Date: 05/20/1998 **ISR Number:** 3080382-6 **Report Type:** Direct **Company Report Number:** **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos		Accutane	PS				
Disability	Mental Disorder Nec							
Required Intervention to Prevent Permanent Impairment/Damage	Schizophrenia Nos							

Date: 05/06/1998 **ISR Number:** 3080757-5 **Report Type:** Direct **Company Report Number:** **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Appetite Decreased		Accutane	PS				
	Depression Nec							
	Fatigue							
	Mental Impairment Nos							
	Nervousness							
	Suicidal Ideation							

Date: 05/20/1998 **ISR Number:** 3081102-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 98350 **Age:** 42 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Upper	Consumer	Accutane	PS		ORAL		
	Anxiety Nec		Loestrin	C				
	Breast Pain		Humulin	C				
	Diplopia		Axid	C				
	Disorientation		Propulsid	C				
	Dizziness (Exc Vertigo)		Lotensin	C				
	Dry Skin		Norvasc	C				
	Feeling Abnormal		Klonopin	C				
	Headache Nos							
	Headache Nos Aggravated							
	Hypertension Nos							
	Lip Dry							
	Tachycardia Nos							
	Tongue Oedema							
	Tremor Nec							

Date: 05/19/1998 **ISR Number:** 3081442-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 93539 **Age:** 54 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos	Consumer	Accutane	PS		ORAL		
	Arthralgia		Premarin	C				
	Back Pain		Tenormin	C				
	Burning Sensation Nos							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 05/22/1998 **ISR Number:** 3081736-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 99244 **Age:** 65 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Collapse	Foreign	Tasmar	PS		ORAL		
	Delusion Nos	Other	Sinemet	C				
	Feeling Abnormal		Dothiepin	C				
	Hypoglycaemia Nos		Bezalip-Mono	C				
	Parkinsonism Aggravated		Aspirin	C				

Date: 05/22/1998 **ISR Number:** 3081748-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 96110 **Age:** 26 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Aggravated	Health Professional	Accutane	PS		ORAL		
	Hyporeflexia		Paxil	C				
	Muscle Disorder Nos							
	Muscle Spasms							
	Myalgia							
	Neurological Disorder Nos							
	Ovarian Disorder Nos							
	Pain Nos							
	Weight Increased							

Date: 05/22/1998 **ISR Number:** 3081750-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 72202 **Age:** 24 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Binocular Eye Movement Disorder Nos	Health Professional	Accutane	PS		ORAL		
Congenital Anomaly	Blindness Transient		Prozac	C				
	Blindness Unilateral		Alcohol	C				
	Cerebral Palsy							
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Congenital Central Nervous System Anomaly Nos							
	Conjunctivitis Nec							
	Convulsions Nos							
	Developmental Coordination Disorder Nos							
	Developmental Delay Nos							
	Eye Discharge							
	Eye Rolling							
	Eyelid Malformation, Congenital Nos							
	Eyelid Ptosis							
	Facial Dysmorphism							

Date: 05/22/1998 **ISR Number:** 3082515-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 99250 **Age:** 14 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alcoholism Cigarette Smoker Depression Nec Drug Abuse Suicidal Ideation	Other	Accutane	PS		ORAL		

Date: 05/27/1998 **ISR Number:** 3083454-5 **Report Type:** Direct **Company Report Number:** **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Emotional Disturbance Nos		Accutane	PS	Roche			

Date: 05/27/1998 **ISR Number:** 3083455-7 **Report Type:** Direct **Company Report Number:** **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anger Condition Aggravated Confusion Depression Aggravated Emotional Disturbance Nos Mental Disorder Nec Stress Symptoms		Accutane	PS	Roche			

Date: 05/08/1998 **ISR Number:** 3086686-5 **Report Type:** Direct **Company Report Number:** **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depressed Mood Fatigue Nervousness		Accutane	PS				

Date: 06/02/1998 **ISR Number:** 3087555-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 89723 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability Congenital Anomaly	Abnormal Behaviour Nos Clumsiness Clumsy Child Syndrome Cognitive Disorder Nec Complications Of Maternal Exposure To Therapuetic Drugs Developmental Delay Nos Difficulty In Walking Disturbance In Attention Nec Hernia Nos	Other	Accutane	PS		ORAL		

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report

Date: 06/02/1998 **ISR Number:** 3087606-X **Report Type:** Expedited (15-Day) **Company Report Number:** 99478 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec		Accutane	PS		ORAL		
	Disturbance In Social Behaviour Nos							
	Influenza Like Illness							
	Suicidal Ideation							

Date: 06/03/1998 **ISR Number:** 3088094-X **Report Type:** Direct **Company Report Number:** **Age:** 27 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide		Accutane	PS				
	Depression Nec							
	Skin Disorder Nos							

Date: 06/03/1998 **ISR Number:** 3088115-4 **Report Type:** Direct **Company Report Number:** **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Abnormal Behaviour Nos		Accutane	PS		ORAL		
	Depression Nec							
	Mood Swings							
	Suicidal Ideation							

Date: 06/02/1998 **ISR Number:** 3088349-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 95384 **Age:** 27 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Bipolar I Disorder	Health Professional	Accutane	PS		ORAL		
Life-Threatening	Completed Suicide	Other						
	Depression Nec							
	Drug Abuse							
	Suicidal Ideation							

Date: 06/02/1998 **ISR Number:** 3088662-5 **Report Type:** Direct **Company Report Number:** **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Crying		Accutane	PS				
	Depression Nec							
	Disturbance In Attention Nec							

Date: 06/04/1998 **ISR Number:** 3089759-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 99789 **Age:** 73 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Nos	Foreign	Tasmar	PS				
	Psychotic Disorder Nos	Other	Sinemet	SS				

Date: 06/09/1998 **ISR Number:** 3091174-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 97796 **Age:** 16 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anorexia	Other	Accutane	PS		ORAL		
	Anxiety Nec							
	Depression Nec							
	Fibromyalgia Syndrome							
	Gastrointestinal Candidiasis							
	Giardiasis							
	Myalgia							
	Sleep Disorder Nos							
	Swelling Nos							
	Weight Decreased							

Date: 06/09/1998 **ISR Number:** 3091176-X **Report Type:** Expedited (15-Day) **Company Report Number:** 99374 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Balance Impaired Nos	Foreign	Accutane	PS		ORAL		
	Diplopia	Health Professional						
	Electroencephalogram Normal							
	Headache Nos							
	Hypertension Nos							
	Hypotension							
	Loss Of Consciousness Nec							
	Stress Symptoms							
	Tremor Nec							
	Vision Blurred							

Date: 06/08/1998 **ISR Number:** 3091562-8 **Report Type:** Expedited (15-Day) **Company Report Number:** SIN980059 **Age:** 72 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Nos	Foreign	Sinemet	PS		ORAL		
	Psychotic Disorder Nos	Health Professional	Sinemet Cr	SS		ORAL		
			Tolcapone	SS				

Date: 06/12/1998 **ISR Number:** 3091845-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 93367 **Age:** 37 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Angina Pectoris	Foreign	Soriatane	PS		ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Angina Unstable	Health Professional	Roaccutane	SS		ORAL		
	Anxiety Nec	Other	Tigason	SS				
	Blood Triglycerides Increased							
	Chest Pain							
	Coronary Artery Occlusion							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 06/10/1998 **ISR Number:** 3092459-X **Report Type:** Expedited (15-Day) **Company Report Number:** 98380 **Age:** 63 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Disorientation	Health Professional	Tasmar	PS		ORAL		
	Hepatic Encephalopathy		Sinemet	C				
	Hepatitis Nos		Vitamin E	C				
	Jaundice Nos							
	Liver Function Tests Nos Abnormal							
	Pyrexia							
	Tremor Nec							
	White Blood Cell Count Decreased							

Date: 06/10/1998 **ISR Number:** 3092796-9 **Report Type:** Direct **Company Report Number:** **Age:** 66 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated		Tasmar	PS		ORAL		
	Confusion		Sinemet	C				
	Disorientation		Buspar	C				
	Hallucinations Aggravated		Klonopin	C				
			Colbenemid	C				
			Pepcid	C				
			Lasix	C				
			Accupril	C				
			Eldepryl	C				
			Zocor	C				

Date: 06/16/1998 **ISR Number:** 3094924-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 95296 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec	Other	Accutane	PS		ORAL		
	Hallucination Nos							
	Suicidal Ideation							

Date: 06/16/1998 **ISR Number:** 3094927-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 97085 **Age:** 44 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Distension	Consumer	Accutane	PS		ORAL		
	Blood Cholesterol Increased	Health Professional						
	Blood Triglycerides Increased							
	Depressed Mood							
	Fluid Retention							
	Headache Nos							

Date: 06/15/1998 **ISR Number:** 3095005-X **Report Type:** Expedited (15-Day) **Company Report Number:** 89723 **Age:** **Gender:** Female

Outcome	PT
Disability	Abnormal Behaviour Nos
Congenital Anomaly	Attention Deficit/Hyperactivity Disorder
	Cardiac Disorder Nos
	Clumsiness
	Complications Of Maternal Exposure To Therapuetic Drugs
	Congenital Ventricular Septal Defect
	Developmental Coordination Disorder Nos
	Developmental Delay Nos
	Difficulty In Walking
	Disturbance In Attention Nec
	Hernia Nos
	Hypospadias
	Increased Activity
	Learning Disorder Nos
	Motor Dysfunction Nos
	Urinary Incontinence

Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Health Professional	Accutane	PS		ORAL		
Other						

Date: 06/19/1998 **ISR Number:** 3096777-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 100516 **Age:** 86 YR **Gender:** Female

Outcome	PT
Other	Condition Aggravated
	Hallucination Nos
	Visual Acuity Reduced
	Visual Field Defect Nos

Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Health Professional	Tasmar	PS		ORAL		

Date: 06/22/1998 **ISR Number:** 3097269-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 98380 **Age:** 63 YR **Gender:** Male

Outcome	PT
Hospitalization - Initial or Prolonged	Biliary Tract Disorder Nos
	Cardiac Failure Congestive
	Coma Nec
	Disorientation
	Gall Bladder Disorder Nos
	Hepatic Cirrhosis Nos
	Hepatic Encephalopathy
	Hepatic Failure
	Hepatitis Nos
	Hyperpyrexia
	Infection Nos

Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Health Professional	Tasmar	PS		ORAL		
	Sinemet 25/250	C				
	Vitamin E	C				
	Amantadine	C				

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 06/22/1998 **ISR Number:** 3097288-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 100402 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Collapse	Foreign	Roaccutane (Isotretinoin)	PS				
	Depression Nec	Consumer	Antidepressant Nos	C				
	Hypersensitivity Nos		Sedative Nos	C				
	Neurodermatitis							
	Pyrexia							
	Suicidal Ideation							

Date: 06/23/1998 **ISR Number:** 3097844-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 100751 **Age:** 14 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Confusion	Foreign	Roaccutane	PS		ORAL		
	Crying	Health Professional	Vallete	C				
	Memory Impairment							
	Repetitive Speech							

Date: 06/24/1998 **ISR Number:** 3098705-0 **Report Type:** Direct **Company Report Number:** **Age:** 81 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Paranoia		Tasmar	PS		ORAL		

Date: 06/30/1998 **ISR Number:** 3100050-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 101148 **Age:** 19 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Anxiety Nec	Health Professional	Accutane	PS		ORAL		
	Burning Sensation Nos		Depakote	C				
	Depression Nec		Effexor	C				
	Dermatitis Nos							
	Facial Palsy							
	Goitre							
	Hypoaesthesia Tongue							
	Insomnia Nec							
	Neck Stiffness							
	Palpitations							
	Skin Discolouration							

Date: 06/30/1998 **ISR Number:** 3100112-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 97781 **Age:** 71 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Confusion	Other	Tasmar	PS		ORAL		
	Hyperglycaemia Nos		Sinemet Cr	C				
	Sedation		Glucophage	C				
	Urinary Incontinence							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 06/30/1998 **ISR Number:** 3100307-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 101424 **Age:** 19 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Adjustment Disorder Nec Cellulitis Depression Nec Educational Problem Flat Affect Gender Identity Disorder Nos Loss Of Employment Scar Sedation Social Avoidant Behaviour	Other	Accutane	PS		ORAL		

Date: 07/02/1998 **ISR Number:** 3101702-X **Report Type:** Expedited (15-Day) **Company Report Number:** 93114 **Age:** 32 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos Bronchitis Nos Complication Of Delivery Nos Complication Of Labour Nec Complications Of Maternal Exposure To Therapuetic Drugs Congenital Abnormality Nos Constipation Epiphyses Delayed Fusion Facial Dysmorphism Growth Retarded Hepatomegaly Hepatotoxicity Nos Herpes Zoster Hypermetropia Jaundice Neonatal Kidney Small Malaise Obstructed Labour Nos Otitis Media Nos Rhinitis Allergic Nos Stammering	Consumer Health Professional	Accutane	PS		ORAL		

Date: 06/09/1998 **ISR Number:** 3101822-X **Report Type:** Periodic **Company Report Number:** 88381 **Age:** 32 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Disturbance In Attention Nec Memory Impairment	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 06/09/1998 **ISR Number:** 3101825-5 **Report Type:** Periodic **Company Report Number:** 88388 **Age:** 38 YR **Gender:** Female

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

Date: 07/07/1998 **ISR Number:** 3102757-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 101476 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Facial Bones Fracture	Health Professional	Accutane	PS		ORAL		
	Loss Of Consciousness Nec		Ritalin (Methylphenidate Hydrochloride)	C				
	Pharyngitis Streptococcal							
	Road Traffic Accident							
	Syncope							

Date: 07/06/1998 **ISR Number:** 3102919-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 101338 **Age:** 64 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Drug Maladministration	Other	Tasmar	PS		ORAL		
	Joint Dislocation Nec		Sinemet (Carbidopa/Levodopa)	C				
	Markedly Reduced Food Intake		Mirapex	C				
	Weakness		Hormone (Hormone Nos)	C				
	Weight Decreased		Xanax (Alprazolam)	C				

Date: 07/01/1998 **ISR Number:** 3104434-7 **Report Type:** Direct **Company Report Number:** **Age:** 80 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated		Tasmar	PS				
	Confusion		Sinemet	C				
	Delusion Nos		Permax	C				
	Hallucinations, Mixed							

Date: 07/13/1998 **ISR Number:** 3104604-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 96303 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Confusion	Health Professional	Accutane	PS		ORAL		
	Psychotic Disorder Nos		Dramamine	SS		ORAL		
	Stupor							

Date: 07/13/1998 **ISR Number:** 3105190-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 100121 **Age:** 62 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aggression	Foreign	Tasmar	PS		ORAL		
	Agitation	Health Professional	Benzhexol	C				
	Confusion		Sinemet Cr	C				
	Psychotic Disorder Nos							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 07/17/1998 **ISR Number:** 3106189-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 102074 **Age:** 29 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Bradycardia Foetal	Consumer	Accutane	PS		ORAL		
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Depression Nec							
	Foetal Maturation Impaired							
	Mood Swings							
	Suicidal Ideation							

Date: 07/21/1998 **ISR Number:** 3107310-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 100121 **Age:** 62 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aggression	Foreign	Tasmar	PS		ORAL		
	Agitation	Health Professional	Benzhexol (Trihexyphenidyl Hydrochloride)	C				
	Confusion		Sinemet Cr (Carbidopa/Levodopa)	C				
	Psychotic Disorder Nos		Sinemet 10/100 (Carbidopale/Levodopa)	C				
			Selegiline (Selegiline Hydrochloride)	C				
			Insulin (Insulin)	C				
			Trimethoprim (Trimethoprim)	C				

Date: 07/21/1998 **ISR Number:** 3107318-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 98350 **Age:** 42 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec	Consumer	Accutane	PS		ORAL		
	Anxiety Nec		Loestrin (Ethinyl Estradiol/Norethindrone Acetate)	C				
	Breast Pain		Humulin (Insulin Human)	C				
	Computerised Tomogram Abnormal		Propulsid (Cispride)	C				
	Condition Aggravated		Axid (Nizatidine)	C				
	Diabetes Mellitus Aggravated		Lotensin (Benazepril Hydrochloride)	C				
	Diplopia		Norvasc (Amlodipine Besylate)	C				
	Disorientation		Klonopin (Clonazepam)	C				
	Dizziness (Exc Vertigo)							
	Dry Skin							
	Eyelid Function Disorder Nos							
	Feeling Abnormal							
	Headache Nos Aggravated							
	Heart Rate Increased							
	Hypertension Aggravated							
	Hypoglycaemia Nos							
	Lip Dry							

Date: 07/24/1998 **ISR Number:** 3108870-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 102871 **Age:** 29 YR **Gender:** Female

PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Acne Aggravated	Health Professional	Roaccutane	PS		ORAL		
Anxiety Nec							
Balance Impaired Nos							
Disorientation							
Fatigue							
Mydriasis							
Photophobia							
Stress Symptoms							

Date: 07/24/1998 **ISR Number:** 3109439-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 102844 **Age:** 68 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Apathy	Foreign	Tasmar	PS		ORAL		
	Convulsions Nos	Study	Nacom	SS				
		Health Professional	Dopergin	C				
		Other	Movergan	C				
			L-Thyroxin	C				

Date: 07/24/1998 **ISR Number:** 3109750-0 **Report Type:** Direct **Company Report Number:** **Age:** 35 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia		Accutane	PS		ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Gastrointestinal Disorder Nos							
	Headache Nos							
	Irritable Bowel Syndrome							
	Lactose Intolerance							

Date: 07/29/1998 **ISR Number:** 3110654-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 101693 **Age:** 29 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos	Consumer	Accutane	PS		ORAL		
	Abortion Spontaneous Nos		Oral Contraceptive Pill	SS		ORAL		
	Depression Nec							
	Mood Swings							
	Post-Abortion Infection Nos							
	Pyrexia							
	Relationship Breakdown							
	Retained Placenta Or Membranes							
	Suicidal Ideation							
	Vaginal Discharge							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 07/29/1998 **ISR Number:** 3110781-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 102074 **Age:** 29 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Abdominal Pain Nos Abortion Spontaneous Nos Bradycardia Foetal Complications Of Maternal Exposure To Therapuetic Drugs Depression Nec Foetal Growth Retardation Infection Nos Intermenstrual Bleeding Mood Swings Pyrexia Retained Placenta Or Membranes Suicidal Ideation Vaginal Discharge	Consumer	Accutane	PS		ORAL		

Date: 07/31/1998 **ISR Number:** 3111343-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 103199 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blindness Transient Cerebrovascular Accident Nos Disorientation Headache Nos Hyperventilation Loss Of Consciousness Nec	Health Professional	Accutane	PS		ORAL		

Date: 07/30/1998 **ISR Number:** 3111493-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 920201380001 **Age:** 21 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Conversion Disorder Crying Drug Interaction Nos Emotional Disturbance Nos Feeling Abnormal Intentional Self-Injury Major Depressive Disorder Nos Suicide Attempt	Health Professional Other	Accutane	PS		ORAL		

Date: 08/03/1998 **ISR Number:** 3112251-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 101537 **Age:** 16 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Aggravated Drug Interaction Nos	Other	Accutane	PS		ORAL		

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 08/04/1998 **ISR Number:** 3113215-X **Report Type:** Expedited (15-Day) **Company Report Number:** 87288 **Age:** 28 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos Cardiac Murmur Nos Complications Of Maternal Exposure To Therapuetic Drugs Crying Dehydration Diarrhoea Neonatal Difficulty In Micturition Feeding Problem In Newborn Fever Neonatal Gastro-Oesophageal Reflux Disease Gastroenteritis Nos Hyperbilirubinaemia Irritability Jaundice Neonatal	Consumer Health Professional	Accutane	PS	Abbott	ORAL		

Date: 08/05/1998 **ISR Number:** 3113448-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 101537 **Age:** 16 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Aggravated Drug Toxicity Nos Overdose Nos	Other	Accutane Aspirin	PS C		ORAL		

Date: 08/06/1998 **ISR Number:** 3113859-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 103250 **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Depression Aggravated Vaginal Haemorrhage	Health Professional	Accutane Lithium Wellbutrin	PS C C		ORAL		

Date: 08/06/1998 **ISR Number:** 3113964-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 103137 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos Aggression Hostility Intentional Self-Injury Suicide Attempt	Foreign Health Professional	Roaccutane Virlix (Cetirizine Hydrochloride0	PS C		ORAL		

FDA's Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report

Date: 08/11/1998 **ISR Number:** 3115186-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 87288 **Age:** 28 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Cardiac Murmur Nos	Consumer	Accutane	PS		ORAL		
	Complications Of Maternal Exposure To Therapuetic Drugs	Health Professional						
	Crying							
	Dehydration							
	Diarrhoea Nos							
	Feeding Problem In Newborn							
	Gastro-Oesophageal Reflux Disease							
	Gastroenteritis Nos							
	Hyperbilirubinaemia Neonatal							
	Infantile Colic							
	Irritability							
	Jaundice Neonatal							
	Jaundice Nos							
	Pyrexia							
	Urination Abnormal Nos							

Date: 08/11/1998 **ISR Number:** 3115188-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 96389 **Age:** 23 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Anorexia Nervosa	Health Professional	Accutane	PS		ORAL		
	Depression Aggravated		Claritin (Loratadine)	C				
	Emotional Disturbance Nos		Paxil (Paroxetine0	C				
	Markedly Reduced Food Intake		Ortho Tri Cyclen (Ethinyl Estradiol/Norgestimate)	C				
	Nausea		Xanax (Alprazolam)	C				
	Weight Decreased		Ritalin (Methylphenidate Hydrochloride)	C				

Date: 08/11/1998 **ISR Number:** 3115217-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 102844 **Age:** 68 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Apathy	Foreign	Tasmar	PS		ORAL		
	Muscle Cramps	Study	Nacom	SS				
	Paralysed	Health Professional	Dopergin (Lisuride)	C				
		Other	Movergan	C				
			L-Thyroxin (Levothyroxine Sodium)	C				

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 08/13/1998 **ISR Number:** 3116697-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 102844 **Age:** 68 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Apathy	Foreign	Tasmar	PS		ORAL		
	Muscle Cramps	Study	Nacon	SS				
	Paralysed	Health Professional	Dopergin	C				
		Other	Movergan (Selegiline Hydrochloride)	C				
			L-Thyroxin (Levothyroxine Sodium)	C				

Date: 08/19/1998 **ISR Number:** 3118878-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 103250 **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Aggravated	Health Professional	Accutane	PS		ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Hypovolaemic Shock		Lithium	C				
	Vaginal Haemorrhage		Bupropion Hydrochloride	C				

Date: 08/19/1998 **ISR Number:** 3118882-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 103199 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blindness Transient	Health Professional	Accutane	PS		ORAL		
	Cerebrovascular Accident Nos							
	Disorientation							
	Dry Skin							
	Fatigue							
	Headache Nos							
	Hyperventilation							
	Loss Of Consciousness Nec							

Date: 08/24/1998 **ISR Number:** 3121305-0 **Report Type:** Direct **Company Report Number:** **Age:** 37 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Alopecia		Accutane	PS		ORAL		
	Depression Nec							
	Epistaxis							
	Hallucination Nos							
	Myalgia							
	Suicidal Ideation							

Date: 08/25/1998 **ISR Number:** 3122075-2 **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	Completed Suicide	Foreign	Roaccutane	PS		ORAL		
	Dry Skin	Health Professional	Flixotide	C				
	Lip Dry							

Date: 08/27/1998 **ISR Number:** 3123130-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 103199 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blindness Nec	Health Professional	Accutane	PS		ORAL		
	Cerebrovascular Accident Nos							
	Disorientation							
	Dry Skin							
	Fatigue							
	Headache Nos Aggravated							
	Hyperventilation							
	Loss Of Consciousness Nec							
	Migraine Nos							
	Transient Ischaemic Attack							

Date: 09/02/1998 **ISR Number:** 3124772-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 98380 **Age:** 63 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Bile Duct Obstruction Nos	Health Professional	Tasmar	PS		ORAL		
	Cardiac Failure Congestive		Sinemet	C				
	Coma Nec		Vitamin E	C				
	Disorientation		Amantadine	C				
	Gall Bladder Obstruction							
	Hepatic Cirrhosis Nos							
	Hepatic Encephalopathy							
	Hepatic Failure							
	Hepatitis Nos							
	Infection Nos							
	Jaundice Nos							
	Liver Function Tests Nos Abnormal							
	Pancreatic Carcinoma Nos							
	Pyrexia							
	Sepsis Nos							
	Tremor Nec							
	Tumour Cell Marker Test Nos							
	Urinary Tract Infection Nos							
	White Blood Cell Count Increased							

Date: 09/03/1998 **ISR Number:** 3124781-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 97085 **Age:** 44 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Distension	Consumer	Accutane	PS		ORAL		
	Blood Cholesterol Increased	Health Professional						
	Blood Triglycerides Increased							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 09/03/1998 **ISR Number:** 3125233-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 97085 **Age:** 44 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Distension	Consumer	Accutane	PS		ORAL		
	Blood Cholesterol Increased	Health Professional						
	Blood Triglycerides Increased							
	Carbohydrate Craving							
	Depressed Mood							
	Fluid Retention							
	Headache Nos							
	Hypertension Nos							
	Lacrimation Increased							
	Mood Alteration Nos							
	Sedation							
	Weight Increased							

Date: 09/04/1998 **ISR Number:** 3125995-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 95261 **Age:** 20 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Dyspareunia Nec	Health Professional	Accutane	PS		ORAL		
	Papilloma Viral Infection Nos		Loestrin (Ethinyl Estradiol/Orethindrone Acetate)	C				
	Vaginal Candidiasis							
	Vaginal Ulceration							
	Vulvovaginal Discomfort							

Date: 09/04/1998 **ISR Number:** 3126024-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 102836 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide	Health Professional	Soriatane	PS		ORAL		
	Rash Erythematous		Accutane	SS		ORAL		
	Rash Papular		Ultravate Ointment (Halobetsol Propionate)	C				
	Rash Pruritic		Cutivate (Fluticasone Propionate)	C				
			Zyrtec (Cetirizine Hydrochloride)	C				
			Insulin	C				
			Glucophage (Metformin Hydrochloride)	C				
			Prednisone	C				

Date: 09/09/1998 **ISR Number:** 3127426-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 105054 **Age:** 73 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Blood Urea Increased	Foreign	Tasmar	PS		ORAL		
	Confusion	Other	Rifinah	C				
	Drug Maladministration							

Date: 09/16/1998 **ISR Number:** 3131046-1 **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	Foreign	Roaccutane	PS		ORAL		
	Dry Skin	Health Professional	Flicotide	C				
	Lip Dry							

Date: 09/16/1998 **ISR Number:** 3131049-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 105468 **Age:** 16 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Aggression	Foreign	Accutane	PS		ORAL		
	Bipolar I Disorder	Other						
	Depression Nec							
	Mood Alteration Nos							
	Screaming							
	Suicidal Ideation							

Date: 09/16/1998 **ISR Number:** 3131052-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 105469 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Aggression	Foreign	Accutane	PS		ORAL		
	Faecal Incontinence	Other						
	Mood Alteration Nos							
	Urinary Incontinence							

Date: 09/17/1998 **ISR Number:** 3132040-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 87288 **Age:** 28 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos	Consumer	Accutane	PS		ORAL		
	Adrenal Neoplasm Nos	Health Professional						
	Appetite Decreased							
	Benign Ovarian Tumour							
	Blood Bilirubin Increased							
	Body Temperature Increased							
	Cardiac Murmur Nos							
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Csf Cell Count Nos Abnormal							
	Dehydration							
	Diarrhoea Nos							
	Gastro-Oesophageal Reflux Disease							
	Gastroenteritis Nos							
	Hyperbilirubinaemia							
	Infantile Colic							
	Influenza							

Date: 09/17/1998 **ISR Number:** 3132069-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 104850 **Age:** 65 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Disorientation	Health Professional	Tasmar	PS		ORAL		
	Dysphagia		Eldepryl	SS		ORAL		
	Hypoxia		Nubain	SS		INTRAMUSCULAR		
	Leucocytosis Nos		Amitriptyline	SS		ORAL		
	Liver Function Tests Nos Abnormal		Permax	C				
	Muscle Rigidity		Sinemet	C				
	Neuroleptic Malignant Syndrome							
	Oedema Nos							
	Pyrexia							
	Tremor Nec							

Date: 04/24/1998 **ISR Number:** 3133797-1 **Report Type:** Direct **Company Report Number:** **Age:** **Gender:**

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		Accutane	PS				
	Dysthymic Disorder							

Date: 09/24/1998 **ISR Number:** 3134647-X **Report Type:** Expedited (15-Day) **Company Report Number:** 105671 **Age:** **Gender:** Unknown

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Foreign	Roaccutane	PS		ORAL		
	Post-Viral Fatigue Syndrome Nos	Health Professional						

Date: 09/23/1998 **ISR Number:** 3134990-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 103250 **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Acute Circulatory Failure	Health Professional	Accutane	PS		ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Depression Aggravated		Lithium	C				
	Vaginal Haemorrhage		Wellbutrin	C				
			...	C				

Date: 09/25/1998 **ISR Number:** 3135496-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 105963 **Age:** 14 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Anxiety Nec	Foreign	Roaccutan	PS		ORAL		
	Blindness Nec	Other	Desolett	SS		ORAL		
	Depression Nec							
	Migraine Nos							
	Syncope							
	Weakness							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 09/30/1998 **ISR Number:** 3136398-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 100515 **Age:** 74 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Activated Partial Thromboplastin Time Prolonged	Foreign	Tasmar	PS		ORAL		
Hospitalization - Initial or Prolonged	Biliary Tract Disorder Nos	Literature	Madopar	SS		ORAL		
	Confusion	Health Professional	Symmetrel (Amantadine Hydrochloride)	C				
	Dizziness (Exc Vertigo)		Effortil (Etilefrine)	C				
	Fall		Rheffuin (Amiloride Hydrochloride/Hydrochlorothiazide)	C				
	Gall Bladder Disease Nos		Seresta (Oxazepam)	C				
	Haematoma Nos							
	Hepatic Encephalopathy							
	Hepatic Necrosis							
	Hepatitis Fulminant							
	Hepatomegaly							
	Hypotension							
	International Normalised Ratio Increased							
	Jaundice Nos							
	Liver Fatty							
	Liver Function Tests Nos Abnormal							
	Loss Of Consciousness Nec							
	Malaise							
	Oedema Lower Limb							
	Palpitations							

Date: 09/30/1998 **ISR Number:** 3136408-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 96185 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthma Nos	Other	Accutane	PS		ORAL		
	Cough							
	Depression Nec							
	Epistaxis							
	Lethargy							
	School Refusal							
	Suicidal Ideation							
	Weakness							

Date: 10/02/1998 **ISR Number:** 3137350-5 **Report Type:** Direct **Company Report Number:** **Age:** 29 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Alopecia		Accutane	PS		ORAL		
	Depression Nec							
	Epistaxis							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 10/06/1998 **ISR Number:** 3138722-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 92747 **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Complications Of Maternal Exposure To Therapuetic Drugs	Health Professional	Accutane	PS		ORAL		
	Cough		Demerol (Meperidine Hydrochloride)	C				
	Dermatitis Nos		Phenergan (Promethazine Hydrochloride)	C				
	Diarrhoea Nos		Ampicillin (Ampicillin)	C				
	Gastritis Nos		Gentamycin (Gentamicin Sulfate)	C				
	Nasal Congestion							
	Omphalitis							
	Oral Candidiasis							
	Otitis Media Nos							
	Pyrexia							
	Rhinorrhoea							
	Skin Fungal Infection Nos							
	Sneezing							
	Sore Throat Nos							
	Upper Respiratory Tract Infection Nos							

Date: 10/15/1998 **ISR Number:** 3141478-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 106129 **Age:** 90 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Blood Albumin Decreased	Foreign	Tasmar	PS		ORAL		
	Blood Creatinine Increased	Health Professional	Sinemet	C				
	Blood Urea Increased		Bromocriptine	C				
	Dyspnoea Exertional		Amantadine	C				
	Hallucination Nos		Domperidone	C				
	Oedema Lower Limb		Docusate	C				

Date: 10/15/1998 **ISR Number:** 3142306-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 96256 **Age:** 35 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Alpha 1 Foetoprotein Increased	Health Professional	Accutane	PS		ORAL		
	Complications Of Maternal Exposure To Therapuetic Drugs		Multiple Vitamins	C				
	Edward'S Syndrome							
	Jaundice Neonatal							

Date: 10/15/1998 **ISR Number:** 3142430-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 106785 **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Fatigue	Foreign	Roaccutane	PS		ORAL		
	Hyperthyroidism	Health Professional						

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 10/20/1998 **ISR Number:** 3143980-7 **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	Arterial Disorder Nos	Foreign	Roaccutane	PS		ORAL		
	Blindness Nec	Other						
	Colitis Ulcerative							
	Confusion							
	Diarrhoea Nos							
	Gangrene Nos							
	Haematuria Present							
	Headache Nos							
	Insomnia Nec							
	Negativism							
	Protein Total Increased							
	Renal Disorder Nos							
	Suspiciousness							
	Thrombosis Nos							
	Vesico-Ureteric Reflux							
	Vomiting Nos							
	Weight Decreased							

Date: 03/06/1998 **ISR Number:** 3144158-3 **Report Type:** Periodic **Company Report Number:** 8-97132-018L **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Effexor	PS		ORAL		
	Drug Interaction Nos		Accutane	SS				

Date: 10/21/1998 **ISR Number:** 3144336-3 **Report Type:** Direct **Company Report Number:** **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide		Accutane	PS	Roche Laboratories			

Date: 10/28/1998 **ISR Number:** 3147267-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 106312 **Age:** 73 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Abdominal Pain Upper	Health Professional	Tasmar	PS		ORAL		
Hospitalization - Initial or Prolonged	Ammonia Increased	Other	Paxil (Paroxetine)	C				
	Anuria		Trazodone (Trazodone Hydrochloride)	C				
	Atelectasis		Prilosec (Omeprazole)	C				
	Blood Creatine Phosphokinase Increased		Vicodin	C				
	Blood Lactate Dehydrogenase Increased							
	Distress							
	Dyspnoea Nos							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 10/28/1998 **ISR Number:** 3148275-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 100515 **Age:** 74 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Ammonia Increased	Foreign	Tasmar	PS		ORAL		
Hospitalization - Initial or Prolonged	Bladder Constriction	Literature	Madopar	SS		ORAL		
	Condition Aggravated	Health Professional	Symmetrel (Amantadine Hydrochloride)	C				
	Confusion		Effortil (Etilefrine)	C				
	Cyst Nos		Rheffuin (Amiloride Hydrochloride/Hydrochlorothiazide)	C				
	Dizziness (Exc Vertigo)		Seresta (Oxazepam)	C				
	Electroencephalogram Abnormal							
	Fall							
	Haematoma Nos							
	Hepatic Encephalopathy							
	Hepatic Necrosis							
	Hepatitis Fulminant							
	Hepatomegaly							
	Hypotension							
	Jaundice Nos							
	Liver Fatty							
	Liver Function Tests Nos Abnormal							
	Loss Of Consciousness Nec							
	Malaise							
	Oedema Lower Limb							
	Palpitations							

Date: 11/02/1998 **ISR Number:** 3151480-3 **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	Arteritis Nos	Foreign	Roaccutane	PS		ORAL		
	Blindness Nec	Other						
	Colitis Ulcerative							
	Confusion							
	Diarrhoea Nos							
	Difficulty In Walking							
	Gangrene Nos							
	Headache Nos							
	Insomnia Nec							
	Negativism							
	Protein Total Increased							
	Proteinuria Present							
	Renal Disorder Nos							
	Semen Volume Decreased							
	Suspiciousness							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 10/28/1998 **ISR Number:** 3148275-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 100515 **Age:** 74 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Ammonia Increased	Foreign	Tasmar	PS		ORAL		
Hospitalization - Initial or Prolonged	Bladder Constriction	Literature	Madopar	SS		ORAL		
	Condition Aggravated	Health Professional	Symmetrel (Amantadine Hydrochloride)	C				
	Confusion		Effortil (Etilefrine)	C				
	Cyst Nos		Rheffuin (Amiloride Hydrochloride/Hydrochlorothiazide)	C				
	Dizziness (Exc Vertigo)		Seresta (Oxazepam)	C				
	Electroencephalogram Abnormal							
	Fall							
	Haematoma Nos							
	Hepatic Encephalopathy							
	Hepatic Necrosis							
	Hepatitis Fulminant							
	Hepatomegaly							
	Hypotension							
	Jaundice Nos							
	Liver Fatty							
	Liver Function Tests Nos Abnormal							
	Loss Of Consciousness Nec							
	Malaise							
	Oedema Lower Limb							
	Palpitations							

Date: 11/02/1998 **ISR Number:** 3151480-3 **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	Arteritis Nos	Foreign	Roaccutane	PS		ORAL		
	Blindness Nec	Other						
	Colitis Ulcerative							
	Confusion							
	Diarrhoea Nos							
	Difficulty In Walking							
	Gangrene Nos							
	Headache Nos							
	Insomnia Nec							
	Negativism							
	Protein Total Increased							
	Proteinuria Present							
	Renal Disorder Nos							
	Semen Volume Decreased							
	Suspiciousness							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 10/02/1998 **ISR Number:** 3151699-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 107532 **Age:** 77 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dyskinesia Nec	Foreign	Tasmar	PS		ORAL		
	Suicide Attempt	Health Professional						

Date: 11/04/1998 **ISR Number:** 3151712-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 100515 **Age:** 74 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Condition Aggravated	Foreign	Tasmar	PS		ORAL		
Hospitalization - Initial or Prolonged	Confusion	Literature	Madopar	SS		ORAL		
	Dizziness (Exc Vertigo)	Health Professional	Symmetrel	C				
	Fall		Effortil	C				
	Haematoma Nos		Rheftuin	C				
	Hepatic Encephalopathy		Seresta	C				
	Hepatitis Fulminant							
	Hepatomegaly							
	Hypotension							
	Inflammation Nos							
	Jaundice Nos							
	Liver Fatty							
	Liver Function Tests Nos Abnormal							
	Loss Of Consciousness Nec							
	Malaise							
	Oedema Lower Limb							
	Palpitations							

Date: 11/03/1998 **ISR Number:** 3151713-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 107647 **Age:** 59 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Aspartate Aminotransferase Increased	Foreign	Tasmar	PS		ORAL		
	Blood Alkaline Phosphatase Nos Decreased	Health Professional	Stilnox	SS		ORAL		
	Blood Triglycerides Increased		Di-Antalvic	SS		ORAL		
	Gamma-Glutamyltransferase Increased		Parlodel	SS		ORAL		
	Insomnia Nec		Sinemet	SS		ORAL		
	Nausea		Cozaar	SS		ORAL		
	Palpitations		Isoptine	SS		ORAL		
	Tremor Nec		Modopar	C				

Date: 11/03/1998 **ISR Number:** 3151718-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 106315 **Age:** 83 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aspiration	Other	Tasmar	PS		ORAL		
	Cerebrovascular Accident Nos		Sinemet	C				
	Coma Nec		Coumadin	C				
	Condition Aggravated		Cardiac Medication Nos	C				
	Dizziness (Exc Vertigo)							
	Lethargy							
	Nausea							
	Sedation							
	Vomiting Nos							

Date: 11/04/1998 **ISR Number:** 3151790-X **Report Type:** Direct **Company Report Number:** **Age:** 22 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Appetite Increased		Accutane	PS	Roche Laboratories			
	Depressed Level Of Consciousness							
	Fatigue							
	Food Allergy							
	Nervousness							
	Sweating Increased							
	Thirst							

Date: 11/04/1998 **ISR Number:** 3151855-2 **Report Type:** Direct **Company Report Number:** **Age:** 19 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide		Accutane Cap Roch	PS	Roche	ORAL		
			Accutane	SS		ORAL		

Date: 11/04/1998 **ISR Number:** 3151895-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 104850 **Age:** 50 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased	Health Professional	Tasmar	PS		ORAL		
	Blood Creatine Phosphokinase Increased		Eldepryl	SS		ORAL		
	Disorientation		Nubain	SS		INTRAMUSCULAR		
	Drug Interaction Nos		Amitriptyline	SS		ORAL		
	Dysphagia		Permax	C				
	Faecal Occult Blood Positive		Sinemet	C				
	Feeling Jittery							
	Haematuria Present							
	Hypoxia							
	Leucocytosis Nos							

Date: 11/02/1998 **ISR Number:** 3152118-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 106785 **Age:** 22 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Exophthalmos Nec	Foreign	Roaccutane (Isotretinoin)	PS		ORAL		
	Fatigue	Health Professional	Trinordiol	C				
	Hyperthyroidism							
	Nervousness							
	Tachycardia Nos							

Date: 11/03/1998 **ISR Number:** 3152650-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 107086 **Age:** **Gender:** Male

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

Date: 11/03/1998 **ISR Number:** 3152651-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 107088 **Age:** **Gender:** Unknown

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Schizophrenia Nos	Foreign	Roaccutane	PS				
		Health Professional						

Date: 11/10/1998 **ISR Number:** 3155770-X **Report Type:** Expedited (15-Day) **Company Report Number:** 106667 **Age:** 20 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos	Health Professional	Accutane	PS		ORAL		
	Dehydration		Ventolin	C				
	Herpes Simplex		Contraceptive Nos	C				
	Immunosuppression Nos							
	Markedly Reduced Food Intake							
	Nausea							
	Oesophageal Ulcer							
	Oesophagitis							
	Venous Thrombosis Deep Limb							
	Vomiting Nos							

Date: 11/17/1998 **ISR Number:** 3158596-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 108511 **Age:** 21 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anger	Health Professional	Accutane	PS		ORAL		
	Blood Bilirubin Increased	Other	Amipicillin	C				
	Depression Nec		Cycline Nos	C				
	Hypersomnia							
	Irritability							
	Personality Change							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 11/17/1998 **ISR Number:** 3158631-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 103199 **Age:** 20 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blindness Transient	Health Professional	Accutane	PS		ORAL		
	Cerebrovascular Accident Nos							
	Disorientation							
	Dry Skin							
	Eye Pain							
	Fatigue							
	Headache Nos							
	Hyperventilation							
	Loss Of Consciousness Nec							
	Migraine Nos							
	Transient Ischaemic Attack							

Date: 11/17/1998 **ISR Number:** 3158793-X **Report Type:** Expedited (15-Day) **Company Report Number:** 107647 **Age:** 59 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Abdominal Pain Nos	Foreign	Tasmar	PS		ORAL		
	Blood Alkaline Phosphatase Nos Decreased	Health Professional	Stilnox	SS		ORAL		
	Blood Triglycerides Increased		Di-Antalvic	SS		ORAL		
	Chorea Nos		Parlodel	SS		ORAL		
	Cyanosis Nos		Sinemet	SS		ORAL		
	Dyskinesia Nec		Cozaar	SS		ORAL		
	Feeling Cold		Isoptine	SS		ORAL		
	Gamma-Glutamyltransferase Increased		Modopar	C		ORAL		
	Insomnia Nec							
	Nausea							
	Nervousness							
	Palpitations							
	Tremor Nec							

Date: 06/09/1998 **ISR Number:** 3158917-4 **Report Type:** Periodic **Company Report Number:** 93350 **Age:** 34 YR **Gender:** Male

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

Date: 06/05/1998 **ISR Number:** 3159025-9 **Report Type:** Periodic **Company Report Number:** 85056 **Age:** 22 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
			Paxil (Paroxetine)	C				

Date: 11/19/1998 **ISR Number:** 3159253-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 108183 **Age:** 65 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Tasmar	PS		ORAL		
	Non-Accidental Overdose	Health Professional	Trivastal	SS		ORAL		
	Pneumonitis Aspiration							
	Suicide Attempt							
	Vomiting Nos							

Date: 11/19/1998 **ISR Number:** 3159262-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 104850 **Age:** 50 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Confusion	Health Professional	Tasmar	PS		ORAL		
	Disorientation		Eldepryl	SS		ORAL		
	Drug Interaction Nos		Nubain	SS		INTRAMUSCULAR		
	Dysphagia		Amitriptyline	SS		ORAL		
	Haematuria Present		Permax	C				
	Hallucination, Visual		Sinemet-25/100	C				
	Hypoxia		Vantin	C				
	Insomnia Nec		Potassium	C				
	Lethargy		Sinemet Cr 50-200	C				
	Leucocytosis Nos		Iron Sulfate	C				
	Liver Function Tests Nos Abnormal		Prevacid	C				
	Muscle Rigidity		Ativan	C				
	Neuroleptic Malignant Syndrome		Tylenol	C				
	Oedema Nos		Sorbitol	C				
	Pyrexia							

Date: 11/19/1998 **ISR Number:** 3159267-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 108076 **Age:** 75 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Acute Circulatory Failure	Foreign	Tasmar	PS				
Required Intervention to Prevent Permanent Impairment/Damage	Agitation	Health Professional	Requip	SS		ORAL		
	Blood Creatine Phosphokinase Increased	Other	Akineton	C				
	Blood Uric Acid Increased		Novodigal	C				
	Cholelithiasis		Nacom	C				
	Ecchymosis							
	Electrocardiogram Abnormal Nos							
	Electroencephalogram Abnormal							
	Excitability							
	Gastric Ulcer Haemorrhage							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 11/19/1998 **ISR Number:** 3159275-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 107532 **Age:** 77 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Dyskinesia Nec	Foreign	Tasmar	PS		ORAL		
	Liver Function Tests Nos Abnormal	Health Professional	Modopar (Benserazide/Levodopa)	C				
	Non-Accidental Overdose		Deprenyl (Selegiline Hydrochloride)	C				
	Suicide Attempt		Gardenal (Phenobarbital)	C				

Date: 11/18/1998 **ISR Number:** 3159505-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 87288 **Age:** 28 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos	Consumer	Accutane	PS		ORAL		
	Appetite Decreased	Health Professional						
	Blood Bilirubin Increased							
	Cardiac Murmur Nos							
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Crying							
	Csf White Blood Cell Count Nos Positive							
	Dehydration							
	Diarrhoea Nos							
	Gastro-Oesophageal Reflux Disease							
	Gastroenteritis Nos							
	Hyperbilirubinaemia							
	Influenza							
	Irritability							
	Jaundice Nos							
	Oliguria							
	Pyrexia							
	Red Blood Cells Csf Positive							
	White Blood Cell Count Increased							

Date: 06/09/1998 **ISR Number:** 3159669-4 **Report Type:** Periodic **Company Report Number:** 92242 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos	Other	Accutane (Isotretinoin)	PS		ORAL		
	Aggression							
	Confusion							
	Dermatitis Nos							
	Dry Skin							
	Increased Activity							
	Memory Impairment							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 06/05/1998 **ISR Number:** 3159700-6 **Report Type:** Periodic **Company Report Number:** 86574 **Age:** 19 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Blood Bilirubin Increased							
	Cheilitis							
	Dry Eye Nec							
	Granuloma Nos							
	Infection Nos							
	Lip Dry							
	Liver Function Tests Nos Abnormal							
	Rectal Bleeding							
	Short-Term Memory Loss							
	Tenderness Nos							

Date: 11/20/1998 **ISR Number:** 3160628-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 108931 **Age:** 72 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Upper	Foreign	Tasmar	PS				
	Confusion	Health Professional	Sinemet	C				
	Diarrhoea Nos	Other	Tolvon	C				
	Dyskinesia Nec							
	Liver Function Tests Nos Abnormal							
	Malaise							

Date: 11/20/1998 **ISR Number:** 3160629-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 108675 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aggression	Consumer	Tasmar	PS				
	Akinesia							
	Amnesia Nec							
	Appetite Decreased							
	Hallucination Nos							
	Human Bite							
	Paralysis Nos							
	Weight Decreased							

Date: 11/30/1998 **ISR Number:** 3164018-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 108798 **Age:** 25 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dizziness (Exc Vertigo)	Consumer	Accutane	PS		ORAL		
	Dry Eye Nec		Oral Contraception	C				
	Dry Skin							
	Feeling Cold							

Date: 12/01/1998 **ISR Number:** 3164630-X **Report Type:** Expedited (15-Day) **Company Report Number:** 109074 **Age:** 66 YR **Gender:** Female

Outcome	PT
Death	Agitation
Hospitalization - Initial or Prolonged	Anorexia
	Anuria
	Blood Chloride Increased
	Blood Creatine Phosphokinase Increased
	Bronchospasm Nos
	Confusion
	Convulsions Nos
	Dehydration
	Difficulty In Walking
	Disorientation
	Drug Interaction Nos
	Dyskinesia Nec
	Haemoglobin Decreased
	Hallucination Nos
	Hypernatraemia
	Hyperreflexia
	Hypertonia
	Hypokalaemia
	Hypotension
	Liver Function Tests Nos Abnormal
	Muscle Rigidity
	Oliguria
	Phobias Nec
	Pyrexia
	Renal Failure Nos
	Rhabdomyolysis
	Sleep Disorder Nos
	Tachycardia Nos
	Ventricular Fibrillation

Report Source
Foreign
Health Professional

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Tasmar	PS		ORAL		
Modopar	SS		ORAL		
Lexomil	SS		ORAL		
Deroxat	SS		ORAL		
Nicergoline	SS		ORAL		
Spironolactone	SS		ORAL		
Atenolol	SS		ORAL		
Tegretol	SS		ORAL		
Amantadine Hydrochloride	SS		ORAL		

Date: 12/01/1998 **ISR Number:** 3164637-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 109250 **Age:** 70 YR **Gender:** Male

Outcome	PT
Hospitalization - Initial or Prolonged	Coma Nec
Required Intervention to Prevent Permanent Impairment/Damage	Non-Accidental Overdose
	Suicide Attempt

Report Source
Foreign
Health Professional

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Tasmar	PS		ORAL		
Alcohol	SS		ORAL		
Modopar	C				
Trivastal	C				

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 12/01/1998 **ISR Number:** 3164950-9 **Report Type:** Direct **Company Report Number:** **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Distress		Accutane	PS	Roche			
	Face Oedema							
	Rash Erythematous							

Date: 12/03/1998 **ISR Number:** 3166659-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 109483 **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec	Consumer	Accutane	PS		ORAL		
	Depression Aggravated	Health Professional						
	Feeling Abnormal							
	Headache Nos							
	Insomnia Nec							
	Ovarian Pain							
	Weight Decreased							

Date: 12/07/1998 **ISR Number:** 3166980-X **Report Type:** Expedited (15-Day) **Company Report Number:** 108782 **Age:** 75 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Alanine Aminotransferase Increased	Foreign	Tasmar	PS		ORAL		
Hospitalization - Initial or Prolonged	Anaemia Nos	Study	Madopar	SS				
	Balance Impaired Nos	Health Professional	Antiparkin (Selegiline Hydrochloride)	C				
	Blood Alkaline Phosphatase Nos Increased	Other	Unat (Torsemide Or Torsemide Sodium)	C				
	Depression Nec		Acerbon Cor (Lisinopril)	C				
	Diarrhoea Nos		Arelix (Piretanide)	C				
	Ileus		Pangrol (Amylase/Lipase/Proteinase)	C				
	Leucopenia Nos		Cabaseril (Cabergoline)	C				
	Rigors		Cipramil (Citalopram)	C				
	Urinary Tract Infection Nos		Berlocombin (Sulfamethoxazole/Trimethoprim)	C				
			Heparin (Heparin Sodium)	C				
			Pk-Merz (Amantadine Sulfate)	C				
			Pk-Merz (Amantadine Sulfate)	C				
			Dipiperon (Pipamperone)	C				

Date: 12/07/1998 **ISR Number:** 3167006-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 109687 **Age:** 70 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign	Tasmar	PS		ORAL		
		Health Professional	Modopar	C				

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 12/08/1998 **ISR Number:** 3168234-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 108076 **Age:** 75 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Acute Circulatory Failure	Foreign	Tasmar	PS		ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Agitation	Health Professional	Requip (Ropinirole Hydrochloride) .5 Mg	SS		ORAL		
	Blood Creatine Phosphokinase Increased	Other	Akineton (Biperiden Hydrochloride)	C				
	C-Reactive Protein Increased		Novodigal(Acetyldigoxin)	C				
	Cholelithiasis		Nacom (Carbidopa/Levodopa)	C				
	Condition Aggravated		Nacom Retard (Carbidopa/Levodopa)	C				
	Dehydration							
	Dementia Due To Pick'S Disease							
	Dysarthria							
	Dysphagia							
	Ecchymosis							
	Electroencephalogram Abnormal							
	Gastric Ulcer							
	Haematoma Nos							
	Haemorrhage Nos							
	Hypotension							
	Oesophagitis							
	Oliguria							
	Pleural Effusion							
	Pulse Absent							
	Renal Cyst Nos							
	Renal Failure Acute							
	Rhabdomyolysis							
	Rigors							
	Sedation							
	Sweating Increased							
	Syncope							
	Tremor Nec							
	Urinary Tract Infection Nos							

Date: 12/08/1998 **ISR Number:** 3168241-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 109250 **Age:** 75 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Coma Nec	Foreign	Tasmar	PS		ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Drug Interaction Nos	Health Professional	Alcohol (Alcohol)	SS		ORAL		
	Non-Accidental Overdose		Modopar	C				
	Suicide Attempt		Trivastal	C				
			Parlodel	C				
			Permixon	C				

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 12/09/1998 **ISR Number:** 3168456-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 109802 **Age:** 38 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos	Consumer	Accutane	PS		ORAL		
	Alopecia		One-A-Day Multivitamins	C				
	Appetite Decreased							
	Collapse							
	Crying							
	Decreased Activity							
	Depression Nec							
	Hyperaesthesia							
	Mental Disorder Nec							
	Mucosal Dryness Nos							
	Skin Disorder Nos							
	Sweating Increased							
	Tremor Nec							
	Weakness							
	Weight Decreased							

Date: 12/11/1998 **ISR Number:** 3169581-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 108188 **Age:** 45 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Appetite Decreased	Consumer	Accutane	PS		ORAL		
	Depression Aggravated	Health Professional	Ritalin	C				
	Fatigue	Other	Imipramine	C				
	Suicidal Ideation							

Date: 12/14/1998 **ISR Number:** 3169845-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 110000 **Age:** 68 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Confusion	Foreign	Tasmar	PS		ORAL		
	Diarrhoea Nos	Study	Madopar	C				
	Markedly Reduced Food Intake	Health Professional	Movergan	C				
	Muscle Rigidity	Other	Pk-Merz	C				
	Parkinsonism							
	Pneumonia Nos							

Date: 12/14/1998 **ISR Number:** 3169858-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 110000 **Age:** 68 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Akinesia	Foreign	Tasmar (Tolcapone) 100 Mg	PS		ORAL		
	Confusion	Study	Madopar	C				
	Diarrhoea Nos	Health Professional	Movergan	C				
	Muscle Rigidity	Other	Pk-Merz	C				
	Parkinsonism							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 12/10/1998 **ISR Number:** 3169919-6 **Report Type:** Direct **Company Report Number:** **Age:** 36 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Aggravated	Consumer	Accutane	PS				

Date: 12/14/1998 **ISR Number:** 3170547-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 109381 **Age:** 28 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Congenital Anomaly	Anomaly Of External Ear Congenital Nos	Health Professional	Accutane	PS		ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Aphasia	Other	Macrodantin	C				
	Autism							
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Difficulty In Walking							
	Dysphasia							
	Eye Disorder Nos							
	Foreign Body Aspiration							
	Hypotonia							
	Malaise							
	Mental Retardation Severity Unspecified							
	Micrognathia							
	Sore Throat Nos							

Date: 12/16/1998 **ISR Number:** 3171069-X **Report Type:** Direct **Company Report Number:** **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos	Health Professional	Accutane	PS				
	Condition Aggravated		Bactrim	C				
	Hyperkalaemia		Prilosec	C				
			Fluconazole	C				
			Lovenox	C				
			Magnesium	C				
			Fluoride	C				

Date: 12/03/1998 **ISR Number:** 3171277-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 109455 **Age:** 41 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depressed Mood	Consumer	Accutane	PS		ORAL		
	Fatigue	Health Professional	Provera	C				
	Premature Menopause							

Date: 12/03/1998 **ISR Number:** 3171298-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 109455 **Age:** 41 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amenorrhoea Nos	Consumer	Accutane	PS		ORAL		
	Fatigue	Health Professional	Provera (Medroxyprogesterone Acetate)	C				
	Menstruation Irregular							
	Mood Disorder Nos							
	Premature Menopause							

Date: 12/17/1998 **ISR Number:** 3171634-X **Report Type:** Expedited (15-Day) **Company Report Number:** 110489 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aggression	Foreign	Roaccutane	PS		ORAL		
	Personality Disorder Nos	Other	Virlix	SS		ORAL		

Date: 06/09/1998 **ISR Number:** 3171928-8 **Report Type:** Periodic **Company Report Number:** 97085 **Age:** 44 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Cholesterol Increased	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Fluid Retention							
	Mood Alteration Nos							
	Sluggishness							
	Weight Increased							

Date: 06/05/1998 **ISR Number:** 3171942-2 **Report Type:** Periodic **Company Report Number:** 83789 **Age:** 18 YR **Gender:** Female

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

Date: 06/05/1998 **ISR Number:** 3171952-5 **Report Type:** Periodic **Company Report Number:** 83853 **Age:** 21 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dry Eye Nec	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Emotional Disturbance Nos							
	Gum Pain							
	Lethargy							
	Sunburn							

Date: 12/21/1998 **ISR Number:** 3172270-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 98590 **Age:** 32 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Apgar Score Low	Health Professional	Accutane Capsules	PS		ORAL		
	Complications Of Maternal Exposure To Therapeutic Drugs							
	Crying							
	Depression Post-Partum (Exc							

Date: 12/21/1998 **ISR Number:** 3172293-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 110264 **Age:** 32 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Tenderness Apgar Score Low Complications Of Maternal Exposure To Therapuetic Drugs Constipation Crying Depression Post-Partum (Exc Psychosis) Endometriosis Flatulence Foetal Malposition Nos Hyperbilirubinaemia Hypotonia Neonatal Neonatal Respiratory Distress Syndrome Pain Nos Placental Disorder Nos Premature Baby Pyrexia Sepsis Neonatal	Health Professional	Accutane	PS		ORAL		

Date: 12/21/1998 **ISR Number:** 3172299-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 110261 **Age:** 32 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Abdominal Tenderness Apgar Score Low Complications Of Maternal Exposure To Therapuetic Drugs Constipation Depression Post-Partum (Exc Psychosis) Disorder Neonatal Nos Endometriosis Flatulence Foetal Malposition Nos Hyperbilirubinaemia Neonatal Hypotonia Neonatal Neonatal Respiratory Distress Syndrome Pain Nos Placental Disorder Nos Premature Baby Pyrexia	Health Professional	Accutane	PS		ORAL		

Date: 06/09/1998 **ISR Number:** 3172708-X **Report Type:** Periodic **Company Report Number:** 94661 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Nos Depression Nec Fatigue Glossodynia Haemorrhage Nos	Other	Accutane Capsules (Isotretinoin) 40.000 Mg Cefadroxil (Cefadroxil)	PS C		ORAL		

Date: 06/09/1998 **ISR Number:** 3172709-1 **Report Type:** Periodic **Company Report Number:** 94668 **Age:** 17 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Dry Skin Insomnia Nec Vomiting Nos Vulvovaginal Dryness	Other	Accutane Capsules (Isotretinoin) 40.000 Mg Xanax (Alprazolam) Dexedrine (Dextroamphetamine Sulfate) Paxil (Paroxetine)	PS C C C		ORAL		

Date: 06/09/1998 **ISR Number:** 3172723-6 **Report Type:** Periodic **Company Report Number:** 94889 **Age:** 27 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Memory Impairment Mood Alteration Nos	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/09/1998 **ISR Number:** 3172731-5 **Report Type:** Periodic **Company Report Number:** 95017 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthralgia Decreased Activity Myalgia	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/09/1998 **ISR Number:** 3172744-3 **Report Type:** Periodic **Company Report Number:** 95233 **Age:** 42 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Atrioventricular Block First Degree Bradycardia Nos Palpitations	Health Professional	Accutane Capsules (Isotretinoin) 10 Mg	PS		ORAL		

Date: 06/09/1998 **ISR Number:** 3173175-2 **Report Type:** Periodic **Company Report Number:** 92415 **Age:** 29 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Dermatitis Nos Fatigue Flushing	Consumer	Accutane Capsules (Isotretinoin) Zantac (Ranitidine)	PS C		ORAL		

Date: 06/09/1998 **ISR Number:** 3173184-3 **Report Type:** Periodic **Company Report Number:** 92447 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Enuresis	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
			Paxil (Paroxetin)	SS		ORAL		
			Prozac (Fluoxetine)	C				

Date: 06/09/1998 **ISR Number:** 3173195-8 **Report Type:** Periodic **Company Report Number:** 92515 **Age:** 12 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Upper	Other	Accutane Capsules (Isotretinoin) 30. 000 Mg	PS		ORAL		
	Dermatitis Nos							
	Mood Swings							

Date: 06/09/1998 **ISR Number:** 3173196-X **Report Type:** Periodic **Company Report Number:** 92523 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Acne Aggravated							
	Appetite Decreased							
	Emotional Disturbance Nos							
	Nausea							
	Vomiting Nos							
	Weight Decreased							

Date: 06/09/1998 **ISR Number:** 3173214-9 **Report Type:** Periodic **Company Report Number:** 94470 **Age:** 25 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Back Pain	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Depression Nec							
	Skin Disorder Nos							

Date: 06/09/1998 **ISR Number:** 3173289-7 **Report Type:** Periodic **Company Report Number:** 95778 **Age:** 15 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dry Skin	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Menstrual Disorder Nos							
	Mood Swings							
	Pruritus							

Date: 06/09/1998 **ISR Number:** 3173298-8 **Report Type:** Periodic **Company Report Number:** 95790 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Aggression		Accutane Capsules (Isotretinoin)	PS		ORAL		
	Blindness Night							

Date: 06/09/1998 **ISR Number:** 3173302-7 **Report Type:** Periodic **Company Report Number:** 95800 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/09/1998 **ISR Number:** 3173324-6 **Report Type:** Periodic **Company Report Number:** 95941 **Age:** 28 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Apathy Premenstrual Syndrome	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/09/1998 **ISR Number:** 3173326-X **Report Type:** Periodic **Company Report Number:** 95944 **Age:** 43 YR **Gender:** Female

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

Date: 06/09/1998 **ISR Number:** 3173365-9 **Report Type:** Periodic **Company Report Number:** 85792 **Age:** 30 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Aggravated Cheilitis Depression Nec Dry Skin Skin Disorder Nos	Consumer	Accutane Capsules (Isotretinoin) 40.000 Mg Ovcon-35	PS C		ORAL		

Date: 12/24/1998 **ISR Number:** 3173486-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 106644 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Cataract Nec Confusion Hallucination Nos Operation Nos Paranoia	Health Professional Company Representative	Tasmar Permax Restoril Valium Sinemat Cr 50-200 (Carbidopa/Levodopa) Sinemat -25/100 (Carbidopa/Levodopa)	PS SS SS SS C C		ORAL ORAL ORAL ORAL		

Date: 12/24/1998 **ISR Number:** 3173492-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 110000 **Age:** 68 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Condition Aggravated Confusion Dehydration Diarrhoea Nos Pneumonia Nos	Foreign Study Health Professional Other	Tasmar Madopar (Benserazide / Levodopa) Movergan (Selegiline Hydrochloride) Pk - Merz (Amantadine Sulfate)	PS C C C		ORAL		

Date: 12/24/1998 **ISR Number:** 3173752-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 110553 **Age:** 27 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Accident Nos Anxiety Nec Appetite Decreased Blindness Night Bone Pain Chest Pain Conjunctivitis Nec Costochondritis Depression Nec Disturbance In Attention Nec Dry Eye Nec Dry Mouth Dyspnoea Exertional Dysuria Eye Disorder Nos Eye Irritation Fatigue Haemophilus Infection Nos Hiatus Hernia Laboratory Test Abnormal Nos Lacrimation Decreased Loss Of Libido Myopia Productive Cough Red Eye Rib Fracture Sleep Disorder Nos Sore Throat Nos Stress Symptoms Swallowing Painful Tachycardia Nos Upper Respiratory Tract Infection Nos Vision Blurred Visual Acuity Reduced Weight Decreased	Other	Accutane	PS		ORAL		

Date: 06/09/1998 **ISR Number:** 3174160-7 **Report Type:** Periodic **Company Report Number:** 97246 **Age:** 27 YR **Gender:** Male

Outcome	PT	Report Source
Other	Depression Nec	Consumer
	Pruritus	

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane Capsules (Isotretinoin) 40.000 Mg	PS		ORAL		
Herbs (Herbal Extracts Nos)	C				
Claritin-D (Loratadine/Pseudoephedrine Sulfate)	C				
Albuterol (Albuterol)	C				

Date: 06/09/1998 **ISR Number:** 3174168-1 **Report Type:** Periodic **Company Report Number:** 97295 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source
Other	Acne Aggravated	Other
	Blood Triglycerides Increased	
	Cheilitis	
	Depression Nec	
	Diabetes Mellitus Inadequate Control	
	Disturbance In Attention Nec	
	Dry Skin	
	Mood Swings	
	Rash Erythematous	
	Rash Scaly	
	Sluggishness	
	Urticaria Nos	

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane Capsules (Isotretinoin) 40.000 Mg	PS		ORAL		

Date: 06/09/1998 **ISR Number:** 3174171-1 **Report Type:** Periodic **Company Report Number:** 97298 **Age:** 32 YR **Gender:** Female

Outcome	PT	Report Source
Other	Amenorrhoea Nos	Health Professional
	Menstrual Disorder Nos	
	Oedema Lower Limb	
	Premenstrual Syndrome	

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

Date: 06/09/1998 **ISR Number:** 3174174-7 **Report Type:** Periodic **Company Report Number:** 97322 **Age:** 20 YR **Gender:** Male

Outcome	PT	Report Source
Other	Mood Alteration Nos	Other

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane Capsules (Isotretinoin)	PS		ORAL		
Ritalin (Methyphenidate Hydrochloride)	C				

Date: 06/09/1998 **ISR Number:** 3174175-9 **Report Type:** Periodic **Company Report Number:** 97415 **Age:** 17 YR **Gender:** Female

Outcome	PT	Report Source
Other	Social Avoidant Behaviour	Health Professional

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane Capsules (Isotretinoin) 40.000 Mg	PS		ORAL		

Date: 06/09/1998	ISR Number: 3174179-6	Report Type: Periodic	Company Report Number: 97650			Age:	Gender: Female	
Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose/Unit**	**Duration**
Other	Libido Decreased	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/09/1998	ISR Number: 3174216-9	Report Type: Periodic	Company Report Number: 90004			Age: 18 YR	Gender: Female	
Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose/Unit**	**Duration**
Other	Depression Nec	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/09/1998	ISR Number: 3174263-7	Report Type: Periodic	Company Report Number: 90460			Age: 15 YR	Gender: Male	
Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose/Unit**	**Duration**
Other	Anaemia Nos Depression Nec Proteinuria Present	Health Professional	Accutane Capsules (Isotretinoin) 40.000 Mg Cleotin T (Clindamycin Phosphate)	PS C		ORAL		

Date: 06/09/1998	ISR Number: 3174283-2	Report Type: Periodic	Company Report Number: 91822			Age: 16 YR	Gender: Male	
Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose/Unit**	**Duration**
Other	Abnormal Behaviour Nos Fatigue Mood Alteration Nos	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/09/1998	ISR Number: 3174293-5	Report Type: Periodic	Company Report Number: 95550			Age:	Gender: Male	
Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose/Unit**	**Duration**
Other	Depression Nec	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/09/1998	ISR Number: 3174298-4	Report Type: Periodic	Company Report Number: 95567			Age: 14 YR	Gender: Female	
Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose/Unit**	**Duration**
Other	Depression Nec Dry Skin Headache Nos	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/09/1998	ISR Number: 3174306-0	Report Type: Periodic	Company Report Number: 95645			Age: 45 YR	Gender: Male	
Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose/Unit**	**Duration**
Other	Depression Nec	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/09/1998 **ISR Number:** 3174314-X **Report Type:** Periodic **Company Report Number:** 95729 **Age:** 14 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthralgia	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Depression Nec		Advil (Ibuprofen)	C				
	Epistaxis							
	Headache Nos							

Date: 06/09/1998 **ISR Number:** 3174316-3 **Report Type:** Periodic **Company Report Number:** 95767 **Age:** **Gender:** Male

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

Date: 06/09/1998 **ISR Number:** 3174320-5 **Report Type:** Periodic **Company Report Number:** 95771 **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Arthralgia		Benadryl (Diphenhydramine Hydrochloride)	C				
	Ecchymosis							
	Insomnia Nec							
	Weakness							

Date: 06/05/1998 **ISR Number:** 3174353-9 **Report Type:** Periodic **Company Report Number:** 92620 **Age:** 36 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Libido Decreased	Health Professional	Accutane Capsules (Isotretinoin) 40.000 Mg	PS		ORAL		

Date: 06/09/1998 **ISR Number:** 3174392-8 **Report Type:** Periodic **Company Report Number:** 91530 **Age:** 36 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Fatigue	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Irritability							
	Mood Alteration Nos							
	Rectal Bleeding							
	Tenesmus							
	Urine Discolouration							

Date: 12/29/1998 **ISR Number:** 3174425-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 109074 **Age:** 66 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Agitation	Foreign	Tasmar	PS		ORAL		
Hospitalization - Initial or Prolonged	Anorexia	Health Professional	Modopar	SS		ORAL		
	Anuria		Lexomil	SS		ORAL		
	Arrhythmia Nos		Deroxat	SS		ORAL		
	Aspartate Aminotransferase Increased							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 12/29/1998 **ISR Number:** 3174428-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 111008 **Age:** 70 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Cognitive Disorder Nec	Foreign	Tasmar	PS		ORAL		
	Dysphagia	Health Professional						
	Jaundice Nos							

Date: 06/09/1998 **ISR Number:** 3174450-8 **Report Type:** Periodic **Company Report Number:** 85315 **Age:** 25 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Distension	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Acne Aggravated		Minocyn (Minocycline)	C				
	Acne Cystic		Tetracycline (Tetracycline)	C				
	Blindness Night		Septra (Sulfamethoxazole/Trimethoprim) Roche	C				
	Colour Blindness Nec							
	Dermatitis Nos							
	Fatigue							
	Glaucoma Nos							
	Hearing Impaired							
	Hypochondriasis							
	Loss Of Eyelashes							
	Nausea							
	Oedema Lower Limb							
	Pain In Limb							
	Pruritus							
	Stress Symptoms							
	Urinary Incontinence							

Date: 06/09/1998 **ISR Number:** 3174451-X **Report Type:** Periodic **Company Report Number:** 85319 **Age:** 27 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dry Eye Nec	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Dry Mouth		Loestrin (Ethinyl Estradiol/Norethindrone Acetate)	C				
	Lip Dry							
	Premenstrual Syndrome							
	Skin Hyperpigmentation							

Date: 06/09/1998 **ISR Number:** 3174457-0 **Report Type:** Periodic **Company Report Number:** 85365 **Age:** 38 YR **Gender:** Female

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

Date: 06/09/1998 **ISR Number:** 3174466-1 **Report Type:** Periodic **Company Report Number:** 85492 **Age:** 29 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Akinesia	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Arthralgia	Health Professional	Sular	C				
	Blood Triglycerides Increased							
	Disturbance In Attention Nec							
	Headache Nos							
	Vertigo Aggravated							

Date: 06/09/1998 **ISR Number:** 3174468-5 **Report Type:** Periodic **Company Report Number:** 85511 **Age:** 44 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dry Eye Nec	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Headache Nos		Synthroid	C				
	Mood Alteration Nos		Ptu	C				
	Sensation Of Pressure Nos							
	Syncope							

Date: 06/09/1998 **ISR Number:** 3174476-4 **Report Type:** Periodic **Company Report Number:** 85579 **Age:** 20 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Attention Deficit/Hyperactivity Disorder	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Depression Nec	Other						

Date: 06/09/1998 **ISR Number:** 3174483-1 **Report Type:** Periodic **Company Report Number:** 85633 **Age:** 52 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Cholesterol Increased	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Fatigue		Estrace	C				
	Feeling Jittery		Amen	C				
	Headache Nos		Allergy Shots	C				
	Hypertriglyceridaemia							
	Irritability							
	Motion Sickness							
	Myalgia							
	Sweating Increased							

Date: 06/05/1998 **ISR Number:** 3174521-6 **Report Type:** Periodic **Company Report Number:** 83487 **Age:** 22 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Emotional Disturbance Nos							

Date: 06/05/1998 **ISR Number:** 3174530-7 **Report Type:** Periodic **Company Report Number:** 83655 **Age:** 38 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Bloodshot Eye Dry Eye Nec Irritability Weight Decreased	Consumer	Accutane Capsules (Isotretinoin) 40.000 Mg Ibuprofen	PS C		ORAL		

Date: 06/05/1998 **ISR Number:** 3174531-9 **Report Type:** Periodic **Company Report Number:** 83713 **Age:** 64 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthralgia Blood Cholesterol Increased Impotence	Health Professional	Accutane Capsules (Isotretinoin) Zocor	PS C		ORAL		

Date: 06/05/1998 **ISR Number:** 3174534-4 **Report Type:** Periodic **Company Report Number:** 83770 **Age:** 15 YR **Gender:** Male

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

Date: 06/09/1998 **ISR Number:** 3174544-7 **Report Type:** Periodic **Company Report Number:** 95440 **Age:** 36 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Triglycerides Increased Mood Alteration Nos	Consumer	Accutane Capsules (Isotretinoin) 20.000 Mg Cozaar (Losartan Potassium) Xanax (Alprezolam)	PS C C		ORAL		

Date: 06/09/1998 **ISR Number:** 3174547-2 **Report Type:** Periodic **Company Report Number:** 95517 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Triglycerides Increased Erythema Nec Liver Function Tests Nos Abnormal Personality Change	Other	Accutane Capsules (Isotretinoin) 40 .000 Mg Vitamins (Multimin Nos)	PS C		ORAL		

Date: 06/09/1998 **ISR Number:** 3174548-4 **Report Type:** Periodic **Company Report Number:** 95521 **Age:** 31 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Consumer	Accutane Capsules (Isotretinoin) Birth Control Pills (Oral Contraceptive Nos)	PS C		ORAL		

Date: 06/05/1998 **ISR Number:** 3174611-8 **Report Type:** Periodic **Company Report Number:** 75615 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Fatigue Hypertriglyceridaemia Irritability Sinusitis Nos	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		

Date: 06/05/1998 **ISR Number:** 3174675-1 **Report Type:** Periodic **Company Report Number:** 88169 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Aggravated Condition Aggravated Mood Swings	Consumer	Accutane Capsules (Isotretinoin) 20.000 Mcg	PS		ORAL		
			Tegretol (Carbamazepine)	C				

Date: 12/24/1998 **ISR Number:** 3174680-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 109103 **Age:** 72 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Anhedonia Ascites Blood Albumin Decreased Blood Glucose Increased Blood Triglycerides Decreased Cachexia Cholelithiasis Depression Nec Difficulty In Walking Electrocardiogram Abnormal Nos Fatigue Haematocrit Decreased Haemoglobin Decreased Hepatic Cirrhosis Nos Hepatic Disorder Nos Hepatic Failure Hepatic Fibrosis Hypertonia Hypokalaemia Hypophosphataemia International Normalised Ratio Increased Jaundice Nos Liver Function Tests Nos Abnormal Lymphocyte Count Decreased	Other	Tasmar	PS		ORAL		
			Sinemet	C				
			Mirapex	C				
			Fosamax	C				
			Acetaminophen	C				

Date: 06/05/1998 **ISR Number:** 3174684-2 **Report Type:** Periodic **Company Report Number:** 96273 **Age:** 23 YR **Gender:** Female

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

Date: 06/05/1998 **ISR Number:** 3174685-4 **Report Type:** Periodic **Company Report Number:** 96303 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Confusion Psychotic Disorder Nos	Health Professional	Accutane Capsules (Isotretinoin) 40.000 Mg	PS		ORAL		
			Ritalin	C				

Date: 06/05/1998 **ISR Number:** 3174686-6 **Report Type:** Periodic **Company Report Number:** 96364 **Age:** 16 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Depression Aggravated Mood Alteration Nos Suicide Attempt	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
			Birth Control Pills	C				

Date: 06/05/1998 **ISR Number:** 3174689-1 **Report Type:** Periodic **Company Report Number:** 96479 **Age:** 20 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Appetite Decreased Depression Nec Social Avoidant Behaviour Weight Decreased	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/05/1998 **ISR Number:** 3174690-8 **Report Type:** Periodic **Company Report Number:** 96499 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Abnormal Behaviour Nos Lip Dry Psychotic Disorder Nos Suicidal Ideation White Blood Cell Count Decreased	Other	Accutane Capsules (Isotretinoin) 40.000 Mg	PS		ORAL		

Date: 06/05/1998 **ISR Number:** 3174691-X **Report Type:** Periodic **Company Report Number:** 96545 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death Life-Threatening	Completed Suicide Depression Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
			Zoloft	C				

Date	ISR Number	Report Type	Company Report Number	Age	Gender
06/05/1998	3174693-3	Periodic	96628	18 YR	Male

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

Date	ISR Number	Report Type	Company Report Number	Age	Gender
06/05/1998	3174694-5	Periodic	96741	50 YR	Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anorexia Hallucination, Auditory	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date	ISR Number	Report Type	Company Report Number	Age	Gender
06/05/1998	3174696-9	Periodic	96941	17 YR	Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date	ISR Number	Report Type	Company Report Number	Age	Gender
06/05/1998	3174697-0	Periodic	96942	16 YR	Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Disturbance In Attention Nec Mood Swings Paranoia	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date	ISR Number	Report Type	Company Report Number	Age	Gender
06/05/1998	3174698-2	Periodic	96992	17 YR	Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Suicide Attempt	Health Professional	Accutane Capsules (Isotretinoin) Unspecified Medication	PS C		ORAL		

Date	ISR Number	Report Type	Company Report Number	Age	Gender
06/09/1998	3174747-1	Periodic	96155	16 YR	Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane Capsules (Isotretinoin) 40.000 Mg Asthma Medications Nos	PS C		ORAL		

Date	ISR Number	Report Type	Company Report Number	Age	Gender
06/09/1998	3174759-8	Periodic	96175	19 YR	Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Other	Accutane Capsules (Isotretinoin) 40.000 Mg	PS		ORAL		

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 06/05/1998 **ISR Number:** 3174784-7 **Report Type:** Periodic **Company Report Number:** 84276 **Age:** 15 YR **Gender:** Male

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

Date: 06/05/1998 **ISR Number:** 3174794-X **Report Type:** Periodic **Company Report Number:** 84291 **Age:** 39 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Disorientation Dizziness (Exc Vertigo)	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
			Tegretol (Carbamazepine)	C				
			Lamictal (Lamotrigine)	C				

Date: 12/30/1998 **ISR Number:** 3174829-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 109687 **Age:** 70 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Non-Accidental Overdose Suicide Attempt	Foreign Health Professional	Tasmar	PS		ORAL		
			Modopar (Benserazide/Levodopa0	C				

Date: 06/05/1998 **ISR Number:** 3174894-4 **Report Type:** Periodic **Company Report Number:** 88277 **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Myalgia	Other	Accutane Capsules (Isotretinoin) 40.000 Mg	PS		ORAL		
			Zoloft (Sertraline Hydrochloride)	C				
			Imitrex (Sumatriptan Succinate)	C				

Date: 06/05/1998 **ISR Number:** 3174977-9 **Report Type:** Periodic **Company Report Number:** 78453 **Age:** 21 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anorexia Loss Of Libido Tinnitus Weight Decreased	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/05/1998 **ISR Number:** 3174978-0 **Report Type:** Periodic **Company Report Number:** 80074 **Age:** 17 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Enuresis	Health Professional	Accutane Capsules (Isotretinoin) 40.000 Mg	PS		ORAL		
			Paxil	C				

Date: 06/05/1998 **ISR Number:** 3175060-9 **Report Type:** Periodic **Company Report Number:** 83284 **Age:** 51 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Increased Activity	Consumer	Accutane Capsules (Isotretinoin) 10.000 Mg	PS		ORAL		
	Insomnia Nec		Flexeril	C				
	Pruritus		Doxepin	C				

Date: 05/06/1998 **ISR Number:** 3175221-9 **Report Type:** Periodic **Company Report Number:** 77280 **Age:** 32 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Palpitations	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
		Health Professional	Vicodin	C				
			Aspirin	C				
			Tri-Cyclen	C				

Date: 06/05/1998 **ISR Number:** 3175227-X **Report Type:** Periodic **Company Report Number:** 84806 **Age:** 20 YR **Gender:** Female

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

Date: 06/05/1998 **ISR Number:** 3175238-4 **Report Type:** Periodic **Company Report Number:** 84901 **Age:** 21 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Disturbance In Attention Nec							
	Sleep Disorder Nos							
	Social Avoidant Behaviour							

Date: 06/05/1998 **ISR Number:** 3175266-9 **Report Type:** Periodic **Company Report Number:** 86862 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Aggravated	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Alopecia							
	Emotional Disturbance Nos							
	Irritability							
	Mood Swings							
	Tremor Nec							

Date: 06/05/1998 **ISR Number:** 3175276-1 **Report Type:** Periodic **Company Report Number:** 87025 **Age:** 42 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Dermatitis Nos		B Complex (Vitamin B Complex)	C				
	Lip Dry							

Date: 06/05/1998 **ISR Number:** 3175320-1 **Report Type:** Periodic **Company Report Number:** 97450 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Suicide Attempt	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/05/1998 **ISR Number:** 3175322-5 **Report Type:** Periodic **Company Report Number:** 97451 **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Depression Nec Suicide Attempt	Health Professional	Accutane Capsules (Isotretinoin) 40.000 Mg	PS		ORAL		
			Demulen	C				

Date: 06/05/1998 **ISR Number:** 3175324-9 **Report Type:** Periodic **Company Report Number:** 97530 **Age:** 13 YR **Gender:** Unknown

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Suicide Attempt	Health Professional	Accutane Capsules (Isotretinoin)	PS				

Date: 06/05/1998 **ISR Number:** 3175325-0 **Report Type:** Periodic **Company Report Number:** 97601 **Age:** 24 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Acne Aggravated Depression Aggravated Suicide Attempt	Consumer Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
			Contraceptives Nos	C				
			Prozac	C				

Date: 06/05/1998 **ISR Number:** 3175329-8 **Report Type:** Periodic **Company Report Number:** 67733 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Thyroid Stimulating Hormone Decreased Emotional Disturbance Nos Malaise Palpitations Tachycardia Nos Thyroiditis Nos Thyroxine Increased	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/09/1998 **ISR Number:** 3175414-0 **Report Type:** Periodic **Company Report Number:** 96073 **Age:** 26 YR **Gender:** Male

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

Date: 06/09/1998 **ISR Number:** 3175416-4 **Report Type:** Periodic **Company Report Number:** 96123 **Age:** 25 YR **Gender:** Female

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

Date: 06/09/1998 **ISR Number:** 3175417-6 **Report Type:** Periodic **Company Report Number:** 96124 **Age:** 18 YR **Gender:** Male

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

Date: 06/09/1998 **ISR Number:** 3175419-X **Report Type:** Periodic **Company Report Number:** 96152 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide Hypertriglyceridaemia	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/09/1998 **ISR Number:** 3175420-6 **Report Type:** Periodic **Company Report Number:** 96223 **Age:** 15 YR **Gender:** Male

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

Date: 06/09/1998 **ISR Number:** 3175421-8 **Report Type:** Periodic **Company Report Number:** 96228 **Age:** 17 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Aggravated	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
			Zoloft (Sertraline Hydrochloride)	C				

Date: 06/09/1998 **ISR Number:** 3175426-7 **Report Type:** Periodic **Company Report Number:** 80426 **Age:** 36 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Bone Disorder Nos Depression Nec Infection Nos	Consumer	Accutane Capsules (Isotretinion)	PS		ORAL		

Date: 06/05/1998 **ISR Number:** 3175437-1 **Report Type:** Periodic **Company Report Number:** 82968 **Age:** 20 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Logorrhoea	Health Professional	Accutane Capsules (Isotretinoin) 40.000 Mg	PS		ORAL		

Date: 06/05/1998 **ISR Number:** 3175451-6 **Report Type:** Periodic **Company Report Number:** 83147 **Age:** **Gender:**

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

Date: 06/09/1998 **ISR Number:** 3175462-0 **Report Type:** Periodic **Company Report Number:** 94537 **Age:** 17 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Aggression	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Dry Eye Nec		Contraceptive	C				
	Dry Skin		Eye Drops	C				
	Headache Nos		Pepto-Bismol	C				
	Mood Alteration Nos							
	Nausea							
	Vision Blurred							

Date: 06/05/1998 **ISR Number:** 3175500-5 **Report Type:** Periodic **Company Report Number:** 81176 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
			Zoloft	C				

Date: 06/09/1998 **ISR Number:** 3175508-X **Report Type:** Periodic **Company Report Number:** 96246 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Hypertriglyceridaemia	Other	Accutane Capsules (Isotretinoin) 40.000 Mg	PS		ORAL		
	Mood Alteration Nos							
	Pain In Limb							
	Pruritus							
	Rash Erythematous							

Date: 06/09/1998 **ISR Number:** 3175510-8 **Report Type:** Periodic **Company Report Number:** 96274 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Eyelid Oedema	Other	Accutane Capsules (Isotretinoin) 40.000 Mg	PS				
	Headache Nos							
	Mood Swings							

Date: 06/05/1998 **ISR Number:** 3175542-X **Report Type:** Periodic **Company Report Number:** 81829 **Age:** 22 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Back Pain	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Depression Nec		Depo-Provera	C				
	Tearfulness							

Date: 06/05/1998 **ISR Number:** 3175548-0 **Report Type:** Periodic **Company Report Number:** 81928 **Age:** 20 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Hypertriglyceridaemia	Health Professional	Birth Control Tablet	C				
	Lymphadenopathy							

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 06/05/1998 **ISR Number:** 3175681-3 **Report Type:** Periodic **Company Report Number:** 84364 **Age:** 47 YR **Gender:** Female

Outcome	PT	Report Source
Other	Depression Nec	Consumer
	Skin Wrinkling	

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane Capsules (Isotretinoin)	PS		ORAL		
Paxil	C				
Doxepin	C				
Retin A Cream	C				

Date: 06/09/1998 **ISR Number:** 3175709-0 **Report Type:** Periodic **Company Report Number:** 89317 **Age:** 23 YR **Gender:** Female

Outcome	PT	Report Source
Other	Fatigue	Health Professional
	Headache Nos	
	Memory Impairment	

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane Capsules (Isotretinoin) 40.000 Mg	PS		ORAL		
Iron Tablets (Iron Nos)	C				

Date: 06/09/1998 **ISR Number:** 3175723-5 **Report Type:** Periodic **Company Report Number:** 96834 **Age:** 14 YR **Gender:** Female

Outcome	PT	Report Source
Other	Abdominal Distension	Other
	Appetite Decreased	
	Fatigue	
	Irritability	
	Mood Alteration Nos	
	Pyrexia	
	Sore Throat Nos	

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane Capsules (Isotretinoin) 40.000 Mg	PS		ORAL		
Ortho Tri-Cyclen (Ethinyl Estradiol / Norgestimate)	C				

Date: 06/09/1998 **ISR Number:** 3175730-2 **Report Type:** Periodic **Company Report Number:** 96883 **Age:** 22 YR **Gender:** Female

Outcome	PT	Report Source
Other	Dizziness (Exc Vertigo)	Consumer
	Palpitations	
	Tremor Nec	

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

Date: 06/09/1998 **ISR Number:** 3175732-6 **Report Type:** Periodic **Company Report Number:** 96910 **Age:** 16 YR **Gender:** Female

Outcome	PT	Report Source
Other	Anger	Other
	Depression Nec	
	Mood Alteration Nos	
	Syncope	
	Vision Blurred	

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane Capsules (Isotretinoin) 40.000 Mg	PS		ORAL		

Date: 06/09/1998 **ISR Number:** 3175734-X **Report Type:** Periodic **Company Report Number:** 93585 **Age:** 22 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Depressed Mood		Oral Contraception (Oral Contraceptive Nos)	C				
	Depression Nec							

Date: 06/09/1998 **ISR Number:** 3176549-9 **Report Type:** Periodic **Company Report Number:** 96557 **Age:** 26 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Consumer	Accutane Capsules (Isotretinoin) 40.000 Mg	PS		ORAL		
	Dry Skin		Ortho Tri Cyclen	C				
	Lip Dry							
	Menstrual Disorder Nos							
	Skin Hypopigmentation							

Date: 06/09/1998 **ISR Number:** 3176554-2 **Report Type:** Periodic **Company Report Number:** 96639 **Age:** 26 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Dermatitis Nos		Loestrin	C				
	Disorientation							
	Dizziness (Exc Vertigo)							
	Dry Skin							
	Pruritus							
	Rash Erythematous							
	Rash Scaly							
	Skin Disorder Nos							

Date: 12/30/1998 **ISR Number:** 3176707-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 109455 **Age:** 41 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Follicle Stimulating Hormone Increased	Consumer	Accutane Capsules (Isotretinoin) 20 Mg	PS		ORAL		
	Fatigue	Health Professional	Provera	C				
	Menstruation Irregular							
	Mood Alteration Nos							
	Oligomenorrhoea Nos							
	Premature Menopause							

Date: 12/31/1998 **ISR Number:** 3176908-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 111140 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Accident Nos	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Depression Nec		Vitamin Supplements	C				
	Mood Alteration Nos							