| Date: 06/09/2000 | ISR Number: 3516870-5 | Report Type: Periodic | Company Report N | iumber: 211056 | | Age: 31 YR | |
|------------------|--------------------------------------|-----------------------|--|----------------|----------------|------------|--------------------|
| Outcome | PT | Report Source | Product | | | | Gender: Female |
| Other | Alopecia | Consumer | Accutane | Role | Manufacturer | Route | Dose/Unit Duration |
| | Depressed Mood | | | PS | Hir Technology | ORAL | |
| | Depression Nec | | Ortho Tri-Cyclen (Ethinyl Estradiol Norgestimate) | 1/ C | | | |
| | Fatigue Lethargy | | | | | | |
| Date: 06/09/2000 | | | | | | | |
| | ISR Number: 3516878-X | Report Type: Periodic | Company Report N | umber: 211310 | | Age: 42 YR | Gender: Female |
| Outcome | PT | Report Source | Product | Role | Manufacturer | | |
| Other | Depression Nec | Consumer | Accutane | PS | Hir Technology | Route | Dose/Unit Duration |
| | Hypercholesterolaemia Mood Swings | Health Professional | | ro | гиг весплоюду | ORAL. | |
| | WOOD SWINGS | Other | | | | | |
| Date: 06/09/2000 | ISR Number: 3516881-X | Report Type: Periodic | Company Report N | | | | |
| Outcome | PT | | | miner: 211314 | | Age: 28 YR | Gender: Female |
| Other | Depression Nec | Report Source | Product | Role | Manufacturer | Route | Dose/Unit Duration |
| | Haemorrhage Nos | Consumer | Accutane | PS | Hlr Technology | ORAL | |
| | Lip Disorder Nos | Other | Ortho-Novum (Ethinyl Estradiol / Norethindrone) | C | | | |
| | Localised Exfoliation | | Synthroid (Levothyroxine Sodium) | С | | | |
| | Mood Alteration Nos Scar | | , | C | | | |
| Date: 06/09/2000 | | | | | | | • |
| Jate; 00/09/2000 | ISR Number: 3516885-7 | Report Type: Periodic | Company Report N | umber: 217396 | | Age: | Gender: Female |
| Outcome | PT | Report Source | Product | D-1- | | | Generi: Temple |
| Other | Dysuria | Consumer | Accutane | Role_ PS | Manufacturer | Route | Dose/Unit Duration |
| | Lip Dry | | · | rs | Hir Technology | ORAL | |
| | Mood Swings Rectal Bleeding | | | | | | |
| | Weight Decreased | | | | | | |
| ate: 06/09/2000 | ISR Number: 3516891-2 | D | | | | | |
| D.4 | | Report Type: Periodic | Company Report N | umber: 211466 | | Age: 34 YR | Gender: Female |
| Outcome | _ <u>PT</u> | Report Source | Product | Role | Manufacturer | Route | |
| Other | Depression Aggravated Lethargy | Consumer | Accutane | PS | Hir Technology | ORAL | Dose/Unit Duration |
| | abj | Health Professional | | | rouniviogj | UKAL | |
| | | Other | | | | | |
| | | | | | | | |
| | | 4 | | | | | |
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| | | 108 | Assets Seedign | Event Report Of Information | | en (AERS) Rejort | | | | |
|------------------|--------------------------|-----------------------|-------------------|--|------------|---------------------|------------|-------------|-------------|------|
| Date: 06/09/2000 | ISR Number: 3516904-8 | Report Type: Periodic | | Company Report Numb | er: 212182 | | Age: 21 YR | 0 | | |
| Outcome | PT | Report Source | Their days a | - · · | | | ger Ziik | , Va | der: Fema | le . |
| Other | Acne Aggravated | Consumer | Product | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Depression Nec | | Accutane | | PS | Hlr Technology | ORAL | | | - |
| | Dry Skin | Health Professional | | 500 miles | | | | | | |
| | Eczema Nos | Other | | | | | | | | |
| · | Epidermal Naevus | | | | | | | | | |
| | Epistaxis | | | | | | | | | |
| | Erythema Nec | | | | | | | | | |
| | Lip Dry | | | | | | | | | |
| | Skin Depigmentation | | | | | | | | | |
| | Sunburn | | | | | | | | | |
| | Xerosis | | | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3516928-0 | Report Type: Periodic | | Company Report Numb | er: 217589 | | Age: 16 YR | Ger | der: Fema | |
| Outcome | PT | Report Source | Product | | | | • | | I Cana | ic |
| Other | Nightmare | Health Professional | | | Role | Manufacturer | Route | Dose/Unit | Duration | _ |
| | | | Accutane | | PS | Hlr Technology | ORAL | | | |
| Date: 06/09/2000 | ISR Number: 3516932-2 | Report Type: Periodic | | Company Report Numb | 217507 | | | | | |
| Outcome | PT | | | | CL. 21/39/ | | Age: | Ger | der: Fema | le , |
| Other | Irritable Bowel Syndrome | Report Source | Product | · · · · · · · · · · · · · · · · · · · | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | milable bower syndrome | Other | Accutance | | PS | Hlr Technology | ORAL | Don't City | Duranon | |
| Date: 06/09/2000 | ISR Number: 3516933-4 | Day of the Day of the | | | | | ORAL | | | |
| | | Report Type: Periodic | | Company Report Numb | er: 217606 | | Age: | Gen | der: Male | |
| Outcome | PT | Report Source | Product | | D.1. | 37 | 1 | | | |
| Other | Irritable Bowel Syndrome | Consumer | Accutane | | Role | Manufacturer | Route | Dose/Unit | Duration | _ |
| · | | | riccitatic | _ | PS | Hlr Technology | ORAL | | | |
| Date: 06/09/2000 | ISR Number: 3516934-6 | Report Type: Periodic | | Company Report Numb | 217507 | | | | | |
| Outcome | PT | | | сопрану кероп минь | er: 21/60/ | | Age: | Gen | der: Male | |
| Other | | Report Source | Product | | Role | Manufacturer | Route | Dose/Unit | D | |
| Outer | Irritable Bowel Syndrome | Other | Accutane | | PS | Hlr Technology | | DOSO UHA | Duration | - |
| Date: 06/09/2000 | | | | | | rm recanology | ORAL | | | |
| Date: 06/09/2000 | ISR Number: 3516938-3 | Report Type: Periodic | | Company Report Numb | 217675 | | 4 | | | |
| Outcome | PT . | | | Topological Control of the Control o | 2. 21,0,5 | | Age: 22 YR | Gen | der: Femal | e |
| Other | Abdominal Pain Nos | Report Source | Product | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Dizziness (Exc Vertigo) | Other | Accutane | | PS | Hlr Technology | ORAL | | Duration | - |
| | Dry Skin | | Ortho-Cept (| Desogestrel/Ethinyl | С | | OKAL | | | |
| | Patigue | | Estradiol) | - , | • | | | | | |
| | Mood Swings | | | | | | | | | |
| | Thirst | | | | | | | | | |
| - | | | | | | | | | | |
| 08/03/2000 | 1 | | | | | - | | | | |
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| | | | recton Of Internatio | | Report | | |
|------------------|------------------------------|-----------------------|--|---------------|----------------|-------------|--------------------|
| Date: 06/09/2000 | ISR Number: 3516946-2 | Report Type: Periodic | Company Report Nu | mbom 217064 | | | |
| Outcome | PT | | | MIDEE: 21/904 | | Age: | Gender: Female |
| Other | Arthralgia | Report Source | Product | Role | Manufacturer | Route | Dose/Unit Duration |
| | Back Pain | Consumer | Accutane | PS | Hlr Technology | ORAL | |
| | Blood Cholesterol Increased | | Claritin (Loratadine) | Ċ | | | |
| | Depression Nec | | Cataflam (Diclofenac Potassium) | С | | | |
| | Dermatitis Nos | | | | | | |
| | Muscle Spasms | | | | | | |
| Pate: 06/09/2000 | ISR Number: 3516955-3 | Report Type: Periodic | Company Report Nu | mber: 202654 | | Age: 34 YR | Gender: Female |
| Outcome | PT | Report Source | Product | | | | Tentale |
| Other | Disturbance In Attention Nec | Consumer | Accutane | Role | Manufacturer | Route | Dose/Unit Duration |
| | Fatigue | | | PS | Hlr Technology | ORAL | |
| | <u> </u> | | Ortho-Tricyclen (Ethinyl Estradio/Norgestimate) | С | | | |
| Date: 06/09/2000 | ISR Number: 3516995-4 | Report Type: Periodic | | | | | |
| Outcome | Turn | | Company Report Nu | nber: 202809 | | Age: 28 YR | Gender: Female |
| Other | PT Constipation | Report Source | Product | Role | Manufacturer | Route | Dose/Unit Duration |
| Omer | Depression Nec | Consumer | Accutane | PS | Hlr Technology | ORAL | Dose/Unit Duration |
| Date: 06/09/2000 | | | | | | ORAL | |
| ALE: 00/09/2000 | ISR Number: 3517003-1 | Report Type: Periodic | Company Report Nu | nber: 233472 | | Age: 17 YR | Gender: Male |
| Outcome | PT | Report Source | | | | rige. 17 IK | Gender: Male |
| Other | Apathy | Consumer | Product | Role | Manufacturer | Route | Dose/Unit Duration |
| | Depression Nec | Consumer | Accutane | PS | HIr Technology | ORAL | |
| | Fatigue | | Accutane | SS | | | |
| | Mood Swings | | Accutane | SS | | | |
| | | | Accutane | SS | | | |
| | | | Claritin | ·C | | | |
| ate: 06/09/2000 | ISR Number: 3517006-7 | Report Type: Periodic | Company B N | 1 202007 | | | |
| Outcome | PT | · · | Company Report Nur | nder: 202997 | | Age: 17 YR | Gender: Male |
| Other | Emresis | Report Source | Product | Role | Manufacturer | Route | Dose/Unit Duration |
| | | Health Professional | Accutane | PS | Hlr Technology | ORAL | <u>Juneau</u> |
| ate: 06/09/2000 | ISR Number: 3517010-9 | D 45 2 4 | | | | | |
| | | Report Type: Periodic | Company Report Nur | nber: 233483 | | Age: | Gender: Female |
| Outcome | PT | Report Source | Product | Dolo | Manufacture | . . | |
| ther | Depression Nec | Consumer | Accutane | Role | Manufacturer | Route | Dose/Unit Duration |
| | Diarrhoea Nos | . Other | | PS | Hlr Technology | ORAL | |
| | Dizziness (Exc Vertigo) | | | | | | |
| | Headache Nos Irritability | | | | | | |

| Date: 06/09/2000 Outcome | ISR Number: 3517016-X | Report Type: Periodic | Company Report Numi | er: 203339 | | Age: | Gen | ıder: Female | |
|--------------------------|----------------------------------|-----------------------|---|------------|---------------------------------------|------------|-------------|--------------|---|
| Other | Alopecia | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration | |
| -met | Arthralgia | Consumer | Accutane | PS | Hlr Technology | ORAL | _ Dusc oint | Duration | |
| | Arthropod Bite | Health Professional | Parnate (Tranylcypromine Sulfate) | С | Im recunology | ORAL. | | | |
| | Aspartate Aminotransferase | | Prozac (Fluoxetine Hydrochloride) | Ċ | | | | | |
| | Increased | | Benzamycin (Benzoyl | c | | | | | |
| | Breast Tendemess | | Peroxide/Erythromycin) | C | | | | | |
| | Cheilitis | | Xanax (Alprazolam) | С | | | | | |
| | Condition Aggravated | | Desowen Ointment (Desonide) | c | | | | | |
| | Confusion | | Aquaphor (Ceresin/Mineral | c | | | | | |
| | Depression Aggravated | | Oil/Petrolatum/Wool Alcohol Or | · | | | | | |
| | Dermatitis Nos | | Xipamide) | | | | | | |
| | Dry Skin | | Advil (Ibuprofen) | C | | | | | |
| | Epistaxis | | Spectazole (Econazola Nitrate) | C | | | | | |
| | Fatigue Lacrimation Increased | | Cutivate Ointment (Fluticasone | C | | | | | |
| | Lip Dry | * | Propionate) Terazol Suppositories (Terconazole) | _ | | | | | |
| | Memory Impairment | | reason suppositories (Terconazole) | С | | | | | |
| | Mental Impairment Nos | | | | | | | | |
| | Mood Disorder Nos | | | | | | | | |
| | Panic Attack | | | | | | | | |
| | Proritos | | | | | | | | |
| | Rhinorrhoea | | | | | | | | • |
| | Vaginal Candidiasis | | | | | | | | |
| | Vision Blurred | | | | | | | | |
| rate: 06/09/2000 | ISR Number: 3517027-4 | Report Type: Periodic | Company Report Numb | er: 233669 | | Age: 50 YR | | | |
| Outcome | PT | Demost C | | | | Age: 30 IK | Gen | der: Female | |
| Other | Acne Aggravated | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Anxiety Nec | Consumer | Accutane | PS | Hir Technology | ORAL | | | |
| | Dermatitis Nos | | Synthroid | С | | ~~~ | | | |
| | Lip Dry | | | | | | | | |
| | Skin Disorder Nos | | | | | | | | |
| Oate: 06/09/2000 | ISR Number: 3517055-9 | Report Type: Periodic | Company Report Numb | er; 203625 | · · · · · · · · · · · · · · · · · · · | Age: 14 YR | | der: Female | |
| Outcome | PT | Report Source | Destant | | | g 1.1K | Gai | der: Female | |
| Other | Back Pain | Health Professional | Product | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Depression Nec | ricatui Professional | Accutane | PS | HlrTechnology | ORAL | | | |
| | Headache Nos | | Birth Control Pills (Oral Contraceptive | С | | | | | |
| | Ingrowing Nail | | Nos) | | | | | | |
| <u> </u> | Localised Exfoliation | | | | | | | | |
| | | | | | | | | | |

| Date: 06/09/2000 | ISR Number: 3517081-X | Report Type: Periodic | | Company Report Numb | er: 230065 | | Age: | 15 YR | Gen | ider: Male | |
|-----------------------------|---|-----------------------|--------------|-----------------------|------------|--------------------------------|-----------|-------|---|-------------|----------|
| Outcome | PT | Report Source | Product | | Role | Manufacturer | • | | | | |
| Other | Nightmare | Health Professional | Accutane | | PS | Hir Technology | | THAL | Dose/Unit | Duration | |
| Date: 06/09/2000 | ISR Number: 3517101-2 | Report Type: Periodic | - | Company Report Numb | er: 230612 | | Age: | 14 YR | Gen | der: Female | |
| Outcome | PT | Report Source | Product | | Role | N | | | | | |
| Other | Blood Cholesterol Increased Depression Nec | Consumer | Accutane | | PS | Manufacturer Hir Technology | Rou OR | | Dose/Unit | Duration | |
| | Lip Dry Low Density Lipoprotein Increased | | | | | | | | | | |
| 20000000 | Throat Oedema | | | | | | | | | | |
| Oate: 06/09/2000 Outcome | ISR Number: 3517155-3 PT | Report Type: Periodic | | Company Report Numb | er: 229184 | | Age: | 18 YR | Gen | der: Male | |
| Other | Memory Impairment | Report Source | Product | | Role | Manufacturer | Rou | ıte | Dose/Unit | Duration | |
| | , impairment | Health Professional | Accutane | | PS | Hlr Technology | ORA | AL . | | - manual | |
| nte: 06/09/2000 | ISR Number: 3517160-7 | Report Type: Periodic | | Company Report Numb | er: 229270 | | Age: | 32 YR | Gen | der: Male | <u> </u> |
| Outcome | PT | Report Source | Product | | Role | Manufacturer | | | | | |
| Other | Disturbance In Attention Nec Dizziness (Exc Vertigo) | Consumer | Accutane | | PS | Hir Technology | Rou | | Dose/Unit | Duration | |
| | Feeling Abnormal Headache Nos | | | | | Tim 1 ecamology | ORA | AL. | | | • |
| | Tired Eyes Vision Blurred | | | , . | | | | | | | |
| ate: 06/09/2000 | ISR Number: 3517222-4 | Report Type: Periodic | | Company Report Number | er: 229610 | <u> </u> | Age: | 41 YR | | der: Female | |
| utcome | PT | Report Source | Product | | | | | | . Gen | der: Female | |
| ther | Depression Nec | Consumer | Accutane | | Role | Manufacturer | Rou | te | Dose/Unit | Duration | |
| | Obsessive-Compulsive Disorder | Other | Lithium | | PS | Hir Technology | ORA | VL. | | | |
| | | | Anafranil | | С | | | | | | |
| | | | Prozac | | C | | | | | | |
| | | | Xanax | | С | | | | | | |
| | | | | | C | | | | | | |
| | | | Amoien (Zolp | idem Tartrate) | С | | | | | | |
| | | | | | | | | | , | - | |
| | | | | | | | | | | | |
| 08/03/2000 | | | | | | | | | | | |
| | | | | | | | | F | age 451 | of 487 | |

| | | | rection ()) Information | | Region | | |
|------------------|-------------------------------|-----------------------|---|-------------|--|---------------------------------------|---------------------------|
| Date: 06/09/2000 | ISR Number: 3517352-7 | Report Type: Periodic | Company Report Numb | per: 97451 | | Age: 18 YR | |
| Outcome | PT | Report Source | | | | WRE: 19 IK | Gender: Female |
| Life-Threatening | Depression Nec | Health Professional | Product | Role | Manufacturer | Route | Dose/Unit Duration |
| | Suicide Attempt | ricanti rioressional | Accutane | PS | Hlr Technology | ORAL | |
| | <u> </u> | | Demulen (Ethinyl Estradiol/Ethynodiol Diacetate) | C | | | |
| Date: 06/09/2000 | ISR Number: 3517353-9 | Report Type: Periodic | | | ······································ | | |
| Outcome | PT | | Company Report Numi | er: 233868 | | Age: 17 YR | Gender: Male |
| Other | Abnormal Behaviour Nos | Report Source | Product | Role | Manufacturer | Route | Dose/Unit Duration |
| | Back Pain | Consumer | Accutane | PS | Hlr Technology | ORAL | Duration |
| | Cheilitis | | Ventolin (Albuterol And Albuterol | c · | 63 | OICIL | |
| | Depression Nec | | Sulfate) Albuterol (Albuterol) | | | | |
| | Emotional Disturbance Nos | | - nontage (Albutage) | С | | | |
| | Praritus | | <u> </u> | | | | |
| late: 06/09/2000 | ISR Number: 3517354-0 | Report Type: Periodic | Company Report Numb | 232975 | | | |
| Outcome | PT . | 75 | | Cr: 2330/3 | | Age: | Gender: Female |
| Other | Depression Nec | Report Source | Product | Role | Manufacturer | Route | Dose/Unit Duration |
| | Immune System Disorder Nos | Consumer | Accutane | PS | Hlr Technology | ORAL | |
| | Infectious Mononucleosis | | | | | | |
| ate: 06/09/2000 | ISR Number: 3517355-2 | Report Type: Periodic | | | | · · · · · · · · · · · · · · · · · · · | |
| Outcome | PT | meport Type. Periodic | Company Report Numb | er: 233923 | | Age: 17 YR | Gender: Male . |
| Other | Nightmare | Report Source | Product | Role | Manufacturer | Route | Dose/Unit Duration |
| | | Other | Accutane | PS | Hlr Technology | ORAL | Dose/Unit Duration |
| ate: 06/09/2000 | ISR Number: 3517359-X | Report Type: Periodic | | | | | |
| utcome | PT | | Company Report Numb | er: 94154 | | Age: 19 YR | Gender: Male |
| ther | Abdominal Pain Nos | Report Source | Product | Role | Manufacturer | Route | Dose/Unit Duration |
| | Aggression | Consumer | Acontane | PS | Hir Technology | ORAL | Dose Chit Duration |
| | Back Pain | Health Professional | Echinacea (Echinacea) | c | | ORAL | |
| | Blood Triglycerides Increased | Other | Amino Acid (Amino Acid) | C | | | |
| | Depression Nec | | | | | | |
| | Dermatitis Nos | | | | | | |
| | Dry Eye Nec | | | | | | |
| | Dry Skin Epistaxis | | | | | | |
| | Erythema Nec | | | | | | |
| | Flushing | ** | | | | | 4.4 |
| | Localised Exfoliation | | | | | | the state of the state of |
| | Mood Alteration Nos | | | | | | |

| Date: 06/09/2000 ISR Number | : 3517360-6 | Report Type: Periodic | | Company Report Nu | uber: 95402 | | Age: 14 YR | | | |
|---------------------------------------|----------------------|-----------------------|-----------------------|-------------------------------|-------------------|--------------------------------|---------------|-------------|-----------------------|--|
| Outcome PT .ife-Threatening Abdomina | | Report Source | Product | | Role | Manufacturer | Route | Dose/Unit | der: Female Duration | |
| Mood Alte Suicide At | | | Accutane Aleve (Na | proxen Sodium) | PS C | HirTechnology | ORAL | | | |
| Vomiting l Weight De | Vos | | | (Ibuprofen) acetaminophen) | C | | | | | |
| Date: 06/09/2000 ISR Number: | 3517365-5 | Report Type: Periodic | | Company Report Nu | C nher: 109710 | - | . Accordance | · · · · · · | | |
| Outcome PT | | Report Source | Product | 1 | | | Age: 16 YR | Gen | der: Male | |
| Increased | line Phosphatase Nos | Health Professional | Accutane | | Role PS | Manufacturer Hir Technology | Route ORAL | Dose/Unit | Duration | |
| Blood Iron Costochone | | | Voltaren (I | Diclofenac Sodium) | c · | | OKAL | | | |
| Dermatitis Dry Skin | Nos | | | | | | | | | |
| | Disturbance Nos | | | | | | | | | |
| | Sedimentation Rate | | | | | | | | | |
| Gait Festing Hypertroph | | | | | | | | | | |
| Lip Dry | c scar | | | | | | | | | |
| Malaise Musculoske | letal Disorder Nos | | | | | | | | | |
| Sacroiliitis Skin Chapp | | | | ¥ | | | | | | |
| White Bloo Decreased | | | | | | | | | | |
| White Blood Increased | Cell Count | | | | | | | | | |
| ite: 06/09/2000 ISR Number: | 3517464-8 | Report Type: Periodic | | Company Report Num | ber: 200150 | | Age: 17 YR | Gen | ler: Male | |
| Outcome PT Other Depression | vian . | Report Source | Product | <u> </u> | Role | Manufacturer | Route | Dose/Unit | | |
| Erythema N Suicidal Ide | ec | Health Professional | Accutane | | PS | Hlr Technology | ORAL | Dose Chi | Duration | |
| te: 06/09/2000 ISR Number: | 2515150 | Report Type: Periodic | | Company Report Num | | | | | | |
| itcome Pr | | Report Source | Product | Company Report 14mil | Role | | Age: 18 YR | Gene | ler: Male | |
| ther Condition A | | | | | | Manufacturer | Route | Dose/Unit | Duration | |

| | | | Autura livent Report | | | | | |
|-------------------|--|-----------------------|--|-------------|----------------|------------|--------------------|---|
| | | | reedom Of Information | | Report | | | |
| Date: 06/09/2000 | ISR Number: 3517475-2 | Report Type: Periodic | Company Report Num | ber: 200892 | | Age: 47 YR | Gender: Female | |
| Outcome | <u>PT</u> | Report Source | Product | D-1 | | | | |
| Other | Arthralgia | Consumer | Accutane | Role | Manufacturer | Route | Dose/Unit Duration | |
| | Blood Cholesterol Increased | Health Professional | Prozac (Fluoxetine Hydrochloride) | PS | Hir Technology | ORAL | | |
| | Depression Aggravated Herpes Simplex | | Serzone (Nefazodone Hydrochloride) | c | | | | |
| | Lip Dry | | Dexedrine (Dextroamphetamine | C, | | | | |
| · | White Blood Cell Count Decreased | | Sulfate) | С | | | | |
| Date: 06/09/2000 | ISR Number: 3517487-9 | Report Type: Periodic | Company Report Numl | ber; 201524 | | Age: | Gender: | _ |
| Outcome | PT | Report Source | Product | | | | Genuer: | |
| Other | Depression Nec | Health Professional | Accutane | Role | Manufacturer | Route | Dose/Unit Duration | |
| | Erythema Nec Skin Lesion Nos | Other | Accurage | PS | Hlr Technology | ORAL | | |
| Date: 06/09/2000 | ISR Number: 3517490-9 | Report Type: Periodic | Company Report Numb | er: 202222 | | Age: 24 YR | Gender: Female | |
| Outcome | <u>PT</u> | Report Source | Product | | | | Gender: Female | |
| Other | Anxiety Nec | Consumer | | Role | Manufacturer | Route | Dose/Unit Duration | |
| | Depression Aggravated | | Accutane Acutane | PS | Hlr Technology | ORAL | | |
| | Panic Attack Suicidal Ideation | | | SS | | | | |
| | Suicidal Ideation | | Ortho Tri-Cyclen (Ethinyl Estradiol/Norgestimate) | С | | | | |
| | | | Alesse (Ethinyl Estradiol/Levonorgestrel) | С | | | | • |
| Date: 06/09/2000 | ISR Number: 3517492-2 | Report Type: Periodic | Company Report Numb | er: 202355 | ·· | A ' 40 VP | | |
| Outcome | _ PT | Report Source | | 202000 | | Age: 42 YR | Gender: Female | |
| Other | Hypertriglyceridaemia | Consumer | Product | Role | Manufacturer | Route | Dose/Unit Duration | |
| | Mood Swings | Health Professional | Accutane | PS | Hlr Technology | ORAL | | |
| ate: 06/09/2000 | ISR Number: 3517501-0 | | | | | | | |
| Outcome | | Report Type: Periodic | Company Report Numb | er: 203250 | | Age: | Gender: Female | |
| Other | PT | Report Source | Product | Role | Manufacturer | . | | |
| лист | Depression Suicidal Suicidal Ideation | Consumer | Accutane | PS | Hlr Technology | Route | Dose/Unit Duration | |
| ate: 06/09/2000 | | Health Professional | | 10 | 1m reamonegy | ORAL | | |
| wite: 00/09/200() | ISR Number: 3517505-8 | Report Type: Periodic | Company Report Numb | er: 203618 | | Age: 15 YR | | _ |
| utcome | PT | Report Source | Product | | | Age: 15 YR | Gender: Female | |
| ther | Depression Nec | Health Professional | | Role | Manufacturer | Route | Dose/Unit Duration | |
| | | - TOTESSIONAL | Accutane | PS | Hir Technology | ORAL | | |

| Date: 06/09/2000 | ISR Number: 3517507-1 | Report Type: Periodic | | Company Report Numbe | r 203730 | | | | |
|------------------|---------------------------------|------------------------|----------------|--|----------|----------------|--|-----------|--------------|
| Outcome | PT | Report Source | . | The state of the s | . 203730 | | Age: 25 YR | Ges | ider: Female |
| Other | Body Image Disorder | Health Professional | Product | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | Suicidal Ideation | The art of the saloual | Accutane | | PS | Hlr Technology | ORAL | | |
| Date: 06/09/2000 | ISR Number: 3517521-6 | Report Type: Periodic | | Company Report Numbe | 207180 | | Age: 48 YR | | |
| Outcome | PT | Report Source | D 3 4 | | | | Age: 48 I K | Ger | ider: Female |
| Other | Blood Triglycerides Increased | Consumer | Product | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | Disturbance In Attention Nec | Consumer | Accutane | | PS | Hlr Technology | ORAL | | |
| | Eye Imitation | | | | | | | | |
| | Headache Nos | | | | | | | | |
| | Nasopharyngitis | | | | | | | | |
| | Peripheral Coldness | | | | | | | | |
| | Rigors | | | | | | | | |
| | Sinus Pain Vision Blurred | | | | | • | | | |
| | Vision Bristed | | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3517527-7 | Report Type: Periodic | | Company Report Number | : 77776 | | Age: 34 YR | - Ge | nder: Female |
| Outcome | PT | Report Source | Product | | | | | · | uer: remaie |
| Other | Amnesia Nec | Health Professional | | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | Osteoma | | Accutane | | PS | Hir Technology | ORAL | , | |
| ate: 06/09/2000 | ISR Number: 3517534-4 | Report Type: Periodic | | Company D. (1) | | | | | |
| Outcome | PT | | | Company Report Number | 92242 | | Age: 15 YR | Gen | der: Male |
| Other | Abnormal Behaviour Nos | Report Source | Product | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | Aggression | Other | Accutane | | PS | | ORAL | SOS CITE | 1741 augs |
| | Confusion | | | | | | ORAL | | |
| | Dermatitis Nos | | | | | | | | |
| | Dry Skin | | | | | | | | |
| | Increased Activity | | | | | | | | |
| | Memory Impairment | | | | | | | | |
| | Mucous Membrane Disorder Nos | | • | | | | | | |
| | Red Eye | | | | | | | | |
| nte: 06/09/2000 | | | | | | | ** ** ** ** ** ** ** ** ** | | |
| 20,05,2000 | ISR Number: 3517547-2 | Report Type: Periodic | | Company Report Number | 96290 | | Age: 39 YR | | : |
| outcome | PT | Report Source | Product | | | | 11ge. 39 IK | Gen | der: Female |
| ther | Alopecia | Consumer | | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | Arthralgia | Health Professional | Accutane | | PS | Hir Technology | ORAL | | |
| | Arthritis Nos | | Dhea (Prastero | | С | | | | |
| | Blepharitis | _ | Vitamin A (Vi | tamin A) | С | | | | |

| | | | rerdom Of Information | | Rebuil | | | | |
|------------------|--------------------------------------|-----------------------|---|-------------|----------------|------------|-----------|--------------|---------|
| Date: 06/09/2000 | ISR Number: 3517588-5 | Report Type: Periodic | Company Report Numb | per: 102135 | | Age: 34 YR | C. | der: Female | ******* |
| Outcome | PT | Report Source | Product | | - | | Ga | tuet: remale | |
| Other | Alopecia | Consumer | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Bone Disorder Nos | | Accutane | PS | Hlr Technology | ORAL | | | |
| | Depression Nec | | | | | | | | |
| | Dry Skin | | | | | | | | |
| | Lip Dry | the second second | | | | | | | |
| | Mood Swings | | | | | | | | |
| | Rash Erythematous | , | | | | | | | |
| | White Blood Cell Count Decreased | | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3517617-9 | Report Type: Periodic | | | | | | | |
| Outcome | PT | | Company Report Numb | er: 108796 | | Age: 35 YR | Gen | der: Female | |
| Other | Anger | Report Source | Product | Role | Manufacturer | Route | D #7 14 | | |
| Oula | Depression Nec | Other | Accutane | PS | Hlr Technology | | Dose/Unit | Duration | |
| | Mood Swings | | Entex (Guafenesin/Phenylephrine | C | Thi Technology | ORAL | | | |
| | Urticaria Nos | | Hydrochloride/Phenylopropanolamine | | | | | | |
| | | | Hydrochloride) | | | | | | |
| | | | Zyrtec (Cetirizine Hydrochloride) | C | | | | | |
| Date: 06/09/2000 | ISR Number: 3517618-0 | | Desogen (Desogestrel/Ethinyl Estradiol) | С | | | | | |
| | | Report Type: Periodic | Company Report Numb | er: 110731 | | Age: 21 YR | Gen | der: Female | |
| Outcome | PT | Report Source | Product | | | | | Tanale | • |
| Other | Depression Nec | Consumer | Accutane | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Liver Function Tests Nos Abnormal | Health Professional | Accutation | PS | Hlr Technology | ORAL | | | |
| | Menstruation Irregular | Other | | | | | | | |
| | Mood Swings | | | | | | | | |
| | Smear Cervix Abnormal | | | | | | | | |
| ate: 06/09/2000 | ISR Number: 3517832-4 | Report Type: Periodic | | | | <u> </u> | | | |
| Outcome | PT | | Company Report Number | er: 227113 | | Age: 27 YR | Gen | der: Female | |
| Other | Acne Aggravated | Report Source | Product | Role | Manufacturer | Route | Decellint | D # | |
| | Arthralgia | Consumer | Accutane | PS | Hlr Technology | | Dose/Unit | Duration | |
| | Back Pain | Other | Birth Control Pill (Oral Contraceptive | Ċ | recinionogy | ORAL | | | |
| | Contact Lens Intolerance | | Nos) | | | | | | |
| | Depression Nec | | | | | | | | |
| | Dry Eye Nec | | | | | | | | |
| | Tearfulness | | | | | | | | |

| Date: 06/09/2000 | ISR Number: 3517847-6 | Report Type: Periodic | Company Report N | umber: 227337 | | Age: 19 YR | Gender: Male |
|-----------------------------|---|-----------------------|---|---------------|----------------|------------|--------------------|
| Outcome | PT | Report Source | Product | | | | Gender: Male |
| Other | Erectile Disturbance | Consumer | Accutane | Role PS | Manufacturer | Route | Dose/Unit Duration |
| <u> </u> | Loss Of Libido Psychosexual Disorder Nos | | Herbal Supplements (Herbal Supplement) | c C | Hlr Technology | ORAL | |
| Date: 06/09/2000 | ISR Number: 3517851-8 | Report Type: Periodic | Company Report N | umber: 227347 | | Age: | Gender: Female |
| Outcome | <u>PT</u> | Report Source | Product | _ | | | Gender: Female |
| Other | Burns Nos | Consumer | Accutane | Role | Manufacturer | Route | Dose/Unit Duration |
| | Capillary Fragility Increased Hyperaesthesia | 7 | Acculane | PS | Hir Technology | ORAL | |
| | Mood Alteration Nos | | | | | | |
| Date: 06/09/2000 Outcome | ISR Number: 3517858-0 | Report Type: Periodic | Company Report N | umber: 227620 | | Age: 14 YR | Gender: Female |
| Other | PT Aggression | Report Source | Product | Role | Manufacturer | Route | |
| | Mood Alteration Nos | Consumer | Accutane | PS | Hlr Technology | ORAL | Dose/Unit Duration |
| Date: 06/09/2000 | ISR Number: 3517863-4 | Report Type: Periodic | Company Report N | mber: 228093 | | Age; | Gender: Female |
| Outcome | PT | Report Source | Product | Role | Manufacturer | | |
| Other | Depression Nec Disturbance In Attention Nec | Consumer | Accutane | PS PS | Hir Technology | Route | Dose/Unit Duration |
| | Patigue | | | | Thi Tecamology | ORAL | |
| | Mood Swings | | | | | | |
| Outcome | ISR Number: 3517866-X | Report Type: Periodic | Company Report No | unber: 228172 | | Age: 33 YR | Gender: Female |
| Other | PT Mood Swings | Report Source | Product | Role | Manufacturer | Route | T |
| Ouna. | Tooth Disorder Nos | Consumer | Accutane | PS | Hir Technology | ORAL | Dose/Unit Duration |
| <u> </u> | A 100 | | Loestrin (Ethinyl Estradiol / Norethindrone Acetate) | c | roundingy | OKAL | |
| Date: 06/09/2000 | ISR Number: 3517874-9 | Report Type: Periodic | Company Report Nu | unber: 228345 | | Age: | Gender: Male |
| Outcome | PT | Report Source | Product | | | | Genuer: Male |
| Other | Acne Aggravated | Consumer | Accutane | Role | Manufacturer | Route | Dose/Unit Duration |
| | Fatigue Milia | | · secondic | PS | Hlr Technology | ORAL | |
| | Mood Swings | | | | | | |
| | Seborrhoea | | | | | | |

| Product | | | | | Officiornation | | | | | |
|--|------------------|-----------------------|-----------------------|--------------|--------------------------|------------|-----------------|-------------|---|-------------|
| Outcome PT Report Source Product Relo Manufacturer Role Dose/Unit Description Other Abdornial Pain Upper Consumer Accetance PS Hir Technology CRAL Very 1 Dependen Nee Dependen Nee Dry Bye Nice Bill Technology CRAL Very 1 Very 1 Very 2 Very | Date: 06/09/2000 | ISR Number: 3518467-X | Report Type: Periodic | | Company Report Numb | er: 222162 | | A 4037D | | |
| Other Accordance Accordance PS Hil'Technology ORAL | Outcome | PT | Damant Cassas | | . ,, | 202102 | | Age: 17 YR | Gen | der: Pemale |
| Depression Nee Dry Eye Nee Hondsche Nos Dry Eye Nee Hondsche Nos Mood Alterntion Nos Red Eye Vounting Nos | Other | Abdominal Pain Upper | | | | Role | Manufacturer | Route | Dose/Unit | Duration |
| Dite: 0609/2000 ISR Number: 3518472-3 Report Type: Periodic Company Report Number: 22254 Age: Genter Pendet Redic Nos Hoddelsenion Nos Red Eye Vorating Nos Outcome PT Report Source Product Role Dyr Bye Nee Dyr Bye Nee Dyr Bye Nee Dyr Bye Nee Paigue Pending Hot Headache Nos Coesum Lower Limb Photopaia Weakness Date: 0609/2000 ISR Number: 3518472-3 Report Type: Periodic Company Report Number: 222584 Age: 32 7R Genter Pendet Outcome PT Report Source Product Role Redic Nos Coesum Lower Limb Photopaia Weakness Date: 0609/2000 ISR Number: 3518472-3 Report Type: Periodic Company Report Number: 222584 Age: 32 7R Genter Pendet Outcome PT Report Source Product Redice Hydrochloride) C Date: 0609/2000 ISR Number: 3518470-3 Report Type: Periodic Company Report Number: 222584 Age: 32 7R Genter Pendet Redice Nos Report Source Product Redice Hydrochloride) C Date: 0609/2000 ISR Number: 3518470-3 Report Type: Periodic Company Report Number: 222584 Age: 32 7R Genter Pendet Redice Nos Report Source Product Redice Hydrochloride) C Date: 0609/2000 ISR Number: 3518470-5 Report Type: Periodic Company Report Number: 222584 Age: 32 7R Genter Pendet Redice Nos Report Source Product Redice Hydrochloride) C Date: 0609/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 222599 Age: 12 YR Genter Pendet Redica Product Redice Nos Report Source Product Redice Manufacturer Redice Deservity Pendet Redica Product Redice Redice Redica Product Redicate Redice Redicate Red | | | Consumer | Accutane | | PS | Hlr Technology | ORAL | | |
| Mood Alteration Nos Red Eye Vonting Nos Date: 0609/2000 Dist Number: 3518468-1 Consumer Report Source Product Accutanc Product Report Source Report Sour | | Dry Eye Nec | | | | | | | | |
| Red Eye Vomiting Nos Nos Report Number: 222374 Age: Report R | | Headache Nos | | | | | | | | |
| Date: 66099/2000 18R Number: 3518468-1 Report Type: Periodic Company Report Number: 222234 Age: Route Does/Unit Durators Other PT Report Source Product Role Manufacturer Route Does/Unit Durators Other Bilindness Night Consumer Accutane PS Hilr Technology ORAL V | | Mood Alteration Nos | | | | | | | | |
| Date: 66/09/2000 ISR Number: 3518468-1 Report Type: Product Role Manufacturer Route Done-Unit Duration Other Blindness Night Consumer Accutane PS Hir Technology ORAL VIIII Duration Duration Other Blindness Night Consumer Accutane PS Hir Technology ORAL VIIII VIIIII VIIII VIIII VIIII VIIII VIIII VIIII VIIII VIIII | | Red Eye | | | | | | | | |
| Outcome FT Report Source Product Roll Manufacturer Route Does/Unit Duration Other Blindness Night Consumer Accutane PS Hil Technology ORAL VEX. VEX. <td></td> <td>Vomiting Nos</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> | | Vomiting Nos | | | | | | | | |
| Other Blindnes Night Consumer Accutane Product Role Manufacturer Route Dose/Unit Duration Other Dispression Nee Dry Skin Erythema Nee Feding Hot Headache Nos Ocdema Lower Limb Photopsia Weakness Date: 06/09/2000 ISR Number: 3518472-3 Report Type: Periodic Company Report Number: 222584 Age: 32 YR Gender: Female Other Headache Nos Lip Dry Bye Nee Consumer Accutane PS Hir Technology ORAL Other Accutane PS Hir Technology ORAL Age: 32 YR Gender: Female Manufacturer Route Dose/Unit Duration Other Accutane PS Hir Technology ORAL Age: 32 YR Gender: Female Manufacturer Route Dose/Unit Duration Other Accutane PS Hir Technology ORAL Age: 32 YR Gender: Female Manufacturer Route Dose/Unit Duration Other Headache Nos Lip Dry Headache Nos Lip Dry Headache Nos Lip Dry Myalgia Nervousness Weakness Other Myalgia Nervousness Weakness Other Office PT Report Source Product Company Report Number: 222595 Age: 12 YR Gender: Female Other Product Route Manufacturer Route Dose/Unit Duration Dry Spe Nervousness Weakness Other Office PT Report Source Product Role Manufacturer Route Dose/Unit Duration Dry Headache Nos Lip Dry Myalgia Nervousness Weakness Other Office PT Report Source Product Role Manufacturer Route Dose/Unit Duration Dry Headache Nos Lip Dry Myalgia Nervousness Weakness Other Office PT Report Source Product Role Manufacturer Route Dose/Unit Duration Duratio | Date: 06/09/2000 | ISR Number: 3518468-1 | Report Type: Periodic | | Company Parasi Name | 2000074 | | | - · · · · · · · · · · · · · · · · · · · | |
| Other Blindness Night Consumer Accutane PS Hir Technology ORAL Depression Nee Dry Skin Erythema Nee Patigne Peeling HG Headache Nos Codema Lower Limb Photopsia Weakness Date: 06/09/2000 ISR Number: 3518472-3 Report Source Product Dry Sye Nee Dry Skin Report Source Allegra (Pexofenadine Hydrochloride) Dry Eye Nee Dry Sye Nee Consumer Accutane PS Hir Technology ORAL Age: 32 YR Gender: Pemale Route Dose/Unit Duration Duration Duration Duration Outcome PT Report Source Allegra (Pexofenadine Hydrochloride) Report Source Allegra (Pexofenadine Hydrochloride) Route Route Route Naminateurer Route Route Naminateurer Nami | Outcome | | Report Source | Product | Company Report Numb | | | Age: | Gen | der: Female |
| Depression Nec Dry Eye Nec Dry Skin Erythema Nec Faigue Feeling Hot Headache Nos Oedema Lower Limb Photopsin Wenkness Date: 06/09/2000 ISR Number: 3518472-3 Report Source PT Report Source Consumer Accutane Allegra (Fexofenadine Hydrochloride) Regards New Swakess Age: 32 YR Gender: Female Duration Duration Duration Depression Nec Duration Port Report Source Product Role Hir Technology ORAL Age: 32 YR Gender: Female Duration Duration Duration Duration Duration Role Hir Technology ORAL Age: 32 YR Gender: Female Consumer Accutane PS Hir Technology ORAL Age: 32 YR Gender: Female Consumer Accutane PS Hir Technology ORAL Age: 32 YR Gender: Female Consumer Accutane PS Hir Technology ORAL Age: 32 YR Gender: Female Consumer Accutane PS Hir Technology ORAL Age: 32 YR Gender: Female Consumer Accutane PS Hir Technology ORAL Age: 32 YR Gender: Female Consumer Oration Duration ORAL Duration Duration Duration Duration Accutane PT Report Source PT Report Source PT Report Source PT Report Source PT Accutane PT Report Source PT Observation Accutance PT Report Source PT Observation Accutance PT Report Source PT Observation Accutance PT Observation Accutance PT Observation Accutance PT Report Source PT Observation Accutance PT Observatio | Other | | | | | | Manufacturer | Route | Dose/Unit | Duration |
| Dry Skin Erytherna Nec Fatigue Feeling Hot Headache Nos Oedeuna Lower Limb Photopsia Weakness Date: 06/09/2000 ISR Number: 3518472-3 Report Type: Periodic Company Report Number: 222584 Age: 32 YR Gender: Female Other Dry Eye Nec Eye Pain Fatigue Allegra (Fexofenadine Hydrochloride) Headache Nos Lip Dry Myalgia Nervousness Weakness Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 222584 Age: 32 YR Gender: Female Other Product Role Manufacturer Route PS Hilr Technology ORAL Allegra (Fexofenadine Hydrochloride) C Headache Nos Lip Dry Myalgia Nervousness Weakness Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 22299 Age: 12 YR Gender: Female Other Duration Duration Duration Duration Product Role Manufacturer Route Dose/Unit Duration | | | COMMITTEE | Accutane | | PS | Hir Technology | ORAL | | |
| Erythema Nec Patigue Pecling Hot Headache Nos Ocdema Lower Limb Photopsia Weakness Date: 06/09/2000 ISR Number: 3518472-3 Report Type: Periodic Other Dry Eye Nec Eye Pain Fetigue Headache Nos Hir Technology Allegra (Fexofenadine Hydrochloride) Headache Nos Lip Dry Myalgia Nervousness Weakness Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Other Product Role Allegra (Fexofenadine Hydrochloride) Role Role Manufacturer Route Dose/Unit Duration Other Role Role Role Role Role Role Role Role | | 7 7 | | | | | | | | |
| Patigue Pecling Hot Headache Nos Ocdema Lower Limb Photopsia Weakness Date: 06/09/2000 ISR Number: 3518472-3 Report Type: Periodic Company Report Number: 222584 Age: 32 YR Gender: Pemak Onteome PT Report Source Product Role Dry Eye Nec Consumer Accutane PS Hir Technology ORAL Fatigue Allegra (Fexofenadine Hydrochloride) C Headache Nos Lip Dry Myalgia Nervousness Weakness Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 222959 Age: 12 YR Gender: Female Company Report Number: 222959 Age: 12 YR Gender: Female Company Report Number: 222959 Age: 12 YR Gender: Female Company Report Number: 222959 Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 222959 Age: 12 YR Gender: Female Company Report Number: 222959 Date: 06/09/2000 ISR Number: 3518490-5 Report Source Product Role Manufacturer Route Dose/Unit Duration | | • | | | | | | | | |
| Peeling Hot Headache Nos Ocdena Lower Limb Photopsia Weakness Date: 06/09/2000 ISR Number: 3518472-3 Report Type: Periodic Company Report Number: 222584 Age: 32 YR Gender: Pemale Other Dry Eye Nec Consumer Accutane PS Hir Technology ORAL Eye Pain Fatigue Allegra (Pexofenadine Hydrochloride) C Headache Nos Lip Dry Myalgia Nervousness Weakness Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 22259 Age: 12 YR Gender: Pemale Other Role Manufacturer Route Dose/Unit Duration Other Role Role Manufacturer Role Role Role Role Role Role Role Role | | ' - ' | | | | | | | | |
| Headache Nos Oedema Lower Limb Photopsia Weakness Date: 06/09/2000 ISR Number: 3518472-3 Report Type: Periodic Company Report Number: 222584 Age: 32 YR Gender: Female Other Dry Eye Nec Consumer Accutane Ps Hir Technology ORAL Fatigue Headache Nos Lip Dry Myalgia Nervousness Weakness Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 222584 Age: 32 YR Gender: Female Other Role Hir Technology ORAL Age: 32 YR Gender: Female One Manufacturer Route Dose/Unit Duration ORAL Age: 32 YR Gender: Female One Manufacturer Route Dose/Unit Duration ORAL Age: 32 YR Gender: Female One Manufacturer Route Dose/Unit Duration One Manufacturer Route Dose/Unit Duration One Manufacturer Route Dose/Unit Duration | | | | | | | | | | |
| Oederna Lower Limb Photopsia Weakness Date: 06/09/2000 ISR Number: 3518472-3 Report Type: Periodic Ontcome PT Report Source Product Role Eye Pain Fatigne Headache Nos Lip Dry Myalgia Nervousness Weakness Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Ontcome PT Report Source Product Role Role Role Manufacturer Route PS Hir Technology ORAL C Headache Nos Lip Dry Myalgia Nervousness Weakness Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 222959 Age: 12 YR Gender: Pemale Ontcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration | | • | | | | | | | | |
| Photopsia Weakness Date: 06/09/2000 ISR Number: 3518472-3 Report Type: Periodic Company Report Number: 222584 Age: 32 YR Gender: Female Other Dry Eye Nec Consumer Accutane PS Hir Technology ORAL Eye Pain Allegra (Fexofenadine Hydrochloride) C Headache Nos Lip Dry Myalgia Nervousness Weakness Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 22299 Age: 12 YR Gender: Female Other Arthralgia Health Professional Accutane Product Role Manufacturer Route Dose/Unit Duration Manufacturer Route Dose/Unit Duration | | | | | | | | | | |
| Weakness Weakness State Weakness W | | | | | | | | | | |
| Date: 06/09/2000 ISR Number: 3518472-3 Report Type: Periodic Company Report Number: 222584 . Age: 32 YR Gender: Pember Controller Dry Eye Nec Consumer Accutane PS Hir Technology ORAL | | | | | | | | | | |
| Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Other Dry Eye Nec Consumer Accutane PS Hir Technology ORAL Fatigue Allegra (Fexofenadine Hydrochloride) C Headache Nos Lip Dry Myalgia Nervousness Weakness Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration | | | | | | | | | | • |
| Other PT Report Source Product Role Manufacturer Route Dose/Unit Duration Other Dry Eye Nec Consumer Accutane PS Hir Technology ORAL Fatigue Allegra (Fexofenadine Hydrochloride) C Headache Nos Lip Dry Myalgia Nervousness Weakness Mate: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 222959 Age: 12 YR Gender: Female Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Accutane Role Manufacturer Route Dose/Unit Duration | Date: 06/09/2000 | ISR Number: 3518472-3 | Report Type: Periodic | | C | | | | | |
| Other Dry Eye Nec Consumer Accutane Product Relevant Product Product Relevant Product | Outcome | Þr | | | Company Report Number | r: 222584 | | .Age: 32 YR | Gene | der: Female |
| Eye Pain Consumer Accutane PS Hir Technology ORAL Fatigue Allegra (Fexofenadine Hydrochloride) C Headache Nos Lip Dry Myalgia Nervousness Weakness Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 222959 Age: 12 YR Gender: Female Onteome PT Report Source Product Role Manufacturer Route Dose/Unit Duration | | | Report Source | Product | | Role | Manufacturer | Donta | D #1 14 | |
| Fatigue Allegm (Fexofenadine Hydrochloride) C Headache Nos Lip Dry Myalgia Nervousness Weakness Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 222959 Age: 12 YR Gender: Female Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration | | | Consumer | Accutane | | | | | Dose/Unit | Duration |
| Headache Nos Lip Dry Myalgia Nervousness Weakness Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 222959 Age: 12 YR Gender: Female Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration | • | | | Allegra (Fex | ofenadine Hydrochloride) | | 1 m 1 commonegy | ORAL | | |
| Lip Dry Myalgia Nervousness Weakness Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 222959 Age: 12 YR Gender: Female Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration | | - | | - (| and any on controlling) | | | | | |
| Myalgia Nervousness Weakness Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 222959 Age: 12 YR Gender: Female Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration | | | | | | | | | | |
| Weakness Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 222959 Age: 12-YR Gender: Female Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Other Arthralgia Health Professional Accutance | | | | | | | | | | |
| Date: 06/09/2000 ISR Number: 3518490-5 Report Type: Periodic Company Report Number: 222959 Age: 12 YR Gender: Female Other Arthralgis Health Professional Accutance Role Manufacturer Route Dose/Unit Duration | | Nervousness | | | | | | | | |
| Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Other Arthralgis Health Professional Accutance | | Weakness | | | | | | | | |
| Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Arthralgis Health Professional Accutance | Date: 06/09/2000 | ISR Number: 3518490.5 | D | | | | | | | |
| Other Arthralgia Health Professional Accutance Role Manufacturer Route Dose/Unit Duration | ~ · | | Report Type: Periodic | | Company Report Numbe | 222959 | | Age: 12 YR | Gené | ler Powel- |
| Other Arthralgia Health Professional Acoutane Role Manufacturer Route Dose/Unit Duration | | · | Report Source | Product | | | | | Jan | remaie |
| | Other | | | | | | | Route | Dose/Unit | Duration |
| Mental Disorder Nec | | | | Accutane | | PS | Hlr Technology | ORAL | · - | - |

| | | | *********** | | (100) | | | | |
|---|---|--|---------------------|-----------------------|----------------------------|---|---------------------------------------|---------------------------|-------------------------------|
| Date: 06/09/2000 | ISR Number: 3518905-2 | Report Type: Periodic | | Company Report Numb | er: 221209 | | Age: 43 YR | - | |
| Outcome | <u>PT</u> | Report Source | Product | | | | nge. 43 IK | Ge | nder: Female |
| Other | Depression Aggravated | Consumer | Accutane | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | | Health Professional Other | Accuding | | PS | Hir Technology | ORAL | | |
| Date: 06/09/2000 | ISR Number: 3518927-1 | Report Type: Periodic | | Company Report Numb | am 221428 | | | | |
| Outcome | PT | Report Source | | | er: 221428 | | Age: 22 YR | Ger | nder: Female |
| Other | Depression Nec | Consumer | Product | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | Mood Swings | Other | Accutane | | PS | Hlr Technology | ORAL | | |
| Date: 06/09/2000 | ISR Number: 3518931-3 | Report Type: Periodic | | Company Report Numb | er: 221548 | | Age: | | |
| Outcome | <u>PT</u> | Report Source | Product | | | | nge. | Ger | nder: Male |
| Other | Alopecia | Consumer | Accutane | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | Amnesia Nec Anhralgia | | Accutane | | PS | Hlr Technology | ORAL | | |
| | Blood Phosphate Increased Depression Nec Visual Disturbance Nos | | | | | | | | |
| | Visual Disturbance Nos | | | | | | | | |
| Pate: 06/09/2000 | ISR Number: 3518941-6 | Report Type: Periodic | | Company Report Numbe | er: 222334 | | Age: 15 VD | - | |
| Outcome | ISR Number: 3518941-6 | Report Type: Periodic | Product | Company Report Number | | | Age: 15 YR | Gen | ider: Male |
| Outcome | ISR Number: 3518941-6 | | Product | Company Report Number | Role | Manufacturer | Age: 15 YR | Gen | ider: Male |
| Outcome Other | ISR Number: 3518941-6 PT Intentional Self-Injury | Report Source Health Professional | Product Accutanc | Company Report Numbe | | Manufacturer Hir Technology | | | |
| Outcome Other ate: 06/09/2000 | ISR Number: 3518941-6 PT Intentional Self-Injury ISR Number: 3518942-8 | Report Source | | Company Report Number | Role PS | | Route | Dose/Unit | Duration |
| Outcome Dutcome ate: 06/09/2000 Dutcome Dutcome | ISR Number: 3518941-6 PT Intentional Self-Injury ISR Number: 3518942-8 PT | Report Source Health Professional | | | Role PS | Hilr Technology | Route ORAL Age: | Dose/Unit | |
| Outcome Other ste: 06/09/2000 Outcome | ISR Number: 3518941-6 PT Intentional Self-Injury ISR Number: 3518942-8 PT Abnormal Behaviour Nos | Report Source Health Professional Report Type: Periodic Report Source Company | Accutane | | Role PS er: 222824 Role | Hir Technology Manufacturer | Route ORAL Age: Route | Dose/Unit | Duration |
| Outcome Other ate: 06/09/2000 | ISR Number: 3518941-6 PT Intentional Self-Injury ISR Number: 3518942-8 PT Abnormal Behaviour Nos Depression Nec Suicidal Ideation | Report Source Health Professional Report Type: Periodic Report Source | Accutane | | Role PS | Hilr Technology | Route ORAL Age: | Dose/Unit | Duration der: Male |
| Outcome ther ate: 06/09/2000 Outcome ther | ISR Number: 3518941-6 PT Intentional Self-Injury ISR Number: 3518942-8 PT Abnormal Behaviour Nos Depression Nec Suicidal Ideation Thinking Abnormal Nec | Report Source Health Professional Report Type: Periodic Report Source Company Representative | Accutane | | Role PS er: 222824 Role | Hir Technology Manufacturer | Route ORAL Age: Route | Dose/Unit | Duration der: Male |
| rationse ther ther tel: 06/09/2000 tutcome ther | ISR Number: 3518941-6 PT Intentional Self-Injury ISR Number: 3518942-8 PT Abnormal Behaviour Nos Depression Nec Sucidal Ideation Thinking Abnormal Nec ISR Number: 3518944-1 | Report Source Health Professional Report Type: Periodic Report Source Company | Accutane | | Role PS er: 222824 Role PS | Hir Technology Manufacturer | Route ORAL Age: Route ORAL | Dose/Unit Gen Dose/Unit | Duration der: Male Duration |
| rutcome ther 06/09/2000 utcome ther 06/09/2000 | ISR Number: 3518941-6 PT Intentional Self-Injury ISR Number: 3518942-8 PT Abaormal Behaviour Nos Depression Nec Suicidal Ideation Thinking Abnormal Nec ISR Number: 3518944-1 PT | Report Source Health Professional Report Type: Periodic Report Source Company Representative | Accutane | Company Report Numbe | Role PS PS Role PS Role PS | Hir Technology Manufacturer Hir Technology | Route ORAL Age: Route ORAL Age: 19 YR | Dose/Unit | Duration der: Male Duration |
| Outcome Other ate: 06/09/2000 Outcome ther | ISR Number: 3518941-6 PT Intentional Self-Injury ISR Number: 3518942-8 PT Abnormal Behaviour Nos Depression Nec Sucidal Ideation Thinking Abnormal Nec ISR Number: 3518944-1 | Report Source Health Professional Report Type: Periodic Report Source Company Representative Report Type: Periodic | Product Accutane | Company Report Numbe | Role PS er: 222824 Role PS | Hir Technology Manufacturer | Route ORAL Age: Route ORAL | Dose/Unit Gen Dose/Unit | Duration der: Male Duration |

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| | | | | i Event Report Of Informatio | | tem (Alberta) | | | | |
|--|---------------------------|-----------------------|-------------|---------------------------------|-------------|--|------------|-----------|---------------|--|
| Date: 06/09/2000 | ISR Number: 3518946-5 | Report Type: Periodic | | | | | | | | |
| Outcome | PT | report Type: Periodic | | Company Report Number | ber: 223640 | | Age: 28 YR | Gen | der: Female | |
| Other | Depression Nec | Report Source | Product | | Role | Manufacturer | | | | |
| | Lip Dry | Other | Accutane | | PS | Hir Technology | Route | Dose/Unit | Duration | |
| | | | Oitho Tri-C | yclen | c | Till Technology | ORAL | | | |
| Date: 06/09/2000 | ISR Number: 3518949-0 | Report Type: Periodic | | | | | | | | |
| Outcome | PT | | | Company Report Numb | er: 223645 | | Age: 26 YR | Gene | der: Female | |
| Disability | Depression Nec | Report Source | Product | | Role | Manufacturer | Route | Th. 47 | | |
| _ | Patigue | Health Professional | Accutane | | PS | Hlr Technology | | Dose/Unit | Duration | |
| Date: 06/09/2000 | TOD No. 1 | Other | | | | connotogy | ORAL | | | |
| | ISR Number: 3518950-7 | Report Type: Periodic | | Company Report Numb | om 223647 | | | | | |
| Outcome | <u>PT</u> | Report Source | D. 1 | T Stopott (tulib | EL: 223041 | | Age: 23 YR | Gene | ler: Female | |
| Other | Depression Nec | Consumer | Product | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Dry Skin | Other | Accutane | | PS | Hlr Technology | ORAL | | | |
| | Lip Dry | | | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3518951-9 | Report Type: Periodic | | | | | · | | | |
| Ontcome | PT | | | Company Report Numb | er: 223649 | | Age: 15 YR | Gend | ler: Female | |
| Other | Depression Suicidal | Report Source | Product | | Role | Manufacturer | Route | D 51 11 | | |
| | , | Consumer | Accutane | | PS | Hlr Technology | ORAL | Dose/Unit | Duration | |
| ate: 06/09/2000 | ISR Number: 3518952-0 | Other | | | | т. т | ORAL | | | |
| | 15K Number: 3518952-0 | Report Type: Periodic | | Company Report Number | 223668 | | | | - | |
| Outcome | PT | Report Source | Product | | 21 220000 | | Age: | Gend | er: Female | |
| Iospitalization - nitial or Prolonged | Depression Nec | Other | | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Panic Attack | | Accutane | | PS | Hlr Technology | ORAL | | | |
| nte: 06/09/2000 | ISR Number: 3518954-4 | Report Type: Periodic | | | | | | | | |
| lutcome | PT | | | Company Report Number | r: 223115 | | Age: 31 YR | Gend | er: Male | |
| ther | Asthma Aggravated | Report Source | Product | <u> </u> | Role | Manufacturer | Route | 7 | | |
| | Depression Aggravated | Consumer | Accutane | | PS | Hlr Technology | | Dose/Unit | Duration | |
| | Dry Eye Nec | | | | | ···· realiology | ORAL | | | |
| | Dry Skin | | | | | | | | | |
| | Epistaxis Folliculitis | | | | | | | | | |
| | Impaired Healing | | | | | | | | | |
| | Lip Dry | | | | | | | | | |
| | Pulmonary Congestion | | | | | | | | | |
| | Sims Congestion | | | | | | | | | |
| <u> </u> | Urethral Disorder Nos | | | | | | | | | |

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| | LDA. | | Salaran Kana | | 0.00 | | |
| | | | (B) Harriston (III) | | | | |
| | | | | | | | |
| ISR Number: 3518955-6 | Report Type: Periodic | | Company Report Nov | nham 222256 | | | |
| PT | Denovit C | _ | | imer: 223230 | | Age: 16 YR | Gender: Female |
| Apathy | | | | Role | Manufacturer | Route | Dose/Unit Duration |
| Appetite Increased | | Accutane | | PS | Hir Technology | ORAL. | 201001 |
| Depression Nec | Outer | | | | | | |
| _ | | | | | * | | |
| Weight Increased | | | | | | | |
| ISR Number: 3518963-5 | Report Types, David II. | | | | | | |
| Den. | report Type: renouse | | Company Report Nun | nber: 223489 | | Age: | Gender: Female |
| | Report Source | Product | | Dala | No | | |
| | Consumer | Accutane | | | | | Dose/Unit Duration |
| | | | | PS | Hir Technology | ORAL | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| 33189/9-9 | Report Type: Peziodic | | Company Report Nun | ber: 224286 | | Acr. 10370 | |
| PT | Report Source | D | | | | wage: 19 1 K | Gender: Female |
| | | | | Role | Manufacturer | Route | Dose/Unit Duration |
| | COMPUTER | Accutane | | PS | Hir Technology | ORAL | |
| | | | | | | | |
| Tired Eyes | | | | | | | |
| ISR Number: 3518982-9 | Report Type: Periodia | | | | | | · · · · · · · · · · · · · · · · · · · |
| DT | | | Company Report Num | ber: 224321 | | Age: 17 YR | Gender: Male |
| | Report Source | Product | | Dala | Manufast | 2.1 | |
| | Consumer | Accutane | | | | | Dose/Unit Duration |
| | | | | 13 | rur i echnology | ORAL | |
| Epistaxis | | | | | | | |
| Face Oedema | | | | | | · · | |
| Lip Dry | | | | | | | |
| Mood Alteration Nos | | | | | | | |
| Sedation | | | | | | | |
| | | | | | <u> </u> | | |
| SR Number: 3518984-2 | Description of the second | | | | | | |
| ISR Number: 3518984-2 | Report Type: Periodic | | Company Report Num | ber: 224348 | | Age: | Candon V |
| PT | Report Type: Periodic Report Source | Product | Company Report Num | | | Age: | Gender: Female |
| | | Product Accutane | Company Report Num | Role PS | Manufacturer Hlr Technology | Age: | Gender: Female Dose/Unit Duration |
| _ | Apathy Appetite Increased Depression Nec Fatigue Weight Increased ISR Number: 3518963-5 PT Abdominal Distension Appetite Increased Fatigue Irritability Weight Increased ISR Number: 3518979-9 PT Anxiety Nec Feeling Abnormal Feeling Intery Tired Eyes ISR Number: 3518982-9 PT Blister Depression Nec Eating Disorder Nec Epistaxis Face Oedema Lip Dry | ISR Number: 3518955-6 PT Apathy Appetite Increased Depression Nee Fatigue Weight Increased ISR Number: 3518963-5 PT Abdominal Distension Appetite Increased Fatigue Irritability Weight Increased ISR Number: 3518979-9 Report Type: Periodic PT Report Source Anxiety Nee Feeling Abnormal Feeling Ithery Tired Eyes ISR Number: 3518982-9 Report Type: Periodic PT Report Source Consumer Report Source Consumer Peeling Abnormal Feeling Ithery Tired Eyes ISR Number: 3518982-9 Report Type: Periodic PT Report Source Consumer Consumer PC Report Type: Periodic Consumer PC Report Type: Periodic Consumer PC Report Type: Periodic | ISR Number: 3518955-6 PT Report Source Product Apathy Appetite Increased Depression Nee Fatigue Weight Increased ISR Number: 3518963-5 Report Type: Periodic PT Report Source Product Accutane Appetite Increased ISR Number: 3518963-5 Report Type: Periodic PT Report Source Product Accutane Accutane ISR Number: 3518979-9 Report Type: Periodic PT Report Source Product Anxiety Nee Preeling Abnormal Peeling Ittery Tired Eyes ISR Number: 3518982-9 Report Type: Periodic PT Report Source Product Consumer Accutane Product Consumer Accutane Accutane Consumer Accutane Accutane Product Consumer Accutane Accutane Accutane Accutane Accutane Product Anxiety Nee Consumer Accutane | ISR Number: 3518955-6 Report Type: Periodic PT Report Source Product Consumer Accutane Other Patigue Weight Increased Fatigue Irritability Weight Increased ISR Number: 3518979-9 Report Type: Periodic Company Report Num PT Report Source Product Consumer Accutane Consumer Accutane Report Type: Periodic Company Report Num Product Consumer Accutane Product Consumer Accutane Product Company Report Num Product Consumer Accutane Product Consumer Accutane Product Consumer Accutane Product Accutane Product Consumer Accutane Accutane Product Consumer Accutane Accutane Accutane Accutane Product Accutane Product Accutane Accutane Accutane Product Accutane Product Accutane Product Accutane Accutane Accutane Accutane Accutane Product Accutane | ISR Number: 3518955-6 PT Report Source Product Apathy Appetite Increased Depression Nec Fatigue Weight Increased ISR Number: 3518963-5 Report Type: Periodic Report Source Product Accutane Role Accutane Role PS Company Report Number: 223489 Report Source Product Accutane PS Accutane Accutane Role Accutane PS ISR Number: 3518963-5 Report Type: Periodic Company Report Number: 223489 PT Report Source Product Accutane Role Accutane PS Report Type: Periodic Company Report Number: 224286 PT Report Source Product Accutane PS Report Type: Periodic Company Report Number: 224286 PT Report Source Product Role Product Role PS Religible Consumer Accutane PS Religible Consumer Accutane PS Report Type: Periodic PT Report Source Product Role PS Report Type: Periodic PT Report Source Product Role PS Report Source Product Role Role PS Report Source Product Role Role PS Report Source Product Role Role Role Role Role Role Role Role | PT Report Source Product Role Apathy Consumer Accutane PS Hir Technology Appetite Increased Other Appetite Increased Weight Increased Weight Increased Abdominal Distension Appetite Increased Appetite Increased Abdominal Distension Appetite Increased Appetite Increased Appetite Increased Abdominal Distension Appetite Increased Accutane Accutane BISR Number: 3518979-9 Report Type: Periodic Company Report Number: 224286 FT Report Source Product Anxiety Nec Peeling Abnormal Peeling Intery Tired Eyes ISR Number: 3518982-9 Report Type: Periodic Company Report Number: 224321 PT Report Source Product Accutane PS Hir Technology Hir Technology Accutane PS Hir Technology Accutane PS Hir Technology Accutane PT Report Source Product Product Role Manufacturer PR Hir Technology Accutane PS Hir Technology Accutane PS Hir Technology Accutane PS Hir Technology Accutane Product Role Accutane PS Hir Technology Accutane A | ISR Number: 3518955-6 Report Type: Periodic Product Apathy Apathy Apottle Increased Apottle Increased Other Page of Type: Periodic Company Report Number: 223256 Age: 16 YR Apathy Apottle Increased Weight Increased Weight Increased Abdominal Distension Appetite Increased Abdominal Distension Appetite Increased Fatigue Irritability Weight Increased ISR Number: 3518979-9 Report Type: Periodic Company Report Number: 223489 Age: Product Abdominal Distension Appetite Increased Fatigue Irritability Weight Increased ISR Number: 3518979-9 Report Type: Periodic Company Report Number: 224286 Age: 19 YR PT Report Source Product Anxiety Nec Anxiety Nec Consumer Accutane Product Accutane Product Role Manufacturer Route Anxiety Nec Peeling Abnormal Peeling Abnormal Peeling Abnormal Peeling Abnormal Peeling Abnormal Peeling Jittery Tired Eyes ISR Number: 3518982-9 Report Type: Periodic Company Report Number: 224321 Age: 17 YR PT Report Source Product Accutane Product Role Manufacturer Route Route Product Role Manufacturer Route Product P |

| | | | 10000 | e Event Reporti GC tulermanen | | Homer | | | |
|------------------|---|-----------------------|----------|----------------------------------|------------|----------------|------------|-----------|-------------|
| Date: 06/09/2000 | ISR Number: 3518992-1 | Report Type: Periodic | | | | | | | |
| Outcome | PT | | | Company Report Number | er: 221113 | | Age: 16 YR | Gene | der: Female |
| Other | Agitation | Report Source | Product | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | Anger | Other | Accutane | | PS | Hir Technology | ORAL | | |
| | Crying | 4 , | | | | | | | |
| | Depression Nec | | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3518995-7 | Report Type: Periodic | | Company Report Numbe | r: 221147 | | Age: 16 YR | Gene | der: Female |
| Outcome | PT | Report Source | Product | | D-1- | 36 | - | | Temate |
| Other | Acne Aggravated | Consumer | Accutane | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | Depression Nec Educational Problem | Health Professional | | | PS | Hir Technology | ORAL | | |
| | Personality Change | Other | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3518998-2 | | | | | | | | |
| | юмлиниет; ээтоуув-2 | Report Type: Periodic | | Company Report Number | r: 221159 | | Age: 56 YR | Gend | ler: Female |
| Outcome | PT | Report Source | Product | | Role | 35 | - | | |
| Other | Appetite Decreased | Health Professional | Accutane | | PS | Manufacturer | Route | Dose/Unit | Duration |
| | Depression Nec Influenza Like Illness | Other | | | , ro | Hlr Technology | ORAL | | |
| Date: 06/09/2000 | | | | | | | | | |
| Date: 00/09/2000 | ISR Number: 3519003-4 | Report Type: Periodic | | Company Report Numbe | r: 221193 | | Age: 19 YR | Gend | ler: Female |
| Outcome | PT | Report Source | Product | | in a | | - | | remaie |
| Other | Blood In Stool | Consumer | Accutane | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | Chest Pressure Sensation Emotional Disturbance Nos | Health Professional | Levening | | PS | Hir Technology | ORAL | | |
| | Epistaxis | Other | | | | | | | |
| | Eye Disorder Nos | | | 100 | | | | | |
| | Lip Dry | | | | | | | | |
| | Myalgia | | | | | | | | |
| | Tendonitis | | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519007-1 | Report Type: Periodic | | Company Report Number | m 221200 | | | | |
| Outcome | PT | Denové Common | | | 1. 461679 | | Age: 14 YR | Gend | ler: Male |
| Other | Abnormal Behaviour Nos | Report Source Other | Product | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | Aspartate Aminotransferase | Juice | Accutane | | PS | Hlr Technology | ORAL | | |
| | Increased Headache Nos | | | | | | | | |
| | Suicidal Ideation | | | | | | | | |

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| | 100 | reedom Of Informatio | | Region | | | | |
|-----------------------|---|--|--|---|---|---|--|---|
| ISR Number: 3519010-1 | Report Type: Periodic | Company Report Num | ber: 221339 | | Age: 21 VD | | J P. 1 | |
| PT . | Report Source | | | | g 21 1K | Gai | uer: remale | |
| Depression Nec | | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| Dry Eye Nec | | | PS | Hlr Technology | ORAL | | | |
| Dry Mouth | | Ortho Tri-Cyclen | С | | | | | |
| Dry Skin | | | | | | | | |
| Dry Throat | | | | | | | | |
| Paranoia | | | | | | | | |
| Proritos | | | | | | | | |
| Vulvovaginal Dryness | | , | | | | | | |
| Yellow Skin | | | | | | | | |
| ISR Number: 3510011 2 | D | | | | | | | |
| macroniner: 3313011-3 | Report Type: Periodic | Company Report Num | ber: 224284 | | Age: 20 YR | Gen | der: Female | |
| _ PT | Report Source | Product | | | • | | . I canage | |
| Anxiety Nec | | | -, | | Route | Dose/Unit | Duration | |
| Depression Nec | Consumer | | PS | Hir Technology | ORAL | | | |
| Dry Skin | | Minocyclin (Minocycline) | . C | | | | | |
| Fatigue | | | | | | | | |
| Increased Activity | | | | | | | | |
| Lip Dry | | | | | | | | |
| Nausea | | | | | | | | |
| Suicidal Ideation | | | | | | | | |
| ISR Number: 3519016-2 | Depose Trans. Dad. # | | | | | | | • |
| | Report Type: Periodic | Company Report Num | ber: 225430 | | Age: | Gen | der: Female | |
| | Report Source | Product | Dolo | | | | | |
| | Consumer | Accutana | | | | Dose/Unit | Duration | |
| | | The state of the s | | Hlr Technology | ORAL | | | |
| | | Estrogen Patches (Estrogens Nos) | С | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | • | | | | | | |
| Pain Nos | | * | | | | | | |
| ISR Number: 3519018-6 | Report Type: Periodic | | | | | | | |
| | Poze Type: 1 Calouic | Company Report Numi | er: 224765 | | Age: 16 YR | Gend | der: Male | |
| | | | | | | | | |
| PT Depression Nec | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | PT Depression Nec Dry Eye Nec Dry Mouth Dry Skin Dry Throat Paranoia Pruritus Vulvovaginal Dryness Yellow Skin ISR Number: 3519011-3 PT Anxiety Nec Depression Nec Dry Skin Fatigue Increased Activity Lip Dry Nausea Suicidal Ideation ISR Number: 3519016-2 PT Alopecia Breast Tenderness Depression Aggravated Dry Skin Gum Pain Headache Nos Pain Nos | ISR Number: 3519010-1 PT Report Source Other Depression Nee Dry Eye Nee Dry Mouth Dry Skin Dry Throat Paranoia Pruitus Vulvovaginal Dryness Yellow Skin ISR Number: 3519011-3 Report Type: Periodic PT Report Source Anxiety Nee Depression Nee Dry Skin Fatigue Increased Activity Lip Dry Nausea Suicidal Ideation ISR Number: 3519016-2 Report Type: Periodic PT Report Source Consumer Single Ideation ISR Number: 3519016-2 Report Type: Periodic PT Report Source Consumer Consumer | ISR Number: 3519010-1 Report Type: Periodic PT Report Source Other Accutane Ortho Tri-Cyclen Dry Eye Nee Dry Mouth Dry Skin Dry Throat Paranoia Prutitus Vulvovaginal Dryness Yellow Skin ISR Number: 3519011-3 Report Type: Periodic Product Company Report Num PT Report Source Product Company Report Num PT Report Source Consumer Accutane Minocyclin (Minocycline) ISR Number: 3519016-2 Report Type: Periodic Company Report Num PT Report Source Consumer Accutane Minocyclin (Minocycline) ISR Number: 3519016-2 Report Type: Periodic Company Report Num Minocyclin (Minocycline) Estrogen Patches (Estrogens Nos) Dry Skin Gum Pain Headache Nos Pain Nos | ISR Number: 3519010-1 Report Type: Periodic PT Report Source Other Other Accutane Ortho Tri-Cyclen Other Other Tri-Cyclen Other | PT Report Source Product Role Depression Nec Other Accutane PS HIr Technology Dry Eye Nec Dry Mouth Crit-Cyclen C Dry Mouth Crit-Cyclen C Dry Skin Dry Throat Paranoia Prufitus Vulvovaginal Dryness Yellow Skin ISR Number: 3519011-3 Report Type: Periodic Company Report Number: 224284 PT Report Source Product Role Depression Nec Consumer Accutane PS Hir Technology Dry Skin Patigue Increased Activity Lip Dry Nausea Suicidal Ideation ISR Number: 3519016-2 Report Type: Periodic Company Report Number: 225430 PT Report Source Product Role Dry Skin Company Report Number: 225430 Report Source Product Role Minocyclin (Minocycline) C Company Report Number: 225430 Company Report Number: 225430 Estrogen Paiches (Estrogens Nos) C Dry Skin Pain Headache Nos Pain Nos | ISR Number: 3519010-1 Report Type: Periodic Product Role Product Company Report Number: 221339 Report Type: Periodic Prurius Yulvovaginal Dryness Yellow Skin ISR Number: 3519011-3 Report Type: Periodic Product Accutanc Product Accutanc Role Product Accutanc Product Accutanc Role Role Role Role Role Role Role Roll Role Roll Role Role | ISR Number: 3519010-1 Report Type: Periodic Depression Nec Dry Sye Nec Dry Mouth Dry Skin Dry Throat Pramoia Pramoia Pramoia Pramitis Vulvovaginal Dryness Yellow Skin ISR Number: 3519011-3 Report Type: Periodic Company Report Number: 224284 Report Source Product Accutane Product Report Number: 224284 Report Source Product Report Number: 224284 Report Number: 224284 Report Number: 2519011-3 Report Type: Periodic Company Report Number: 224284 Report Source Product Report Source Product Report Report Number: 224284 Report Number: 2519016-2 Report Source Report Number: 2519016-2 Report Type: Periodic Company Report Number: 224284 Report Number: 25430 Report Number: 25430 Report Type: Periodic Report Source Product Report Report Number: 25430 Report Number: 25430 Report Report Source Report Source Product Report Report Number: 25430 Report Report Number: 25430 Report Report Source Report Report Number: 25430 Report Report Report Number: 25430 Report Report Report Number: 25430 Report Report Source Report Source Report Source Report Source Report Report Number: 25430 Report Report Number: 25430 Report Report Report Report Number: 25430 Report Report Report Report Number: 25430 Report R | ISR Number: 3519010-1 Report Type: Periodic PT Report Source Product Report Number: 221339 Doy Eye No. Doy Sain Doy Sain Doy Sain Doy Throat Panaio Prufins Vulvovaginal Dyness Yellow Skin Prufins SISR Number: 3519011-3 Report Source Product Report Source Product Report Number: 224284 Report Source Product Report Number: 224284 Report Source Product Report Report Number: 224284 Report Report Source Prufins Report Source Product Report Report Number: 224284 Report Report Source Product Report Report Number: 224284 Report Report Source Product Report Report Report Number: 224284 Report Report Source Product Report Report Report Number: 224284 Report Report Source Product Report Report Report Number: 224284 Report Report Source Report Report Report Number: 224284 Report Report Source Report Report Report Number: 224284 Report Source Report Report Report Report Number: 224284 Report Report Source Report Report Report Number: 225430 Report Repor |

| | | T | Advisor Event Rep resion Of Informs | ion (EG) | Report | | |
|------------------|------------------------|-----------------------|--|----------------|---------------------------------------|-------------|--|
| Date: 06/09/2000 | ISR Number: 3519023-X | Report Type: Periodic | Company Report | Number: 225591 | | Age: 31 YR | Gender: Female |
| Outcome | PT | Report Source | Product | | | g SIIR | Guiter: Female |
| Other | Appetite Decreased | Other | | Role | Manufacturer | Route | Dose/Unit Duration |
| | Depression Nec | Ould | Accutane | PS | Hir Technology | ORAL | |
| | Fatigue | | Oral Contraceptive Pill (Oral | C | | | |
| | Influenza | | Contraceptive Nos) Vitamins (Multivitamin Nos) | _ | | | |
| | Insomnia Nec | | VICALIBRIS (MILITAVITATION NOS) | С | | | |
| | Nausea | | | | | | |
| | Nipple Pain | | | | | | |
| | Thirst | | | | | | |
| | Vaginitis | | | | | | |
| | Vomiting Nos | | | | | | |
| | Weight Decreased | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519049-6 | Description Date of | | | | | |
| | | Report Type: Periodic | Company Report ! | Number: 225600 | | Age: 15 YR | Gender: Male |
| Outcome | PT | Report Source | Product | | | | The state of the s |
| Other | Abnormal Behaviour Nos | Other | Accutane | Role | Manufacturer | Route | Dose/Unit Duration |
| | Hallucination Nos | | Accurate | PS | Hir Technology | ORAL | |
| | Psychotic Disorder Nos | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519058-7 | Report Type: Periodic | | | · · · · · · · · · · · · · · · · · · · | | |
| Outcome | | report Type: Tenoute | Company Report ? | Number: 225721 | | Age: 38 YR | Gender: Female |
| | PT | Report Source | Product | Role | Manufacturer | T | |
| Other | Depression Aggravated | Health Professional | Accutane | | | Route | Dose/Unit Duration |
| | Epistaxis | Other | | PS | Hlr Technology | ORAL | |
| | Hair Growth Abnormal | | Lo/Ovral (Ethinyl Estradiol/Nortge | strel) C | | | • |
| | Joint Stiffness | and the second second | | | | | |
| | Lip Dry | | Na a seliku su s | | | | |
| | Skin Chapped | | | | | | |
| | Weight Increased | | | | | | |
| ate: 06/09/2000 | ISR Number: 3519063-0 | Report Type: Periodic | | | | | |
| Outcome | Term | T JP talout | Company Report N | Number: 225806 | | Age: 15 YR | Gender: Female |
| Other | . PT | Report Source | Product | Role | Manufacturer | Route | TO 100 - 2 |
| Junear | Malaise | Other | Accutane | | | | Dose/Unit Duration |
| | Mood Swings | | | PS . | Hir Technology | ORAL | |
| ate: 06/09/2000 | ISR Number: 3519071-X | Report Type: Periodic | | | | | |
| | PT | | Company Report N | (umber: 226012 | | Age: 17 YR | Gender: Male |
| Informe | | Th | | | | | |
| utcome | Personality Change | Report Source | Product | Role | Manufacturer | Route | Dose/Unit Duration |

| Date: 06/09/2000 | ISR Number: 3519075-7 | Report Type: Periodic | | Company Report Numb | er: 226637 | · · · · · · · · · · · · · · · · · · · | Age: 17 YR | Ger | ider: Male | - |
|----------------------|---|------------------------|-------------|--------------------------------|------------|---------------------------------------|------------|-----------|---------------|---|
| Outcome | PT | Report Source | Product | | Role | 36 | | | | |
| Other | Drug Interaction Nos | Health Professional | Accutane | | PS | Manufacturer Hir Technology | Route | Dose/Unit | Duration | |
| <u> </u> | Schizophrenia Nos Aggravated | | Zyprexa | | SS | THE LECTION OF | ORAL | | | |
| Date: 06/09/2000 | ISR Number: 3519078-2 | Report Type: Periodic | | C | | | | | | |
| Outcome | PT | | | Company Report Number | er: 226658 | | Age: 24 YR | Ger | nder: Female | |
| Other | C-Reactive Protein Increased | Report Source | Product | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Decreased Activity | Health Professional | Accutane | | PS | Hlr Technology | ORAL | | | |
| | Erythrocyte Sedimentation Rate Increased | | Zithromax | (Azithromycin) | C | | | | - | |
| | Fatigue | | | | | | | | | |
| | Hypoaesthesia | | | | | | | | | |
| | Joint Stiffness | | | | | | | | | |
| | Muscle Weakness Pain Nos | | | | | | | | | |
| | Streptococcal Infection Nos | • | | | | | | | | |
| | Streptolysin O Antibody Positive | | | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519084-8 | Report Type: Periodic | | | | | | | | |
| Outcome . | PT | | | Company Report Number | r: 226732 | | Age: 24 YR | Gen | der: Female | |
| Other | Dermatitis Nos | Report Source | Product | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Epistaxis | Consumer | Accutane | | PS | Hlr Technology | ORAL | | D at the lost | • |
| | Hair Texture Abnormal | | Ortho Tri C | yclen (Ethinyl orgestimate) | C | | | | | |
| | Headache Nos Insomnia Nec | | | Orgestimate) | | | | | | |
| | Lip Dry | | | | | | | | | |
| | Skin Disorder Nos | | W. C. | | | | | | | |
| | Vein Disorder Nos | <u> </u> | | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519087-3 | Report Type: Periodic | | Company | | | | | · | |
| Outcome | PT | D4.0 | _ | Company Report Numbe | r: 226981 | | Age: 23 YR | Gen | der: Female | |
| Hospitalization - | Amnesia Nec | Report Source Consumer | Product | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| Initial or Prolonged | Anxiety Nec | Health Professional | Accutane | | PS | Hir Technology | ORAL | | | |
| | Depression Nec Fatigue | Other | | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519089-7 | | | | | | | | | |
| | | Report Type: Periodic | | Company Report Number | r: 227032 | | Age: 13 YR | Cen | der: Female | |
| Outcome | PT | Report Source | Product | | Role | Minne | = | | uci: remaie | |
| Other | Alopecia | Consumer | Accutane | | PS | Manufacturer | Route | Dose/Unit | Duration | |
| | Appetite Increased | | | | | | ORAL | | | |

| | | 1004 | Adverse Event Report | | tein (édilké) | | | |
|------------------|---|-----------------------|--|------------|---------------------------------------|------------|--------------------|---|
| | | | readom Of Information | | Reputs | | | |
| Date: 06/09/2000 | ISR Number: 3519090-3 | Report Type: Periodic | Company Report Numb | er: 227070 | | Age: 26 YR | G-1 P | |
| Outcome | PT | Report Source | Product | | | Age. 20 IR | Gender: Female | |
| Other | Depression Nec | Consumer | Accutane | Role | Manufacturer | Route | Dose/Unit Duration | |
| | Hypersensitivity Nos Insomnia Nec | · | Acculance | PS | HlrTechnology | ORAL | | |
| Date: 06/09/2000 | ISR Number: 3519092-7 | Report Type: Periodic | Company Report Numb | er: 227109 | | Age: 28 YR | Gender: Female | _ |
| Outcome | PT | Report Source | Product | Role | Manufacturer | - · | | |
| Other | Acne Aggravated | Health Professional | Accutane | PS | | Route | Dose/Unit Duration | |
| | Depression Nec Dry Skin | Other | Wellbutrin (Bupropion Hydrochloride) | C | Hlr Technology | ORAL | | |
| | DIJ SKIII | | Adderall (Amphetamine Aspartate / | c | | | | |
| | | | Amphetamine Sulfate / Dextroamphetamine Sacchara / Dextroamphetami | Ü | | | | |
| | | · | Cylert (Pernoline) | C | | | | |
| Date: 06/09/2000 | ISR Number: 3519095-2 | Report Type: Periodic | Company Report Numb | er: 227353 | · · · · · · · · · · · · · · · · · · · | Age: 22 YR | Gender: Male | _ |
| Outcome | <u>PT</u> | Report Source | Product | n.s. | | | 7,200 | |
| Other | Dry Skin | Consumer | Accutane | Role PS | Manufacturer | Route | Dose/Unit Duration | |
| * | Emotional Disturbance Nos Insomnia Nec | | | L9 | Hlr Technology | ORAL | | |
| | Lip Dry | | | | | • | | |
| | Palpitations | | | | | | | • |
| | Suicidal Ideation | | sayahara sayahara | | | | | |
| Date: 06/09/2000 | ISR Number: 3519096-4 | Report Type: Periodic | Company Report Numb | - 022000 | | | | |
| Outcome | PT | | 그리즘 그는 얼마나의 하나 하다. | er: 233229 | | Age: 16 YR | Gender: Male | |
| Death | Aggression | Report Source Other | Product | Role | Manufacturer | Route | Dose/Unit Duration | |
| | Agitation | . Other | Accutane | PS | | ORAL | | |
| | Confusion | | | | | | | |
| | Depression Nec | | | | | | | |
| | Irritab <u>ility</u> | | | | | | | |
| | Suicidal Ideation | | | | | | | |
| hate: 06/09/2000 | ISR Number: 3519100-3 | Report Type: Periodic | Company Report Numb | er: 232008 | | Age: | Gender: Female | - |
| Outcome | PT | Report Source | Product | | | _ | | |
| Other | Depression Nec | Health Professional | Accutane | Role | Manufacturer | Route | Dose/Unit Duration | |
| | Suicidal Ideation | | Actualit | PS | Hir Technology | ORAL | | |

| | | FDA : | Aitverse Event Reporti Sedom Of Lifermation | | tem (AERS) | | | | |
|-----------------------------|---|------------------------|--|-----------------|-----------------|-----------------|------------|-------------|------|
| Date: 06/09/2000 | ISR Number: 3519102-7 | Report Type: Periodic | Company Report Numbe | | atopert . | Age: 20 YR | Gen | der: Female | H.: |
| Outcome | PT | Report Source | Product | | | - | | I Gilling | - 19 |
| Other | Anxiety Nec | Other | Accutane | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Depression Nec | | Birth Control Pill | PS | Hir Technology | ORAL | | | |
| | | | (Oral Contracetive Nos) | C | | | | | |
| Date: 06/09/2000 | ISR Number: 3519105-2 | Report Type: Periodic | Company Report Number | C er: 232431 | | Age: 17 YR | | | |
| Outcome | PT | Report Source | Product | | | Age. 17 1K | Gen | der: Male | |
| Other | Psychotic Disorder Nos | Health Professional | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | · | Titalian I Toressional | Accutane | PS . | Hir Technology | ORAL | | | |
| Date: 06/09/2000 Outcome | ISR Number: 3519106-4 | Report Type: Periodic | Company Report Numbe | er: 232494 | | Age: 18 YR | Gen | der: Pemale | |
| | PT Delusion Nos | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration | |
| Disability | Disturbance In Attention Nec | Consumer | Accutane | PS | Hlr Technology | ORAL | Don't Call | Duration | |
| | Emotional Disturbance Nos | Health Professional | | | | OKAL | | | |
| | Paranoia Psychotic Disorder Nos | | | | | | | | |
| | Short-Term Memory Loss | | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519108-8 | Report Type: Periodic | Company Report Numbe | r: 232571 | | Age: 36 YR | Gen | der: Female | |
| Outcome | PT | Report Source | Product | Role | Manufacturer | Dt- | | | • |
| Other | Depression Nec | Other | Accutane | PS | | Route | Dose/Unit | Duration | |
| | Suicidal Ideation | | Birth Control Pills | C | Hir Technology | ORAL | | | |
| | | | (Oral Contraceptive Nos) | C | | | | | |
| Date: 06/09/2000 | ISR Number: 3519110-6 | Report Type: Periodic | Company Report Numbe | r: 232612 | | Age: 17 YR | Gen | der: Female | |
| Outcome | PT P | Report Source | Product | Role | Manufacturer | Route | Desemble | | |
| Other | Depression Nec | Health Professional | Accutane | PS | Hlr Technology | | Dose/Unit | Duration | |
| Date: 06/09/2000 | ISR Number: 3519113-1 | Report Type: Periodic | Company Report Numbe | | Thi Tetaliology | ORAL Age: 15 YR | Gen | der: Female | |
| Outcome | PT | Report Source | Product | | | | Jun | der: Female | |
| Other | Agitation | Health Professional | Accutane | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Hallucination, Auditory Insomnia Nec | | Accutant | PS | Hlr Technology | ORAL | | | |
| | Schizophrenia Nos | | | | | | | | |

| | | T, | | e Beant Reporti Of Information | | Keper | | | |
|------------------|---|-----------------------|---------------------|--|------------|----------------|------------|--------------------|---|
| Date: 06/09/2000 | ISR Number: 3519115-5 | Report Type: Periodic | | Company Report Number | | | Age: 31 YR | Gender: Female | |
| Outcome | PT | Report Source | Product | | | | | odiaer, remaie | |
| Other | Alopecia | Consumer | Accutane | | Role PS | Manufacturer | Route | Dose/Unit Duration | |
| | Crying | | | | ra | Hir Technology | ORAL | | |
| | Depression Nec Hair Texture Abnormal | | | | | | | | |
| | Suicidal Ideation | | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519118-0 | Report Type: Periodic | | Company Report Numbe | er: 204242 | | Age: 24 YR | Gender: Female | |
| Outcome | <u>PT</u> | Report Source | Product | | | | - | Culter. Penale | |
| Other | Depression Aggravated | Consumer | Accutane | | Role | Manufacturer | Route | Dose/Unit Duration | |
| | Suicidal Ideation | Health Professional | | (February Pares 11 1 / F | PS | Hlr Technology | ORAL | | |
| | | Other | Fumarate / | (Ethynyl Estradiol / Ferrous Norethindrone Acetate) | C · | | | | |
| Date: 06/09/2000 | ISR Number: 3519127-1 | Report Type: Periodic | | Company Report Numbe | er: 204725 | | Age: 35 YR | Gender: Female | _ |
| Outcome | <u>PT</u> | Report Source | Product | | Role | Manufacturer | Route | | |
| Other | Depression Nec | Consumer | Accutane | | PS | Hlr Technology | | Dose/Unit Duration | |
| | Stye Suicidal Ideation | • | | | •• | im recinology | ORAL | | |
| Date: 06/09/2000 | ISR Number: 3519131-3 | Report Type: Periodic | | Company Report Numbe | er: 204859 | | Age: 16 YR | Gender: Female | |
| Outcome | PT | Report Source | Product | | | | | Canali. Telling | • |
| Other | Alopecia | Consumer | Accutane | | Role | Manufacturer | Route | Dose/Unit Duration | |
| | Depression Nec | Health Professional | . Avuians | | PS | Hlr Technology | ORAL | | |
| | Dry Mouth | Other | NSC WEEK THE THE | | 백화를 가는 | | | | |
| Onte: 06/09/2000 | ISR Number: 3519139-8 | Report Type: Periodic | : | Company Report Numbe | er: 218539 | | Age: 17 YR | Gender: Female | |
| Outcome | <u>PT</u> | Report Source | Product | | Role | Manufacturer | Route | Describet D # | |
| Other | Amnesia Nec Dry Skin | Health Professional | Accutane | | PS | Hir Technology | | Dose/Unit Duration | |
| | Lip Dry | | | | | - Company | ORAL | | |
| Date: 06/09/2000 | ISR Number: 3519144-1 | Report Type: Periodic | | Company Report Numbe | r: 205135 | | Age: 20 YR | Gender: Male | |
| Outcome | <u>PT</u> | Report Source | Product | | | | | Gender: Male | |
| Death | Completed Suicide | Other | | | Role | Manufacturer | Route | Dose/Unit Duration | |
| | Road Traffic Accident | ~ | Accutane | | PS | Hlr Technology | ORAL. | | |

| Date: 06/09/2000 | ISR Number: 3519145-3 | Report Type: Periodic | | Company Report Number: 20 | NE140 | | | | | ********** |
|---|---|-----------------------|---------------------|----------------------------|-------|--------------------------------|---------------|-----------|--------------|------------|
| Outcome | _ PT | Report Source | Dandard | - · · | | | Age: 21 YR | Ge | nder: Female | |
| Hospitalization - Initial or Prolonged | Depression Nec Psychotic Disorder Nos | Other | Product Accutane | Ro. | | Manufacturer Hir Technology | Route ORAL | Dose/Unit | Duration | |
| Date: 06/09/2000 | ISR Number: 3519146-5 | Report Type: Periodic | | Company Report Number: 20 | 5210 | | _ | · . | | |
| Outcome | PT | Report Source | D | Company Report Number: 20 | 3219 | | Age: 15 YR | Ge | nder: Male | |
| Other | Abnormal Behaviour Nos | Other | Product Accutane | Ro | _ | Manufacturer | Route | Dose/Unit | Duration | |
| | Aggression Depression Nec | | According | PS | | | ORAL | | | |
| | Disturbance In Social Behaviour Nos Suicidal Ideation | | | · | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519150-7 | | | | | | | | | |
| Outcome | | Report Type: Periodic | | Company Report Number: 23 | 0702 | * | Age: | Ge | nder: Male | |
| Death | PT Completed Suicide | Report Source | Product | Rol | le_ | Manufacturer | Route | Dose/Unit | Duration | |
| - - | Depression Nec | Other | · Accutane | PS | | Hlr Technology | ORAL | | | |
| | Emotional Disturbance Nos Suicidal Ideation | | | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519152-0 | Report Type: Periodic | | Company Report Number: 22 | 0541 | | | | | |
| Outcome | PT | Report Source | Product | | | | Age: 34 YR | Ga | nder: Female | ٠., |
| Disability | Depression Nec | Consumer | Accutane | Rol PS | le_ | Manufacturer | Route | Dose/Unit | Duration | |
| | Lethargy | Health Professional | | | | Hir Technology | ORAL | 100 | | |
| Date: 06/09/2000 | TODAY . | Other | 2.4 | | 18. | | | | | |
| | ISR Number: 3519153-2 | Report Type: Periodic | | Company Report Number: 22 | 9622 | 46.0 | Age: 20 YR | Ge | nder: Female | |
| Outcome Other | PT Anxiety Nec | Report Source | Product | Rol | le | Manufacturer | Route | Dose/Unit | Duration | |
| Oute. | Depression Nec | Consumer Other | Accutane | PS | _ | Hlr Technology | ORAL | Tose Ouli | Datation | |
| Date: 06/09/2000 | ISR Number: 3519160-X | | | | | · | | | | |
| Outcome | PT | Report Type: Periodic | | Company Report Number: 229 | 9813 | | Age: | Ger | nder: Female | |
| Other | Suicidal Ideation | Report Source | Product | Rol | e | Manufacturer | Route | Dose/Unit | Duration | |
| | | Health Professional | Accutane | PS | | Hlr Technology | ORAL | | | |
| Date: 06/09/2000 | ISR Number: 3519164-7 | Report Type: Periodic | - | Company Report Number: 230 | 0298 | | Age: 17 YR | | | |
| Outcome | PT | Report Source | Product | | | Manufastana | - | | ader: Male | |
| Hospitalization - Initial or Prolonged | Suicide Attempt | Consumer | Accutane | Role PS | _ | Manufacturer Hir Technology | Route | Dose/Unit | Duration | |

| | 100 | Tir | | e byent Reporte Of Information | | | | |
|--|---|-----------------------|---------------------------------------|-----------------------------------|------------|-----------------------------|------------|--|
| | | | | | | 110 110 11 | | |
| Date: 06/09/2000 | ISR Number: 3519171-4 | Report Type: Periodic | | Company Report Number | : 213097 | | Age: 15 YR | Gender: Male |
| Outcome | PT | Report Source | Product | | Role | Manufacturer | D4- | To #7.44 |
| Other | Blood Creatine Phosphokinase Increased | Health Professional | Accutane | | PS | Hir Technology | Route | Dose/Unit Duration |
| | Decreased Activity | | | | 1.5 | rur recunology | ORAL | |
| ······································ | Drug Effect Decreased | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519173-8 | Report Type: Periodic | | Company Report Number | : 219092 | | Age: 15 YR | Gender: Female |
| Outcome | PT | Report Source | Product | | | | • | Guiter. Penale |
| Other | Panic Attack | Other | Accutane | | Role | Manufacturer | Route | Dose/Unit Duration |
| | Vomiting Nos | | Accurance | | PS | Hlr Technology | ORAL | |
| Date: 06/09/2000 | ISR Number: 3519175-1 | Report Type: Periodic | | Company Report Number | : 213537 | | Age: 16 YR | Gender: Female |
| Ontcome | PT | Report Source | Product | | Role | Manufacturer | Route | 70 #7.14 |
| Other | Crying Depressed Mood | Other | Accutane | | PS | Hir Technology | | Dose/Unit Duration |
| | Depression Nec | | | | | Tail Tecaniology | ORAL | |
| Date: 06/09/2000 | ISR Number: 3519180-5 | Report Type: Periodic | | Company Report Number | : 213837 | | Age: 18 YR | Gender: Female |
| Outcome | PT | Report Source | Product | | | | | |
| Other | Acne Aggravated | Consumer | Accutane | | Role PS | Manufacturer | Route | Dose/Unit Duration |
| | Depression Nec | | · · · · · · · · · · · · · · · · · · · | | rs | HIr Technology | ORAL | |
| | Headache Nos Visual Acuity Reduced | | | | | | | |
| Date: 06/09/2000 | | | | <u> </u> | | on the second second second | | the state of the s |
| Jaie. 00/09/2000 | ISR Number: 3519182-9 | Report Type: Periodic | | Company Report Number | 231043 | | Age: | Gender: Male |
| Outcome | PT | Report Source | Product | | | | | |
| Disability | Emotional Disturbance Nos | Other | Accutane | | Role | Manufacturer | Route | Dose/Unit Duration |
| 2-4 | | | | | PS | Hlr Technology | ORAL | |
| Date: 06/09/2000 | ISR Number: 3519184-2 | Report Type: Periodic | | Company Report Number | 214155 | | Age: 19 YR | C |
| Outcome | PT | Report Source | D34 | | | | nge. 191K | Gender: Female |
| Disability | Decreased Activity | Health Professional | Product | | Role | Manufacturer | Route | Dose/Unit Duration |
| | Depression Nec | Other | Accutane | | PS | Hlr Technology | ORAL | |
| | Social Avoidant Behaviour | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519186-6 | Report Type: Periodic | | Company Report Number: | 214220 | . , | Ass. 10 Im | |
| Outcome | PT | Report Source | D 3 4 | t A b-rerreminet | | | Age: 19 YR | Gender: Female |
| Hospitalization - | Depression Nec | Other | Product | | Role | Manufacturer | Route | Dose/Unit Duration |
| Initial or Prolonged | | Outer | Accutane | | PS | Hlr Technology | ORAL | |

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|--|---|---------------------------------------|----------------------------------|------------|----------------|------------|---------------------------------------|
| | | FDA | Adverse Rivert Report | 10.595 | em (AERS) | | |
| | | | reedom Of Intermetion | | Report | | |
| Date: 06/09/2000 | ISR Number: 3519187-8 | Report Type: Periodic | Company Report Numb | 221211 | | | |
| Outcome | PT | | | er: 231211 | | Age: 14 YR | Gender: Male |
| Hospitalization - | Depression Nec | Report Source Health Professional | Product | Role | Manufacturer | Route | Dose/Unit Duration |
| Initial or Prolonged | Insomnia Nec | ricajui Professionaj | Accutane | PS | Hir Technology | ORAL | |
| Disability | Suicidal Ideation | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519189-1 | Report Type: Periodic | Company Report Numb | er: 214321 | | Age: 16 YR | Gender: Male |
| Outcome | <u>PT</u> | Report Source | Product | | | - | Scatter: Male |
| Other | Aspartate Aminotransferase | Health Professional | Accutane | Role | Manufacturer | Route | Dose/Unit Duration |
| | Aspartate Aminotransferase Increased | 7 | · www.made | PS | Hlr Technology | ORAL | |
| | Blood Creatine Phosphokinase | | | | | | |
| | Increased Blood Glucose Increased | | | | | | |
| | Blood Iron Increased | | | | | | |
| | Blood Phosphate Increased | | | | | | |
| | Blood Potassium Decreased | | | | | | |
| | Disturbance In Attention Nec | | | | | | |
| | Irritability | | | | | | |
| 2406.000.000 | Mood Alteration Nos | · · · · · · · · · · · · · · · · · · · | | | | | |
| Onte: 06/09/2000 | ISR Number: 3519191-X | Report Type: Periodic | Company Report Number | r: 231219 | | Age: 17 YR | Gender: Female |
| Outcome | PT | Report Source | Product | | | 1, 11 | Gender: Female |
| Other | Confusion | Consumer | Accutane | Role | Manufacturer | Route | Dose/Unit Duration |
| | Convulsions Nos | Health Professional | Ortho Tri-Cyclen (Ethinyl | PS | Hir Technology | ORAL | |
| | Headache Nos Menstruation Irregular | | Estradiol/Norgestimate) | c | | | |
| _ | Speech Disorder Nec | | Tylenol (Acetaminophen) | С | | | |
| Pate: 06/09/2000 | ISR Number: 3519192-1 | | | | | | |
| | ************************************** | Report Type: Periodic | Company Report Number | er: 214322 | | Age: 21 YR | Gender: Female |
| Outcome | PT | Report Source | Product | Dela | Manufacture | | |
| lospitalization - nitial or Prolonged | Alopecia | Health Professional | Accutane | Role PS | Manufacturer | Route | Dose/Unit Duration |
| or r rotalised | Depression Nec Scar | • | Ortho-Cyclen | rs C | HlrTechnology | ORAL | • |
| | | | (Ethinyl Estradiol/Norgestimate) | C | | | |
| Pate: 06/09/2000 | ISR Number: 3519193-3 | Report Type: Periodic | | | | | · · · · · · · · · · · · · · · · · · · |
| Outcome | PT | | Company Report Number | r: 231417 | | Age: 19 YR | Gender: Male |
| Iospitalization - | Psychotic Disorder Nos | Report Source | Product | Role | Manufacturer | Route | Dose/Unit Duration |
| nitial or Prolonged | | Health Professional | Accutane | PS | Hlr Technology | | |

| | | 1114 | | e Event Keparin | | | | | |
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| | | and the first | | Ci luformation | | adili i valore. Romini | | | |
| Date: 06/09/2000 | ISR Number: 3519196-9 | | | | | | | | |
| 0 | | Report Type: Periodic | | Company Report Number | : 231487 | | Age: 15 YR | Gender: | Male |
| Outcome Other | PT Depression Nec | Report Source | Product | | Role | Manufacturer | Route | Dose/Unit Du | |
| Other | Suicidal Ideation | Consumer | Accutane | | PS | Hir Technology | ORAL | Dose Chit Du | ration |
| Date: 06/09/2000 | ISR Number: 3519197-0 | Report Type: Periodic | | Company Report Number | 215166 | · · · · · · · · · · · · · · · · · · · | Age: 26 YR | Gender: | Female |
| Outcome | PT | Report Source | Product | | D.1. | 34 | | | 1 CHAIR |
| Other | Depression Nec | Consumer | Accutane | | Role | Manufacturer | Route | Dose/Unit Du | ration |
| | Dry Skin Lip Ulceration | Other | . wednine | | PS | Hlr Technology | ORAL | | |
| Date: 06/09/2000 | ISR Number: 3519199-4 | Report Type: Periodic | | Company Report Number | 215197 | | Age: | Gender: | Para -1- |
| Outcome | <u>PT</u> | Report Source | Product | | | | | Guidei. | remaie |
| Hospitalization - | Depression Nec | Other | Accutane | | Role | Manufacturer | Route | Dose/Unit Du | ration |
| Initial or Prolonged | | | Accutatie | _ | PS | Hlr Technology | ORAL | | |
| Onte: 06/09/2000 Outcome | ISR Number: 3519204-5 | Report Type: Periodic | - | Company Report Number | 215629 | | Age: 16 YR | Gender: | Male |
| | - <u>PT</u> | Report Source | Product | • | Role | Manufacturer | Route | D. 177 4 | |
| Other . | Alopecia Depression Nec | Other | Accutane | | PS | Hir Technology | ORAL | Dose/Unit Du | ration |
| Pate: 06/09/2000 | ISR Number: 3519209-4 | Report Type: Periodic | | Company Report Number | : 216346 | | Age: 25 YR | Gender: | Female |
| Outcome | PT | Report Source | Product | | | 12.1 | | | i triiațe |
| Other | Crying | Health Professional | Accutane | | Role | Manufacturer | Route | Dose/Unit Du | ration |
| | Depression Nec Localised Exfoliation | Other | | | PS | Hlr Technology | ORAL | | |
| Pate: 06/09/2000 | ISR Number: 3519211-2 | Report Type: Periodic | | Company Report Number | 216359 | | Age: | Gender: | Romala |
| Outcome | PT | Report Source | Product | | | | | Galact. | remate |
| Other | Acne Aggravated | Consumer | Accutane | | Role | Manufacturer | Route | Dose/Unit Du | ration |
| | Alopecia | Health Professional | *************************************** | | PS | Hlr Technology | ORAL | | |
| | Blood Cholesterol Increased Blood Pressure Increased | Other | | | | | | | |
| | Cheilitis | | | | | | | | |
| _ | Depression Nec | | | | | | | | |
| | Dry Skin | | | | | | | | |
| | Lip Disorder Nos | | | | | | | | |
| | Lip Dry | | | | | | | | |
| | Menstrual Disorder Nos | | | | | | | | |
| | Mental Disorder Nec | | | | | | | | |
| | Red Eye | | | | | | | | |

| Date: 06/09/2000 | ISR Number: 3519212-4 | Report Type: Periodic | | Company Report Numbe | r; 216387 | | Age: | Ger | ıder: Female |
|----------------------------------|--|-----------------------|------------------|-----------------------|-----------|--------------------------------|------------|------------------|----------------------|
| Outcome | PT | Report Source | Product | | D.1. | 36 | | | |
| Hospitalization - | Depression Nec | Other | Accutane | | Role | Manufacturer | Route | Dose/Unit | Duration |
| Initial or Prolonged | | | Treontaile | | PS | Hlr Technology | ORAL | | |
| Date: 06/09/2000 | ISR Number: 3519214-8 | Report Type: Periodic | | Company Report Numbe | r: 210255 | | | | |
| Outcome | PΤ | D G | | I O ziepozezianio | 1. 217233 | | Age: | Ges | nder: Female |
| Other | Epistaxis | Report Source | Product | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | Localised Exfoliation | Consumer | Accutane | | PS | Hlr Technology | ORAL. | | |
| | Pruritus | | | | | | | | |
| | Stress Symptoms | * | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519224-0 | Report Type: Periodic | | C | | | | | |
| Outcome | PT | • | | Company Report Number | r: 219874 | | Age: 22 YR | Ger | i der: Female |
| Other | Apathy | Report Source | Product | | Role | Manufacturer | Route | Dose/Unit | Duration |
| Ould | Depression Nec | Consumer | Accutane | | PS | Hlr Technology | ORAL | 17000 01111 | Duration |
| * | Headache Nos | | | | | | OKAL | | |
| | Lethargy | | | | | | | | |
| | | | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519227-6 | D | | | | | | | |
| , | ISR Number: 3519227-6 | Report Type: Periodic | | Company Report Number | r: 219720 | | Age: 33 YR | Gen | ıder: Female |
| Outcome | PT | Report Type: Periodic | Product | Company Report Number | | Manufacturer | | | |
| Outcome | PT Agoraphobia | | Product Accutane | Company Report Number | Role | Manufacturer | Route | Gen Dose/Unit | nder: Female |
| Outcome | PT Agoraphobia Anxiety Nec | Report Source | | Company Report Number | | Manufacturer Hlr Technology | | | |
| Outcome | PT Agoraphobia Anxiety Nec Apathy | Report Source | | Company Report Number | Role | | Route | | |
| Outcome | PT Agorsphobia Anxiety Nec Apathy Burning Sensation Nos | Report Source | | Company Report Number | Role | | Route | | |
| Outcome | PT Agoraphobia Anxiety Nec Apathy | Report Source | | Company Report Number | Role | | Route | | |
| Outcome | PT Agoraphobia Anxiety Nec Apathy Burning Sensation Nos Crying | Report Source | | Company Report Number | Role | | Route | | |
| Outcome | PT Agoraphobia Anxiety Nec Apathy Burning Sensation Nos Crying Depression Nec | Report Source | | Company Report Number | Role | | Route | | |
| Outcome | PT Agoraphobia Anxiety Nec Apathy Burning Sensation Nos Crying Depression Nec Dyskinesia Nec | Report Source | | Company Report Number | Role | | Route | | |
| Outcome | PT Agoraphobia Anxiety Nec Apathy Burning Sensation Nos Crying Depression Nec Dyskinesia Nec Bye Disorder Nos | Report Source | | Company Report Number | Role | | Route | | |
| Outcome | PT Agoraphobia Anxiety Nec Apathy Burning Sensation Nos Crying Depression Nec Dyskinesia Nec Eye Disorder Nos Eye Pain | Report Source | | Company Report Number | Role | | Route | | |
| Outcome | PT Agoraphobia Anxiety Nec Apathy Burning Sensation Nos Crying Depression Nec Dyskinesia Nec Bye Disorder Nos Bye Pain Feeling Abnormal | Report Source | | Company Report Number | Role | | Route | | |
| Outcome | PT Agoraphobia Anxiety Nec Apathy Burning Sensation Nos Crying Depression Nec Dyskinesia Nec Eye Disorder Nos Eye Pain Feeling Abnormal Headache Nos | Report Source | | Company Report Number | Role | | Route | | |
| Outcome | PT Agoraphobia Anxiety Nec Apathy Borning Sensation Nos Crying Depression Nec Dyskinesia Nec Bye Disorder Nos Eye Pain Feeling Abnormal Headache Nos Insomaia Nec | Report Source | | Company Report Number | Role | | Route | | |
| Outcome | PT Agoraphobia Anxiety Nec Apathy Burning Sensation Nos Crying Depression Nec Dyskinesia Nec Eye Disorder Nos Eye Pain Feeling Abnormal Headache Nos Insonnaia Nec Menorrhagia Neck Pain Nervousness | Report Source | | Company Report Number | Role | | Route | | |
| Outcome | PT Agoraphobia Anxiety Nec Apathy Burning Sensation Nos Crying Depression Nec Dyskinesia Nec Bye Disorder Nos Bye Pain Feeling Abnormal Headache Nos Insomaia Nec Menornhagia Neck Pain | Report Source | | Company Report Number | Role | | Route | | |
| Date: 06/09/2000 Outcome Other | PT Agoraphobia Anxiety Nec Apathy Burning Sensation Nos Crying Depression Nec Dyskinesia Nec Eye Disorder Nos Eye Pain Feeling Abnormal Headache Nos Insonnaia Nec Menorrhagia Neck Pain Nervousness | Report Source | | Company Report Number | Role | | Route | | |

| Date: 06/09/2000 | ISR Number: 3519236-7 | Report Type: Periodic | | Company Report Numb | er: 220657 | | Age: 17 YR | Gender: Male |
|------------------|-------------------------------------|------------------------|-----------|---------------------|------------|---------------------------------------|------------|-----------------------|
| Outcome | PT | Report Source | Product | | Role | Manufacturer | Route | |
| Other | Depression Nec Dry Skin | Consumer | Accutance | | PS | Hir Technology | ORAL | Dose/Unit Duration |
| | Praritus | | | | | | OKAL | |
| | Scar | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519257-4 | Report Type: Periodic | | | | | | |
| Out | | respore Type. Periodic | | Company Report Numb | er: 216765 | | Age: 16 YR | Gender: Male |
| Outcome | PT Agitation | Report Source | Product | | Role | Manufacturer | Route | Dose/Unit Duration |
| Other | Depression Nec | Consumer | Accutane | | PS | Hir Technology | ORAL | Data Citation |
| | Suicidal Ideation | | | | | | CICAL | |
| Date: 06/09/2000 | ISR Number: 3519263-X | D | | | | · · · · · · · · · · · · · · · · · · · | | |
| | | Report Type: Periodic | | Company Report Numb | er: 217075 | | Age: 24 YR | Gender: Male |
| Outcome | PT Aggression | Report Source | Product | | Role | Manufacturer | Route | Dose/Unit Duration |
| Outer | Aggression Depression Aggravated | Consumer | Accutane | | PS | Hlr Technology | ORAL | - con onic ioni audii |
| | Dry Mouth | | Paxil | | С. | | Oldin | |
| | Irritability | | | | | | | |
| | Libido Decreased | | | | | | | |
| | Skin Chapped | | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519269-0 | Report Type: Periodic | | Company Report Numb | 217160 | | 45.00 | |
| Outcome | PT | D | • | company Report Humb | er. 21/109 | | Age: 15 YR | Gender: Male |
| Other | Depression Aggravated | Report Source Consumer | Product | <u> </u> | Role | Manufacturer | Route | Dose/Unit Duration |
| | Intentional Self-Injury | | Accutane | | PS | Hlr Technology | ORAL | |
| | Mood Swings | Health Professional | | | | | | |
| Date: 06/09/2000 | ISR Number: 3519272-0 | Report Type: Periodic | | C | | | | |
| Outcome | PT · | - | | Company Report Numb | er: 21/319 | | Age: 24 YR | Gender: Male |
| Other | Abdominal Pain Nos | Report Source | Product | | Role | Manufacturer | Route | Dose/Unit Duration |
| | Appetite Decreased | Consumer | Accutane | | PS | Hir Technology | ORAL | |
| | Crying | | Alcohol | | SS | | ORAL | |
| | Dehydration | | | | | | O.C. IL | |
| | Depressed Level Of | | | | | | | |
| | Consciousness Depression Aggravated | | | | | | • | |
| | Dizziness (Exc Vertigo) | | | | | | | |
| | Haematuria Present | | | | | | | |
| | Lethargy | | | | | | | |
| | | | | | | | | |

| D-4: 06/00/0000 | | | | | | | | |
|---|---|-----------------------|--------------------------------------|--------------------------|------|---------------------------------------|------------|--------------------|
| Date: 06/09/2000 | ISR Number: 3519275-6 | Report Type: Periodic | Com | pany Report Number: 217 | 403 | | Age: 14 YR | Gender: Male |
| Outcome | PT | Report Source | Product | Role | | Manufacturer | P | |
| Hospitalization - Initial or Prolonged | Depression Nec | Consumer | Accutane | PS | | Hir Technology | Route | Dose/Unit Duration |
| | | Health Professional | | 10 | | im reamology | ORAL | |
| Date: 06/09/2000 | ISR Number: 3519370-1 | Report Type: Periodic | Com | pany Report Number: 227 | 995 | | Age: 19 YR | Gender: Male |
| Outcome | PT | Report Source | Product | n.ı. | | · | | |
| Death | Completed Suicide | Health Professional | Accutane | Role PS | | Manufacturer | Route | Dose/Unit Duration |
| | Road Traffic Accident | | | ro | | HIr Technology | ORAL. | |
| Date: 06/09/2000 | ISR Number: 3519375-0 | Report Type: Periodic | Com | pany Report Number: 227 | 536 | · · · · · · · · · · · · · · · · · · · | Age: | Gender: Male |
| Outcome | PT | Report Source | Product | Role | | Manufacturer | Route | |
| Other | Suicide Attempt | Health Professional | Accutane | PS | | Hir Technology | | Dose/Unit Duration |
| Date: 06/09/2000 | ISR Number: 3519383-X | | | | | | ORAL | |
| | * * | Report Type: Periodic | Com | pany Report Number: 227 | 700 | | Age: 16 YR | Gender: Male |
| Outcome | PT | Report Source | Product | Role | . 1. | Janufacturer | Route | Description D. 11 |
| Life-Threatening | Abnormal Behaviour Nos Suicide Attempt | Health Professional | Accutane | PS | | Hr Technology | ORAL | Dose/Unit Duration |
| | - Cuciae Anempt | | Benadryl (Diphenhy Hydrochloride) | | · | an readingy | OKAL, | |
| Date: 06/09/2000 | ISR Number: 3519396-8 | Report Type: Periodic | Com | pany Report Number: 228 | 346 | | Age: 40 YR | Gender: Female |
| Outcome | PT | Report Source | Product | | | | | Gender: Female |
| Other | Mood Alteration Nos | Health Professional | Accutane | Role | _ = | /lanufacturer | Route | Dose/Unit Duration |
| | Suicidal Ideation | | | PS | ł | Ilr Technology | ORAL | |
| Date: 06/09/2000 | ISR Number: 3519400-7 | Report Type: Periodic | Com | pany Report Number: 228 | 347 | | Age: 17 YR | |
| Outcome | PT | Report Source | Product | | | | Age: 1/ IK | Gender: Male |
| Other | Abnormal Behaviour Nos | Consumer | Accutane | Role | | fanufacturer | Route | Dose/Unit Duration |
| | | | Lecutane | PS | H | Ilr Technology | ORAL | |
| Date: 06/09/2000 | ISR Number: 3519403-2 | Report Type: Periodic | Com | pany Report Number: 228 | 412 | | Age: 32 YR | 0 |
| Outcome | PT | Report Source | Product | | | | Ago. 32 IK | Gender: Female |
| Other | Depression Nec | Health Professional | Accutane | Role | | lanufacturer | Route | Dose/Unit Duration |
| | Dizziness (Exc Vertigo) Skin Papilloma | | Acculance | PS | H | Ilr Technology | ORAL | • |
| Date: 06/09/2000 | ISR Number: 3519408-1 | Report Type: Periodic | Com | pany Report Number: 2288 | 882 | | Age: 17 YR | |
| Outcome | PT | Report Source | Product | _ | | | Age: 1/YR | Gender: Male |
| Other | Parancia | Health Professional | | Role | | lanufacturer | Route | Dose/Unit Duration |
| | Psychotic Disorder Nos | - and a forestonial | Accutane | PS | · H | llr Technology | ORAL | — |

| | | | Adversa livera Repo Geologi Of Intormat | | | | |
|--|---|---------------------------|--|---------------|----------------|------------|--------------------|
| Date: 06/09/2000 | VOD N | | | | | | |
| | ISR Number: 3519411-1 | Report Type: Periodic | Company Report N | umber: 228930 | | Age: 47 YR | Gender: Female |
| Outcome | <u>PT</u> | Report Source | Product | Role | Manufacturer | D | |
| Other | Alopecia | Health Professional | Accutane | PS PS | | Route | Dose/Unit Duration |
| | Blood Cholesterol Increased Depression Nec | Company Representative | | rs | Hir Technology | ORAL | |
| Date: 06/09/2000 | ISR Number: 3519413-5 | Report Type: Periodic | Company Report N | umber: 228994 | | Age: 21 YR | Gender: Female |
| Outcome | PT | Report Source | Product | ъ. | <u>.</u> | | |
| Other | Cheilitis | Consumer | Accutane | Role | Manufacturer | Route | Dose/Unit Duration |
| | Depression Nec Epistaxis | Other | Birth Control Pill (Oral Contracepti Nos) | PS ve C | Hlr Technology | ORAL | |
| Date: 06/09/2000 | ISR Number: 3519414-7 | Report Type: Periodic | : Company Report N | nmber: 229011 | | Age: 36 YR | Gender: Female |
| Outcome | PT | Report Source | Product | | | • | Galact. Tanate |
| Other | Depression Suicidal | Consumer | | Role | Manufacturer | Route | Dose/Unit Duration |
| | Suicidal Ideation | Other | Accutane | PS | Hlr Technology | ORAL | |
| Date: 06/09/2000 | ISR Number: 3519419-6 | Report Type: Periodic | Company Report N | umber: 229393 | | Age: 15 YR | Gender: Male |
| Outcome | PT | Report Source | Product | D.1. | | | |
| Other | Depression Aggravated | Health Professional | Accutane | Role | Manufacturer | Route | Dose/Unit Duration |
| | | ; ; | Antidepressants Nos (Antidepressant Nos) | PS C | Hir Technology | ORAL | • |
| Date: 06/09/2000 | ISR Number: 3519420-2 | Report Type: Periodic | Company Report N | umber: 229461 | - | Age: 19 YR | Gender: Female |
| Outcome | PT | Report Source | Product | | | | Genuer: Pensale |
| Disability | Depression Nec | Consumer | | Role | Manufacturer | Route | Dose/Unit Duration |
| · | Dry Skin | Other | Accutane | PS | HlrTechnology | ORAL | |
| Date: 06/27/2000 | ISR Number: 3520145-8 | Report Type: Direct | Company Report No | umber: | | Age: 39 YR | Gender: Female |
| Outcome | PT | Report Source | Product | Role | Manufacturer | | _ |
| Other ' | Alopecia | | Accutane-Isotretinoin 40 Mg Roche | PS | Roche | Route | Dose/Unit Duration |
| Required Intervention o Prevent Permanent | Arthralgia | | TO MIS ROCHE | го | Rocale | ORAL | |
| mpairment/Damage | Blindness Night Dry Skin | | | | | | |
| | Headache Nos | | | | | | |
| | Hypersensitivity Nos | | | | | | |
| | Pruritus | | | | | | |
| | Social Avoidant Behaviour | | | | | | |
| | Suicidal Ideation | | | | | | |

| Date: 06/27/2000 | ISR Number: 3520219-1 | Report Type: Direct | Company Report Num | ber: | | Age: | | | |
|----------------------|--|---------------------------|-----------------------------------|-------------|----------------|------------|-----------|------------|-----|
| Outcome | PT | Report Source | Product | | | • | Gend | er: Male | |
| Death | Aphasia | Consumer | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| Life-Threatening | Cerebral Oedema | Consumer | Accutane | PS | | | | 4 | |
| Hospitalization - | Depression Nec | | | | | | | | |
| Initial or Prolonged | Diplopia | | | | | | | Ĭ., | |
| Disability | Dizziness (Exc Vertigo) | | | | | | | | |
| • | Motor Dysfunction Nos | | | | | | | | |
| | Neurological Disorder Nos | | | | | | | | |
| | Panic Attack | | | | | | | | 1 |
| | Respiratory Arrest (Exc | | | | | | | | |
| | Neonatal) | | | | | | - | | i |
| | Sedation | | | | | | | | 1 |
| | Vegetative State Chronic | | | | | | | | |
| Date: 06/27/2000 | ISR Number: 3520428-1 | Report Type: Expedited (| 5-Day) Company Report Num | ber: 214314 | | Age: | Gend | er: Female | |
| Outcome | PT | Report Source | Product | | | | | | |
| Other | Acne Infantile | Health Professional | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Birth Mark Nos | Other | Accutane | PS | Hir Technology | ORAL | | | |
| | Blood Human Chorionic | Other | Zoloft (Sextraline Hydrochloride) | С | | | | | |
| | Gonadotrophin Abnormal | | Prenatal Vitamins(Minerals | C . | | | | | - 1 |
| | Complications Of Maternal | | Nos/Multivitamins Nos) | | | | | | |
| | Exposure To Therapuetic Drugs Down'S Syndrome | | | | | | | | , |
| | Eye Discharge | | | | | | | | - 1 |
| | Meconium Increased | | | | | | | |] |
| | Pregnancy Nos | | n engan | | | | | | - 1 |
| | | | | | | | | | 1 |
| | Umbilical Cord Around Neck | | | | | | | | |
| , | Vaginal Haemorrhage | - | | | | | | | |
| Date: 06/27/2000 | ISR Number: 3520668-1 | Report Type: Expedited (1 | 5-Day) Company Barrell N | 200000 | | | | | |
| Outcome | PT | | 5-Day) Company Report Num | ber: 222823 | | Age: 32 YR | Gende | er: Female | - 1 |
| Disability | Alopecia | Report Source | Product | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Depression Nec | Consumer | Accutane | PS | Hlr Technology | ORAL | | | 1 |
| | Dizziness (Exc Vertigo) | | Ortho Tri-Cyclen (Ethinyl | С | | OKAL | | | - 1 |
| | Emotional Disturbance Nos | | Estradiol/Norgestimate) | _ | | | | | |
| | Hair Colour Changes | | | | | | | | |
| | Hair Growth Abnormal | | | | | | | | ļ |
| | Hair Texture Abnormal | | | | | | | | |
| | Headache Nos | | | | | | | | - 1 |
| | High Density Lipoprotein | | | | | | | | 1 |
| | Increased | | | | | | | | |
| | | | | | | | | | |

| | | P | e (selece | e Event Rep Of Informat | lone (11) | Report | | | | |
|-----------------|--|--------------------------|------------|----------------------------|--|-----------------|------------|-----------|-------------|---|
| ate: 06/26/2000 | ISR Number: 3520778-9 | Report Type: Expedited (| 15-Day) | Company Report P | Jumber: 235209 | | Age: 40 YR | Gen | der: Female | |
| Outcome | PT | Report Source | Product | | Role | Manufacturer | Post. | | | |
| ther | Aspartate Aminotransferase Increased | Consumer | Accutane | | PS | Hlr Technology | Route | Dose/Unit | Duration | |
| | Blood Alkaline Phosphatase Nos | | Depo-Prove | ··· | | rur i ecnnology | ORAL | | | |
| | Increased | | | | C | | | | | |
| | Blood Carbon Dioxide Decreased | | Meuroxypro | ogesterone Acetate | С | | | | | |
| | Blood Thyroid Stimulating | | | | | | | | | |
| | Hormone Decreased Blood Triglycerides Increased | | | | | | | | | |
| | Depression Nec | | | | | | | | | |
| | Dyspnoea Nos | 7 | | | | | | | | |
| | Erythema Nec | | | | | | | | | |
| | Eyelid Disorder Nos | | | | | | | | | |
| | Eyelid Oedema | | | | | | | | | |
| * | Patigue | | | | | | | | | |
| | Feeling Hot | | | | | | | | | |
| | Flushing | | | | | | | | | |
| | Goitre | | | | | | | | | |
| | Heart Rate Increased | | | | | | | | | |
| | Hyperthyroidism | | | | | | | | | |
| | Monocyte Count Increased | | | | | | | | | |
| | Rash Erythematous | | | | | | | | | |
| | Thyroxine Increased | | | | | | | | | ٠ |
| | Tri-Iodothyronine Increased | | | | | | | | | |
| | Urine Abnormal Nos | | | | er e | | | | | |
| ate: 06/26/2000 | ISR Number: 3520786-8 | Report Type: Expedited (| 15-Day) | Company Report N | umber: 234803 | | Age: 15 YR | Gene | der: Male | - |
| utcome | PT | Report Source | Product | | | 36 . | | | | |
| ther | Accident Nos | Health Professional | Accutane | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Benign Intracranial Hypertension Blindness Night | | Accuaige | | PS | Hir Technology | ORAL | | | |
| | Csf Pressure Increased | | | | | | | | | |
| | Dysarthria | | | | | | | | | |
| | Head Injury | | | | | | | | | |
| | Headache Nos | | | | | | • | | | |
| | Hypoaesthesia | | | | | | | | | |

| Date: 06/26/2000 Outcome Hospitalization - | ISR Number: 3520788-1 | | | Ollinorga | | | | | | |
|--|---|--------------------------|------------------------------|--------------------------------|----------------|----------------|------------|-----------|-------------|---|
| | | Report Type: Expedited | (15-Day) | Company Report ! | Number 225799 | | | | | |
| Joseph Hand | PT | | | ounipus, report | Number: 233766 | | Age: 17 YR | Gen | der: Male | |
| - TOSPARATICATION - | Abnormal Behaviour Nos | Report Source | Product | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| Initial or Prolonged | Bacterial Infection Nos Bipolar Disorder Nec | Health Professional | Accutance | | PS | Hlr Technology | ORAL | | | |
| | Cerebral Oedema | | | | | | 1 | 1 | | |
| | Csf Abnormal Nos | • | | | | | | 3 | | |
| | Drug Abuse | | | | | | | | | |
| | Ear Disorder Nos | | | | | | | | | |
| | Emotional Disturbance Nos | | | | | | | | | |
| | Encephalitis Nos | | | | | | | | | |
| | Headache Nos | | | | | | | | | |
| | Hearing Impaired | | | | | | | | | |
| | Herpes Simplex | | | * | | | | F. | | |
| | Mastoiditis Nos | | | | | | | ė! | | |
| | Meningeal Disorder Nos | | | | | | | 7 | | |
| | Neck Stiffness | | | | | | | | | |
| | Nuclear Magnetic Resonance Imaging Abnormal Otitis Media Nos | | | | | | | i. B | | |
| | Reaction To Spinal Or Lumbar Puncture | | | | | | | Š. | | |
| | Simusitis Acute Nos | | | | | | | | | |
| | Syncope | | | | | | | | | • |
| | Toxicology Nos Abnormal | | | | | | | | | |
| te: 06/28/2000] | ISR Number: 3521569-5 | Report Type: Expedited (| 15-Day) | Company Report N | lumber: 229263 | <u></u> | Age: | | | |
| utcome | PT | Report Source | D- 1 - | | | | Age: | Gene | ler: Female | |
| her | Agitation | Health Professional | Product | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Bronchitis Nos | Other | Accutane | | PS | Hir Technology | ORAL | | | |
| | Bronchospasm Nos Complications Of Maternal Exposure To Thempuetic Drugs | Other | Birth Contro Contraceptiv | ol Pills Nos (Oral ves Nos) | С | | | | | |
| | Cough | | | | - | | | | | |
| | Crystalluria Present | | | | | * | | | | |
| | Dermatitis Nos | | | | | | | | | |
| | Disorder Neonatal Nos | | | | | | | 3 | | |
| | Dyspnoea Nos | | | | | | | | | |
| | Eating Disorder Nec | | | | | | | | | |
| | Eosinophil Count Increased | | | | | | | | | |
| | Erythema Nec | | | • | | | | | | |
| | Haematocrit Decreased Haematuria Present | | | | | | | | | |

| Date: 06/21/2000 | ISR Number: 3521896-1 | Report Type: Expedited | (15-Day) | Company Report Numb | er: 236644 | | Age: 71 YR | Gen | der: Male | |
|---|--|---|--------------|--------------------------|------------|--|-------------|-----------|-------------|---|
| Outcome | PT | Report Source | Product | | D.1. | | | | MINIE | |
| Hospitalization - Initial or Prolonged | Atrioventricular Block First Degree | Foreign | Tasmar | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| Required Intervention | Confusion | Health Professional | | r (Benserazide/Levodopa) | PS | Hoffmann La Roche Inc | UNKNOWN | | | |
| to Prevent Permanent | Depression Nec | | 250 Mg | | SS | | ORAL | | | |
| impairment/Damage | Disorientation | | | rgolide Mesylate) | C | | | | | |
| | Dizziness (Exc Vertigo) | | Motilium (I | Oomperidone) | C | * | | | | |
| | Dystonia | | Gutron (Mi | dodrine Hydrochloride) | С | | | | | |
| | Haematocrit Decreased | | Importal (I. | actitol) | С | | | | | |
| | Haemoglobin Decreased Hallucination Nos | * | | | - | | | | | |
| | Hypoproteinaemia | | | | | | | | | |
| | Pancytopenia | | | | | | | | | |
| | Parkinson'S Disease Aggravated | | | | | | | | | |
| | Prothrombin Level Decreased | | | | | | | | | |
| | Red Blood Cell Count Decreased | | | | | | | | | |
| | Swelling Nos | | | | | | | | | |
| | Thrombocytopenia | | | | | | | | | |
| | Venous Thrombosis Deep Limb | | | | | | | | | |
| ate: 06/29/2000 | SR Number: 3522432-6 | Report Type: Expedited (| 15-Day) | Company Report Numb | . 011606 | ······································ | | | | |
| utcome | PT | | | Company Report Number | er: 211085 | | Age: 81 YR | Gen | der: Male | |
| eath | Blood Creatinine Increased | Report Source | Product | | Role | Manufacturer | Route | Dose/Unit | Duration | • |
| | . Condition Aggravated | Foreign | Tasmar | | PS | Hoffmann La Roche Inc | ORAL | | Dugadon | |
| | Confusion | Health Professional | Madopar (B | enserazide/Levodopa) | C | | - | | | |
| | Erythropenia | | | | | | | | | |
| | Haematocrit Decreased | | | | | | | | | |
| | Haemoglobin Decreased | | | | | | | | | |
| | Hypokalaemia Liver Function Tests Nos | | | | | | | | | |
| | Abnormal | | | | | | | | | |
| | Nephropathy Toxic | • | | | | | | | | |
| | Renal Failure Nos | | | | | | | | | |
| te: 06/29/2000 I | SR Number: 3522441-7 | Denovi Ton D. W. L. | | | | | | | | |
| atcome | | Report Type: Expedited (1 | 3-Day) | Company Report Number | r: 237282 | | Age: 42 YR | Gen | der: Female | |
| | PT | Report Source | Product | | Dole | Manufacture | | | | |
| sability | Abdominal Pain Nos | Consumer | Accutane | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Acne Aggravated Blood Triglycerides Decreased | Health Professional | | | 1.2 | Hir Technology | ORAL | | | |
| | Acne Aggravated | | Accutane | | PS | Hlr Technology | ORAL | | | |

| Date: 07/05/2000 Outcome Hospitalization - Initial or Prolonged | ISR Number: 3524243-4 PT | Report Type: Expedited | | Officientation | | | | | | |
|---|--|------------------------|------------|-----------------------|------------|-----------------|------------|-----------|-------------|---|
| Hospitalization - | | Report Type: Expedited | | | | | | | | |
| Hospitalization - | <u>Pr</u> | | I (15-Day) | Company Report Number | er: 232009 | | Age: 15 YR | Gen | der: Male | _ |
| | Abnormal Behaviour Nos | Report Source | Product | | Role | Manufacturer | D4- | | | |
| | Acute Psychosis | Consumer | Accutane | | PS | Hir Technology | Route | Dose/Unit | Duration | |
| | Adjustment Disorder Nec | Health Professional | | | 10 | TIII Technology | ORAL | | | |
| | Depression Nec | | | | | | | | | |
| | Educational Problem | | | | | | | | | |
| | Increased Activity | | | | | | | | | |
| | Mania | | | • . | | | | | | |
| | Psychotic Disorder Nos | | | | | | | | | |
| Date: 07/05/2000 | ISR Number: 3524399-3 | D | | | | | | | | |
| Outcome | | Report Type: Expedited | (15-Day) | Company Report Numbe | r: 235549 | * | Age: 17 YR | Gen | der: Female | |
| Life-Threatening | PT | Report Source | Product | | Role | Manufacturer | | | x canage | |
| .ne-inreatening | Abdominal Pain Upper Abrasion Nos | Consumer | Accutane | | PS | | Route | Dose/Unit | Duration | |
| | Acute Circulatory Failure | Other | | | гэ | Hlr Technology | ORAL | | | |
| | Alopecia | | | | | | | | | |
| | Anxiety Nec | | | | | | | | | |
| | Appetite Decreased | | | | | | | | | |
| | Back Pain | | | | | | | | | |
| | Blood Cholesterol Increased | | | | | | | | | |
| | Blood Glucose Decreased | | | | | | | | | |
| | Collapse | | | | | • | | | | |
| | Convulsions Nos | | | | | | | | | |
| | Depression Nec | | | | | | | | | |
| | Dermatitis Nos | | | | | | | | | |
| | Diarrhoea Nos | | | | | | | | | |
| • | Dizziness (Exc Vertigo) Dry Eye Nec | | | | | | | | | |
| | Dry Skin | | | | | | | | | |
| | Dyspnoea Nos | | • | | | | | | | |
| | Epistaxis | | | | | | | | | |
| | Erythema Nec | | | | | | | | | |
| | Eye Initation | | | | | | | | | |
| | Face Oedema | | | | | | | | | |
| | Patigue | | | | | | | | | |
| | Gastrointestinal Disorder Nos | | | | | | | | | |
| | Haemorrhage Nos | | | | | | | | | |
| | Headache Nos | | | | | | | | | |
| | Heart Rate Increased | | | | | | | | | |
| | Hot Flushes Nos Hyperventilation | | | 7 | | | | | | |

| Outcome | ISR Number: 3525992-4 | Report Type: Periodic | | Company Report Number | er: TAP1999 | 9Q00408 | Age: | 14 YR | Ge | nder: Female | e |
|-----------------|---|----------------------------|-------------|--------------------------|-------------|------------------------------------|-------|-------|-----------|--------------|---|
| Other | PT Abdominal Pain Nos | Report Source | Product | | Role | Manufacturer | Rot | ıte | Dose/Unit | Duration | |
| Juner | Asthenia | Health Professional | Prevacid | | PS | Tap Pharmaceutical Products Inc | . OR. | AL | | | - |
| | Dry Skin Gastritis Nos | | Accutane (I | (sotretinoin) | SS | | OR. | AL | | | |
| | Hyperventilation | | | | | | | | | | |
| | Melaena | | | | | | | | | | |
| | Oesophagitis | | | | | | | | | | |
| nte: 07/10/2000 | ISR Number: 3526816-1 | Report Type: Expedited (1: | 5-Day) | Company Report Numbe | er: 205994 | | Age: | 75 YR | Ge | nder: Female | |
| utcome | PT | Report Source | Product | | Dala | Manufacture | _ | | | | |
| Other | Blood Bilirubin Increased | Foreign | Tasmar | | Role PS | Manufacturer | Rot | ITE | Dose/Unit | Duration | - |
| | Dysthymic Disorder | Health Professional | | r (Benserazide/Levodopa) | C | Hoffmann La Roche Inc | | | | | |
| | Eczema Nos Hypercholesterolaemia | Other | | romocriptine Mesylate) | c | | | | | | |
| | Liver Punction Tests Nos | | | upentixol/Melitracen | c | | | | | | |
| | Abnormal | | Hydrochlor | ide) | | | | | | | |
| | Nervousness | | | ravastatin Sodium) | C | | | | | | |
| | Stress Symptoms | | Cortison (C | ortisone Acetate) | C | | | | | | |
| | | | | dio (Aspirin) | C | | | | | | |
| | | | Temesta (L | | C | | | | | | |
| | | | Rebalance (| Hypericum) | С | | | | | | |
| ate: 07/10/2000 | ISR Number: 3526970-1 | Report Type: Expedited (1. | 5-Day) | Company Report Number | er: 205994 | | Age: | 75 YR | Ge | nder: Female | |
| Outcome | - Pr | Report Source | Product | · | Role | Manufacturer | Rot | ute | Dose/Unit | Demetter | |
| Other | Blood Cholesterol Increased Dysthymic Disorder | Poreign | Tasmar | | PS | Hoffmann La Roche Inc | | | Dose Chit | Duration | - |
| | Eczema Nos | Health Professional | Madopar D | r (Benserazide/Levodopa) | C | A ROUGE INC | | | | | |
| | Liver Function Tests Nos | Other . | | romocriptine Mesylate) | С | | | | | | |
| | Abnormal | | | spentixol/Melitracen | С | | | | | | |
| | | | | avastatin Sodium) | С | | | | | | |
| | | | Cortison (C | ortiosne Acetate) | С | | | | | | |
| | | | Aspirin Car | dio (Aspirin) | С | | | | | | |
| | | | Temesta (Le | orazepam) | С | | | | | | |
| | | | | | С | | | | | | |
| | | | Rebalance (| Hypericum) | С | | | | | | |

| | | IDA | 1.000 | e Event Reporti | 100 | en (auto) | | | |
|----------------------|--|--------------------------|-------------|---|-----------|---------------------------------------|-------------|---------------|-------------|
| Date: 07/11/2000 | ISR Number: 3527341-4 | Report Type: Expedited | | E. 2. INFORTMATION Company Report Number | | Repart | Age: 60 YR | Ge | ider: Male |
| Outcome | PT | Report Source | Product | | | | - GO IK | Ga | ıder: Male |
| Other | Abdominal Pain Upper | Foreign | Tasmar | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | Constipation | Health Professional | | | PS | Hoffmann La Roche Inc | | | |
| | Dermatitis Nos | | | Benserazide/Levodopa) | C · | | | • | |
| | Erectile Disturbance Irritable Bowel Syndrome | | | (Amantadine Hydrochloride) | С | | | | |
| | Libido Decreased | | Permax (Pe | ergolide Mesylate) | С | | | | |
| Date: 07/11/2000 | ISR Number: 3527540-1 | Report Type: Expedited | (15-Day) | Company Report Numbe | 239728 | | A | - | |
| Outcome | PT | Report Source | D | | | | Age: | Ger | ıder: Male |
| Other | Apraxia | Other | Product | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | Complications Of Maternal | Other | Accutane | | PS ' | Hir Technology | ORAL | | |
| | Exposure To Therapuetic Drugs Pregnancy Nos | | | | | | | | |
| Date: 07/11/2000 | ISR Number: 3527542-5 | Report Type: Expedited | (15-Day) | Company Report Numbe | m 230060 | | | | |
| Outcome | PT | P4 C | | 1 V are part 1 million | 1. 237900 | | Age: | Gen | der: Male |
| Death | Aphasia | Report Source | Product | | Role | Manufacturer | Route | Dose/Unit | Duration . |
| | Cerebral Oederna | Consumer | Accutane | | PS | Hlr Technology | ORAL | - | 2001 |
| | Difficulty In Walking | | | | | | | | |
| | Diplopia | | | | | | | | |
| | Neurological Disorder Nos | | | | | | | | |
| | Vision Blurred | | | | | | | | |
| Date: 07/11/2000 | ISR Number: 3527625-X | Report Type: Expedited (| 15 Daw | | | · · · · · · · · · · · · · · · · · · · | | | |
| Outcome | PT | | 13-Day) | Company Report Number | r: 227868 | | Age: 18 YR | Gen | der: Male |
| Hospitalization - | Bone Disorder Nos | Report Source | Product | | Role | Manufacturer | Route | D#1-14 | . . |
| Initial or Prolonged | Depression Nec | Health Professional | Accutane | | PS | Hlr Technology | ORAL | Dose/Unit | Duration |
| - | Fatigue | | | | _ | commoney | UKAL | | |
| | Oedema Upper Limb | | | | | | | | |
| | Skin Discolouration | | | | | | | | |
| | Venous Embolism Nos | | | | | | | | |
| rate: 07/11/2000 | ISR Number: 3527629-7 | Report Type: Expedited (| IS-Day) | C | | | | | |
| utcome | PT | | is-vay) | Company Report Number | : 239779 | | Age: 30 YR | Gen | der: Female |
| Other | Acne Nos | Report Source | Product | | Role | Manufacturer | Route | Danefflett | |
| | Anxiety Nec | Consumer | Accutane | | PS | Hir Technology | | Dose/Unit | Duration |
| | Depression Nec | | Ortho Tri-C | yelen | C | realitorogy | ORAL | | |
| | Disturbance In Attention Nec | | | | Ų. | | | | |
| | Dry Mouth | | | | | | | | |

| | | File. | | EVERT Coparis | | | | | | |
|--|--|---|------------|-----------------------|-----------|-----------------------|------------|-----------|-------------|---|
| | | | | E information | | CHILD OF SEC. | | | | |
| | | | | and the second second | | 300) pro 1 | | | | |
| ite: 07/11/2000 | ISR Number: 3527632-7 | Report Type: Expedited (1 | 5 Deep | ~ | | | | | | |
| | | resport Type: Expedited () | (3-Day) | Company Report Number | r: 239876 | | Age: 15 YR | Gend | ler: Female | |
| utcome | _ <u>PT</u> | Report Source | Product | <u> </u> | Role | Manufacturer | Route | Dose/Unit | Duration | |
| lospitalization - uitial or Prolonged | Eating Disorder Nec Epistaxis | Consumer | Accutane | | PS | Hlr Technology | ORAL | | Duredon | • |
| | Haemorrhage Nos | Other | | | | | OLU ID | | | |
| | Herpes Simplex | | | | | | | | | |
| | Immune System Disorder Nos | | | | | | | | | |
| | Impetigo Nos | | | | | | | | | |
| | Lip Dry | | | | | | | | | |
| | Markedly Increased Food Intake | | | | | | | | | |
| | Nasal Ulcer | 7 | | | | | | | | |
| | Pharyngeal Ulceration | | | | | | | | | |
| | Pyrexia | | | | | | | | | |
| | Scar | | | | | | | | | |
| <u>. </u> | Weight Decreased | | | | | | | | | |
| utcome | PT | Report Type: Expedited (1 Report Source | Product | Company Report Number | | | Age: 68 YR | Gend | | |
| ther | Alanine Aminotransferase | Foreign | Tasmar | | Role | Manufacturer | Route | Dose/Unit | Duration | - |
| | Increased Blood Amylase Increased | Health Professional | Sifrol | | PS | Hoffmann La Roche Inc | | | | |
| | Blood Bilirubin Increased | | | | SS | | ORAL | | | |
| | Blood Creatine Kinase Low | | Madopar Hb | 5 | С | | | | | |
| | Blood Iron Increased | | Madopar Dr | | С | | | | | |
| | Drug Ineffective | | Jumexal | | С | | | | | |
| | Hallucination Nos | | Pk-Merz | | C. | | | | | |
| | Hyperglycaemia Nos | | Saroten | | С | | | | | |
| | Lipase Increased | | Dafalgan | | C. | | | | | |
| | | | Mst | | c | | | | | |
| | | | Effortil | | C | | | | | |
| ate: 07/11/2000 | ISR Number: 3527827-2 | Report Type: Expedited (1 | 5-Day) | Company Report Number | | | Age: 49 YR | | | |
| Outcome | <u>PT</u> | Report Source | Product | | | | | Gend | er: Male | |
| ther | Alanine Aminotransferase | Poreign | | | Role | Manufacturer | Route | Dose/Unit | Duration | |
| | Increased | Health Professional | Tasmar | | PS | Hoffmann La Roche Inc | | | | |
| | Description of the Control of the Co | | Madopar Dr | | C | | | | | |
| | Drug Ineffective | | - | | _ | | | | | |
| | Parkinson'S Disease Aggravated | | Akineton | | c | | | | | |
| | | | - | | | | | | | |

| nte: 07/14/2000 | ISR Number: 3529783-X | Report Type: Expedited | l (15-Day) | Company Report Number: | 237445 | | Age: 38 YR | Gend | der: Female |
|----------------------------|---|--------------------------------------|--|------------------------|--|--------------------------------|--------------------------|-------------------|-------------|
| utcome | PT | Report Source | Product | | Role | Manufacturer | | | |
| Other | Agoraphobia | Foreign | Roaccutane | | PS | | Route | Dose/Unit | Duration |
| | Anxiety Nec | Health Professional | Tardyferon | | C · | Hir Technology | ORAL | | |
| | Dizziness (Exc Vertigo) Hot Flushes Nos | | Varnoline | | c | | | | |
| | Palpitations | | | | | | | | |
| | Panic Attack | | | | | | | | |
| | Sweating Increased | | | | | | | | |
| ite: 07/14/2000 | ISR Number: 3529784-1 | Report Type: Expedited | (15-Day) | Company Report Number: | 240325 | | Age: 15 YR | Gend | der: Male |
| Outcome | PT | Report Source | Product | | n.ı. | | | | |
| Other | Ankylosing Spondylitis | Health Professional | Accutane | | Role PS | Manufacturer | Route | Dose/Unit | Duration |
| | Arthralgia | | . noodunit | | rs . | HlrTechnology | ORAL | | |
| | Chromosomal Abnormality Nos | | | | | | | | |
| | Depression Nec Gingivitis | | | | | | | | |
| | | | | | | | | | |
| | Haematocht Decreased | | | | | | | | |
| | Haematocrit Decreased Haemoglobin Decreased | | | | | | | | |
| nte: 07/18/2000 | | Report Type: Expedited | (15-Day) | Company Report Number: | 234822 | | Age: 44 YR | Cani | dan Famili |
| utcome | Haemoglobin Decreased Mean Cell Haemoglobin Concentration Increased ISR Number: 3531196-1 PT | Report Type: Expedited Report Source | (15-Day) Product | | | Manufacturer | Age: 44 YR | Gend | |
| Outcome | Haemoglobin Decreased Mean Cell Haemoglobin Concentation Increased ISR Number: 3531196-1 PT Acne Aggravated | | | <u> </u> | Role | Manufacturer Hir Technology | Route | Gend Dose/Unit | der: Female |
| ate: 07/18/2000 Outcome | Haemoglobin Decreased Mean Cell Haemoglobin Concentration Increased ISR Number: 3531196-1 PT Acne Aggravated Amnesia Nec | Report Source | Product | | Role PS | Manufacturer Hlr Technology | Route | | |
| Outcome | Haemoglobin Decreased Mean Cell Haemoglobin Concentation Increased ISR Number: 3531196-1 PT Acne Aggravated | Report Source Consumer | Product Accutane | : | Role PS SS | | Route ORAL ORAL | | |
| Outcome | Haemoglobin Decreased Mean Cell Haemoglobin Concentration Increased ISR Number: 3531196-1 PT Acne Aggnvated Armesia Nec Bipolar I Disorder | Report Source Consumer | Product Accutane Klonopin Lupron Depot | | Role PS SS SS | | Route | | |
| Outcome | Haemoglobin Decreased Mean Cell Haemoglobin Concentration Increased ISR Number: 3531196-1 PT Acne Aggravated Armesia Nee Bipolar I Disorder Confusion Feeling Abnormal Irritability | Report Source Consumer | Product Accutane Klonopin Lupron Depot Neurontin | | Role PS SS SS | | Route ORAL ORAL INTRAMUS | | |
| Outcome | Haemoglobin Decreased Mean Cell Haemoglobin Concentration Increased ISR Number: 3531196-1 PT Acne Aggravated Armesia Nee Bipolar I Disorder Confusion Feeling Abnormal Irritability Panic Disorder Nee | Report Source Consumer | Product Accutane Klonopin Lupron Depot Neurontin Seroquel | | Role PS SS SS C C | | Route ORAL ORAL INTRAMUS | | |
| Outcome | Haemoglobin Decreased Mean Cell Haemoglobin Concentration Increased ISR Number: 3531196-1 PT Acne Aggravated Armesia Nee Bipolar I Disorder Confusion Feeling Abnormal Irritability Panic Disorder Nee Seborthoea | Report Source Consumer | Product Accutane Klonopin Lupron Depot Neurontin Seroquel Allegra | | Role PS SS SS C C | | Route ORAL ORAL INTRAMUS | | |
| Outcome | Haemoglobin Decreased Mean Cell Haemoglobin Concentration Increased ISR Number: 3531196-1 PT Acne Aggravated Armesia Nee Bipolar I Disorder Confusion Feeling Abnormal Irritability Panic Disorder Nee | Report Source Consumer | Product Accutane Klonopin Lupron Depot Neurontin Seroquel Allegra Primrose Oil | | Role PS SS CC CC CC | | Route ORAL ORAL INTRAMUS | | |
| Outcome | Haemoglobin Decreased Mean Cell Haemoglobin Concentration Increased ISR Number: 3531196-1 PT Acne Aggravated Armesia Nee Bipolar I Disorder Confusion Feeling Abnormal Irritability Panic Disorder Nee Seborthoea | Report Source Consumer | Product Accutane Klonopin Lupron Depot Neurontin Seroquel Allegra Primrose Oil Coenzyme Qi | 0 | Role PS SS C C C C C C | | Route ORAL ORAL INTRAMUS | | |
| Outcome | Haemoglobin Decreased Mean Cell Haemoglobin Concentration Increased ISR Number: 3531196-1 PT Acne Aggravated Armesia Nee Bipolar I Disorder Confusion Feeling Abnormal Irritability Panic Disorder Nee Seborthoea | Report Source Consumer | Product Accutane Klonopin Lupron Depot Neurontin Seroquel Allegra Primrose Oil Coenzyme Q1 Garlic | o | Role PS SS CC CC CC CC CC | | Route ORAL ORAL INTRAMUS | | |
| utcome | Haemoglobin Decreased Mean Cell Haemoglobin Concentration Increased ISR Number: 3531196-1 PT Acne Aggravated Armesia Nee Bipolar I Disorder Confusion Feeling Abnormal Irritability Panic Disorder Nee Seborthoea | Report Source Consumer | Product Accutane Klosopin Lupron Depot Neurontin Seroquel Allegra Primrose Oil Coenzyme Qi Gatlic Chromium Pic | O volinate | Role PS SS C C C C C C | | Route ORAL ORAL INTRAMUS | | |
| utcome | Haemoglobin Decreased Mean Cell Haemoglobin Concentration Increased ISR Number: 3531196-1 PT Acne Aggravated Armesia Nee Bipolar I Disorder Confusion Feeling Abnormal Irritability Panic Disorder Nee Seborthoea | Report Source Consumer | Product Accutane Klonopin Lupron Depot Neurontin Seroquel Allegra Primrose Oil Coenzyme Q1 Garlic Chromium Pic Vitamin C | 0 volinate | Role PS SS SS C C C C C C C C | | Route ORAL ORAL INTRAMUS | | |
| Outcome | Haemoglobin Decreased Mean Cell Haemoglobin Concentration Increased ISR Number: 3531196-1 PT Acne Aggravated Armesia Nee Bipolar I Disorder Confusion Feeling Abnormal Irritability Panic Disorder Nee Seborthoea | Report Source Consumer | Product Accutane Klonopin Lupron Depot Neurontin Seroquel Allegra Primrose Oil Coenzyme QI Garlic Chromium Pic Vitamin C Vitamin E | 0 volinate | Role PS SS C C C C C C C C C C C C C C C C C | | Route ORAL ORAL INTRAMUS | | |
| Outcome | Haemoglobin Decreased Mean Cell Haemoglobin Concentration Increased ISR Number: 3531196-1 PT Acne Aggravated Armesia Nee Bipolar I Disorder Confusion Feeling Abnormal Irritability Panic Disorder Nee Seborthoea | Report Source Consumer | Product Accutane Klonopin Lupron Depot Neurontin Seroquel Allegra Primrose Oil Coenzyme Q1 Garlic Chromium Pic Vitamin C | O volinate | Role PS SS SS C C C C C C C C | | Route ORAL ORAL INTRAMUS | | |

| | | | resion | e Event Repor Of Informatio | 10000508 160000 | em (Ali RS). Bajart | | | |
|---|--|------------------------|--------------|--------------------------------|--------------------|------------------------|---------------------------------------|-----------|--------------|
| Date: 07/18/2000 | ISR Number: 3531302-9 | Report Type: Expedited | 1 (15-Day) | Company Report Nun | iber: 240501 | | Age: 26 YR | Ga | ider: Female |
| Outcome | _ <u>PT</u> | Report Source | Product | | n | 35 | | | Taliale |
| Hospitalization - Initial or Prolonged | Abnormal Behaviour Nos Bipolar I Disorder | Foreign | Accutane | | PS Role | Manufacturer | Route | Dose/Unit | Duration |
| | Logorhoea | Health Professional | Diane 35 | | rs C | HlrTechnology | ORAL | | |
| | Mental Disorder Nec | | | | C | | | | |
| Date: 07/19/2000 | ISR Number: 3532233-0 | | | | | -, - | | | |
| | 224 (Talliner: 3332233-0 | Report Type: Expedited | l (15-Day) | Company Report Num | ber: 239572 | | Age: 34 YR | C | |
| Outcome | PT PT | Report Source | Product | | | | · · · · · · · · · · · · · · · · · · · | Gen | ider: Female |
| Disability | Confusion | Health Professional | Accutane | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | Depressed Level Of Consciousness | | | 7-4 | PS | Hlr Technology | ORAL. | | |
| | Hypoaesthesia | | Millioniu | Interferon Alfa-2a) 6 | SS | | SUBCUTAN | | |
| | Sedation | | Vitamin E | | С | | EOUS | | |
| | Sore Throat Nos | | | | | | | | |
| Date: 07/21/2000 | ISR Number: 3534070-X | Report Type: Expedited | 45.0 | | | | | | |
| Outcome | PT | report Type: Expensed | (13-Day) | Company Report Num | ber: 240657 | | Age: 18 YR | Ger | der: Female |
| Hospitalization - | Acne Aggravated | Report Source | Product | | Role | Manufacturer | D | | |
| Initial or Prolonged | Mood Swings | Other | Accutane | | PS PS | | Route | Dose/Unit | Duration |
| | Scar | | Oral Contra | ceptive Nos (Oral | c | Hir Technology | ORAL | | |
| Date: 07/24/2000 | TODAY | | Contraceptiv | ve Nos) | | | | | |
| | ISR Number: 3534241-2 | Report Type: Expedited | (15-Day) | Company Report Num | her: 240222 | | | | |
| Outcome | PT | Report Source | | | D411 1 10111 | | Age: 17 YR | Gen | der: Male |
| lospitalization - | Blood Bilirubin Increased | Foreign | Product | | Role | Manufacturer | Route | Dose/Unit | Duration |
| nitial or Prolonged | Ileus | Other | Accutane | | PS | Hlr Technology | ORAL | | |
| | Insomnia Nec | - 4444 | | | | | | | |
| | Liver Function Tests Nos Abnormal | | | | | | | | * |
| | Vomiting Nos | | | • | | | • | | |
| ate: 07/25/2000 | ISR Number: 3534746-4 | B | | | | | | | |
| utcome | | Report Type: Expedited | (15-Day) | Company Report Numb | ber: 240963 | | Age: 18 YR | Gen | der: Female |
| | PT | Report Source | Product | | | | | Jen | remaie |
| ther | Binge Eating | Consumer | Accutane | | Role | Manufacturer | Route | Dose/Unit | Duration |
| | Depression Nec Eating Disorder Nec | Other | | | PS | Hlr Technology | ORAL | | |
| | Lang Disorder Nec | | Rhinocort (B | | С | | | | |
| | | | | ofenadine Hydrochloride) | С | | | | |
| | | | Ortho Tri Cy | clen (Ethiovi | C | | | | |

| ate: 11/07/1997 | ISR Number: 1000002015-3 | Report Type: Expedited | 1 (15 Day) Com | | 90044 | | | | |
|---|---|--------------------------------|----------------|--------------------|------------|--------------|------------|-----------|----------|
| Outcome | PT | Report Source | Product Com | pany Report Number | | | Age: 17 YR | Gende | er: Male |
| Hospitalization - Initial or Prolonged | Balance Impaired Nos Cheilitis Disturbance In Attention Nec | Poreign Health Professional | Accutane | | Role PS | Manufacturer | ORAL | Dose/Unit | Duration |
| | Dizziness (Exc Vertigo) Fatigue | | | | | | | | |
| | Headache Nos Loss Of Consciousness Nec | | | | | | | | |
| | Syncope Visual Disturbance Nos | | | | | | | | |

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