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

**Date:** 12/30/1998 **ISR Number:** 3177154-0 **Report Type:** Direct **Company Report Number:** **Age:** 51 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| | Anxiety Nec<br>Depression Nec | | Accutane | PS | | | | |

**Date:** 06/05/1998 **ISR Number:** 3177413-1 **Report Type:** Periodic **Company Report Number:** 96823 **Age:** 25 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Blindness Night<br>Contact Lens Intolerance<br>Dry Eye Nec<br>Mood Alteration Nos<br>Red Eye | Consumer | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177415-5 **Report Type:** Periodic **Company Report Number:** 95155 **Age:** 14 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Agitation<br>Depression Nec | Other | Accutane Capsules (Isotretinoin) 40.000 Mg | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177416-7 **Report Type:** Periodic **Company Report Number:** 95278 **Age:** 19 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec<br>Weight Decreased | Other | Accutane Capsules (Isotretinoin) 40.000 Mg | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177417-9 **Report Type:** Periodic **Company Report Number:** 95279 **Age:** 21 YR **Gender:** Female

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

**Date:** 06/09/1998 **ISR Number:** 3177420-9 **Report Type:** Periodic **Company Report Number:** 95288 **Age:** 16 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec<br>Irritability<br>Mood Disorder Nos<br>Weight Decreased | Other | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177423-4 **Report Type:** Periodic **Company Report Number:** 95373 **Age:** 15 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Abnormal Behaviour Nos<br>Depression Nec<br>Personality Disorder Nos | Other | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

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

**Date:** 06/09/1998 **ISR Number:** 3177424-6 **Report Type:** Periodic **Company Report Number:** 95386 **Age:** **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Life-Threatening | Depression Nec<br>Suicide Attempt | Other | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177425-8 **Report Type:** Periodic **Company Report Number:** 95388 **Age:** 17 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Depression Nec<br>Hallucination Nos<br>Insomnia Nec<br>Psychotic Disorder Nos<br>Thinking Abnormal Nec | Other | Accutane Capsules (Isotretinoin) 40.000 Mg | PS | | ORAL | | |

**Date:** 12/31/1998 **ISR Number:** 3177649-X **Report Type:** Expedited (15-Day) **Company Report Number:** 111230 **Age:** 50 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Dementia Nos<br>Short-Term Memory Loss | Health Professional | Accutane | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177865-7 **Report Type:** Periodic **Company Report Number:** 95399 **Age:** 14 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec<br>Mood Swings<br>Suicide Attempt | Other | Accutane Capsules (Isotretinoin) 40.000 Mg | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177866-9 **Report Type:** Periodic **Company Report Number:** 95402 **Age:** 14 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Life-Threatening | Abdominal Pain Nos<br>Mood Alteration Nos<br>Suicide Attempt<br>Vomiting Nos<br>Weight Decreased | Other | Accutane Capsules (Isotretinoin) 40.000 Mg<br>Aleve<br>Ibuprofen<br>Tylenol | PS<br>C<br>C<br>C | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177868-2 **Report Type:** Periodic **Company Report Number:** 95438 **Age:** 17 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec | Other | Accutane Capsules (Isotretinoin) 40.000 Mg | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177869-4 **Report Type:** Periodic **Company Report Number:** 95458 **Age:** 15 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Life-Threatening | Depression Nec | Other | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177869-4 **Report Type:** Periodic **Company Report Number:** 58658 **Age:** **Gender:**

| Outcome | PT | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Depression Nec | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Liver Function Tests Nos Abnormal | Tylenol (Acetaminophen) | SS | | | | |
| | Suicide Attempt | Allergy Shots | C | | | | |

**Date:** 06/09/1998 **ISR Number:** 3177872-4 **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 | | Nasalcrom | C | | | | |
| | Insomnia Nec | | Aleve | C | | | | |
| | Lethargy | | | | | | | |

**Date:** 06/09/1998 **ISR Number:** 3177873-6 **Report Type:** Periodic **Company Report Number:** 95553 **Age:** 30 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Confusion | Consumer | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Depression Nec | | | | | | | |
| | Euphoric Mood | | | | | | | |

**Date:** 06/09/1998 **ISR Number:** 3177874-8 **Report Type:** Periodic **Company Report Number:** 97662 **Age:** 38 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Acne Aggravated | Consumer | Accutane | PS | | ORAL | | |
| | Arthralgia | | Ortho Tri-Cyclen | C | | | | |
| | Depression Nec | | | | | | | |
| | Mood Swings | | | | | | | |
| | Myalgia | | | | | | | |

**Date:** 06/09/1998 **ISR Number:** 3177886-4 **Report Type:** Periodic **Company Report Number:** 97806 **Age:** 18 YR **Gender:** Male

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

**Date:** 06/09/1998 **ISR Number:** 3177888-8 **Report Type:** Periodic **Company Report Number:** 59576 **Age:** 14 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Anger | Health Professional | Accutane | PS | | ORAL | | |
| | Anxiety Nec | Other | | | | | | |
| | Discomfort Nos | | | | | | | |
| | Distress | | | | | | | |
| | Epiphyses Premature Fusion | | | | | | | |

**Date:** 06/09/1998 **ISR Number:** 3177915-8 **Report Type:** Periodic **Company Report Number:** 89550 **Age:** 36 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Alopecia | Consumer | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Depression Nec | | | | | | | |
| | Pain Nos | | | | | | | |
| | Personality Change | | | | | | | |

**Date:** 06/09/1998 **ISR Number:** 3177927-4 **Report Type:** Periodic **Company Report Number:** 89625 **Age:** **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Acne Aggravated | Consumer | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Dry Skin | | Ativan | C | | | | |
| | Lip Dry | | Birth Control Pill | C | | | | |
| | Palpitations | | | | | | | |

**Date:** 06/09/1998 **ISR Number:** 3177929-8 **Report Type:** Periodic **Company Report Number:** 86484 **Age:** 32 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec | Consumer | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Epistaxis | | Dura-Vent (Fuaifensin/Phenypropanolamine Hydrochloride) | C | | | | |
| | Hair Disorder Nos | | Birth Control Pill(Oral Contraceptive Nos) | C | | | | |
| | Insomnia Nec | | | | | | | |
| | Mood Swings | | | | | | | |

**Date:** 06/09/1998 **ISR Number:** 3177933-X **Report Type:** Periodic **Company Report Number:** 86911 **Age:** 32 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Aggravated | Consumer | Accutane Capsules (Isotretinoin) 40.000 Mg | PS | | ORAL | | |
| | Suicidal Ideation | Health Professional | Effexor (Venlafaxine Hydrochloride) | C | | | | |
| | | | Klonopin (Clonazepam) | C | | | | |
| | | | Trilafon (Perphenazine) | C | | | | |
| | | | Theophyllin (Theophylline) | C | | | | |
| | | | Proventil (Albuterol Sulfate) | C | | | | |
| | | | Vancenase (Beclomethasone Dipropionate) | C | | | | |

**Date:** 06/09/1998 **ISR Number:** 3177937-7 **Report Type:** Periodic **Company Report Number:** 87326 **Age:** 27 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Arthralgia | Health Professional | Accutane Capsules (Isotretinoin) 40.000 Mg | PS | | ORAL | | |
| | Blood Bilirubin Increased | | | | | | | |
| | Blood Lactate Dehydrogenase Increased | | | | | | | |
| | Depression Nec | | | | | | | |

**Date:** 06/09/1998 **ISR Number:** 3177957-2 **Report Type:** Periodic **Company Report Number:** 95579 **Age:** 48 YR **Gender:** Male

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

**Date:** 06/09/1998 **ISR Number:** 3177958-4 **Report Type:** Periodic **Company Report Number:** 95581 **Age:** 26 YR **Gender:** Female

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

**Date:** 06/09/1998 **ISR Number:** 3177959-6 **Report Type:** Periodic **Company Report Number:** 95582 **Age:** 17 YR **Gender:** Male

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

**Date:** 06/09/1998 **ISR Number:** 3177960-2 **Report Type:** Periodic **Company Report Number:** 95583 **Age:** 16 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Depression Nec<br>Suicide Attempt | Other | Accutane Capsules (Isotretinoin)<br>Zoloft | PS<br>C | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177961-4 **Report Type:** Periodic **Company Report Number:** 95585 **Age:** 32 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Paranoia<br>Suicidal Ideation | Other | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177962-6 **Report Type:** Periodic **Company Report Number:** 95587 **Age:** 16 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Depression Nec<br>Dissociation<br>Intentional Self-Injury<br>Suicidal Ideation | Health Professional<br>Other | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177963-8 **Report Type:** Periodic **Company Report Number:** 95607 **Age:** 20 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec | Other | Accutane Capsules (Isotretinoin)<br>Marijuana | PS<br>C | | ORAL | | |

# FDA - Adverse Event Reporting System (AERS)
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**Date:** 06/09/1998 **ISR Number:** 3177964-X **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<br>Anger<br>Depression Nec<br>Hepatic Disorder Nos | Consumer | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177967-5 **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 Aggravated<br>Depression Nec<br>Psychotic Disorder Nos | Health Professional | Accutane Capsules (Isotretinoin)<br>Zoloft | PS<br>C | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177968-7 **Report Type:** Periodic **Company Report Number:** 95720 **Age:** 24 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec<br>Emotional Disturbance Nos<br>Insomnia Nec<br>Markedly Reduced Food Intake | Consumer | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177969-9 **Report Type:** Periodic **Company Report Number:** 95777 **Age:** 17 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec<br>Headache Nos | Other | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177970-5 **Report Type:** Periodic **Company Report Number:** 95804 **Age:** 13 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Anger<br>Anxiety Nec<br>Depression Nec | Other | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177971-7 **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 | Depression Nec<br>Disturbance In Attention Nec | Health Professional | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177972-9 **Report Type:** Periodic **Company Report Number:** 95857 **Age:** 15 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Death | Back Pain<br>Blindness Night<br>Completed Suicide | Other | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

# FDA - Adverse Event Reporting System (AERS)
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**Date:** 06/09/1998 **ISR Number:** 3177975-4 **Report Type:** Periodic **Company Report Number:** 95985 **Age:** 27 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Aggravated | Consumer | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177977-8 **Report Type:** Periodic **Company Report Number:** 92941 **Age:** 16 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Acne Aggravated<br>Dry Skin<br>Lip Dry<br>Mood Swings | Health Professional | Accutane Capsules (Isotretinoin)<br>40.000 Mg | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3177978-X **Report Type:** Periodic **Company Report Number:** 93005 **Age:** 16 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec<br>Dermatitis Nos<br>Fatigue | Health Professional | Accutane Capsules (Isotretinoin)<br>40.000 Mg | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3178312-1 **Report Type:** Periodic **Company Report Number:** 88644 **Age:** 22 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec<br>Myalgia<br>Pneumonia Nos | Consumer | Accutane Capsules (Isotretinoin)<br>40.000 Mg | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3178321-2 **Report Type:** Periodic **Company Report Number:** 90136 **Age:** 24 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Disability | Dry Eye Nec<br>Dysphonia<br>Fatigue<br>Lip Dry<br>Photosensitivity Reaction Nos<br>Rectal Bleeding<br>Skin Disorder Nos<br>Vulvovaginal Dryness | Consumer | Accutane Capsules (Isotretinoin)<br>Clozaril | PS<br>C | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3178326-1 **Report Type:** Periodic **Company Report Number:** 90772 **Age:** 17 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec | Other | Accutane Capsules (Isotretinoin)<br>40.000 Mg<br>Advil (Ibuprofen) | PS<br><br>SS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3178335-2 **Report Type:** Periodic **Company Report Number:** 77341 **Age:** 20 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Dizziness (Exc Vertigo) | Consumer | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Dyspnoea Nos | | Multivitamin | C | | | | |
| | Headache Nos | | | | | | | |
| | Hypoaesthesia | | | | | | | |
| | Panic Attack | | | | | | | |
| | Rectal Bleeding | | | | | | | |

**Date:** 06/09/1998 **ISR Number:** 3178340-6 **Report Type:** Periodic **Company Report Number:** 77777 **Age:** 16 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Headache Nos | Health Professional | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Mood Alteration Nos | | | | | | | |

**Date:** 06/09/1998 **ISR Number:** 3178342-X **Report Type:** Periodic **Company Report Number:** 77958 **Age:** **Gender:** Male

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

**Date:** 06/09/1998 **ISR Number:** 3178343-1 **Report Type:** Periodic **Company Report Number:** 77969 **Age:** 26 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Antinuclear Factor Positive | Consumer | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Arthralgia | Health Professional | | | | | | |
| | Dyspareunia Nec | | | | | | | |
| | Headache Nos | | | | | | | |
| | Menstruation Irregular | | | | | | | |
| | Muscle Injury Nos | | | | | | | |
| | Muscle Spasms | | | | | | | |
| | Palpitations | | | | | | | |
| | Tired Eyes | | | | | | | |
| | Vulvovaginitis Nos | | | | | | | |

**Date:** 06/09/1998 **ISR Number:** 3178344-3 **Report Type:** Periodic **Company Report Number:** 77975 **Age:** 31 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec | Health Professional | Accutane Capsules (Isotretinoin) 20.000 Mg | PS | | ORAL | | |
| | | | Bcp | C | | | | |

**Date:** 06/05/1998 **ISR Number:** 3178350-9 **Report Type:** Periodic **Company Report Number:** 81479 **Age:** 26 YR **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Other | Depression Nec | Consumer |
| | Mood Swings | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| Oral Contraceptive Pill (Oral Contraceptive Nos) | C | | | | |

**Date:** 06/05/1998 **ISR Number:** 3178354-6 **Report Type:** Periodic **Company Report Number:** 81490 **Age:** **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Other | Depression Nec | Consumer |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Accutane Capsules (Isotretinoin) | PS | | | | |

**Date:** 06/09/1998 **ISR Number:** 3178372-8 **Report Type:** Periodic **Company Report Number:** 76328 **Age:** 17 YR **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Other | Anorexia | Health Professional |
| | Depression Nec | Other |
| | Weight Decreased | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3178374-1 **Report Type:** Periodic **Company Report Number:** 49955 **Age:** 18 YR **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Other | Alopecia | Other |
| | Depression Nec | |
| | Stye | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3178376-5 **Report Type:** Periodic **Company Report Number:** 58042 **Age:** 42 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Other | Conjunctivitis Nec | Consumer |
| | Dry Mouth | |
| | Dry Skin | |
| | Eczema Nos | |
| | Emotional Disturbance Nos | |
| | Eyelid Disorder Nos | |
| | Oral Mucosal Blistering | |
| | Seborrhoea | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| Unipres | C | | | | |
| Xanax | C | | | | |

**Date:** 06/09/1998 **ISR Number:** 3178384-4 **Report Type:** Periodic **Company Report Number:** 67940 **Age:** 30 YR **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Other | Arthralgia | Consumer |
| | Depression Nec | |
| | Fatigue | |
| | Joint Stiffness | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| Birth Control Pill | C | | | | |

**Date:** 06/09/1998 **ISR Number:** 3178413-8 **Report Type:** Periodic **Company Report Number:** 92727 **Age:** 17 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Acne Aggravated<br>Diarrhoea Nos<br>Epistaxis<br>Lip Dry<br>Nightmare<br>Vomiting Nos | Other | Accutane Capsules (Isotretinoin) 40.000 Mg | PS | | ORAL | | |

**Date:** 06/05/1998 **ISR Number:** 3178430-8 **Report Type:** Periodic **Company Report Number:** 84043 **Age:** 37 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Anaemia Nos<br>Depression Nec | Consumer | Accutane Capsules (Isotretinoin) 40.000 Mg | PS | | ORAL | | |

**Date:** 06/05/1998 **ISR Number:** 3178445-X **Report Type:** Periodic **Company Report Number:** 82627 **Age:** 19 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Disturbance In Attention Nec | Company Representative | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3178476-X **Report Type:** Periodic **Company Report Number:** 84838 **Age:** 17 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Acne Aggravated<br>Depression Nec<br>Drug Ineffective<br>Face Oedema<br>Muscle Stiffness | Other | Accutane Capsules (Isotretinoin)<br>Steroid Nos (Steroid Nos) | PS<br>C | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3178487-4 **Report Type:** Periodic **Company Report Number:** 85217 **Age:** 19 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Anorexia<br>Depression Nec<br>Lip Dry<br>Vision Blurred<br>Weight Decreased | Other | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3178492-8 **Report Type:** Periodic **Company Report Number:** 85718 **Age:** 15 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec<br>Mental Disorder Nec | Health Professional | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3178559-4 **Report Type:** Periodic **Company Report Number:** 72197 **Age:** 15 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Condition Aggravated<br>Tic Nec | Consumer | Accutane Capsules (Isotretinoin) 40.000 Mg | PS | | ORAL | | |

**Date:** 06/05/1998 **ISR Number:** 3178570-3 **Report Type:** Periodic **Company Report Number:** 82572 **Age:** 35 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Contact Lens Intolerance<br>Depression Nec<br>Dermatitis Nos<br>Dry Skin<br>Lip Dry<br>Weight Decreased | Consumer | Accutane Capsules (Isotretinoin) 40.000 Mg | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3178573-9 **Report Type:** Periodic **Company Report Number:** 74873 **Age:** 48 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec<br>Pain In Limb<br>Pruritus<br>Urticaria Nos | Health Professional | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3178575-2 **Report Type:** Periodic **Company Report Number:** 75096 **Age:** 14 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Alopecia<br>Depression Nec<br>Face Oedema<br>Fatigue<br>Lip Dry<br>Weight Decreased | Other | Accutane Capsules (Isotretinoin)<br>Minocycline | PS<br>C | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3178579-X **Report Type:** Periodic **Company Report Number:** 91589 **Age:** 14 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 | | |

**Date:** 06/09/1998 **ISR Number:** 3178594-6 **Report Type:** Periodic **Company Report Number:** 92904 **Age:** 15 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Cough<br>Depression Nec<br>Headache Nos<br>Mood Swings | Health Professional | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/09/1998 **ISR Number:** 3178596-X **Report Type:** Periodic **Company Report Number:** 93052 **Age:** 21 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec | Consumer | Accutane Capsules (Isotretinoin) 40.000 Mg | PS | | ORAL | | |
| | | | Triphasil (Ethinyl Estradiol/Levonorgestrel) | C | | | | |

**Date:** 06/09/1998 **ISR Number:** 3178600-9 **Report Type:** Periodic **Company Report Number:** 93566 **Age:** 15 YR **Gender:** Male

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

**Date:** 06/05/1998 **ISR Number:** 3178608-3 **Report Type:** Periodic **Company Report Number:** 82736 **Age:** 15 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Blood Triglycerides Increased<br>Depression Nec<br>Fatigue<br>High Density Lipoprotein Decreased | Other | Accutane Capsules (Isotretinoin) 40.000 Mg | PS | | ORAL | | |
| | | | Serevent | C | | | | |
| | | | Azmacort | C | | | | |
| | | | Proventil | C | | | | |

**Date:** 06/05/1998 **ISR Number:** 3178610-1 **Report Type:** Periodic **Company Report Number:** 82760 **Age:** 32 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Anxiety Nec<br>Chest Pain<br>Heart Rate Increased<br>Rectal Bleeding | Consumer | Accutane Capsules (Isotretinoin) 40.000 Mg | PS | | ORAL | | |

**Date:** 06/05/1998 **ISR Number:** 3178621-6 **Report Type:** Periodic **Company Report Number:** 82803 **Age:** 53 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Aggression<br>Cheilitis<br>Pruritus<br>Vision Blurred | Consumer | Accutane Capsules (Isotretinoin ) 10.000 Mg | PS | | ORAL | | |
| | | | Ceftin | C | | | | |

**Date:** 06/09/1998 **ISR Number:** 3178981-6 **Report Type:** Periodic **Company Report Number:** 94154 **Age:** 19 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Abdominal Pain Nos<br>Back Pain<br>Completed Suicide<br>Dry Eye Nec<br>Dry Skin | Other | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | | | Echinacea | C | | | | |
| | | | Amino Acids | C | | | | |

**Date:** 06/05/1998 **ISR Number:** 3178984-1 **Report Type:** Periodic **Company Report Number:** 94238 **Age:** 15 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Crying | Health Professional | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Depressed Mood | | | | | | | |
| | Depression Nec | | | | | | | |

**Date:** 06/09/1998 **ISR Number:** 3178986-5 **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:** 06/09/1998 **ISR Number:** 3178989-0 **Report Type:** Periodic **Company Report Number:** 94795 **Age:** 15 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Aggression Aggravated | Health Professional | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Blood Cholesterol Increased | | Beclovent | C | | | | |
| | Blood Triglycerides Increased | | Inhaler Nos | C | | | | |
| | Mood Swings | | | | | | | |

**Date:** 06/09/1998 **ISR Number:** 3179001-X **Report Type:** Periodic **Company Report Number:** 93246 **Age:** 19 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Mood Alteration Nos | Health Professional | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | | | Paxil | C | | | | |

**Date:** 06/05/1998 **ISR Number:** 3179108-7 **Report Type:** Periodic **Company Report Number:** 85810 **Age:** 21 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Anxiety Nec | Consumer | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/05/1998 **ISR Number:** 3179131-2 **Report Type:** Periodic **Company Report Number:** 86268 **Age:** 28 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Alopecia | Health Professional | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Lymphadenopathy | | Darvocet | C | | | | |
| | Mood Swings | | | | | | | |
| | Pain Nos | | | | | | | |

**Date:** 06/09/1998 **ISR Number:** 3179238-X **Report Type:** Periodic **Company Report Number:** 94162 **Age:** 15 YR **Gender:** Male

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

**Date:** 01/11/1999 **ISR Number:** 3179326-8 **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 | Foreign | Tasmar (Tolcapone) | PS | | | | |
| | Blood Creatinine Increased | Health Professional | Sinemet -25/100 (Carbidopa/Levodopa) | C | | | | |
| | Confusion | Other | Tolvon (Mianserin Hydrochloride) | C | | | | |
| | Diarrhoea Nos | | Eldepryl (Selegiline Hydrochloride) | C | | | | |
| | Dyskinesia Nec | | Imovane (Zopiclone) | C | | | | |
| | Liver Function Tests Nos Abnormal | | | | | | | |
| | Malaise | | | | | | | |
| | Motor Dysfunction Nos | | | | | | | |

**Date:** 01/11/1999 **ISR Number:** 3179336-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 109074 **Age:** 66 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Death | Acute Circulatory Failure | Foreign | Tasmar (Tolcapone) | PS | | ORAL | | |
| Hospitalization - Initial or Prolonged | Agitation | Health Professional | Modopar (Benserazide/Levodopa) 125 Mg | SS | | ORAL | | |
| | Anorexia | Other | Lexomil (Bromazepam) | SS | | ORAL | | |
| | Anuria | | Sermion (Nicergoline) | SS | | ORAL | | |
| | Blood Creatine Phosphokinase Increased | | Tenormine (Atenolol) | SS | | ORAL | | |
| | Blood Creatine Phosphokinase Mb Increased | | Amantadine (Amantadine Hydrochloride) | SS | | ORAL | | |
| | Blood Creatinine Increased | | Tegretol (Carbamazepine) | SS | | ORAL | | |
| | Bronchospasm Nos | | Spironolactone (Spironolactone) | SS | | | | |
| | Cardiac Failure Nos | | Deroxat (Paroxetine) | SS | | ORAL | | |
| | Cardiac Murmur Nos | | Ginkor (Ginkgo/Troxerutin) | C | | | | |
| | Coma Nec | | | | | | | |
| | Condition Aggravated | | | | | | | |
| | Confusion | | | | | | | |
| | Convulsions Nos | | | | | | | |
| | Dehydration | | | | | | | |
| | Difficulty In Walking | | | | | | | |
| | Disorientation | | | | | | | |
| | Drug Interaction Nos | | | | | | | |
| | Extrapyramidal Disorder Nec | | | | | | | |
| | Hallucination Nos | | | | | | | |
| | Hypernatraemia | | | | | | | |
| | Hyperreflexia | | | | | | | |

**Date:** 01/13/1999 **ISR Number:** 3180229-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 110947 **Age:** 66 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Hospitalization - Initial or Prolonged | Decreased Activity<br>Liver Function Tests Nos Abnormal | Health Professional |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar | PS | | ORAL | | |
| Sinemet (Carbidopa/Levodopa) | C | | | | |
| Phenylephrine (Phenylephrine Hydrochloride) | C | | | | |
| Midodrine (Midodrine Hydrochloride) | C | | | | |
| Florinef (Fludrocortisone Acetate) | C | | | | |
| Milk Of Magnesia (Magnesia, (Milk Of)) | C | | | | |
| Magnesium Citrate (Magnesium Citrate) | C | | | | |
| Pepcid (Famotidine) | C | | | | |

**Date:** 01/14/1999 **ISR Number:** 3180783-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 109103 **Age:** 72 YR **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Hospitalization - Initial or Prolonged | Abdominal Distension<br>Anhedonia<br>Ascites<br>Biopsy Liver Abnormal<br>Blood Albumin Decreased<br>Blood Alkaline Phosphatase Nos Increased<br>Blood Bilirubin Increased<br>Cholelithiasis<br>Depression Nec<br>Differential White Blood Cell Count Abnormal<br>Difficulty In Walking<br>Dyskinesia Nec<br>Electrocardiogram Abnormal Nos<br>Fatigue<br>Haematocrit Decreased<br>Haemoglobin Decreased<br>Hepatic Failure<br>Hepatic Fibrosis<br>Hepatic Necrosis<br>Hepatitis Viral Nos<br>Hepatotoxicity Nos<br>Hyperglycaemia Nos<br>Hypertonia<br>Hypokalaemia | Health Professional<br>Other |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar | PS | | ORAL | | |
| Sinemet (Carbidopa/Levodopa) | C | | | | |
| Mirapex (Pramipexole) | C | | | | |
| Fosamax (Lendronate Sodium) | C | | | | |
| Acetaminophen (Acetaminophen) | C | | | | |

**Date:** 06/05/1998 **ISR Number:** 3181104-0 **Report Type:** Periodic **Company Report Number:** 81030 **Age:** 17 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Blood Triglycerides Increased<br>Depression Nec<br>Fatigue<br>Pain Nos | Consumer | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/05/1998 **ISR Number:** 3181106-4 **Report Type:** Periodic **Company Report Number:** 81034 **Age:** 12 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Glossodynia<br>Tongue Oedema | Health Professional | Accutane Capsules (Isotretinoin) 40.000 Mg | PS | | ORAL | | |

**Date:** 06/05/1998 **ISR Number:** 3181122-2 **Report Type:** Periodic **Company Report Number:** 81129 **Age:** 16 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec<br>Headache Nos<br>Lip Disorder Nos<br>Lip Dry | Health Professional | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 01/19/1999 **ISR Number:** 3182155-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 107086 **Age:** 20 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Delusion Nos<br>Hallucination, Auditory<br>Paranoia<br>Psychotic Disorder Nos<br>Schizophrenia Nos | Foreign<br>Health Professional | Roaccutane (Isotretinoin) | PS | | ORAL | | |

**Date:** 01/19/1999 **ISR Number:** 3182176-X **Report Type:** Expedited (15-Day) **Company Report Number:** 108798 **Age:** 25 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Dizziness (Exc Vertigo)<br>Dry Eye Nec<br>Dry Skin<br>Fear, Focus Nec<br>Feeling Cold<br>Hypertension Nos<br>Lip Dry<br>Middle Insomnia<br>Myalgia<br>Panic Attack<br>Tachycardia Nos<br>Tremor Nec | Consumer<br>Health Professional | Accutane<br>Oral Contraception | PS<br>C | | ORAL | | |

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

**Date:** 01/21/1999 **ISR Number:** 3183706-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 1998SIN0135 **Age:** 79 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Agitation | Foreign | Sinemet | PS | | ORAL | | |
| | Communication Disorder Nos | Health Professional | Tasmar | SS | | | | |
| | Drug Effect Decreased | | | | | | | |

**Date:** 01/22/1999 **ISR Number:** 3184275-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 110000 **Age:** 75 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Death | Abdominal Distension | Foreign | Tasmar | PS | | ORAL | | |
| | Agitation | Study | Madopar (Benserazide/Levodopa) | C | | | | |
| | Benign Prostatic Hyperplasia | Health Professional | Movergan (Selegiline Hydrochloride) | C | | | | |
| | Blood Bilirubin Increased | Other | Pk-Merz (Amantadine Sulfate) | C | | | | |
| | Bronchitis Acute Nos | | Digimerck Minor (Digitoxin) | C | | | | |
| | Bronchopneumonia Nos | | Leponex (Clozapine) | C | | | | |
| | Cardiac Failure Nos | | | | | | | |
| | Cardiomegaly Nos | | | | | | | |
| | Condition Aggravated | | | | | | | |
| | Confusion | | | | | | | |
| | Dehydration | | | | | | | |
| | Diarrhoea Nos | | | | | | | |
| | Disorientation | | | | | | | |
| | Dry Skin | | | | | | | |
| | Gastrointestinal Disorder Nos | | | | | | | |
| | Infection Nos | | | | | | | |
| | Muscle Rigidity | | | | | | | |
| | Pneumonia Nos | | | | | | | |
| | Pyrexia | | | | | | | |
| | Renal Disorder Nos | | | | | | | |
| | Respiratory Failure (Exc Neonatal) | | | | | | | |
| | Sedation | | | | | | | |
| | Weakness | | | | | | | |
| | White Blood Cell Count Increased | | | | | | | |

**Date:** 01/25/1999 **ISR Number:** 3185543-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 112083 **Age:** 18 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Abnormal Behaviour Nos | Foreign | Roaccutane (Isotretinoin) | PS | | ORAL | | |
| | | Health Professional | | | | | | |

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

**Date:** 01/27/1999 **ISR Number:** 3186544-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 108183 **Age:** 51 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Agitation | Foreign | Tasmar | PS | | ORAL | | |
| | Non-Accidental Overdose | Health Professional | Trivastal | SS | | ORAL | | |
| | Pneumonitis Aspiration | | Modopar | C | | | | |
| | Suicide Attempt | | Dopergin | C | | | | |
| | Vomiting Nos | | | | | | | |

**Date:** 02/01/1999 **ISR Number:** 3189043-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 110256 **Age:** 75 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Aggression | Foreign | Tasmar (Tolcapone) | PS | | ORAL | | |
| | Gait Festinating | Health Professional | Madopar (Benserazide/Levodopa_ | C | | | | |
| | Jerky Movement Nos | | Co-Beneldopa (Benserazide/Levodopa) | C | | | | |
| | Liver Function Tests Nos Abnormal | | Selegiline (Selegiline Hydrochloride) | C | | | | |
| | Nodding Of Head | | Pergolide (Pergolide Mesylate) | C | | | | |

**Date:** 02/01/1999 **ISR Number:** 3189144-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 111092 **Age:** 76 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Aggression | Foreign | Tasmar (Tolcapone) | PS | | ORAL | | |
| | Appetite Increased | Health Professional | Bactrim Forte (Sulfamethoxazole /Trimethoprim | SS | | | | |
| | Cholestasis | | Madopar Dr | C | | | | |
| | Diarrhoea Nos | | Levodopa | C | | | | |
| | Hepatic Cyst Nos | | Benserazid | C | | | | |
| | Hepatotoxicity Nos | | Prednisone | C | | | | |
| | Jaundice Nos | | Konakion | C | | | | |
| | Liver Function Tests Nos Abnormal | | | | | | | |
| | Weight Decreased | | | | | | | |

**Date:** 02/01/1999 **ISR Number:** 3190996-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 106035 **Age:** **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Abdominal Distension | Consumer | Tasmar | PS | | ORAL | | |
| | Abdominal Pain Nos | Other | Sinemet | C | | | | |
| | Asthma Nos | | Permax | C | | | | |
| | Decreased Activity | | Synthroid | C | | | | |
| | Diarrhoea Nos | | Norvasc | C | | | | |
| | Difficulty In Walking | | | | | | | |
| | Dyspnoea Nos | | | | | | | |
| | Flatulence | | | | | | | |
| | Food Interaction | | | | | | | |

**Date:** 02/04/1999 **ISR Number:** 3191837-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 100199 **Age:** 72 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Abdominal Pain Nos | Health Professional | Tasmar | PS | | ORAL | | |
| | Anxiety Nec | | Sinemet-25/100 | C | | | | |
| | Aortic Atherosclerosis | | | | | | | |
| | Calculus Renal Nos | | | | | | | |
| | Dehydration | | | | | | | |
| | Dyskinesia Nec | | | | | | | |
| | Dysuria | | | | | | | |
| | Hypertonia | | | | | | | |
| | Leucopenia Nos | | | | | | | |
| | Lymphoma Nos | | | | | | | |
| | Muscle Cramps | | | | | | | |
| | Nausea | | | | | | | |
| | Pain Nos | | | | | | | |
| | Pancytopenia | | | | | | | |
| | Parkinson'S Disease Aggravated | | | | | | | |
| | Pericardial Effusion | | | | | | | |
| | Rash Erythematous | | | | | | | |
| | Renal Cyst Nos | | | | | | | |
| | Renal Vascular Disorder Nos | | | | | | | |
| | Splenomegaly | | | | | | | |
| | Sweating Increased | | | | | | | |
| | Thrombocytopenia | | | | | | | |
| | Thyroid Neoplasm Nos | | | | | | | |
| | Tremor Nec | | | | | | | |
| | Tricuspid Valve Incompetence | | | | | | | |
| | Urinary Frequency | | | | | | | |
| | Vomiting Nos | | | | | | | |

**Date:** 02/04/1999 **ISR Number:** 3192331-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 110423 **Age:** 19 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Abnormal Behaviour Nos | Foreign | Roaccutane | PS | | ORAL | | |
| | Aggression | Health Professional | | | | | | |
| | Asthenia | | | | | | | |
| | Crying | | | | | | | |
| | Emotional Disturbance Nos | | | | | | | |
| | Insomnia Nec | | | | | | | |
| | Mania | | | | | | | |
| | Mood Swings | | | | | | | |
| | Thinking Abnormal Nec | | | | | | | |

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

**Date:** 02/04/1999 **ISR Number:** 3192338-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 112555 **Age:** 36 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Complications Of Maternal Exposure To Therapuetic Drugs | Consumer | Accutane | PS | | ORAL | | |
| | Disturbance In Attention Nec | | Oral Contraceptive Pill (Oral Contraceptive Nos) | C | | | | |
| | Eye Movement Disorder Nos | | | | | | | |
| | Learning Disorder Nos | | | | | | | |
| | Speech Disorder Nec | | | | | | | |
| | Undescended Testicle | | | | | | | |

**Date:** 02/04/1999 **ISR Number:** 3192344-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 108188 **Age:** 45 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Appetite Decreased | Consumer | Accutane | PS | | ORAL | | |
| | Breast Cancer Female Nos | Health Professional | Ritalin (Methyphenidate Hydrochloride) | C | | | | |
| | Depression Aggravated | Other | Imipramine (Mipramine Hydrochloride) | C | | | | |
| | Suicidal Ideation | | | | | | | |

**Date:** 02/08/1999 **ISR Number:** 3193332-9 **Report Type:** Direct **Company Report Number:** **Age:** 17 YR **Gender:** Male

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

**Date:** 02/08/1999 **ISR Number:** 3193581-X **Report Type:** Expedited (15-Day) **Company Report Number:** 113009 **Age:** **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Death | Appetite Decreased | Foreign | Tasmar | PS | | ORAL | | |
| | Confusion | Other | Haldol (Haloperidol) | C | | | | |
| | Sepsis Nos | | Morphine (Morphine Sulfate) | C | | | | |
| | Suicidal Ideation | | Sinemet (Carbidopa/Levodopa) | C | | | | |

**Date:** 02/08/1999 **ISR Number:** 3193599-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 112718 **Age:** 76 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Death | Coma Nec | Foreign | Tasmar | PS | | ORAL | | |
| | Confusion | Health Professional | Sinemet Slow Release (Carbidopa/Levodopa) | C | | | | |
| | Immobile | | Sinemet Cr (Carbidopa/Levodopa) | C | | | | |
| | Leucocytosis Nos | | Ismo (Isosorbide Mononitrate) | C | | | | |
| | Myocardial Infarction | | Adalat Retard (Nifedipine) | C | | | | |
| | Neuroleptic Malignant Syndrome | | Atenolol (Atenolol) | C | | | | |
| | | | Warfarin (Warfarin Sodium) | C | | | | |
| | | | Pergolide (Pergolide Mesylate) | C | | | | |

**Date:** 02/08/1999 **ISR Number:** 3193602-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 100846 **Age:** 70 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged<br>Required Intervention to Prevent Permanent Impairment/Damage | Anxiety Nec<br>Blood Creatine Phosphokinase Increased<br>Blood Creatinine Increased<br>Convulsions Nos<br>Depressed Level Of Consciousness<br>Dialysis Nos<br>Diarrhoea Nos<br>Dyskinesia Nec<br>Electrocardiogram Qt Prolonged<br>Fall<br>Fatigue<br>Hyponatraemia<br>Hypotension<br>Leucocytosis Nos<br>Loss Of Consciousness Nec<br>Metabolic Acidosis Nos<br>Muscle Rigidity<br>Oliguria<br>Pain Nos<br>Radial Nerve Injury<br>Renal Failure Nos<br>Renal Impairment Nos<br>Rhabdomyolysis<br>Syncope<br>Tremor Nec<br>Urinary Incontinence<br>Urinary Tract Infection Nos | Health Professional | Tasmar<br>Sinemet Cr (Carbidopa/Levodopa) | PS<br>C | | ORAL | | |

**Date:** 02/09/1999 **ISR Number:** 3194531-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 112192 **Age:** 15 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Abdominal Pain Nos<br>Abnormal Behaviour Nos<br>Acne Aggravated<br>Depression Aggravated<br>Depression Nec<br>Duodenitis<br>Feeling Abnormal<br>Irritability | Other | Accutane<br>Prednisone<br>Prevacid | PS<br>C<br>C | | ORAL | | |

**Date:** 02/11/1999 **ISR Number:** 3195892-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 111092 **Age:** 76 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Aggression | Foreign | Tasmar (Tolcapone) | PS | | ORAL | | |
| | Anaemia Nos | Health Professional | Bactrim Forte (Sulfamethoxazole/Trimethoprim) | SS | | | | |
| | Appetite Increased | | Madopar Dr | C | | | | |
| | Blood Albumin Increased | | Levodopa | C | | | | |
| | Blood Alkaline Phosphatase Nos Increased | | Benserazid | C | | | | |
| | Blood Glucose Decreased | | Prednisone | C | | | | |
| | Blood Immunoglobulin M Increased | | Konakion | C | | | | |
| | Blood Lactate Dehydrogenase Increased | | | | | | | |
| | C-Reactive Protein Increased | | | | | | | |
| | Cholestasis | | | | | | | |
| | Cyst Nos | | | | | | | |
| | Diarrhoea Nos | | | | | | | |
| | Erythrocyte Sedimentation Rate Increased | | | | | | | |
| | Faecal Abnormality Nos | | | | | | | |
| | Gamma-Glutamyltransferase Increased | | | | | | | |
| | Haemoglobin Decreased | | | | | | | |
| | Hepatic Disorder Nos | | | | | | | |
| | Hepatotoxicity Nos | | | | | | | |
| | Hunger | | | | | | | |
| | Jaundice Nos | | | | | | | |
| | Laboratory Test Abnormal Nos | | | | | | | |
| | Liver Function Tests Nos Abnormal | | | | | | | |
| | Ultrasound Scan Nos Abnormal | | | | | | | |
| | Weight Decreased | | | | | | | |

**Date:** 02/16/1999 **ISR Number:** 3199591-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 200082 **Age:** 16 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Mental Impairment Nos | Health Professional | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Nausea | | | | | | | |
| | Pyrexia | | | | | | | |
| | Rigors | | | | | | | |
| | Toxic Shock Syndrome Nos | | | | | | | |

**Date:** 02/16/1999 **ISR Number:** 3200013-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 100846 **Age:** 70 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Anxiety Nec | Health Professional | Tasmar (Tolcapone) 100 Mg | PS | | ORAL | | |
| Required Intervention to Prevent Permanent Impairment/Damage | Blood Creatine Phosphokinase Increased | | Sinemet Cr 50-200 (Carbidopa / Levodopa) | C | | | | |
| | Blood Creatinine Increased | | Sinemet 25/100 (Carbidopa / Levodopa) | C | | | | |
| | Blood Glucose Increased | | | | | | | |
| | Blood Urea Increased | | | | | | | |
| | Convulsions Nos | | | | | | | |
| | Death Of Parent | | | | | | | |
| | Depressed Level Of Consciousness | | | | | | | |
| | Dialysis Nos | | | | | | | |
| | Diarrhoea Nos | | | | | | | |
| | Dyskinesia Aggravated | | | | | | | |
| | Electrocardiogram Abnormal Nos | | | | | | | |
| | Electrocardiogram Qt Prolonged | | | | | | | |
| | Fall | | | | | | | |
| | Fatigue | | | | | | | |
| | Heart Rate Increased | | | | | | | |
| | Hyponatraemia | | | | | | | |
| | Hypotension | | | | | | | |
| | Leucocytosis Nos | | | | | | | |
| | Loose Stools | | | | | | | |
| | Metabolic Acidosis Nos | | | | | | | |
| | Muscle Rigidity | | | | | | | |
| | Oliguria | | | | | | | |
| | Pain Nos | | | | | | | |
| | Radial Nerve Injury | | | | | | | |
| | Renal Failure Nos | | | | | | | |
| | Renal Impairment Nos | | | | | | | |
| | Respiratory Rate Increased | | | | | | | |
| | Rhabdomyolysis | | | | | | | |
| | Syncope | | | | | | | |
| | Tremor Nec | | | | | | | |
| | Urinary Incontinence | | | | | | | |
| | Urinary Tract Infection Nos | | | | | | | |
| | Urine Abnormal Nos | | | | | | | |
| | Urine Analysis Abnormal Nos | | | | | | | |
| | Weakness | | | | | | | |

**Date:** 02/19/1999 **ISR Number:** 3202993-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 109364 **Age:** 62 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Colon Spastic | Consumer | Tasmar (Tolcapone) | PS | | ORAL | | |
| | Diverticulum Nos | Health Professional | Sinemet 9carbidopa?Levodopa) | C | | | | |
| | Flatulence | | Inderal (Propranolol Hydrochloride) | C | | | | |
| | Gastro-Oesophageal Reflux Disease | | Aricept (Donepezil) | C | | | | |
| | Hepatic Cyst Nos | | | | | | | |
| | Hepatitis Nos | | | | | | | |
| | Hiatus Hernia | | | | | | | |
| | Influenza Like Illness | | | | | | | |
| | Jaundice Nos | | | | | | | |
| | Liver Function Tests Nos Abnormal | | | | | | | |
| | Nausea | | | | | | | |
| | Nightmare | | | | | | | |
| | Tremor Nec | | | | | | | |
| | Urine Discolouration | | | | | | | |

**Date:** 02/18/1999 **ISR Number:** 3203070-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 113245 **Age:** 78 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Life-Threatening | Depression Nec | Study | Isotretinoin (Isotretinoin) | PS | | ORAL | | |
| | Fatigue | Health Professional | Quinine (Quinine) | C | | | | |
| | Jaundice Nos | | Meclizine (Meclizine Hydrochloride) | C | | | | |
| | Liver Function Tests Nos Abnormal | | Zoloft (Sertraline Hydrochloride) | C | | | | |
| | | | Asa (Aspirin) | C | | | | |
| | | | Allopurinol (Allopurinol) | C | | | | |

**Date:** 02/19/1999 **ISR Number:** 3203414-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 200193 **Age:** 16 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Depression Nec | Other | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Intentional Self-Injury | | Amoxicillin | C | | | | |
| | Nasopharyngitis | | Cough Syrup | C | | | | |
| | | | Augmentin | C | | | | |
| | | | Zoloft | C | | | | |

**Date:** 02/19/1999 **ISR Number:** 3203521-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 111092 **Age:** 76 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Anaemia Nos | Foreign | Tasmar (Tolcapone) | PS | | ORAL | | |
| | Appetite Increased | | | | | | | |

**Date:** 02/19/1999 **ISR Number:** 3203521-2 **Report Type:** Expedited (15-Day) **Company Report Number:** RDH092 **Age:** **Gender:**

| PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|
| Anaemia Nos | Health Professional | Tasmar (Tolcapone) | PS | | ORAL | | |
| Appetite Increased | | Bactrim Forte (Sulfamethoxazole/Trimethoprim) | SS | | | | |
| Blood Lactate Dehydrogenase Increased | | Madopar Dr | C | | | | |
| C-Reactive Protein Increased | | Levodopa | C | | | | |
| Cholestasis | | Benserazid | C | | | | |
| Condition Aggravated | | Prednisone | C | | | | |
| Diarrhoea Nos | | Konakion | C | | | | |
| Erythrocyte Sedimentation Rate Increased | | | | | | | |
| Faecal Abnormality Nos | | | | | | | |
| Haemoglobin Decreased | | | | | | | |
| Hepatotoxicity Nos | | | | | | | |
| Hunger | | | | | | | |
| Jaundice Nos | | | | | | | |
| Liver Function Tests Nos Abnormal | | | | | | | |
| Prothrombin Time Prolonged | | | | | | | |
| Renal Cyst Nos | | | | | | | |
| Weight Decreased | | | | | | | |

**Date:** 02/22/1999 **ISR Number:** 3205300-9 **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 | Condition Aggravated | Foreign | Tasmar | PS | | ORAL | | |
| | Delusion Nos | Health Professional | Madopar Dr (Benserazide/Levodopa) | C | | | | |
| | Depression Aggravated | | Rohypnol (Flunitrazepam) | C | | | | |
| | Dystonia | | Valium (Diazepam) | C | | | | |
| | Gliosis | | Permax (Pergolide Mesylate) | C | | | | |
| | Hallucination Nos | | Kalium Tabletten (Potassium Nos) | C | | | | |
| | Hallucination, Auditory | | Beloc-Zok (Metoprolol Succinate) | C | | | | |
| | Hypoparathyroidism | | Glucophage (Metformin Hydrochloride) | C | | | | |
| | Joint Stiffness | | Daonil (Glyburide) | C | | | | |
| | Monoparesis | | Naproxen (Naproxen) | C | | | | |
| | Motor Dysfunction Nos | | At-10 (Dihydrotachysterol) | C | | | | |
| | Muscle Contractions Involuntary | | Saroten (Amitriptyline Hydrochloride) | C | | | | |
| | Persecutory Delusion | | Sirdalud (Tizanidine Hydrochloride) | C | | | | |
| | Psychotic Disorder Nos | | Tonopan (Aminopyrine/Butalbital/Caffeine/Dihydroergotamine Mesylate) | C | | | | |
| | Speech Disorder Nec | | | | | | | |
| | Suicidal Ideation | | | | | | | |
| | Suicide Attempt | | | | | | | |
| | Sweating Increased | | | | | | | |

**Date:** 02/24/1999 **ISR Number:** 3205979-1 **Report Type:** Direct **Company Report Number:** **Age:** 62 YR **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Other | Panic Attack | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar | PS | Roche | ORAL | | |
| Diltiazem Xr | C | | | | |
| Sinemet 25/100 | C | | | | |
| Sinemet Cr 50/200 | C | | | | |

**Date:** 02/24/1999 **ISR Number:** 3206436-9 **Report Type:** Direct **Company Report Number:** **Age:** 16 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Death | Completed Suicide | Consumer |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Accutane 40 Mg Capsules | PS | Roche | | | |

**Date:** 02/25/1999 **ISR Number:** 3208410-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 100515 **Age:** 74 YR **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Death | Ammonia Increased | Foreign |
| Hospitalization - Initial or Prolonged | Confusion | Literature |
| | Dizziness (Exc Vertigo) | Health Professional |
| | Drug Maladministration | |
| | Electroencephalogram Abnormal | |
| | Fall | |
| | Haematoma Nos | |
| | Hepatic Encephalopathy | |
| | Hepatic Necrosis | |
| | Hepatitis Fulminant | |
| | Hepatomegaly | |
| | Hypotension | |
| | Jaundice Nos | |
| | Liver Fatty | |
| | Liver Function Tests Nos Abnormal | |
| | Loss Of Consciousness Nec | |
| | Malaise | |
| | Palpitations | |
| | Prothrombin Time Prolonged | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) 100 Mg | PS | | ORAL | | |
| Madopar (Benserazide/Levodopa) 125 Mg | SS | | ORAL | | |
| Symmetrel | C | | | | |
| Effortil | C | | | | |
| Rheftuin | C | | | | |
| Seresta | C | | | | |

**Date:** 02/25/1999 **ISR Number:** 3209935-9 **Report Type:** Periodic **Company Report Number:** 9824192 **Age:** **Gender:**

| Outcome | PT | Report Source |
|---|---|---|
| Other | Depression Nec | Health Professional |
| | | Company Representative |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Zoloft Tablets | PS | | ORAL | | |
| Accutane | SS | | ORAL | | |

**Date:** 03/01/1999 **ISR Number:** 3210639-7 **Report Type:** Direct **Company Report Number:** **Age:** 76 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Required Intervention to Prevent Permanent Impairment/Damage | Confusion | |
| | Dystonia | |
| | Hip Fracture | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) | PS | Roche | | | |
| Pennax | C | | | | |
| Sinemet | C | | | | |
| Lorazepam | C | | | | |
| Prilosec | C | | | | |
| Eldepryl | C | | | | |
| Senokot | C | | | | |
| Multivitamin C Minerals | C | | | | |
| Timoptic | C | | | | |

**Date:** 03/03/1999 **ISR Number:** 3210908-0 **Report Type:** Direct **Company Report Number:** **Age:** **Gender:**

| Outcome | PT | Report Source |
|---|---|---|
| | Dystonia | |
| | Hallucination Nos | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar | PS | Hoffman La Roche Inc | | | |

**Date:** 03/03/1999 **ISR Number:** 3211637-X **Report Type:** Expedited (15-Day) **Company Report Number:** 200406 **Age:** 82 YR **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Other | Blood Alkaline Phosphatase Nos Increased | Other |
| | Constipation | |
| | Fall | |
| | Groin Pain | |
| | Hallucination Nos | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) | PS | | ORAL | | |
| Sinemet | C | | | | |
| Paxil | C | | | | |
| Mylanta | C | | | | |

**Date:** 03/03/1999 **ISR Number:** 3211645-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 110947 **Age:** 66 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Hospitalization - Initial or Prolonged | Decreased Activity | Health Professional |
| | Liver Function Tests Nos Abnormal | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) | PS | | ORAL | | |
| Sinemet (Carbidopa/Levodopa) | C | | | | |
| Phenylephrine (Phenylephrine Hydrochloride) | C | | | | |
| Midodrine (Midodrine Hydrochloride) | C | | | | |
| Florinef (Fludrocortisone Acetate) | C | | | | |
| Milk Of Magnesia (Magnesia (Milk Of)) | C | | | | |
| Magnesium Citrate (Magnesium Citrate) | C | | | | |
| Pepcid (Famotidine) | C | | | | |

**Date:** 02/25/1999 **ISR Number:** 3212214-7 **Report Type:** Periodic **Company Report Number:** 9802532 **Age:** 16 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depersonalisation | Consumer | Zoloft Tablets | PS | | ORAL | | |
| | Hallucination Nos | Health Professional | Accutane | SS | | ORAL | | |
| | Thinking Abnormal Nec | | Ritalin | SS | | ORAL | | |

**Date:** 03/01/1999 **ISR Number:** 3213754-7 **Report Type:** Periodic **Company Report Number:** 95797 **Age:** 53 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Crying | Consumer | Soriatane (Acitretin) | PS | | ORAL | | |
| | Depression Nec | Health Professional | Accutane Capsules (Isotretinoin) 10mg | SS | | ORAL | | |
| | Lethargy | | Vitamins | C | | | | |
| | Mental Disorder Nec | | | | | | | |
| | Myalgia | | | | | | | |

**Date:** 03/11/1999 **ISR Number:** 3218114-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 109510 **Age:** 16 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Abdominal Tenderness | Foreign | Roaccutan (Isotretinoin) | PS | | ORAL | | |
| | Acne Aggravated | Health Professional | | | | | | |
| | Blood Iron Decreased | Other | | | | | | |
| | Collapse | | | | | | | |
| | Decreased Activity | | | | | | | |
| | Dizziness (Exc Vertigo) | | | | | | | |
| | Dizziness Postural | | | | | | | |
| | Gastric Erosions | | | | | | | |
| | Gastric Ulcer | | | | | | | |
| | Gastrointestinal Haemorrhage Nos | | | | | | | |
| | Haematocrit Decreased | | | | | | | |
| | Haemoglobin Decreased | | | | | | | |
| | Haemorrhage Nos | | | | | | | |
| | Headache Nos | | | | | | | |
| | Inflammatory Bowel Disease Nos | | | | | | | |
| | Melaena | | | | | | | |
| | Normochromic Normocytic Anaemia | | | | | | | |
| | Red Blood Cell Count Decreased | | | | | | | |
| | Tinnitus | | | | | | | |
| | Weakness | | | | | | | |

**Date:** 03/12/1999 **ISR Number:** 3218933-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 201190 **Age:** 19 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Dermatitis Exfoliative Nos | Foreign | Roaccutane (Isotretinoin) 20 Mg | PS | | ORAL | | |
| | Glossodynia | Health Professional | | | | | | |
| | Penile Pain | Other | | | | | | |

**Date:** 03/12/1999 **ISR Number:** 3218937-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 112083 **Age:** 18 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Abnormal Behaviour Nos | Foreign | Roaccutane (Isotretinoin) | PS | | ORAL | | |
| | | Other | | | | | | |

**Date:** 03/12/1999 **ISR Number:** 3218994-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 111144 **Age:** 18 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Alcohol Interaction | Foreign | Roaccutane (Isotretinoin) 20 Mg | PS | | ORAL | | |
| | Amnesia Nec | Health Professional | Alcohol (Alcohol) | SS | | ORAL | | |
| | Convulsions Nos | | | | | | | |
| | Drug Maladministration | | | | | | | |
| | Extrasystoles Nos | | | | | | | |
| | Fall | | | | | | | |
| | Head Injury | | | | | | | |
| | Loss Of Consciousness Nec | | | | | | | |

**Date:** 03/12/1999 **ISR Number:** 3219002-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 90195 **Age:** 42 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Depression Nec | Consumer | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Relationship Breakdown | Other | Klonopin | C | | | | |
| | Suicidal Ideation | | Trazodone | C | | | | |
| | | | Benadryl | C | | | | |
| | | | Ortho Tri-Cyclen | C | | | | |

**Date:** 03/01/1999 **ISR Number:** 3219533-9 **Report Type:** Periodic **Company Report Number:** 108318 **Age:** 74 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Diarrhoea Nos | Health Professional | Tasmar | PS | | ORAL | | |
| | Hallucination Nos | | Levodopa (Levodopa) | C | | | | |
| | | | Albuterol (Albuterol) | C | | | | |

**Date:** 03/01/1999 **ISR Number:** 3219535-2 **Report Type:** Periodic **Company Report Number:** 109052 **Age:** 69 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Hospitalization - Initial or Prolonged | Cerebrovascular Accident Nos | Health Professional |
| | Coma Nec | Other |
| | Dizziness (Exc Vertigo) | |
| | Increased Activity | |
| | Intraocular Pressure Increased | |
| | Nausea | |
| | Pyrexia | |
| | Sedation | |
| | Weakness | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar | PS | | ORAL | | |
| Sinemet Cr | C | | | | |
| Prednisone | C | | | | |
| Theo-Dur (Theophylline) | C | | | | |
| Bufferin | C | | | | |
| Klor-Con (Potassium Chloride) | C | | | | |

**Date:** 03/01/1999 **ISR Number:** 3219539-X **Report Type:** Periodic **Company Report Number:** 109296 **Age:** 58 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Hospitalization - Initial or Prolonged | Condition Aggravated | Health Professional |
| | Diarrhoea Nos | |
| | Difficulty In Micturition | |
| | Dyskinesia Nec | |
| | Dystonia | |
| | Mania | |
| | Nausea | |
| | Sweating Increased | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar | PS | | ORAL | | |
| Sinemet Cr | C | | | | |
| Sinemet-25/100 | C | | | | |
| Hytrin | C | | | | |

**Date:** 03/01/1999 **ISR Number:** 3219546-7 **Report Type:** Periodic **Company Report Number:** 108214 **Age:** 71 YR **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Other | Extrasystoles Nos | Consumer |
| | Palpitations | |
| | Urinary Tract Infection Nos | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar | PS | | ORAL | | |
| Sinemet | C | | | | |
| Sinemet Cr | C | | | | |
| Benadryl | C | | | | |

**Date:** 03/01/1999 **ISR Number:** 3219554-6 **Report Type:** Periodic **Company Report Number:** 109398 **Age:** 83 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Other | Abnormal Dreams | Consumer |
| | Anorexia | Other |
| | Arrhythmia Nos | |
| | Chest Pain | |
| | Confusion | |
| | Digoxin Toxicity | |
| | Dizziness (Exc Vertigo) | |
| | Hallucination Nos | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar | PS | | ORAL | | |
| Lanoxin | C | | | | |
| Sinemet | C | | | | |
| Aricept | C | | | | |
| Maxzide | C | | | | |

**Date:** 03/01/1999 **ISR Number:** 3219556-X **Report Type:** Periodic **Company Report Number:** 109782 **Age:** **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Amnesia Nec | Health Professional | Tasmar | PS | | ORAL | | |
| | Motor Dysfunction Nos | | | | | | | |

**Date:** 03/01/1999 **ISR Number:** 3219566-2 **Report Type:** Periodic **Company Report Number:** 110937 **Age:** 75 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Bruxism | Other | Tasamar | PS | | ORAL | | |
| | Jerky Movement Nos | | Sinemet | C | | | | |
| | Nausea | | Glucotrol | C | | | | |
| | Vision Blurred | | | | | | | |

**Date:** 03/01/1999 **ISR Number:** 3219578-9 **Report Type:** Periodic **Company Report Number:** 107622 **Age:** 50 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Abdominal Pain Nos | Consumer | Tasmar | PS | | ORAL | | |
| Required Intervention to Prevent Permanent Impairment/Damage | Burning Sensation Nos | | Sinemet (Carbidopa/Levodopa) | C | | | | |
| | Dry Throat | | Eldepryl (Selegiline Hydrochloride) | C | | | | |
| | Hallucination Nos | | | | | | | |
| | Hoarseness | | | | | | | |
| | Paraesthesia Nec | | | | | | | |
| | Pyrexia | | | | | | | |
| | Rigors | | | | | | | |
| | Throat Irritation | | | | | | | |
| | Urinary Tract Infection Nos | | | | | | | |

**Date:** 03/01/1999 **ISR Number:** 3219580-7 **Report Type:** Periodic **Company Report Number:** 102349 **Age:** 71 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Back Pain | Consumer | Tasmar | PS | | ORAL | | |
| | Constipation | Other | Sinemet | C | | | | |
| | Peeling Hot | | Eldepryl | C | | | | |
| | Muscle Cramps | | Permax | C | | | | |
| | Nervousness | | Fosamax | C | | | | |
| | Taste Disturbance | | Benadryl | C | | | | |
| | Tremor Nec | | | | | | | |

**Date:** 03/01/1999 **ISR Number:** 3219585-6 **Report Type:** Periodic **Company Report Number:** 105780 **Age:** 73 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Confusion | Health Professional | Tasmar | PS | | ORAL | | |
| | Dizziness (Exc Vertigo) | Other | Sinemet | C | | | | |
| | Movement Disorder Nos | | Neurontin | C | | | | |
| | Nausea | | | | | | | |

**Date:** 03/17/1999 **ISR Number:** 3222169-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 200082 **Age:** 16 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Mental Impairment Nos | Health Professional | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Nausea | | | | | | | |
| | Pyrexia | | | | | | | |
| | Rigors | | | | | | | |
| | Toxic Shock Syndrome Nos | | | | | | | |

**Date:** 03/19/1999 **ISR Number:** 3223855-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 200193 **Age:** 16 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Cough | Other | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Depressed Mood | | Amoxicillin (Amoxicillin) | C | | | | |
| | Depression Nec | | Cough Syrup (Antitussive Nos) | C | | | | |
| | Nasopharyngitis | | Augmentin (Amoxicillin Or Amocicillin Sodium/Clavulanate Potassium) | C | | | | |
| | Self Mutilation | | Zoloft (Sertraline Hydrochloride) | C | | | | |
| | Stress Symptoms | | | | | | | |

**Date:** 03/22/1999 **ISR Number:** 3224341-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 201957 **Age:** **Gender:**

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Arthritis Nos | Health Professional | Tasmar (Tolcapone) | PS | | ORAL | | |
| | Aspartate Aminotransferase Increased | Other | Sinemet 25/100 (Carbidopa/Levodopa) | C | | | | |
| | Blood Alkaline Phosphatase Nos Increased | | Permax (Pergolide Mesylate) | C | | | | |
| | Blood Lactate Dehydrogenase Increased | | Mirapex (Pramipexole) | C | | | | |
| | Cough | | Amantadine (Amantadine Hydrochloride) | C | | | | |
| | Dyspnoea Nos | | Lanoxin (Digoxin) | C | | | | |
| | Hallucination Nos | | Klonopin (Clonazepam) | C | | | | |
| | Pleural Effusion | | Vivactil (Protriptyline Hydrdochloride) | C | | | | |
| | Pulmonary Function Test Nos Decreased | | Ismo (Isosorbide Mononitrate) | C | | | | |
| | | | Zocor (Simvastatin) | C | | | | |
| | | | Demadex (Torsemide) | C | | | | |
| | | | Trovan (Trovafloxacin Mesylate) | C | | | | |
| | | | Allopurinol (Allopurinol) | C | | | | |
| | | | Lanoxin (Digoxin) | C | | | | |
| | | | Baby Aspirin (Aspirin) | C | | | | |

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

**Date:** 03/23/1999 **ISR Number:** 3224753-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 202198 **Age:** 54 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Acne Aggravated | Foreign | Roaccutane (Isotretinoin) | PS | | ORAL | | |
| | Aphasia | Health Professional | Antibiotics Unspecified | C | | | | |
| | Cerebrovascular Accident Nos | | | | | | | |
| | Hemiplegia | | | | | | | |

**Date:** 04/05/1999 **ISR Number:** 3233053-7 **Report Type:** Direct **Company Report Number:** **Age:** **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| | Hallucinations, Mixed | | Tasmar | PS | Roche | ORAL | | |
| | | | Levodopa | C | | | | |
| | | | Carbidopapergolide | C | | | | |

**Date:** 04/08/1999 **ISR Number:** 3234997-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 109041 **Age:** **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Cardiac Murmur Nos | Health Professional | Accutane Capsules (Isotretinoin | PS | | ORAL | | |
| | Complications Of Maternal Exposure To Therapuetic Drugs | | Effexor (Venlafaxine Hydrochloride) | C | | | | |
| | Depression Nec | | Flagyl (Metronidazole) | C | | | | |
| | Eating Disorder Nec | | | | | | | |
| | Foetal Distress Syndrome | | | | | | | |
| | Foetal Growth Retardation | | | | | | | |
| | Genital Pruritus Female | | | | | | | |
| | Genitourinary Tract Infection Nos | | | | | | | |
| | Mitral Valve Incompetence | | | | | | | |
| | Oligohydramnios | | | | | | | |
| | Premature Rupture Of Membranes | | | | | | | |
| | Rash Papular | | | | | | | |
| | Smear Cervix Abnormal | | | | | | | |
| | Streptococcal Infection Nos | | | | | | | |
| | Tricuspid Valve Incompetence | | | | | | | |
| | Umbilical Cord Vascular Disorder | | | | | | | |
| | Uterine Hypertonus | | | | | | | |
| | Vaginal Discharge | | | | | | | |
| | Vaginitis Bacterial Nos | | | | | | | |
| | Vulvovaginal Dryness | | | | | | | |

**Date:** 04/13/1999 **ISR Number:** 3239053-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 111092 **Age:** 76 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Death | Akinesia | Foreign | Tasmar (Tolcapone) | PS | | ORAL | | |
| | Blood Pressure Decreased | Health Professional | Bactrim Forte 9sulfamethoxazole/Trimehoprim | SS | | | | |
| | Bone Pain | | Madopar | C | | | | |
| | Cachexia | | Levodopa | C | | | | |
| | Condition Aggravated | | Benserazid | C | | | | |
| | Constipation | | Prednisone | C | | | | |
| | Dehydration | | Konakion | C | | | | |
| | Diarrhoea Nos | | Leponex | C | | | | |
| | Dyskinesia Nec | | Insulin Mixtard | C | | | | |
| | Gall Bladder Disorder Nos | | Duphalac | C | | | | |
| | Jaundice Nos | | | | | | | |
| | Liver Function Tests Nos Abnormal | | | | | | | |
| | Loose Stools | | | | | | | |
| | Markedly Reduced Food Intake | | | | | | | |
| | Motion Sickness | | | | | | | |
| | Oliguria | | | | | | | |
| | Pruritus | | | | | | | |
| | Renal Cyst Nos | | | | | | | |
| | Ultrasound Scan Nos Abnormal | | | | | | | |
| | Urinary Incontinence | | | | | | | |
| | Weight Decreased | | | | | | | |

**Date:** 04/13/1999 **ISR Number:** 3239059-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 203460 **Age:** **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Suicide Attempt | Health Professional | Tasmar (Tolcapone) | PS | | | | |

**Date:** 04/14/1999 **ISR Number:** 3239848-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 109041 **Age:** **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Arthralgia | Health Professional | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Cardiac Murmur Nos | | Effexor | C | | | | |
| | Complications Of Maternal Exposure To Therapuetic Drugs | | Flagyl | C | | | | |
| | Eating Disorder Nec | | Metronidazole | C | | | | |
| | Foetal Distress Syndrome | | | | | | | |
| | Foetal Growth Retardation | | | | | | | |
| | Foetal Movements Decreased | | | | | | | |
| | Genital Pruritus Female | | | | | | | |
| | Mitral Valve Incompetence | | | | | | | |

**Date:** 04/14/1999 **ISR Number:** 3239891-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 203426 **Age:** 60 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Alanine Aminotransferase Increased | Health Professional | Tasmar (Tolcapone) 100 Mg | PS | | ORAL | | |
| | Aspartate Aminotransferase Increased | | Sinemet Cr 50-200 (Carbidopa/Levodopa) | C | | | | |
| | Decreased Activity | | Sinemet-25/100 (Carbidopa/Levodopa) | C | | | | |
| | Diarrhoea Nos | | Zoloft (Sertraline Hydrochloride) | C | | | | |
| | Fatigue | | Clonazepam (Clonazepam) | C | | | | |
| | Nausea | | | | | | | |
| | Transaminase Nos Increased | | | | | | | |
| | Weakness | | | | | | | |

**Date:** 04/16/1999 **ISR Number:** 3241726-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 112625 **Age:** 73 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Blood Creatine Phosphokinase Increased | Foreign | Tasmar (Tolcapone) | PS | | ORAL | | |
| | Cardiomegaly Nos | Health Professional | | | | | | |
| | Fall | | | | | | | |
| | Hallucination Nos | | | | | | | |
| | Liver Function Tests Nos Abnormal | | | | | | | |
| | Pulmonary Congestion | | | | | | | |
| | X-Ray Nos Chest Abnormal | | | | | | | |

**Date:** 09/01/1998 **ISR Number:** 3242136-7 **Report Type:** Periodic **Company Report Number:** 101655 **Age:** 61 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Hallucination Nos | Other | Tasmar (Tolcapone) | PS | | ORAL | | |
| | Restlessness | | Sinemet (Carbidopa/Levodopa) | C | | | | |

**Date:** 09/01/1998 **ISR Number:** 3242143-4 **Report Type:** Periodic **Company Report Number:** 102644 **Age:** 80 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Anxiety Nec | Other | Tasmar (Tolcapone) | PS | | ORAL | | |
| | Dyskinesia Nec | | Sinemet (Carbidopa/Levodopa) | C | | | | |
| | Feeling Jittery | | | | | | | |

**Date:** 09/01/1998 **ISR Number:** 3242190-2 **Report Type:** Periodic **Company Report Number:** 99369 **Age:** 80 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Drug Withdrawal Syndrome | Other | Tasmar (Tolcapone) | PS | | ORAL | | |
| | Hallucination Nos | | Sinemet 25/100 (Carbidopa/Levodopa) | C | | | | |
| | Lethargy | | | | | | | |
| | Staring | | | | | | | |

**Date:** 09/01/1998 **ISR Number:** 3242196-3 **Report Type:** Periodic **Company Report Number:** 100000 **Age:** 75 YR **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Other | Confusion | Consumer |
| | Feeling Abnormal | |
| | Weakness | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) 100.000 Mg | PS | | ORAL | | |
| Sinemet (Carbidopa/Levodopa) | C | | | | |
| Xanax (Alprazolam) | C | | | | |

**Date:** 09/01/1998 **ISR Number:** 3242210-5 **Report Type:** Periodic **Company Report Number:** 101025 **Age:** 84 YR **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Other | Appetite Decreased | Consumer |
| | Dehydration | Other |
| | Insomnia Nec | |
| | Syncope | |
| | Urinary Frequency | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) | PS | | ORAL | | |
| Sinemet Cr 50-200 (Carbidopa/Levodopa) | C | | | | |
| Sinemet 25/100 (Carbidopa/Levodopa) | C | | | | |
| Lanoxin (Digoxin) | C | | | | |
| Zyprexa (Olanzapine) | C | | | | |

**Date:** 09/01/1998 **ISR Number:** 3242212-9 **Report Type:** Periodic **Company Report Number:** 101417 **Age:** 73 YR **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Other | Hallucinations Aggravated | Other |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) 100.000 Mg | PS | | ORAL | | |
| Sinemet (Carbidopa/Levodopa) | C | | | | |
| Neurontin (Gabapentin) | C | | | | |
| Vitamins (Multivitamins Nos) | C | | | | |

**Date:** 09/01/1998 **ISR Number:** 3242220-8 **Report Type:** Periodic **Company Report Number:** 103431 **Age:** 75 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Hospitalization - Initial or Prolonged | Condition Aggravated | Other |
| | Confusion | |
| | Depression Nec | |
| | Fall | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) | PS | | ORAL | | |
| Sinemet 25/100 (Carbidopa/Levodopa) | C | | | | |
| Lupron (Leuprolide Acetate) | C | | | | |

**Date:** 06/05/1998 **ISR Number:** 3242241-5 **Report Type:** Periodic **Company Report Number:** 96803 **Age:** 67 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Other | Anxiety Nec | Consumer |
| | Blood Potassium Decreased | |
| | Condition Aggravated | |
| | Depression Aggravated | |
| | Dizziness (Exc Vertigo) | |
| | Flushing | |
| | Headache Nos | |
| | Muscle Rigidity | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) | PS | | ORAL | | |
| Experimental Drug (Investigational Drug) | SS | | ORAL | | |
| Sinement Cr 50-200 | C | | | | |
| Eldepryl | C | | | | |
| Indapamide | C | | | | |
| Monopril | C | | | | |

**Date:** 06/05/1998 **ISR Number:** 3242246-4 **Report Type:** Periodic **Company Report Number:** 97782 **Age:** **Gender:** Unknown

| Outcome | PT | Report Source |
|---|---|---|
| Other | Hallucination Nos | Health Professional |
| | Psychotic Disorder Nos | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) 100.000 Mg | PS | | | | |

**Date:** 06/05/1998 **ISR Number:** 3242253-1 **Report Type:** Periodic **Company Report Number:** 96252 **Age:** 73 YR **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Other | Aphonia | Consumer |
| | Hoarseness | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) | PS | | ORAL | | |
| Sinemet Cr | C | | | | |
| Sinemet | C | | | | |
| Snythroid | C | | | | |
| Multivitamin | C | | | | |
| Calcium | C | | | | |

**Date:** 06/05/1998 **ISR Number:** 3242262-2 **Report Type:** Periodic **Company Report Number:** 96610 **Age:** 67 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Other | Condition Aggravated | Other |
| | Confusion | |
| | Fatigue | |
| | Headache Nos | |
| | Insomnia Nec | |
| | Muscle Rigidity | |
| | Nausea | |
| | Nervousness | |
| | Oral Pain | |
| | Tremor Nec | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) 100.000 Mg | PS | | ORAL | | |
| Sinemet | C | | | | |
| Eldepryl | C | | | | |
| Vitamin E | C | | | | |
| Baby Aspirin | C | | | | |

**Date:** 06/05/1998 **ISR Number:** 3242274-9 **Report Type:** Periodic **Company Report Number:** 97325 **Age:** 64 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Other | Dyskinesia Nec | Consumer |
| | Feeling Abnormal | |
| | Increased Activity | |
| | Parkinsonism Aggravated | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) 100.000 Mg | PS | | ORAL | | |
| Sinemet | C | | | | |
| Parlodel | C | | | | |
| Xanax | C | | | | |
| Ambien | C | | | | |

**Date:** 06/05/1998 **ISR Number:** 3242276-2 **Report Type:** Periodic **Company Report Number:** 97405 **Age:** **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Other | Hallucination Nos | Health Professional |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) | PS | | ORAL | | |

**Date:** 06/05/1998 **ISR Number:** 3242281-6 **Report Type:** Periodic **Company Report Number:** 97661 **Age:** 66 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Other | Nervousness | Other |
| | Tinnitus Aggravated | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) | PS | | ORAL | | |
| Sinemet | C | | | | |
| Ativan | C | | | | |
| Luvox | C | | | | |

**Date:** 06/05/1998 **ISR Number:** 3242301-9 **Report Type:** Periodic **Company Report Number:** 97822 **Age:** 83 YR **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Other | Amnesia Nec | Other |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) | PS | | ORAL | | |

**Date:** 06/05/1998 **ISR Number:** 3242323-8 **Report Type:** Periodic **Company Report Number:** 98315 **Age:** 45 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Other | Irritability | Consumer |
| | Nausea | Health Professional |
| | Nervousness | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) | PS | | ORAL | | |
| Compazine (Prochlorperazine) 25 Mg | SS | | ORAL | | |

**Date:** 06/05/1998 **ISR Number:** 3242339-1 **Report Type:** Periodic **Company Report Number:** 98569 **Age:** 78 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Other | Dysarthria | Other |
| | Hostility | |
| | Stammering | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) | PS | | ORAL | | |
| Sinemet | C | | | | |
| Aricept | C | | | | |
| Vitamin E | C | | | | |
| Vitamin C | C | | | | |

**Date:** 04/20/1999 **ISR Number:** 3243440-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 111092 **Age:** 76 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Death | Anxiety Nec | Foreign |
| | Blood Bilirubin Increased | Health Professional |
| | Blood Lactate Dehydrogenase Increased | |
| | Cardiac Failure Nos | |
| | Chest Pain | |
| | Condition Aggravated | |
| | Diverticulitis Nos | |
| | Dysphagia | |
| | Dyspnoea Nos | |
| | Gamma-Glutamyltransferase Increased | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) | PS | | ORAL | | |
| Bactrim Forte (Sulfamethoxazole/Trimethoprim) | SS | | ORAL | | |
| Madopar | C | | | | |
| Levodopa | C | | | | |
| Benserazid | C | | | | |
| Prednisone | C | | | | |
| Konakion | C | | | | |
| Leponex | C | | | | |
| Insulin Mixtard | C | | | | |

**Date:** 04/20/1999 **ISR Number:** 3243443-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 108675 **Age:** 63 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Aggression | Consumer | Tasmar (Tolcapone) | PS | | | | |
| Required Intervention to Prevent Permanent Impairment/Damage | Amnesia Nec | Health Professional | Sinemet | C | | | | |
| | Appetite Decreased | | Amantadine | C | | | | |
| | Coma Nec | | Valium | C | | | | |
| | Confusion | | | | | | | |
| | Difficulty In Walking | | | | | | | |
| | Dyskinesia Nec | | | | | | | |
| | Dysphagia | | | | | | | |
| | Eating Disorder Symptom Nos | | | | | | | |
| | Encephalopathy Nos | | | | | | | |
| | Facial Palsy | | | | | | | |
| | Gait Abnormal Nos | | | | | | | |
| | Hallucination Nos | | | | | | | |
| | Hypothyroidism | | | | | | | |
| | Immobile | | | | | | | |
| | Laboratory Test Abnormal Nos | | | | | | | |
| | Lethargy | | | | | | | |
| | Proteus Infection Nos | | | | | | | |
| | Weight Decreased | | | | | | | |
| | Wheelchair User | | | | | | | |

**Date:** 04/20/1999 **ISR Number:** 3243450-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 203893 **Age:** 23 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Required Intervention to Prevent Permanent Impairment/Damage | Accident At Work | Foreign | Roaccutan (Isotretinoin) | PS | | | | |
| | Alanine Aminotransferase Increased | Health Professional | | | | | | |
| | Aspartate Aminotransferase Increased | | | | | | | |
| | Depression Nec | | | | | | | |
| | Gamma-Glutamyltransferase Increased | | | | | | | |
| | Hand Fracture | | | | | | | |
| | Head Injury | | | | | | | |
| | Spinal Disorder Nos | | | | | | | |

**Date:** 04/22/1999 **ISR Number:** 3244448-X **Report Type:** Direct **Company Report Number:** **Age:** 21 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Life-Threatening | Anorgasmia | | Accutane | PS | | | | |
| Disability | Chromatopsia | | | | | | | |
| | Depression Nec | | | | | | | |

**Date:** 04/22/1999 **ISR Number:** 3244471-5 **Report Type:** Direct **Company Report Number:** **Age:** 76 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| | Chorea Nos | | Tasmar Tablets (Tolcapone) | PS | Hoffmann La Roche Inc | | | |
| | Dysphagia | | | | | | | |
| | Dystonia | | | | | | | |
| | Hallucination Nos | | | | | | | |
| | Muscle Rigidity | | | | | | | |

**Date:** 04/22/1999 **ISR Number:** 3244683-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 200406 **Age:** 82 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Abdominal Pain Nos | Other | Tasmar | PS | | ORAL | | |
| | Blood Alkaline Phosphatase Nos Increased | | Sinemet 25/100 (Carbidopa/Levodopa) | C | | | | |
| | Condition Aggravated | | Paxil (Paroxetine) | C | | | | |
| | Constipation | | Mylanta (Aluminum Hydroxide/Magnesium Hydroxide/Simethicone) | C | | | | |
| | Dyskinesia Nec | | | | | | | |
| | Dyspnoea Nos | | | | | | | |
| | Faecal Impaction | | | | | | | |
| | Fall | | | | | | | |
| | Groin Pain | | | | | | | |
| | Hallucination Nos | | | | | | | |
| | Muscle Injury Nos | | | | | | | |
| | Palpitations | | | | | | | |

**Date:** 04/22/1999 **ISR Number:** 3244710-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 202854 **Age:** 25 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 | | |
| | Endometriosis | | Claritin (Loratadine) | C | | | | |
| | Mood Swings | | | | | | | |
| | Ovarian Cyst | | | | | | | |
| | Thinking Abnormal Nec | | | | | | | |

**Date:** 04/22/1999 **ISR Number:** 3245241-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 201957 **Age:** 74 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Death | Cough | Health Professional | Tasmar (Tolcapone) | PS | | ORAL | | |
| | Dyspnoea Nos | Other | Sinemet | C | | | | |
| | Hallucination Nos | | Permax | C | | | | |
| | Liver Function Tests Nos Abnormal | | Mirapex | C | | | | |
| | Myocardial Infarction | | Amantadine | C | | | | |
| | Pleural Effusion | | Lanoxin | C | | | | |

**Date:** 04/28/1999 **ISR Number:** 3249004-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 203893 **Age:** 23 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Required Intervention to Prevent Permanent Impairment/Damage | Accident At Work<br>Back Disorder Nos<br>Depression Nec<br>Hand Fracture<br>Head Injury<br>Liver Function Tests Nos Abnormal | Foreign<br>Health Professional | Roaccutan (Isotretinoin) | PS | | | | |

**Date:** 05/04/1999 **ISR Number:** 3253915-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 204535 **Age:** **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Disability<br>Congenital Anomaly | Accidental Exposure<br>Autism<br>Congenital Abnormality Nos<br>Mental Retardation Severity Unspecified<br>Microtia<br>Mutism Nec<br>Strabismus Nec | Other | Accutane Capsules (Isotretinoin)<br>Retin A Cream (Tretinoin)<br>Prenatal Vitamins (Minerals Nos/Multivitamin Nos) | PS<br>C<br>C | | ORAL | | |

**Date:** 05/04/1999 **ISR Number:** 3253941-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 204304 **Age:** 39 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Acne Aggravated<br>Alopecia<br>Blood In Stool<br>Cyst Nos<br>Depression Nec<br>Duodenitis<br>Gastritis Nos<br>Haematemesis<br>Haemorrhoids<br>Lip Dry<br>Mood Swings<br>Rectal Bleeding<br>Skin Infection Nos<br>Staphylococcal Infection Nos<br>Suicidal Ideation | Consumer<br>Health Professional | Accutane Capsules (Isotretinoin)<br>Combivir<br>Colace<br>Mvi | PS<br>C<br>C<br>C | | ORAL | | |

**Date:** 05/04/1999 **ISR Number:** 3253946-4 **Report Type:** Expedited (15-Day) **Company Report Number:** 204662 **Age:** 16 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Depression Nec | Foreign | Roaccutane (Isotretinoin) | PS | | ORAL | | |
| | Non-Accidental Overdose | Other | | | | | | |
| | Obsessive-Compulsive Disorder | | | | | | | |

**Date:** 05/11/1999 **ISR Number:** 3258927-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 112718 **Age:** 76 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Death | Blood Urea Increased | Foreign | Tasmar (Tolcapone) | PS | | ORAL | | |
| | Coma Nec | Health Professional | Sinemet Slow Release | C | | | | |
| | Confusion | | Sinemet Cr | C | | | | |
| | Coronary Artery Disease Nos | | Ismo | C | | | | |
| | Hypernatraemia | | Adalat Retard | C | | | | |
| | Immobile | | Atenolol | C | | | | |
| | Leucocytosis Nos | | Warfarin | C | | | | |
| | Lower Respiratory Tract Infection Nos | | Pergolide | C | | | | |
| | Myocardial Infarction | | | | | | | |
| | Neuroleptic Malignant Syndrome | | | | | | | |
| | White Blood Cell Count Increased | | | | | | | |

**Date:** 05/11/1999 **ISR Number:** 3258980-6 **Report Type:** Expedited (15-Day) **Company Report Number:** 205299 **Age:** 63 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Depression Aggravated | Health Professional | Tasmar (Tolcapone) | PS | | ORAL | | |
| | Non-Accidental Overdose | | Sinemet | C | | | | |
| | Suicide Attempt | | Remeron | C | | | | |
| | | | Xanax | C | | | | |
| | | | Artane | C | | | | |

**Date:** 05/11/1999 **ISR Number:** 3259284-8 **Report Type:** Expedited (15-Day) **Company Report Number:** 112555 **Age:** **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Arrested Labour | Consumer | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Caesarean Section | | Oral Contraceptive Pill | C | | | | |
| | Complications Of Maternal Exposure To Therapuetic Drugs | | | | | | | |
| | Condition Aggravated | | | | | | | |
| | Disturbance In Attention Nec | | | | | | | |
| | Expressive Language Disorder | | | | | | | |
| | Eye Movement Disorder Nos | | | | | | | |
| | Learning Disorder Nos | | | | | | | |

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

**Date:** 05/12/1999 **ISR Number:** 3260039-9 **Report Type:** Expedited (15-Day) **Company Report Number:** 204528 **Age:** **Gender:** Unknown

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Required Intervention to Prevent Permanent Impairment/Damage | Abortion Incomplete Nos<br>Complications Of Maternal Exposure To Therapuetic Drugs<br>Crying<br>Dyspareunia Nec<br>Mood Disorder Nos<br>Unwanted Pregnancy<br>Vaginal Odour<br>Vaginitis Bacterial Nos<br>Vulvovaginitis Nos | Health Professional | Accutane Capsules (Isotretinoin)<br>Birth Control Pills | PS<br>C | | ORAL | | |

**Date:** 05/12/1999 **ISR Number:** 3260058-2 **Report Type:** Expedited (15-Day) **Company Report Number:** 110489 **Age:** 15 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Abnormal Behaviour Nos<br>Aggression | Foreign<br>Other | Roaccutane (Isotretinoin)<br>Virlix (Cetrizine Hydrochloride) | PS<br>SS | | ORAL<br>ORAL | | |

**Date:** 05/13/1999 **ISR Number:** 3261087-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 201521 **Age:** 18 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Conjunctivitis Nec<br>Eye Discharge<br>Hallucination, Auditory<br>Insomnia Nec<br>Obsessive-Compulsive Disorder<br>Palpitations<br>Red Eye | Health Professional | Accutane Capsules (Isotretinoin) 40 Mg | PS | | ORAL | | |

**Date:** 05/14/1999 **ISR Number:** 3262580-1 **Report Type:** Expedited (15-Day) **Company Report Number:** 200082 **Age:** 16 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Mental Impairment Nos<br>Nausea<br>Pyrexia<br>Rigors<br>Toxic Shock Syndrome Nos | Health Professional | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |

**Date:** 05/14/1999 **ISR Number:** 3262581-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 203460 **Age:** 71 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Depression Aggravated<br>Overdose Nos<br>Suicide Attempt | Health Professional | Tasmar (Tolcapone)<br>Sinemet (Carbidopa/Levodopa) | PS<br>C | | | | |

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

**Date:** 05/26/1999 **ISR Number:** 3269431-X **Report Type:** Expedited (15-Day) **Company Report Number:** 206296 **Age:** **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Hallucination Nos | Health Professional | Tasmar (Tolcapone) | PS | | ORAL | | |
| | Liver Function Tests Nos Abnormal | | Sinemet (Carbidopa/Levodopa) | C | | | | |

**Date:** 05/25/1999 **ISR Number:** 3269598-3 **Report Type:** Expedited (15-Day) **Company Report Number:** 201957 **Age:** 74 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Death | Arthritis Nos | Health Professional | Tasmar (Tolcapone) | PS | | ORAL | | |
| | Aspartate Aminotransferase Increased | Other | Sinemet | C | | | | |
| | Blood Alkaline Phosphatase Nos Increased | | Permax | C | | | | |
| | Blood Lactate Dehydrogenase Increased | | Mirapex | C | | | | |
| | Cough | | Amantadine | C | | | | |
| | Dyspnoea Nos | | Lanoxin | C | | | | |
| | Hallucination Nos | | Klonopin | C | | | | |
| | Myocardial Infarction | | Vivactil | C | | | | |
| | Pleural Effusion | | Ismo | C | | | | |
| | | | Zocor | C | | | | |
| | | | Demadex | C | | | | |
| | | | Trovan | C | | | | |
| | | | Allopurinol | C | | | | |
| | | | Baby Aspirin | C | | | | |
| | | | ... | C | | | | |

**Date:** 05/25/1999 **ISR Number:** 3269601-0 **Report Type:** Expedited (15-Day) **Company Report Number:** 203460 **Age:** 73 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Hospitalization - Initial or Prolonged | Depression Aggravated | Health Professional | Tasmar (Tolcapone) | PS | | | | |
| | Overdose Nos | | Sinemet | C | | | | |
| | Suicide Attempt | | Permax | C | | | | |
| | | | Clozan | C | | | | |

**Date:** 06/02/1999 **ISR Number:** 3275302-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 204746 **Age:** 14 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Acne Aggravated | Other | Accutane Capsules (Isotretinoin) 20 Mg | PS | | ORAL | | |
| | Arthralgia | | | | | | | |
| | Decreased Activity | | | | | | | |
| | Lip Dry | | | | | | | |
| | Pain Nos | | | | | | | |

**Date:** 06/02/1999 **ISR Number:** 3275437-7 **Report Type:** Expedited (15-Day) **Company Report Number:** 202989 **Age:** 16 YR **Gender:** Male

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Abdominal Pain Upper<br>Arthralgia<br>Depressed Mood<br>Hypertriglyceridaemia<br>Nausea<br>Personality Disorder Nos<br>Polydipsia<br>Social Avoidant Behaviour<br>Stress Symptoms<br>Suicidal Ideation<br>Suicide Attempt<br>Theft<br>Urine Discolouration | Other | Accutane Capsules (Isotretinoin) 20 Mg | PS | | ORAL | | |

**Date:** 06/02/1999 **ISR Number:** 3275556-5 **Report Type:** Expedited (15-Day) **Company Report Number:** 200462 **Age:** 21 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Death<br>Hospitalization - Initial or Prolonged<br>Required Intervention to Prevent Permanent Impairment/Damage | Accessory Nerve Disorder Nos<br>Acute Circulatory Failure<br>Anaemia Nos<br>Cardio-Respiratory Arrest<br>Convulsions Nos<br>Dna Antibody Nos Positive<br>Dyspnoea Exertional<br>Ecchymosis<br>Electrocardiogram T Wave Amplitude Decreased<br>Encephalopathy Nos<br>Haemorrhagic Stroke<br>Menometrorrhagia<br>Petechiae<br>Proteinuria Present<br>Pulmonary Alveolar Haemorrhage<br>Red Blood Cell Schistocytes Present<br>Reticulocyte Count Increased<br>Thrombocytopenia<br>Thrombotic Microangiopathy Nos<br>White Blood Cell Count Decreased | Foreign<br>Health Professional | Roaccutane (Isotretinoin) | PS | | ORAL | | |

**Date:** 06/01/1999 **ISR Number:** 3276808-5 **Report Type:** Periodic **Company Report Number:** 109052 **Age:** 69 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Hospitalization - Initial or Prolonged | Abnormal Eye Movements Nos | Health Professional |
| Required Intervention to Prevent Permanent Impairment/Damage | Coma Nec | Other |
| | Dizziness (Exc Vertigo) | |
| | Haemorrhagic Stroke | |
| | Hypertension Nos | |
| | Increased Activity | |
| | Nausea | |
| | Neck Stiffness | |
| | Pyrexia | |
| | Weakness | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) | PS | | ORAL | | |
| Sinemet Cr | C | | | | |
| Prednisone | C | | | | |
| Theo-Dur | C | | | | |
| Bufferin | C | | | | |
| Klor-Con | C | | | | |

**Date:** 06/01/1999 **ISR Number:** 3276826-7 **Report Type:** Periodic **Company Report Number:** 201192 **Age:** 44 YR **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Other | Headache Nos | Consumer |
| | Orgasm Abnormal | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) 100 Mg | PS | | ORAL | | |
| Herbal Diuretic Nos (Herbal Diuretic Nos) | SS | | ORAL | | |
| Sinemet Cr | C | | | | |
| Sinemet | C | | | | |
| Carmex | C | | | | |
| Excedrin | C | | | | |

**Date:** 06/01/1999 **ISR Number:** 3276830-9 **Report Type:** Periodic **Company Report Number:** 202278 **Age:** 83 YR **Gender:** Female

| Outcome | PT | Report Source |
|---|---|---|
| Other | Abdominal Distension | Other |
| | Appetite Decreased | |
| | Constipation | |
| | Depression Aggravated | |
| | Dizziness (Exc Vertigo) | |
| | Headache Nos | |
| | Nervousness | |
| | Oedema Lower Limb | |
| | Weakness | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) 200 Mg | PS | | ORAL | | |
| Sinemet Cr | C | | | | |
| Lecodopa-Carbidopa | C | | | | |
| Bumetanide | C | | | | |
| K Dur | C | | | | |
| Atenolol | C | | | | |
| Norvasc | C | | | | |
| Zestril | C | | | | |
| Lorazepam | C | | | | |
| Amaryl | C | | | | |

**Date:** 06/01/1999 **ISR Number:** 3276840-1 **Report Type:** Periodic **Company Report Number:** 204693 **Age:** 83 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Other | Abnormal Behaviour Nos | Other |
| | Condition Aggravated | |
| | Diarrhoea Nos | |
| | Emotional Disturbance Nos | |
| | Hallucination Nos | |
| | Hypernatraemia | |
| | Hypokalaemia | |
| | Parkinsonism Aggravated | |
| | Syncope | |
| | Weight Decreased | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) 100mg | PS | | ORAL | | |
| Trazodone (Trazodone Hydrochloride) | SS | | | | |
| Sinemet Cr | C | | | | |
| Sinemet | C | | | | |
| Vitamin B12 | C | | | | |
| Aspirin Enteric Coated | C | | | | |
| Eye Drops | C | | | | |
| Stool Softener | C | | | | |

**Date:** 06/01/1999 **ISR Number:** 3276849-8 **Report Type:** Periodic **Company Report Number:** 200410 **Age:** 76 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Other | Abrasion Nos | Health Professional |
| | Anaemia Nos | |
| | Confusion | |
| | Dermatitis Nos | |
| | Diplopia | |
| | Ecchymosis | |
| | Fall | |
| | Hallucination Nos | |
| | Headache Nos | |
| | Insomnia Nec | |
| | Oedema Lower Limb | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) | PS | | ORAL | | |
| Sinemet Cr 50-200 | C | | | | |
| Sinemet-25/100 | C | | | | |
| Olanzapine | C | | | | |
| Bromocriptine | C | | | | |

**Date:** 06/01/1999 **ISR Number:** 3276854-1 **Report Type:** Periodic **Company Report Number:** 200463 **Age:** 55 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Other | Hallucination Nos | Health Professional |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) 100 Mg | PS | | ORAL | | |
| Sinemet | C | | | | |

**Date:** 06/01/1999 **ISR Number:** 3276859-0 **Report Type:** Periodic **Company Report Number:** 201632 **Age:** 40 YR **Gender:** Male

| Outcome | PT | Report Source |
|---|---|---|
| Hospitalization - Initial or Prolonged | Bipolar Disorder Nec | Health Professional |
| | Mania | |

| Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|
| Tasmar (Tolcapone) | PS | | ORAL | | |
| Sinemet Cr 25-100 | C | | | | |
| Sinemet | C | | | | |
| Mirapex | C | | | | |
| Periactin | C | | | | |

**Date:** 06/14/1999 **ISR Number:** 3282664-1 **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 | Tasmar (Tolcapone) | PS | | | | |
| | Parkinson'S Disease Aggravated | Health Professional | Madopar Dr | C | | | | |
| | Personality Change | | Akineton | C | | | | |

**Date:** 06/07/1999 **ISR Number:** 3283548-5 **Report Type:** Periodic **Company Report Number:** 111649 **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) | PS | | ORAL | | |
| | Mood Swings | | | | | | | |

**Date:** 06/07/1999 **ISR Number:** 3283565-5 **Report Type:** Periodic **Company Report Number:** 111863 **Age:** 26 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Aggression | Consumer | Accutane Capsules (Isotretinoin) 40 Mg | PS | | ORAL | | |
| | Back Pain | Health Professional | Birth Control Pills Nos | C | | | | |
| | Coma Nec | | | | | | | |
| | Crying | | | | | | | |
| | Hypertriglyceridaemia | | | | | | | |
| | Lip Dry | | | | | | | |
| | Mood Swings | | | | | | | |
| | Muscle Cramps | | | | | | | |
| | Nightmare | | | | | | | |
| | Thrombocytopenia | | | | | | | |

**Date:** 06/07/1999 **ISR Number:** 3283583-7 **Report Type:** Periodic **Company Report Number:** 112111 **Age:** 33 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Irritability | Consumer | Accutane Capsules (Isotretinoin) | PS | | ORAL | | |
| | Mood Swings | Health Professional | Contraceptive Pill Nos | C | | | | |
| | Personality Change | | | | | | | |

**Date:** 06/07/1999 **ISR Number:** 3283589-8 **Report Type:** Periodic **Company Report Number:** 112137 **Age:** 19 YR **Gender:** Female

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration |
|---|---|---|---|---|---|---|---|---|
| Other | Coma Nec | Consumer | Accutane Capsules (Isotretinoin) 40mg | PS | | ORAL | | |
| | Depression Nec | Health Professional | | | | | | |
| | Disturbance In Attention Nec | | | | | | | |
| | Mood Swings | | | | | | | |