

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

Date: 12/07/1989	ISR Number: 624636-9	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	Bipolar I Disorder Central Nervous System Depression Nec Depression Nec	Consumer	Accutane	PS	Roche	ORAL		14
Date: 12/12/1989	ISR Number: 625269-0	Report Type: Direct	Company Report Number:	Age:	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Dermatitis Exfoliative Nos Dry Skin Gingivitis Impotence	Consumer	Accutane	PS	Roche			854
Date: 11/20/1989	ISR Number: 626413-1	Report Type: Direct	Company Report Number:	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Chest Pain Muscle Spasms Neck Pain Palpitations	Consumer	Accutane	PS	Roche	ORAL		32
Date: 12/19/1989	ISR Number: 632208-5	Report Type: Expedited (15-Day)	Company Report Number: 890500081001	Age: 20 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health Professional	Roacutane	PS	Roche	ORAL		1
Date: 02/22/1990	ISR Number: 642098-2	Report Type: Expedited (15-Day)	Company Report Number: 900200122001	Age: 16 YR	Gender: Unknown			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Anorexia Depression Nec Sedation Suicide Attempt	Health Professional	Accutane	PS	Roche	ORAL		60
Date: 02/23/1990	ISR Number: 644420-X	Report Type: Expedited (15-Day)	Company Report Number: 900100010001	Age: 19 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Coma Nec Sweating Increased	Health Professional	Roacutane	PS	Roche	ORAL		579

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Date: 03/14/1990	ISR Number: 646860-1	Report Type: Expedited (15-Day)	Company Report Number: 900200228001	Age: 17 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Bipolar I Disorder Emotional Disturbance Nos Suicide Attempt	Study Health Professional	Accutane Duricef Doxycycline	PS C C	Roche	ORAL		42
Date: 03/01/1990	ISR Number: 647435-0	Report Type: Expedited (15-Day)	Company Report Number: 900100020001	Age: 19 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Paranoia Personality Disorder Nos Psychotic Disorder Nos	Foreign Health Professional	Roaccutane	PS	Roche	ORAL		2
Date: 04/04/1990	ISR Number: 657492-3	Report Type: Direct	Company Report Number: PDR	Age: 16 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Nos Dystonia Paranoia Psychotic Disorder Nos	Health Professional	Accutane Retin-A Tetracycline	PS C C	Roche	ORAL		17
Date: 06/11/1990	ISR Number: 667406-8	Report Type: Periodic	Company Report Number: 890200751001	Age: 19 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		136
Date: 06/11/1990	ISR Number: 667419-6	Report Type: Periodic	Company Report Number: 890200694001	Age: 24 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Amnesia Nec Anxiety Nec Insomnia Nec Thinking Abnormal Nec	Health Professional	Accutane Tagamet	PS C	Roche	ORAL		1119
Date: 06/11/1990	ISR Number: 667547-5	Report Type: Periodic	Company Report Number: 890201223001	Age: 26 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anorexia Anxiety Nec	Health Professional	Accutane	PS	Roche	ORAL		123
Date: 06/11/1990	ISR Number: 667562-1	Report Type: Periodic	Company Report Number: 890201105001	Age: 21 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Dyspnoea Nos	Consumer	Accutane	PS	Roche	ORAL		260

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Date: 06/11/1990	ISR Number: 667577-3	Report Type: Periodic	Company Report Number: 900200076001	Age: 35 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Delusion Nos Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		
Date: 06/11/1990	ISR Number: 667588-8	Report Type: Periodic	Company Report Number: 900200256001	Age: 28 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Diarrhoea Nos Dysparennia Nec Gastric Ulcer Rectal Disorder Nos	Health Professional	Accutane Bactrim Ds	PS C	Roche	ORAL		90
Date: 06/11/1990	ISR Number: 667605-5	Report Type: Periodic	Company Report Number: 900200280001	Age:	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Amenorrhoea Nos Depression Nec Dry Skin Epistaxis	Consumer	Accutane Lo/Ovral	PS C	Roche	ORAL		243
Date: 06/11/1990	ISR Number: 667616-X	Report Type: Periodic	Company Report Number: 900200238001	Age: 16 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		32
Date: 06/11/1990	ISR Number: 667621-3	Report Type: Periodic	Company Report Number: 900200212001	Age: 28 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Prolactin Increased Impotence Lymphadenopathy	Health Professional	Accutane Zovirax	PS C	Roche	ORAL		177
Date: 06/11/1990	ISR Number: 667624-9	Report Type: Periodic	Company Report Number: 900200200001	Age: 38 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Impotence	Health Professional	Accutane	PS	Roche	ORAL		210
Date: 06/11/1990	ISR Number: 667633-X	Report Type: Periodic	Company Report Number: 900200072001	Age: 16 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anorexia Hostility Personality Disorder Nos Sedation	Health Professional	Accutane Tegretol	PS C	Roche	ORAL		138

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Date: 06/11/1990	ISR Number: 667741-3	Report Type: Periodic	Company Report Number: 890200474001	Age: 32 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Dry Eye Nec Libido Decreased Photosensitivity Reaction Nos Vulvovaginal Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		112
Date: 06/11/1990	ISR Number: 667751-6	Report Type: Periodic	Company Report Number: 890200522003	Age: 19 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Emotional Disturbance Nos Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		5
Date: 06/11/1990	ISR Number: 667771-1	Report Type: Periodic	Company Report Number: 890200581002	Age: 16 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Blood Lactate Dehydrogenase Increased Hostility Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		36
Date: 06/11/1990	ISR Number: 667772-3	Report Type: Periodic	Company Report Number: 890200581001	Age: 16 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Hostility Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		146
Date: 05/23/1990	ISR Number: 667906-0	Report Type: Expedited (15-Day)	Company Report Number: 900200423001	Age: 17 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Death	Amnesia Nec Arrhythmia Nos Dry Skin Stupor	Health Professional	Accutane	PS	Roche	ORAL		93
Date: 06/11/1990	ISR Number: 667960-6	Report Type: Periodic	Company Report Number: 890201083001	Age: 31 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Condition Aggravated Hyperthyroidism Nervousness Tachycardia Nos	Health Professional	Accutane	PS	Roche	ORAL		143

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Date: 06/11/1990	ISR Number: 667990-4	Report Type: Periodic	Company Report Number: 890200884001			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec	Health Professional	Accutane	PS	Roche	ORAL		
Date: 06/11/1990	ISR Number: 668366-6	Report Type: Periodic	Company Report Number: 900200135001			Age: 35 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		17
			Aventyl	C				
			Antabuse	C				
			Tranxene	C				
Date: 06/11/1990	ISR Number: 668397-6	Report Type: Periodic	Company Report Number: 890200997001			Age: 29 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		2
Date: 06/11/1990	ISR Number: 668407-6	Report Type: Periodic	Company Report Number: 900200383001			Age: 17 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Epistaxis Myalgia	Health Professional	Accutane	PS	Roche	ORAL		23
Date: 06/11/1990	ISR Number: 668835-9	Report Type: Periodic	Company Report Number: 890200639001			Age: 19 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Confusion Grand Mal Convulsion Muscle Twitching Syncope	Health Professional	Accutane	PS	Roche	ORAL		140
Date: 06/11/1990	ISR Number: 668841-4	Report Type: Periodic	Company Report Number: 890200854001			Age: 20 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		4
Date: 06/11/1990	ISR Number: 668849-9	Report Type: Periodic	Company Report Number: 890201012008			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Blindness Night Headache Nos Insomnia Nec	Study Health Professional	Accutane	PS	Roche	ORAL		3

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

Date: 06/11/1990		ISR Number: 668850-5	Report Type: Periodic	Company Report Number: 890201012011			Age:	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration		
	Amblyopia Nos	Study	Accutane	PS	Roche	ORAL				
	Candida Nos	Health Professional	Elavil	C						
	Dermatitis Nos									
	Emotional Disturbance Nos									
Date: 06/11/1990		ISR Number: 668859-1	Report Type: Periodic	Company Report Number: 900200338001			Age:	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration		
	Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL				
	Thinking Abnormal Nec									
Date: 06/11/1990		ISR Number: 668874-8	Report Type: Periodic	Company Report Number: 900200154001			Age: 26 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration		
Other	Alopecia	Health Professional	Accutane	PS	Roche	ORAL		64		
	Depression Nec									
	Emotional Disturbance Nos									
	Infection Nos									
Date: 06/11/1990		ISR Number: 668878-5	Report Type: Periodic	Company Report Number: 890200740001			Age: 18 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration		
Hospitalization - Initial or Prolonged	Hostility	Health Professional	Accutane	PS	Roche	ORAL		24		
	Insomnia Nec		Tetracycline	C						
	Personality Disorder Nos									
Date: 06/11/1990		ISR Number: 668879-7	Report Type: Periodic	Company Report Number: 890200431001			Age: 44 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration		
Other	Aspartate Aminotransferase Increased	Health Professional	Accutane	PS	Roche	ORAL		1		
	Gamma-Glutamyltransferase Increased		Alcohol	C						
	Non-Accidental Overdose									
	Suicide Attempt									
Date: 06/11/1990		ISR Number: 668903-1	Report Type: Periodic	Company Report Number: 890201039001			Age:	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration		
Other	Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL				
	Hyperkinetic Syndrome									

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Date: 06/11/1990	ISR Number: 668912-2	Report Type: Periodic	Company Report Number: 890200373001	Age: 27 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Depression Nec Photosensitivity Reaction Nos Skin Discolouration	Health Professional	Accutane	PS	Roche	ORAL		97
Date: 07/06/1990	ISR Number: 671863-0	Report Type: Periodic	Company Report Number: 890200036001	Age: 50 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Impotence	Health Professional	Accutane	PS	Roche	ORAL		147
Date: 07/06/1990	ISR Number: 671872-1	Report Type: Periodic	Company Report Number: 890200023001	Age: 16 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		508
Date: 07/06/1990	ISR Number: 671909-X	Report Type: Periodic	Company Report Number: 880201453001	Age: 15 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		152
Date: 07/06/1990	ISR Number: 671927-1	Report Type: Periodic	Company Report Number: 890200279001	Age: 31 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Eye Disorder Nos Headache Nos Schizophrenia Nos	Health Professional	Accutane Feldene C	PS C	Roche	ORAL		93
Date: 07/06/1990	ISR Number: 671929-5	Report Type: Periodic	Company Report Number: 890200284001	Age: 20 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Palpitations	Health Professional	Accutane	PS	Roche	ORAL		140
Date: 07/06/1990	ISR Number: 671933-7	Report Type: Periodic	Company Report Number: 890200309001	Age: 14 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Aspartate Aminotransferase Increased Depression Nec Hepatic Function Abnormal Nos Hypocholesterolaemia	Health Professional	Accutane	PS	Roche	ORAL		35

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Date: 07/06/1990	ISR Number: 671988-X	Report Type: Periodic	Company Report Number: 890200187001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		140
Date: 07/06/1990	ISR Number: 672126-X	Report Type: Periodic	Company Report Number: 880201242001			Age: 14 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia Confusion Depression Nec Myalgia	Health Professional	Accutane	PS	Roche	ORAL		15
Date: 07/06/1990	ISR Number: 672556-6	Report Type: Periodic	Company Report Number: 880201425001			Age: 16 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Depression Nec Suicide Attempt	Health Professional	Accutane	PS	Roche	ORAL		113
Date: 06/20/1990	ISR Number: 672873-X	Report Type: Expedited (15-Day)	Company Report Number: 900200599001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Delusion Nos Hallucination Nos Paranoia Psychotic Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		7
Date: 06/20/1990	ISR Number: 672874-1	Report Type: Expedited (15-Day)	Company Report Number: 900200597001			Age: 23 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Delusion Nos Personality Disorder Nos Psychotic Disorder Nos Sleep Disorder Nos	Health Professional	Accutane Tetracycline	PS C	Roche	ORAL		47
Date: 06/15/1990	ISR Number: 673050-9	Report Type: Expedited (15-Day)	Company Report Number: 900100237001			Age:	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Depression Nec Insomnia Nec Suicide Attempt Weight Decreased	Foreign Health Professional	Roaccutane	PS	Roche	ORAL		54

FDA Adverse Event Reporting System (AERS)
 National Drug Information (NDI) Report

Date: 06/26/1990	ISR Number: 675196-8	Report Type: Expedited (15-Day)	Company Report Number: 890800046001	Age:	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Ashenia Depression Nec Psychotic Disorder Nos	Foreign Health Professional	Roaccutane	PS	Roche	ORAL		103
Date: 07/19/1990	ISR Number: 682006-1	Report Type: Expedited (15-Day)	Company Report Number: 900200749001	Age: 24 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Hallucination Nos Major Depressive Disorder Nos Psychotic Disorder Nos	Health Professional	Accutane Retin-A	PS C	Roche	ORAL		1
Date: 07/17/1990	ISR Number: 682387-9	Report Type: Expedited (15-Day)	Company Report Number: 890315726001	Age: 35 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Acute Circulatory Failure Amnesia Nec Syncope	Foreign Health Professional	Roaccutane	PS	Roche	ORAL		
Date: 08/16/1990	ISR Number: 687204-9	Report Type: Expedited (15-Day)	Company Report Number: 900316487001	Age: 22 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Cheilitis Conjunctivitis Nec Pain Nos Suicide Attempt	Foreign Health Professional	Roaccutane	PS	Roche	ORAL		451
Date: 09/27/1990	ISR Number: 692327-4	Report Type: Direct	Company Report Number: DEN2720	Age:	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Alopecia Chromosomal Abnormality Nos Depression Nec Skin Discolouration	Consumer	Accutane	PS	Roche	ORAL		152
Date: 10/10/1990	ISR Number: 697260-X	Report Type: Direct	Company Report Number:	Age:	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Alopecia Menometrorrhagia Pain Nos Palpitations	Health Professional	Accutane Keflex	PS C	Roche			93

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Date: 01/16/1991	ISR Number: 716667-5	Report Type: Expedited (15-Day)	Company Report Number: 900201460001	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Arthralgia	Health Professional	Accutane	PS	Roche	ORAL		105
Other	Major Depressive Disorder Nos Myalgia Suicide Attempt							
Date: 03/25/1991	ISR Number: 736346-8	Report Type: Expedited (15-Day)	Company Report Number: 910200256001	Age: 38 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Anxiety Nec Arthralgia	Health Professional	Accutane	PS	Roche	ORAL		76
Disability	Collagen Disorder Nos							
Other	Scleroderma							
Date: 03/13/1991	ISR Number: 737374-9	Report Type: Expedited (15-Day)	Company Report Number: 910200279001	Age: 16 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Amblyopia Nos Arthralgia	Consumer	Accutane	PS	Roche	ORAL		123
	Depression Nec Influenza Like Illness							
Date: 04/09/1991	ISR Number: 741365-1	Report Type: Expedited (15-Day)	Company Report Number: 900500246001	Age: 20 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Anxiety Nec Headache Nos	Foreign Health Professional	Roaccutane	PS	Roche	ORAL		184
	Hydrocephalus Nos							
Date: 04/12/1991	ISR Number: 741874-5	Report Type: Expedited (15-Day)	Company Report Number: 910100093001	Age: 19 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Arthralgia Cheilitis Conjunctivitis Nec Suicide Attempt	Foreign Consumer	Roaccutane	PS	Roche	ORAL		173
Date: 04/16/1991	ISR Number: 742951-5	Report Type: Direct	Company Report Number:	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Alopecia Blindness Night Depression Nec Suicide Attempt	Consumer	Accutane	PS	Roche	ORAL		105

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FDA Adverse Event Reporting System (AERS)
 Product Information (PI) Report

Date: 04/16/1991	ISR Number: 743620-8	Report Type: Direct	Company Report Number:	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		98
Date: 04/02/1991	ISR Number: 745098-7	Report Type: Direct	Company Report Number:	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthralgia Cheilitis Depression Nec Vision Abnormal Nec	Health Professional	Accutane Bicillin C-R Amoxicillin Pee	PS C C C	Roche	ORAL		113
Date: 05/23/1991	ISR Number: 751005-3	Report Type: Direct	Company Report Number:	Age: 39 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alcohol Intolerance Apathy Condition Aggravated Depression Nec	Health Professional	Accutane Prozac	PS C	Roche	ORAL		32
Date: 06/11/1991	ISR Number: 751891-7	Report Type: Direct	Company Report Number:	Age: 22 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Constipation Depression Nec Photosensitivity Reaction Nos	Consumer	Accutane Triavil 2-10	PS C	Roche	ORAL		55
Date: 06/07/1991	ISR Number: 753224-9	Report Type: Periodic	Company Report Number: 900201166001	Age: 15 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Leucopenia Nos	Health Professional	Accutane Anafranil	PS C	Roche	ORAL		94
Date: 06/07/1991	ISR Number: 753251-1	Report Type: Periodic	Company Report Number: 910200474001	Age: 16 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Hostility Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		26
Date: 06/07/1991	ISR Number: 753258-4	Report Type: Periodic	Company Report Number: 900201399001	Age: 31 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia	Health Professional	Accutane	PS	Roche	ORAL		62

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FDA Adverse Event Reporting System (AERS)
 Product Information (PI) Report

Date: 04/16/1991	ISR Number: 743620-8	Report Type: Direct	Company Report Number:	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		98
Date: 04/02/1991	ISR Number: 745098-7	Report Type: Direct	Company Report Number:	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthralgia Cheilitis Depression Nec Vision Abnormal Nec	Health Professional	Accutane Bicillin C-R Amoxicillin Pee	PS C C C	Roche	ORAL		113
Date: 05/23/1991	ISR Number: 751005-3	Report Type: Direct	Company Report Number:	Age: 39 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alcohol Intolerance Apathy Condition Aggravated Depression Nec	Health Professional	Accutane Prozac	PS C	Roche	ORAL		32
Date: 06/11/1991	ISR Number: 751891-7	Report Type: Direct	Company Report Number:	Age: 22 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Constipation Depression Nec Photosensitivity Reaction Nos	Consumer	Accutane Triavil 2-10	PS C	Roche	ORAL		55
Date: 06/07/1991	ISR Number: 753224-9	Report Type: Periodic	Company Report Number: 900201166001	Age: 15 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Leucopenia Nos	Health Professional	Accutane Anafranil	PS C	Roche	ORAL		94
Date: 06/07/1991	ISR Number: 753251-1	Report Type: Periodic	Company Report Number: 910200474001	Age: 16 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Hostility Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		26
Date: 06/07/1991	ISR Number: 753258-4	Report Type: Periodic	Company Report Number: 900201399001	Age: 31 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia	Health Professional	Accutane	PS	Roche	ORAL		62

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

Date: 06/07/1991	ISR Number: 753975-6	Report Type: Periodic	Company Report Number: 90201393001			Age: 30 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos Emotional Disturbance Nos Malaise	Health Professional	Accutane Alcohol	PS C	Roche	ORAL		62
Date: 06/07/1991	ISR Number: 753976-8	Report Type: Periodic	Company Report Number: 900201391001			Age: 23 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amblyopia Nos Anxiety Nec Myasthenic Syndrome Paresthesia Nec	Health Professional	Accutane Prednisone	PS C	Roche	ORAL		65
Date: 06/07/1991	ISR Number: 753983-5	Report Type: Periodic	Company Report Number: 900201369001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Dreams Asthenia Depression Nec Headache Nos	Health Professional	Accutane	PS	Roche	ORAL		154
Date: 06/07/1991	ISR Number: 753994-X	Report Type: Periodic	Company Report Number: 900201348001			Age: 38 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Depression Nec Dry Skin Skin Atrophy	Health Professional	Accutane Minocin	PS C	Roche	ORAL		153
Date: 06/07/1991	ISR Number: 754077-5	Report Type: Periodic	Company Report Number: 900201302001			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Emotional Disturbance Nos Hyperlipidaemia Nos	Health Professional	Accutane	PS	Roche	ORAL		14
Date: 06/07/1991	ISR Number: 754090-8	Report Type: Periodic	Company Report Number: 900201258001			Age: 17 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL		15

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

Date: 06/07/1991	ISR Number: 754176-8	Report Type: Periodic	Company Report Number: 910200271001	Age: 22 YR	Gender: Unknown			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Arthritis Nos Depression Nec Vision Abnormal Nec	Consumer	Accutane	PS	Roche	ORAL		
Date: 06/07/1991	ISR Number: 754177-X	Report Type: Periodic	Company Report Number: 910200270001	Age:	Gender: Unknown			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amblyopia Nos Back Pain Chellitis Depression Nec	Consumer	Accutane	PS	Roche	ORAL		1
Date: 06/07/1991	ISR Number: 754182-3	Report Type: Periodic	Company Report Number: 910200277001	Age: 43 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos Depression Nec Headache Nos Vision Abnormal Nec	Consumer	Accutane	PS	Roche	ORAL		14
Date: 06/07/1991	ISR Number: 754183-5	Report Type: Periodic	Company Report Number: 910200274001	Age:	Gender: Unknown			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Cyst Nos Depression Nec Infection Nos Vision Abnormal Nec	Consumer	Accutane	PS	Roche	ORAL		1826
Date: 06/07/1991	ISR Number: 754194-X	Report Type: Expedited (15-Day)	Company Report Number: 910200300001	Age: 20 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Amnesia Nec Haematuria Present Hostility Laboratory Test Abnormal Nos	Consumer	Accutane	PS	Roche	ORAL		27
Date: 06/07/1991	ISR Number: 754268-3	Report Type: Periodic	Company Report Number: 900201448001	Age: 28 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dry Eye Nec Dry Skin Dyspareunia Nec Vaginitis	Health Professional	Accutane	PS	Roche	ORAL		141

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

Date	ISR Number	Report Type	Company Report Number	Age	Gender			
06/07/1991	754272-5	Periodic	910200021001		Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Alopecia Conjunctivitis Nec Face Oedema Hallucination Nos	Health Professional	Accutane	PS	Roche	ORAL		
06/07/1991	754289-0	Periodic	910200074001	31 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Dry Skin Electrocardiogram Abnormal Nos Palpitations Supraventricular Extrasystoles	Health Professional	Accutane Retin-A Cleocin	PS C C	Roche	ORAL		148
06/07/1991	754292-0	Periodic	910200086001	16 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Dry Skin Emotional Disturbance Nos Hostility	Health Professional	Accutane	PS	Roche	ORAL		18
06/07/1991	754393-7	Periodic	900201045001	25 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Abnormal Dreams Chest Pain Nausea	Health Professional	Accutane Triphasil Tetracycline	PS C C	Roche	ORAL		48
06/07/1991	754700-5	Periodic	910200151001	45 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Arthralgia Condition Aggravated Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		32
06/07/1991	754713-3	Periodic	910200186001	30 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Amblyopia Nos Depression Nec Diarrhoea Nos Epistaxis	Health Professional	Accutane Cleocin	PS C	Roche	ORAL		31

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

Date: 06/07/1991		ISR Number: 754716-9		Report Type: Periodic		Company Report Number: 910200191001		Age: 38 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Dysphonia	Health Professional	Accutane	PS	Roche	ORAL		150			
Date: 06/07/1991		ISR Number: 754723-6		Report Type: Periodic		Company Report Number: 910200207001		Age:		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Disability	Drug Ineffective Emotional Disturbance Nos Headache Nos Weight Increased	Consumer	Accutane Tetracycline	PS C	Roche	ORAL		22			
Date: 06/07/1991		ISR Number: 754783-2		Report Type: Periodic		Company Report Number: 910200322001		Age: 21 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Depression Nec Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL		121			
Date: 06/07/1991		ISR Number: 754784-4		Report Type: Periodic		Company Report Number: 910200343001		Age: 27 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Hospitalization - Initial or Prolonged Other	Depression Nec Dizziness (Exc Vertigo)	Health Professional	Accutane	PS	Roche	ORAL		162			
Date: 06/07/1991		ISR Number: 754801-1		Report Type: Periodic		Company Report Number: 910200215001		Age: 24 YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Dyspnoea Nos Palpitations Supraventricular Extrasystoles	Health Professional	Accutane	PS	Roche	ORAL		53			
Date: 06/07/1991		ISR Number: 754816-3		Report Type: Periodic		Company Report Number: 910200238001		Age: 34 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Alopecia Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		84			
Date: 06/07/1991		ISR Number: 754820-5		Report Type: Periodic		Company Report Number: 910200250001		Age: 16 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Depression Nec Rectal Bleeding	Health Professional	Accutane	PS	Roche	ORAL		124			

FDA Adverse Event Reporting System (AERS)
 Division Of Information (D.I.) Report

Date: 06/07/1991	ISR Number: 754946-6	Report Type: Periodic	Company Report Number: 900200573001			Age: 46 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Breast Abscess Hyperventilation Neoplasm Nos	Health Professional	Accutane Retin-A	PS C	Roche	ORAL		227
Date: 06/07/1991	ISR Number: 754952-1	Report Type: Periodic	Company Report Number: 900200441001			Age: 19 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Breast Enlargement Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL		166
Date: 06/07/1991	ISR Number: 755165-X	Report Type: Periodic	Company Report Number: 910200119001			Age: 19 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Cheilitis Emotional Disturbance Nos Epistaxis	Health Professional	Accutane	PS	Roche	ORAL		151
Date: 06/07/1991	ISR Number: 755515-4	Report Type: Periodic	Company Report Number: 910200326001			Age: 15 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL		15
Date: 06/07/1991	ISR Number: 755524-5	Report Type: Periodic	Company Report Number: 910200358001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arrhythmia Nos Chest Pain Palpitations	Health Professional	Accutane	PS	Roche	ORAL		15
Date: 06/07/1991	ISR Number: 755533-6	Report Type: Periodic	Company Report Number: 910200392001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Cheilitis Drug Ineffective Dry Skin Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL		148
Date: 06/07/1991	ISR Number: 755549-X	Report Type: Periodic	Company Report Number: 900200522001			Age: 24 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Depression Nec Dry Mouth	Health Professional	Accutane	PS	Roche	ORAL		169

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

Date: 06/07/1991	ISR Number: 755586-5	Report Type: Periodic	Company Report Number: 910200461001			Age: 34 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Impotence	Health Professional	Accutane	PS	Roche	ORAL		167
Date: 06/07/1991	ISR Number: 755596-8	Report Type: Periodic	Company Report Number: 900200637001			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Condition Aggravated Confusion Oedema Nos Renal Failure Nos	Study Health Professional	Accutane	PS	Roche	ORAL		
Date: 06/07/1991	ISR Number: 755631-7	Report Type: Periodic	Company Report Number: 900200748001			Age: 28 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Migraine Nos Urine Abnormal Nos Vision Abnormal Nec	Health Professional	Accutane	PS	Roche	ORAL		40
Date: 06/07/1991	ISR Number: 755633-0	Report Type: Periodic	Company Report Number: 900200753001			Age: 34 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dry Skin Hypertension Nos Muscle Twitching Palpitations	Consumer	Accutane	PS	Roche	ORAL		60
Date: 06/07/1991	ISR Number: 755639-1	Report Type: Periodic	Company Report Number: 900201416001			Age: 31 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arrhythmia Nos Electrocardiogram Abnormal Nos Palpitations	Health Professional	Accutane Hydroxyzine	PS C	Roche	ORAL		48
Date: 06/07/1991	ISR Number: 755698-6	Report Type: Periodic	Company Report Number: 900201397001			Age: 15 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Arthralgia Depression Nec Headache Nos Personality Disorder Nos	Study Health Professional	Accutane	PS	Roche	ORAL		86

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

Date: 06/07/1991	ISR Number: 755844-4	Report Type: Periodic	Company Report Number: 900200474001			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos Depression Nec Emotional Disturbance Nos Headache Nos	Health Professional	Accutane	PS	Roche	ORAL		117
Date: 06/07/1991	ISR Number: 755846-8	Report Type: Periodic	Company Report Number: 900200470001			Age: 30 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Dry Skin Dyspareunia Nec Vaginitis	Health Professional	Accutane Thorazine	PS C	Roche	ORAL		
Date: 06/07/1991	ISR Number: 755847-X	Report Type: Periodic	Company Report Number: 900200460001			Age: 37 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Libido Decreased	Health Professional	Accutane	PS	Roche	ORAL		42
Date: 06/07/1991	ISR Number: 756223-6	Report Type: Periodic	Company Report Number: 900200420001			Age: 33 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia Cellulitis Depression Nec Dermatitis Nos	Health Professional	Accutane	PS	Roche	ORAL		42
Date: 07/07/1991	ISR Number: 762362-6	Report Type: Periodic	Company Report Number: 890200320001			Age: 25 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos Hypercholesterolaemia Hyperlipidaemia Nos Influenza Like Illness	Health Professional	Accutane	PS	Roche	ORAL		178
Date: 09/09/1991	ISR Number: 771120-8	Report Type: Expedited (15-Day)	Company Report Number: 910201131001			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Dyspareunia Nec Urinary Tract Infection Nos Vaginitis	Health Professional	Accutane	PS	Roche	ORAL		

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

Date	ISR Number	Report Type	Company Report Number	Age	Gender			
09/04/1991	771125-7	Expedited (15-Day)	910201137001	14 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Catonia Hallucination Nos Paranoia Psychotic Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		2
09/12/1991	775500-6	Direct		40 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Arthritis Nos Depression Nec Influenza Like Illness Photosensitivity Reaction Nos	Consumer	Accutane Vitamin A	PS SS	Roche			
09/20/1991	776989-9	Direct			Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
	Amblyopia Nos Back Pain Depression Nec Dry Mouth	Consumer	Accutane	PS	Roche	ORAL		90
09/20/1991	777487-9	Direct		14 YR	Unknown			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
	Arthritis Nos Depression Nec Photosensitivity Reaction Nos Vision Abnormal Nec	Consumer	Accutane	PS	Roche	ORAL		147
09/20/1991	778954-4	Direct			Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
	Back Pain Depression Nec Influenza Like Illness	Consumer	Accutane	PS	Roche			
10/03/1991	780023-4	Direct			Unknown			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
	Cyst Nos Depression Nec Influenza Like Illness Vision Abnormal Nec	Consumer	Accutane	PS	Roche			1826

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

Date: 10/18/1991	ISR Number: 785566-5	Report Type: Expedited (15-Day)	Company Report Number: 910700071001			Age:	Gender: Unknown	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Major Depressive Disorder Nos Suicide Attempt	Foreign Literature Health Professional	Roaccutane	PS	Roche	ORAL		120
Date: 10/30/1991	ISR Number: 789216-3	Report Type: Direct	Company Report Number:			Age: 42 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Disability	Arthritis Nos Depression Nec Infection Nos Vision Abnormal Nec	Consumer	Accutane	PS	Roche	ORAL		93
Date: 03/04/1992	ISR Number: 815546-2	Report Type: Expedited (15-Day)	Company Report Number: 910800213001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec Headache Nos Insomnia Nec Mania	Foreign Health Professional	Accutane	PS	Roche	ORAL		14
Date: 04/15/1992	ISR Number: 833866-2	Report Type: Direct	Company Report Number:			Age: 31 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Dry Skin Personality Disorder Nos Speech Disorder Nec Tooth Disorder Nos	Health Professional	Accutane	PS	Roche			
Date: 05/13/1992	ISR Number: 840102-X	Report Type: Expedited (15-Day)	Company Report Number: 920100201001			Age: 32 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Asthenia Depression Nec Dyspnoea Nos Myalgia	Foreign Health Professional	Roaccutane	PS	Roche	ORAL		
Date: 06/18/1992	ISR Number: 848612-6	Report Type: Periodic	Company Report Number: 910200878001			Age: 36 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Emotional Disturbance Nos Headache Nos Myalgia	Health Professional	Accutane	PS	Roche	ORAL		40

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

Date: 06/18/1992	ISR Number: 848804-6	Report Type: Periodic	Company Report Number: 920200358001			Age:	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Depersonalisation	Health Professional	Accutane	PS	Roche	ORAL			
Date: 06/18/1992	ISR Number: 848813-7	Report Type: Periodic	Company Report Number: 920200388001			Age: 25 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Dyspepsia Headache Nos Impotence	Health Professional	Accutane	PS	Roche	ORAL		33	
Date: 06/18/1992	ISR Number: 848818-6	Report Type: Periodic	Company Report Number: 920200386001			Age: 19 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL			
Date: 06/18/1992	ISR Number: 849190-8	Report Type: Periodic	Company Report Number: 920200519001			Age: 14 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Convulsions Nos Diarrhoea Nos Hallucination Nos Headache Nos	Health Professional	Accutane Erythromycin	PS C	Roche	ORAL		1	
Date: 06/18/1992	ISR Number: 849191-X	Report Type: Periodic	Company Report Number: 920200522001			Age: 19 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Depression Nec Insomnia Nec Thinking Abnormal Nec	Health Professional	Accutane	PS	Roche	ORAL		117	
Date: 06/18/1992	ISR Number: 849193-3	Report Type: Periodic	Company Report Number: 920200527001			Age: 39 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Condition Aggravated Depression Nec Emotional Disturbance Nos	Health Professional	Accutane Klonopin Trifluoperazine	PS C C	Roche	ORAL		61	
Date: 06/18/1992	ISR Number: 849196-9	Report Type: Periodic	Company Report Number: 920200461001			Age: 20 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Anxiety Nec Depression Nec Neurosis Nos	Health Professional	Accutane	PS	Roche	ORAL		149	

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

Date: 06/18/1992	ISR Number: 849212-4	Report Type: Periodic	Company Report Number: 920200463001	Age: 23 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Cough Dysphonia Infection Nos Pharyngitis Nos	Health Professional	Accutane	PS	Roche	ORAL		63
Date: 06/18/1992	ISR Number: 849227-6	Report Type: Periodic	Company Report Number: 920200034001	Age: 24 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		
Date: 06/18/1992	ISR Number: 850217-8	Report Type: Periodic	Company Report Number: 910201470001	Age: 20 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthralgia Cheilitis Insomnia Nec	Health Professional	Accutane Ampicillin	PS C	Roche	ORAL		99
Date: 06/18/1992	ISR Number: 850237-3	Report Type: Periodic	Company Report Number: 920200610001	Age: 23 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blepharitis Depression Nec Emotional Disturbance Nos Paranoia	Health Professional	Accutane	PS	Roche	ORAL		26
Date: 06/18/1992	ISR Number: 850239-7	Report Type: Periodic	Company Report Number: 920200606001	Age: 19 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Palpitations	Health Professional	Accutane Erythromycin	PS C	Roche	ORAL		29
Date: 06/18/1992	ISR Number: 850240-3	Report Type: Periodic	Company Report Number: 920200602001	Age: 22 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Confusion Depersonalisation Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		
Date: 06/18/1992	ISR Number: 850249-X	Report Type: Periodic	Company Report Number: 920200343001	Age: 31 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthritis Nos Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		100

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Freedom Of Information (FOI) Report

Date: 06/18/1992	ISR Number: 850283-X	Report Type: Periodic	Company Report Number: 910201601001	Age: 28 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Impotence	Health Professional	Accutane	PS	Roche	ORAL		15
Date: 06/18/1992	ISR Number: 850662-0	Report Type: Periodic	Company Report Number: 910201720001	Age: 38 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Cheilitis Corneal Lesion Nos Emotional Disturbance Nos Epistaxis	Health Professional	Accutane	PS	Roche	ORAL		38
Date: 06/18/1992	ISR Number: 850664-4	Report Type: Periodic	Company Report Number: 910201718001	Age: 18 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL		13
Date: 06/18/1992	ISR Number: 850689-9	Report Type: Periodic	Company Report Number: 910201757001	Age: 38 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Glaucoma Nos Headache Nos Thinking Abnormal Nec	Health Professional	Accutane	PS	Roche	ORAL		128
Date: 06/18/1992	ISR Number: 850696-6	Report Type: Periodic	Company Report Number: 910201544001	Age: 24 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Confusion Hallucination Nos Headache Nos	Health Professional	Accutane	PS	Roche	ORAL		1
Date: 06/18/1992	ISR Number: 850697-8	Report Type: Periodic	Company Report Number: 910201541001	Age: 23 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Impotence	Health Professional	Accutane	PS	Roche	ORAL		9
Date: 06/18/1992	ISR Number: 850903-X	Report Type: Periodic	Company Report Number: 910201577001	Age: 27 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Dermatitis Nos Dizziness (Exc Vertigo) Tachycardia Nos	Health Professional	Accutane	PS	Roche	ORAL		3

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

Date: 06/24/1992		ISR Number: 851232-0		Report Type: Expedited (15-Day)		Company Report Number: 920200962001		Age: 40 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Hospitalization - Initial or Prolonged	Major Depressive Disorder Nos Suicide Attempt	Health Professional	Accutane Prozac	PS C	Roche	ORAL		86			
Date: 06/18/1992		ISR Number: 851241-1		Report Type: Periodic		Company Report Number: 910201001001		Age: 16 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Anxiety Nec Tremor Nec	Health Professional	Accutane	PS	Roche	ORAL		151			
Date: 06/18/1992		ISR Number: 851311-8		Report Type: Periodic		Company Report Number: 910201808001		Age: 30 YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Depression Nec Emotional Disturbance Nos Nervousness	Health Professional	Accutane	PS	Roche	ORAL		106			
Date: 06/18/1992		ISR Number: 851322-2		Report Type: Periodic		Company Report Number: 910201815001		Age: 25 YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Thinking Abnormal Nec	Health Professional	Accutane Eryc	PS C	Roche	ORAL		43			
Date: 06/18/1992		ISR Number: 851341-6		Report Type: Periodic		Company Report Number: 910201790001		Age: 26 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Dry Mouth Dysphonia	Health Professional	Accutane	PS	Roche	ORAL		427			
Date: 06/18/1992		ISR Number: 851345-3		Report Type: Expedited (15-Day)		Company Report Number: 910201575001		Age: 41 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Disability	Amblyopia Nos Lipodystrophy Major Depressive Disorder Nos Thyroiditis Nos	Health Professional	Accutane Hismanal	PS C	Roche	ORAL		60			
Date: 06/18/1992		ISR Number: 851487-2		Report Type: Periodic		Company Report Number: 910201723001		Age: 34 YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Abdominal Pain Nos Impotence	Health Professional	Accutane	PS	Roche	ORAL		2			

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

Date: 06/18/1992	ISR Number: 851635-4	Report Type: Periodic	Company Report Number: 920200142001			Age: 26 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Anxiety Nec Conjunctivitis Nec	Health Professional	Accutane	PS	Roche	ORAL		82
Date: 06/18/1992	ISR Number: 851637-8	Report Type: Periodic	Company Report Number: 920200110001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos Headache Nos Hostility	Health Professional	Accutane	PS	Roche	ORAL		30
Date: 06/19/1992	ISR Number: 851641-X	Report Type: Periodic	Company Report Number: 920200131001			Age: 50 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Skin Atrophy Skin Hypertrophy	Health Professional	Accutane Estrace Premarin	PS C C	Roche	ORAL		93
Date: 06/18/1992	ISR Number: 851666-4	Report Type: Periodic	Company Report Number: 910200979001			Age: 34 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec	Health Professional	Accutane	PS	Roche	ORAL		76
Date: 06/18/1992	ISR Number: 851667-6	Report Type: Periodic	Company Report Number: 910200979002			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		
Date: 06/18/1992	ISR Number: 851696-2	Report Type: Periodic	Company Report Number: 910201652001			Age: 2 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Creatine Phosphokinase Increased Insomnia Nec Nervousness	Health Professional	Accutane	PS	Roche	ORAL		151
Date: 06/18/1992	ISR Number: 851697-4	Report Type: Periodic	Company Report Number: 910201651001			Age: 14 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Emotional Disturbance Nos Headache Nos Hyperlipidaemia Nos	Health Professional	Accutane Ortho-Novum 7/7/7	PS C	Roche	ORAL		14

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

Date: 06/18/1992	ISR Number: 851698-6	Report Type: Periodic	Company Report Number: 910201649001	Age: 34 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Seborrhea Speech Disorder Nec Urticaria Nos	Health Professional	Accutane	PS	Roche	ORAL		
Date: 06/18/1992	ISR Number: 851751-7	Report Type: Periodic	Company Report Number: 920200573001	Age: 31 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Migraine Nos	Health Professional	Accutane	PS	Roche	ORAL		30
Date: 06/18/1992	ISR Number: 851757-8	Report Type: Periodic	Company Report Number: 910201381001	Age: 37 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane Lorazepam	PS C	Roche	ORAL		
Date: 06/18/1992	ISR Number: 851758-X	Report Type: Periodic	Company Report Number: 910201378001	Age: 42 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Nervousness	Health Professional	Accutane	PS	Roche	ORAL		56
Date: 06/18/1992	ISR Number: 851803-1	Report Type: Periodic	Company Report Number: 910200483001	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		
Date: 06/18/1992	ISR Number: 851806-7	Report Type: Periodic	Company Report Number: 910201258001	Age: 16 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amblyopia Nos Headache Nos Hostility	Health Professional	Accutane Imipramine	PS C	Roche	ORAL		25
Date: 06/18/1992	ISR Number: 852025-0	Report Type: Periodic	Company Report Number: 910200589001	Age: 17 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Major Depressive Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		32

FDA Adverse Event Reporting System (AERS)
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Date: 06/18/1992	ISR Number: 852037-7	Report Type: Periodic	Company Report Number: 910200995001			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Hypoglycaemia Nos Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		104
Date: 06/18/1992	ISR Number: 852043-2	Report Type: Periodic	Company Report Number: 910201805002			Age: 25 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Chest Pain Depression Nec	Health Professional	Accutane Naprosyn Proventil	PS C C	Roche	ORAL		397
Date: 06/18/1992	ISR Number: 852050-X	Report Type: Periodic	Company Report Number: 910200671001			Age: 38 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Syncope	Health Professional	Accutane Anaprox	PS C	Roche	ORAL		150
Date: 06/18/1992	ISR Number: 852280-7	Report Type: Periodic	Company Report Number: 920200086001			Age: 34 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		92
Date: 07/07/1992	ISR Number: 852717-3	Report Type: Expedited (15-Day)	Company Report Number: 920201008001			Age: 40 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Agitation Depression Nec Dizziness (Excl Vertigo) Palpitations	Health Professional	Accutane	PS	Roche	ORAL		95
Date: 06/18/1992	ISR Number: 853032-4	Report Type: Periodic	Company Report Number: 910201376001			Age: 60 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Impotence	Health Professional	Accutane Tenormin Procordia Labetalol	PS C C C	Roche	ORAL		91

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

Date: 06/18/1992	ISR Number: 853302-X	Report Type: Periodic	Company Report Number: 910200637001			Age: 19 YR	Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Disability	Arthritis Nos	Consumer	Accutane	PS	Roche	ORAL		1188
Other	Asthenia Depression Nec Tendon Disorder Nos							
Date: 06/18/1992	ISR Number: 853365-1	Report Type: Periodic	Company Report Number: 920200315001			Age: 19 YR	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Disability	Dysphonia	Health Professional	Accutane	PS	Roche	ORAL		156
Other	Laryngitis Nos Pneumonia Nos Systemic Lupus Erythematosus							
Date: 06/18/1992	ISR Number: 853374-2	Report Type: Periodic	Company Report Number: 92020060001			Age: 13 YR	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Major Depressive Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		108
Date: 06/18/1992	ISR Number: 853380-8	Report Type: Periodic	Company Report Number: 910200981001			Age: 34 YR	Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Disability	Confusion Dizziness (Exc Vertigo) Dry Eye Nec Vision Abnormal Nec	Health Professional	Accutane	PS	Roche	ORAL		55
Date: 06/18/1992	ISR Number: 853392-4	Report Type: Periodic	Company Report Number: 910200708001			Age: 15 YR	Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Alopecia Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		112
Date: 06/18/1992	ISR Number: 853529-7	Report Type: Periodic	Company Report Number: 910200500001			Age: 23 YR	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL		140
Date: 06/18/1992	ISR Number: 853544-3	Report Type: Periodic	Company Report Number: 910200528001			Age: 41 YR	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Anxiety Nec Dyspnoea Nos Tachycardia Nos	Health Professional	Accutane Cipro	PS C	Roche	ORAL		37

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FDA Adverse Event Reporting System (AERS)
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Date: 06/18/1992	ISR Number: 853545-5	Report Type: Periodic	Company Report Number: 910200530001	Age: 16 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Anxiety Nec Blood Creatine Phosphokinase Increased Dysautonomia Hypoglycaemia Nos	Health Professional	Accutane	PS	Roche	ORAL		95
Date: 06/18/1992	ISR Number: 853565-0	Report Type: Periodic	Company Report Number: 910200592001	Age: 39 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Condition Aggravated Depression Nec Insomnia Nec Libido Increased	Health Professional	Accutane Prozac	PS C	Roche	ORAL		32
Date: 06/18/1992	ISR Number: 853566-2	Report Type: Periodic	Company Report Number: 910200593001	Age: 17 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec Tooth Discolouration	Health Professional	Accutane Prednisone	PS C	Roche	ORAL		243
Date: 06/18/1992	ISR Number: 853719-3	Report Type: Periodic	Company Report Number: 920200172001	Age: 16 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Emotional Disturbance Nos Hyperlipidaemia Nos	Health Professional	Accutane	PS	Roche	ORAL		119
Date: 06/18/1992	ISR Number: 854569-4	Report Type: Periodic	Company Report Number: 910200772001	Age: 38 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Arthralgia Depression Nec Emotional Disturbance Nos Vaginal Discharge	Health Professional	Accutane	PS	Roche	ORAL		148
Date: 06/18/1992	ISR Number: 855186-2	Report Type: Periodic	Company Report Number: 910200973001	Age: 16 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL		138
Date: 08/04/1992	ISR Number: 863294-5	Report Type: Expedited (15-Day)	Company Report Number: 920201158001	Age: 13 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Asthenia Confusion	Health Professional	Accutane	PS	Roche	ORAL		42

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FDA Adverse Event Reporting System (AERS)
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Date: 10/20/1992	ISR Number: 888717-7	Report Type: Expedited (15-Day)	Company Report Number: 920400268001	Age:	Gender: Unknown			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Psychotic Disorder Nos	Foreign Health Professional	Roacutane	PS	Roche	ORAL		
Date: 10/15/1992	ISR Number: 889484-3	Report Type: Expedited (15-Day)	Company Report Number: 920201380001	Age: 21 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Major Depressive Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		61
Date: 10/28/1992	ISR Number: 898067-0	Report Type: Direct	Company Report Number: U015635	Age: 16 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Appetite Increased Diarrhoea Nos Drug Withdrawal Syndrome Personality Disorder Nos		Accutane	PS	Roche	ORAL		
Date: 10/28/1992	ISR Number: 898117-1	Report Type: Expedited (15-Day)	Company Report Number: 920400247001	Age: 22 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec Hallucination Nos Schizophrenia Nos	Foreign Health Professional	Roacutane	PS	Roche	ORAL		81
Date: 10/28/1992	ISR Number: 905866-5	Report Type: Expedited (15-Day)	Company Report Number: 920151009001	Age: 58 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Cheilitis Confusion Hallucination Nos Sepsis Nos	Foreign Study	Roferon-A Roacutane Cytotec Senokot Naprosyn	PS SS C C C	Roche	SUBCUTAN EOUS		48
Date: 12/21/1992	ISR Number: 912122-8	Report Type: Expedited (15-Day)	Company Report Number: 920201903001	Age:	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Back Pain Cyst Nos Depression Nec Leucocytosis Nos	Health Professional	Accutane	PS	Roche	ORAL		2

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

Date: 01/21/1993 ISR Number: 914896-9 Report Type: Expedited (15-Day) Company Report Number: 920201990001 Age: 27 YR Gender: Female									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Hospitalization - Initial or Prolonged	Psychotic Disorder Nos	Health Professional	Accutane Excedrin	PS C	Roche	ORAL		5	
Date: 01/26/1993 ISR Number: 927191-9 Report Type: Expedited (15-Day) Company Report Number: 920200661001 Age: 37 YR Gender: Female									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Disability	Agitation Convulsions Nos Thinking Abnormal Nec Thyroid Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		119	
Date: 02/03/1993 ISR Number: 928856-5 Report Type: Expedited (15-Day) Company Report Number: 930400007001 Age: 18 YR Gender: Male									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Death Life-Threatening	Anxiety Nec Hypothermia Overdose Nos Suicide Attempt	Foreign Health Professional	Roaccutane Alcohol	PS C	Roche	ORAL		74	
Date: 06/03/1991 ISR Number: 929064-4 Report Type: Direct Company Report Number: Age: 18 YR Gender: Male									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Death	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		98	
Date: 02/17/1993 ISR Number: 931094-3 Report Type: Expedited (15-Day) Company Report Number: 930400028001 Age: 39 YR Gender: Male									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
	Cyst Nos Depression Nec Dry Skin	Foreign Health Professional	Roaccutane	PS	Roche	ORAL		183	
Date: 02/17/1993 ISR Number: 931095-5 Report Type: Expedited (15-Day) Company Report Number: 920100645001 Age: 13 YR Gender: Female									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Hospitalization - Initial or Prolonged	Apathy Electroencephalogram Abnormal Sedation Tremor Nec	Foreign Health Professional	Roaccutane	PS	Roche	ORAL			

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

Date: 02/17/1993		ISR Number: 931096-7		Report Type: Expedited (15-Day)		Company Report Number: 930318887001		Age:		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Death	Suicide Attempt	Foreign	Roaccutane	PS	Roche	ORAL					
Disability		Health Professional									
Date: 02/24/1993		ISR Number: 933530-5		Report Type: Expedited (15-Day)		Company Report Number: 930200278001		Age: 40 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Hospitalization - Initial or Prolonged	Palpitations	Health Professional	Accutane	PS	Roche	ORAL		161			
Other	Supraventricular Tachycardia										
	Vasodilatation										
Date: 04/07/1993		ISR Number: 945923-0		Report Type: Expedited (15-Day)		Company Report Number: 93010007701		Age: 21 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Hospitalization - Initial or Prolonged	Amnesia Nec	Foreign	Roaccutane	PS	Roche						
Disability	Anxiety Nec	Health Professional									
	Depression Nec										
	Vertigo Nec										
Date: 03/17/1993		ISR Number: 946287-9		Report Type: Expedited (15-Day)		Company Report Number: 930100081001		Age: 24 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Disability	Amnesia Nec	Foreign	Roaccutane	PS	Roche						
	Asthenia	Health Professional									
	Confusion										
	Depression Nec										
Date: 03/24/1993		ISR Number: 946384-8		Report Type: Expedited (15-Day)		Company Report Number: 930200382001		Age:		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased	Health Professional	Accutane	PS	Roche	ORAL		150			
	Delusion Nos										
	Hyperlipidaemia Nos										
Date: 06/02/1993		ISR Number: 972064-9		Report Type: Expedited (15-Day)		Company Report Number: 930200855001		Age: 18 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Hospitalization - Initial or Prolonged	Agitation	Study	Accutane	PS	Roche	ORAL	G	10			
	Emotional Disturbance Nos	Health Professional	Benadryl	C							
	Mania		Eskalith	C							
	Nervousness		Trilafon	C							
			Triphasil	C							

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

Date: 06/04/1993 ISR Number: 973188-2 Report Type: Expedited (15-Day) Company Report Number: 930200913001 Age: 31 YR Gender: Male									
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Death	Insomnia Nec Pain Nos Suicide Attempt	Health Professional	Accutane Liver Iron	PS C C	Roche	ORAL		92	
Date: 06/21/1993 ISR Number: 978237-3 Report Type: Periodic Company Report Number: 930200233001 Age: 33 YR Gender: Female									
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Hospitalization - Initial or Prolonged	Depression Nec	Health Professional	Accutane Asendin Tegretol Trilafon	PS C C C	Roche	ORAL		32	
Date: 06/21/1993 ISR Number: 978238-5 Report Type: Periodic Company Report Number: 930200859001 Age: 17 YR Gender: Male									
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Disability	Acne Nos Condition Aggravated Depression Nec Skin Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		29	
Date: 06/21/1993 ISR Number: 978239-7 Report Type: Periodic Company Report Number: 93020064001 Age: 21 YR Gender: Female									
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Disability Other	Alopecia Depression Nec Hypercholesterolaemia Infection Nos	Health Professional	Accutane	PS	Roche	ORAL		123	
Date: 06/21/1993 ISR Number: 978240-3 Report Type: Periodic Company Report Number: 920200953001 Age: 16 YR Gender: Male									
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Hospitalization - Initial or Prolonged Other	Depression Nec Emotional Disturbance Nos Mania	Health Professional	Accutane	PS	Roche	ORAL		62	
Date: 06/21/1993 ISR Number: 978241-5 Report Type: Periodic Company Report Number: 930200440001 Age: 20 YR Gender: Female									
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Hospitalization - Initial or Prolonged Other	Major Depressive Disorder Nos Melanoderma	Health Professional	Accutane	PS	Roche	ORAL		21	

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

Date: 06/21/1993		ISR Number: 978242-7		Report Type: Periodic		Company Report Number: 920201786001		Age:		Gender: Unknown	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Hospitalization - Initial or Prolonged	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		14			
Date: 06/24/1993		ISR Number: 979354-4		Report Type: Periodic		Company Report Number: 920201688001		Age: 16 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Dermatitis Nos Drug Withdrawal Syndrome Hostility Nervousness	Health Professional	Accutane Augmentin	PS C	Roche	ORAL		63			
Date: 06/24/1993		ISR Number: 979379-9		Report Type: Periodic		Company Report Number: 920200856001		Age: 15 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Emotional Disturbance Nos Influenza Like Illness Personality Disorder Nos Rhinitis Nos	Health Professional	Accutane	PS	Roche	ORAL		8			
Date: 06/24/1993		ISR Number: 979389-1		Report Type: Periodic		Company Report Number: 920200830001		Age: 27 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Agitation Cystitis Nos Menometrorrhagia	Health Professional	Accutane Azo Gantrisin Ortho-Novum 7/7/7 Klonopin	PS C C C	Roche	ORAL		15			
Date: 06/24/1993		ISR Number: 979390-8		Report Type: Periodic		Company Report Number: 920200823001		Age: 15 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Dysphonia Hypersensitivity Nos Laryngeal Neoplasm Nos Rhinitis Nos	Health Professional	Accutane	PS	Roche	ORAL					
Date: 06/24/1993		ISR Number: 979391-X		Report Type: Periodic		Company Report Number: 920200827001		Age: 19 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Impotence	Health Professional	Accutane	PS	Roche	ORAL		59			

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

Date: 06/24/1993	ISR Number: 979393-3	Report Type: Periodic	Company Report Number: 920200821001			Age:	Gender: Male		
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Amnesia Nec Headache Nos	Health Professional	Accutane	PS	Roche	ORAL			
Date: 06/24/1993	ISR Number: 979400-8	Report Type: Periodic	Company Report Number: 920200792001			Age: 60 YR	Gender: Male		
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Asthenia Endocrine Disorder Nos Hormone Level Nos Abnormal Libido Decreased	Health Professional	Accutane	PS	Roche	ORAL		162	
Date: 06/24/1993	ISR Number: 979418-5	Report Type: Periodic	Company Report Number: 920200754001			Age: 30 YR	Gender: Female		
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Alopecia Depression Nec Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL		92	
Date: 06/24/1993	ISR Number: 979425-2	Report Type: Periodic	Company Report Number: 920201012001			Age: 17 YR	Gender: Male		
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Acne Nos Condition Aggravated Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		137	
Date: 06/24/1993	ISR Number: 979447-1	Report Type: Periodic	Company Report Number: 920201135001			Age: 25 YR	Gender: Male		
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Impotence Libido Decreased	Health Professional	Accutane	PS	Roche	ORAL		1	
Date: 06/24/1993	ISR Number: 979869-9	Report Type: Periodic	Company Report Number: 920201202001			Age: 20 YR	Gender: Female		
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Dysphonia High Density Lipoprotein Decreased Hyperlipidaemia Nos Hyperphosphataemia	Health Professional	Accutane	PS	Roche	ORAL		98	
Date: 06/24/1993	ISR Number: 979870-5	Report Type: Periodic	Company Report Number: 920201203001			Age: 33 YR	Gender: Female		
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Dysphonia Laryngeal Neoplasm Nos	Health Professional	Accutane	PS	Roche	ORAL		203	

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

Date: 06/24/1993	ISR Number: 979875-4	Report Type: Periodic	Company Report Number: 920200702001			Age: 35 YR	Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Hyperlipidaemia Nos Impotence Myalgia	Health Professional	Accutane	PS	Roche	ORAL		28
Date: 06/24/1993	ISR Number: 979889-4	Report Type: Periodic	Company Report Number: 920200676001			Age: 17 YR	Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec Dry Mouth Sedation	Health Professional	Accutane Vitamins	PS C	Roche	ORAL		378
Date: 06/24/1993	ISR Number: 979907-3	Report Type: Periodic	Company Report Number: 920200618001			Age: 15 YR	Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec Nail Disorder Nos Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		42
Date: 06/24/1993	ISR Number: 979926-7	Report Type: Periodic	Company Report Number: 920201126001			Age:	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Asthenia Depression Nec Headache Nos Systemic Lupus Erythematosus	Health Professional	Accutane	PS	Roche	ORAL		152
Date: 06/24/1993	ISR Number: 980368-9	Report Type: Periodic	Company Report Number: 920201836001			Age: 17 YR	Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec Emotional Disturbance Nos	Health Professional	Accutane Minocin	PS C	Roche	ORAL		66
Date: 06/24/1993	ISR Number: 980369-0	Report Type: Periodic	Company Report Number: 920201836002			Age: 15 YR	Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Agitation Albuminuria Present Anaemia Nos Depression Nec	Health Professional	Accutane Minocin	PS C	Roche	ORAL		14

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

Date: 06/24/1993	ISR Number: 980373-2	Report Type: Periodic	Company Report Number: 920201890001			Age: 26 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos	Health Professional	Accutane Premarin	PS C	Roche	ORAL		21
Date: 06/24/1993	ISR Number: 980793-6	Report Type: Periodic	Company Report Number: 920201519001			Age: 30 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Anxiety Nec Eye Pain Sinusitis Nos	Health Professional	Accutane	PS	Roche	ORAL		6
Date: 06/24/1993	ISR Number: 980817-6	Report Type: Periodic	Company Report Number: 920201886001			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos Thinking Abnormal Nec	Health Professional	Accutane Bactroban	PS C	Roche	ORAL		141
Date: 06/24/1993	ISR Number: 980820-6	Report Type: Periodic	Company Report Number: 930200134001			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Anxiety Nec Blindness Night Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		73
Date: 06/24/1993	ISR Number: 980824-3	Report Type: Periodic	Company Report Number: 930200053001			Age: 15 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Condition Aggravated Major Depressive Disorder Nos Suicide Attempt	Health Professional	Accutane	PS	Roche	ORAL	80	99
Date: 06/24/1993	ISR Number: 980828-0	Report Type: Periodic	Company Report Number: 920201984001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Dry Mouth Dry Skin Emotional Disturbance Nos Major Depressive Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		140
Date: 06/24/1993	ISR Number: 980830-9	Report Type: Periodic	Company Report Number: 920201962001			Age: 14 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Dizziness (Exc Vertigo)	Health Professional	Accutane	PS	Roche	ORAL		31

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FDA Adverse Event Reporting System (AERS)
 Division Of Biologics (DOD) Report

Date: 06/24/1993	ISR Number: 980830-9	Report Type: Periodic	Product	Company Report Number: 930201962000	Manufacturer	Route	Dose/Unit	Duration
Outcome	PT		Accutane	PS	Roche	ORAL		31
Other	Dizziness (Exc Vertigo) Headache Nos Lymphadenopathy Neurosis Nos							
Date: 06/24/1993	ISR Number: 980836-X	Report Type: Periodic	Product	Company Report Number: 930200219001	Manufacturer	Route	Dose/Unit	Duration
Outcome	PT	Report Source	Accutane	PS	Roche	ORAL		123
Other	Emotional Disturbance Nos Hostility Hyperkinetic Syndrome	Health Professional						
Date: 06/24/1993	ISR Number: 980838-3	Report Type: Periodic	Product	Company Report Number: 930200222001	Manufacturer	Route	Dose/Unit	Duration
Outcome	PT	Report Source	Accutane	PS	Roche	ORAL		21
Other	Depression Nec	Health Professional						
Date: 06/24/1993	ISR Number: 980851-6	Report Type: Periodic	Product	Company Report Number: 920200727001	Manufacturer	Route	Dose/Unit	Duration
Outcome	PT	Report Source	Accutane	PS	Roche	ORAL		366
Other	Depression Nec	Consumer						
Date: 06/24/1993	ISR Number: 980861-9	Report Type: Periodic	Product	Company Report Number: 920201033001	Manufacturer	Route	Dose/Unit	Duration
Outcome	PT	Report Source	Accutane	PS	Roche	ORAL		164
Other	Acne Nos Bone Disorder Nos Libido Decreased Pallor	Health Professional						
Date: 06/24/1993	ISR Number: 980864-4	Report Type: Periodic	Product	Company Report Number: 920201039001	Manufacturer	Route	Dose/Unit	Duration
Outcome	PT	Report Source	Accutane	PS	Roche	ORAL		67
Other	Appetite Increased Condition Aggravated Hypoglycaemia Nos Nervousness	Health Professional	Glucose, D-	C				
Date: 06/24/1993	ISR Number: 980867-X	Report Type: Periodic	Product	Company Report Number: 920201041001	Manufacturer	Route	Dose/Unit	Duration
Outcome	PT	Report Source	Accutane	PS	Roche	ORAL		
Other	Dermatitis Nos Dry Mouth	Health Professional						

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

Date: 06/24/1993	ISR Number: 981132-7	Report Type: Periodic	Company Report Number: 930200174001	Age:	Gender: Female				
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Amblyopia Nos Emotional Disturbance Nos Headache Nos Simsitis Nos	Health Professional	Accutane	PS	Roche	ORAL		71	
Date: 06/24/1993	ISR Number: 981143-1	Report Type: Periodic	Company Report Number: 930200140001	Age: 32 YR	Gender: Female				
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Dizziness (Exc Vertigo) Palpitations	Health Professional	Accutane	PS	Roche	ORAL		17	
Date: 06/24/1993	ISR Number: 981213-8	Report Type: Periodic	Company Report Number: 930200402001	Age: 30 YR	Gender: Female				
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Asthenia Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		105	
Date: 06/24/1993	ISR Number: 981247-3	Report Type: Periodic	Company Report Number: 920201960001	Age: 36 YR	Gender: Male				
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Depression Nec Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		121	
Date: 06/24/1993	ISR Number: 981259-X	Report Type: Periodic	Company Report Number: 920201861001	Age: 17 YR	Gender: Male				
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Arthralgia Asthenia Cheilitis Insomnia Nec	Health Professional	Accutane	PS	Roche	ORAL		107	
Date: 06/24/1993	ISR Number: 981299-0	Report Type: Periodic	Company Report Number: 920201644001	Age: 15 YR	Gender: Male				
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		140	
Date: 06/24/1993	ISR Number: 981300-4	Report Type: Periodic	Company Report Number: 930200319001	Age: 35 YR	Gender: Female				
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Neurosis Nos	Health Professional	Accutane	PS	Roche	ORAL			

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

Date: 06/24/1993	ISR Number: 981330-2	Report Type: Periodic	Company Report Number: 920201526001			Age: 18 YR	Gender: Male
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u> <u>Duration</u>
Other	Depression Nec Leucopenia Nos	Health Professional	Accutane	PS	Roche	ORAL	28
Date: 06/24/1993	ISR Number: 981657-4	Report Type: Periodic	Company Report Number: 920201963001			Age: 30 YR	Gender: Female
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u> <u>Duration</u>
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	144
Date: 06/24/1993	ISR Number: 982043-3	Report Type: Periodic	Company Report Number: 92020121001			Age: 24 YR	Gender: Male
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u> <u>Duration</u>
Other	Paranoia	Health Professional	Accutane Lithium Navane Thorazine	PS C C C	Roche	ORAL	15
Date: 06/24/1993	ISR Number: 982059-7	Report Type: Periodic	Company Report Number: 920201545001			Age:	Gender: Male
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u> <u>Duration</u>
Other	Confusion Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	
Date: 06/24/1993	ISR Number: 982070-6	Report Type: Periodic	Company Report Number: 920201582001			Age: 29 YR	Gender: Female
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u> <u>Duration</u>
Other	Acne Nos Anxiety Nec Depression Nec Insomnia Nec	Health Professional	Accutane	PS	Roche	ORAL	119
Date: 06/24/1993	ISR Number: 982270-5	Report Type: Periodic	Company Report Number: 920201664001			Age:	Gender: Male
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u> <u>Duration</u>
Other	Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL	1
Date: 06/24/1993	ISR Number: 982892-1	Report Type: Periodic	Company Report Number: 930200648001			Age:	Gender: Female
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u> <u>Duration</u>
Other	Anxiety Nec Depression Nec Vaginal Candidiasis Vaginitis	Consumer	Accutane	PS	Roche	ORAL	150

FDA Adverse Event Reporting System (AERS)
 Problem Of Information (POI) Report

Date: 06/24/1993		ISR Number: 982899-4		Report Type: Periodic		Company Report Number: 930200631001		Age: 36 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Alopecia Arthralgia Depression Nec Systemic Lupus Erythematosus Rash	Health Professional	Accutane	PS	Roche	ORAL		113			
Date: 06/24/1993		ISR Number: 982910-0		Report Type: Periodic		Company Report Number: 930200599001		Age: 17 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Emotional Disturbance Nos	Health Professional	Accutane Ritalin	PS C	Roche	ORAL	80	101			
Date: 06/24/1993		ISR Number: 982959-8		Report Type: Periodic		Company Report Number: 920201067001		Age: 14 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Agitation Emotional Disturbance Nos Insomnia Nec	Health Professional	Accutane	PS	Roche	ORAL		75			
Date: 06/24/1993		ISR Number: 983217-8		Report Type: Periodic		Company Report Number: 930200234001		Age: 19 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Aspartate Aminotransferase Increased Blood Lactate Dehydrogenase Increased Leucocytosis Nos Palpitations	Health Professional	Accutane	PS	Roche	ORAL		91			
Date: 06/24/1993		ISR Number: 983229-4		Report Type: Periodic		Company Report Number: 930200564001		Age: 20 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Alopecia Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		140			
Date: 06/24/1993		ISR Number: 983249-X		Report Type: Periodic		Company Report Number: 930200514001		Age: 22 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Nervousness	Foreign Health Professional	Accutane	PS	Roche	ORAL	80	127			

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

Date: 06/24/1993	ISR Number: 983257-9	Report Type: Periodic	Company Report Number: 930200396001			Age: 21 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Depression Nec Dry Skin Vasodilatation	Health Professional	Accutane Prozac Synthroid	PS SS C	Roche Dista Prod	ORAL	31
Date: 06/24/1993	ISR Number: 983262-2	Report Type: Periodic	Company Report Number: 930200378001			Age: 16 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Dysphonia	Health Professional	Accutane	PS	Roche	ORAL	160
Date: 06/24/1993	ISR Number: 983313-5	Report Type: Periodic	Company Report Number: 930200104001			Age: 20 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Amblyopia Nos Amnesia Nec Conjunctivitis Nec	Health Professional	Accutane	PS	Roche	ORAL	31
Date: 06/24/1993	ISR Number: 983314-7	Report Type: Periodic	Company Report Number: 930200112001			Age: 15 YR	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Hostility	Health Professional	Accutane	PS	Roche	ORAL	2
Date: 06/24/1993	ISR Number: 983799-6	Report Type: Periodic	Company Report Number: 920201817001			Age: 16 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Acne Nos Condition Aggravated Insomnia Nec	Health Professional	Accutane	PS	Roche	ORAL	
Date: 06/24/1993	ISR Number: 983810-2	Report Type: Periodic	Company Report Number: 920201786005			Age: 30 YR	Gender: Unknown
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	
Date: 06/24/1993	ISR Number: 983811-4	Report Type: Periodic	Company Report Number: 920201789001			Age: 38 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Acne Nos Alopecia Dermatitis Nos Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL	43

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

Date: 06/24/1993	ISR Number: 983812-6	Report Type: Periodic	Company Report Number: 920201786002			Age:	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL			
Date: 06/24/1993	ISR Number: 984149-1	Report Type: Periodic	Company Report Number: 920201732001			Age: 35 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Amnesia Nec Face Oedema	Health Professional	Accutane	PS	Roche	ORAL			
Date: 06/24/1993	ISR Number: 984150-8	Report Type: Periodic	Company Report Number: 920201715001			Age: 30 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Dysphonia	Health Professional	Accutane	PS	Roche	ORAL		41	
Date: 06/24/1993	ISR Number: 984173-9	Report Type: Periodic	Company Report Number: 930200483001			Age: 15 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Glossitis Headache Nos Thinking Abnormal Nec	Health Professional	Accutane	PS	Roche	ORAL	80	112	
Date: 06/24/1993	ISR Number: 984177-6	Report Type: Periodic	Company Report Number: 930200470001			Age: 15 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Agitation Hostility Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL	80	94	
Date: 06/24/1993	ISR Number: 984185-5	Report Type: Periodic	Company Report Number: 930200430001			Age: 16 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Alopecia Cheilitis Depression Nec Hyperlipidemia Nos	Consumer	Accutane	PS	Roche	ORAL	80	116	
Date: 06/24/1993	ISR Number: 984187-9	Report Type: Periodic	Company Report Number: 930200422001			Age: 16 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Hostility	Health Professional	Accutane	PS	Roche	ORAL		60	

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

Date: 06/24/1993	ISR Number: 985064-X	Report Type: Periodic	Company Report Number: 930200004001			Age: 27 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dry Eye Nec Emotional Disturbance Nos Skin Discolouration Taste Disturbance	Health Professional	Accutane	PS	Roche	ORAL		10
Date: 06/24/1993	ISR Number: 985075-4	Report Type: Periodic	Company Report Number: 920202055001			Age: 21 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amblyopia Nos Blindness Night Depression Nec Epistaxis	Health Professional	Accutane	PS	Roche	ORAL		
Date: 06/24/1993	ISR Number: 985079-1	Report Type: Periodic	Company Report Number: 920202047001			Age: 29 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		3165
Date: 06/24/1993	ISR Number: 985084-5	Report Type: Periodic	Company Report Number: 920202034001			Age: 32 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Major Depressive Disorder Nos	Health Professional	Accutane Estrace	PS C	Roche	ORAL	40	146
Date: 06/24/1993	ISR Number: 985088-2	Report Type: Periodic	Company Report Number: 920202021001			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Major Depressive Disorder Nos Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		116
Date: 06/24/1993	ISR Number: 985095-X	Report Type: Periodic	Company Report Number: 920201681001			Age: 21 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Agitation Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		32
Date: 06/24/1993	ISR Number: 985102-4	Report Type: Periodic	Company Report Number: 920201064001			Age: 30 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Abdominal Pain Nos Arthralgia Bone Pain	Health Professional	Accutane	PS	Roche	ORAL		

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

Date: 06/24/1993	ISR Number: 985103-6	Report Type: Periodic	Company Report Number: 920201096001			Age: 15 YR	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Disability	Back Pain Insomnia Nec	Health Professional	Accutane	PS	Roche	ORAL	40	7
Date: 06/24/1993	ISR Number: 985110-3	Report Type: Periodic	Company Report Number: 930200598001			Age: 46 YR	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Abnormal Dreams Depression Nec Emotional Disturbance Nos Hostility	Foreign Consumer	Accutane Loestrin	PS C	Roche	ORAL		246
Date: 06/24/1993	ISR Number: 985113-9	Report Type: Periodic	Company Report Number: 930200373001			Age: 16 YR	Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Hostility	Health Professional	Accutane	PS	Roche	ORAL		
Date: 06/24/1993	ISR Number: 985119-X	Report Type: Periodic	Company Report Number: 930200673001			Age: 31 YR	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Major Depressive Disorder Nos Nail Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		204
Date: 06/24/1993	ISR Number: 985166-8	Report Type: Periodic	Company Report Number: 920201416001			Age: 46 YR	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		130
Date: 06/24/1993	ISR Number: 985168-1	Report Type: Periodic	Company Report Number: 920201277001			Age: 21 YR	Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL		3
Date: 06/24/1993	ISR Number: 985178-4	Report Type: Periodic	Company Report Number: 920201280001			Age:	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Dysphonia	Health Professional	Accutane	PS	Roche	ORAL		7

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

Date: 06/24/1993	ISR Number: 985197-8	Report Type: Periodic	Company Report Number: 920201408001			Age: 35 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia Speech Disorder Nec Thinking Abnormal Nec	Health Professional	Accutane	PS	Roche	ORAL		33
Date: 06/24/1993	ISR Number: 985206-6	Report Type: Periodic	Company Report Number: 920201298001			Age: 36 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Drug Interaction Nos Emotional Disturbance Nos Urinary Retention	Health Professional	Accutane Ativan	PS C	Roche	ORAL		22
Date: 06/24/1993	ISR Number: 985901-9	Report Type: Periodic	Company Report Number: 920201609001			Age: 42 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Skin Disorder Nos	Health Professional	Accutane Carisoprodol Triamcinolone Trichloroacetic Acid Naprosyn	PS C C C C	Roche	ORAL	40	175 1
Date: 06/24/1993	ISR Number: 985917-2	Report Type: Periodic	Company Report Number: 92021387001			Age: 23 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Depression Nec Headache Nos Leucopenia Nos	Health Professional	Accutane	PS	Roche	ORAL		105
Date: 07/01/1993	ISR Number: 1342518-4	Report Type: Expedited (15-Day)	Company Report Number: 930201072001			Age: 35 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Agitation Amblyopia Nos Dry Skin Migraine Nos	Health Professional	Accutane	PS	Roche	ORAL		38
Date: 06/24/1993	ISR Number: 1344076-7	Report Type: Periodic	Company Report Number: 920201291001			Age: 68 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Condition Aggravated Depression Nec	Health Professional	Accutane Atarax Doxepin	PS C C	Roche	ORAL		8

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

Date: 07/23/1993	ISR Number: 1346156-9	Report Type: Expedited (15-Day)	Company Report Number: 930201135001	Age: 19 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec Genitourinary Tract Neoplasm Nos	Health Professional	Accutane	PS	Roche	ORAL		120
Date: 07/27/1993	ISR Number: 1346441-0	Report Type: Expedited (15-Day)	Company Report Number: 930200707001	Age: 24 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability Other	Arthralgia Depression Nec Face Oedema Skin Atrophy	Health Professional	Accutane	PS	Roche	ORAL	60	123
Date: 07/21/1993	ISR Number: 1347425-9	Report Type: Expedited (15-Day)	Company Report Number: 930200952001	Age: 30 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Anxiety Nec Major Depressive Disorder Nos Neurosis Nos Pruritus	Study Health Professional	Accutane Dapsone	PS C	Roche	ORAL		104
Date: 08/20/1993	ISR Number: 1353597-2	Report Type: Expedited (15-Day)	Company Report Number: 930201351001	Age: 37 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Hallucination Nos Psychotic Disorder Nos Schizophrenia Nos	Health Professional	Accutane	PS	Roche	ORAL		45
Date: 10/18/1993	ISR Number: 1377555-7	Report Type: Expedited (15-Day)	Company Report Number: 930201689001	Age: 30 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability Other	Depression Nec Headache Nos Urinary Tract Infection Nos Weight Decreased	Health Professional	Accutane	PS	Roche	ORAL		100
Date: 12/01/1993	ISR Number: 1392680-2	Report Type: Expedited (15-Day)	Company Report Number: 930202072001	Age: 17 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Cheilitis Depression Nec Emotional Disturbance Nos Suicide Attempt	Consumer	Accutane	PS	Roche	ORAL		119

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

Date: 02/18/1994	ISR Number: 1415650-4	Report Type: Periodic	Company Report Number: 920200509001			Age: 18 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Cheilitis Conjunctivitis Nec Depression Nec Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		230
Date: 02/15/1994	ISR Number: 1423876-9	Report Type: Expedited (15-Day)	Company Report Number: 940200275001			Age: 14 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Suicide Attempt	Health Professional	Accutane	PS	Roche	ORAL	40	85
Date: 03/14/1994	ISR Number: 1427679-0	Report Type: Expedited (15-Day)	Company Report Number: 940200369001			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Amnesia Nec Benign Intracranial Hypertension Personality Disorder Nos	Health Professional	Accutane	PS	Roche			
Date: 03/14/1994	ISR Number: 1428577-9	Report Type: Expedited (15-Day)	Company Report Number: 940200372001			Age: 14 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death Life-Threatening	Dry Skin Suicide Attempt	Health Professional	Accutane Bactrim Ds	PS C	Roche	ORAL	80	61
Date: 03/29/1994	ISR Number: 1435876-3	Report Type: Expedited (15-Day)	Company Report Number: 940804020001			Age: 28 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aphasia Cerebrovascular Accident Nos Headache Nos	Foreign Health Professional	Accutane	PS	Roche	ORAL	40	21
Date: 03/30/1994	ISR Number: 1453476-6	Report Type: Expedited (15-Day)	Company Report Number: 940200453001			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Agitation Hostility	Health Professional	Accutane	PS	Roche	ORAL		
Date: 05/31/1994	ISR Number: 1458316-7	Report Type: Expedited (15-Day)	Company Report Number: 940400238001			Age:	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Mania	Foreign Health Professional	Roaccutane Lithium	PS C	Roche	ORAL		

FDA Adverse Event Reporting System (AERS)
 Program Of Information (POI) Report

Date: 05/18/1994	ISR Number: 1460002-4	Report Type: Direct	Company Report Number:			Age: 42 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Amnesia Nec Arthralgia Ecchymosis Hyperlipidemia Nos	Health Professional	Accutane Voltaren Tylenol	PS C C	Roche	ORAL	80	24
Date: 05/23/1994	ISR Number: 1463654-8	Report Type: Periodic	Company Report Number: 930201621001			Age: 28 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Alopecia Depression Nec Headache Nos	Consumer	Accutane	PS	Roche	ORAL		76
Date: 05/23/1994	ISR Number: 1463671-8	Report Type: Periodic	Company Report Number: 930201598001			Age: 27 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Dry Eye Nec Emotional Disturbance Nos Hostility	Consumer	Accutane	PS	Roche	ORAL		51
Date: 05/23/1994	ISR Number: 1463674-3	Report Type: Periodic	Company Report Number: 930201601001			Age: 16 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Hallucination Nos Insomnia Nec Major Depressive Disorder Nos Personality Disorder Nos	Consumer	Accutane Triphasil	PS C	Roche	ORAL		42
Date: 05/23/1994	ISR Number: 1463677-9	Report Type: Periodic	Company Report Number: 930201608001			Age: 24 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Amblyopia Nos Depression Nec Emotional Disturbance Nos Headache Nos	Consumer	Accutane Ortho-Novum	PS C	Roche	ORAL		31
Date: 05/23/1994	ISR Number: 1463709-8	Report Type: Periodic	Company Report Number: 930201580001			Age: 19 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Abdominal Pain Nos Depression Nec Migraine Nos Vaginitis	Health Professional	Accutane	PS	Roche	ORAL		6