dystonia							
	Joint Stiffness							
	Liver Function Tests Nos Abnormal							
	Muscle Cramps							
	Muscle Spasms							
	Oedema Lower Limb							
	Pain In Jaw							
	Posture Abnormal							
	Sedation							
	Sleep Disorder Nos							
	Tardive Dyskinesia							
	Weight Decreased							

Date: 10/25/1999 **ISR Number:** 3382585-X **Report Type:** Expedited (15-Day) **Company Report Number:** 205301 **Age:** 17 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Ankylosing Spondylitis	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Antinuclear Factor Positive							
	Arthralgia							
	Blood Alkaline Phosphatase Nos Decreased							
	Depression Nec							
	Dermatitis Nos							
	Dry Mouth							
	Dry Skin							
	Erythrocyte Sedimentation Rate Increased							

Date: 10/26/1999 **ISR Number:** 3382631-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 214389 **Age:** 37 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Arrhythmia Nos	Health Professional	Accutane Capsules (Isotretinoin) 40mg	PS		ORAL		
	Chest Tightness		Insulin (Insulin)	C				
	Dermatitis Nos							
	Dyspnoea Nos							
	Herpes Zoster							
	Palpitations							

Date: 10/26/1999 **ISR Number:** 3382634-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 207894 **Age:** 36 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Acne Aggravated		Loestrin (Ethinyl Estradiol/Norethindrone Acetate)	C				
	Arthralgia		Paxil (Paroxetine)	C				
	Aspartate Aminotransferase Increased							
	Back Pain							
	Capillary Fragility Increased							
	Chest Pain							
	Depression Nec							
	Dry Skin							
	Fatigue							
	Headache Nos							
	Hypertriglyceridaemia							
	Irritability							
	Kidney Infection Nos							
	Myalgia							
	Ovarian Cyst							
	Pregnancy Nos							
	Tunnel Vision							
	Urine Discolouration							
	Vision Blurred							

Date: 10/27/1999 **ISR Number:** 3383684-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 111034 **Age:** 63 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Upper	Health Professional	Tasmar (Tolcapone) 200 Mg	PS		ORAL		
	Akinesia		Levodopa-Carbidopa (Carbidopa/Levodopa)	C				
	Anorexia		Mirapex (Pramipexole)	C				
	Back Pain		Effexor (Venlafaxine Hydrochloride)	C				
	Blood Albumin Decreased		Premarin (Estrogens, Conjugated)	C				
	Bradykinesia							
	Carpal Tunnel Syndrome							

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Date: 10/27/1999 **ISR Number:** 3383816-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 112764 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Blood Bilirubin Increased	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Depression Nec	Health Professional	Ortho Tri-Cyclen (Ethinylestradiol/Norgestimate)	C				
	Jaundice Neonatal							
	Pregnancy Nos							

Date: 10/28/1999 **ISR Number:** 3384820-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 218289 **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Acne Aggravated	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Hospitalization - Initial or Prolonged	Loss Of Consciousness Nec		Desogen (Desofestrel/ Ethinyl Estradiol)	C				
	Suicide Attempt		Tilade (Nedocromil Sodium)	C				
			Proventil (Albuterol Sulfate)	C				
			Seldane (Terfenadine)	C				

Date: 10/28/1999 **ISR Number:** 3384844-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 216399 **Age:** 36 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Computerised Tomogram Abnormal	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Diabetes Mellitus Nos	Other						
	Dyspnoea Nos							
	Eye Pain							
	Granuloma Nos							
	Headache Nos							
	Hemiparesis							
	Hypertension Nos							
	Palpitations							
	Parotid Gland Enlargement							
	Stress Symptoms							
	Visual Disturbance Nos							

Date: 11/02/1999 **ISR Number:** 3388335-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 215637 **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation	Foreign	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Delirium	Health Professional	Baclofen (Baclofen)	C				
	Emotional Disturbance Nos		Dixarit (Clonidine Hydrochloride)	C				

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Date: 11/03/1999 **ISR Number:** 3388792-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 206823 **Age:** 24 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Extrasystoles Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Palpitations							
	Pulsus Bigeminus							
	Ventricular Extrasystoles							

Date: 11/05/1999 **ISR Number:** 3390181-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 216464 **Age:** 59 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alanine Aminotransferase Increased	Foreign	Tasmar (Tolcapone)	PS				
	Condition Aggravated	Health Professional	Madopar (Benserazide/Levodopa)	C				
	Hyperbilirubinaemia		Sinemet (Carbidopa/Levodopa)	C				
	Liver Fatty		Mirapex (Pramipexole)	C				
	Markedly Increased Food Intake		Lexotanil (Bromazepam)	C				

Date: 11/08/1999 **ISR Number:** 3391373-X **Report Type:** Expedited (15-Day) **Company Report Number:** 206256 **Age:** 68 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Akinesia	Foreign	Tasmar (Tolcapone) 100 Mg	PS		ORAL		
	Blood Lactate Dehydrogenase Increased	Health Professional	Madopar (Benserazide/Levodopa)	C				
	C-Reactive Protein Increased	Other	Madopar Hbs (Benserazide/Levodopa)	C				
	Cerebrovascular Accident Nos		Proscar (Finasteride)	C				
	Condition Aggravated		Tolvon (Mianserin Hydrochloride)	C				
	Confusion		Importal (Lactitol)	C				
	Fall		Parlodel (Bromocriptine Mesylate)	C				
	Haematuria Present							
	Mental Impairment Nos							
	Parkinson'S Disease Aggravated							
	Proteinuria Present							
	Pyrexia							
	Rigors							
	Transaminase Nos Increased							
	Tremor Nec							
	Urinary Tract Infection Nos							
	Urine Analysis Abnormal Nos							
	Urine Discolouration							
	White Blood Cells Urine Positive							

Date: 11/16/1999 **ISR Number:** 3398298-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 213780 **Age:** 51 YR **Gender:** Female

Outcome	PT
Hospitalization - Initial or Prolonged	Back Pain
	Depression Nec
	Drooling
	Drug Interaction Nos
	Dysphagia
	Dyspnoea Nos
	Dystonia
	Eating Disorder Nec
	Fatigue
	Joint Stiffness
	Liver Function Tests Nos Abnormal
	Muscle Spasms
	Oedema Lower Limb
	Pain In Jaw
	Pain Nos
	Posture Abnormal
	Sedation
	Sleep Disorder Nos
	Tardive Dyskinesia
	Weight Decreased

Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Consumer	Tasmar (Tolcapone)	PS		ORAL		
Health Professional	Sinemet (Carbidopa/Levodopa) 275 Mg	SS		ORAL		
	Norvasc	C				
	Synthroid (Levothyroxine Sodium)	C				
	Miacalcin (Salcatonin)	C				

Date: 11/17/1999 **ISR Number:** 3398586-1 **Report Type:** Direct **Company Report Number:** **Age:** 69 YR **Gender:** Male

Outcome	PT
Hospitalization - Initial or Prolonged	Confusion
	Hallucination Nos

Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Health Professional	Tasmar (Tolcapone)	PS				
	Sinemet	SS				

Date: 11/19/1999 **ISR Number:** 3402811-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 213055 **Age:** 26 YR **Gender:** Female

Outcome	PT
Other	Abdominal Tenderness
	Anorexia
	Anxiety Nec
	Arrhythmia Nos
	Arthralgia
	Chest Pain
	Depression Nec
	Dizziness (Exc Vertigo)
	Dyspnoea Nos
	Hyperthyroidism

Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Birth Control Pills (Oral Contraceptive Nos)	C				

Date: 11/19/1999 **ISR Number:** 3402815-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 112585 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Acne Infantile	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Blood Bilirubin Increased		Oral Contraceptive Pill (Oral Contraceptive Nos)	C				
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Dry Skin							
	Eye Discharge							
	Hypersomnia							
	Intestinal Functional Disorder Nos							
	Jaundice Nos							
	Lacrimal Duct Obstruction Congenital							
	Nasal Congestion							
	Pregnancy Nos							
	Premature Baby							
	Pyrexia							
	Red Eye							
	Seborrhoea							
	Small For Dates Baby							
	Upper Respiratory Tract Infection Nos							

Date: 11/22/1999 **ISR Number:** 3405415-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 213780 **Age:** 51 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Back Pain	Consumer	Tasmar (Tolcapone)	PS		ORAL		
	Constipation	Health Professional	Sinemet (Carbidopa/Levodopa) 275 Mg	SS		ORAL		
	Depression Nec		Norvasc	C				
	Drooling		Synthroid	C				
	Drug Interaction Nos		Miacalcin	C				
	Dysphagia							
	Dyspnoea Nos							
	Dystonia							
	Fatigue							
	Joint Stiffness							
	Liver Function Tests Nos Abnormal							
	Muscle Cramps							
	Muscle Spasms							
	Oedema Lower Limb							
	Pain In Jaw							
	Posture Abnormal							

Date: 11/29/1999 **ISR Number:** 3409743-X **Report Type:** Expedited (15-Day) **Company Report Number:** 213286 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Acne Nos	Other						
	Choking							
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Cough							
	Dermatitis Nos							
	Diarrhoea Nos							
	Granuloma Nos							
	Insomnia Nec							
	Meconium Increased							
	Nasal Congestion							
	Pyrexia							
	Rhinorrhoea							
	Seborrhoea							
	Sneezing							
	Umbilical Cord Around Neck							
	Upper Respiratory Tract Infection Nos							
	Vomiting Nos							

Date: 11/24/1999 **ISR Number:** 3409908-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 214389 **Age:** 37 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Arrhythmia Nos	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
	Chest Tightness		Insulin	C				
	Dyspnoea Nos							
	Herpes Zoster							
	Palpitations							

Date: 11/26/1999 **ISR Number:** 3410148-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 220614 **Age:** 20 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Disability	Anxiety Nec		Excedrin Pm (Acetaminophen/Diphenhydramine Citrate)	C				
	Atrial Fibrillation		Lipoic Acid (Thioctic Acid)	C				
	Burning Sensation Nos		Herbal Drugs Nos (Herbal Extract Nos)	C				
	Coma Nec		Multivitamin (Multivitamin Nos)	C				
	Convulsions Nos							
	Depression Nec							
	Dry Eye Nec							
	Dry Mouth							

Date: 11/26/1999 **ISR Number:** 3411147-0 **Report Type:** Periodic **Company Report Number:** 217892 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Feeling Abnormal Nervousness	Consumer	Tasmar (Tolcapone)	PS				

Date: 11/26/1999 **ISR Number:** 3411149-4 **Report Type:** Periodic **Company Report Number:** 201192 **Age:** 44 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthralgia Headache Nos Hormone Level Nos Abnormal Orgasm Abnormal Pain In Limb	Consumer	Tasmar (Tolcapone) 100 Mg	PS		ORAL		
			Herbal Diuretic Nos (Herbal Diuretic Nos)	SS		ORAL		
			Sinemet Cr (Carbidopa/Levodopa)	C				
			Sinemet (Carbidopa/Levodopa)	C				
			Carmex (Aluminum Salicylic Acid/Camphor/Menthol)	C				
			Excedrin (Acetaminophen/*Aspirin/Caffeine)	C				
			Eldepryl (Selegiline Hydrochloride)	C				

Date: 12/02/1999 **ISR Number:** 3412817-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 213780 **Age:** 51 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Back Pain Constipation Depression Nec Drooling Drug Interaction Nos Dysphagia Dyspnoea Nos Dystonia Fatigue Joint Stiffness Liver Function Tests Nos Abnormal Movement Disorder Nos Muscle Spasms Oedema Lower Limb Pain In Jaw Posture Abnormal Sedation Sleep Disorder Nos Tardive Dyskinesia Weight Decreased	Consumer Health Professional	Tasmar (Tolcapone)	PS		ORAL		
			Sinemet (Carbidopa/Levodopa) 275 Mg	SS		ORAL		
			Norvasc (Amlodipine Besylate)	C				
			Synthroid (Levothyroxine Sodium)	C				
			Miacalcin (Salcatonin)	C				

Date: 12/02/1999 **ISR Number:** 3413257-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 213055 **Age:** 26 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Tenderness	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Anorexia		Birth Control Pills (Oral Contraceptive Nos)	C				
	Anxiety Nec							
	Arthralgia							
	Blood Amylase Increased							
	Chest Pain							
	Depression Nec							
	Dizziness (Exc Vertigo)							
	Dyspnoea Nos							
	Extrasystoles Nos							
	Liver Tenderness							
	Myalgia							
	Pulmonary Valve Incompetence							
	Pulsus Bigeminus							
	Sinus Arrhythmia							
	Sinus Bradycardia							
	Supraventricular Tachycardia							
	Tremor Nec							
	Tricuspid Valve Incompetence							
	Ventricular Extrasystoles							

Date: 12/02/1999 **ISR Number:** 3413315-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 213780 **Age:** 51 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Back Pain	Consumer	Tasmar (Tolcapone)	PS		ORAL		
	Constipation	Health Professional	Sinemet (Carbidopa/Levodpa) 275 Mg	SS		ORAL		
	Depression Nec		Norvasc (Amlodipine Besylate)	C				
	Drooling		Synthroid (Levothyroxine Sodium)	C				
	Drug Interaction Nos		Miacalcin (Salactonin)	C				
	Dysphagia							
	Dyspnoea Nos							
	Dystonia							
	Fatigue							
	Liver Function Tests Nos Abnormal							
	Muscle Spasms							
	Muscle Stiffness							
	Oedema Lower Limb							
	Pain In Jaw							
	Posture Abnormal							
	Restlessness							

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Date: 12/02/1999 **ISR Number:** 3413316-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 215436 **Age:** 68 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alanine Aminotransferase Increased	Foreign	Tasmar (Tolcapone)	PS				
	Blood Amylase Increased	Health Professional	Sifrol (Pramipexole)	SS				
	Blood Bilirubin Increased		Madopar Hbs (Benserazide/Levodopa)	C				
	Blood Creatine Kinase Low		Madopar Dr (Benserazide/Levodopa)	C				
	Blood Iron Increased		Jumexal (Selegiline Hydrochloride)	C				
	Hallucination Nos		Pk-Merz (Amantadine Sulfate)	C				
	Hyperglycaemia Nos		Saroten (Amitriptyline Hydrochloried)	C				
	Lipase Increased		Dafalgan (Acetaminophen)	C				
			Mst (Morphine Sulfate)	C				
			Effortil (Etilefrine)	C				

Date: 12/03/1999 **ISR Number:** 3413772-X **Report Type:** Expedited (15-Day) **Company Report Number:** 220614 **Age:** 20 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Anxiety Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Disability	Burning Sensation Nos		Excedrin Prn	C				
	Coma Nec		Lipoic Acid	C				
	Convulsions Nos		Herbal Drug Nos	C				
	Cyanosis Nos		Multivitamin	C				
	Depression Nec							
	Dry Mouth							
	Dry Skin							
	Flushing							
	Hyponatraemia							
	Lymphadenopathy							
	Pain Nos							
	Paraesthesia Nec							
	Psoriasis							
	Pyrexia							
	Skin Discolouration							
	Tachycardia Nos							
	Thinking Abnormal Nec							
	Vision Blurred							
	Weight Decreased							

Date: 12/06/1999 **ISR Number:** 3415083-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 216931 **Age:** 19 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos	Health Professional	Accutane Capsules (Isotretinoin) 60 Mg	PS		ORAL		

Date: 12/06/1999 **ISR Number:** 3415083-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 221931

PT	Report Source
Abnormal Behaviour Nos	Other
Appetite Disorder Nos	
Confusion	
Crying	
Delusion Nos	
Hair Growth Abnormal	
Hirsutism	
Insomnia Nec	
Paranoia	
Psychotic Disorder Nos	
Rectal Bleeding	

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane Capsules (Isotretinoin) 60 Mg	PS		ORAL		

Date: 12/14/1999 **ISR Number:** 3421131-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 216188 **Age:** **Gender:** Unknown

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Depression Nec	Other
	Ectopic Pregnancy	
	Insomnia Nec	
	Pregnancy Nos	

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 12/14/1999 **ISR Number:** 3421204-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 221924 **Age:** 35 YR **Gender:** Female

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Blindness Night	Consumer
	Breast Neoplasm Nos	
	Condition Aggravated	
	Depression Aggravated	
	Fibrocystic Breast Disease	
	Myalgia	

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 12/14/1999 **ISR Number:** 3421351-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 221710 **Age:** 70 YR **Gender:** Female

Outcome	PT	Report Source
Life-Threatening	Blood Creatine Phosphokinase Increased	Foreign
Hospitalization - Initial or Prolonged	Coma Nec	Health Professional
	Depression Nec	Other
	Drug Interaction Nos	
	Gastrointestinal Disorder Nos	
	Hepatic Disorder Nos	
	Liver Function Tests Nos Abnormal	
	Mental Disorder Nec	

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Tasmar (Tolcapone) 100 Mg	PS		ORAL		
Madopar Dr (Benserazide/Levodopa) 250 Mg	SS		ORAL		
Ditropan (Oxybutynin Chloride) 5 Mg	SS		ORAL		
Tryptizol (Amitriptyline Hydrochloride) 25 Mg	SS		ORAL		
Motilium (Domperidone) 10 Mg	SS		ORAL		
Leponex (Clozapine) 25 Mg	SS		ORAL		
Celebrex (Celecoxib) 100 Mg	SS		ORAL		

Date: 12/17/1999 **ISR Number:** 3425364-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 213055 **Age:** 26 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Tenderness Anorexia Anxiety Nec Arthralgia Chest Pain Depression Nec Dermatitis Nos Disorientation Dizziness (Exc Vertigo) Dyspnoea Nos Gastrointestinal Disorder Nos Heart Rate Irregular Liver Tenderness Myalgia Pulmonary Valve Incompetence Sinus Arrhythmia Sinus Bradycardia Supraventricular Tachycardia Tricuspid Valve Incompetence Ventricular Extrasystoles	Health Professional	Accutane Capsules (Isotretinoin) Birth Control Pills (Oral Contraceptive Nos)	PS C		ORAL		

Date: 12/20/1999 **ISR Number:** 3425788-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 221924 **Age:** 35 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Blindness Night Breast Neoplasm Nos Condition Aggravated Depression Aggravated Fibrocystic Breast Disease Myalgia	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 12/20/1999 **ISR Number:** 3425805-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 222459 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Congenital Anomaly	Abdominal Pain Nos Apnoea Blindness Congenital Complications Of Maternal Exposure To Therapuetic Drugs Convulsions Nos Deafness Congenital Deafness Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		

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Date: 12/21/1999 **ISR Number:** 3426814-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 218289 **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Acne Aggravated	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Hospitalization - Initial or Prolonged	Loss Of Consciousness Nec		Desogen (Desogestrel/Ethinyl Estradiol)	C				
	Suicide Attempt		Tilade (Nedocromil Sodium)	C				
			Slo-Bid (Theophylline)	C				
			Proventil (Albuterol Sulfate)	C				
			Seldane (Trefenadine)	C				

Date: 12/21/1999 **ISR Number:** 3426937-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 222670 **Age:** 71 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos	Consumer	Tasmar (Tolcapone)	PS		ORAL		
	Back Pain		Sinemet Cr (Carbidopa/Levodopa)	C				
	Confusion							
	Drug Withdrawal Syndrome							
	Fatigue							
	Increased Activity							
	Insomnia Nec							
	Nervousness							
	Pain In Limb							

Date: 12/23/1999 **ISR Number:** 3430498-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 222691 **Age:** 4 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Ataxia Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Cerebral Oedema		Versed Injection (Midazolam Hydrochloride) 1.5 Mg	SS		INTRAVENOUS DRIP		
	Coma Nec		Pentamidine (Pentamidine)	C				
	Convulsions Nos							
	Electroencephalogram Abnormal							
	Hallucination Nos							
	Hypoxia							
	Inappropriate Adh Secretion							
	Muscle Twitching							
	Mydriasis							
	Tardive Dyskinesia							

Date: 12/23/1999 **ISR Number:** 3430539-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 222455 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Complications Of Maternal Exposure To Therapuetic Drugs	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Deafness Nos							

Date: 12/23/1999 **ISR Number:** 3430540-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 222433 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos Biliary Tract Disorder Nos Depression Nec Hepatic Disorder Nos Hepatitis Nos Operation Nos Pancreatitis Nos Pregnancy Nos Pyelonephritis Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 12/28/1999 **ISR Number:** 3432761-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 221924 **Age:** 35 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Blindness Night Breast Neoplasm Nos Condition Aggravated Depression Aggravated Drug Ineffective Fibrocystic Breast Disease Myalgia	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 12/28/1999 **ISR Number:** 3432800-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 107096 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blindness Transient Colitis Ulcerative Confusion Diarrhoea Nos Difficulty In Walking Drug Ineffective Fear, Focus Nec Gangrene Nos Haematuria Present Headache Nos Insomnia Nec Lip Dry Listless Negativism Personality Change Protein Total Increased Suspiciousness	Foreign Literature Other	Roaccutane (Isotretinoin)	PS		ORAL		

Date: 01/04/2000 **ISR Number:** 3436586-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 214314 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Human Chorionic Gonadotrophin Abnormal	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Chromosome Analysis Nos Abnormal	Other	Zoloft (Sertraline Hydrochloride)	C				
	Complications Of Maternal Exposure To Therapuetic Drugs		Prenatal Vitamins (Minerals Nos/Multivitam Nos)	C				
	Meconium Increased							
	Pregnancy Nos							
	Umbilical Cord Around Neck							
	Vaginal Haemorrhage							

Date: 01/04/2000 **ISR Number:** 3436628-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 222823 **Age:** 32 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Alopecia	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Blood Cholesterol Increased		Ortho Tri-Cyclen	C				
	Blood Triglycerides Increased							
	Depression Nec							
	Dizziness (Exc Vertigo)							
	Hair Growth Abnormal							
	Hair Texture Abnormal							
	Headache Nos							
	High Density Lipoprotein Increased							
	Palpitations							
	Panic Attack							

Date: 12/29/1999 **ISR Number:** 3442667-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 212007 **Age:** 54 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Akinesia	Foreign	Tasmar (Tolcapone)	PS				
	Alanine Aminotransferase Increased	Health Professional	Madopar (Benserazide/Levodopa)	C				
	Blood Calcium Decreased		Parlodel (Bromocriptine Mesylate)	C				
	Blood Sodium Decreased		Jumexal (Selegiline Hydrochloride)	C				
	Culture Urine Positive		Lexotanil (Bromazepam)	C				
	Drug Maladministration							
	Dyskinesia Nec							
	Dystonia							
	Haematocrit Decreased							
	Haemoglobin Decreased							
	Muscle Cramps							
	Myalgia							

Date: 12/29/1999 **ISR Number:** 3443284-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 212007 **Age:** 54 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Akinesia	Foreign	Tasmar (Tolcapone)	PS				
	Aspartate Aminotransferase Increased	Health Professional	Madopar (Benserazide/Levodopa)	C				
	Blood Uric Acid Decreased		Parlodel (Bromocriptine Mesylate)	C				
	Discomfort Nos		Jumexal (Selegiline Hydrochloride)	C				
	Dyskinesia Nec		Lexotanil (Bromazepam)	C				
	Dystonia							
	Hypotension							
	Motor Dysfunction Nos							
	Muscle Cramps							
	Muscle Rigidity							
	Myalgia							
	Nail Dystrophy							
	Pain Nos							
	Parkinson'S Disease Aggravated							
	Rash Maculo-Papular							
	Red Blood Cell Count Decreased							
	Restlessness							
	Speech Disorder Nec							
	Tremor Nec							
	White Blood Cells Urine Positive							

Date: 01/12/2000 **ISR Number:** 3443466-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 215867 **Age:** 17 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos	Foreign	Roaccutane (Isotretinoin)	PS				
	Depression Nec	Other						
	Drug Abuse							
	Emotional Disturbance Nos							
	Hiv Test Positive							
	Suicidal Ideation							

Date: 01/13/2000 **ISR Number:** 3443551-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 212007 **Age:** 54 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Akinesia	Foreign	Tasmar (Tolcapone)	PS				
	Aspartate Aminotransferase Increased	Health Professional	Madopar (Benserazide/Levodopa)	C				
	Dyskinesia Nec		Parlodel (Bromocriptine Mesylate)	C				
	Hallucination Nos		Jumexal (Selegiline Hydrochloride)	C				
	Hyporeflexia		Lexotanil (Bromazepam)	C				

Date: 01/20/2000 **ISR Number:** 3445706-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 213686 **Age:** 30 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Cerebrovascular Disorder Nos	Health Professional	Accutane	PS		ORAL		
	Hypoaesthesia							
	Memory Impairment							
	Paraesthesia Nec							
	Visual Disturbance Nos							

Date: 01/13/2000 **ISR Number:** 3445851-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 212007 **Age:** 54 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Akinesia	Foreign	Tasmar (Tolcapone)	PS				
	Aspartate Aminotransferase Increased	Health Professional	Madopar (Benserazide/Levdopa)	C				
	Dyskinesia Nec		Parlodel (Bromocriptine Mesylate)	C				
	Hallucination Nos		Jumexal (Selegiline Hydrochloride)	C				
	Masked Facies		Lexotanil (Bromazepam)	C				
	Muscle Cramps							
	Muscle Rigidity							
	Myalgia							
	Nail Dystrophy							
	Parkinson'S Disease Aggravated							
	Rash Maculo-Papular							
	Reflexes Abnormal Nec							
	Restlessness							
	Tremor Nec							

Date: 01/24/2000 **ISR Number:** 3447037-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 225455 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane Capsules (Isotretinoin) 20 Mg	PS		ORAL		
	Disorientation							
	Lethargy							

Date: 01/28/2000 **ISR Number:** 3448134-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 223642 **Age:** 16 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Back Pain	Other						
	Blister							
	Depression Nec							
	Fatigue							
	Gastrointestinal Disorder Nos							
	Lip Disorder Nos							
	Lip Dry							

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Date: 01/28/2000 **ISR Number:** 3448196-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 209062 **Age:** 42 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Condition Aggravated	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Deafness Nos	Other	Birth Control Pills (Oral Contraceptive Nos)	C				
	Dry Eye Nec		Calcium Supplement (Calcium Nos)	C				
	Lip Disorder Nos		Ziac (Bisoprolol Fumarate/Hydrochlorothiazide)	C				
	Localised Exfoliation		Potassium (Potassium Nos)	C				
	Paranoia		Zantac (Ranitidine)	C				
	Red Eye							

Date: 02/01/2000 **ISR Number:** 3449624-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 222763 **Age:** 20 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Appetite Increased	Foreign	Roaccutane (Isotretinoin)	PS		ORAL		
	Depression Aggravated	Health Professional	Cycline Nos (Cycline Nos)	C				
	Self-Induced Vomiting		Meliane (Ethinyl Estradiol/Gestodene)	C				

Date: 02/03/2000 **ISR Number:** 3451611-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 216377 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Abnormal Behaviour Nos	Other						
	Anger							
	Blood Pressure Diastolic Decreased							
	Blood Pressure Fluctuation							
	Bradycardia Nos							
	Delusion Nos							
	Drug Maladministration							
	Educational Problem							
	Fatigue							
	Hallucination, Visual							
	Headache Nos							
	Insomnia Nec							
	Mood Alteration Nos							
	Nausea							
	Paranoia							
	Physical Abuse							
	Psychotic Disorder Nos							
	Stress Symptoms							
	Suicidal Ideation							

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Date: 02/08/2000 **ISR Number:** 3454679-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 215250 **Age:** 25 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Prolactin Increased	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Pituitary Tumour Benign Nos		Vancenase Inhaler (Beclomethasone Dipropionate)	C				
	Sexual Dysfunction Nos							

Date: 02/08/2000 **ISR Number:** 3455299-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 222246 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Appetite Decreased	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Complication Of Delivery Nos	Other	Oral Contraceptive Pill (Oral Contraceptive Nos)	C				
	Complications Of Maternal Exposure To Therapuetic Drugs		Vitamins (Multivitamin Nos)	C				
	Complications Of Pregnancy Nos							
	Depression Nec							
	Fatigue							
	Feeding Problem In Newborn							
	Foetal Malposition Nos							
	Influenza							
	Insomnia Nec							
	Jaundice Neonatal							
	Nipple Pain							
	Perineal Laceration							
	Pregnancy Nos							
	Sedation							
	Tenesmus							
	Thirst							
	Uterine Hypertonus							
	Vaginitis							
	Vomiting Nos							
	Weight Decreased							

Date: 02/11/2000 **ISR Number:** 3457295-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 227340 **Age:** 17 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Intentional Self-Injury	Other						
	Obsessive-Compulsive Disorder							
	Stress Symptoms							

Date: 02/15/2000 **ISR Number:** 3458434-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 216377 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Anger	Other						
	Blood Pressure Fluctuation							
	Bradycardia Nos							
	Delusion Nos							
	Drug Maladministration							
	Fatigue							
	Hallucination, Visual							
	Headache Nos							
	Insomnia Nec							
	Mood Alteration Nos							
	Nausea							
	Paranoia							
	Psychotic Disorder Nos							
	Stress Symptoms							
	Suicidal Ideation							

Date: 02/15/2000 **ISR Number:** 3458461-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 227780 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Anomaly Of External Ear Congenital Nos	Literature	Accutane Capsules (Isotretinoin)	PS		ORAL		
Congenital Anomaly	Anomaly Of Inner Ear Congenital Nos	Health Professional						
	Anomaly Of Middle Ear Congenital Nos							
	Cardiac Arrest							
	Chiari Malformation							
	Colonic Haemorrhage							
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Congenital Abnormality Nos							
	Congenital Central Nervous System Anomaly Nos							
	Congenital Hydrocephalus							
	Congenital Skull Malformation Nos							
	Convulsions Nos							
	Facial Nerve Disorder Nos							
	Gastrointestinal Malformation Nos							
	Mucosal Haemorrhage Nos							
	Profound Mental Retardation							

Date: 02/17/2000 **ISR Number:** 3459430-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 227868 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
	Fatigue							
	Oedema Upper Limb							
	Skin Discolouration							
	Venous Thrombosis Nos							

Date: 02/17/2000 **ISR Number:** 3459462-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 220614 **Age:** 20 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Anxiety Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Disability	Burning Sensation Nos		Excedrin Pm (Acetaminophen/Diphenhydramine Citrate)	C				
	Cyanosis Nos		Lipoic Acid (Thioctic Acid)	C				
	Depression Nec		Herbal Drug Nos (Herbal Extract Nos)	C				
	Distress		Multivitamin (Multivitamin Nos)	C				
	Dry Eye Nec							
	Dry Mouth							
	Dry Skin							
	Fatigue							
	Feeling Hot							
	Flushing							
	Heart Rate Increased							
	Hypoaesthesia							
	Hyponatraemia							
	Lymphadenopathy							
	Nasal Dryness							
	Obsessive-Compulsive Disorder							
	Pain Nos							
	Palpitations							
	Paraesthesia Nec							
	Psoriasis							
	Pyrexia							
	Rash Scaly							
	Skin Discolouration							
	Tachycardia Nos							
	Thinking Abnormal Nec							
	Thirst							
	Tremor Nec							
	Vision Blurred							
	Weakness							
	Weight Decreased							

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Date: 02/24/2000 **ISR Number:** 3462602-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 228996 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos Appendicitis Caesarean Section Complications Of Maternal Exposure To Therapuetic Drugs Eczema Nos Foetal Distress Syndrome Jaundice Nos Lip Dry Mood Swings Multiple Allergies Myalgia Pregnancy Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 02/24/2000 **ISR Number:** 3462603-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 228998 **Age:** 20 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Abdominal Pain Nos Appendicitis Caesarean Section Foetal Distress Syndrome Jaundice Nos Lip Dry Mood Swings Myalgia	Consumer	Accutane Capsules (Isotretinoin) Multivitamin (Multivitamin Nos)	PS C		ORAL		

Date: 02/29/2000 **ISR Number:** 3465882-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 224385 **Age:** 25 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Depression Nec Diarrhoea Nos Dry Eye Nec Lip Dry Mood Alteration Nos Mood Swings Nasal Dryness Personality Change	Foreign Health Professional	Roaccutane (Isotretinoin) 20 Mg	PS		ORAL		

Date: 02/29/2000 **ISR Number:** 3465884-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 229400 **Age:** 19 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Acute Psychosis Panic Attack	Consumer	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		

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Date: 03/01/2000 **ISR Number:** 3466579-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 225455 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane Capsules (Isotretinoin) 20 Mg	PS		ORAL		
	Disorientation							
	Lethargy							
	Thinking Abnormal Nec							

Date: 03/01/2000 **ISR Number:** 3466587-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 222433 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Apnoea							
	Biliary Tract Disorder Nos							
	Blindness Congenital							
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Convulsions Nos							
	Deafness Congenital							
	Depression Nec							
	Ear Infection Nos							
	Hepatic Disorder Nos							
	Hepatitis Nos							
	Operation Nos							
	Pancreatitis Nos							
	Pregnancy Nos							
	Pyelonephritis Nos							

Date: 03/03/2000 **ISR Number:** 3469799-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 216222 **Age:** 1 HR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Air Swallowing	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Apgar Score Low	Other	Oral Contraceptive Pill	C				
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Constipation							
	Cough							
	Disorder Foetal Nos							
	Ear Infection Nos							
	Feeding Problem In Newborn							
	Flatulence							
	Foetal Distress Syndrome							
	Foetal Movements Decreased							
	Haemangioma Nos							
	Heart Rate Decreased							

Date: 03/03/2000 **ISR Number:** 3469803-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 224469 **Age:** 32 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Cerebrovascular Accident Nos	Consumer	Accutane Capsules (Isotretinoin) 10 Mg	PS		ORAL		
	Headache Nos							
	Hemiplegia							
	Memory Impairment							
	Speech Disorder Nec							
	Vertigo Nec							

Date: 03/08/2000 **ISR Number:** 3471112-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 220614 **Age:** 20 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Anxiety Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Disability	Burning Sensation Nos		Excedrin Pm (Acetaminophen / Diphenhydramine Citrate	C				
	Coma Nec		Lipoic Acid (Thioctic Acid)	C				
	Confusion		Herbal Drug Nos (Herbal Extract Nos)	C				
	Convulsions Nos		Multivitamin (Multivitamin Nos)	C				
	Cyanosis Nos							
	Depression Nec							
	Distress							
	Dry Eye Nec							
	Dry Mouth							
	Dry Skin							
	Fatigue							
	Feeling Abnormal							
	Feeling Hot							
	Flushing							
	Groin Pain							
	Heart Rate Increased							
	Hypoaesthesia							
	Hyponatraemia							
	Lymphadenopathy							
	Nasal Dryness							
	Obsessive-Compulsive Disorder							
	Pain Nos							
	Palpitations							
	Paresthesia Nec							
	Psoriasis							
	Pyrexia							
	Rash Scaly							
	Respiratory Rate Increased							
	Skin Discolouration							
	Skin Disorder Nos							

Date: 02/29/2000 **ISR Number:** 3471405-0 **Report Type:** Periodic **Company Report Number:** 224544 **Age:** 65 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Atrial Fibrillation	Consumer	Tasmar (Tolcapone)	PS		ORAL		
	Dyspnoea Nos		Sinemet Cr	C				
	Palpitations		Vitamins And Minerals	C				
	Tachycardia Nos		Vitamin B12 Injection	C				

Date: 03/08/2000 **ISR Number:** 3472116-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 217494 **Age:** 29 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Arthralgia	Health Professional	Naprosyn (Naproxen)	SS		ORAL		
	Back Pain		Amitriptyline (Amitriptyline Hydrochloride)	C				
	Bronchitis Nos		Xanax (Alprazolam)	C				
	Burning Sensation Nos		Cortisone Cream (Cortisone Acetate)	C				
	Condition Aggravated							
	Cough							
	Decreased Activity							
	Dermatitis Nos Aggravated							
	Dry Eye Nec							
	Dry Skin							
	Dry Throat							
	Ecchymosis							
	Eczema Exacerbated							
	Epistaxis							
	Erythrocyte Sedimentation Rate Increased							
	Headache Nos							
	Herpes Simplex							
	Hypercholesterolaemia							
	Hyperglycaemia Nos							
	Hypertriglyceridaemia							
	Injury Nos							
	Keratitis Nec							
	Laryngitis Nos							
	Lip Dry							
	Localised Exfoliation							
	Menstrual Disorder Nos							
	Migraine Nos							
	Muscle Cramps							
	Photophobia							
	Pulmonary Oedema Nos							

Date: 03/09/2000 **ISR Number:** 3472118-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 227340 **Age:** 17 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Anxiety Nec	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Depression Nec	Other						
	Hair Plucking							
	Intentional Self-Injury							
	Obsessive-Compulsive Disorder							
	Stress Symptoms							

Date: 03/09/2000 **ISR Number:** 3472398-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 228883 **Age:** 70 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Cognitive Disorder Nec	Consumer	Tasmar (Tolcapone)	PS		ORAL		
	Depression Nec	Health Professional	Sinemet-25/100 (Carbidopa/Levodopa)	C				
	Gambling		Vitamin (Vitamin Nos)	C				
	Mania							
	Nervousness							
	Obsessive-Compulsive Disorder							
	Road Traffic Accident							

Date: 03/09/2000 **ISR Number:** 3472594-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 228989 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Acne Aggravated	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Blood Triglycerides Increased							
	Convulsions Nos							
	Depression Nec							
	Insomnia Nec							
	Lipids Nos Increased							
	Loss Of Consciousness Nec							
	Road Traffic Accident							

Date: 03/10/2000 **ISR Number:** 3473395-3 **Report Type:** Direct **Company Report Number:** **Age:** 39 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Congenital Anomaly	Abortion Induced Nos	Consumer	Accutane	PS				
Other	Alopecia							
	Benign Intracranial Hypertension							
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Cystic Hygroma							
	Depression Nec							
	Disorder Foetal Nos							
	Dry Eye Nec							

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Date: 03/10/2000 **ISR Number:** 3473773-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 83462 **Age:** 21 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Abnormal Behaviour Nos	Foreign	Roaccutane (Isotretinoin)	PS		ORAL		
	Appetite Decreased	Literature	Flixotide (Fluticasone Propionate)	C				
	Cheilitis	Health Professional	Clindamycin (Clindamycin)	C				
	Completed Suicide	Other	Minocin (Minocycline Hydrochloride)	C				
	Decreased Interest							
	Dry Mouth							
	Dry Skin							
	Fatigue							
	Lip Dry							
	Localised Exfoliation							
	Personality Change							
	Photophobia							
	Social Avoidant Behaviour							

Date: 03/14/2000 **ISR Number:** 3475557-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 228200 **Age:** 17 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos	Foreign	Roaccutane (Isotretinoin)	PS		ORAL		
	Psychotic Disorder Nos	Health Professional						
	Thyrotoxicosis							

Date: 03/14/2000 **ISR Number:** 3475559-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 222433 **Age:** 34 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Apnoea							
	Biliary Tract Disorder Nos							
	Blindness Congenital							
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Convulsions Nos							
	Deafness Congenital							
	Depression Nec							
	Diarrhoea Nos							
	Ear Infection Nos							
	Hepatectomy (Partial)							
	Hepatic Disorder Nos							
	Hepatitis Nos							
	Malabsorption							
	Nausea							
	Operation Nos							
	Pancreatitis Nos							

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Date: 03/15/2000 **ISR Number:** 3476304-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 230859 **Age:** 13 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos Acne Aggravated Blood Alkaline Phosphatase Nos Increased Hyperglycaemia Nos Hypertriglyceridaemia	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		

Date: 03/20/2000 **ISR Number:** 3477855-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 229298 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Alkaline Phosphatase Nos Decreased Blood Calcium Increased Dyspnoea Nos Eosinophilia (Exc Pulmonary) Epiphyses Premature Fusion Fatigue Haemoglobin Decreased Hyperparathyroidism Nos Irritability Lethargy Liver Function Tests Nos Abnormal Monocytosis Skin Discolouration	Foreign Consumer	Accutane (Isotretinoin) Beconase (Beclomethasone Dipropionate)	PS C		ORAL		

Date: 03/21/2000 **ISR Number:** 3478193-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 228989 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Acne Aggravated Blood Triglycerides Increased Convulsions Nos Depression Nec Drug Maladministration Insomnia Nec Loss Of Consciousness Nec Road Traffic Accident	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 03/20/2000 **ISR Number:** 3478284-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 93625 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Anhedonia Asphyxiation	Health Professional Other	Accutane Capsules (Isotretinoin)	PS		ORAL		