FDA - Adverse Event Reporting System (AERS)
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Date: 05/13/1997 **ISR Number:** 1924270-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 80661 **Age:** 21 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Consumer	Accutane	PS	Roche	ORAL		
	Haemoptysis							
	Sinusitis Nos							

Date: 04/28/1997 **ISR Number:** 1928328-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 80117 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Amnesia Nec	Health Professional	Accutane	PS	Roche	ORAL	80	1
	Delusion Nos							
	Hallucination Nos							
	Speech Disorder Nec							

Date: 06/09/1997 **ISR Number:** 1930045-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 81719 **Age:** 16 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aphasia	Foreign	Roaccutane	PS		ORAL	1	91
	Facial Palsy	Health Professional	Cilest	SS		ORAL		39
	Haemorrhagic Stroke							
	Hemiplegia							

Date: 06/10/1997 **ISR Number:** 1932182-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 76795 **Age:** 15 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Disorder Neonatal Nos	Health Professional	Accutane	PS	Roche	ORAL		170
	Hyperventilation							
	Otitis Media Nos							
	Pneumonia Nos							

Date: 06/18/1997 **ISR Number:** 1932702-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 82370 **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		1
	Suicide Attempt							

Date: 05/23/1997 **ISR Number:** 1940398-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 81258 **Age:** 21 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Paranoia	Foreign	Roaccutane	PS		ORAL		62
	Psychotic Disorder Nos							

Date: 06/24/1997 **ISR Number:** 1941955-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 82537 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Foreign	Roaccutane	PS	Roche			91
	Psychotic Disorder Nos							

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Date: 06/11/1997 **ISR Number:** 1948993-6 **Report Type:** Periodic **Company Report Number:** 74771 **Age:** 17 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Dry Skin Insomnia Nec	Consumer	Accutane	PS	Roche	ORAL		

Date: 06/11/1997 **ISR Number:** 1949100-6 **Report Type:** Periodic **Company Report Number:** 74270 **Age:** 35 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Dermatitis Nos Urticaria Nos Vasodilatation	Consumer	Accutane	PS	Roche	ORAL	40	80

Date: 06/11/1997 **ISR Number:** 1949120-1 **Report Type:** Periodic **Company Report Number:** 73983 **Age:** 54 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Impotence	Health Professional	Accutane	PS	Roche	ORAL	80	122

Date: 06/11/1997 **ISR Number:** 1949141-9 **Report Type:** Periodic **Company Report Number:** 75051 **Age:** 24 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos Libido Decreased Vaginitis	Consumer	Accutane	PS	Roche	ORAL	40	

Date: 06/11/1997 **ISR Number:** 1949149-3 **Report Type:** Periodic **Company Report Number:** 74930 **Age:** 20 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos	Consumer	Accutane	PS	Roche	ORAL		92

Date: 06/11/1997 **ISR Number:** 1949481-3 **Report Type:** Periodic **Company Report Number:** 74926 **Age:** 20 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec	Consumer	Accutane	PS	Roche	ORAL	80	154

Date: 06/11/1997 **ISR Number:** 1949510-7 **Report Type:** Periodic **Company Report Number:** 74873 **Age:** 48 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Pain Nos Pruritus Urticaria Nos	Health Professional	Accutane	PS	Roche	ORAL	60	

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Date: 06/11/1997 **ISR Number:** 1949679-4 **Report Type:** Periodic **Company Report Number:** 75238 **Age:** 37 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Diarrhoea Nos Dry Skin Dyspnoea Nos	Health Professional	Accutane	PS	Roche	ORAL	60	36

Date: 06/11/1997 **ISR Number:** 1949700-3 **Report Type:** Periodic **Company Report Number:** 75163 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia Depression Nec Headache Nos Sedation	Consumer	Accutane	PS	Roche	ORAL	120	141

Date: 06/11/1997 **ISR Number:** 1951133-0 **Report Type:** Periodic **Company Report Number:** 68118 **Age:** 49 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Dermatitis Nos Insomnia Nec Pain Nos	Consumer	Accutane	PS	Roche	ORAL	40	6

Date: 06/11/1997 **ISR Number:** 1955987-3 **Report Type:** Periodic **Company Report Number:** 76887 **Age:** 23 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Dry Eye Nec Nervousness	Consumer	Accutane	PS	Roche	ORAL	40	27

Date: 06/11/1997 **ISR Number:** 1955990-3 **Report Type:** Periodic **Company Report Number:** 76871 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Depression Nec Thinking Abnormal Nec	Health Professional	Accutane	PS	Roche	ORAL	40	92

Date: 06/11/1997 **ISR Number:** 1956054-5 **Report Type:** Periodic **Company Report Number:** 76785 **Age:** 37 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dyspareunia Nec Vaginitis	Health Professional	Accutane	PS	Roche	ORAL	60	

Date: 06/11/1997 **ISR Number:** 1956154-X **Report Type:** Periodic **Company Report Number:** 77341 **Age:** 20 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Dizziness (Exc Vertigo)	Consumer	Accutane	PS	Roche	ORAL	70	

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Date: 06/11/1997 **ISR Number:** 1958869-6 **Report Type:** Periodic **Company Report Number:** 77830 **Age:** 26 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Drug Ineffective Emotional Disturbance Nos Muscle Cramps	Consumer	Accutane	PS	Roche	ORAL	40	

Date: 06/11/1997 **ISR Number:** 1958889-1 **Report Type:** Periodic **Company Report Number:** 78355 **Age:** 23 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amblyopia Nos Dermatitis Nos Dry Skin Emotional Disturbance Nos	Consumer	Accutane Ceftin	PS C	Roche	ORAL	80	

Date: 06/11/1997 **ISR Number:** 1959132-X **Report Type:** Periodic **Company Report Number:** 77975 **Age:** 31 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	80	69

Date: 06/11/1997 **ISR Number:** 1959139-2 **Report Type:** Periodic **Company Report Number:** 77958 **Age:** **Gender:** Unknown

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

Date: 06/11/1997 **ISR Number:** 1959175-6 **Report Type:** Periodic **Company Report Number:** 77777 **Age:** 16 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos Headache Nos	Health Professional	Accutane	PS	Roche	ORAL	60	

Date: 06/11/1997 **ISR Number:** 1959178-1 **Report Type:** Periodic **Company Report Number:** 77776 **Age:** 34 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec	Health Professional	Accutane	PS	Roche	ORAL	100	159

Date: 06/11/1997 **ISR Number:** 1959270-1 **Report Type:** Periodic **Company Report Number:** 77469 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Depression Nec Myalgia Personality Disorder Nos	Consumer	Accutane Beconase	PS C	Roche	ORAL	60	66

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Date: 06/11/1997 **ISR Number:** 1959280-4 **Report Type:** Periodic **Company Report Number:** 77461 **Age:** 39 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia	Consumer	Accutane	PS	Roche	ORAL	40	
	Palpitations		Xanax	C				

Date: 06/11/1997 **ISR Number:** 1959459-1 **Report Type:** Periodic **Company Report Number:** 63526 **Age:** 16 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Palpitations	Health Professional	Accutane	PS	Roche	ORAL		
	Ventricular Extrasystoles							

Date: 06/11/1997 **ISR Number:** 1959645-0 **Report Type:** Periodic **Company Report Number:** 68575 **Age:** 28 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Drug Interaction Nos	Consumer	Accutane	PS	Roche	ORAL	20	60
	Major Depressive Disorder Nos		Paxil	C				
			Synthroid	C				

Date: 06/11/1997 **ISR Number:** 1959658-9 **Report Type:** Periodic **Company Report Number:** 64803 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Hostility	Health Professional	Accutane	PS	Roche	ORAL	80	153
	Personality Disorder Nos							

Date: 06/11/1997 **ISR Number:** 1959664-4 **Report Type:** Periodic **Company Report Number:** 64762 **Age:** 35 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Confusion	Consumer	Accutane	PS	Roche	ORAL	80	32
	Emotional Disturbance Nos							

Date: 06/11/1997 **ISR Number:** 1959749-2 **Report Type:** Periodic **Company Report Number:** 64667 **Age:** 16 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia	Consumer	Accutane	PS	Roche	ORAL	40	86
	Emotional Disturbance Nos							
	Mucous Membrane Disorder Nos							

Date: 06/11/1997 **ISR Number:** 1959790-X **Report Type:** Periodic **Company Report Number:** 64541 **Age:** 28 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Cyst Nos	Health Professional	Accutane	PS	Roche	ORAL	80	
	Insomnia Nec							
	Pain Nos							

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Date: 06/11/1997 **ISR Number:** 1960003-3 **Report Type:** Periodic **Company Report Number:** 66743 **Age:** 34 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Hallucination Nos	Health Professional	Accutane	PS	Roche	ORAL		212

Date: 06/11/1997 **ISR Number:** 1960006-9 **Report Type:** Periodic **Company Report Number:** 66735 **Age:** 41 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Palpitations	Health Professional	Accutane	PS	Roche	ORAL	40	
			Acyclovir	C				

Date: 06/11/1997 **ISR Number:** 1960012-4 **Report Type:** Periodic **Company Report Number:** 66676 **Age:** 27 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anorexia	Health Professional	Accutane	PS	Roche	ORAL	40	75
	Depression Nec							
	Stupor							

Date: 06/11/1997 **ISR Number:** 1960017-3 **Report Type:** Periodic **Company Report Number:** 66674 **Age:** 34 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Confusion	Consumer	Accutane	PS	Roche	ORAL	20	
	Face Oedema							
	Hallucination Nos							
	Mucous Membrane Disorder Nos							

Date: 06/11/1997 **ISR Number:** 1960027-6 **Report Type:** Periodic **Company Report Number:** 66639 **Age:** 23 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amblyopia Nos	Health Professional	Accutane	PS	Roche	ORAL	80	
	Confusion							
	Dizziness (Exc Vertigo)							
	Paraesthesia Nec							

Date: 06/11/1997 **ISR Number:** 1960056-2 **Report Type:** Periodic **Company Report Number:** 67016 **Age:** 27 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Consumer	Accutane	PS	Roche	ORAL	1	72
			Prozac	C				
			Ativan	C				

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Date: 06/11/1997 **ISR Number:** 1960059-8 **Report Type:** Periodic **Company Report Number:** 67010 **Age:** 40 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Bone Pain	Consumer	Accutane	PS	Roche	ORAL	120	92
	Depression Nec							
	Myalgia							
	Viral Infection Nos							

Date: 06/11/1997 **ISR Number:** 1960174-9 **Report Type:** Periodic **Company Report Number:** 67752 **Age:** 17 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dysphonia	Health Professional	Accutane	PS	Roche	ORAL	40	99
	Hypercholesterolaemia							

Date: 06/11/1997 **ISR Number:** 1960185-3 **Report Type:** Periodic **Company Report Number:** 67733 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Hormone Level Nos Abnormal	Health Professional	Accutane	PS	Roche	ORAL	60	89
	Palpitations							
	Tachycardia Nos							
	Thyroiditis Nos							

Date: 06/11/1997 **ISR Number:** 1960583-8 **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	Health Professional	Accutane	PS	Roche	ORAL	40	30
			Vicodin	C				
			Aspirin	C				

Date: 06/11/1997 **ISR Number:** 1960778-3 **Report Type:** Periodic **Company Report Number:** 68355 **Age:** 23 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	40	

Date: 06/11/1997 **ISR Number:** 1961064-8 **Report Type:** Periodic **Company Report Number:** 70220 **Age:** 20 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Consumer	Accutane	PS	Roche	ORAL	80	
	Emotional Disturbance Nos							

Date: 06/11/1997 **ISR Number:** 1961071-5 **Report Type:** Periodic **Company Report Number:** 70218 **Age:** 23 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Consumer	Accutane	PS	Roche	ORAL	40	53
	Insomnia Nec							
	Thinking Abnormal Nec							

Date: 06/11/1997 **ISR Number:** 1961083-1 **Report Type:** Periodic **Company Report Number:** 69930 **Age:** 16 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	60	23

Date: 06/11/1997 **ISR Number:** 1961133-2 **Report Type:** Periodic **Company Report Number:** 70328 **Age:** 19 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Depression Nec Epistaxis Myalgia	Consumer	Accutane	PS	Roche	ORAL		139

Date: 06/11/1997 **ISR Number:** 1961154-X **Report Type:** Periodic **Company Report Number:** 76301 **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Hyperkinetic Syndrome Nervousness	Health Professional	Accutane	PS	Roche	ORAL	60	17

Date: 06/11/1997 **ISR Number:** 1961261-1 **Report Type:** Periodic **Company Report Number:** 72915 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia Depression Nec Dizziness (Exc Vertigo) Hypercholesterolaemia	Consumer	Accutane	PS	Roche	ORAL	80	103

Date: 06/11/1997 **ISR Number:** 1961675-X **Report Type:** Periodic **Company Report Number:** 63528 **Age:** 29 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Dry Skin Emotional Disturbance Nos Headache Nos	Health Professional	Accutane	PS	Roche	ORAL	40	157

Date: 06/11/1997 **ISR Number:** 1961708-0 **Report Type:** Periodic **Company Report Number:** 63458 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Dermatitis Nos Dry Skin Myalgia	Consumer	Accutane	PS	Roche	ORAL	80	

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Date: 06/11/1997 **ISR Number:** 1962002-4 **Report Type:** Periodic **Company Report Number:** 62931 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL	100	

Date: 06/11/1997 **ISR Number:** 1962021-8 **Report Type:** Periodic **Company Report Number:** 62374 **Age:** 14 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL	80	158

Date: 06/11/1997 **ISR Number:** 1962755-5 **Report Type:** Periodic **Company Report Number:** 62230 **Age:** 36 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Confusion Vascular Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL	80	182

Date: 06/11/1997 **ISR Number:** 1962822-6 **Report Type:** Periodic **Company Report Number:** 66491 **Age:** 33 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dry Mouth Dysphonia	Health Professional	Accutane Aspirin Naphazoline	PS C C	Roche	ORAL	120	134

Date: 06/11/1997 **ISR Number:** 1963311-5 **Report Type:** Periodic **Company Report Number:** 67940 **Age:** 30 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthralgia Asthenia Depression Nec	Consumer	Accutane	PS	Roche	ORAL	60	7

Date: 06/11/1997 **ISR Number:** 1963313-9 **Report Type:** Periodic **Company Report Number:** 61989 **Age:** 40 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia Diarrhoea Nos Dry Skin Palpitations	Health Professional	Accutane	PS	Roche	ORAL		123

Date: 06/11/1997 **ISR Number:** 1963340-1 **Report Type:** Periodic **Company Report Number:** 62441 **Age:** 34 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia Depression Nec Libido Decreased	Consumer	Accutane	PS	Roche	ORAL		123

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Date: 06/11/1997 **ISR Number:** 1963417-0 **Report Type:** Periodic **Company Report Number:** 70346 **Age:** 21 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Dreams	Health Professional	Accutane	PS	Roche	ORAL	40	
			Nordette	C				

Date: 06/11/1997 **ISR Number:** 1963533-3 **Report Type:** Periodic **Company Report Number:** 71221 **Age:** 23 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos	Consumer	Accutane	PS	Roche	ORAL	80	141
	Visual Field Defect Nos		Claritin-D	C				
			Vitamins	C				

Date: 06/11/1997 **ISR Number:** 1963547-3 **Report Type:** Periodic **Company Report Number:** 71280 **Age:** 22 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL	80	

Date: 06/11/1997 **ISR Number:** 1963703-4 **Report Type:** Periodic **Company Report Number:** 76515 **Age:** 35 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		76

Date: 06/11/1997 **ISR Number:** 1963730-7 **Report Type:** Periodic **Company Report Number:** 72347 **Age:** 22 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec	Health Professional	Accutane	PS	Roche	ORAL	40	181
	Myalgia							
	Paraesthesia Nec							
	Weight Decreased							

Date: 06/11/1997 **ISR Number:** 1963748-4 **Report Type:** Periodic **Company Report Number:** 73303 **Age:** 27 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Palpitations	Health Professional	Accutane	PS	Roche	ORAL	40	56

Date: 06/11/1997 **ISR Number:** 1963802-7 **Report Type:** Periodic **Company Report Number:** 73182 **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	60	124
	Weight Decreased							

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Date: 06/11/1997 **ISR Number:** 1963962-8 **Report Type:** Periodic **Company Report Number:** 72351 **Age:** 33 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Hair Disorder Nos	Consumer	Accutane Valium Ibuprofen	PS C C	Roche	ORAL	80	22

Date: 06/11/1997 **ISR Number:** 1965194-6 **Report Type:** Periodic **Company Report Number:** 70616 **Age:** 29 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amenorrhoea Nos Dyspareunia Nec Mucous Membrane Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL	20	92

Date: 06/11/1997 **ISR Number:** 1965408-2 **Report Type:** Periodic **Company Report Number:** 72008 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anorexia Depression Nec Emotional Disturbance Nos	Consumer	Accutane	PS	Roche	ORAL		184

Date: 06/11/1997 **ISR Number:** 1965565-8 **Report Type:** Periodic **Company Report Number:** 71278 **Age:** 39 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Depression Nec Influenza Like Illness Rhinitis Nos	Consumer	Accutane	PS	Roche	ORAL	40	154

Date: 06/11/1997 **ISR Number:** 1965622-6 **Report Type:** Periodic **Company Report Number:** 66158 **Age:** 20 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Bacterial Infection Nos Dyspareunia Nec Vaginitis	Health Professional	Accutane	PS	Roche	ORAL		124

Date: 06/11/1997 **ISR Number:** 1965629-9 **Report Type:** Periodic **Company Report Number:** 66136 **Age:** 34 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Dizziness (Exc Vertigo) Headache Nos Myalgia	Consumer	Accutane	PS	Roche	ORAL	20	178

Date: 06/11/1997 **ISR Number:** 1965741-4 **Report Type:** Periodic **Company Report Number:** 73477 **Age:** 29 YR **Gender:** Female

Outcome	PT	Report Source
Other	Amblyopia Nos Amenorrhoea Nos Depression Nec Dry Eye Nec	

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane	PS	Roche	ORAL	80	

Date: 06/11/1997 **ISR Number:** 1965743-8 **Report Type:** Periodic **Company Report Number:** 73476 **Age:** 32 YR **Gender:** Female

Outcome	PT	Report Source
Other	Abnormal Dreams Asthenia Emotional Disturbance Nos Skin Disorder Nos	Consumer

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane	PS	Roche	ORAL	20	21
Zoloft	C				

Date: 06/11/1997 **ISR Number:** 1965847-X **Report Type:** Periodic **Company Report Number:** 75899 **Age:** 41 YR **Gender:** Female

Outcome	PT	Report Source
Other	Emotional Disturbance Nos	Health Professional

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane	PS	Roche	ORAL	40	80

Date: 06/11/1997 **ISR Number:** 1965939-5 **Report Type:** Periodic **Company Report Number:** 75290 **Age:** 41 YR **Gender:** Male

Outcome	PT	Report Source
Other	Emotional Disturbance Nos Gastritis Nos Skin Disorder Nos	Consumer

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane	PS	Roche	ORAL	40	30
Erythromycin	C				
Valium	C				

Date: 06/11/1997 **ISR Number:** 1965984-X **Report Type:** Periodic **Company Report Number:** 65917 **Age:** 34 YR **Gender:** Female

Outcome	PT	Report Source
Other	Alopecia Depression Nec Dermatitis Nos Ecchymosis	Consumer

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane	PS	Roche	ORAL	40	
Paxil	C				

Date: 06/11/1997 **ISR Number:** 1966213-3 **Report Type:** Periodic **Company Report Number:** 75904 **Age:** 37 YR **Gender:** Female

Outcome	PT	Report Source
Other	Depression Nec Drug Interaction Nos Drug Level Nos Below Therapeutic	Health Professional

Product	Role	Manufacturer	Route	Dose/Unit	Duration
Accutane	PS	Roche	ORAL	160	
Depakote	SS	Abbott	ORAL		
Wellbutrin	C				
Cytomel	C				

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Date: 06/11/1997 **ISR Number:** 1966230-3 **Report Type:** Periodic **Company Report Number:** 75807 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia Thinking Abnormal Nec	Consumer	Accutane	PS	Roche	ORAL	80	

Date: 06/11/1997 **ISR Number:** 1966614-3 **Report Type:** Periodic **Company Report Number:** 75615 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia Hyperlipidaemia Nos Nervousness Sinusitis Nos	Health Professional	Accutane	PS	Roche	ORAL	40	245

Date: 06/11/1997 **ISR Number:** 1966615-5 **Report Type:** Periodic **Company Report Number:** 75611 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Corneal Lesion Nos Depression Nec Dry Eye Nec	Consumer	Accutane	PS	Roche	ORAL	60	

Date: 06/11/1997 **ISR Number:** 1966616-7 **Report Type:** Periodic **Company Report Number:** 75609 **Age:** 41 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Palpitations Supraventricular Extrasystoles	Consumer	Accutane	PS	Roche	ORAL	80	154

Date: 06/11/1997 **ISR Number:** 1966622-2 **Report Type:** Periodic **Company Report Number:** 75492 **Age:** 41 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Libido Decreased	Health Professional	Accutane	PS	Roche	ORAL		

Date: 06/11/1997 **ISR Number:** 1967172-X **Report Type:** Periodic **Company Report Number:** 75960 **Age:** 40 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Menstrual Disorder Nos Nervousness	Health Professional	Accutane	PS	Roche	ORAL	80	
			Multivitamins	C				
			Synthroid	C				
			Propranolol	C				
			Florinal	C				

Date: 11/13/1997 **ISR Number:** 3000460-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 80181 **Age:** 17 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Congenital Anomaly	Cardiac Murmur Nos Complications Of Maternal	Health Professional	Accutane	PS		ORAL		

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Date: 11/17/1997 **ISR Number:** 3000973-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 89723 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Congenital Anomaly	Complications Of Maternal Exposure To Therapeutic Drugs Developmental Coordination Disorder Nos Difficulty In Walking Thinking Abnormal Nec	Other	Accutane	PS		ORAL		

Date: 12/01/1997 **ISR Number:** 3003385-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 89535 **Age:** 39 YR **Gender:**

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Confusion Herpes Simplex Lymphadenopathy Mumps Pyrexia Sore Throat Nos Swelling Nos Weakness	Health Professional	Accutane	PS		ORAL		

Date: 12/01/1997 **ISR Number:** 3003535-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 88810 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Anorexia Balance Impaired Nos Cheilitis Confusion Disturbance In Attention Nec Dizziness (Exc Vertigo) Fatigue Headache Nos Loss Of Consciousness Nec Muscle Weakness Syncope Visual Disturbance Nos	Foreign Health Professional	Roaccutane	PS		ORAL		

Date: 12/01/1997 **ISR Number:** 3003537-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 90195 **Age:** 42 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Suicidal Ideation		Accutane	PS		ORAL		
			Klonopin	C				
			Trazodone	C				
			Benadryl	C				

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Date: 12/02/1997 **ISR Number:** 3003878-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 90489 **Age:** 19 YR **Gender:** Male

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

Date: 12/08/1997 **ISR Number:** 3004624-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 90973 **Age:** 30 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening Congenital Anomaly	Failure To Thrive Lipid Metabolism Disorder Nos Low Set Ears Mental Retardation Severity Unspecified		Accutane	PS		ORAL		

Date: 12/08/1997 **ISR Number:** 3004636-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 55633 **Age:** 28 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Depression Nec Suicide Attempt	Foreign Health Professional	Roaccutane Lexomil Ludiomil Maprotiline	PS SS C C		ORAL		

Date: 12/10/1997 **ISR Number:** 3005621-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 88658 **Age:** 16 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dizziness (Exc Vertigo) Headache Nos Syncope Visual Disturbance Nos	Foreign Health Professional	Roaccutane Diane 35	PS C		ORAL		

Date: 12/23/1997 **ISR Number:** 3010724-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 91491 **Age:** **Gender:**

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Coma Nec Convulsions Nos Depression Nec Dysarthria Hypotension Short-Term Memory Loss Status Epilepticus Suicide Attempt	Health Professional	Accutane Dilantin	PS SS		ORAL INTRAVENOUS DRIP		

Date: 12/31/1997 **ISR Number:** 3013336-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 90404 **Age:** 19 YR **Gender:** Male

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

Date: 12/31/1997 **ISR Number:** 3013345-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 91903 **Age:** 13 YR **Gender:** Female

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

Date: 12/31/1997 **ISR Number:** 3013358-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 90195 **Age:** 42 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Consumer	Accutane	PS		ORAL		
	Suicidal Ideation		Klonopin	C				
			Trazodone	C				
			Benadryl	C				

Date: 12/31/1997 **ISR Number:** 3013361-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 91718 **Age:** 29 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anger	Consumer	Accutane	PS		ORAL		
	Crying	Other						
	Lip Dry							
	Major Depressive Disorder Nos							
	Visual Disturbance Nos							

Date: 12/31/1997 **ISR Number:** 3013364-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 904789 **Age:** 19 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							

Date: 01/08/1998 **ISR Number:** 3016841-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 92130 **Age:** 38 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos	Foreign	Roaccutane	PS		ORAL		
	Cognitive Disorder Nec	Other	Cortancyl	SS		ORAL		
	Condition Aggravated		Solumedrol	C				
	Encephalopathy Nos		Endoxan	C				
			Synacthene	C				
			Colchicine	C				

Date: 01/21/1998 **ISR Number:** 3017857-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 92822 **Age:** 44 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec	Health Professional	Accutane	PS		ORAL		
	Bipolar Disorder Nec		Prozac	C				
	Thinking Abnormal Nec							

Date: 01/21/1998 **ISR Number:** 3017873-X **Report Type:** Expedited (15-Day) **Company Report Number:** 92735 **Age:** 18 YR **Gender:** Male

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

Date: 01/21/1998 **ISR Number:** 3017887-X **Report Type:** Expedited (15-Day) **Company Report Number:** 88218 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aggression	Foreign	Roaccutane	PS		ORAL		
	Amnesia Nec	Health Professional						
	Asthenia							
	Dry Skin							
	Hypertension Nos							
	Mucosal Dryness Nos							
	Muscle Cramps							
	Phobias Nec							
	Polydipsia							
	Sweating Increased							
	Tachycardia Nos							

Date: 01/27/1998 **ISR Number:** 3019417-5 **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	Bronchitis Nos	Consumer	Accutane	PS		ORAL		
Congenital Anomaly	Complications Of Maternal Exposure To Therapuetic Drugs							
	Growth Retarded							
	Hepatotoxicity Nos							
	Jaundice Nos							
	Kidney Small							
	Malaise							
	Stammering							

Date: 01/27/1998 **ISR Number:** 3019422-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 93037 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos	Literature	Accutane	PS		ORAL		
	Aggression	Health Professional	Lsd	SS				
	Drug Abuse							

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Date: 01/27/1998 **ISR Number:** 3019460-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 93035 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Dystonia	Literature	Accutane	PS		ORAL		
	Hallucination Nos	Health Professional	Tetracycline	SS		ORAL		
	Paranoia							
	Psychotic Disorder Nos							
	Speech Disorder Nec							

Date: 02/02/1998 **ISR Number:** 3022832-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 93274 **Age:** 39 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dry Skin	Consumer	Accutane	PS		ORAL		
	Hyperthyroidism Aggravated		Tofranil	C				
	Nervousness		Xanax	C				
	Skin Chapped							

Date: 02/09/1998 **ISR Number:** 3026038-7 **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 Upper	Consumer	Accutane	PS		ORAL		
	Anxiety Nec		Premarin	C				
	Back Pain		Tenormin	C				
	Burning Sensation Nos							
	Calculus Renal Nos							
	Constipation							
	Ecchymosis							
	Eye Infection Viral Nos							
	Eye Irritation							
	Gall Bladder Disorder Nos							
	Haematuria Present							
	Heart Rate Irregular							
	Hepatic Disorder Nos							
	Lethargy							
	Nail Disorder Nos							
	Rash Erythematous							
	Rash Pruritic							
	Skin Discolouration							
	Sore Throat Nos							
	Tic Nec							
	Urine Abnormal Nos							
	Vasculitis Nos							

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Date: 01/27/1998 **ISR Number:** 3019460-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 93035 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Dystonia	Literature	Accutane	PS		ORAL		
	Hallucination Nos	Health Professional	Tetracycline	SS		ORAL		
	Paranoia							
	Psychotic Disorder Nos							
	Speech Disorder Nec							

Date: 02/02/1998 **ISR Number:** 3022832-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 93274 **Age:** 39 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dry Skin	Consumer	Accutane	PS		ORAL		
	Hyperthyroidism Aggravated		Tofranil	C				
	Nervousness		Xanax	C				
	Skin Chapped							

Date: 02/09/1998 **ISR Number:** 3026038-7 **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 Upper	Consumer	Accutane	PS		ORAL		
	Anxiety Nec		Premarin	C				
	Back Pain		Tenormin	C				
	Burning Sensation Nos							
	Calculus Renal Nos							
	Constipation							
	Ecchymosis							
	Eye Infection Viral Nos							
	Eye Irritation							
	Gall Bladder Disorder Nos							
	Haematuria Present							
	Heart Rate Irregular							
	Hepatic Disorder Nos							
	Lethargy							
	Nail Disorder Nos							
	Rash Erythematous							
	Rash Pruritic							
	Skin Discolouration							
	Sore Throat Nos							
	Tic Nec							
	Urine Abnormal Nos							
	Vasculitis Nos							

Date: 02/10/1998 **ISR Number:** 3026743-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 93458 **Age:** 22 YR **Gender:** Male

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

Date: 02/10/1998 **ISR Number:** 3026744-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 93625 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide Depression Nec	Health Professional Other	Accutane	PS		ORAL		

Date: 02/12/1998 **ISR Number:** 3030329-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 94020 **Age:** 19 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Candida Nos Condition Aggravated Insomnia Nec Panic Attack	Health Professional	Accutane	PS		ORAL		

Date: 02/12/1998 **ISR Number:** 3030330-X **Report Type:** Expedited (15-Day) **Company Report Number:** 94041 **Age:** 27 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Congenital Anomaly	Chromosomal Abnormality Nos Complications Of Maternal Exposure To Therapeutic Drugs Down'S Syndrome Premature Labour	Health Professional	Accutane	PS		ORAL		

Date: 02/12/1998 **ISR Number:** 3030332-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 83906 **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Candida Nos Cephalhaematoma Chlamydial Infection Nos Congenital Urinary Tract Anomaly Nos Eczema Nos Hydrocele Insomnia Nec Panic Attack	Health Professional	Accutane	PS		ORAL		

Date: 02/12/1998 **ISR Number:** 3030336-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 91431 **Age:** 56 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Benign Eye Neoplasm Nos Chorioretinitis	Health Professional	Accutane	PS		ORAL		

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Date: 02/12/1998 **ISR Number:** 3030339-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 93881 **Age:** 29 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Eye Movements Nos	Consumer	Accutane	PS		ORAL		
	Anxiety Nec		Retin A	SS		TOPICAL		
	Cerebral Oedema		Vitamin A	C				
	Convulsions Nos		Vitamin E	C				
	Diabetes Mellitus Nos		Vitamin B	C				
	Diplopia							
	Dizziness (Exc Vertigo)							
	Epistaxis							
	Fatigue							
	Headache Nos							
	Insomnia Nec							
	Malaise							
	Menstrual Disorder Nos							
	Movement Disorder Nos							
	Muscle Twitching							
	Nausea							
	Nervousness							
	Panic Attack							
	Pyrexia							
	Salivary Hypersecretion							
	Sensation Of Pressure Nos							
	Stress Symptoms							
	Syncope							
	Tremor Nec							
	Vision Blurred							

Date: 02/12/1998 **ISR Number:** 3030587-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 91720 **Age:** 14 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Aspartate Aminotransferase Increased	Health Professional	Accutane	PS		ORAL		
	Blood Alkaline Phosphatase Nos Increased		Bactrim Ds	SS		ORAL		
	Blood Lactate Dehydrogenase Increased							
	Blood Triglycerides Increased							
	Completed Suicide							
	Dry Skin							

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Date: 02/18/1998 **ISR Number:** 3031267-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 92114 **Age:** 32 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		
	Bronchitis Nos	Health Professional						
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Congenital Abnormality Nos							
	Constipation							
	Growth Retarded							
	Hypermetropia							
	Jaundice Nos							
	Kidney Small							
	Otitis Media Nos							
	Rhinitis Allergic Nos							
	Stammering							

Date: 02/18/1998 **ISR Number:** 3031272-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 93881 **Age:** 29 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec	Consumer	Accutane	PS		ORAL		
	Cerebral Oedema	Health Professional	Retin A	SS		TOPICAL		
	Convulsions Nos		Vitamin A	C				
	Diabetes Mellitus Nos		Vitamin E	C				
	Diplopia		Vitamin B	C				
	Dizziness (Exc Vertigo)							
	Emotional Disturbance Nos							
	Epistaxis							
	Fatigue							
	Headache Nos							
	Hypoglycaemia Nos							
	Increased Activity							
	Insomnia Nec							
	Loss Of Consciousness Nec							
	Malaise							
	Menstrual Disorder Nos							
	Muscle Twitching							
	Nausea							
	Nervousness							
	Panic Attack							
	Pyrexia							
	Salivary Hypersecretion							
	Sedation							
	Sensation Of Pressure Nos							

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Date: 02/18/1998 **ISR Number:** 3031286-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 91431 **Age:** 56 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Benign Eye Neoplasm Nos	Health Professional	Accutane	PS		ORAL		
	Chorioretinitis							
	Clamminess							
	Eating Disorder Nec							
	Eye Inflammation Nos							
	Hypersensitivity Nos							
	Mental Impairment Nos							
	Shivering							
	Tremor Nec							
	Vision Abnormal Nec							
	Vision Blurred							

Date: 02/18/1998 **ISR Number:** 3032237-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 93625 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide	Health Professional	Accutane	PS		ORAL		
	Depression Nec	Other						
	Dry Skin							

Date: 02/19/1998 **ISR Number:** 3032263-1 **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	Consumer	Accutane	PS		ORAL		
	Bronchitis Nos	Health Professional						
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Constipation							
	Growth Retarded							
	Hypermetropia							
	Jaundice Nos							
	Kidney Small							
	Otitis Media Nos							
	Rhinitis Allergic Nos							
	Stammering							

Date: 02/19/1998 **ISR Number:** 3032273-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 93881 **Age:** 29 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec	Consumer	Accutane	PS		ORAL		
	Convulsions Nos	Health Professional	Retin A	SS		TOPICAL		
	Diabetes Mellitus Nos		Vitamin A	C				
	Diplopia		Vitamin E	C				
	Dizziness (Exc Vertigo)							

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Date: 02/23/1998 **ISR Number:** 3035850-X **Report Type:** Expedited (15-Day) **Company Report Number:** 87461 **Age:** 35 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Consumer	Accutane	PS		ORAL		
	Influenza		Betoptic	C				
	Liver Fatty		Trusopt	C				
	Liver Function Tests Nos Abnormal							
	Oesophageal Erosions							
	Pain Nos							
	Pruritus							

Date: 02/23/1998 **ISR Number:** 3037179-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 94423 **Age:** 13 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Other	Accutane	PS		ORAL		
	Epistaxis		Chlor-Trimeton	C				
	Migraine Nos		Claritin-D	C				
	Mood Swings		Nebulizer	C				
	Rash Erythematous							
	Vision Blurred							

Date: 02/27/1998 **ISR Number:** 3037624-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 94721 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos	Health Professional	Accutane	PS				
	Mania		Lithium	C				

Date: 02/27/1998 **ISR Number:** 3037626-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 89723 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Attention Deficit/Hyperactivity Disorder	Other	Accutane	PS				
Congenital Anomaly	Cardiac Disorder Nos							
	Clumsiness							
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Difficulty In Walking							
	Foot Deformity Nos							
	Motor Dysfunction Nos							

Date: 03/02/1998 **ISR Number:** 3038633-X **Report Type:** Expedited (15-Day) **Company Report Number:** 94721 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos	Health Professional	Accutane	PS		OPHTHALMIC		
	Increased Activity							
	Mania							

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Date: 03/03/1998 **ISR Number:** 3040349-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 94940 **Age:** 16 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Hallucination Nos Lyme'S Disease Nausea Sedation Taste Disturbance	Foreign Health Professional	Roaccutane	PS		ORAL		

Date: 03/05/1998 **ISR Number:** 3044287-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 93309 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Upper Back Pain Jaundice Nos Sleep Disorder Due To General Medical Condition, Mixed Type	Consumer	Accutane	PS		ORAL		

Date: 03/05/1998 **ISR Number:** 3050346-7 **Report Type:** Direct **Company Report Number:** **Age:** 16 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Suicide Attempt		Accutane	PS				

Date: 03/04/1998 **ISR Number:** 3050470-9 **Report Type:** Direct **Company Report Number:** **Age:** 18 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Depression Nec Suicide Attempt		Accutane	PS	Roche			

Date: 03/04/1998 **ISR Number:** 3050493-X **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	Health Professional	Accutane	PS				

Date: 03/10/1998 **ISR Number:** 3054552-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 95430 **Age:** 23 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Blindness Night Blood Cholesterol Increased Blood Pressure Increased Blood Triglycerides Increased Depression Nec Epistaxis Headache Nos	Consumer	Accutane Antidepressants	PS C		ORAL		

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Date: 03/10/1998 **ISR Number:** 3054593-X **Report Type:** Expedited (15-Day) **Company Report Number:** 95291 **Age:** 19 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Depression Nec	Consumer	Accutane	PS		ORAL		
	Non-Accidental Overdose		Prozac	SS				
	Overdose Nos							
	Suicide Attempt							

Date: 03/10/1998 **ISR Number:** 3054597-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 91162 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Anxiety Nec	Other	Accutane	PS		ORAL		
	Depression Nec							
	Suicide Attempt							

Date: 03/10/1998 **ISR Number:** 3054664-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 95304 **Age:** 20 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide	Health Professional	Accutane	PS		ORAL		
	Vomiting Nos		Dermulen	C				
			Spironolactone	C				

Date: 03/10/1998 **ISR Number:** 3054939-2 **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		
	Suicidal Ideation							

Date: 03/10/1998 **ISR Number:** 3055037-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 90195 **Age:** 42 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Consumer	Accutane	PS		ORAL		
	Suicidal Ideation		Klonopin	C				
			Trazodone	C				
			Benadryl	C				

Date: 03/10/1998 **ISR Number:** 3055040-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 95293 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Overdose Nos	Health Professional	Accutane	PS		ORAL		
	Suicide Attempt		Prozac	C				

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Date: 03/16/1998 **ISR Number:** 3055125-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 95287 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anorexia	Other	Accutane	PS		ORAL		
	Depression Nec		Prozac	C				
	Insomnia Nec							
	Mental Disorder Nec							
	Tic Nec							
	Tourette'S Disorder							

Date: 03/16/1998 **ISR Number:** 3055809-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 95445 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos	Other	Accutane	PS		ORAL		
	Aggression		...	SS				
	Confusion							
	Hostility							
	Lethargy							
	Pallor							
	Social Avoidant Behaviour							
	Weakness							

Date: 03/16/1998 **ISR Number:** 3055853-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 95448 **Age:** 27 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec	Consumer	Accutane	PS		ORAL		
	Depression Nec							
	Dry Eye Nec							
	Dry Skin							
	Lip Dry							
	Panic Attack							

Date: 03/16/1998 **ISR Number:** 3055855-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 95265 **Age:** **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos	Other	Accutane	PS		ORAL		
	Depression Nec							
	Insomnia Nec							
	Suicidal Ideation							

Date: 03/16/1998 **ISR Number:** 3055858-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 95443 **Age:** 16 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Abnormal Behaviour Nos	Other	Accutane	PS		ORAL		
	Drug Abuse		Lsd	C				
	Mood Swings							

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Date: 03/17/1998 **ISR Number:** 3055879-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 860200853001 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Abnormal Behaviour Nos	Other	Accutane	PS		ORAL		
Life-Threatening	Anorexia							
Disability	Completed Suicide							
	Depression Nec							
	Mood Swings							

Date: 03/17/1998 **ISR Number:** 3055884-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 95304 **Age:** 20 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide	Health Professional	Accutane	PS		ORAL		
	Vomiting Nos		Dermalen	C				
			Spironolactone	C				

Date: 03/17/1998 **ISR Number:** 3055918-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 95448 **Age:** 27 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec	Consumer	Accutane	PS		ORAL		
	Depression Nec							
	Dry Eye Nec							
	Dry Skin							
	Lip Dry							
	Panic Attack							

Date: 03/16/1998 **ISR Number:** 3055928-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 920200145001 **Age:** 37 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Alanine Aminotransferase Increased	Consumer	Accutane	PS		ORAL		
Hospitalization - Initial or Prolonged	Antibody Nost Abnormal	Health Professional						
Disability	Anxiety Nec							
	Arthralgia							
	Back Pain							
	Biopsy Peripheral Nerve Abnormal							
	Blood Creatine Phosphokinase Increased							
	Blood Magnesium Decreased							
	Carpal Tunnel Syndrome							
	Chronic Fatigue Syndrome							
	Completed Suicide							
	Demyelination Nos							
	Depressed Mood							
	Disturbance In Attention Nec							

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Date: 03/16/1998 **ISR Number:** 3055942-9 **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	Other	Accutane	PS		ORAL		
Life-Threatening	Completed Suicide							
	Depression Nec							
	Suicidal Ideation							

Date: 03/16/1998 **ISR Number:** 3055960-0 **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		
	Anxiety Nec		Premarin	C				
	Arthralgia		Tenormin	C				
	Back Pain							
	Burning Sensation Nos							
	Calculus Renal Nos							
	Constipation							
	Dry Eye Nec							
	Ecchymosis							
	Erythema Nec							
	Eye Infection Viral Nos							
	Eye Irritation							
	Gall Bladder Disease Nos							
	Haematuria Present							
	Heart Rate Irregular							
	Hepatic Cyst Nos							
	Paraesthesia Nec							
	Rash Pruritic							
	Skin Discolouration							
	Sore Throat Nos							
	Urine Abnormal Nos							
	Vasculitis Nos							
	Vein Pain							

Date: 03/16/1998 **ISR Number:** 3055962-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 95341 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Appetite Decreased	Other	Accutane	PS		ORAL		
	Bipolar Disorder Nec							
	Depression Aggravated							
	Mood Alteration Nos							
	Suicidal Ideation							
	Weight Decreased							

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Date: 03/16/1998 **ISR Number:** 3056036-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 95333 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide Non-Accidental Overdose	Other	Accutane	PS				

Date: 03/16/1998 **ISR Number:** 3056037-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 95333 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide Non-Accidental Overdose Suicide Attempt	Other	Accutane	PS		ORAL		

Date: 03/18/1998 **ISR Number:** 3056373-8 **Report Type:** Direct **Company Report Number:** **Age:** 16 YR **Gender:** Male

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

Date: 03/19/1998 **ISR Number:** 3057782-3 **Report Type:** Direct **Company Report Number:** **Age:** **Gender:** Female

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

Date: 03/19/1998 **ISR Number:** 3057827-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 95976 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Anxiety Nec Cerebrovascular Accident Nos Convulsions Nos Coordination Abnormal Nos Diplopia Disability Nos Dysarthria Eye Movement Disorder Nos Inflammation Nos Vascular Disorder Nos Vision Blurred	Other	Accutane	PS		ORAL		

Date: 03/24/1998 **ISR Number:** 3058987-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 95864 **Age:** 21 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Delirium	Foreign Health Professional	Roaccutane	PS		ORAL		

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Date: 03/12/1998 **ISR Number:** 3059142-8 **Report Type:** Direct **Company Report Number:** **Age:** 15 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Depression Nec		Accutane	PS	Hoffman La Roche	ORAL		
Hospitalization - Initial or Prolonged	Ear Haemorrhage							
	Epistaxis							
	Lip Dry							
	Rectal Bleeding							
	Suicidal Ideation							

Date: 03/12/1998 **ISR Number:** 3059190-8 **Report Type:** Direct **Company Report Number:** **Age:** 15 YR **Gender:** Male

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

Date: 03/12/1998 **ISR Number:** 3059197-0 **Report Type:** Direct **Company Report Number:** **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anger	Consumer	Accutane	PS	Roche			
	Anxiety Nec							
	Appetite Decreased							
	Crying							
	Depression Nec							

Date: 03/24/1998 **ISR Number:** 3059391-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 96389 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Anorexia Nervosa	Health Professional	Accutane	PS		ORAL		
	Nausea							

Date: 03/24/1998 **ISR Number:** 3059394-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 96392 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anorexia Nervosa	Foreign	Roaccutan	PS				
	Breast Lump Nos	Health Professional						
	Lymphadenopathy							
	Nausea							
	Skin Cysts Nos							

Date: 03/24/1998 **ISR Number:** 3059463-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 910700071001 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide	Foreign	Roaccutane	PS				
Life-Threatening	Depression Nec	Literature						

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Date: 03/24/1998 **ISR Number:** 3059492-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 96225 **Age:** 37 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Hypersomnia	Consumer	Accutane	PS		ORAL		
	Hypothyroidism		Zoloft	C				
	Pruritus							
	Urticaria Nos							
	Weight Increased							

Date: 03/24/1998 **ISR Number:** 3059494-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 91903 **Age:** 13 YR **Gender:** Female

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

Date: 03/24/1998 **ISR Number:** 3059498-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 96084 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Condition Aggravated	Other	Accutane	PS		ORAL		
	Depression Aggravated		Zoloft	C				
	Dry Eye Nec		Artificial Tears	C				
	Hypertriglyceridaemia							
	Lip Dry							
	Obsessive-Compulsive Disorder							

Date: 03/24/1998 **ISR Number:** 3059502-5 **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							
	Weakness							

Date: 03/24/1998 **ISR Number:** 3059554-2 **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		
	Depression Nec		Paxil	C				
	Muscle Spasms							
	Ovarian Disorder Nos							

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Date: 03/24/1998 **ISR Number:** 3059555-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 96187 **Age:** 21 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos	Other	Accutane	PS		ORAL		
	Antisocial Personality Disorder Nec							
	Dry Skin							
	Economic Problem Nos							
	Educational Problem							
	Headache Nos							
	Hypersomnia							
	Impulsive Behaviour Nos							

Date: 03/24/1998 **ISR Number:** 3059572-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 860200853001 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide	Other	Accutane	PS		ORAL		
Life-Threatening	Depression Nec							
Disability	Eating Disorder Nec							
	Feeling Abnormal							
	Mood Swings							

Date: 03/24/1998 **ISR Number:** 3059577-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 94721 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos	Health Professional	Accutane	PS		ORAL		
	Hallucination Nos		Lithium	SS		ORAL		
	Mania							
	Psychotic Disorder Nos							
	Self Mutilation							

Date: 03/24/1998 **ISR Number:** 3060187-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 94423 **Age:** 13 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS		ORAL		
	Dermatitis Nos	Other	Chlor-Trimeton	C				
	Epistaxis		Claritin-D	C				
	Insomnia Nec		Nebulizer	C				
	Migraine Nos		Zoloft	C				
	Mood Swings							
	Suicidal Ideation							
	Vision Blurred							

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Date: 03/24/1998 **ISR Number:** 3060188-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 94704 **Age:** 29 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Nos	Consumer	Accutane	PS		ORAL		
	Dry Eye Nec	Health Professional	Imitrex	C				
	Headache Nos		Synthroid	C				
	Insomnia Nec							
	Migraine Aggravated							
	Photophobia							
	Vision Blurred							

Date: 03/24/1998 **ISR Number:** 3060298-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 95287 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Appetite Decreased	Other	Accutane	PS		ORAL		
	Depression Nec		Prozac (Fluoxetine)	C				
	Insomnia Nec		Serzone (Nefazodone Hydrochloride)	C				
	Mental Disorder Nec							
	Tic Nec							
	Tourette'S Disorder							
	Weight Decreased							

Date: 03/31/1998 **ISR Number:** 3060332-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 96390 **Age:** 20 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec	Health Professional	Accutane	PS		ORAL		
			Minocin	C				

Date: 03/26/1998 **ISR Number:** 3060376-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 95293 **Age:** 15 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Overdose Nos	Health Professional	Accutane	PS		ORAL		
	Suicide Attempt		Prozac	C				

Date: 04/03/1998 **ISR Number:** 3060773-X **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	C				
	Eating Disorder Nec		Paxil	C				
	Nausea		Ortho Tri Cyclen	C				
	Weight Decreased		Xanax	C				
			Ritalin	C				

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Date: 04/03/1998 **ISR Number:** 3060778-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 870103027001 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Bone Pain	Foreign	Roaccutane	PS		ORAL		
	Dry Skin	Literature	Oxazepam	C				
	Headache Nos		Doxepin Hydrochloride	C				
	Paraesthesia Nec		Methylprednisolone	C				
	Pruritus		Erythromycin	C				
	Rash Scaly							
	Sedation							
	Speech Disorder Nec							
	Suicide Attempt							

Date: 04/07/1998 **ISR Number:** 3061694-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 96343 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos	Foreign	Roaccutane	PS		ORAL		
	Confusion	Health Professional	Agyrax	C				
	Coordination Abnormal Nos		Vogalene	C				
	Disorientation							
	Dizziness (Exc Vertigo)							
	Electroencephalogram Abnormal							
	Encephalopathy Nos							
	Facial Palsy							
	Hypersomnia							
	Hyperventilation							
	Influenza Like Illness							

Date: 04/07/1998 **ISR Number:** 3061704-9 **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	Abnormal Eye Movements Nos	Health Professional	Accutane	PS		ORAL		
Congenital Anomaly	Blindness Transient		Prozac	C				
	Cerebral Palsy		Alcohol	C				
	Conjunctivitis Nec							
	Convulsions Nos							
	Developmental Delay Nos							
	Dyskinesia Nec							
	Eyelid Ptosis							
	Hyperplasia Nos							
	Hypotonia							
	Irritability							
	Multiple Congenital Abnormalities							
	Mydriasis							

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Date: 03/31/1998 **ISR Number:** 3063222-0 **Report Type:** Direct **Company Report Number:** **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide	Consumer	Accutane	PS	Hoffman-Laroche			
	Depression Nec							
	Feeling Of Despair							

Date: 04/16/1998 **ISR Number:** 3064753-X **Report Type:** Expedited (15-Day) **Company Report Number:** 95445 **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Aggression	Other	Accutane	PS		ORAL		
	Belligerence		Mescaline	SS				
	Depression Nec							
	Disturbance In Social Behaviour Nos							
	Drug Abuse							
	Educational Problem							
	Hostility							
	Lethargy							
	Pallor							
	Schizophrenia Nos							
	Social Avoidant Behaviour							
	Weakness							

Date: 04/16/1998 **ISR Number:** 3064755-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 95261 **Age:** **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		
	Genital Pain Female		Loestrin	C				
	Vulval Ulceration							
	Vulvitis							
	Vulvovaginal Discomfort							

Date: 04/15/1998 **ISR Number:** 3066241-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 97351 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Accident Nos	Health Professional	Accutane	PS		ORAL		
	Loss Of Consciousness Nec		Ampicillin	C				
	Mood Alteration Nos							
	Weight Decreased							

Date: 04/21/1998 **ISR Number:** 3067215-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 91162 **Age:** 21 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Anxiety Nec	Other	Accutane	PS		ORAL		
	Depression Nec							

FDA - Adverse Event Reporting System (AERS)
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Date: 04/27/1998 **ISR Number:** 3069022-X **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							
	Weight Decreased							

Date: 04/27/1998 **ISR Number:** 3070608-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 96390 **Age:** 20 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec	Health Professional	Accutane	PS		ORAL		
	Fear, Focus Nec		Minocin	C				

Date: 04/16/1998 **ISR Number:** 3070773-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 97439 **Age:** 25 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos	Consumer	Accutane	PS		ORAL		
	Acne Aggravated							
	Cholelithiasis							
	Complications Of Maternal Exposure To Therapuetic Drugs							
	Congenital Hearing Disorder							
	Flatulence							
	Headache Nos							
	Speech Disorder (Developmental)							

Date: 04/30/1998 **ISR Number:** 3071512-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 92223 **Age:** 17 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anorexia Nervosa	Foreign	Roaccutane	PS		ORAL		
	Appetite Decreased	Health Professional	Meliane (Ethinyl Estradiol/Gestodene)	SS		ORAL		
	Condition Aggravated		Stimycine	C				
	Cyanosis Peripheral		(Erythromycin)	C				
	Peripheral Vascular Disease Nos							
	Raynaud'S Phenomenon							
	Rigors							
	Weight Decreased							

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Date: 04/30/1998 **ISR Number:** 3071514-4 **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	C				
	Eating Disorder Nec		Paxil	C				
	Nausea		Ortho Tri Cyclen	C				
	Weight Decreased		Xanax	C				
			Ritalin	C				

Date: 04/30/1998 **ISR Number:** 3071521-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 98139 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Cellulitis	Health Professional	Accutane	PS		ORAL		
	Depression Nec							
	Infection Nos							
	Inflammation Nos							
	Mood Swings							

Date: 04/30/1998 **ISR Number:** 3073227-1 **Report Type:** Direct **Company Report Number:** **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos		Accutane	PS				
Other	Depression Nec							
	Mental Disorder Nec							
	Mood Swings							

Date: 05/05/1998 **ISR Number:** 3073596-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 96084 **Age:** 16 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Triglycerides Increased	Other	Accutane	PS		ORAL		
	Condition Aggravated		Zoloft	C				
	Depression Aggravated		Artificial Tears	C				
	Dry Eye Nec							
	Lip Dry							
	Obsessive-Compulsive Disorder							

Date: 05/05/1998 **ISR Number:** 3073795-X **Report Type:** Expedited (15-Day) **Company Report Number:** 98139 **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Cellulitis	Health Professional	Accutane	PS		ORAL		
	Depression Nec	Other						
	Mood Swings							
	Skin Infection Nos							
	Skin Inflammation Nos							

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Date: 05/05/1998 **ISR Number:** 3073845-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 98332 **Age:** 80 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos	Other	Tasmar	PS		ORAL		
	Aggression		Sinemet	C				
	Dementia Nos Aggravated		Zoloft	C				
	Euphoric Mood		Imdur	C				
	Hypersomnia		Lanoxin	C				
	Weight Decreased		Folic Acid	C				
			K-Dur	C				
			Vitamin E	C				
			Feosol	C				
			Vitamin B1	C				
			Vitamin B12	C				
			One-A-Day	C				
			Ecotrin	C				

Date: 05/05/1998 **ISR Number:** 3073852-8 **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							
	Pancreatic Carcinoma Nos							
	Pyrexia							
	Tremor Nec							
	White Blood Cell Count Decreased							

Date: 04/30/1998 **ISR Number:** 3073944-3 **Report Type:** Direct **Company Report Number:** **Age:** **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Anxiety Nec		Accutane	PS	Roche			
	Depressed Mood							
	Depression Nec							
	Diarrhoea Nos							
	Disturbance In Attention Nec							
	Faecal Occult Blood							
	Irritability							
	Suicidal Ideation							

FDA - Adverse Event Reporting System (AERS)
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Date: 05/04/1998 **ISR Number:** 3073952-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 68417 **Age:** 41 YR **Gender:**

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Colitis Nos	Foreign	Roaccutane	PS		ORAL		
	Diarrhoea Haemorrhagic	Health Professional		C				

Date: 04/30/1998 **ISR Number:** 3074426-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 92643 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS		ORAL		
	Gonorrhoea Nos							
	Urethral Discharge Nos							

Date: 04/21/1998 **ISR Number:** 3074823-8 **Report Type:** Direct **Company Report Number:** **Age:** 20 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Anger		Accutane	PS				
Other	Asocial Behaviour							
	Economic Problem Nos							
	Headache Nos							
	Impulsive Behaviour Nos							
	Intermittent Explosive Disorder							
	Loss Of Employment							
	Social Avoidant Behaviour							

Date: 05/13/1998 **ISR Number:** 3075587-4 **Report Type:** Direct **Company Report Number:** **Age:** 19 YR **Gender:** Male

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

Date: 05/12/1998 **ISR Number:** 3076718-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 98567 **Age:** 47 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos	Foreign	Tasmar	PS		ORAL		
		Health Professional	Sinemet	C				

Date: 04/29/1998 **ISR Number:** 3078877-4 **Report Type:** Direct **Company Report Number:** **Age:** 18 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Asthma Nos		Accutane	PS	Hoffman Laroche, Inc			
	Cough							
	Depression Nec							
	Dyspnoea Nos							
	Epistaxis							

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Date: 05/15/1998 **ISR Number:** 3079356-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 94423 **Age:** 13 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS		ORAL		
	Epistaxis	Other	Chlor-Trimeton	C				
	Insomnia Nec		Claritin	C				
	Migraine Nos		Nebulizer	C				
	Mood Swings		Zoloft	C				
	Rash Maculo-Papular							
	Vision Blurred							

Date: 05/15/1998 **ISR Number:** 3079361-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 98139 **Age:** 20 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Cellulitis	Health Professional	Accutane	PS		ORAL		
	Depression Nec	Other						
	Epistaxis							
	Inflammation Nos							
	Localised Infection							
	Mood Swings							
	Pyrexia							

Date: 05/15/1998 **ISR Number:** 3079381-X **Report Type:** Expedited (15-Day) **Company Report Number:** 94704 **Age:** 29 YR **Gender:** Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Aggravated	Consumer	Accutane	PS		ORAL		
	Drug Ineffective	Health Professional	Imitrex	C				
	Dry Eye Nec		Synthroid	C				
	Headache Nos							
	Insomnia Nec							
	Migraine Aggravated							
	Nausea							
	Photophobia							
	Vision Blurred							

Date: 05/15/1998 **ISR Number:** 3079458-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 97351 **Age:** 17 YR **Gender:** Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Accident Nos	Health Professional	Accutane	PS		ORAL		
	Loss Of Consciousness Nec		Ampicillin	C				
	Mood Alteration Nos							
	Weight Decreased							

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							

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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							

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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							

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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				

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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							