

FDA Adverse Event Reporting System (AERS)
 Division of Information (D/OI) 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		Company Report Number: 930200219001		Age: 24 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos Hostility Hyperkinetic Syndrome	Health Professional	Accutane	PS	Roche	ORAL		123
Date: 06/24/1993	ISR Number: 980838-3	Report Type: Periodic		Company Report Number: 930200222001		Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		21
Date: 06/24/1993	ISR Number: 980851-6	Report Type: Periodic		Company Report Number: 920200727001		Age: 27 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Consumer	Accutane	PS	Roche	ORAL		366
Date: 06/24/1993	ISR Number: 980861-9	Report Type: Periodic		Company Report Number: 920201033001		Age: 22 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Nos Bone Disorder Nos Libido Decreased Pallor	Health Professional	Accutane	PS	Roche	ORAL		164
Date: 06/24/1993	ISR Number: 980864-4	Report Type: Periodic		Company Report Number: 920201039001		Age: 22 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Appetite Increased Condition Aggravated Hypoglycaemia Nos Nervousness	Health Professional	Accutane Glucose, D-	PS C	Roche	ORAL		67
Date: 06/24/1993	ISR Number: 980867-X	Report Type: Periodic		Company Report Number: 920201041001		Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dermatitis Nos Dry Mouth	Health Professional	Accutane	PS	Roche	ORAL		

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

Date: 05/23/1994	ISR Number: 1463899-7	Report Type: Periodic	Company Report Number: 930201632001	Age: 42 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Anxiety Nec Headache Nos Rash Maculo-Papular Vision Abnormal Nec	Health Professional	Accutane	PS	Roche	ORAL	40	91
Date: 05/23/1994	ISR Number: 1463936-X	Report Type: Periodic	Company Report Number: 930201646001	Age: 16 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Palpitations	Health Professional	Accutane	PS	Roche	ORAL	80	39
Date: 05/23/1994	ISR Number: 1464124-3	Report Type: Periodic	Company Report Number: 930202088001	Age: 24 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Dyspareunia Nec Infection Nos Ovarian Disorder Nos Vaginal Discharge	Consumer	Accutane Tri-Norinyl Tylenol	PS C C	Roche		80	
Date: 05/23/1994	ISR Number: 1464134-6	Report Type: Periodic	Company Report Number: 930200772001	Age: 38 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Abnormal Dreams	Health Professional	Accutane	PS	Roche	ORAL	40	165
Date: 05/23/1994	ISR Number: 1464189-9	Report Type: Periodic	Company Report Number: 940200127001	Age: 17 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Chest Pain Palpitations Tachycardia Nos	Health Professional	Accutane	PS	Roche	ORAL	60	88
Date: 05/23/1994	ISR Number: 1464193-0	Report Type: Periodic	Company Report Number: 930202092001	Age:	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Amnesia Nec Dizziness (Exc Vertigo) Headache Nos	Health Professional	Accutane	PS	Roche			1
Date: 05/23/1994	ISR Number: 1464209-1	Report Type: Periodic	Company Report Number: 930200816001	Age: 17 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Apathy High Density Lipoprotein Decreased	Health Professional	Accutane	PS	Roche	ORAL	80	109

FDA Adverse Event Reporting System (AERS)
 Division Of Information (DQI) Report

Date: 05/23/1994	ISR Number: 1464242-X	Report Type: Periodic	Company Report Number: 930202135001			Age: 38 YR	Gender: Female	
Outcome	PT Palpitations	Report Source Consumer	Product Accutane Norplant	Role PS C	Manufacturer Roche	Route ORAL	Dose/Unit 60	Duration 156
Date: 05/23/1994	ISR Number: 1464245-5	Report Type: Periodic	Company Report Number: 930202136001			Age: 20 YR	Gender: Female	
Outcome	PT Dry Eye Nec Emotional Disturbance Nos Urinary Incontinence Vomiting Nos	Report Source Consumer	Product Accutane	Role PS	Manufacturer Roche	Route ORAL		
Date: 05/23/1994	ISR Number: 1465441-3	Report Type: Periodic	Company Report Number: 940200500001			Age: 30 YR	Gender: Male	
Outcome	PT Impotence	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 141
Date: 05/23/1994	ISR Number: 1465510-8	Report Type: Periodic	Company Report Number: 940200473001			Age: 17 YR	Gender: Male	
Outcome	PT Acne Nos Asthenia Depression Nec Eczema Nos	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration 2656
Date: 05/23/1994	ISR Number: 1465520-0	Report Type: Periodic	Company Report Number: 940200423001			Age: 16 YR	Gender: Male	
Outcome	PT Cheilitis Insomnia Nec	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration 109
Date: 05/23/1994	ISR Number: 1465529-7	Report Type: Periodic	Company Report Number: 940200452001			Age:	Gender: Unknown	
Outcome	PT Hallucination Nos	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL		
Date: 05/23/1994	ISR Number: 1465564-9	Report Type: Periodic	Company Report Number: 940200263001			Age: 27 YR	Gender: Male	
Outcome	PT Depression Nec	Report Source Consumer	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration 169

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

Date: 05/23/1994	ISR Number: 1465572-8	Report Type: Periodic	Company Report Number: 940200276001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Chest Pain Hypoesthesia Palpitations	Health Professional	Accutane Ae-Allergenic Extracts	PS C	Roche	ORAL		60
Date: 05/23/1994	ISR Number: 1465582-0	Report Type: Periodic	Company Report Number: 940200348001			Age: 27 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Emotional Disturbance Nos Hostility	Consumer	Accutane	PS	Roche	ORAL		32
Date: 05/23/1994	ISR Number: 1465618-7	Report Type: Periodic	Company Report Number: 940200460001			Age: 37 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Headache Nos Skin Discolouration Vision Abnormal Nec	Consumer	Accutane	PS	Roche	ORAL	60	21
Date: 05/23/1994	ISR Number: 1465704-1	Report Type: Periodic	Company Report Number: 940200683001			Age: 28 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Alopecia Depression Nec Drug Ineffective Myalgia	Consumer	Accutane Erythromycin	PS C	Roche	ORAL		130
Date: 05/23/1994	ISR Number: 1465742-9	Report Type: Periodic	Company Report Number: 940200314001			Age: 18 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Hypercholesterolemia Palpitations Tachycardia Nos	Health Professional	Accutane Triphasil	PS C	Roche	ORAL	40	45
Date: 05/23/1994	ISR Number: 1465752-1	Report Type: Periodic	Company Report Number: 940200358001			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Acne Nos Bone Pain Depression Nec Dry Skin	Consumer	Accutane	PS	Roche	ORAL		77

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

Date: 05/23/1994	ISR Number: 1465766-1	Report Type: Periodic	Company Report Number: 940200372002	Age: 14 YR	Gender: Male			
Outcome	PT Depression Nec	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration 166
Date: 05/23/1994	ISR Number: 1465786-7	Report Type: Periodic	Company Report Number: 930201321001	Age: 43 YR	Gender: Male			
Outcome	PT Anxiety Nec Depression Nec	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 22
Date: 05/23/1994	ISR Number: 1465849-6	Report Type: Periodic	Company Report Number: 940200687001	Age: 23 YR	Gender: Male			
Outcome	PT Impotence	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 125
Date: 05/23/1994	ISR Number: 1465852-6	Report Type: Periodic	Company Report Number: 940200701001	Age: 52 YR	Gender: Female			
Outcome	PT Depression Nec	Report Source Consumer	Product Accutane Maxzide Tenormin	Role PS C C	Manufacturer Roche	Route ORAL	Dose/Unit	Duration
Date: 05/23/1994	ISR Number: 1465926-X	Report Type: Periodic	Company Report Number: 940200733001	Age: 36 YR	Gender: Female			
Outcome	PT Depression Nec Emotional Disturbance Nos	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 56
Date: 05/23/1994	ISR Number: 1465928-3	Report Type: Periodic	Company Report Number: 940200738001	Age: 26 YR	Gender: Female			
Outcome	PT Depression Nec Headache Nos	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 50	Duration 1
Date: 05/23/1994	ISR Number: 1465931-3	Report Type: Periodic	Company Report Number: 940200741001	Age: 18 YR	Gender: Female			
Outcome	PT Emotional Disturbance Nos	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 152
Date: 05/23/1994	ISR Number: 1465943-X	Report Type: Periodic	Company Report Number: 940200705001	Age: 17 YR	Gender: Male			
Outcome	PT Dysphonia Urticaria Nos	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 23

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

Date: 05/23/1994	ISR Number: 1465995-7	Report Type: Periodic	Company Report Number: 940200621001			Age: 34 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Ataxia Nec Emotional Disturbance Nos Hostility Photosensitivity Reaction Nos	Consumer	Accutane	PS	Roche	ORAL	80	121
Date: 05/23/1994	ISR Number: 1466005-8	Report Type: Periodic	Company Report Number: 940200473002			Age: 17 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Emotional Disturbance Nos Myalgia Vision Abnormal Nec	Health Professional	Accutane Ortho-Novum	PS C	Roche	ORAL		42
Date: 05/23/1994	ISR Number: 1466015-0	Report Type: Periodic	Company Report Number: 940200210001			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Agitation Hallucination Nos Hostility Hyperkinetic Syndrome	Health Professional	Accutane Cipro	PS C	Roche	ORAL		90
Date: 05/23/1994	ISR Number: 1466062-9	Report Type: Periodic	Company Report Number: 940200376001			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Hostility Personality Disorder Nos Thinking Abnormal Nec	Health Professional	Accutane	PS	Roche	ORAL	80	28
Date: 05/23/1994	ISR Number: 1466080-0	Report Type: Periodic	Company Report Number: 940200328001			Age: 37 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Varicose Veins Nos Vascular Disorder Nos	Health Professional	Accutane	PS	Roche			93
Date: 05/23/1994	ISR Number: 1466083-6	Report Type: Periodic	Company Report Number: 940200326001			Age: 48 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Dry Skin Eye Pain	Health Professional	Accutane Estraderm	PS C	Roche	ORAL	80	3

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

Date: 05/23/1994	ISR Number: 1466124-6	Report Type: Periodic	Company Report Number: 940200241001	Age: 17 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	40	
	Emotional Disturbance Nos							
Date: 05/23/1994	ISR Number: 1469077-X	Report Type: Periodic	Company Report Number: 930201176001	Age: 14 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL	60	95
			Desquam-X	C				
Date: 05/23/1994	ISR Number: 1469105-1	Report Type: Periodic	Company Report Number: 930201175001	Age: 21 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	80	24
Date: 05/23/1994	ISR Number: 1469107-5	Report Type: Periodic	Company Report Number: 930201093001	Age: 30 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos	Health Professional	Accutane	PS	Roche	ORAL		1948
	Alopecia							
	Conjunctivitis Nec							
	Nervousness							
Date: 05/23/1994	ISR Number: 1469109-9	Report Type: Periodic	Company Report Number: 930200923001	Age: 34 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	10	14
			Lithium	C				
Date: 05/23/1994	ISR Number: 1469165-8	Report Type: Periodic	Company Report Number: 930201160001	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	70	215
Date: 05/23/1994	ISR Number: 1469373-6	Report Type: Periodic	Company Report Number: 930201255001	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	160	41
	Dry Skin							
	Dyspnoea Nos							

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

Date: 05/23/1994	ISR Number: 1469476-6	Report Type: Periodic	Company Report Number: 930200895001			Age: 23 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Asthenia Depression Nec Nausea Weight Decreased	Consumer	Accutane	PS	Roche	ORAL	160	187
Date: 05/23/1994	ISR Number: 1469489-4	Report Type: Periodic	Company Report Number: 930200865001			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Drug Interaction Nos Drug Level Nos Below Therapeutic	Health Professional	Accutane Amitriptyline	PS SS	Roche	ORAL		120 120
Date: 05/23/1994	ISR Number: 1469491-2	Report Type: Periodic	Company Report Number: 930200864001			Age:	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Palpitations	Health Professional	Accutane	PS	Roche	ORAL		
Date: 05/23/1994	ISR Number: 1469497-3	Report Type: Periodic	Company Report Number: 930200863001			Age: 17 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		59
Date: 05/23/1994	ISR Number: 1469509-7	Report Type: Periodic	Company Report Number: 930201718001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Acne Nos Condition Aggravated Insomnia Nec Pain Nos	Health Professional	Accutane	PS	Roche	ORAL	80	20
Date: 05/23/1994	ISR Number: 1469513-9	Report Type: Periodic	Company Report Number: 930202229001			Age: 26 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL		46
Date: 05/23/1994	ISR Number: 1469524-3	Report Type: Periodic	Company Report Number: 940200326002			Age: 19 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Cheilitis Conversion Disorder	Health Professional	Accutane	PS	Roche	ORAL		134

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

Date: 05/23/1994	ISR Number: 1469545-0	Report Type: Periodic	Company Report Number: 940200495001			Age:	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Life-Threatening Hospitalization - Initial or Prolonged	Cheilitis Depression Nec Emotional Disturbance Nos Suicide Attempt	Health Professional	Accutane	PS	Roche	ORAL		97	
Date: 05/23/1994	ISR Number: 1469623-6	Report Type: Periodic	Company Report Number: 930201224001			Age: 25 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
	Cheilitis Depression Nec Gingival Bleeding Headache Nos	Health Professional	Accutane	PS	Roche	ORAL		154	
Date: 05/23/1994	ISR Number: 1469905-8	Report Type: Periodic	Company Report Number: 940200063001			Age: 24 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
	Convulsions Nos Depersonalisation Headache Nos Sedation	Health Professional	Accutane	PS	Roche	ORAL	60	31	
Date: 05/23/1994	ISR Number: 1469926-5	Report Type: Periodic	Company Report Number: 930201683001			Age: 16 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
	Condition Aggravated Depression Nec Emotional Disturbance Nos Headache Nos	Health Professional	Accutane Desyrel	PS SS	Roche Bristol Labs	ORAL ORAL	60	98	
Date: 05/23/1994	ISR Number: 1469957-5	Report Type: Periodic	Company Report Number: 930201640001			Age: 16 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
	Asthenia Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	60	1	
Date: 05/23/1994	ISR Number: 1469980-0	Report Type: Periodic	Company Report Number: 940200095001			Age: 16 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
	Thinking Abnormal Nec	Health Professional	Accutane	PS	Roche	ORAL	40	131	

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

Date: 05/23/1994	ISR Number: 1469999-X	Report Type: Periodic	Company Report Number: 940200084001	Age: 15 YR	Gender: Male			
Outcome	PT Depression Nec	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 20	Duration 31
Date: 05/23/1994	ISR Number: 1470068-3	Report Type: Periodic	Company Report Number: 930201712001	Age: 15 YR	Gender: Female			
Outcome	PT Depression Nec	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration
Date: 05/23/1994	ISR Number: 1470169-X	Report Type: Periodic	Company Report Number: 930201791001	Age: 49 YR	Gender: Male			
Outcome	PT Appetite Increased Libido Decreased	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration
Date: 05/23/1994	ISR Number: 1470244-X	Report Type: Periodic	Company Report Number: 930201839001	Age: 29 YR	Gender: Female			
Outcome	PT Amnesia Nec	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration 158
Date: 05/23/1994	ISR Number: 1470389-4	Report Type: Periodic	Company Report Number: 930201914001	Age: 35 YR	Gender: Female			
Outcome	PT Arthralgia Back Pain Insomnia Nec Joint Disorder Nos	Report Source Consumer	Product Accutane Triphasil	Role PS C	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration
Date: 05/23/1994	ISR Number: 1470398-5	Report Type: Periodic	Company Report Number: 930201913001	Age: 43 YR	Gender: Female			
Outcome	PT Palpitations	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 15
Date: 05/23/1994	ISR Number: 1470503-0	Report Type: Periodic	Company Report Number: 930201888001	Age: 35 YR	Gender: Female			
Outcome	PT Alopecia Hyperlipidaemia Nos Palpitations Skin Discolouration	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration 25

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

Date: 05/23/1994	ISR Number: 1470522-4	Report Type: Periodic	Company Report Number: 930201549001			Age: 45 YR	Gender: Female		
Outcome	PT Abnormal Dreams Depression Nec	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration	
Date: 05/23/1994	ISR Number: 1470526-1	Report Type: Periodic	Company Report Number: 940200129001			Age: 32 YR	Gender: Female		
Outcome	PT Dry Skin Emotional Disturbance Nos Hostility	Report Source Consumer	Product Accutane Vitamin B Complex	Role PS C	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 37	
Date: 05/23/1994	ISR Number: 1470735-1	Report Type: Periodic	Company Report Number: 930201373001			Age: 18 YR	Gender: Male		
Outcome	PT Depression Nec Thinking Abnormal Nec	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 12	
Date: 05/23/1994	ISR Number: 1470805-8	Report Type: Periodic	Company Report Number: 930201170001			Age: 38 YR	Gender: Female		
Outcome	PT Hospitalization - Initial or Prolonged Agitation Depression Nec Thinking Abnormal Nec	Report Source Health Professional	Product Accutane Lithium	Role PS C	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration 115	
Date: 05/23/1994	ISR Number: 1470856-3	Report Type: Periodic	Company Report Number: 940200035001			Age:	Gender: Male		
Outcome	PT Depression Nec	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route	Dose/Unit	Duration	
Date: 05/23/1994	ISR Number: 1470895-2	Report Type: Periodic	Company Report Number: 940200080001			Age: 36 YR	Gender: Female		
Outcome	PT Dyspnoea Nos Hypercholesterolaemia Hyperlipidaemia Nos Palpitations	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration 130	
Date: 05/23/1994	ISR Number: 1472107-2	Report Type: Periodic	Company Report Number: 930201466001			Age: 25 YR	Gender: Female		
Outcome	PT Arthralgia Chellitis Depression Nec Hyperlipidaemia Nos	Report Source Health Professional	Product Accutane Norplant	Role PS C	Manufacturer Roche	Route ORAL	Dose/Unit 160	Duration 123	

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

Date	ISR Number	Report Type	Company Report Number	Age	Gender			
05/23/1994	1472748-2	Periodic	930202024001	75 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>
	Anxiety Nec Back Pain Puruncle (Exc Genital) Hypertonia	Health Professional	Accutane	PS	Roche	ORAL	40	57
05/23/1994	1472883-9	Periodic	930201286001	16 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>
	Anxiety Nec Depression Nec Palpitations Rectal Bleeding	Health Professional	Accutane	PS	Roche	ORAL	80	145
05/23/1994	1472962-6	Periodic	930201349001	29 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>
	Abnormal Dreams Dry Skin Photosensitivity Reaction Nos Sleep Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		61
05/23/1994	1473007-4	Periodic	930201191001	30 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>
	Hospitalization - Initial or Prolonged Disability Alopecia Emotional Disturbance Nos Headache Nos Hepatic Function Abnormal Nos	Health Professional	Accutane	PS	Roche	ORAL	40	75
05/23/1994	1473012-8	Periodic	930201012001	19 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>
	Dry Skin Emotional Disturbance Nos Epistaxis Hostility	Health Professional	Accutane	PS	Roche	ORAL	60	142
05/23/1994	1473022-0	Periodic	930201022002	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>
	Confusion Dizziness (Exc Vertigo)	Health Professional	Accutane	PS	Roche	ORAL	60	62

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

Date: 05/23/1994	ISR Number: 1473030-X	Report Type: Periodic	Company Report Number: 930201146002			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL		
Date: 05/23/1994	ISR Number: 1473033-5	Report Type: Periodic	Company Report Number: 930201148001			Age: 41 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL	80	
			Carafate	C				
			Zantac	C				
Date: 05/23/1994	ISR Number: 1473062-1	Report Type: Periodic	Company Report Number: 930200998001			Age: 29 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	40	49
Date: 05/23/1994	ISR Number: 1473112-2	Report Type: Periodic	Company Report Number: 930201076001			Age: 35 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Amnesia Nec	Health Professional	Accutane	PS	Roche	ORAL	60	156
Date: 07/27/1994	ISR Number: 1483540-7	Report Type: Expedited (15-Day)	Company Report Number: 930501129001			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Suicide Attempt	Health Professional	Rosaccutane	PS	Roche			
Life-Threatening								
Date: 05/23/1994	ISR Number: 1484036-9	Report Type: Periodic	Company Report Number: 930200906001			Age: 42 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	40	64
			Pepcid	C				
Date: 08/09/1994	ISR Number: 1488982-1	Report Type: Expedited (15-Day)	Company Report Number: 940201392001			Age: 24 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Alopecia	Consumer	Accutane	PS	Roche	ORAL	80	66
	Anorexia							
	Delusion Nos							

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

Date: 07/21/1994	ISR Number: 1489427-8	Report Type: Direct	Company Report Number:			Age: 20 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depersonalisation Thinking Abnormal Nec	Health Professional	Accutane Minocycline	PS SS	Roche		80	
Date: 08/17/1994	ISR Number: 1492317-8	Report Type: Expedited (15-Day)	Company Report Number: 940201502001			Age: 14 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Condition Aggravated Hostility Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		547
Date: 08/09/1994	ISR Number: 1495828-4	Report Type: Expedited (15-Day)	Company Report Number: 940201166001			Age: 42 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Amnesia Nec Arthralgia Headache Nos Myalgia	Health Professional	Accutane Tylenol Voltaren	PS C C	Roche	ORAL	80	24
Date: 10/06/1994	ISR Number: 1507952-8	Report Type: Periodic	Company Report Number: USA9304017PAM			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Drug Interaction Nos Drug Level Nos Below Therapeutic	Health Professional	Nortriptyline Hydrochloride Amitriptyline Accutane	PS SS SS	Sandoz Roche	ORAL ORAL		
Date: 09/14/1994	ISR Number: 1508503-4	Report Type: Expedited (15-Day)	Company Report Number: 940501039001			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death Life-Threatening	Delirium Depression Nec Non-Accidental Injury Suicide Attempt	Foreign Health Professional	Roaccutane	PS	Roche	ORAL	40	238
Date: 09/19/1994	ISR Number: 1508530-7	Report Type: Expedited (15-Day)	Company Report Number: 930500702001			Age:	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death Life-Threatening	Suicide Attempt	Foreign Health Professional	Roaccutane	PS	Roche	ORAL		

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

Date: 10/25/1994		ISR Number: 1516306-X		Report Type: Expedited (15-Day)		Company Report Number: 940201970001		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>			
Life-Threatening	Convulsions Nos	Health Professional	Accutane	PS	Roche	ORAL	70				
Hospitalization - Initial or Prolonged	Overdose Nos Suicide Attempt		Bacitracin	C							
			Benadryl	C							
			Claritin	C							
			Sudafed	C							
Date: 11/01/1994		ISR Number: 1518823-5		Report Type: Expedited (15-Day)		Company Report Number: 940202049001		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>			
Life-Threatening	Pain Nos	Consumer	Accutane	PS	Roche	ORAL					
Hospitalization - Initial or Prolonged	Peripheral Neuropathy Nec Psychotic Disorder Nos										
Date: 11/08/1994		ISR Number: 1519340-9		Report Type: Expedited (15-Day)		Company Report Number: 940202019001		Age: 14 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>			
Life-Threatening	Alanine Aminotransferase Increased	Health Professional	Accutane	PS	Roche	ORAL	60	23			
Hospitalization - Initial or Prolonged	Emotional Disturbance Nos Suicide Attempt										
Date: 01/09/1995		ISR Number: 1539023-9		Report Type: Expedited (15-Day)		Company Report Number: 940500844001		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>			
Life-Threatening	Dermatitis Nos	Foreign	Roaccutane	PS	Roche	ORAL		1			
	Nervousness	Health Professional									
	Suicide Attempt										
Date: 01/31/1995		ISR Number: 1546076-0		Report Type: Direct		Company Report Number:		Age: 42 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>			
	Alopecia	Consumer	Accutane	PS	Roche	ORAL		17			
	Amenorrhoea Nos										
	Depression Nec										
	Hair Disorder Nos										
Date: 02/16/1995		ISR Number: 1556577-7		Report Type: Expedited (15-Day)		Company Report Number: 940600114001		Age:		Gender: 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>			
Hospitalization - Initial or Prolonged	Psychotic Disorder Nos	Foreign	Roaccutane	PS	Roche	ORAL					
		Health Professional									

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

Date: 03/02/1995	ISR Number: 1560460-0	Report Type: Direct	Company Report Number:			Age: 21 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation	Health Professional	Accutane	PS	Roche	ORAL	80	108
Required Intervention to Prevent Permanent Impairment/Damage	Emotional Disturbance Nos Personality Disorder Nos							
Date: 05/23/1995	ISR Number: 1589578-3	Report Type: Expedited (15-Day)	Company Report Number: 43862			Age: 35 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Confusion	Foreign	Accutane	PS	Roche	ORAL		35
	Depersonalisation	Health Professional	Surmontil	SS	Ives Lab	ORAL		
	Drug Interaction Nos							
	Thinking Abnormal Nec							
Date: 05/05/1995	ISR Number: 1590229-2	Report Type: Direct	Company Report Number:			Age: 28 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Amblyopia Nos	Consumer	Accutane	PS	Roche	ORAL	1	91
Other	Convulsions Nos							
	Emotional Disturbance Nos							
	Headache Nos							
Date: 06/08/1995	ISR Number: 1596924-3	Report Type: Periodic	Company Report Number: 940201199001			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Asthenia	Health Professional	Accutane	PS	Roche	ORAL	40	56
	Emotional Disturbance Nos							
Date: 06/08/1995	ISR Number: 1596931-0	Report Type: Periodic	Company Report Number: 940201244001			Age: 47 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Asthenia	Consumer	Accutane	PS	Roche	ORAL	40	31
	Depression Nec		Thyroid	C				
	Headache Nos							
	Skin Atrophy							
Date: 06/08/1995	ISR Number: 1597133-4	Report Type: Periodic	Company Report Number: 940200843001			Age: 14 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Arthralgia	Consumer	Accutane	PS	Roche	ORAL	40	93
	Depression Nec							
	Joint Disorder Nos							

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

Date: 06/08/1995	ISR Number: 1597135-8	Report Type: Periodic	Company Report Number: 940200846001	Age: 33 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Asthenia Depression Nec Headache Nos Tinnitus	Consumer	Accutane	PS	Roche	ORAL	40	9
Date: 06/02/1995	ISR Number: 1597164-4	Report Type: Expedited (15-Day)	Company Report Number: 44825	Age: 17 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Dysphonia Laryngitis Nos	Health Professional	Accutane	PS	Roche	ORAL		
Date: 06/08/1995	ISR Number: 1597168-1	Report Type: Periodic	Company Report Number: 940200878001	Age: 25 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Agitation Dermatitis Nos Emotional Disturbance Nos Headache Nos	Consumer	Accutane Demlen	PS C	Roche	ORAL	20	29
Date: 06/08/1995	ISR Number: 1597184-X	Report Type: Periodic	Company Report Number: 940201107001	Age: 15 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Amnesia Nec Asthenia Headache Nos	Consumer	Accutane Monodox	PS C	Roche	ORAL		95
Date: 06/08/1995	ISR Number: 1597233-9	Report Type: Periodic	Company Report Number: 940201177001	Age: 33 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Cheilitis Depression Nec Vaginitis	Health Professional	Accutane Buspar Demlen	PS C C	Roche	ORAL	60	24
Date: 07/06/1995	ISR Number: 1608144-4	Report Type: Expedited (15-Day)	Company Report Number: 45747	Age: 21 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aphasia Headache Nos Hypoesthesia Visual Field Defect Nos	Foreign Health Professional	Roaccutane Desogestrel Ethinyl Estradiol	PS SS SS	Roche	ORAL	30	377

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

Date: 07/19/1995	ISR Number: 1614711-4	Report Type: Expedited (15-Day)	Company Report Number: 46762	Age: 23 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Convulsions Nos Suicide Attempt	Foreign Health Professional	Roaccutane	PS	Roche	ORAL	20	180
Date: 06/17/1995	ISR Number: 1615167-8	Report Type: Direct	Company Report Number:	Age: 17 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Electrocardiogram Abnormal Nos Hypercalcaemia Palpitations Ventricular Extrasystoles	Health Professional	Accutane Ery-Tab	PS C	Roche		80	62
Date: 06/08/1995	ISR Number: 1616217-5	Report Type: Periodic	Company Report Number: 940201206001	Age: 20 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depersonalisation Dizziness (Exc Vertigo) Headache Nos Thinking Abnormal Nec	Health Professional	Accutane Minocin	PS SS	Roche Lederle	ORAL	60	1
Date: 06/08/1995	ISR Number: 1616413-7	Report Type: Periodic	Company Report Number: 940201932001	Age: 16 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos	Consumer	Accutane	PS	Roche	ORAL	50	1
Date: 06/08/1995	ISR Number: 1616423-X	Report Type: Periodic	Company Report Number: 940202249001	Age: 32 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Arthralgia Depression Nec Muscle Cramps	Consumer	Accutane	PS	Roche	ORAL		30
Date: 06/08/1995	ISR Number: 1616467-8	Report Type: Periodic	Company Report Number: 940202254001	Age: 41 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Insomnia Nec Nervousness	Health Professional	Accutane	PS	Roche	ORAL	160	9
Date: 06/08/1995	ISR Number: 1616471-X	Report Type: Periodic	Company Report Number: 940202258001	Age: 15 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Amenorrhoea Nos Anorexia Depression Nec	Consumer	Accutane	PS	Roche	ORAL		548

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

Date: 06/08/1995	ISR Number: 1616476-9	Report Type: Periodic	Company Report Number: 940202083001	Age: 28 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u> Alopecia Depression Nec Dry Skin Rhinitis Nos	<u>Report Source</u> Health Professional	<u>Product</u> Accutane	<u>Role</u> PS	<u>Manufacturer</u> Roche	<u>Route</u> ORAL	<u>Dose/Unit</u> 40	<u>Duration</u> 147
Date: 06/08/1995	ISR Number: 1616514-3	Report Type: Periodic	Company Report Number: 940202286001	Age: 16 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u> Alopecia Back Pain Depression Nec Vocal Cord Paralysis	<u>Report Source</u> Health Professional	<u>Product</u> Accutane	<u>Role</u> PS	<u>Manufacturer</u> Roche	<u>Route</u> ORAL	<u>Dose/Unit</u> 40	<u>Duration</u> 113
Date: 06/08/1995	ISR Number: 1616606-9	Report Type: Periodic	Company Report Number: 940201352001	Age: 21 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u> Arthralgia Asthenia Depression Nec Weight Decreased	<u>Report Source</u> Consumer	<u>Product</u> Accutane	<u>Role</u> PS	<u>Manufacturer</u> Roche	<u>Route</u> ORAL	<u>Dose/Unit</u> 80	<u>Duration</u>
Date: 06/08/1995	ISR Number: 1616635-5	Report Type: Periodic	Company Report Number: 940201377001	Age: 20 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u> Depression Nec	<u>Report Source</u> Health Professional	<u>Product</u> Accutane Prozac	<u>Role</u> PS C	<u>Manufacturer</u> Roche	<u>Route</u> ORAL	<u>Dose/Unit</u> 50	<u>Duration</u>
Date: 06/08/1995	ISR Number: 1616639-2	Report Type: Periodic	Company Report Number: 940201375001	Age: 24 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u> Arthralgia Back Pain Dysphonia Dyspnoea Nos	<u>Report Source</u> Consumer	<u>Product</u> Accutane	<u>Role</u> PS	<u>Manufacturer</u> Roche	<u>Route</u> ORAL	<u>Dose/Unit</u> 60	<u>Duration</u> 66
Date: 06/08/1995	ISR Number: 1616660-4	Report Type: Periodic	Company Report Number: 940201395001	Age: 23 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u> Hormone Level Nos Abnormal Impotence	<u>Report Source</u> Health Professional	<u>Product</u> Accutane Amoxicillin	<u>Role</u> PS C	<u>Manufacturer</u> Roche	<u>Route</u> ORAL	<u>Dose/Unit</u> 40	<u>Duration</u> 10

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

Date: 06/08/1995	ISR Number: 1616661-6	Report Type: Periodic	Company Report Number: 950200186001	Age: 25 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Anorexia Depression Nec	Consumer	Accutane	PS	Roche	ORAL	20	24
Date: 06/08/1995	ISR Number: 1616663-X	Report Type: Periodic	Company Report Number: 940201903001	Age: 24 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Amnesia Nec Conjunctivitis Nec Drug Interaction Nos Sleep Disorder Nos	Consumer	Accutane	PS	Roche	ORAL	80	81
Date: 06/08/1995	ISR Number: 1616669-0	Report Type: Periodic	Company Report Number: 940201399001	Age: 17 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Alopecia Blindness Night Depression Nec Emotional Disturbance Nos	Consumer	Accutane	PS	Roche	ORAL		132
Date: 06/08/1995	ISR Number: 1616684-7	Report Type: Periodic	Company Report Number: 940201402001	Age: 37 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Amnesia Nec Asthenia Depression Nec Pruritus	Consumer	Accutane	PS	Roche	ORAL	80	
Date: 06/08/1995	ISR Number: 1616689-6	Report Type: Periodic	Company Report Number: 940201415001	Age: 19 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Nail Disorder Nos Sweating Increased	Health Professional	Accutane	PS	Roche	ORAL	100	31
Date: 06/08/1995	ISR Number: 1616700-2	Report Type: Periodic	Company Report Number: 940202353001	Age: 21 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Emotional Disturbance Nos	Consumer	Accutane	PS	Roche			96
Date: 06/08/1995	ISR Number: 1616707-5	Report Type: Periodic	Company Report Number: 940202349001	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL	80	93

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

Date: 06/08/1995	ISR Number: 1616717-8	Report Type: Periodic	Company Report Number: 950200216001			Age: 23 YR	Gender: Female		
Outcome	PT Dermatitis Nos Emotional Disturbance Nos Pruritus	Report Source Consumer	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 63	
Date: 06/08/1995	ISR Number: 1616726-9	Report Type: Periodic	Company Report Number: 940202370001			Age: 17 YR	Gender: Female		
Outcome	PT Depression Nec Emotional Disturbance Nos Menstrual Disorder Nos	Report Source Consumer	Product Accutane Ortho-Novum	Role PS SS	Manufacturer Roche Ortho	Route ORAL ORAL	Dose/Unit 80	Duration 1 56	
Date: 06/08/1995	ISR Number: 1616733-6	Report Type: Periodic	Company Report Number: 940202409001			Age: 32 YR	Gender: Female		
Outcome	PT Depression Nec Diarrhoea Nos Emotional Disturbance Nos	Report Source Consumer	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 21	
Date: 06/08/1995	ISR Number: 1616761-0	Report Type: Periodic	Company Report Number: 950200235001			Age: 15 YR	Gender: Female		
Outcome	PT Dysphonia	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 50	Duration 10	
Date: 06/08/1995	ISR Number: 1616762-2	Report Type: Periodic	Company Report Number: 940202390001			Age: 28 YR	Gender: Female		
Outcome	PT Benign Intracranial Hypertension Depression Nec Diplopia Emotional Disturbance Nos	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 25	
Date: 06/08/1995	ISR Number: 1616774-9	Report Type: Periodic	Company Report Number: 940201002001			Age: 43 YR	Gender: Female		
Outcome	PT Depression Nec	Report Source Consumer	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration	
Date: 06/08/1995	ISR Number: 1616784-1	Report Type: Periodic	Company Report Number: 950200237001			Age: 17 YR	Gender: Male		
Outcome	PT Depression Nec Emotional Disturbance Nos	Report Source Consumer	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 182	

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

Date: 06/08/1995	ISR Number: 1616831-7	Report Type: Periodic	Company Report Number: 950200438001			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Blood Alkaline Phosphatase Nos Increased Depression Nec Hyperlipidaemia Nos Vomiting Nos	Health Professional	Accutane	PS	Roche	ORAL	40	219
Date: 06/08/1995	ISR Number: 1616857-3	Report Type: Periodic	Company Report Number: 940202086001			Age: 14 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos Emotional Disturbance Nos Laboratory Test Abnormal Nos Pelvic Pain Nos	Consumer	Accutane Alpent Rynatan Slo-Bid Zolof	PS C C C C	Roche	ORAL	60	37
Date: 06/08/1995	ISR Number: 1616882-2	Report Type: Periodic	Company Report Number: 950200267001			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Impotence Pyrexia	Consumer	Accutane Anacin Oxymetazoline Hydrochloride	PS C C	Roche	ORAL	40	1 2 4
Date: 06/08/1995	ISR Number: 1616890-1	Report Type: Periodic	Company Report Number: 950200274001			Age: 14 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Arthralgia Asthenia Emotional Disturbance Nos Hypokinesia	Consumer	Accutane Sudafed	PS C	Roche	ORAL	80	41
Date: 06/08/1995	ISR Number: 1616893-7	Report Type: Periodic	Company Report Number: 940202018001			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	40	113
Date: 10/13/1994	ISR Number: 1616898-6	Report Type: Periodic	Company Report Number: 940202013001			Age: 27 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Amnesia Nec	Health Professional	Accutane	PS	Roche	ORAL	40	4

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

Date: 06/08/1995	ISR Number: 1616899-8	Report Type: Periodic	Company Report Number: 950200277001			Age: 19 YR	Gender: Male
<u>Outcome</u>	<u>PT</u> Depression Nec Emotional Disturbance Nos Personality Disorder Nos	<u>Report Source</u> Consumer	<u>Product</u> Accutane	<u>Role</u> PS	<u>Manufacturer</u> Roche	<u>Route</u> ORAL	<u>Dose/Unit</u> 1 <u>Duration</u>
Date: 06/08/1995	ISR Number: 1616904-9	Report Type: Periodic	Company Report Number: 940202034001			Age: 44 YR	Gender: Female
<u>Outcome</u>	<u>PT</u> Headache Nos Insomnia Nec Paranoia Rectal Bleeding	<u>Report Source</u> Consumer	<u>Product</u> Accutane	<u>Role</u> PS	<u>Manufacturer</u> Roche	<u>Route</u> ORAL	<u>Dose/Unit</u> 40 6 <u>Duration</u>
Date: 06/08/1995	ISR Number: 1616906-2	Report Type: Periodic	Company Report Number: 940202032001			Age: 20 YR	Gender: Male
<u>Outcome</u>	<u>PT</u> Dysphonia Laryngeal Neoplasm Nos	<u>Report Source</u> Health Professional	<u>Product</u> Accutane	<u>Role</u> PS	<u>Manufacturer</u> Roche	<u>Route</u> ORAL	<u>Dose/Unit</u> 40 169 <u>Duration</u>
Date: 06/08/1995	ISR Number: 1616909-8	Report Type: Periodic	Company Report Number: 950200283001			Age: 17 YR	Gender: Male
<u>Outcome</u>	<u>PT</u> Agitation Amblyopia Nos Epistaxis Hypertension Nos	<u>Report Source</u> Health Professional	<u>Product</u> Accutane	<u>Role</u> PS	<u>Manufacturer</u> Roche	<u>Route</u> ORAL	<u>Dose/Unit</u> 100 182 <u>Duration</u>
Date: 06/08/1995	ISR Number: 1616926-8	Report Type: Periodic	Company Report Number: 950200292001			Age: 26 YR	Gender: Female
<u>Outcome</u>	<u>PT</u> Constipation Depression Nec Epistaxis Myalgia	<u>Report Source</u> Consumer	<u>Product</u> Accutane Claritin	<u>Role</u> PS C	<u>Manufacturer</u> Roche	<u>Route</u> ORAL	<u>Dose/Unit</u> 80 1 <u>Duration</u>
Date: 06/08/1995	ISR Number: 1616927-X	Report Type: Periodic	Company Report Number: 940202039001			Age: 32 YR	Gender: Female
<u>Outcome</u>	<u>PT</u> Hypersensitivity Nos Nervousness Rash Maculo-Papular Urticaria Nos	<u>Report Source</u> Health Professional	<u>Product</u> Accutane	<u>Role</u> PS	<u>Manufacturer</u> Roche	<u>Route</u> ORAL	<u>Dose/Unit</u> 80 2 <u>Duration</u>

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

Date: 06/08/1995	ISR Number: 1616930-X	Report Type: Periodic	Company Report Number: 940201278001			Age: 20 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Dysphonia Laryngitis Nos	Health Professional	Accutane	PS	Roche	ORAL		178
Date: 06/08/1995	ISR Number: 1616947-5	Report Type: Periodic	Company Report Number: 940202046001			Age: 25 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Apathy Dizziness (Excl Vertigo) Nervousness Sedation	Consumer	Accutane	PS	Roche	ORAL	40	2
Date: 06/08/1995	ISR Number: 1616963-3	Report Type: Periodic	Company Report Number: 940201441001			Age: 19 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Impotence	Health Professional	Accutane	PS	Roche	ORAL		21
Date: 06/08/1995	ISR Number: 1617014-7	Report Type: Periodic	Company Report Number: 940201068001			Age: 25 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Acne Nos Alopecia Depression Nec Hair Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL	120	
Date: 06/08/1995	ISR Number: 1617018-4	Report Type: Periodic	Company Report Number: 940201465001			Age: 31 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Anaemia Nos Arthralgia Depression Nec Headache Nos	Consumer	Accutane Desogen	PS C	Roche	ORAL	80	41
Date: 06/08/1995	ISR Number: 1617030-5	Report Type: Periodic	Company Report Number: 940202068001			Age: 14 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Alopecia Coordination Abnormal Nos Dystonia Emotional Disturbance Nos	Consumer	Accutane Proventil	PS C	Roche	ORAL		

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

Date: 06/08/1995	ISR Number: 1617031-7	Report Type: Periodic	Company Report Number: 940201469001			Age: 18 YR	Gender: Male		
Outcome	PT Chest Pain Palpitations Tachycardia Nos	Report Source Health Professional	Product Accutane Minocycline	Role PS C	Manufacturer Roche	Route ORAL	Dose/Unit	Duration	
Date: 06/08/1995	ISR Number: 1617037-8	Report Type: Periodic	Company Report Number: 950200312001			Age: 17 YR	Gender: Female		
Outcome	PT Condition Aggravated Depression Nec	Report Source Consumer	Product Accutane Prozac	Role PS C	Manufacturer Roche	Route ORAL	Dose/Unit 20	Duration 5 1	
Date: 06/08/1995	ISR Number: 1617049-4	Report Type: Periodic	Company Report Number: 940201498001			Age: 28 YR	Gender: Female		
Outcome	PT Palpitations Paraesthesia Nec Tachycardia Nos	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration 5	
Date: 06/08/1995	ISR Number: 1617095-0	Report Type: Periodic	Company Report Number: 940201022001			Age:	Gender: Female		
Outcome	PT Infection Nos Myalgia Palpitations	Report Source Consumer	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 30	Duration 22	
Date: 06/08/1995	ISR Number: 1617112-8	Report Type: Periodic	Company Report Number: 940201013001			Age: 16 YR	Gender: Male		
Outcome	PT Amnesia Nec Depression Nec Emotional Disturbance Nos Thinking Abnormal Nec	Report Source Consumer	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 121	
Date: 06/08/1995	ISR Number: 1617113-X	Report Type: Periodic	Company Report Number: 940201808001			Age: 36 YR	Gender: Male		
Outcome	PT Insomnia Nec	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration 9	
Date: 06/08/1995	ISR Number: 1617121-9	Report Type: Periodic	Company Report Number: 940201005001			Age: 21 YR	Gender: Female		
Outcome	PT Emotional Disturbance Nos Paranoia	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 41	

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

Date: 06/08/1995	ISR Number: 1617129-3	Report Type: Periodic	Company Report Number: 940201004001			Age: 18 YR	Gender: Male	
Outcome	PT Apathy Dermatitis Exfoliative Nos Vasodilatation	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 180	Duration 32
Date: 06/08/1995	ISR Number: 1617141-4	Report Type: Periodic	Company Report Number: 940200990001			Age: 27 YR	Gender: Female	
Outcome	PT Asthenia Depression Nec Refractive Errors Nos Vasodilatation	Report Source Consumer	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 10
Date: 06/08/1995	ISR Number: 1617151-7	Report Type: Periodic	Company Report Number: 940202079001			Age: 15 YR	Gender: Male	
Outcome	PT Depression Nec Headache Nos Hostility	Report Source Consumer	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration 7
Date: 06/08/1995	ISR Number: 1617172-4	Report Type: Periodic	Company Report Number: 950200338001			Age: 24 YR	Gender: Male	
Outcome	PT Asthenia Chest Pain Conversion Disorder Hyperlipidaemia Nos	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration 128
Date: 06/08/1995	ISR Number: 1617178-5	Report Type: Periodic	Company Report Number: 940201852001			Age: 25 YR	Gender: Female	
Outcome	PT Arrhythmia Nos Palpitations	Report Source Consumer	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 60	Duration 93
Date: 06/08/1995	ISR Number: 1617213-4	Report Type: Periodic	Company Report Number: 950200361001			Age: 16 YR	Gender: Male	
Outcome	PT Dry Skin Lacrimal Disorder Nos Thinking Abnormal Nec	Report Source Consumer	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration 126
Date: 06/08/1995	ISR Number: 1617225-0	Report Type: Periodic	Company Report Number: 950200371001			Age: 15 YR	Gender: Male	
Outcome	PT Hallucination Nos Pyrexia	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 11

08/03/2000

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

Date: 06/08/1995	ISR Number: 1617227-4	Report Type: Periodic	Company Report Number: 940200933001			Age: 36 YR	Gender: Female	
Outcome	PT Amnesia Nec	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 60	Duration
Date: 06/08/1995	ISR Number: 1617228-6	Report Type: Periodic	Company Report Number: 950200373001			Age: 12 YR	Gender: Female	
Outcome	PT Alopecia Arthralgia Emotional Disturbance Nos Vomiting Nos	Report Source Consumer	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 60	Duration 3
Date: 06/08/1995	ISR Number: 1617351-6	Report Type: Periodic	Company Report Number: 940202142001			Age: 47 YR	Gender: Female	
Outcome	PT Palpitations	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 66
Date: 06/08/1995	ISR Number: 1617368-1	Report Type: Periodic	Company Report Number: 940202157001			Age: 32 YR	Gender: Female	
Outcome	PT Headache Nos Insomnia Nec Myalgia	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 8
Date: 06/08/1995	ISR Number: 1617372-3	Report Type: Periodic	Company Report Number: 940202154001			Age: 11 YR	Gender: Female	
Outcome	PT Bone Disorder Nos Depersonalisation	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 152
Date: 06/08/1995	ISR Number: 1617390-5	Report Type: Periodic	Company Report Number: 940202167001			Age: 30 YR	Gender: Female	
Outcome	PT Depression Nec	Report Source Consumer	Product Accutane	Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
Date: 06/08/1995	ISR Number: 1617397-8	Report Type: Periodic	Company Report Number: 940202193001			Age: 16 YR	Gender: Female	
Outcome	PT Emotional Disturbance Nos Weight Decreased	Report Source Health Professional	Product Accutane Norplant	Role PS C	Manufacturer Roche	Route ORAL	Dose/Unit 50	Duration 43

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

Date: 06/08/1995	ISR Number: 1617431-5	Report Type: Periodic	Company Report Number: 940202179001	Age: 16 YR	Gender: Male			
Outcome	PT Depression Nec Emotional Disturbance Nos Personality Disorder Nos	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 50	Duration
Date: 06/08/1995	ISR Number: 1617445-5	Report Type: Periodic	Company Report Number: 940202414001	Age: 38 YR	Gender: Female			
Outcome	PT Amnesia Nec	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 60	Duration
Date: 06/08/1995	ISR Number: 1617457-1	Report Type: Periodic	Company Report Number: 940202423001	Age: 28 YR	Gender: Female			
Outcome	PT Cerebral Cedema Conjunctivitis Nec Depression Nec Headache Nos	Report Source Consumer	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 10	Duration 1
Date: 06/08/1995	ISR Number: 1617466-2	Report Type: Periodic	Company Report Number: 940202443001	Age: 28 YR	Gender: Male			
Outcome	PT Arthralgia Myalgia Palpitations	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 60	Duration
Date: 06/08/1995	ISR Number: 1617719-8	Report Type: Periodic	Company Report Number: 940201014001	Age: 20 YR	Gender: Female			
Outcome	PT Agitation	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 52
Date: 06/08/1995	ISR Number: 1617821-0	Report Type: Periodic	Company Report Number: 940200960001	Age: 35 YR	Gender: Female			
Outcome	PT Antinuclear Factor Positive Back Pain Emotional Disturbance Nos Headache Nos	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 120	Duration 117
Date: 06/08/1995	ISR Number: 1617833-7	Report Type: Periodic	Company Report Number: 940200965001	Age: 42 YR	Gender: Female			
Outcome	PT Benign Intracranial Hypertension Emotional Disturbance Nos	Report Source Health Professional	Product Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 215

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

Date: 06/08/1995	ISR Number: 1622453-4	Report Type: Periodic	Company Report Number: 950200390001	Age: 34 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Impotence Testicular Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		1
Date: 06/08/1995	ISR Number: 1622463-7	Report Type: Periodic	Company Report Number: 950200392002	Age: 43 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Impotence	Health Professional	Accutane	PS	Roche	ORAL	60	
Date: 06/08/1995	ISR Number: 1622466-2	Report Type: Periodic	Company Report Number: 950200392001	Age: 23 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Impotence	Health Professional	Accutane	PS	Roche	ORAL	80	67
Date: 06/08/1995	ISR Number: 1622481-9	Report Type: Periodic	Company Report Number: 940201517001	Age: 40 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Insomnia Nec Nervousness Paresthesia Nec	Health Professional	Accutane	PS	Roche	ORAL	40	79
Date: 06/08/1995	ISR Number: 1622498-4	Report Type: Periodic	Company Report Number: 940201529001	Age: 15 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Acne Nos Asthenia Depression Nec Otitis Media Nos	Health Professional	Accutane	PS	Roche	ORAL	80	154
Date: 06/08/1995	ISR Number: 1622508-4	Report Type: Periodic	Company Report Number: 950200423001	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Dermatitis Nos Hyperaesthesia Vasodilatation	Consumer	Accutane	PS	Roche			185
Date: 06/08/1995	ISR Number: 1622511-4	Report Type: Periodic	Company Report Number: 940201566001	Age: 7 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Abnormal Dreams Tooth Discolouration	Health Professional	Accutane	PS	Roche	ORAL	20	

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

Date: 06/08/1995	ISR Number: 1622512-6	Report Type: Periodic	Company Report Number: 950200422002	Age: 24 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>
	Acne Nos Condition Aggravated Depression Nec	Consumer	Accutane	PS	Roche	ORAL		79
Date: 06/08/1995	ISR Number: 1622534-5	Report Type: Periodic	Company Report Number: 940201597001	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>
	Palpitations Tachycardia Nos	Health Professional	Accutane Prozac	PS C	Roche	ORAL	80	43
Date: 06/08/1995	ISR Number: 1622576-X	Report Type: Periodic	Company Report Number: 940201621001	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>
	Gingivitis Metal Poisoning Palpitations	Health Professional	Accutane	PS	Roche	ORAL		39
Date: 06/08/1995	ISR Number: 1622634-X	Report Type: Expedited (15-Day)	Company Report Number: 950200467001	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>
Disability	Conversion Disorder Depression Nec Headache Nos Syncope	Health Professional	Accutane	PS	Roche	ORAL	80	28
Date: 06/08/1995	ISR Number: 1622665-X	Report Type: Periodic	Company Report Number: 940201693001	Age: 39 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>
	Impotence	Health Professional	Accutane	PS	Roche	ORAL		
Date: 06/08/1995	ISR Number: 1622666-1	Report Type: Periodic	Company Report Number: 940201705001	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>
	Depression Nec	Health Professional	Accutane Erythromycin Hytone Ortho-Cept	PS C C C	Roche	ORAL	20	32
Date: 06/08/1995	ISR Number: 1622767-8	Report Type: Periodic	Company Report Number: 950200496001	Age: 24 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>
	Agitation	Health Professional	Accutane	PS	Roche	ORAL		17

08/03/2000

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

Date: 06/08/1995	ISR Number: 1622771-X	Report Type: Periodic	Company Report Number: 950200501001			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>	
	Insomnia Nec Nervousness	Consumer	Accutane	PS	Roche	ORAL			
Date: 06/08/1995	ISR Number: 1622809-X	Report Type: Periodic	Company Report Number: 950200514001			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	Amnesia Nec	Health Professional	Accutane	PS	Roche	ORAL			
Date: 06/08/1995	ISR Number: 1622817-9	Report Type: Periodic	Company Report Number: 950200080001			Age: 22 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>	
	Depression Nec Drug Withdrawal Syndrome	Consumer	Accutane	PS	Roche	ORAL		185	
Date: 06/08/1995	ISR Number: 1622848-9	Report Type: Periodic	Company Report Number: 950200090001			Age: 29 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>	
	Libido Decreased	Consumer	Accutane	PS	Roche	ORAL	40	106	
Date: 06/08/1995	ISR Number: 1622892-1	Report Type: Periodic	Company Report Number: 950200111001			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>	
	Depression Nec Granuloma Nos Skin Hypertrophy Weight Decreased	Health Professional	Accutane	PS	Roche	ORAL	80	90	
Date: 06/08/1995	ISR Number: 1622982-3	Report Type: Periodic	Company Report Number: 950200185001			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>	
	Depression Nec	Consumer	Accutane	PS	Roche	ORAL	80	182	
Date: 06/08/1995	ISR Number: 1623067-2	Report Type: Periodic	Company Report Number: 950200598001			Age: 18 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>	
	Cheilitis Dry Skin Emotional Disturbance Nos Peripheral Vascular Disease Nos	Consumer	Accutane Aloe Vitamin B Complex Vitamin E	PS C C C	Roche	ORAL	20	31	

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

Date: 06/08/1995	ISR Number: 1623765-0	Report Type: Periodic	Company Report Number: 940202430001	Age: 23 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Acne Nos Depression Nec Drug Ineffective	Consumer	Accutane	PS	Roche	ORAL		
Date: 06/08/1995	ISR Number: 1623809-6	Report Type: Periodic	Company Report Number: 950200003001	Age: 30 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Asthenia Emotional Disturbance Nos Headache Nos Hypoesthesia	Health Professional	Accutane Demulen	PS C	Roche	ORAL	40	26
Date: 06/08/1995	ISR Number: 1623859-X	Report Type: Periodic	Company Report Number: 950200060001	Age: 29 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Nervousness Rigors Sweating Increased Vasodilatation	Consumer	Accutane	PS	Roche	ORAL	80	
Date: 06/08/1995	ISR Number: 1623875-8	Report Type: Periodic	Company Report Number: 950200062001	Age: 18 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Anorexia Emotional Disturbance Nos Vomiting Nos Weight Decreased	Consumer	Accutane Vitamins	PS C	Roche	ORAL	40	152
Date: 06/08/1995	ISR Number: 1623877-1	Report Type: Periodic	Company Report Number: 950200086001	Age: 27 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Alopecia Chelitis Depression Nec Dry Skin	Consumer	Accutane Alcohol	PS SS	Roche	ORAL	40	123
Date: 07/31/1995	ISR Number: 1624202-2	Report Type: Expedited (15-Day)	Company Report Number: 48073	Age: 23 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Suicide Attempt	Foreign Health Professional	Rosaccutane	PS	Roche	ORAL		366

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

Date: 09/19/1995 ISR Number: 1641671-2 Report Type: Expedited (15-Day) Company Report Number: 49144 Age: 3 YR Gender: Female								
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Haemorrhagic Stroke Headache Nos Nausea Personality Disorder Nos	Foreign	Roaccutane	PS	Roche	ORAL	10	677
Date: 09/19/1995 ISR Number: 1643903-3 Report Type: Expedited (15-Day) Company Report Number: 48312 Age: 16 YR Gender: Male								
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Hostility Non-Accidental Injury Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL	60	
Date: 09/19/1995 ISR Number: 1644960-0 Report Type: Expedited (15-Day) Company Report Number: 50851 Age: 18 YR Gender: Female								
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec Suicide Attempt	Foreign Health Professional	Roaccutane Cyproterone Acetate Ethinyl Estradiol	PS C C	Roche	ORAL	25	113
Date: 09/19/1995 ISR Number: 1644980-6 Report Type: Expedited (15-Day) Company Report Number: 50853 Age: 28 YR Gender: Female								
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Depression Nec Suicide Attempt	Foreign Health Professional	Roaccutane Lexomil Ludionil	PS C C	Roche	ORAL	35	206
Date: 09/29/1995 ISR Number: 1649674-9 Report Type: Expedited (15-Day) Company Report Number: 45948 Age: 19 YR Gender: Male								
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Confusion Depersonalisation Personality Disorder Nos Schizophrenia Nos	Foreign Health Professional	Roaccutane Cannabis	PS C	Roche	ORAL	20	201
Date: 10/03/1995 ISR Number: 1651791-4 Report Type: Expedited (15-Day) Company Report Number: 51403 Age: 23 YR Gender: Female								
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Non-Accidental Overdose Suicide Attempt Unintended Pregnancy	Foreign Health Professional	Roaccutane Lysanxia Tinordiol	PS SS C	Roche	ORAL		120

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

Date: 10/23/1995	ISR Number: 1663144-3	Report Type: Expedited (15-Day)	Company Report Number: 52115	Age:	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Hallucination Nos Psychotic Disorder Nos	Foreign Health Professional	Roaccutane	PS	Roche	ORAL	40	7
Date: 10/27/1995	ISR Number: 1663233-3	Report Type: Expedited (15-Day)	Company Report Number: 50223	Age: 15 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia Depression Nec Emotional Disturbance Nos Suicide Attempt	Health Professional	Accutane Claritin Paxil	PS C C	Roche	ORAL	80	228
Date: 11/07/1995	ISR Number: 1664531-X	Report Type: Expedited (15-Day)	Company Report Number: 52660	Age: 19 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec Hallucination Nos Paranoia Schizophrenia Nos	Consumer	Accutane	PS	Roche	ORAL		366
Date: 10/31/1995	ISR Number: 1665438-4	Report Type: Expedited (15-Day)	Company Report Number: 52563	Age: 17 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Non-Accidental Overdose Suicide Attempt Thinking Abnormal Nec	Health Professional	Accutane Tylenol W/Codeine No. 3	PS SS	Roche R W Johnson	ORAL	80	141 1
Date: 11/13/1995	ISR Number: 1671043-6	Report Type: Expedited (15-Day)	Company Report Number: 52947	Age: 22 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Hepatic Function Abnormal Nos Non-Accidental Injury Suicide Attempt	Consumer	Accutane	PS	Roche	ORAL		
Date: 12/05/1995	ISR Number: 1682383-9	Report Type: Expedited (15-Day)	Company Report Number: 53857	Age: 17 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Asthenia Depression Nec Insomnia Nec Suicide Attempt	Foreign Health Professional	Roaccutane	PS	Roche	ORAL		107

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

Date: 01/18/1996 ISR Number: 1691903-X Report Type: Expedited (15-Day) Company Report Number: 55633 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>
Life-Threatening	Depression Nec	Foreign	Roaccutane	PS	Roche	ORAL	35	206
Hospitalization - Initial or Prolonged	Suicide Attempt	Health Professional	Lexomil	SS	Upjohn	ORAL	18	
			Ludomil	C				
			Maprotiline	C				
Date: 01/30/1996 ISR Number: 1700773-2 Report Type: Expedited (15-Day) Company Report Number: 56829 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>
Life-Threatening	Suicide Attempt	Foreign	Roaccutane	PS	Roche	ORAL		122
		Health Professional						
Date: 02/27/1996 ISR Number: 1713235-3 Report Type: Expedited (15-Day) Company Report Number: 58392 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>
Life-Threatening	Amnesia Nec	Foreign	Accutane	PS	Roche	ORAL		62
Hospitalization - Initial or Prolonged	Major Depressive Disorder Nos	Health Professional						
Disability	Thinking Abnormal Nec							
Date: 02/23/1996 ISR Number: 1718090-3 Report Type: Expedited (15-Day) Company Report Number: 57993 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>
Hospitalization - Initial or Prolonged	Aphasia	Foreign	Roaccutane	PS	Roche	ORAL		150
	Cerebral Artery Thrombosis							
	Headache Nos							
	Hemiplegia							
Date: 03/06/1996 ISR Number: 1720890-0 Report Type: Expedited (15-Day) Company Report Number: 58625 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>
Hospitalization - Initial or Prolonged	Aphasia	Foreign	Roaccutane	PS	Roche	ORAL	20	89
	Cerebral Artery Thrombosis	Health Professional						
	Headache Nos							
	Hemiplegia							
Date: 04/30/1996 ISR Number: 1745385-X Report Type: Expedited (15-Day) Company Report Number: 61784 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>
Life-Threatening	Suicide Attempt	Health Professional	Accutane	PS	Roche	ORAL		

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

Date: 04/30/1996	ISR Number: 1747358-X	Report Type: Direct	Company Report Number:			Age: 22 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Suicide Attempt	Health Professional	Accutane	PS	Roche			37
Date: 06/13/1996	ISR Number: 1763027-4	Report Type: Periodic	Company Report Number: 950200692001			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Insomnia Nec	Health Professional	Accutane Kenalog	PS C	Roche			158 1
Date: 06/13/1996	ISR Number: 1763037-7	Report Type: Periodic	Company Report Number: 950200685001			Age: 21 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Condition Aggravated	Consumer	Accutane Ritalin	PS C	Roche	ORAL	80	22
Date: 06/18/1996	ISR Number: 1763058-4	Report Type: Expedited (15-Day)	Company Report Number: 63060			Age: 21 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health Professional	Roaccutane Trinordiol	PS C	Roche	ORAL	40	163
Date: 06/13/1996	ISR Number: 1763094-8	Report Type: Periodic	Company Report Number: 950200643001			Age: 34 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dyspareunia Nec Epistaxis Headache Nos Vaginal Discharge	Consumer	Accutane	PS	Roche	ORAL	20	118
Date: 06/13/1996	ISR Number: 1763098-5	Report Type: Periodic	Company Report Number: 950200636001			Age: 15 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos Hostility	Health Professional	Accutane Erythromycin	PS C	Roche	ORAL		
Date: 06/13/1996	ISR Number: 1763106-1	Report Type: Periodic	Company Report Number: 950200621001			Age: 29 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Bone Disorder Nos Depression Nec	Consumer	Accutane	PS	Roche	ORAL	80	

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

Date: 06/13/1996	ISR Number: 1763108-5	Report Type: Periodic	Company Report Number: 950200620001			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	Alopecia Condition Aggravated Emotional Disturbance Nos	Consumer	Accutane Amitriptyline	PS C	Roche	ORAL	80		
Date: 06/13/1996	ISR Number: 1763402-8	Report Type: Periodic	Company Report Number: 950200678001			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>	
Disability	Cheilitis Depression Nec Epistaxis Vomiting Nos	Consumer	Accutane	PS	Roche	ORAL	80		
Date: 06/13/1996	ISR Number: 1767948-8	Report Type: Periodic	Company Report Number: 51642			Age:	Gender: 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>	
Other	Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL			
Date: 06/13/1996	ISR Number: 1769065-X	Report Type: Periodic	Company Report Number: 61373			Age: 28 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 Anxiety Nec Dry Skin Tachycardia Nos	Health Professional	Accutane	PS	Roche	ORAL	40	71	
Date: 06/13/1996	ISR Number: 1769070-3	Report Type: Periodic	Company Report Number: 950200686001			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	Emotional Disturbance Nos	Consumer	Accutane	PS	Roche	ORAL	40		
Date: 06/13/1996	ISR Number: 1769071-5	Report Type: Periodic	Company Report Number: 43985			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	Health Professional	Accutane	PS	Roche	ORAL		91	
Date: 06/13/1996	ISR Number: 1769081-8	Report Type: Periodic	Company Report Number: 52188			Age: 18 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	Chest Pain Hypotension Palpitations Tachycardia Nos	Health Professional	Accutane Nyquil Desogen	PS C C	Roche	ORAL	40	51 1	

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

Date: 06/13/1996	ISR Number: 1769088-0	Report Type: Periodic	Company Report Number: 47315			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	Hostility Mania Nervousness Thinking Abnormal Nec	Health Professional	Accutane Demilen Anaprox	PS C C	Roche	ORAL	60	122
Date: 06/13/1996	ISR Number: 1769139-3	Report Type: Periodic	Company Report Number: 55348			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	Impotence	Health Professional	Accutane	PS	Roche	ORAL	10	
Date: 06/13/1996	ISR Number: 1769374-4	Report Type: Periodic	Company Report Number: 56892			Age: 14 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	Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL	40	62
Date: 06/13/1996	ISR Number: 1769385-9	Report Type: Periodic	Company Report Number: 56830			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>
Other	Dysphonia	Health Professional	Accutane	PS	Roche	ORAL	60	
Date: 06/13/1996	ISR Number: 1769404-X	Report Type: Periodic	Company Report Number: 57286			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	Personality Disorder Nos	Health Professional	Accutane Kenalog	PS C	Roche	ORAL	40	215
Date: 06/13/1996	ISR Number: 1769411-7	Report Type: Periodic	Company Report Number: 57292			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	Health Professional	Accutane Zolof Retin-A	PS C C	Roche	ORAL		182
Date: 06/13/1996	ISR Number: 1769472-5	Report Type: Periodic	Company Report Number: 57845			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	Agitation Emotional Disturbance Nos Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL	60	142

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

Date: 06/13/1996	ISR Number: 1769482-8	Report Type: Periodic	Company Report Number: 57900			Age: 30 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Tooth Disorder Nos Urine Abnormal Nos Vaginal Discharge	Consumer	Accutane	PS	Roche	ORAL	40	121
Date: 06/13/1996	ISR Number: 1769503-2	Report Type: Periodic	Company Report Number: 58042			Age: 42 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Conjunctivitis Nec Dermatitis Bulloos Emotional Disturbance Nos Seborrhoea	Consumer	Accutane Unipres Xanax	PS C C	Roche	ORAL	120	150
Date: 06/13/1996	ISR Number: 1769518-4	Report Type: Periodic	Company Report Number: 58218			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Depression Nec	Consumer	Accutane	PS	Roche	ORAL	50	
Date: 06/13/1996	ISR Number: 1769592-5	Report Type: Periodic	Company Report Number: 48220			Age: 19 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL	60	108
Date: 06/13/1996	ISR Number: 1769623-2	Report Type: Periodic	Company Report Number: 48842			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	60	85
Date: 06/13/1996	ISR Number: 1769689-X	Report Type: Periodic	Company Report Number: 49468			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Dermatitis Nos Emotional Disturbance Nos Pruritus	Consumer	Accutane	PS	Roche	ORAL		
Date: 06/13/1996	ISR Number: 1770987-4	Report Type: Periodic	Company Report Number: 50458			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Emotional Disturbance Nos Sedation	Consumer	Accutane	PS	Roche	ORAL	80	96

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

Date: 06/13/1996	ISR Number: 1771002-9	Report Type: Periodic	Company Report Number: 50548			Age: 37 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		118
Date: 06/13/1996	ISR Number: 1771105-9	Report Type: Periodic	Company Report Number: 46702			Age: 25 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Condition Aggravated Depression Nec Headache Nos	Consumer	Accutane Ativan	PS C	Roche	ORAL	20	65
Date: 06/13/1996	ISR Number: 1771152-7	Report Type: Periodic	Company Report Number: 53831			Age: 17 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec Headache Nos Menorrhagia Pruritus	Health Professional	Accutane	PS	Roche	ORAL	50	157
Date: 06/13/1996	ISR Number: 1771157-6	Report Type: Periodic	Company Report Number: 47029			Age: 15 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dysphonia Laryngitis Nos Pharyngitis Nos	Health Professional	Accutane	PS	Roche	ORAL		60
Date: 06/13/1996	ISR Number: 1771230-2	Report Type: Periodic	Company Report Number: 46616			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL	80	173
Date: 06/13/1996	ISR Number: 1771265-X	Report Type: Periodic	Company Report Number: 46069			Age: 19 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos Melaena	Consumer	Accutane Ventolin	PS C	Roche	ORAL	80	
Date: 06/13/1996	ISR Number: 1771285-5	Report Type: Periodic	Company Report Number: 43952			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Emotional Disturbance Nos Hostility	Consumer	Accutane	PS	Roche	ORAL	40	

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

Date: 06/13/1996	ISR Number: 1771325-3	Report Type: Periodic	Company Report Number: 45046			Age: 32 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthralgia Emotional Disturbance Nos Headache Nos Pain Nos	Consumer	Accutane	PS	Roche	ORAL	40	
Date: 06/13/1996	ISR Number: 1771347-2	Report Type: Periodic	Company Report Number: 44941			Age: 48 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Back Pain Depression Nec	Consumer	Accutane Capoten Clindamycin	PS C C	Roche	ORAL	80	
Date: 06/13/1996	ISR Number: 1771361-7	Report Type: Periodic	Company Report Number: 51284			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	40	112
Date: 06/13/1996	ISR Number: 1771372-1	Report Type: Periodic	Company Report Number: 51460			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	80	121
Date: 06/13/1996	ISR Number: 1771379-4	Report Type: Periodic	Company Report Number: 44384			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Thinking Abnormal Nec	Health Professional	Accutane Ventolin	PS C	Roche	ORAL		97
Date: 06/13/1996	ISR Number: 1771404-0	Report Type: Periodic	Company Report Number: 43915			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Conjunctivitis Nec Depression Nec Emotional Disturbance Nos Thinking Abnormal Nec	Consumer	Accutane	PS	Roche	ORAL	40	147
Date: 06/13/1996	ISR Number: 1771508-2	Report Type: Periodic	Company Report Number: 52417			Age: 19 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Palpitations Sedation	Consumer	Accutane	PS	Roche	ORAL		

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

Date: 06/13/1996	ISR Number: 1771509-4	Report Type: Periodic	Company Report Number: 52419			Age: 27 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Hepatic Function Abnormal Nos	Consumer	Accutane	PS	Roche	ORAL	80	182
Date: 06/13/1996	ISR Number: 1771523-9	Report Type: Periodic	Company Report Number: 52538			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL	40	188
Date: 06/13/1996	ISR Number: 1771557-4	Report Type: Periodic	Company Report Number: 52593			Age: 20 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Insomnia Nec Menstrual Disorder Nos Nervousness	Health Professional	Accutane Tavist D	PS C	Roche	ORAL	60	23
Date: 06/13/1996	ISR Number: 1771573-2	Report Type: Periodic	Company Report Number: 51277			Age: 25 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		44
Date: 06/13/1996	ISR Number: 1771616-6	Report Type: Periodic	Company Report Number: 52078			Age: 20 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amblyopia Nos Thinking Abnormal Nec	Health Professional	Accutane	PS	Roche	ORAL	60	
Date: 06/13/1996	ISR Number: 1771657-9	Report Type: Periodic	Company Report Number: 50868			Age: 31 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Palpitations	Health Professional	Accutane	PS	Roche	ORAL	20	
Date: 06/13/1996	ISR Number: 1771670-1	Report Type: Periodic	Company Report Number: 50875			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Consumer	Accutane Prozac	PS C	Roche	ORAL	120	121 133
Date: 06/13/1996	ISR Number: 1771675-0	Report Type: Periodic	Company Report Number: 52348			Age: 31 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Condition Aggravated	Health Professional	Accutane Xanax	PS C	Roche	ORAL	40	98

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

Date: 06/13/1996	ISR Number: 1771696-8	Report Type: Periodic	Company Report Number: 50978			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	Dry Skin Emotional Disturbance Nos Headache Nos	Consumer	Accutane	PS	Roche	ORAL	40	32
Date: 06/13/1996	ISR Number: 1771714-7	Report Type: Periodic	Company Report Number: 51000			Age: 64 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	Difficulty In Micturition Epistaxis Hyperglycaemia Nos Impotence	Consumer	Accutane Lopressor	PS C	Roche	ORAL	40	121
Date: 06/13/1996	ISR Number: 1771734-2	Report Type: Periodic	Company Report Number: 60241			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	Emotional Disturbance Nos Hyperkinetic Syndrome Joint Disorder Nos Rhinitis Nos	Consumer	Accutane	PS	Roche	ORAL	30	416
Date: 06/13/1996	ISR Number: 1771741-X	Report Type: Periodic	Company Report Number: 60330			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	Acne Nos Breast Enlargement Emotional Disturbance Nos Myalgia	Health Professional	Accutane	PS	Roche	ORAL	80	194
Date: 06/13/1996	ISR Number: 1771748-2	Report Type: Periodic	Company Report Number: 60066			Age: 22 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	Agitation Depression Nec	Consumer	Accutane	PS	Roche	ORAL	40	433
Date: 06/13/1996	ISR Number: 1771752-4	Report Type: Periodic	Company Report Number: 58876			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	Cough Palpitations	Consumer	Accutane	PS	Roche	ORAL		
Date: 06/13/1996	ISR Number: 1771753-6	Report Type: Periodic	Company Report Number: 58905			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	Migraine Nos Sleep Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL	60	140

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

Date: 06/13/1996	ISR Number: 1771754-8	Report Type: Periodic	Company Report Number: 58890			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	Libido Decreased	Health Professional	Accutane	PS	Roche	ORAL			
Date: 06/13/1996	ISR Number: 1771783-4	Report Type: Periodic	Company Report Number: 59009			Age: 14 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	80		
Date: 06/13/1996	ISR Number: 1771785-8	Report Type: Periodic	Company Report Number: 60323			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	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL			
Date: 06/13/1996	ISR Number: 1772242-5	Report Type: Periodic	Company Report Number: 58658			Age: 25 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	Amnesia Nec	Health Professional	Accutane	PS	Roche	ORAL	50	51	
			Denalea	C					
Date: 06/13/1996	ISR Number: 1772247-4	Report Type: Periodic	Company Report Number: 58651			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	Asthenia Insomnia Nec	Health Professional	Accutane	PS	Roche	ORAL	40		
Date: 06/13/1996	ISR Number: 1772470-9	Report Type: Periodic	Company Report Number: 60819			Age: 28 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	Amnesia Nec Rectal Bleeding Tremor Nec Vitreous Disorder Nos	Consumer	Accutane	PS	Roche	ORAL	1	184	
Date: 06/13/1996	ISR Number: 1772487-4	Report Type: Periodic	Company Report Number: 61036			Age: 28 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 Headache Nos Pain Nos Paresthesia Nec	Consumer	Accutane	PS	Roche	ORAL	80	111	

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

Date: 06/13/1996	ISR Number: 1772537-5	Report Type: Periodic	Company Report Number: 60875			Age: 17 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dry Eye Nec Emotional Disturbance Nos Refractive Errors Nos	Health Professional	Accutane	PS	Roche	ORAL	60	61
Date: 06/13/1996	ISR Number: 1772591-0	Report Type: Periodic	Company Report Number: 59965			Age: 52 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec	Health Professional	Accutane Tetracycline	PS C	Roche	ORAL	20	353
Date: 06/13/1996	ISR Number: 1772999-3	Report Type: Periodic	Company Report Number: 45203			Age: 14 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia Infection Nos Major Depressive Disorder Nos Myalgia	Health Professional	Accutane Kenalog Amoxil	PS C C	Roche	ORAL	60	82
Date: 06/13/1996	ISR Number: 1773008-2	Report Type: Periodic	Company Report Number: 50941			Age: 35 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blindness Night Cyst Nos Depression Nec Menstrual Disorder Nos	Consumer	Accutane Micronor Synthroid	PS C C	Roche	ORAL	80	92
Date: 06/13/1996	ISR Number: 1773013-6	Report Type: Periodic	Company Report Number: 50280			Age: 30 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amblyopia Nos Depression Nec Hypertonia Peripheral Neuropathy Nec	Health Professional	Accutane	PS	Roche	ORAL		246
Date: 06/13/1996	ISR Number: 1773022-7	Report Type: Periodic	Company Report Number: 50455			Age: 31 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Anxiety Nec Tremor Nec	Consumer	Accutane Xanax	PS C	Roche	ORAL	60	

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

Date: 06/13/1996	ISR Number: 1774354-9	Report Type: Periodic	Company Report Number: 59666			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Hostility	Health Professional	Accutane	PS	Roche	ORAL	40	146
Date: 06/13/1996	ISR Number: 1774506-8	Report Type: Periodic	Company Report Number: 53278			Age: 19 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Dry Eye Nec Dyspepsia Emotional Disturbance Nos	Consumer	Accutane	PS	Roche	ORAL		187
Date: 06/13/1996	ISR Number: 1774519-6	Report Type: Periodic	Company Report Number: 53405			Age: 20 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos	Health Professional	Accutane Darvocet-N Deltasone	PS C C	Roche	ORAL	40	
Date: 06/13/1996	ISR Number: 1774522-6	Report Type: Periodic	Company Report Number: 53284			Age: 25 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		
Date: 06/13/1996	ISR Number: 1774528-7	Report Type: Periodic	Company Report Number: 53568			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Ejaculation Disorder Nos Faccal Abnormality Nos Urinary Frequency	Health Professional	Accutane	PS	Roche	ORAL	80	61
Date: 06/13/1996	ISR Number: 1774745-6	Report Type: Periodic	Company Report Number: 54452			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Dreams Impotence	Health Professional	Accutane	PS	Roche	ORAL		
Date: 06/13/1996	ISR Number: 1774780-8	Report Type: Periodic	Company Report Number: 54534			Age: 48 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Insomnia Nec Myalgia	Consumer	Accutane Synthroid	PS C	Roche		40	697

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

Date: 06/13/1996		ISR Number: 1778108-9		Report Type: Periodic		Company Report Number: 54992		Age: 24 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Thinking Abnormal Nec	Consumer	Accutane Nytol	PS C	Roche	ORAL	80				
Date: 06/13/1996		ISR Number: 1778184-3		Report Type: Periodic		Company Report Number: 54800		Age: 39 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Breast Pain Depression Nec Epistaxis Menstrual Disorder Nos	Consumer	Accutane Prednisone	PS C	Roche	ORAL	60	123 1			
Date: 06/13/1996		ISR Number: 1778216-2		Report Type: Periodic		Company Report Number: 56403		Age: 37 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Appetite Increased Depression Nec Emotional Disturbance Nos Flatulence	Consumer	Accutane	PS	Roche	ORAL	40				
Date: 06/13/1996		ISR Number: 1778231-9		Report Type: Periodic		Company Report Number: 56187		Age: 18 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Amblyopia Nos Depression Nec Dry Skin Emotional Disturbance Nos	Consumer	Accutane	PS	Roche	ORAL	80	35			
Date: 06/13/1996		ISR Number: 1778308-8		Report Type: Periodic		Company Report Number: 55937		Age: 35 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Emotional Disturbance Nos Hypersensitivity Nos Palpitations Rectal Bleeding	Health Professional	Accutane	PS	Roche	ORAL	40	9			
Date: 06/13/1996		ISR Number: 1778442-2		Report Type: Periodic		Company Report Number: 56812		Age: 25 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Libido Decreased	Health Professional	Accutane	PS	Roche	ORAL					

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

Date: 06/13/1996	ISR Number: 1778533-6	Report Type: Periodic	Company Report Number: 53042	Age: 40 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Nervousness	Health Professional	Accutane	PS	Roche	ORAL	20	13
Date: 09/18/1996	ISR Number: 1795768-7	Report Type: Expedited (15-Day)	Company Report Number: 67928	Age: 25 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Disability	Confusion Depression Nec Emotional Disturbance Nos Thinking Abnormal Nec	Health Professional	Accutane	PS	Roche	ORAL	80	124
Date: 09/10/1996	ISR Number: 1801886-7	Report Type: Expedited (15-Day)	Company Report Number: 67453	Age: 28 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aphasia Confusion Headache Nos Vomiting Nos	Health Professional	Accutane	PS	Roche	ORAL	80	5
Date: 10/01/1996	ISR Number: 1820874-8	Report Type: Expedited (15-Day)	Company Report Number: 68681	Age: 16 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Major Depressive Disorder Nos Suicide Attempt	Foreign Health Professional	Roacutane Diane	PS C	Roche	ORAL	20	
Date: 11/20/1996	ISR Number: 1841822-0	Report Type: Expedited (15-Day)	Company Report Number: 71977	Age: 15 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Dysarthria Headache Nos Paresthesia Nec Peripheral Neuropathy Nec	Foreign Health Professional	Roacutane	PS	Roche	ORAL	35	9
Date: 11/12/1996	ISR Number: 1847288-9	Report Type: Expedited (15-Day)	Company Report Number: 68760	Age: 17 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Suicide Attempt Thinking Abnormal Nec	Foreign	Roacutane	PS	Roche	ORAL	40	86

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

Date: 11/12/1996	ISR Number: 1847313-5	Report Type: Expedited (15-Day)	Company Report Number: 68764	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Psychotic Disorder Nos	Foreign	Roscutane	PS	Roche	ORAL	60	87
Date: 12/09/1996	ISR Number: 1847904-1	Report Type: Expedited (15-Day)	Company Report Number: 72443	Age: 20 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Noc Suicide Attempt	Foreign Health Professional	Roscutane	PS	Roche	ORAL		
Date: 11/07/1996	ISR Number: 1848747-5	Report Type: Expedited (15-Day)	Company Report Number: 71105	Age: 17 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Extrapyramidal Disorder Nec Insomnia Nec Mydriasis Pain Nos	Foreign Health Professional	Roscutane Vitamin C Acetaminophen	PS C C	Roche	ORAL		
Date: 11/12/1996	ISR Number: 1849153-X	Report Type: Expedited (15-Day)	Company Report Number: 71470	Age: 26 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Suicide Attempt	Foreign Health Professional	Roscutane Prednisone	PS C	Roche	ORAL	100	148 64
Date: 12/10/1996	ISR Number: 1849258-3	Report Type: Expedited (15-Day)	Company Report Number: 72895	Age:	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Amblyopia Nos Ataxia Nec Thinking Abnormal Nec Tinnitus	Consumer	Accutane Phenergan Prozac Lortab Baclofen	PS C C C C	Roche	ORAL	80	3
Date: 12/26/1996	ISR Number: 1869957-7	Report Type: Expedited (15-Day)	Company Report Number: 73516	Age: 15 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aphasia Laboratory Test Abnormal Nos Migraine Nos Peripheral Neuropathy Nec	Foreign Health Professional	Roscutane	PS	Roche	ORAL	35	10

**FDA Adverse Event Reporting System (AERS)
Exemption Of Information (EOI) Report**

Date: 03/11/1997	ISR Number: 1891089-2	Report Type: Expedited (15-Day)	Company Report Number: 76693	Age: 15 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Suicide Attempt	Foreign Health Professional	Roacutane	PS	Roche	ORAL		367
Date: 01/21/1997	ISR Number: 1896111-5	Report Type: Expedited (15-Day)	Company Report Number: 63416	Age: 42 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Myalgia Peripheral Neuropathy Nec Rhinitis Nos	Consumer	Accutane Librium Norpramin	PS SS C	Roche Roche	ORAL	10	71
Date: 01/24/1997	ISR Number: 1899346-0	Report Type: Expedited (15-Day)	Company Report Number: 74849	Age:	Gender: Unknown			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Congenital Anomaly	Blindness Nec Congenital Abnormality Nos Congenital Central Nervous System Anomaly Nos Mental Retardation Severity Unspecified	Foreign	Roacutane	PS	Roche	TRANSPLA CENTAL		14
Date: 02/11/1997	ISR Number: 1906164-3	Report Type: Periodic	Company Report Number: 896290007N	Age: 32 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Acne Nos Benign Intracranial Hypertension Depression Nec Weight Increased	Consumer	Norplant Accutane	PS SS	Wyeth Roche	SUBCUTAN EOUS ORAL		426
Date: 05/20/1997	ISR Number: 1924247-9	Report Type: Expedited (15-Day)	Company Report Number: 80953	Age: 13 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt		Accutane	PS	Roche	ORAL	40	14
Date: 04/28/1997	ISR Number: 1924269-8	Report Type: Expedited (15-Day)	Company Report Number: 80102	Age: 21 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Paranoia Psychotic Disorder Nos	Foreign	Roacutane	PS	Roche	ORAL		62