

U.S. Food and Drug Administration (FDA)
 Center for Drug Evaluation and Research
 Division of Neurology
 Adverse Drug Reaction Reporting System (ADRS)

Date: 06/07/1999		ISR Number: 3283680-6		Report Type: Periodic		Company Report Number: 201725		Age: 27 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Arthralgia Coma Nec Depression Aggravated Fatigue Influenza Like Illness Lethargy Mood Alteration Nos Rhinorrhoea	Consumer Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3283722-8		Report Type: Periodic		Company Report Number: 202267		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	Coma Nec Depressed Mood Depression Nec Dizziness (Exc Vertigo) Emotional Disturbance Nos	Other	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3284310-X		Report Type: Periodic		Company Report Number: 99614		Age: 31 YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Impotence	Consumer	Accutane Capsules (Isotretinoin) 20 Mg	PS		ORAL					
Date: 06/07/1999		ISR Number: 3284323-8		Report Type: Periodic		Company Report Number: 100026		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	Libido Decreased	Health Professional	Accutane Capsules (Isotretinoin) Cleocin T Solution	PS C		ORAL					
Date: 06/07/1999		ISR Number: 3284324-X		Report Type: Periodic		Company Report Number: 100084		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	Anxiety Nec Dizziness (Exc Vertigo) Headache Nos Hypoesthesia Panic Attack Paresthesia Nec Vision Blurred	Consumer	Accutane Capsules (Isotretinoin) 20 Mg Aspirin Contiming	PS C		ORAL					

Division of Drug Reporting System (ADRS)
 Division of Health Service Regulation (DHSR)

Date: 06/07/1999	ISR Number: 3284335-4	Report Type: Periodic	Company Report Number: 102013			Age: 22 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depressed Mood Increased Activity Mood Swings Sore Throat Nos	Consumer	Accutane Capsules (Isotretinoin) 20 Mg	PS		ORAL		
Date: 06/07/1999	ISR Number: 3284343-3	Report Type: Periodic	Company Report Number: 102685			Age: 21 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Aggravated Arthralgia Depression Nec Fatigue Liver Function Tests Nos Abnormal Myalgia Nail Discolouration Sleep Disorder Nos	Other	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Date: 06/07/1999	ISR Number: 3284346-9	Report Type: Periodic	Company Report Number: 100152			Age: 14 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Erectile Disturbance	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Date: 06/07/1999	ISR Number: 3284347-0	Report Type: Periodic	Company Report Number: 100165			Age:	Gender:	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3284348-2	Report Type: Periodic	Company Report Number: 100173			Age: 38 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Impotence	Consumer	Accutane Capsules (Isotretinoin) Acified (Pseudoephedrine Hydrochloride/Tripolidine Hydrochloride)	PS C		ORAL		
Date: 06/07/1999	ISR Number: 3284362-7	Report Type: Periodic	Company Report Number: 100801			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Dry Skin Dyspnoea Nos Lip Dry	Consumer Health Professional	Accutane Capsules (Isotretinoin) Ortho Tri-Cyclen (Ethinyl Estradiol/Norgestimate)	PS C		ORAL		

Drug Event Reporting System (ADRS)
Division of Information (D-3) Report

Date: 06/07/1999	ISR Number: 3284366-4	Report Type: Periodic	Company Report Number: 102691	Age: 21 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Short-Term Memory Loss	Consumer	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Date: 06/07/1999	ISR Number: 3284372-X	Report Type: Periodic	Company Report Number: 102821	Age: 34 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Fatigue Pain Nos Weight Increased	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3284400-1	Report Type: Periodic	Company Report Number: 103918	Age: 54 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Triglycerides Increased Coma Nec Condition Aggravated Diarrhoea Nos Epistaxis Flatulence Irritable Bowel Syndrome Skin Lesion Nos	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg Synthroid Provera Premarin Benadryl	PS C C C C		ORAL		
Date: 06/07/1999	ISR Number: 3284404-9	Report Type: Periodic	Company Report Number: 104002	Age: 21 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blindness Night Confusion	Other	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Date: 06/07/1999	ISR Number: 3284415-3	Report Type: Periodic	Company Report Number: 112348	Age: 24 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Blister Diarrhoea Nos Dry Skin Fatigue Gingival Bleeding Headache Nos Hypoesthesia Localised Exfoliation Nausea Oedema Lower Limb	Consumer	Accutane Capsules (Isotretinoin) 20 Mg Ibuprofen	PS C		ORAL		

FDA Adverse Event Reporting System (AERS)
 Product Information (PSI) Form

Date: 06/07/1999		ISR Number: 3284439-6		Report Type: Periodic		Company Report Number: 202809		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	Constipation Depression Nec	Consumer	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL					
Date: 06/07/1999		ISR Number: 3284450-5		Report Type: Periodic		Company Report Number: 202945		Age: 49 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 Menopausal Symptoms Stress Symptoms	Consumer Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3284455-4		Report Type: Periodic		Company Report Number: 202997		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	Enuresis	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL					
Date: 06/07/1999		ISR Number: 3284462-1		Report Type: Periodic		Company Report Number: 104983		Age: 34 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Alanine Aminotransferase Increased Anxiety Nec Aspartate Aminotransferase Increased Blood Triglycerides Increased Crying Headache Nos Paroshesia Nec	Health Professional	Accutane Capsules (Isotretinoin) Dep Provera (Medroxyprogesterone Acetate) Nutracort (Hydrocortisone) Hc 1% In Petroleum Jelly (Hydrocortisone) Cleocin T (Clindamycin Phosphate) Temovate (Clobetasol Propionate) Sulfur Precipitated (Sulfur) Cutivate Cream (Cloticasone Propionate)	PS C C C C C C C		ORAL					
Date: 06/17/1999		ISR Number: 3284464-5		Report Type: Periodic		Company Report Number: 104987		Age: 36 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 Capsules (Isotretinoin) Sulfa Drug (Sulfa Drug Nos) Advil (Ibuprofen) ...	PS C C C		ORAL					

FDA Adverse Event Reporting System (AERS)
 Division of Individual Child Reports

Date: 06/07/1999	ISR Number: 3284467-0	Report Type: Periodic	Company Report Number: 105216	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	Phenylketonuria	Health Professional Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3284472-4	Report Type: Periodic	Company Report Number: 105310	Age: 20 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 Capsules (Isotretinoin) 20 Mg Metronidazole Cream (Metronidazole) Novacet (Sulfacetamide Sodium/Sulfur)	PS C C		ORAL		
Date: 06/07/1999	ISR Number: 3284488-8	Report Type: Periodic	Company Report Number: 200981	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 Arthralgia Depression Nec Hirsutism Weight Increased	Consumer Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3284490-6	Report Type: Periodic	Company Report Number: 200990	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 Antinuclear Factor Positive Candida Nos Depression Nec Migraine Nos Mood Swings Visual Disturbance Nos Weight Decreased	Consumer	Accutane Capsules (Isotretinoin) Ginsana	PS C		ORAL		
Date: 06/07/1999	ISR Number: 3284496-7	Report Type: Periodic	Company Report Number: 201056	Age: 23 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	Loss Of Libido Mood Swings	Consumer	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Date: 06/07/1999	ISR Number: 3284498-0	Report Type: Periodic	Company Report Number: 104096	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	Aene Aggravated Back Pain Depression Nec.	Other	Accutane Capsules (Isotretinoin) 40 Mg Ortho-Cyclen	PS C		ORAL		

FDA Adverse Event Reporting System (FAERS)
 Patient Information (PI) Report

Date: 06/07/1999		ISR Number: 3284500-6		Report Type: Periodic		Company Report Number: 104256		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	Alopecia Blister Coma Nec Depression Nec Emotional Disturbance Nos Epistaxis Mood Swings Nasal Dryness Photophobia Vitreous Floaters	Consumer	Accutane Capsules (Isotretinoin) 40 Mg Ortho-Novum	PS C		ORAL					
Date: 06/07/1999		ISR Number: 3284503-1		Report Type: Periodic		Company Report Number: 201106		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>			
Other	Abdominal Pain Nos Dyspnoea Nos Haemorrhage Nos Hypoesthesia Muscle Spasms Palpitations	Consumer	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL					
Date: 06/07/1999		ISR Number: 3284513-4		Report Type: Periodic		Company Report Number: 201313		Age: 45 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Arthralgia Depression Nec Myalgia Weight Increased	Consumer Health Professional	Accutane Capsules (Isotretinoin) Naprosyn	PS C		ORAL					
Date: 06/07/1999		ISR Number: 3284523-7		Report Type: Periodic		Company Report Number: 104884		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	Blood Prolactin Increased Blood Testosterone Decreased Erectile Disturbance	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3284524-9		Report Type: Periodic		Company Report Number: 104936		Age: 27 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	Anger Depression Nec Drug Interaction Nos Paranoia Aggravated	Health Professional	Accutane Capsules (Isotretinoin) Zyprexa (Olanzapine) Minocycline	PS SS C		ORAL ORAL					

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

Date: 06/07/1999		ISR Number: 3284527-4		Report Type: Periodic		Company Report Number: 104978		Age: 35 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Alopecia Arthralgia Blood Thyroid Stimulating Hormone Increased Disturbance In Attention Nec Dry Eye Nec Dry Skin Memory Impairment Mental Impairment Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3284531-6		Report Type: Periodic		Company Report Number: 98779		Age: 35 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Depression Nec Influenza Like Illness	Consumer	Accutane Capsules (Isotretinoin) 60 Mg	PS		ORAL					
Date: 06/07/1999		ISR Number: 3284537-7		Report Type: Periodic		Company Report Number: 98853		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	Aggression Confusion Emotional Disturbance Nos Groin Swelling	Other	Accutane Capsules (Isotretinoin) 20 Mg	PS		ORAL					
Date: 06/07/1999		ISR Number: 3284570-5		Report Type: Periodic		Company Report Number: 97970		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	Abnormal Behaviour Nos Depression Nec Memory Impairment	Health Professional	Accutane Capsules (Isotretinoin) Oral Contraceptive	PS C		ORAL					
Date: 06/07/1999		ISR Number: 3284580-8		Report Type: Periodic		Company Report Number: 200444		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	Dermatitis Nos Impotence Loss Of Libido	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3284582-1		Report Type: Periodic		Company Report Number: 98220		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	Libido Increased	Consumer	Accutane Capsules (Isotretinoin) 20 Mg	PS		ORAL					

FDA Adverse Event Reporting System (AERS)
 System Of Information (SOI) Report

Date: 06/07/1999	ISR Number: 3284590-0	Report Type: Periodic	Company Report Number: 98386	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	Blood Bilirubin Increased Depression Nec Diarrhoea Nos Lip Dry Mood Swings	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3284594-8	Report Type: Periodic	Company Report Number: 201524	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 Rash Erythematous Skin Lesion Nos	Other	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Date: 06/07/1999	ISR Number: 3284595-X	Report Type: Periodic	Company Report Number: 201530	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>
Hospitalization - Initial or Prolonged	Depression Nec Dry Skin Mood Swings Suicidal Ideation Suicide Attempt	Consumer Health Professional	Accutane Capsules (Isotretinoin) 40 Mg Depo-Provera Paxil	PS C C		ORAL		
Date: 06/07/1999	ISR Number: 3284597-3	Report Type: Periodic	Company Report Number: 201684	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	Abnormal Behaviour Nos Depression Nec Psychotic Disorder Nos	Health Professional	Accutane Capsules (Isotretinoin) Fluoxetine Hcl	PS C		ORAL		
Date: 06/07/1999	ISR Number: 3284599-7	Report Type: Periodic	Company Report Number: 200554	Age: 27 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Aggression Capillary Fragility Increased Coma Nec Dry Eye Nec Dry Skin Epistaxis Headache Nos Hyperaesthesia Impaired Healing Mood Swings Myalgia	Consumer	Accutane Capsules (Isotretinoin) Ortho Tri-Cyclen	PS C		ORAL		

Adverse Event Reporting System (AERS)
 Division Of Information (DI) Report

Date: 06/07/1999	ISR Number: 3284600-0	Report Type: Periodic	Company Report Number: 202222			Age: 24 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Anxiety Nec Depression Aggravated Panic Attack Suicidal Ideation	Consumer	Accutane Capsules (Isotretinoin) Ortho Tri-Cyclen Alesse	PS C C		ORAL	
Date: 06/07/1999	ISR Number: 3284602-4	Report Type: Periodic	Company Report Number: 202355			Age: 42 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Hypertiglyceridemia Mood Swings	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL	
Date: 06/07/1999	ISR Number: 3284616-4	Report Type: Periodic	Company Report Number: 203730			Age: 25 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Dry Skin Skin Wrinkling Suicidal Ideation	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL	
Date: 06/07/1999	ISR Number: 3284619-X	Report Type: Periodic	Company Report Number: 200742			Age: 19 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Fatigue Headache Nos Insomnia Nec Muscle Disorder Nos Syncope	Consumer	Accutane Capsules (Isotretinoin) 40 Mg Birth Control Pills	PS C		ORAL	
Date: 06/07/1999	ISR Number: 3284621-8	Report Type: Periodic	Company Report Number: 200883			Age: 30 YR	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Erectile Disturbance	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL	
Date: 06/07/1999	ISR Number: 3284625-5	Report Type: Periodic	Company Report Number: 200977			Age: 17 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Aggression	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL	
Date: 06/07/1999	ISR Number: 3284629-2	Report Type: Periodic	Company Report Number: 113029			Age: 21 YR	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Depression Nec Erectile Disturbance	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL	

UNITED STATES FOOD AND DRUG ADMINISTRATION
 DEPARTMENT OF HEALTH AND HUMAN SERVICES

Date: 06/07/1999		ISR Number: 3284634-6		Report Type: Periodic		Company Report Number: 113098		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	Goitre Hyporeflexia Initial Insomnia	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3284638-3		Report Type: Periodic		Company Report Number: 113257		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	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3284644-9		Report Type: Periodic		Company Report Number: 200022		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	Arthralgia Change In Bowel Habit Nos Depression Nec Eating Disorder Nec Genital Pruritus Female Mitral Valve Incompetence Pulmonary Valve Incompetence Tricuspid Valve Incompetence Urinary Tract Infection Nos Vaginal Discharge Vaginitis Bacterial Nos Vulvovaginal Dryness	Health Professional	Accutane Capsules (Isotretinoin) Effexor Flagyl	PS C C		ORAL					
Date: 06/07/1999		ISR Number: 3284652-8		Report Type: Periodic		Company Report Number: 200357		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	Chest Tightness Dyspnoea Nos Fatigue Gingival Bleeding Gingivitis Palpitations	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3284691-7		Report Type: Periodic		Company Report Number: 203338		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	Acne Aggravated Depression Nec Weight Increased	Consumer Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL					

FDA Adverse Event Reporting System (AERS)
 System of Information (SOI) Report

Date: 06/07/1999 ISR Number: 3284693-0 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 Capsules (Isotretinoin)	PS		ORAL		
	Arthralgia	Health Professional	Parnate (Tranylcypromine Sulfate)	C				
	Anthropod 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		Terazole Suppositories (Terconazole)	C				
	Epistaxis							
	Fatigue							
	Lacrimation Increased							
	Lip Dry							
	Memory Impairment							
	Mood Alteration Nos							
	Panic Attack							
	Pruritus							
	Rhinorrhoea							
	Vaginal Candidiasis							
	Vision Blurred							

Date: 06/07/1999 ISR Number: 3284705-4 Report Type: Periodic Company Report Number: 94518 Age: 15 YR Gender: Male

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

Date: 06/07/1999 ISR Number: 3284710-8 Report Type: Periodic Company Report Number: 95531 Age: 39 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthralgia	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Depression Aggravated		Paxil	C				
	Dry Mouth		Nasalacrom	C				
	Insomnia Nec		Aleve	C				
	Lethargy							
	Psychiatric Symptom Nos							

FDA Adverse Event Reporting System (AERS)
Division Of Information Operations

Date: 06/07/1999		ISR Number: 3284711-X		Report Type: Periodic		Company Report Number: 95553		Age: 30 YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Coma Nec Confusion Depression Nec Euphoric Mood Mental Impairment Nos Neurological Disorder Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3284712-1		Report Type: Periodic		Company Report Number: 95607		Age: 20 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	Other	Accutane Capsules (Isotretinoin) Marijuana	PS C		ORAL					
Date: 06/07/1999		ISR Number: 3284732-7		Report Type: Periodic		Company Report Number: 203617		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	Agitation Depression Nec Lethargy Short-Term Memory Loss	Health Professional	Accutane Capsules (Isotretinoin) Contraceptive (Contraceptive Nos)	PS C		ORAL					
Date: 06/07/1999		ISR Number: 3284736-4		Report Type: Periodic		Company Report Number: 203698		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	Candida Nos Depression Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3284744-3		Report Type: Periodic		Company Report Number: 84838		Age: 17 YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Acne Aggravated Coma Nec Depression Nec Drug Ineffective Face Oedema Joint Stiffness	Health Professional Other	Accutane Capsules (Isotretinoin) Steroid Nos (Steroid Nos)	PS C		ORAL					
Date: 06/07/1999		ISR Number: 3285326-X		Report Type: Periodic		Company Report Number: 105992		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	Dysarthria Sore Throat Nos Tongue Oedema	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL					

FDA Adverse Event Reporting System (FAERS)
 Version 11.0 (10/14/01) (10/11/01) (10/11/01)

Date: 06/07/1999		ISR Number: 3285327-1		Report Type: Periodic		Company Report Number: 105994		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	Dysarthria	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3285338-6		Report Type: Periodic		Company Report Number: 106144		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	Dry Skin Headache Nos Localised Exfoliation Mood Swings Nausea Palpitations Red Eye	Consumer	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL					
Date: 06/07/1999		ISR Number: 3285372-6		Report Type: Periodic		Company Report Number: 110107		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	Anxiety Nec Depression Nec	Consumer	Accutane Capsules (Isotretinoin)	PS							
Date: 06/07/1999		ISR Number: 3285376-3		Report Type: Periodic		Company Report Number: 110186		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	Alopecia Constipation Corneal Ulcer Nec Depression Nec Epistaxis Faeces Discoloured Lip Disorder Nos Myalgia Pruritus	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3285377-5		Report Type: Periodic		Company Report Number: 110200		Age: 28 YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Alopecia Confusion Depression Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL					

U.S. Food and Drug Administration
Division of Drug Information
Product Information (PI) Table

Date: 06/07/1999	ISR Number: 3285378-7	Report Type: Periodic	Company Report Number: 110202	Age: 20 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Short-Term Memory Loss	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285382-9	Report Type: Periodic	Company Report Number: 110589	Age: 17 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Chest Tightness Condition Aggravated Menorrhagia Myalgia Premenstrual Syndrome	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285391-X	Report Type: Periodic	Company Report Number: 110935	Age: 41 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Blindness Night Dyspnoea Nos Myalgia Tremor Nec Weakness	Consumer	Accutane Capsules (Isotretinoin) 40 Mg Vitamin E	PS C		ORAL		
Date: 06/07/1999	ISR Number: 3285397-0	Report Type: Periodic	Company Report Number: 111223	Age:	Gender: Unknown			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Upper Back Pain Coma Nec Depression Nec Dyspnoea Nos Headache Nos Hypertension Nos Palpitations Vomiting Nos	Other	Accutane Capsules (Isotretinoin)	PS				
Date: 06/07/1999	ISR Number: 3285399-4	Report Type: Periodic	Company Report Number: 111373	Age: 30 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Blister Bronchitis Nos Coma Nec Cough	Consumer Health Professional	Accutane Capsules (Isotretinoin) Triphasil	PS C		ORAL		

FD-302 (Rev. 10-1-95) Reporting Suspected Adverse
 Reaction of Information on U.S. Report

Date: 06/07/1999	ISR Number: 3285401-X	Report Type: Periodic	Company Report Number: 111410	Age: 30 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthralgia Libido Decreased	Consumer Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285498-7	Report Type: Periodic	Company Report Number: 107610	Age: 16 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Short-Term Memory Loss	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285501-4	Report Type: Periodic	Company Report Number: 107700	Age: 22 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Headache Nos Irritability Mood Swings Neck Pain	Consumer	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285512-9	Report Type: Periodic	Company Report Number: 106626	Age: 15 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos Aggression Coma Nec	Other	Accutane Capsules (Isotretinoin) 40 Mg Antihistamatics	PS C		ORAL		
Date: 06/07/1999	ISR Number: 3285516-6	Report Type: Periodic	Company Report Number: 106830	Age: 27 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blindness Night Depression Nec Dizziness (Exc Vertigo) Dry Skin Hot Flashes Nos Hypoesthesia Migraine Nos Vision Blurred Vulvovaginal Dryness	Consumer Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285520-8	Report Type: Periodic	Company Report Number: 106908	Age: 25 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Aggression Depression Nec	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

Drug-Induced Event Reporting System (DAERS)
 Division of Information Control Report

Date: 06/07/1999		ISR Number: 3285526-9		Report Type: Periodic		Company Report Number: 107122		Age: 16 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Acne Aggravated Alanine Aminotransferase Increased Alopecia Aspartate Aminotransferase Increased Back Pain Coma Nec Dermatitis Nos Dyspnoea Nos Fatigue Granuloma Nos Irritability Mood Alteration Nos Nail Discolouration Nausea Scar Urticaria Nos Vertigo Nec	Health Professional Other	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999											
ISR Number: 3285529-4		Report Type: Periodic		Company Report Number: 107180		Age: 36 YR		Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Mood Swings Weight Decreased	Consumer Health Professional Other	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999											
ISR Number: 3285612-3		Report Type: Periodic		Company Report Number: 97604		Age: 47 YR		Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Depression Nec Pain Nos Suicidal Ideation	Consumer Health Professional	Accutane Capsules (Isotretinoin) Effexor	PS C		ORAL					
Date: 06/07/1999											
ISR Number: 3285615-9		Report Type: Periodic		Company Report Number: 97629		Age: 18 YR		Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Death	Completed Suicide	Health Professional Other	Accutane Capsules (Isotretinoin) 40mg	PS		ORAL					

Patient Safety Reporting System
 Division of Information & Statistics

Date: 06/07/1999	ISR Number: 3285616-0	Report Type: Periodic	Company Report Number: 97744			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Aggravated Suicidal Ideation	Health Professional	Accutane Capsules (Isotretinoin) Zolof	PS C		ORAL		
Date: 06/07/1999	ISR Number: 3285617-2	Report Type: Periodic	Company Report Number: 97745			Age: 21 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Eating Disorder Nec	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285618-4	Report Type: Periodic	Company Report Number: 97850			Age: 14 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Abdominal Pain Nos Mood Swings Suicide Attempt Vomiting Nos Weight Decreased	Health Professional Other	Accutane Capsules (Isotretinoin) 40mg Aleve Ibuprofen Tylenol	PS C C C		ORAL		
Date: 06/07/1999	ISR Number: 3285619-6	Report Type: Periodic	Company Report Number: 97903			Age: 18 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Crying Depression Nec Diarrhoea Haemorrhagic Disturbance In Attention Nec Tremor Nec Weight Decreased	Other	Accutane Capsules (Isotretinoin) 40mg Depakote	PS C		ORAL		
Date: 06/07/1999	ISR Number: 3285620-2	Report Type: Periodic	Company Report Number: 97929			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anger Depression Nec Night Sweats	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285621-4	Report Type: Periodic	Company Report Number: 97969			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

ADVERSE Event Reporting System (AERS)
 System Of Information On Drugs

Date: 06/07/1999	ISR Number: 3285622-6	Report Type: Periodic	Company Report Number: 98042	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 Suicidal	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285623-8	Report Type: Periodic	Company Report Number: 98112	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 Suicidal Ideation	Other	Accutane Capsules (Isotretinoin) 40mg	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285625-1	Report Type: Periodic	Company Report Number: 98175	Age: 13 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285626-3	Report Type: Periodic	Company Report Number: 98176	Age: 15 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec Obsessive-Compulsive Disorder	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285627-5	Report Type: Periodic	Company Report Number: 98369	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 Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285637-8	Report Type: Periodic	Company Report Number: 96053	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	Trichotillomania	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285640-8	Report Type: Periodic	Company Report Number: 96241	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 Distension Acne Aggravated Alopecia Depression Nec Fatigue Headache Nos Menstrual Disorder Nos Paraesthesia Nec Rash Papular	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

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

Date: 06/07/1999 ISR Number: 3285641-X 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	Consumer	Accutane Capsules (Isotretinoin) 20 Mg	PS		ORAL		
	Arthralgia	Health Professional	Dhea	C				
	Arthritis Nos							
	Blepharitis							
	Depression Nec							
	Dermatitis Nos							
	Diarrhoea Nos							
	Dry Eye Nec							
	Dry Skin							
	Ear Disorder Nos							
	Earache							
	Fatigue							
	Gum Pain							
	Headache Nos							
	Hypoesthesia							
	Insomnia Nec							
	Nasal Dryness							
	Pain In Limb							
	Sweat Gland Disorder Nos							
	Tongue Oedema							

Date: 06/07/1999 ISR Number: 3285645-7 Report Type: Periodic Company Report Number: 96639 Age: 26 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia	Consumer	Accutane Capsules (Isotretinoin) 60 Mg	PS		ORAL		
	Coma Nec		Loestrin	C				
	Dermatitis Nos							
	Disorientation							
	Dizziness (Exc Vertigo)							
	Dry Skin							
	Pruritus							
	Rash Erythematous							
	Rash Scaly							

Date: 06/07/1999 ISR Number: 3285648-2 Report Type: Periodic Company Report Number: 98427 Age: 15 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
	Hypertriglyceridaemia							
	Nightmare							
	Vertigo Nec							

**FD-424 - Adverse Event Reporting Form (AERS)
 Division Of Information & OD Report**

Date: 06/07/1999	ISR Number: 3285649-4	Report Type: Periodic	Company Report Number: 98471			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Aggression Coma Nec Depression Nec Emotional Disturbance Nos Mood Swings	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285651-2	Report Type: Periodic	Company Report Number: 98557			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Suicide Attempt	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285652-4	Report Type: Periodic	Company Report Number: 98586			Age: 34 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Aggravated Alopecia Coma Nec Depression Nec Mood Swings Vomiting Nos	Consumer Health Professional	Accutane Capsules (Isotretinoin) 40 Mg Vitamin C	PS C		ORAL		
Date: 06/07/1999	ISR Number: 3285660-3	Report Type: Periodic	Company Report Number: 99025			Age: 13 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec Suicide Attempt	Consumer Health Professional	Accutane Capsules (Isotretinoin) 40 Mg Paxil	PS C		ORAL		
Date: 06/07/1999	ISR Number: 3285661-5	Report Type: Periodic	Company Report Number: 99028			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anorexia Beniga Intracranial Hypertension Coma Nec Depression Nec Headache Nos Lethargy	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285667-6	Report Type: Periodic	Company Report Number: 99251			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aggression Coma Nec	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

FDA Adverse Event Reporting System
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Date: 06/07/1999		ISR Number: 3285668-8		Report Type: Periodic		Company Report Number: 99252		Age: 17 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Depression Nec Suicidal Ideation	Health Professional	Accutane Capsules (Isotretinoin) Ritalin	PS C		ORAL					
Date: 06/07/1999		ISR Number: 3285669-X		Report Type: Periodic		Company Report Number: 99261		Age: 30 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Life-Threatening Hospitalization - Initial or Prolonged	Bone Pain Depression Nec Suicide Attempt	Consumer	Accutane Capsules (Isotretinoin) Demulen	PS C		ORAL					
Date: 06/07/1999		ISR Number: 3285671-8		Report Type: Periodic		Company Report Number: 99308		Age: 15 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Depression Nec Suicidal Ideation	Health Professional Other	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3285672-X		Report Type: Periodic		Company Report Number: 99310		Age: 18 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Abnormal Behaviour Nos Blood Cholesterol Increased Blood Triglycerides Increased Depression Nec Mood Swings	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL					
Date: 06/07/1999		ISR Number: 3285673-1		Report Type: Periodic		Company Report Number: 99311		Age:		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Depression Aggravated	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3285674-3		Report Type: Periodic		Company Report Number: 99346		Age: 17 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Depression Nec Suicidal Ideation	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3285675-5		Report Type: Periodic		Company Report Number: 99399		Age: 26 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Crying Depression Nec Suicidal Ideation	Other	Accutane Capsules (Isotretinoin)	PS		ORAL					

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

Date: 06/07/1999	ISR Number: 3285676-7	Report Type: Periodic	Company Report Number: 99413	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	Appetite Decreased Depression Nec Social Avoidant Behaviour Weight Decreased	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285677-9	Report Type: Periodic	Company Report Number: 99475	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 Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285678-0	Report Type: Periodic	Company Report Number: 99550	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	Aggression Apathy Depression Nec	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285679-2	Report Type: Periodic	Company Report Number: 99993	Age: 37 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Arthralgia Depression Aggravated Myalgia Suicidal Ideation	Health Professional	Accutane Capsules (Isotretinoin) Wellbutrin Prozac Antabuse	PS C C C		ORAL		
Date: 06/07/1999	ISR Number: 3285680-9	Report Type: Periodic	Company Report Number: 100085	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	Depression Aggravated	Health Professional	Accutane Capsules (Isotretinoin) Depo Provera (Medroxyprogesterone Acetate) 150mg Wellbutrin Estinyl	PS SS C C		ORAL		
Date: 06/07/1999	ISR Number: 3285681-0	Report Type: Periodic	Company Report Number: 100090	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>
Hospitalization - Initial or Prolonged	Suicide Attempt	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		

FDA Adverse Event Reporting System (AERS)
 Division Of Information On Drugs

Date: 06/07/1999 ISR Number: 3285682-2

Report Type: Periodic

Company Report Number: 100372

Age: 16 YR

Gender: Male

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

Date: 06/07/1999 ISR Number: 3285683-4

Report Type: Periodic

Company Report Number: 100469

Age: 23 YR

Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos Disturbance In Attention Nec Hallucination, Auditory Insomnia Nec Memory Impairment Mood Swings Paresthesia Nec	Health Professional	Accutane Capsules (Isotretinoin) Oral Contraceptives	PS C		ORAL		

Date: 06/07/1999 ISR Number: 3285684-6

Report Type: Periodic

Company Report Number: 100509

Age: 17 YR

Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Suicide Attempt Tremor Nec	Other	Accutane Capsules (Isotretinoin) Stelazine (Trifluoperazine Hydrochloride)	PS SS		ORAL		

Date: 06/07/1999 ISR Number: 3285685-8

Report Type: Periodic

Company Report Number: 100589

Age: 24 YR

Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Antinuclear Factor Positive Crying Depressed Mood Depression Nec Emotional Disturbance Nos Fatigue	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/07/1999 ISR Number: 3285687-1

Report Type: Periodic

Company Report Number: 100742

Age: 16 YR

Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Suicide Attempt	Health Professional	Accutane Capsules (Isotretinoin) 40mg	PS		ORAL		

Date: 06/07/1999 ISR Number: 3285688-3

Report Type: Periodic

Company Report Number: 100773

Age: 21 YR

Gender: Male

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

FDA Adverse Event Reporting System (AERS)
 Division of Information Operations

Date: 06/07/1999	ISR Number: 3285690-1	Report Type: Periodic	Company Report Number: 100778			Age: 21 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Depression Aggravated Psychotic Disorder Nos	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285691-3	Report Type: Periodic	Company Report Number: 100782			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Psychotic Disorder Nos	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285692-5	Report Type: Periodic	Company Report Number: 100854			Age: 15 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Mood Swings Suicide Attempt	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285693-7	Report Type: Periodic	Company Report Number: 100996			Age: 16 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Anger Coma Nec Depression Nec Feeling Abnormal	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285694-9	Report Type: Periodic	Company Report Number: 100999			Age: 21 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Coma Nec Depression Nec Dermatitis Nos Listless Sedation Suicidal Ideation	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285695-0	Report Type: Periodic	Company Report Number: 101293			Age: 16 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Tooth Caries Nos	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285697-4	Report Type: Periodic	Company Report Number: 101428			Age: 47 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		

FDA Adverse Event Reporting System (AERS)
 Division of Databases (DDI) Reports

Date: 06/07/1999	ISR Number: 3285702-5	Report Type: Periodic	Company Report Number: 102006	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	Convulsions Nos Depression Nec Flashback Grand Mal Convulsion Insomnia Nec Nausea Petit Mal Epilepsy Sedation Weakness	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285703-7	Report Type: Periodic	Company Report Number: 102033	Age: 23 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Coma Nec Depression Aggravated Suicidal Ideation	Consumer	Accutane (Isotretinoin) Ortho Tri-Cyclen Xanax	PS C C		ORAL		
Date: 06/07/1999	ISR Number: 3285705-0	Report Type: Periodic	Company Report Number: 102050	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	Depression Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285706-2	Report Type: Periodic	Company Report Number: 102067	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	Aggression Depression Nec Suicidal Ideation	Other	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285708-6	Report Type: Periodic	Company Report Number: 102867	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	Appetite Decreased Blood Glucose Decreased Confusion Depression Nec	Health Professional Other	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285709-8	Report Type: Periodic	Company Report Number: 103059	Age: 23 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Dizziness (Exc Vertigo) Dry Skin	Consumer	Accutane Capsules (Isotretinoin) 60 Mg	PS		ORAL		

FDA Adverse Event Reporting System (AERS)
 Division of Informatics and Statistics

Date: 06/07/1999	ISR Number: 3285711-6	Report Type: Periodic	Company Report Number: 103319	Age: 17 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285713-X	Report Type: Periodic	Company Report Number: 103491	Age: 13 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Depression Nec Suicide Attempt	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285714-1	Report Type: Periodic	Company Report Number: 103954	Age: 75 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Back Pain Bone Disorder Nos Coma Nec Depression Nec Difficulty In Walking Soft Tissue Disorder Nos Swelling Nos Weakness	Consumer	Accutane Capsules (Isotretinoin) 40 Mg Aspirin Unknown Hypertension Drug	PS C C		ORAL		
Date: 06/07/1999	ISR Number: 3285716-5	Report Type: Periodic	Company Report Number: 104463	Age: 15 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Mood Swings Suicide Attempt	Other	Accutane Capsules (Isotretinoin) 20 Mg	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285717-7	Report Type: Periodic	Company Report Number: 104721	Age: 20 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Aggravated	Consumer	Accutane Capsules (Isotretinoin) Antidepressant Continuing	PS C		ORAL		
Date: 06/07/1999	ISR Number: 3285721-9	Report Type: Periodic	Company Report Number: 106302	Age: 17 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aggression Depression Suicidal	Consumer Health Professional	Accutane Capsules (Isotretinoin) Birth Control Pill	PS C		ORAL		

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

Date: 06/07/1999	ISR Number: 3285722-0	Report Type: Periodic	Company Report Number: 106377	Age: 25 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Coma Nec Crying Depression Nec Headache Nos Insomnia Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285723-2	Report Type: Periodic	Company Report Number: 106552	Age: 20 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285727-X	Report Type: Periodic	Company Report Number: 106930	Age: 17 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide	Other	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285729-3	Report Type: Periodic	Company Report Number: 110768	Age: 16 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Suicidal Ideation	Consumer Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285730-X	Report Type: Periodic	Company Report Number: 110829	Age: 15 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285732-3	Report Type: Periodic	Company Report Number: 110965	Age: 45 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Coma Nec Depression Nec Insomnia Nec Mood Swings Suicidal Ideation	Health Professional	Accutane Capsules (Isotretinoin) Demilen	PS C		ORAL		
Date: 06/07/1999	ISR Number: 3285733-5	Report Type: Periodic	Company Report Number: 111017	Age: 31 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anger Blister Blood Cholesterol Increased	Consumer Health Professional	Accutane Capsules (Isotretinoin) 41 Mg Citrous Transdermal	PS C		ORAL		

FDA Adverse Event Reporting System
 Periodic Information Report

Date: 06/07/1999 ISR Number: 3285734-7 Report Type: Periodic Company Report Number: 111046 Age: 38 YR Gender: Female

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

Date: 06/07/1999 ISR Number: 3285735-9 Report Type: Periodic Company Report Number: 111077 Age: 14 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional Other	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		

Date: 06/07/1999 ISR Number: 3285736-0 Report Type: Periodic Company Report Number: 111139 Age: 21 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Mood Swings	Other	Accutane Capsules (Isotretinoin) Birth Control Pills Nos	PS C		ORAL		

Date: 06/07/1999 ISR Number: 3285738-4 Report Type: Periodic Company Report Number: 111320 Age: 23 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Crying Depression Nec Insomnia Nec Mood Swings	Consumer Health Professional	Accutane Capsules (Isotretinoin) Oral Contraception	PS C		ORAL		

Date: 06/07/1999 ISR Number: 3285741-4 Report Type: Periodic Company Report Number: 111676 Age: 17 YR Gender: Female

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

Date: 06/07/1999 ISR Number: 3285742-6 Report Type: Periodic Company Report Number: 111716 Age: 41 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Coma Nec Crying Depression Nec Mood Swings Sleep Disorder Nos Social Avoidant Behaviour Suicidal Ideation	Health Professional	Accutane Capsules (Isotretinoin) 20 Mg	PS		ORAL		

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

Date: 06/07/1999 ISR Number: 3285744-X Report Type: Periodic Company Report Number: 111802 Age: 27 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Major Depressive Disorder Nos	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
			Ortho Tri Cyclen	C				

Date: 06/07/1999 ISR Number: 3285747-5 Report Type: Periodic Company Report Number: 111894 Age: 32 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Therapeutic Agent Toxicity		Birth Control Pills	C				
			Paxil	C				
			Advil	C				

Date: 06/07/1999 ISR Number: 3285750-5 Report Type: Periodic Company Report Number: 108439 Age: 25 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Apathy	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Appetite Decreased	Other	Oral Contraceptives Nos	C				
	Asthenia		Minocycline	C				
	Coma Nec		Claritin	C				
	Depression Nec		Motrin	C				
	Emotional Disturbance Nos							
	Epistaxis							
	Headache Nos							
	Lip Disorder Nos							

Date: 06/07/1999 ISR Number: 3285751-7 Report Type: Periodic Company Report Number: 108490 Age: 16 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Coma Nec	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Depression Aggravated	Health Professional	Ortho Tri-Cyclen	C				
	Insomnia Nec		Desogen	C				
	Tearfulness		Zoloft	C				

Date: 06/07/1999 ISR Number: 3285753-0 Report Type: Periodic Company Report Number: 108560 Age: 26 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Acne Aggravated	Consumer	Accutane (Isotretinoin)	PS		ORAL		
	Apathy	Health Professional	Contraceptive Nos	C				
	Depression Aggravated							
	Dry Mouth							
	Haemorrhage Nos							
	Lip Disorder Nos							

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

Date: 06/07/1999 ISR Number: 3285755-4 Report Type: Periodic Company Report Number: 108654 Age: 19 YR Gender: Female

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

Date: 06/07/1999 ISR Number: 3285757-8 Report Type: Periodic Company Report Number: 109130 Age: 16 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Aggression	Other	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
	Crying							
	Depression Nec							
	Disturbance In Attention Nec							
	Insomnia Nec							
	Nausea							

Date: 06/07/1999 ISR Number: 3285760-8 Report Type: Periodic Company Report Number: 109402 Age: 19 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Menstruation Irregular							
	Weight Increased		Paxil	C				

Date: 06/07/1999 ISR Number: 3285762-1 Report Type: Periodic Company Report Number: 109641 Age: 15 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
			Wellbutrin	C				
			Prozac	C				
			Oral Contraception	C				

Date: 06/07/1999 ISR Number: 3285763-3 Report Type: Periodic Company Report Number: 109710 Age: 16 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Alkaline Phosphatase Nos Increased	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
	Blood Iron Decreased							
	Cheilitis		Voltaren	C				
	Costochondritis							
	Dermatitis Nos							
	Dry Skin							
	Emotional Disturbance Nos							
	Epistaxis							
	Erythrocyte Sedimentation Rate							

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
 Division of Drug Information (DDI) Report

Date: 06/07/1999 **ISR Number:** 3285766-9 **Report Type:** Periodic **Company Report Number:** 110346 **Age:** 36 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	Alcoholism Androgens Nos Increased Blood Cholesterol Increased Blood Triglycerides Increased Depression Nec	Consumer Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/07/1999 **ISR Number:** 3285770-0 **Report Type:** Periodic **Company Report Number:** 107059 **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>
Hospitalization - Initial or Prolonged	Abnormal Dreams Aggression Depression Nec Mood Swings	Other	Accutane Capsules (Isotretinoin) 40 Mg Antidepressants Antianxiety Agent	PS C C		ORAL		

Date: 06/07/1999 **ISR Number:** 3285773-6 **Report Type:** Periodic **Company Report Number:** 107586 **Age:** 17 YR **Gender:** Male

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

Date: 06/07/1999 **ISR Number:** 3285774-8 **Report Type:** Periodic **Company Report Number:** 107679 **Age:** 37 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	Coma Nec Depression Nec Headache Nos Mood Swings Suicidal Ideation	Health Professional Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/07/1999 **ISR Number:** 3285775-X **Report Type:** Periodic **Company Report Number:** 107680 **Age:** 25 YR **Gender:** Male

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

Date: 06/07/1999 **ISR Number:** 3285776-1 **Report Type:** Periodic **Company Report Number:** 107744 **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	Coma Nec Depression Nec Disturbance In Attention Nec Fatigue Headache Nos Insomnia Nec	Consumer Health Professional	Accutane Capsules (Isotretinoin) 20 Mg	PS		ORAL		

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

Date: 06/07/1999	ISR Number: 3285778-5	Report Type: Periodic	Company Report Number: 107754			Age: 32 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Depression Suicidal	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL	
Date: 06/07/1999	ISR Number: 3285779-7	Report Type: Periodic	Company Report Number: 107768			Age: 30 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Hospitalization - Initial or Prolonged	Depression Nec Suicidal Ideation	Health Professional	Accutane Capsules (Isotretinoin) Birth Control Pills	PS C		ORAL	
Date: 06/07/1999	ISR Number: 3285782-7	Report Type: Periodic	Company Report Number: 107928			Age:	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Death	Completed Suicide Depression Nec	Other	Accutane Capsules (Isotretinoin)	PS		ORAL	
Date: 06/07/1999	ISR Number: 3285784-0	Report Type: Periodic	Company Report Number: 108127			Age: 39 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Blood Cholesterol Increased Depression Aggravated Eosinophil Count Decreased	Health Professional	Accutane Capsules (Isotretinoin) Effexor	PS C		ORAL	
Date: 06/07/1999	ISR Number: 3285785-2	Report Type: Periodic	Company Report Number: 108198			Age: 18 YR	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Hospitalization - Initial or Prolonged	Coma Nec Mood Swings Suicidal Ideation Suicide Attempt	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL	
Date: 06/07/1999	ISR Number: 3285786-4	Report Type: Periodic	Company Report Number: 108271			Age: 17 YR	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Depression Nec Panic Attack Suicidal Ideation	Other	Accutane (Isotretinoin) 40 Mg	PS		ORAL	
Date: 06/07/1999	ISR Number: 3285791-8	Report Type: Periodic	Company Report Number: 95643			Age: 34 YR	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Abnormal Behaviour Nos Anger Coma Nec Depression Nec	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL	

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

Date: 06/07/1999	ISR Number: 3285794-3	Report Type: Periodic	Company Report Number: 95719			Age: 18 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Nos Condition Aggravated Depression Nec Psychotic Disorder Nos	Health Professional	Accutane Capsules (Isotretinoin) Zolof	PS C		ORAL		
Date: 06/07/1999	ISR Number: 3285795-5	Report Type: Periodic	Company Report Number: 95856			Age: 18 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Coma Nec Depression Nec Disturbance In Attention Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285797-9	Report Type: Periodic	Company Report Number: 95944			Age: 43 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Psychotic Disorder Nos	Health Professional	Accutane Capsules (Isotretinoin) Lithium	PS C		ORAL		
Date: 06/07/1999	ISR Number: 3285801-8	Report Type: Periodic	Company Report Number: 96273			Age: 23 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Anger Anxiety Nec Depression Nec Suicide Attempt	Health Professional	Accutane Capsules Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285804-3	Report Type: Periodic	Company Report Number: 96545			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death Life-Threatening	Completed Suicide Depression Nec	Health Professional	Accutane Capsules (Isotretinoin) Zolof	PS C		ORAL		
Date: 06/07/1999	ISR Number: 3285806-7	Report Type: Periodic	Company Report Number: 96942			Age: 16 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Disturbance In Attention Nec Mood Swings Paranoia	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

FDA Adverse Event Reporting System
 Form of Information (FD) Form

Date: 06/07/1999		ISR Number: 3285807-9		Report Type: Periodic		Company Report Number: 96992		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>			
Life-Threatening	Suicide Attempt	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL					
			Unspecified Medication	C							
Date: 06/07/1999		ISR Number: 3285810-9		Report Type: Periodic		Company Report Number: 97450		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>			
Life-Threatening	Suicide Attempt	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL					
			E-Mycin	C							
			Benzamycin	C							
Date: 06/07/1999		ISR Number: 3285811-0		Report Type: Periodic		Company Report Number: 97451		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>			
Life-Threatening	Depression Nec Suicide Attempt	Health Professional	Accutane Capsules (Isotretinoin) 40mg	PS		ORAL					
			Denmilen	C							
Date: 06/07/1999		ISR Number: 3285816-X		Report Type: Periodic		Company Report Number: 80978		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	Anxiety Nec Back Pain Depression Nec Mood Swings Panic Attack Personality Disorder Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL					
			Tetracycline	C							
			Zytec	C							
Date: 06/07/1999		ISR Number: 3285826-2		Report Type: Periodic		Company Report Number: 89317		Age: 23 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Fatigue Headache Nos Memory Impairment Personality Change	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL					
			Iron	C							
Date: 06/07/1999		ISR Number: 3285834-1		Report Type: Periodic		Company Report Number: 91380		Age: 35 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Abdominal Pain Nos Alopecia Flatulence Irritable Bowel Syndrome Lactose Intolerance	Consumer	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL					

FDA Adverse Event Reporting System (AERS)
 Freedom Of Information Act Request

Date: 06/07/1999		ISR Number: 3285835-3		Report Type: Periodic		Company Report Number: 92727		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	Acne Aggravated Diarrhoea Nos Epistaxis Lip Dry Nightmare Vomiting Nos	Other	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL					
Date: 06/07/1999		ISR Number: 3285837-7		Report Type: Periodic		Company Report Number: 93590		Age: 37 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 Smear Cervix Abnormal	Consumer	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL					
Date: 06/07/1999		ISR Number: 3285840-7		Report Type: Periodic		Company Report Number: 94448		Age: 27 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Blood Glucose Abnormal Depression Nec Fatigue Weight Increased	Consumer Health Professional Other	Accutane Capsules (Isotretinoin) Contraceptive	PS C		ORAL					
Date: 06/07/1999		ISR Number: 3285865-1		Report Type: Periodic		Company Report Number: 113292		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	Anhedonia Appetite Decreased Depression Nec Dermatitis Nos Disturbance In Attention Nec Dry Skin Emotional Disturbance Nos Epistaxis Fatigue Headache Nos Hypersomnia Hypertiglyceridemia Libido Decreased Lip Dry Social Avoidant Behaviour Weight Decreased	Consumer Health Professional	Accutane Capsules (Isotretinoin) 40 Mg Ortho Tri-Cyclen	PS C		ORAL					

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

Date: 06/07/1999 ISR Number: 3285867-5 Report Type: Periodic Company Report Number: 200131 Age: 22 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Mood Swings	Health Professional	Birth Control Pills	C				
	Suicidal Ideation							
	Suicide Attempt							

Date: 06/07/1999 ISR Number: 3285870-5 Report Type: Periodic Company Report Number: 200150 Age: 17 YR Gender: Male

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

Date: 06/07/1999 ISR Number: 3285871-7 Report Type: Periodic Company Report Number: 200167 Age: 32 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depressed Mood	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Depression Aggravated	Health Professional						
	Irritability							
	Sleep Disorder Nos							

Date: 06/07/1999 ISR Number: 3285875-4 Report Type: Periodic Company Report Number: 200298 Age: 16 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
	Appetite Decreased							
	Arthralgia							
	Chellitis							
	Condition Aggravated							
	Depression Nec							
	Headache Nos							
	Menstrual Disorder Nos							
	Myalgia							
	Raynaud'S Phenomenon							
	Suicidal Ideation							
	Weight Decreased							

Date: 06/07/1999 ISR Number: 3285879-1 Report Type: Periodic Company Report Number: 200327 Age: 17 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Depression Nec	Other	Birth Control Pill	C				
	Dry Skin							
	Suicidal Ideation							

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

Date: 06/07/1999 ISR Number: 3285886-9 Report Type: Periodic Company Report Number: 200724 Age: 15 YR Gender: Male

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

Date: 06/07/1999 ISR Number: 3285888-2 Report Type: Periodic Company Report Number: 200762 Age: 18 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Condition Aggravated Depression Aggravated Mood Swings Suicidal Ideation Violence-Related Symptom	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/07/1999 ISR Number: 3285890-0 Report Type: Periodic Company Report Number: 200892 Age: 47 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthralgia Depression Aggravated Lip Dry Mouth Ulceration White Blood Cell Count Decreased	Consumer Health Professional	Accutane Capsules (Isotretinoin) 40 Mg Prozac Serzone Dexedrine	PS C C C		ORAL		

Date: 06/07/1999 ISR Number: 3285892-4 Report Type: Periodic Company Report Number: 200999 Age: 33 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthralgia Depression Nec Epistaxis Fatigue Headache Nos Irritability Joint Stiffness Lethargy	Consumer Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 06/07/1999 ISR Number: 3285896-1 Report Type: Periodic Company Report Number: 201089 Age: Gender: Male

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

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

Date: 06/07/1999 ISR Number: 3285898-5 Report Type: Periodic Company Report Number: 201149 Age: 32 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Cholesterol Increased Blood Triglycerides Increased Depression Nec Dry Skin Lip Dry Nasal Dryness Suicidal Ideation	Health Professional Other	Accutane Capsules (Isotretinoin) Oral Contraceptive	PS C		ORAL		

Date: 06/07/1999 ISR Number: 3285901-2 Report Type: Periodic Company Report Number: 201250 Age: 16 YR Gender: Male

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

Date: 06/07/1999 ISR Number: 3285908-5 Report Type: Periodic Company Report Number: 112182 Age: 17 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Coma Nec Completed Suicide Corneal Oedema Lip Dry Refractive Errors Nos	Health Professional	Accutane Capsules (Isotretinoin) Cleocin Unk (Clindamycin)	PS C		ORAL		

Date: 06/07/1999 ISR Number: 3285909-7 Report Type: Periodic Company Report Number: 112306 Age: 16 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aggression Agitation Bipolar I Disorder Insomnia Nec	Other	Accutane Capsules (Isotretinoin) 80 Mg Pariactin Unk (Cyproheptadine Hydrochloride)	PS C		ORAL		

Date: 06/07/1999 ISR Number: 3285912-7 Report Type: Periodic Company Report Number: 97082 Age: 31 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Arthralgia Arthritis Nos Back Pain Coma Nec Condition Aggravated Depression Nec Dermatitis Nos Diarrhoea Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		

FOIA - Adverse Event Reporting System (AERS)
 System Of Information (SOI) Report

Date: 06/07/1999 ISR Number: 3285913-9 Report Type: Periodic Company Report Number: 112480 Age: 25 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anaemia Nos Blood Cholesterol Increased Depression Nec Irritability Mood Swings	Consumer Health Professional	Accutane Capsules (Isotretinoin) Ortho Tri-Cyclen (Ethinyl Estradiol/Norgestimate)	PS C		ORAL		

Date: 06/07/1999 ISR Number: 3285915-2 Report Type: Periodic Company Report Number: 112581 Age: 40 YR Gender: Female

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

Date: 06/07/1999 ISR Number: 3285917-6 Report Type: Periodic Company Report Number: 112659 Age: 42 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Consumer Other	Accutane Capsules (Isotretinoin) Ortho Tri-Cyclen (Ethinyl Estradiol/Norgestimate) Trazodone (Trazodone Hydrochloride)	PS C C		ORAL		

Date: 06/07/1999 ISR Number: 3285918-8 Report Type: Periodic Company Report Number: 97295 Age: 18 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Aggravated Blood Glucose Abnormal Blood Triglycerides Increased Cheilitis Coma Nec Depression Nec Disturbance In Attention Nec Dry Skin Fatigue Mood Swings Rash Erythematous Urticaria Nos	Other	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		

Date: 06/07/1999 ISR Number: 3285919-X Report Type: Periodic Company Report Number: 112781 Age: 26 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Aggravated	Consumer Health Professional	Accutane Capsules (Isotretinoin) 20 Mg	PS		ORAL		

FD-626 (Rev. 05-22-97) (Continuation Sheet) (AERS)
 Freedom Of Information (FOI) Report

Date: 06/07/1999		ISR Number: 3285919-X		Report Type: Periodic		Company Report Number: R02781		Age:		Gender:	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Depression Aggravated	Other	Accutane Capsules (Isotretinoin) 20 Mg	PS		ORAL					
			Prozac (Fluoxetine Hydrochloride)	C							
			Zoloft (Sertraline Hydrochloride)	C							
			Ortho Tri-Cyclen Unk (Ethinyl Estradiol/Norgestimate)	C							
Date: 06/07/1999		ISR Number: 3285920-6		Report Type: Periodic		Company Report Number: 112826		Age: 19 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Coma Nec Depression Nec Disturbance In Attention Nec Sensory Disturbance Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3285922-X		Report Type: Periodic		Company Report Number: 112837		Age: 40 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Coma Nec Condition Aggravated Depression Aggravated Social Avoidant Behaviour Suicidal Ideation	Consumer Other	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL					
			Demlen Unk (Ethinyl Estradiol/Ethinodiol Diacetate)	C							
			Paxil (Paroxetine)	C							
Date: 06/07/1999		ISR Number: 3285925-5		Report Type: Periodic		Company Report Number: 920200189001		Age: 25 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Headache Nos Lip Dry Loss Of Libido Paresthesia Nec	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL					
Date: 06/07/1999		ISR Number: 3285927-9		Report Type: Periodic		Company Report Number: 940202353001		Age: 21 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Mood Swings Suicidal Ideation	Consumer	Accutane Capsules (Isotretinoin)	PS							
Date: 06/07/1999		ISR Number: 3285928-0		Report Type: Periodic		Company Report Number: 112872		Age: 20 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Agitation Coma Nec Crying Depression Nec Sedation	Consumer Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL					

FDA - Agency Event Reporting System (AERS)
Freedom of Information Act (FOIA)

Date: 06/07/1999 ISR Number: 3285929-2 Report Type: Periodic Company Report Number: 950200111001 Age: 15 YR Gender: Male

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

Date: 06/07/1999 ISR Number: 3285932-2 Report Type: Periodic Company Report Number: 950200191001 Age: 23 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Condition Aggravated Depression Nec Dry Skin Eye Disorder Nos Hair Texture Abnormal Lip Dry Rash Erythematous Visual Acuity Reduced	Consumer	Accutane Capsules (Isotretinoin) Prednisone	PS C		ORAL		

Date: 06/07/1999 ISR Number: 3285934-6 Report Type: Periodic Company Report Number: 112942 Age: 28 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Aggravated Feeling Hot Insomnia Nec Nausea Rigors	Health Professional	Accutane Capsules (Isotretinoin) Contraceptive (Contraceptive Nos) Morphine (Morphine Sulfate) Anti-Inflammatory Nos (Anti-Inflammatory Agent Nos)	PS C C C		ORAL		

Date: 06/07/1999 ISR Number: 3285935-8 Report Type: Periodic Company Report Number: 113023 Age: 23 YR Gender: Female

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

Date: 06/07/1999 ISR Number: 3285936-X Report Type: Periodic Company Report Number: 202469 Age: 33 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Depression Nec Diplopia Eye Disorder Nos Headache Nos Pain Nos	Consumer User Facility Other	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		

FDA Adverse Event Reporting System (FAERS)
 Division Of Information & Quality Reports

Date: 06/07/1999	ISR Number: 3285937-1	Report Type: Periodic	Company Report Number: 113200	Age: 21 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Death	Completed Suicide	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285938-3	Report Type: Periodic	Company Report Number: 202649	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	Condition Aggravated Insomnia Exacerbated Myalgia Panic Attack	Consumer	Accutane Capsules (Isotretinoin) 40 Mg Klonopin Lithobid Trazodone Birth Control Pill	PS C C C C		ORAL		
Date: 06/07/1999	ISR Number: 3285939-5	Report Type: Periodic	Company Report Number: 202654	Age: 34 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Disturbance In Attention Nec Fatigue	Consumer	Accutane Capsules (Isotretinoin) Ortho Tri-Cyclen	PS C		ORAL		
Date: 06/07/1999	ISR Number: 3285964-4	Report Type: Periodic	Company Report Number: 109031	Age: 26 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Arthralgia Blindness Night Dry Skin Impaired Healing Lip Dry Muscle Disorder Nos Skin Disorder Nos Thinking Abnormal Nec	Consumer	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Date: 06/07/1999	ISR Number: 3285979-6	Report Type: Periodic	Company Report Number: 109388	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	Alopecia Headache Nos Hypertension Nos Lip Dry Palpitations	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		

Adverse Event Reporting System (AERS)
Version Of Information Only Report

Date: 06/07/1999	ISR Number: 3285980-2	Report Type: Periodic	Company Report Number: 109488	Age: 15 YR	Gender: Female				
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Back Pain Chest Pain Depression Nec Dyspnoea Nos Hyperaesthesia Mood Swings Rash Erythematous	Other	Accutane Capsules (Isotretinoin)	PS		ORAL			
Date: 06/07/1999	ISR Number: 3285982-6	Report Type: Periodic	Company Report Number: 109611	Age: 20 YR	Gender: Male				
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Dysuria Erectile Disturbance Genital Rash Penile Disorder Nos	Consumer	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL			
Date: 06/07/1999	ISR Number: 3285983-8	Report Type: Periodic	Company Report Number: 109655	Age:	Gender: Male				
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Appetite Decreased Diarrhoea Neonatal Irritability Nasal Congestion	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL			
Date: 06/07/1999	ISR Number: 3285989-9	Report Type: Periodic	Company Report Number: 108390	Age: 48 YR	Gender: Female				
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Depression Nec Joint Stiffness	Other	Accutane Capsules (Isotretinoin)	PS		ORAL			
Date: 06/07/1999	ISR Number: 3285993-0	Report Type: Periodic	Company Report Number: 108527	Age: 32 YR	Gender: Female				
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Alopecia Dry Eye Nec Lip Dry Nervousness Panic Reaction Skin Hyperpigmentation	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL			

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

Date: 06/07/1999	ISR Number: 3285998-X	Report Type: Periodic	Company Report Number: 108557	Age: 19 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 06/07/1999	ISR Number: 3286004-3	Report Type: Periodic	Company Report Number: 108657	Age: 27 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Aggravated Dermatitis Nos Fatigue Herpes Simplex Lip Dry	Consumer Health Professional	Accutane Capsules (Isotretinoin) 20 Mg	PS		ORAL		
Date: 06/07/1999	ISR Number: 3286013-4	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 Capsules (Isotretinoin) Entex	PS C		ORAL		
Date: 06/17/1999	ISR Number: 3286273-X	Report Type: Expedited (15-Day)	Company Report Number: 205994	Age: 75 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Bilirubin Increased Condition Aggravated Stress Symptoms Transaminase Nos Increased	Foreign Health Professional	Tasmar (Tolcapone) Madopar Dr Parfodel Deanxit	PS C C C		UNKNOWN		
Date: 06/17/1999	ISR Number: 3286277-7	Report Type: Expedited (15-Day)	Company Report Number: 207406	Age: 62 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Balance Impaired Nos Blood Alkaline Phosphatase Nos Increased Dysarthria Hemiparesis Hepatic Encephalopathy Hyperglycaemia Nos Spinal Cord Disorder Nos Spinal Osteoarthritis	Health Professional	Tasmar (Tolcapone) Vasotec Peri-Colace Tegretol	PS C C C		ORAL		

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

Date: 06/17/1999 ISR Number: 3286280-7 Report Type: Expedited (15-Day) Company Report Number: 207406 Age: 62 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Balance Impaired Nos	Health Professional	Tasmar (Tocapone)	PS		ORAL		
	Blood Alkaline Phosphatase Nos Increased		Vasotec	C				
	Difficulty In Walking		Peri-Colace	C				
	Dysarthria		Tegretol	C				
	Hepatic Encephalopathy							
	Hyperglycaemia Nos							
	Monoparesis							
	Paresis							
	Spinal Cord Disorder Nos							

Date: 06/07/1999 ISR Number: 3286916-0 Report Type: Periodic Company Report Number: 98373 Age: 15 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Back Pain	Other	Accutane Capsules (Isotretinoin) 40mg	PS		ORAL		
	Depression Nec							
	Fatigue							
	Pain In Limb							

Date: 06/07/1999 ISR Number: 3286919-6 Report Type: Periodic Company Report Number: 98422 Age: 16 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Blood Bilirubin Increased	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
	Depression Nec							
	Dry Skin							
	Mood Alteration Nos							

Date: 06/17/1999 ISR Number: 3288335-X Report Type: Expedited (15-Day) Company Report Number: 208256 Age: 31 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Hospitalization - Initial or Prolonged	Depression Aggravated	Other	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL			
	Marital Problem								
	Mood Swings						Desipramine	C	
	Personality Change						Zoloft	C	
	Theft						Clonidine	C	
							Xanax	C	

Date: 06/24/1999 ISR Number: 3290878-X Report Type: Expedited (15-Day) Company Report Number: 206256 Age: 68 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Hospitalization - Initial or Prolonged	Akinesia	Foreign	Tasmar (Tocapome) 100 Mg	PS		ORAL			
	Blood Creatine Phosphokinase Increased						Madopar	C	
	Blood Lactate Dehydrogenase						Madopar Hbs	C	

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Adverse Drug Reporting System (ADRS)
 Division of Information (DI) Report

Date: 06/24/1999 ISR Number: 3290879-1 Report Type: Expedited (15-Day) Company Report Number: 112776 Age: 52 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Akinetic Mutism	Foreign	Tasmur (Tolcapone)	PS		ORAL		
	Delusion Nos	Health Professional	Madopar	C				
	Depression Aggravated		Rohypnol	C				
	Depression Nec		Kalium Tabletten	C				
	Dystonia		Beloc-Zok	C				
	Hallucination Nos		Glucophage	C				
	Hypoesthesia		Daonil	C				
	Hypokinesia		Naproxen	C				
	Joint Stiffness		At-10	C				
	Loose Associations		Saroten	C				
	Mania		Sirdalud	C				
	Monoparesis		Tonopan	C				
	Nuclear Magnetic Resonance Imaging Abnormal							
	Persecutory Delusion							
	Psychotic Disorder Nos							
	Rigors							
	Suicidal Ideation							
	Suicide Attempt							
	Swelling Nos							
	Tremor Nec							

Date: 06/24/1999 ISR Number: 3290882-1 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	Tasmur (Tolcapone)	PS				
	Parkinson'S Disease Aggravated	Health Professional	Madopar Dr	C				
	Personality Change		Akineton	C				
			Permax	C				
			Leponex	C				

Date: 06/21/1999 ISR Number: 3291737-9 Report Type: Periodic Company Report Number: 1998SIN0091 Age: 50 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Agitation	Health Professional	Sinemet (Carbidopa/Levodopa)	PS		ORAL		
	Back Pain		Ni (Amiripityline)	SS		ORAL		
	Gait Abnormal Nos		Permax (Pergolide Mesilate)	SS		ORAL		
	Peripheral Neuropathy Nec		Eldepryl (Selegiline Hydrochloride)	SS		ORAL		
	Tremor Nec		Tasmur (Tolcapone)	SS		ORAL		

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

Date: 06/28/1999		ISR Number: 3292940-4		Report Type: Expedited (15-Day)		Company Report Number: 206256		Age: 68 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Hospitalization - Initial or Prolonged	Akinesia	Foreign	Tasmar (Tolcapone) 100 Mg	PS		ORAL					
	Blood Creatine Phosphokinase Increased	Health Professional	Madopar (Benserazide/Levodopa)	C							
	Blood Lactate Dehydrogenase Increased	Other	Madopar Hbs (Benserazide/Levodopa)	C							
	C-Reactive Protein Increased		Parlodol (Finasteride)	C							
	Cerebrovascular Accident Nos		Proscar (Finasteride)	C							
	Confusion		Tolvon (Mianserin Hydrochloride)	C							
	Dementia Nos		Importal (Lactitol)	C							
	Disturbance In Attention Nec										
	Erythrocyte Sedimentation Rate Increased										
	Fall										
	Haematuria Present										
	Liver Function Tests Nos										
	Abnormal										
	Parkinson'S Disease Aggravated										
	Proteinuria Present										
	Pyrexia										
	Urinary Tract Infection Nos										
Urine Discolouration											
White Blood Cells Urine Positive											
Date: 06/28/1999 ISR Number: 3292946-5 Report Type: Expedited (15-Day) Company Report Number: 207951 Age: 70 YR Gender: Female											
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Insomnia Nec	Health Professional	Tasmar (Tolcapone)	PS		ORAL					
	Liver Function Tests Nos		Mirapex (Pramipexole)	C							
	Abnormal		Estrogen (Estrogens Nos)	C							
			Triamterene (Triamterene)	C							
			Tylenol (Acetaminophen)	C							
			Symmetrel (Amantadine Hydrochloride)	C							
Date: 07/01/1999 ISR Number: 3297269-6 Report Type: Expedited (15-Day) Company Report Number: 97850 Age: 14 YR Gender: Female											
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Life-Threatening	Abnormal Behaviour Nos	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL					
Hospitalization - Initial or Prolonged	Aggression	Other	Aleve	C							
	Appetite Decreased		Ibuprofen	C							
	Arthralgia		Tylenol	C							
	Back Pain										

FDA - Adverse Event Reporting System (AERS)
Division of Information Systems

Date: 07/02/1999 ISR Number: 3297643-8 Report Type: Expedited (15-Day) Company Report Number: 205976 Age: 74 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alanine Aminotransfense Increased	Foreign	Tazmar (Tolcapone)	PS		ORAL		
	Apraxia	Health Professional	Madopar	C				
	Aspartate Aminotransferase Increased		Aspirin	C				
	Bradykinesia		Eltroxin	C				
	Coordination Abnormal Nos		Fosamax	C				
	Extrapyramidal Disorder Nec		Sirdalud	C				
	Insomnia Nec		Venoruton	C				
	Movement Disorder Nos		Paragar	C				
	Muscle Rigidity		Calcium D Sauter	C				
	Oedema Lower Limb							
	Restless Leg Syndrome							
	Restlessness							
	Rigors							
	Tremor Nec							
	Varicose Veins Nos							

Date: 07/06/1999 ISR Number: 3298115-7 Report Type: Expedited (15-Day) Company Report Number: 208050 Age: 38 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Acid Fast Stain Positive	Foreign	Rocaccutane(Isotretinoin) 55 Mg	PS		ORAL		
	Alopecia	Health Professional						
	Cough							
	Depression Nec							
	Dry Mouth							
	Epistaxis							
	Haemoglobin Decreased							
	Hiv Test Positive							
	Leucopenia Nos							
	Night Sweats							
	Pyrexia							
	Tuberculosis Nos							
	Weight Decreased							
	White Blood Cell Count Decreased							

Date: 07/06/1999 ISR Number: 3298125-X Report Type: Expedited (15-Day) Company Report Number: 207406 Age: 62 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Balance Impaired Nos	Health Professional	Tazmar (Tolcapone)	PS		ORAL		
	Difficulty In Walking		Vasotec (Enalapril Maleate)	C				

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

Date: 07/08/1999		ISR Number: 3299554-0		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 Parkinsonism Aggravated Personality Change	Foreign Health Professional	Tasmar (Tolcapone) Madopar Dr (Benserazide/Levodopa) Akineton (Biperiden Hydrochloride) Permax (Pergolide Mesylate) Leponex (Clozapine)	PS C C C C							
Date: 07/09/1999		ISR Number: 3300674-2		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	Abnormal Behaviour Nos Murder Personality Disorder Nos	Health Professional	Accutane Capsules (Isotretinoin) Deltason	PS C		ORAL					
Date: 07/12/1999		ISR Number: 3301939-0		Report Type: Expedited (15-Day)		Company Report Number: 112585		Age:		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Hospitalization - Initial or Prolonged	Acne Infantile Complications Of Maternal Exposure To Therapeutic Drugs Constipation Dry Skin Eye Discharge Eye Disorder Nos Fever Neonatal Hyperbilirubinaemia Neonatal Hypersomnia Jaundice Neonatal Lacrimal Duct Obstruction Congenital Nasal Congestion Pregnancy Nos Rash Scaly Seborrhea Upper Respiratory Tract Infection Nos	Other	Accutane Capsules (Isotretinoin) Oral Contraceptive Pill	PS C		ORAL					
Date: 07/14/1999		ISR Number: 3303983-6		Report Type: Expedited (15-Day)		Company Report Number: 108931		Age: 72 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Abdominal Pain Upper Confusion Diarrhea Nos	Foreign Health Professional Other	Tasmar (Tolcapone) Sinemet 25/100	PS C		ORAL					

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

Date:	ISR Number:	Report Type:	Company Report Number:	Age:	Gender:			
07/15/1999	3304614-1	Expedited (15-Day)	83462	21 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>
Death	Completed Suicide Dry Skin	Foreign Health Professional Other	Roaccutane (Isotretinoin) Fibrotide	PS C		ORAL		
07/19/1999	3306906-9	Expedited (15-Day)	210391	83 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>
Death	Dehydration Hypotension Markedly Reduced Food Intake Pneumonia Nos Pyrexia Tachycardia Nos Tachypnoea Weakness	Foreign Health Professional	Tasmar (Tolcapone) Madopar Hbs (Benserazide/Levodopa) Madopar Liq '125' (Benserazide/Levodopa) Jumexal (Selegiline Hydrochloride)	PS C C C		ORAL		
07/19/1999	3307277-4	Expedited (15-Day)	202838	69 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	Abdominal Pain Nos Appetite Decreased Blood Creatinine Increased Blood Potassium Decreased Blood Urea Increased Bundle Branch Block Right C-Reactive Protein Increased Fatigue Hypotension Influenza Liver Function Tests Nos Abnormal Loose Stools Mental Impairment Nos Pyelonephritis Nos Pyrexia Renal Cyst Nos Tenderness Nos Urinary Tract Infection Nos Weakness	Foreign Health Professional	Tasmar (Tolcapone) Madopar Madopar Hbs	PS C C				

FDA Adverse Event Reporting System (FAERS)
 Division Of Information System Report

Date:	ISR Number:	Report Type:	Company Report Number:	Age:	Gender:			
07/19/1999	3307670-X	Expedited (15-Day)	207406	62 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Balance Impaired Nos Difficulty In Walking Dysarthria Hyperglycaemia Nos Paresis Spinal Osteoarthritis	Health Professional	Tasmar (Tolcapone) Vasotec Peri-Colace Tegretol	PS C C C		ORAL		
07/22/1999	3309016-X	Expedited (15-Day)	206552	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>
Other	Blood Pressure Abnormal Cardiovascular Disorder Nos Mental Disorder Nec Neurological Disorder Nos Social Avoidant Behaviour Stress Symptoms Valvular Heart Disease Nos	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
07/22/1999	3309157-7	Expedited (15-Day)	202838	69 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	Abdominal Pain Nos Appetite Decreased Blood Creatinine Increased Blood Potassium Decreased Blood Urea Increased Bundle Branch Block Right C-Reactive Protein Increased Fatigue Gastric Function Disorder Nos Hypotension Influenza Liver Function Tests Nos Abnormal Loose Stools Malaise Mental Impairment Nos Nausea Pyelonephritis Nos Pyrexia Renal Cyst Nos Urinary Tract Infection Nos	Foreign Health Professional	Tasmar (Tolcapone) Madopar Modopar Hbs	PS C C				