

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

Date	ISR Number	Report Type	Company Report Number	Age	Gender			
06/09/2000	3516870-5	Periodic	211056	31 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Alopecia Depressed Mood Depression Nec Fatigue Lethargy	Consumer	Accutane Ortho Tri-Cyclen (Ethinyl Estradiol / Norgestimate)	PS C	Hlr Technology	ORAL		
06/09/2000	3516878-X	Periodic	211310	42 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec Hypercholesterolaemia Mood Swings	Consumer Health Professional Other	Accutane	PS	Hlr Technology	ORAL		
06/09/2000	3516881-X	Periodic	211314	28 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec Haemorrhage Nos Lip Disorder Nos Localised Exfoliation Mood Alteration Nos Scar	Consumer Other	Accutane Ortho-Novum (Ethinyl Estradiol / Norethindrone) Synthroid (Levothyroxine Sodium)	PS C C	Hlr Technology	ORAL		
06/09/2000	3516885-7	Periodic	217396		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	Dysuria Lip Dry Mood Swings Rectal Bleeding Weight Decreased	Consumer	Accutane	PS	Hlr Technology	ORAL		
06/09/2000	3516891-2	Periodic	211466	34 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Aggravated Lethargy	Consumer Health Professional Other	Accutane	PS	Hlr Technology	ORAL		

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

Date: 06/09/2000		ISR Number: 3516904-8		Report Type: Periodic		Company Report Number: 212182		Age: 21 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Acne Aggravated Depression Nec Dry Skin Eczema Nos Epidermal Naevus Epistaxis Erythema Nec Lip Dry Skin Depigmentation Sunburn Xerosis	Consumer Health Professional Other	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3516928-0		Report Type: Periodic		Company Report Number: 217589		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	Nightmare	Health Professional	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3516932-2		Report Type: Periodic		Company Report Number: 217597		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	Irritable Bowel Syndrome	Other	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3516933-4		Report Type: Periodic		Company Report Number: 217606		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	Irritable Bowel Syndrome	Consumer	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3516934-6		Report Type: Periodic		Company Report Number: 217607		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	Irritable Bowel Syndrome	Other	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3516938-3		Report Type: Periodic		Company Report Number: 217675		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	Abdominal Pain Nos Dizziness (Exc Vertigo) Dry Skin Fatigue Mood Swings Thirst	Other	Accutane Ortho-Cept (Desogestrel/Ethinyl Estradiol)	PS C	Hlr Technology	ORAL					

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

Date: 06/09/2000	ISR Number: 3516946-2	Report Type: Periodic	Company Report Number: 217964			Age:	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Arthralgia Back Pain Blood Cholesterol Increased Depression Nec Dermatitis Nos Muscle Spasms	Consumer	Accutane Claritin (Loratadine) Cataflam (Diclofenac Potassium)	PS C C	Hlr Technology	ORAL			
Date: 06/09/2000	ISR Number: 3516955-3	Report Type: Periodic	Company Report Number: 202654			Age: 34 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Disturbance In Attention Nec Fatigue	Consumer	Accutane Ortho-Tricyclen (Ethiny) Estradio/Norgestimate)	PS C	Hlr Technology	ORAL			
Date: 06/09/2000	ISR Number: 3516995-4	Report Type: Periodic	Company Report Number: 202809			Age: 28 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Constipation Depression Nec	Consumer	Accutane	PS	Hlr Technology	ORAL			
Date: 06/09/2000	ISR Number: 3517003-1	Report Type: Periodic	Company Report Number: 233472			Age: 17 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Apathy Depression Nec Fatigue Mood Swings	Consumer	Accutane Accutane Accutane Accutane Claritin	PS SS SS SS C	Hlr Technology	ORAL			
Date: 06/09/2000	ISR Number: 3517006-7	Report Type: Periodic	Company Report Number: 202997			Age: 17 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Emuresis	Health Professional	Accutane	PS	Hlr Technology	ORAL			
Date: 06/09/2000	ISR Number: 3517010-9	Report Type: Periodic	Company Report Number: 233483			Age:	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Depression Nec Diarhoea Nos Dizziness (Exc Vertigo) Headache Nos Irritability	Consumer Other	Accutane	PS	Hlr Technology	ORAL			

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

Date: 06/09/2000		ISR Number: 3517016-X		Report Type: Periodic		Company Report Number: 203339		Age:		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Alopecia	Consumer	Accutane	PS	Hlr Technology	ORAL					
	Arthralgia	Health Professional	Pamate (Tranlycypromine Sulfate)	C							
	Arthropod Bite		Prozac (Fluoxetine Hydrochloride)	C							
	Aspartate Aminotransferase Increased		Benzamycin (Benzoyl Peroxide/Erythromycin)	C							
	Breast Tenderness		Xanax (Alprazolam)	C							
	Cheilitis		Desowen Ointment (Desonide)	C							
	Condition Aggravated		Aquaphor (Ceresin/Mineral Oil/Petrolatum/Wool Alcohol Or Xipamide)	C							
	Confusion		Advil (Ibuprofen)	C							
	Depression Aggravated		Spectazole (Econazole Nitrate)	C							
	Dermatitis Nos		Cutivate Ointment (Fluticasone Propionate)	C							
	Dry Skin		Terazol Suppositories (Terconazole)	C							
	Epistaxis										
	Fatigue										
	Lacrimation Increased										
	Lip Dry										
	Memory Impairment										
	Mental Impairment Nos										
	Mood Disorder Nos										
	Panic Attack										
	Pruritus										
	Rhinorrhoea										
	Vaginal Candidiasis										
	Vision Blurred										

Date: 06/09/2000		ISR Number: 3517027-4		Report Type: Periodic		Company Report Number: 233669		Age: 50 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Acne Aggravated	Consumer	Accutane	PS	Hlr Technology	ORAL					
	Anxiety Nec		Synthroid	C							
	Dermatitis Nos										
	Lip Dry										
	Skin Disorder Nos										

Date: 06/09/2000		ISR Number: 3517055-9		Report Type: Periodic		Company Report Number: 203625		Age: 14 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Back Pain	Health Professional	Accutane	PS	Hlr Technology	ORAL					
	Depression Nec		Birth Control Pills (Oral Contraceptive Nos)	C							
	Headache Nos										
	Ingrowing Nail										
	Localized Exfoliation										

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

Date: 06/09/2000	ISR Number: 3517081-X	Report Type: Periodic	Company Report Number: 230065			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Nightmare	Health Professional	Accutane	PS	HlrTechnology	OPHTHAL MIC		
Date: 06/09/2000	ISR Number: 3517101-2	Report Type: Periodic	Company Report Number: 230612			Age: 14 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Cholesterol Increased Depression Nec Lip Dry Low Density Lipoprotein Increased Throat Oedema	Consumer	Accutane	PS	HlrTechnology	ORAL		
Date: 06/09/2000	ISR Number: 3517155-3	Report Type: Periodic	Company Report Number: 229184			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Memory Impairment	Health Professional	Accutane	PS	HlrTechnology	ORAL		
Date: 06/09/2000	ISR Number: 3517160-7	Report Type: Periodic	Company Report Number: 229270			Age: 32 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Disturbance In Attention Nec Dizziness (Exc Vertigo) Feeling Abnormal Headache Nos Tired Eyes Vision Blurred	Consumer	Accutane	PS	HlrTechnology	ORAL		
Date: 06/09/2000	ISR Number: 3517222-4	Report Type: Periodic	Company Report Number: 229610			Age: 41 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Obsessive-Compulsive Disorder	Consumer Other	Accutane Lithium Anafranil Prozac Xanax Ambien (Zolpidem Tartrate)	PS C C C C C	HlrTechnology	ORAL		

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

Date: 06/09/2000	ISR Number: 3517352-7	Report Type: Periodic	Company Report Number: 97451			Age: 18 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Depression Nec Suicide Attempt	Health Professional	Accutane Demlen (Ethinyl Estradiol/Ethinodiol Diacetate)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3517353-9	Report Type: Periodic	Company Report Number: 233868			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos Back Pain Cheilitis Depression Nec Emotional Disturbance Nos Pruritus	Consumer	Accutane Ventolin (Albuterol And Albuterol Sulfate) Albuterol (Albuterol)	PS C C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3517354-0	Report Type: Periodic	Company Report Number: 233875			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Immune System Disorder Nos Infectious Mononucleosis	Consumer	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3517355-2	Report Type: Periodic	Company Report Number: 233923			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Nightmare	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3517359-X	Report Type: Periodic	Company Report Number: 94154			Age: 19 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos Aggression Back Pain Blood Triglycerides Increased Depression Nec Dermatitis Nos Dry Eye Nec Dry Skin Epistaxis Erythema Nec Flushing Localised Exfoliation Mood Alteration Nos	Consumer Health Professional Other	Accutane Echinacea (Echinacea) Amino Acid (Amino Acid)	PS C C	Hlr Technology	ORAL		

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

Date	ISR Number	Report Type	Company Report Number	Age	Gender			
06/09/2000	3517360-6	Periodic	95402	14 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>
Life-Threatening	Abdominal Pain Nos Mood Alteration Nos Suicide Attempt Vomiting Nos Weight Decreased	Other	Acetane Aleve (Naproxen Sodium) Ibuprofen (Ibuprofen) Tylenol (Acetaminophen)	PS C C C	Hlr Technology	ORAL		
06/09/2000	3517365-5	Periodic	109710	16 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Blood Alkaline Phosphatase Nos Increased Blood Iron Decreased Costochondritis Dermatitis Nos Dry Skin Emotional Disturbance Nos Epistaxis Erythrocyte Sedimentation Rate Increased Gait Festinating Hypertrophic Scar Lip Dry Malaise Musculoskeletal Disorder Nos Sacroiliitis Skin Chapped White Blood Cell Count Decreased White Blood Cell Count Increased	Health Professional	Acetane Voltaren (Diclofenac Sodium)	PS C	Hlr Technology	ORAL		
06/09/2000	3517464-8	Periodic	200150	17 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec Erythema Nec Suicidal Ideation	Health Professional	Acetane	PS	Hlr Technology	ORAL		
06/09/2000	3517470-3	Periodic	200762	18 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Condition Aggravated Depression Aggravated Mood Swings	Health Professional	Acetane	PS	Hlr Technology	ORAL		

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FDA Adverse Event Reporting System (FAERS)
 Product of Information (POI) Report

Date: 06/09/2000		ISR Number: 3517475-2		Report Type: Periodic		Company Report Number: 200892		Age: 47 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Arthralgia	Consumer	Accutane	PS	Hlr Technology	ORAL					
	Blood Cholesterol Increased	Health Professional	Prozac (Fluoxetine Hydrochloride)	C							
	Depression Aggravated		Serzone (Nefazodone Hydrochloride)	C							
	Herpes Simplex		Dexedrine (Dextroamphetamine Sulfate)	C							
	Lip Dry										
	White Blood Cell Count Decreased										
Date: 06/09/2000		ISR Number: 3517487-9		Report Type: Periodic		Company Report Number: 201524		Age:		Gender:	
<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	Hlr Technology	ORAL					
	Erythema Nec	Other									
	Skin Lesion Nos										
Date: 06/09/2000		ISR Number: 3517490-9		Report Type: Periodic		Company Report Number: 202222		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>			
Other	Anxiety Nec	Consumer	Accutane	PS	Hlr Technology	ORAL					
	Depression Aggravated		Accutane	SS							
	Panic Attack		Ortho Tri-Cyclen (Ethinyl Estradiol/Norgestimate)	C							
	Suicidal Ideation		Alesse (Ethinyl Estradiol/Levonorgestrel)	C							
Date: 06/09/2000		ISR Number: 3517492-2		Report Type: Periodic		Company Report Number: 202355		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>			
Other	Hypertriglyceridaemia	Consumer	Accutane	PS	Hlr Technology	ORAL					
	Mood Swings	Health Professional									
Date: 06/09/2000		ISR Number: 3517501-0		Report Type: Periodic		Company Report Number: 203250		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	Depression Suicidal	Consumer	Accutane	PS	Hlr Technology	ORAL					
	Suicidal Ideation	Health Professional									
Date: 06/09/2000		ISR Number: 3517505-8		Report Type: Periodic		Company Report Number: 203618		Age: 15 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Depression Nec	Health Professional	Accutane	PS	Hlr Technology	ORAL					

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

Date: 06/09/2000	ISR Number: 3517507-1	Report Type: Periodic	Company Report Number: 203730			Age: 25 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Body Image Disorder Suicidal Ideation	Health Professional	Accutane	PS	HlrTechnology	ORAL		
Date: 06/09/2000	ISR Number: 3517521-6	Report Type: Periodic	Company Report Number: 207180			Age: 48 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Triglycerides Increased Disturbance In Attention Nec Eye Irritation Headache Nos Nasopharyngitis Peripheral Coldness Rigors Sinus Pain Vision Blurred	Consumer	Accutane	PS	HlrTechnology	ORAL		
Date: 06/09/2000	ISR Number: 3517527-7	Report Type: Periodic	Company Report Number: 77776			Age: 34 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Osteoma	Health Professional	Accutane	PS	HlrTechnology	ORAL		
Date: 06/09/2000	ISR Number: 3517534-4	Report Type: Periodic	Company Report Number: 92242			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos Aggression Confusion Dermatitis Nos Dry Skin Increased Activity Memory Impairment Mucous Membrane Disorder Nos Red Eye	Other	Accutane	PS		ORAL		
Date: 06/09/2000	ISR Number: 3517547-2	Report Type: Periodic	Company Report Number: 96290			Age: 39 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Arthralgia Arthritis Nos Blepharitis	Consumer Health Professional	Accutane Dhea (Prasterone) Vitamin A (Vitamin A)	PS C C	HlrTechnology	ORAL		

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FD-302 (Rev. 05-08-10) Reporting System (A-F) (PS)
 Prescription Information (PDR) Report

Date: 06/09/2000		ISR Number: 3517588-5		Report Type: Periodic		Company Report Number: 102135		Age: 34 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Alopecia Bone Disorder Nos Depression Nec Dry Skin Lip Dry Mood Swings Rash Erythematous White Blood Cell Count Decreased	Consumer	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000											
ISR Number: 3517617-9		Report Type: Periodic		Company Report Number: 108796		Age: 35 YR		Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Anger Depression Nec Mood Swings Urticaria Nos	Other	Accutane Entex (Guafenesin/Phenylephrine Hydrochloride/Phenylpropanolamine Hydrochloride) Zyrtec (Cetirizine Hydrochloride) Desogen (Desogestrel/Ethinyl Estradiol)	PS C C C	Hlr Technology	ORAL					
Date: 06/09/2000											
ISR Number: 3517618-0		Report Type: Periodic		Company Report Number: 110731		Age: 21 YR		Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Depression Nec Liver Function Tests Nos Abnormal Menstruation Irregular Mood Swings Smear Cervix Abnormal	Consumer Health Professional Other	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000											
ISR Number: 3517832-4		Report Type: Periodic		Company Report Number: 227113		Age: 27 YR		Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Acne Aggravated Arthralgia Back Pain Contact Lens Intolerance Depression Nec Dry Eye Nec Tearfulness	Consumer Other	Accutane Birth Control Pill (Oral Contraceptive Noe)	PS C	Hlr Technology	ORAL					

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

Date: 06/09/2000	ISR Number: 3517847-6	Report Type: Periodic	Company Report Number: 227337			Age: 19 YR	Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Erectile Disturbance Loss Of Libido Psychosexual Disorder Nos	Consumer	Accutane Herbal Supplements (Herbal Supplement)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3517851-8	Report Type: Periodic	Company Report Number: 227347			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	Burns Nos Capillary Fragility Increased Hyperaesthesia Mood Alteration Nos	Consumer	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3517858-0	Report Type: Periodic	Company Report Number: 227620			Age: 14 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	Aggression Mood Alteration Nos	Consumer	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3517863-4	Report Type: Periodic	Company Report Number: 228093			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	Depression Nec Disturbance In Attention Nec Fatigue Mood Swings	Consumer	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3517866-X	Report Type: Periodic	Company Report Number: 228172			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	Mood Swings Tooth Disorder Nos	Consumer	Accutane Loestrin (Ethinyl Estradiol / Norethindrone Acetate)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3517874-9	Report Type: Periodic	Company Report Number: 228345			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	Acne Aggravated Fatigue Milia Mood Swings Seborrhoea	Consumer	Accutane	PS	Hlr Technology	ORAL		

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

Date: 06/09/2000		ISR Number: 3518467-X		Report Type: Periodic		Company Report Number: 222162		Age: 17 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Abdominal Pain Upper Depression Nec Dry Eye Nec Headache Nos Mood Alteration Nos Red Eye Vomiting Nos	Consumer	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3518468-1		Report Type: Periodic		Company Report Number: 222374		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	Blindness Night Depression Nec Dry Eye Nec Dry Skin Erythema Nec Fatigue Feeling Hot Headache Nos Oedema Lower Limb Photopsia Weakness	Consumer	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3518472-3		Report Type: Periodic		Company Report Number: 222584		Age: 32 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Dry Eye Nec Eye Pain Fatigue Headache Nos Lip Dry Myalgia Nervousness Weakness	Consumer	Accutane Allegra (Fexofenadine Hydrochloride)	PS C	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3518490-5		Report Type: Periodic		Company Report Number: 222959		Age: 12 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Arthralgia Arthritis Nos Mental Disorder Nec	Health Professional	Accutane	PS	Hlr Technology	ORAL					

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U.S. Food & Drug Administration
 Division of Information (D-1) Report

Date: 06/09/2000		ISR Number: 3518905-2		Report Type: Periodic		Company Report Number: 221209		Age: 43 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Depression Aggravated	Consumer	Accutane	PS	Hlr Technology	ORAL					
		Health Professional									
		Other									
Date: 06/09/2000		ISR Number: 3518927-1		Report Type: Periodic		Company Report Number: 221428		Age: 22 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Depression Nec	Consumer	Accutane	PS	Hlr Technology	ORAL					
	Mood Swings	Other									
Date: 06/09/2000		ISR Number: 3518931-3		Report Type: Periodic		Company Report Number: 221548		Age:		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Alopecia	Consumer	Accutane	PS	Hlr Technology	ORAL					
	Amnesia Nec										
	Arthralgia										
	Blood Phosphate Increased										
	Depression Nec										
	Visual Disturbance Nos										
Date: 06/09/2000		ISR Number: 3518941-6		Report Type: Periodic		Company Report Number: 222334		Age: 15 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Intentional Self-Injury	Health Professional	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3518942-8		Report Type: Periodic		Company Report Number: 222824		Age:		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Abnormal Behaviour Nos	Company Representative	Accutane	PS	Hlr Technology	ORAL					
	Depression Nec										
	Suicidal Ideation										
	Thinking Abnormal Nec										
Date: 06/09/2000		ISR Number: 3518944-1		Report Type: Periodic		Company Report Number: 223439		Age: 19 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Depression Nec	Consumer	Accutane	PS	Hlr Technology	ORAL					
		Health Professional									
		Other									

FD-302a (Rev. 05-08-10) Reporting Suspected Adverse
 Events (SUSPECTED ADVERSE REACTIONS) (SARs)
 Department of Information (DOI) Form

Date: 06/09/2000	ISR Number: 3518946-5	Report Type: Periodic	Company Report Number: 223640	Age: 28 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Lip Dry	Other	Accutane Ortho Tri-Cyclen	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3518949-0	Report Type: Periodic	Company Report Number: 223645	Age: 26 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Depression Nec Fatigue	Health Professional Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3518950-7	Report Type: Periodic	Company Report Number: 223647	Age: 23 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Dry Skin Lip Dry	Consumer Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3518951-9	Report Type: Periodic	Company Report Number: 223649	Age: 15 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Suicidal	Consumer Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3518952-0	Report Type: Periodic	Company Report Number: 223668	Age:	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec Panic Attack	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3518954-4	Report Type: Periodic	Company Report Number: 223115	Age: 31 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthma Aggravated Depression Aggravated Dry Eye Nec Dry Skin Epistaxis Folliculitis Impaired Healing Lip Dry Pulmonary Congestion Sims Congestion Urethral Disorder Nos	Consumer	Accutane	PS	Hlr Technology	ORAL		

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

Date: 06/09/2000		ISR Number: 3518955-6		Report Type: Periodic		Company Report Number: 223256		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	Apathy Appetite Increased Depression Nec Fatigue Weight Increased	Consumer Other	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3518963-5		Report Type: Periodic		Company Report Number: 223489		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	Abdominal Distension Appetite Increased Fatigue Irritability Weight Increased	Consumer	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3518979-9		Report Type: Periodic		Company Report Number: 224286		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	Anxiety Nec Feeling Abnormal Feeling Jittery Tired Eyes	Consumer	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3518982-9		Report Type: Periodic		Company Report Number: 224321		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	Blister Depression Nec Eating Disorder Nec Epistaxis Face Oedema Lip Dry Mood Alteration Nos Sedation	Consumer	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3518984-2		Report Type: Periodic		Company Report Number: 224348		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	Depression Nec Mood Swings Panic Attack	Other	Accutane	PS	Hlr Technology	ORAL					

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

Date: 06/09/2000	ISR Number: 3518992-1	Report Type: Periodic	Company Report Number: 221113			Age: 16 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Anger Crying Depression Nec	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3518995-7	Report Type: Periodic	Company Report Number: 221147			Age: 16 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Aggravated Depression Nec Educational Problem Personality Change	Consumer Health Professional Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3518998-2	Report Type: Periodic	Company Report Number: 221159			Age: 56 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Appetite Decreased Depression Nec Influenza Like Illness	Health Professional Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519003-4	Report Type: Periodic	Company Report Number: 221193			Age: 19 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood In Stool Chest Pressure Sensation Emotional Disturbance Nos Epistaxis Eye Disorder Nos Lip Dry Myalgia Tendonitis	Consumer Health Professional Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519007-1	Report Type: Periodic	Company Report Number: 221299			Age: 14 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos Aspartate Aminotransferase Increased Headache Nos Suicidal Ideation	Other	Accutane	PS	Hlr Technology	ORAL		

FDA Adverse Event Reporting System (AERS)
 Event Information (OI) Report

Date: 06/09/2000	ISR Number: 3519010-1	Report Type: Periodic	Company Report Number: 221339	Age: 21 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec Dry Eye Nec Dry Mouth Dry Skin Dry Throat Paranoia Pruritus Vulvovaginal Dryness Yellow Skin	Other	Accutane Ortho Tri-Cyclen	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519011-3	Report Type: Periodic	Company Report Number: 224284	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	Anxiety Nec Depression Nec Dry Skin Fatigue Increased Activity Lip Dry Nausea Suicidal Ideation	Consumer	Accutane Minocyclin (Minocycline)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519016-2	Report Type: Periodic	Company Report Number: 225430	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	Alopecia Breast Tenderness Depression Aggravated Dry Skin Gum Pain Headache Nos Pain Nos	Consumer	Accutane Estrogen Patches (Estrogens Nos)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519018-6	Report Type: Periodic	Company Report Number: 224765	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	Depression Nec Homosexuality	Health Professional	Accutane	PS	Hlr Technology	ORAL		

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

Date: 06/09/2000 ISR Number: 3519023-X Report Type: Periodic Company Report Number: 225591 Age: 31 YR Gender: Female								
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Appetite Decreased Depression Nec Fatigue Influenza Insomnia Nec Nausea Nipple Pain Thirst Vaginitis Vomiting Nos Weight Decreased	Other	Accutane Oral Contraceptive Pill (Oral Contraceptive Nos) Vitamins (Multivitamin Nos)	PS C C	Hlr Technology	ORAL		
Date: 06/09/2000 ISR Number: 3519049-6 Report Type: Periodic Company Report Number: 225600 Age: 15 YR Gender: Male								
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Abnormal Behaviour Nos Hallucination Nos Psychotic Disorder Nos	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000 ISR Number: 3519058-7 Report Type: Periodic Company Report Number: 225721 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	Depression Aggravated Epistaxis Hair Growth Abnormal Joint Stiffness Lip Dry Skin Chapped Weight Increased	Health Professional Other	Accutane Lo/Ovral (Ethinyl Estradiol/Norgestrel)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000 ISR Number: 3519063-0 Report Type: Periodic Company Report Number: 225806 Age: 15 YR Gender: Female								
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Malaise Mood Swings	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000 ISR Number: 3519071-X Report Type: Periodic Company Report Number: 226012 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	Personality Change	Consumer	Accutane	PS	Hlr Technology	ORAL		

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

Date: 06/09/2000	ISR Number: 3519075-7	Report Type: Periodic	Company Report Number: 226637	Age: 17 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Drug Interaction Nos Schizophrenia Nos Aggravated	Health Professional	Accutane Zyprexa	PS SS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519078-2	Report Type: Periodic	Company Report Number: 226658	Age: 24 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	C-Reactive Protein Increased Decreased Activity Erythrocyte Sedimentation Rate Increased Fatigue Hypoesthesia Joint Stiffness Muscle Weakness Pain Nos Streptococcal Infection Nos Streptolysin O Antibody Positive	Health Professional	Accutane Zithromax (Azithromycin)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519084-8	Report Type: Periodic	Company Report Number: 226732	Age: 24 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dermatitis Nos Epistaxis Hair Texture Abnormal Headache Nos Insomnia Nec Lip Dry Skin Disorder Nos Vein Disorder Nos	Consumer	Accutane Ortho Tri Cyclen (Ethinyl Estradiol/Norgestimate)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519087-3	Report Type: Periodic	Company Report Number: 226981	Age: 23 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Amnesia Nec Anxiety Nec Depression Nec Fatigue	Consumer Health Professional Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519089-7	Report Type: Periodic	Company Report Number: 227032	Age: 13 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Appetite Increased	Consumer	Accutane	PS		ORAL		

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Adverse Event Reporting System (AERS)
 Patient Information (PI) Report

Date: 06/09/2000	ISR Number: 3519090-3	Report Type: Periodic	Company Report Number: 227070		Age: 26 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose/Unit Duration
Other	Depression Nec Hypersensitivity Nos Insomnia Nec	Consumer	Accutane	PS	Hlr Technology	ORAL
Date: 06/09/2000	ISR Number: 3519092-7	Report Type: Periodic	Company Report Number: 227109		Age: 28 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose/Unit Duration
Other	Acne Aggravated Depression Nec Dry Skin	Health Professional Other	Accutane Wellbutrin (Bupropion Hydrochloride) Adderall (Amphetamine Aspartate / Amphetamine Sulfate / Dextroamphetamine Sacchara / Dextroamphetamine Cylert (Pemoline)	PS C C C	Hlr Technology	ORAL
Date: 06/09/2000	ISR Number: 3519095-2	Report Type: Periodic	Company Report Number: 227353		Age: 22 YR	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose/Unit Duration
Other	Dry Skin Emotional Disturbance Nos Insomnia Nec Lip Dry Palpitations Suicidal Ideation	Consumer	Accutane	PS	Hlr Technology	ORAL
Date: 06/09/2000	ISR Number: 3519096-4	Report Type: Periodic	Company Report Number: 233229		Age: 16 YR	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose/Unit Duration
Death	Aggression Agitation Confusion Depression Nec Irritability Suicidal Ideation	Other	Accutane	PS		ORAL
Date: 06/09/2000	ISR Number: 3519100-3	Report Type: Periodic	Company Report Number: 232008		Age:	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose/Unit Duration
Other	Depression Nec Suicidal Ideation	Health Professional	Accutane	PS	Hlr Technology	ORAL

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

Date: 06/09/2000	ISR Number: 3519102-7	Report Type: Periodic	Company Report Number: 232323			Age: 20 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Depression Nec	Other	Accutane Birth Control Pill (Oral Contraceptive Nos)	PS C C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519105-2	Report Type: Periodic	Company Report Number: 232431			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Psychotic Disorder Nos	Health Professional	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519106-4	Report Type: Periodic	Company Report Number: 232494			Age: 18 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Delusion Nos Disturbance In Attention Nec Emotional Disturbance Nos Paranoia Psychotic Disorder Nos Short-Term Memory Loss	Consumer Health Professional	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519108-8	Report Type: Periodic	Company Report Number: 232571			Age: 36 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Suicidal Ideation	Other	Accutane Birth Control Pills (Oral Contraceptive Nos)	PS C C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519110-6	Report Type: Periodic	Company Report Number: 232612			Age: 17 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519113-1	Report Type: Periodic	Company Report Number: 204094			Age: 15 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Hallucination, Auditory Insomnia Nec Schizophrenia Nos	Health Professional	Accutane	PS	Hlr Technology	ORAL		

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

Date: 06/09/2000	ISR Number: 3519115-5	Report Type: Periodic	Company Report Number: 233167			Age: 31 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Crying Depression Nec Hair Texture Abnormal Suicidal Ideation	Consumer	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519118-0	Report Type: Periodic	Company Report Number: 204242			Age: 24 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Aggravated Suicidal Ideation	Consumer Health Professional Other	Accutane Loestrin Fe (Ethinyl Estradiol / Ferrous Fumarate / Norethindrone Acetate)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519127-1	Report Type: Periodic	Company Report Number: 204725			Age: 35 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Stye Suicidal Ideation	Consumer	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519131-3	Report Type: Periodic	Company Report Number: 204859			Age: 16 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Depression Nec Dry Mouth	Consumer Health Professional Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519139-8	Report Type: Periodic	Company Report Number: 218539			Age: 17 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Dry Skin Lip Dry	Health Professional	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519144-1	Report Type: Periodic	Company Report Number: 205135			Age: 20 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide Road Traffic Accident	Other	Accutane	PS	Hlr Technology	ORAL		

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

Date: 06/09/2000	ISR Number: 3519145-3	Report Type: Periodic	Company Report Number: 205149	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>
Hospitalization - Initial or Prolonged	Depression Nec Psychotic Disorder Nos	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519146-5	Report Type: Periodic	Company Report Number: 205219	Age: 15 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Abnormal Behaviour Nos Aggression Depression Nec Disturbance In Social Behaviour Nos Suicidal Ideation	Other	Accutane	PS		ORAL		
Date: 06/09/2000	ISR Number: 3519150-7	Report Type: Periodic	Company Report Number: 230702	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>
Death	Completed Suicide Depression Nec Emotional Disturbance Nos Suicidal Ideation	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519152-0	Report Type: Periodic	Company Report Number: 229541	Age: 34 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Disability	Depression Nec Lethargy	Consumer Health Professional Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519153-2	Report Type: Periodic	Company Report Number: 229622	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	Anxiety Nec Depression Nec	Consumer Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519160-X	Report Type: Periodic	Company Report Number: 229813	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	Suicidal Ideation	Health Professional	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519164-7	Report Type: Periodic	Company Report Number: 230298	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>
Hospitalization - Initial or Prolonged	Suicide Attempt	Consumer	Accutane	PS	Hlr Technology	ORAL		

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

Date: 06/09/2000	ISR Number: 3519171-4	Report Type: Periodic	Company Report Number: 213097	Age: 15 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Blood Creatine Phosphokinase Increased Decreased Activity Drug Effect Decreased	Health Professional	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519173-8	Report Type: Periodic	Company Report Number: 219092	Age: 15 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Panic Attack Vomiting Nos	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519175-1	Report Type: Periodic	Company Report Number: 213537	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	Crying Depressed Mood Depression Nec	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519180-5	Report Type: Periodic	Company Report Number: 213837	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>
Other	Acne Aggravated Depression Nec Headache Nos Visual Acuity Reduced	Consumer	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519182-9	Report Type: Periodic	Company Report Number: 231043	Age:	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Disability	Emotional Disturbance Nos	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519184-2	Report Type: Periodic	Company Report Number: 214155	Age: 19 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Disability	Decreased Activity Depression Nec Social Avoidant Behaviour	Health Professional Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519186-6	Report Type: Periodic	Company Report Number: 214220	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>
Hospitalization - Initial or Prolonged	Depression Nec	Other	Accutane	PS	Hlr Technology	ORAL		

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

Date: 06/09/2000	ISR Number: 3519187-8	Report Type: Periodic	Company Report Number: 231211			Age: 14 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec	Health Professional	Accutane	PS	Hlr Technology	ORAL		
Disability	Insomnia Nec Suicidal Ideation							
Date: 06/09/2000	ISR Number: 3519189-1	Report Type: Periodic	Company Report Number: 214321			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Aspartate Aminotransferase Increased Aspartate Aminotransferase Increased Blood Creatine Phosphokinase Increased Blood Glucose Increased Blood Iron Increased Blood Phosphate Increased Blood Potassium Decreased Disturbance In Attention Nec Irritability Mood Alteration Nos	Health Professional	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519191-X	Report Type: Periodic	Company Report Number: 231219			Age: 17 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Confusion Convulsions Nos Headache Nos Menstruation Irregular Speech Disorder Nec	Consumer Health Professional	Accutane Ortho Tri-Cyclen (Ethinyl Estradiol/Norgestimate) Tylenol (Acetaminophen)	PS C C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519192-1	Report Type: Periodic	Company Report Number: 214322			Age: 21 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Alopecia Depression Nec Scar	Health Professional	Accutane Ortho-Cyclen (Ethinyl Estradiol/Norgestimate)	PS C C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519193-3	Report Type: Periodic	Company Report Number: 231417			Age: 19 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Psychotic Disorder Nos	Health Professional	Accutane	PS	Hlr Technology	ORAL		

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

<u>Date:</u> 06/09/2000	<u>ISR Number:</u> 3519196-9	<u>Report Type:</u> Periodic	<u>Company Report Number:</u> 231487			<u>Age:</u> 15 YR	<u>Gender:</u> 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 Suicidal Ideation	Consumer	Accutane	PS	Hlr Technology	ORAL	
<u>Date:</u> 06/09/2000	<u>ISR Number:</u> 3519197-0	<u>Report Type:</u> Periodic	<u>Company Report Number:</u> 215166			<u>Age:</u> 26 YR	<u>Gender:</u> 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 Dry Skin Lip Ulceration	Consumer Other	Accutane	PS	Hlr Technology	ORAL	
<u>Date:</u> 06/09/2000	<u>ISR Number:</u> 3519199-4	<u>Report Type:</u> Periodic	<u>Company Report Number:</u> 215197			<u>Age:</u>	<u>Gender:</u> Female
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u> <u>Duration</u>
Hospitalization - Initial or Prolonged	Depression Nec	Other	Accutane	PS	Hlr Technology	ORAL	
<u>Date:</u> 06/09/2000	<u>ISR Number:</u> 3519204-5	<u>Report Type:</u> Periodic	<u>Company Report Number:</u> 215629			<u>Age:</u> 16 YR	<u>Gender:</u> Male
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u> <u>Duration</u>
Other	Alopecia Depression Nec	Other	Accutane	PS	Hlr Technology	ORAL	
<u>Date:</u> 06/09/2000	<u>ISR Number:</u> 3519209-4	<u>Report Type:</u> Periodic	<u>Company Report Number:</u> 216346			<u>Age:</u> 25 YR	<u>Gender:</u> 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	Crying Depression Nec Localised Exfoliation	Health Professional Other	Accutane	PS	Hlr Technology	ORAL	
<u>Date:</u> 06/09/2000	<u>ISR Number:</u> 3519211-2	<u>Report Type:</u> Periodic	<u>Company Report Number:</u> 216359			<u>Age:</u>	<u>Gender:</u> 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 Aggravated Alopecia Blood Cholesterol Increased Blood Pressure Increased Cheilitis Depression Nec Dry Skin Lip Disorder Nos Lip Dry Menstrual Disorder Nos Mental Disorder Nec Red Eye	Consumer Health Professional Other	Accutane	PS	Hlr Technology	ORAL	

FDAS Adverse Event Reporting System (AERS)
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Date: 06/09/2000	ISR Number: 3519212-4	Report Type: Periodic	Company Report Number: 216387			Age:	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Hospitalization - Initial or Prolonged	Depression Nec	Other	Accutane	PS	Hlr Technology	ORAL			
Date: 06/09/2000	ISR Number: 3519214-8	Report Type: Periodic	Company Report Number: 219255			Age:	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Epistaxis Localised Exfoliation Pruritus Stress Symptoms	Consumer	Accutane	PS	Hlr Technology	ORAL			
Date: 06/09/2000	ISR Number: 3519224-0	Report Type: Periodic	Company Report Number: 219874			Age: 22 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Apathy Depression Nec Headache Nos Lethargy	Consumer	Accutane	PS	Hlr Technology	ORAL			
Date: 06/09/2000	ISR Number: 3519227-6	Report Type: Periodic	Company Report Number: 219720			Age: 33 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Agoraphobia Anxiety Nec Apathy Burning Sensation Nos Crying Depression Nec Dyskinesia Nec Eye Disorder Nos Eye Pain Feeling Abnormal Headache Nos Insomnia Nec Menorrhagia Neck Pain Nervousness Panic Disorder Nec Photophobia Tinnitus	Health Professional	Accutane	PS	Hlr Technology	ORAL			

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

Date: 06/09/2000	ISR Number: 3519236-7	Report Type: Periodic	Company Report Number: 220657			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Dry Skin Pruritus Scar	Consumer	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519257-4	Report Type: Periodic	Company Report Number: 216765			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Depression Nec Suicidal Ideation	Consumer	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519263-X	Report Type: Periodic	Company Report Number: 217075			Age: 24 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Aggression Depression Aggravated Dry Mouth Irritability Libido Decreased Skin Chapped	Consumer	Accutane Paxil	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519269-0	Report Type: Periodic	Company Report Number: 217169			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Aggravated Intentional Self-Injury Mood Swings	Consumer Health Professional	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519272-0	Report Type: Periodic	Company Report Number: 217319			Age: 24 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos Appetite Decreased Crying Dehydration Depressed Level Of Consciousness Depression Aggravated Dizziness (Exo Vertigo) Haematuria Present Lethargy Nausea	Consumer	Accutane Alcohol	PS SS	Hlr Technology	ORAL ORAL		

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

Date: 06/09/2000	ISR Number: 3519275-6	Report Type: Periodic	Company Report Number: 217403			Age: 14 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Hospitalization - Initial or Prolonged	Depression Nec	Consumer	Accutane	PS	Hlr Technology	ORAL			
		Health Professional							
Date: 06/09/2000	ISR Number: 3519370-1	Report Type: Periodic	Company Report Number: 227995			Age: 19 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Death	Completed Suicide	Health Professional	Accutane	PS	Hlr Technology	ORAL			
	Road Traffic Accident								
Date: 06/09/2000	ISR Number: 3519375-0	Report Type: Periodic	Company Report Number: 227536			Age:	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Suicide Attempt	Health Professional	Accutane	PS	Hlr Technology	ORAL			
Date: 06/09/2000	ISR Number: 3519383-X	Report Type: Periodic	Company Report Number: 227700			Age: 16 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Life-Threatening	Abnormal Behaviour Nos	Health Professional	Accutane	PS	Hlr Technology	ORAL			
	Suicide Attempt		Benadryl (Diphenhydramine Hydrochloride)	C					
Date: 06/09/2000	ISR Number: 3519396-8	Report Type: Periodic	Company Report Number: 228346			Age: 40 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Mood Alteration Nos	Health Professional	Accutane	PS	Hlr Technology	ORAL			
	Suicidal Ideation								
Date: 06/09/2000	ISR Number: 3519400-7	Report Type: Periodic	Company Report Number: 228347			Age: 17 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Abnormal Behaviour Nos	Consumer	Accutane	PS	Hlr Technology	ORAL			
Date: 06/09/2000	ISR Number: 3519403-2	Report Type: Periodic	Company Report Number: 228412			Age: 32 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Depression Nec	Health Professional	Accutane	PS	Hlr Technology	ORAL			
	Dizziness (Exe Vertigo)								
	Skin Papilloma								
Date: 06/09/2000	ISR Number: 3519408-1	Report Type: Periodic	Company Report Number: 228882			Age: 17 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Paranoia	Health Professional	Accutane	PS	Hlr Technology	ORAL			
	Psychotic Disorder Nos								

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

Date: 06/09/2000	ISR Number: 3519411-1	Report Type: Periodic	Company Report Number: 228930			Age: 47 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Blood Cholesterol Increased Depression Nec	Health Professional Company Representative	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519413-5	Report Type: Periodic	Company Report Number: 228994			Age: 21 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Chelitis Depression Nec Epistaxis	Consumer Other	Accutane Birth Control Pill (Oral Contraceptive Nos)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519414-7	Report Type: Periodic	Company Report Number: 229011			Age: 36 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Suicidal Suicidal Ideation	Consumer Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519419-6	Report Type: Periodic	Company Report Number: 229393			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Aggravated	Health Professional	Accutane Antidepressants Nos (Antidepressant Nos)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3519420-2	Report Type: Periodic	Company Report Number: 229461			Age: 19 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Depression Nec Dry Skin	Consumer Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/27/2000	ISR Number: 3520145-8	Report Type: Direct	Company Report Number:			Age: 39 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Arthralgia		Accutane-Isotretinoin 40 Mg Roche	PS	Roche	ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Blindness Night Dry Skin Headache Nos Hypersensitivity Nos Pruritus Social Avoidant Behaviour Suicidal Ideation							

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

Date: 06/27/2000	ISR Number: 3520219-1	Report Type: Direct	Company Report Number:	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>
Death	Aphasia	Consumer	Accutane	PS				
Life-Threatening	Cerebral Oedema							
Hospitalization - Initial or Prolonged	Depression Nec							
Disability	Diplopia							
	Dizziness (Exc Vertigo)							
	Motor Dysfunction Nos							
	Neurological Disorder Nos							
	Panic Attack							
	Respiratory Arrest (Exc Neonatal)							
	Sedation							
	Vegetative State Chronic							

Date: 06/27/2000	ISR Number: 3520428-1	Report Type: Expedited (15-Day)	Company Report Number: 214314	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	Acne Infantile	Health Professional	Accutane	PS	Hlr Technology	ORAL		
	Birth Mark Nos	Other	Zoloft (Sertraline Hydrochloride)	C				
	Blood Human Chorionic		Prenatal Vitamins(Minerals Nos/Multivitamins Nos)	C				
	Gonadotrophin Abnormal							
	Complications Of Maternal							
	Exposure To Therapeutic Drugs							
	Down'S Syndrome							
	Eye Discharge							
	Meconium Increased							
	Pregnancy Nos							
	Umbilical Cord Around Neck							
	Vaginal Haemorrhage							

Date: 06/27/2000	ISR Number: 3520668-1	Report Type: Expedited (15-Day)	Company Report Number: 222823	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>
Disability	Alopecia	Consumer	Accutane	PS	Hlr Technology	ORAL		
	Depression Nec		Ortho Tri-Cyclen (Ethinyl Estradiol/Norgestimate)	C				
	Dizziness (Exc Vertigo)							
	Emotional Disturbance Nos							
	Hair Colour Changes							
	Hair Growth Abnormal							
	Hair Texture Abnormal							
	Headache Nos							
	High Density Lipoprotein Increased							
	Hypercholesterolaemia							

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

Date: 06/26/2000 ISR Number: 3520778-9 Report Type: Expedited (15-Day) Company Report Number: 235209 Age: 40 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Aspartate Aminotransferase Increased	Consumer	Accutane	PS	HlrTechnology	ORAL		
	Blood Alkaline Phosphatase Nos Increased		Depo-Provera	C				
	Blood Carbon Dioxide Decreased		Medroxyprogesterone Acetate	C				
	Blood Thyroid Stimulating Hormone Decreased							
	Blood Triglycerides Increased							
	Depression Nec							
	Dyspnoea Nos							
	Erythema Nec							
	Eyelid Disorder Nos							
	Eyelid Oedema							
	Fatigue							
	Feeling Hot							
	Flushing							
	Goitre							
	Heart Rate Increased							
	Hyperthyroidism							
	Monocyte Count Increased							
	Rash Erythematous							
	Thyroxine Increased							
	Tri-Iodothyronine Increased							
	Urine Abnormal Nos							

Date: 06/26/2000 ISR Number: 3520786-8 Report Type: Expedited (15-Day) Company Report Number: 234803 Age: 15 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Accident Nos	Health Professional	Accutane	PS	HlrTechnology	ORAL		
	Benign Intracranial Hypertension							
	Blindness Night							
	Csf Pressure Increased							
	Dysarthria							
	Head Injury							
	Headache Nos							
	Hypoesthesia							

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

Date: 06/26/2000 ISR Number: 3520788-1 Report Type: Expedited (15-Day) Company Report Number: 235788 Age: 17 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos Bacterial Infection Nos Bipolar Disorder Nec Cerebral Oedema Csf Abnormal Nos Drug Abuse Ear Disorder Nos Emotional Disturbance Nos Encephalitis Nos Headache Nos Hearing Impaired Herpes Simplex Mastoiditis Nos Meningeal Disorder Nos Neck Stiffness Nuclear Magnetic Resonance Imaging Abnormal Otitis Media Nos Reaction To Spinal Or Lumbar Puncture Sinusitis Acute Nos Syncope Toxicology Nos Abnormal	Health Professional	Accutane	PS	Hlr Technology	ORAL		

Date: 06/28/2000 ISR Number: 3521569-5 Report Type: Expedited (15-Day) Company Report Number: 229263 Age: Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Bronchitis Nos Bronchospasm Nos Complications Of Maternal Exposure To Therapeutic Drugs Cough Crystalluria Present Dermatitis Nos Disorder Neonatal Nos Dyspnoea Nos Eating Disorder Nec Eosinophil Count Increased Erythema Nec Haematocrit Decreased Haematuria Present	Health Professional Other	Accutane Birth Control Pills Nos (Oral Contraceptives Nos)	PS C	Hlr Technology	ORAL		

Drug Adverse Event Reporting System (DAERS)
Freedom Of Information (FOI) Request

Date:	ISR Number:	Report Type:	Company Report Number:	Age:	Gender:			
06/21/2000	3521896-1	Expedited (15-Day)	236644	71 YR	Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block First Degree	Foreign	Tasmar	PS	Hoffmann La Roche Inc	UNKNOWN		
Required Intervention to Prevent Permanent Impairment/Damage	Confusion	Health Professional	Madopar Dr (Benserazide/Levodopa) 250 Mg	SS		ORAL		
	Depression Nec		Pemax (Pergolide Mesylate)	C				
	Disorientation		Motilium (Domperidone)	C				
	Dizziness (Exc Vertigo)		Gutron (Midodrine Hydrochloride)	C				
	Dystonia		Importal (Lactitol)	C				
	Haematocrit Decreased							
	Haemoglobin Decreased							
	Hallucination Nos							
	Hypoproteinaemia							
	Pancytopenia							
	Parkinson'S Disease Aggravated							
	Prothrombin Level Decreased							
	Red Blood Cell Count Decreased							
	Swelling Nos							
	Thrombocytopenia							
	Venous Thrombosis Deep Limb							
06/29/2000	3522432-6	Expedited (15-Day)	211685	81 YR	Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Blood Creatinine Increased	Foreign	Tasmar	PS	Hoffmann La Roche Inc	ORAL		
	Condition Aggravated	Health Professional	Madopar (Benserazide/Levodopa)	C				
	Confusion							
	Erythropenia							
	Haematocrit Decreased							
	Haemoglobin Decreased							
	Hypokaemia							
	Liver Function Tests Nos Abnormal							
	Nephropathy Toxic							
	Renal Failure Nos							
06/29/2000	3522441-7	Expedited (15-Day)	237282	42 YR	Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Abdominal Pain Nos	Consumer	Accutane	PS	Hlr Technology	ORAL		
	Acne Aggravated	Health Professional						
	Blood Triglycerides Decreased							
	Brittle Nails							
	Decreased Activity							

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

Date: 07/05/2000 ISR Number: 3524243-4 Report Type: Expedited (15-Day) Company Report Number: 232009 Age: 15 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos Acute Psychosis Adjustment Disorder Nec Depression Nec Educational Problem Increased Activity Mania Psychotic Disorder Nos	Consumer Health Professional	Accutane	PS	Hlr Technology	ORAL		

Date: 07/05/2000 ISR Number: 3524399-3 Report Type: Expedited (15-Day) Company Report Number: 235549 Age: 17 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Abdominal Pain Upper Abrasion Nos Acute Circulatory Failure Alopecia Anxiety Nec Appetite Decreased Back Pain Blood Cholesterol Increased Blood Glucose Decreased Collapse Convulsions Nos Depression Nec Dermatitis Nos Diarrhoea Nos Dizziness (Exc Vertigo) Dry Eye Nec Dry Skin Dyspnoea Nos Epistaxis Erythema Nec Eye Irritation Face Oedema Fatigue Gastrointestinal Disorder Nos Haemorrhage Nos Headache Nos Heart Rate Increased Hot Flashes Nos Hyperventilation	Consumer Other	Accutane	PS	Hlr Technology	ORAL		

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

Date:	ISR Number:	Report Type:	Company Report Number:	Age:	Gender:			
06/30/2000	3525992-4	Periodic	TAP1999Q00408	14 YR	Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos	Health Professional	Prevacid	PS	Tap Pharmaceutical Products Inc	ORAL		
	Ashenia							
	Dry Skin		Accutane (Isotretinoin)	SS		ORAL		
	Gastitis Nos							
	Hyperventilation							
	Melasma							
	Oesophagitis							
07/10/2000	3526816-1	Expedited (15-Day)	205994	75 YR	Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Bilirubin Increased	Foreign	Tasmar	PS	Hoffmann La Roche Inc			
	Dythymic Disorder	Health Professional	Madopar Dr (Benserazide/Levodopa)	C				
	Eczema Nos	Other	Parlodol (Bromocriptine Mesylate)	C				
	Hypercholesterolaemia							
	Liver Function Tests Nos		Deanxit (Flupentixol/Melitracen Hydrochloride)	C				
	Abnormal		Selipran (Pravastatin Sodium)	C				
	Nervousness		Cortison (Cortisone Acetate)	C				
	Stress Symptoms		Aspirin Cardio (Aspirin)	C				
			Temesta (Lorazepam)	C				
			Rebalance (Hypericum)	C				
07/10/2000	3526970-1	Expedited (15-Day)	205994	75 YR	Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Cholesterol Increased	Foreign	Tasmar	PS	Hoffmann La Roche Inc			
	Dythymic Disorder	Health Professional	Madopar Dr (Benserazide/Levodopa)	C				
	Eczema Nos	Other	Parlodol (Bromocriptine Mesylate)	C				
	Liver Function Tests Nos		Deanxit (Flupentixol/Melitracen Hydrochloride)	C				
	Abnormal		Selipran (Pravastatin Sodium)	C				
			Cortison (Cortisone Acetate)	C				
			Aspirin Cardio (Aspirin)	C				
			Temesta (Lorazepam)	C				
			...	C				
			Rebalance (Hypericum)	C				

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

Date: 07/11/2000		ISR Number: 3527341-4		Report Type: Expedited (15-Day)		Company Report Number: 215487		Age: 60 YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Abdominal Pain Upper Constipation Dermatitis Nos Erectile Disturbance Irritable Bowel Syndrome Libido Decreased	Foreign Health Professional	Tasmar Madopar (Benserazide/Levodopa) Symmetrel (Amantadine Hydrochloride) Permax (Pergolide Mesylate)	PS C C C	Hoffmann La Roche Inc						
Date: 07/11/2000		ISR Number: 3527540-1		Report Type: Expedited (15-Day)		Company Report Number: 239728		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	Apraxia Complications Of Maternal Exposure To Therapeutic Drugs Pregnancy Nos	Other	Accutane	PS	Hlr Technology	ORAL					
Date: 07/11/2000		ISR Number: 3527542-5		Report Type: Expedited (15-Day)		Company Report Number: 239960		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>			
Death	Aphasia Cerebral Oedema Difficulty In Walking Diplopia Neurological Disorder Nos Vision Blurred	Consumer	Accutane	PS	Hlr Technology	ORAL					
Date: 07/11/2000		ISR Number: 3527625-X		Report Type: Expedited (15-Day)		Company Report Number: 227868		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>			
Hospitalization - Initial or Prolonged	Bone Disorder Nos Depression Nec Fatigue Oedema Upper Limb Skin Discolouration Venous Embolism Nos	Health Professional	Accutane	PS	Hlr Technology	ORAL					
Date: 07/11/2000		ISR Number: 3527629-7		Report Type: Expedited (15-Day)		Company Report Number: 239779		Age: 30 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Acne Nos Anxiety Nec Depression Nec Disturbance In Attention Nec Dry Mouth	Consumer	Accutane Ortho Tri-Cyclen	PS C	Hlr Technology	ORAL					

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

Date: 07/11/2000		ISR Number: 3527632-7		Report Type: Expedited (15-Day)		Company Report Number: 239876		Age: 15 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Hospitalization - Initial or Prolonged	Eating Disorder Nec	Consumer	Accutane	PS	Hlr Technology	ORAL					
	Epistaxis	Other									
	Haemorrhage Nos										
	Herpes Simplex										
	Immune System Disorder Nos										
	Impetigo Nos										
	Lip Dry										
	Markedly Increased Food Intake										
	Nasal Ulcer										
	Pharyngeal Ulceration										
	Pyrexia										
	Scar										
	Weight Decreased										
	<hr/>										
Date: 07/11/2000		ISR Number: 3527824-7		Report Type: Expedited (15-Day)		Company Report Number: 215436		Age: 68 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Alanine Aminotransferase Increased	Foreign	Tasmar	PS	Hoffmann La Roche Inc						
	Blood Amylase Increased	Health Professional	Sifrol	SS		ORAL					
	Blood Bilirubin Increased		Madopar Hbs	C							
	Blood Creatine Kinase Low		Madopar Dr	C							
	Blood Iron Increased		Junexal	C							
	Drug Ineffective		Pk-Merz	C							
	Hallucination Nos		Saroten	C							
	Hyperglycaemia Nos		Dafalgan	C							
	Lipase Increased		Mst	C							
			Effordil	C							
	<hr/>										
Date: 07/11/2000		ISR Number: 3527827-2		Report Type: Expedited (15-Day)		Company Report Number: 207260		Age: 49 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Alanine Aminotransferase Increased	Foreign	Tasmar	PS	Hoffmann La Roche Inc						
	Drug Ineffective	Health Professional	Madopar Dr	C							
	Parkinson'S Disease Aggravated		Akineton	C							
	Personality Change		Permax	C							
				Leponex	C						

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

Date: 07/14/2000		ISR Number: 3529783-X		Report Type: Expedited (15-Day)		Company Report Number: 237445		Age: 38 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Agoraphobia Anxiety Nec Dizziness (Exc Vertigo) Hot Flashes Nos Palpitations Panic Attack Sweating Increased	Foreign Health Professional	Roaccutane Tardyferon Vamoline	PS C C	Hlr Technology	ORAL					
Date: 07/14/2000		ISR Number: 3529784-1		Report Type: Expedited (15-Day)		Company Report Number: 240325		Age: 15 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Ankylosing Spondylitis Arthralgia Chromosomal Abnormality Nos Depression Nec Gingivitis Haematocrit Decreased Haemoglobin Decreased Mean Cgl Haemoglobin Concentration Increased	Health Professional	Accutane	PS	Hlr Technology	ORAL					
Date: 07/18/2000		ISR Number: 3531196-1		Report Type: Expedited (15-Day)		Company Report Number: 234822		Age: 44 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Disability	Acne Aggravated Amnesia Nec Bipolar I Disorder Confusion Feeling Abnormal Irritability Panic Disorder Nec Seborrhoea Suicidal Ideation	Consumer Other	Accutane Klonopin Lupron Depot Neurontin Seroquel Allegra Primrose Oil Coenzyme Q10 Gadic Chromium Picolinate Vitamin C Vitamin E Vitamin B6 Vitamin B12	PS SS SS C C C C C C C C C C C	Hlr Technology	ORAL ORAL INTRAMUSCULAR					

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

Date: 07/18/2000	ISR Number: 3531302-9	Report Type: Expedited (15-Day)	Company Report Number: 240501			Age: 26 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos Bipolar I Disorder Logonhoes Mental Disorder Nec	Foreign Health Professional	Accutane Diane 35	PS C	Hlr Technology	ORAL		
Date: 07/19/2000	ISR Number: 3532233-0	Report Type: Expedited (15-Day)	Company Report Number: 239572			Age: 34 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Confusion Depressed Level Of Consciousness Hypoesthesia Sedation Sore Throat Nos	Health Professional	Accutane Roferon-A (Interferon Alfa-2a) 6 Millioniu Vitamin E	PS SS C	Hlr Technology	ORAL SUBCUTAN EOUS		
Date: 07/21/2000	ISR Number: 3534070-X	Report Type: Expedited (15-Day)	Company Report Number: 240657			Age: 18 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Acne Aggravated Mood Swings Scar	Other	Accutane Oral Contraceptive Nos (Oral Contraceptive Nos)	PS C	Hlr Technology	ORAL		
Date: 07/24/2000	ISR Number: 3534241-2	Report Type: Expedited (15-Day)	Company Report Number: 240222			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Blood Bilirubin Increased Ileus Insomnia Nec Liver Function Tests Nos Abnormal Vomiting Nos	Foreign Other	Accutane	PS	Hlr Technology	ORAL		
Date: 07/25/2000	ISR Number: 3534746-4	Report Type: Expedited (15-Day)	Company Report Number: 240963			Age: 18 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Binge Eating Depression Nec Eating Disorder Nec	Consumer Other	Accutane Rhinocort (Budesonide) Allegra (Fexofenadine Hydrochloride) Ortho Tri Cyclen (Ethinyl Estradiol/Norgestimate)	PS C C C	Hlr Technology	ORAL		

08/03/2000

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

Date: 11/07/1997	ISR Number: 1000002015-3	Report Type: Expedited (15-Day)	Company Report Number: 88810		Age: 17 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Balance Impaired Nos Cheilitis Disturbance In Attention Nec Dizziness (Exc Vertigo) Fatigue Headache Nos Loss Of Consciousness Nec Syncope Visual Disturbance Nos	Foreign Health Professional	Accutane	PS		ORAL		