# FDA - Adverse Event Reporting System (FAERS)

## FOIA Case Report Information

## Case ID: 10035170

### Case Information:

**Case Type:** EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 21-Jul-1998 **Outcomes:** OT **Application Type:** NDA

**FDA Rcvd Date:** 25-Mar-2014 **Mfr Rcvd Date:** 04-Aug-2009 **Mfr Control #:** US-GE HEALTHCARE MEDICAL DIAGNOSTICS-OSCN-PR-0807S-0463 **Application #:** 020123

### Patient Information:

**Age:** 48 YR **Sex:** Female **Weight:**

### Suspect Products:

| # | Product Name | Compounded Drug ? | Dose/ Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date |
|---|---|---|---|---|---|---|---|---|
| 1 | OMNISCAN | | 11 ML/ | Intravenous (not otherwise specified) | | Localised oedema | 09-Feb-1999 | 09-Feb-1999 |
| 2 | GADOLINIUM (UNSPECIFIED) | | | Intravenous (not otherwise specified) | | Breast mass | 07-Apr-2008 | 07-Apr-2008 |
| 3 | GADOLINIUM (UNSPECIFIED) | | | Intravenous (not otherwise specified) | | Hepatic cancer | 09-Feb-1998 | 09-Feb-1998 |
| 4 | MAGNEVIST | | | | | Asthenia | | |
| 5 | MAGNEVIST | | | Intravenous (not otherwise specified) | | Cerebrovascular accident | 06-Jul-1998 | 06-Jul-1998 |
| 6 | MAGNEVIST | | | Intravenous (not otherwise specified) | | Headache | 12-May-1991 | 12-May-1991 |
| 7 | MAGNEVIST | | | Intravenous (not otherwise specified) | | Nervous system disorder | 24-Jun-1998 | 24-Jun-1998 |
| 8 | OMNISCAN | | | | | | 10-Oct-2003 | 10-Oct-2003 |

| # | Product Name | Interval 1st Dose to Event | DeC | ReC | Lot# | Exp Date | NDC # | MFR/Labeler | OTC |
|---|---|---|---|---|---|---|---|---|---|
| 1 | OMNISCAN | | NA | NA | | | | | |
| 2 | GADOLINIUM (UNSPECIFIED) | | NA | NA | | | | | |

## Case ID: 10035170

| | Product Name | Compounded Drug ? | Dose/ Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date |
|---|---|---|---|---|---|---|---|---|
| | Product Name | Interval 1st Dose to Event | DeC | ReC | Lot# | Exp Date | NDC # | MFR/Labeler | OTC |
| 3 | GADOLINIUM (UNSPECIFIED) | | NA | NA | | | | | |
| 4 | MAGNEVIST | | NA | NA | | | | | |
| 5 | MAGNEVIST | | NA | NA | | | | | |
| 6 | MAGNEVIST | | NA | NA | | | | | |
| 7 | MAGNEVIST | | NA | NA | | | | | |
| 8 | OMNISCAN | | NA | NA | | | | | |

**Event Information:**

| Preferred Term ( MedDRA Version: 21.0) | ReC |
|---|---|
| Nephrogenic systemic fibrosis | NA |

**Event/Problem Narrative:**

A female patient received administration of gadolinium (unspecified) and experienced NSF. Further information has been requested.

On 03-Mar-2010 this case was re-evaluated for reporting requirements of gadolinium (unspecified) adverse events.

Additional information was received via the litigation process starting on 04-Aug-2009. This information revealed:

Report # OSCN-PR-0807S-0463 is a consumer report from the USA that involves a 48 year old African American female male who experienced possible nephrogenic systemic fibrosis (NSF) after the administration of OMNISCAN (gadodiamide) for the indication of fullness in the right neck, GADOLINIUM (UNSPECIFIED) for the indication of left breast mass and liver cancer and Magnevist (gadopentetate dimeglumine) for the indications of headache, rule out central nervous system Lupus, questionable stroke, and spasmatic weakness.

Relevant past medical history included: end stage renal disease (ESRD, 1984 and 11-Oct-1999), lupus nephritis (1984), first cadaveric kidney transplant ((b) (6)), removal of first renal transplant ((b) (6)), myocardial infarction ((b) (6)), Lupus cerebritis (Oct-1999), bilateral femoral chondromalacia patellae (Oct-2000), partial parathyroidectomy ((b) (6)), atrial fibrillation, second cadaveric renal transplant ((b) (6)), chronic allograft nephropathy (18-Jan-2007), third renal transplant evaluation ((b) (6)), transplant failure of second transplant (Jun-2008), and nontoxic multinodular goiter (Sep-2010).

**Case ID: 10035170**

Concurrent medical conditions included: uncontrolled hypertension, systemic lupus erythematosis with ESRD (Sep-1984), chronic kidney disease (Jun-1998, various stages) peritoneal dialysis, hepatitis C (1995), seizures (Oct-1999), diabetes mellitus (Dapsone (diamino-diphenyl sulfone) induced, 2002), overactive parathyroid (2003), nerve damage, poor circulation, rotator cuff disease in both shoulders, osteoporosis (both wrists and spine), arthritis (both wrist and spine), gout, human papilloma virus (HPV), peritoneal dialysis (1998 to 2002 and Jun-2008 onwards), cytomegalovirus (CMV), Hepatitis B, secondary hyperparathyroidism, sensory polyneuropathy axonal and Raynauds disease.

Concomitant medications included: Absorbase cream (topical), Acular eyedrops (ketoralac tromethamine), Acyclovir, Ambien (zolpidem tartrate), Amiodarone, Amlodipine, Amoxicillin, Amphojel (aluminum hydroxide), Aranesp (darbepoetin alfa), Aspirin (acetylsalicylic acid), Atarax (hydroxyzine), Atgam (antithimocyte immunoglobulin), Avapro (irbesartan), Benadryl (diphenhydramine hydrochloride), Betadine 5 percent Ophthalmic (povidone iodine), Bicitra (shohls), Bisacodyl, Bumex (bumetanide), Calci-Mix (calcium carbonate), Calcitrol (active form of vitamin D), Calcium, Calcium gluconate, Cardizem (diltiazem), Cardura (doxazosin mesilate), Celestone (betamethasone), CellCept (mycophenolate mofetil), Cephalexin, Cholecalciferol (Vitamin D3), Cholestyramine-lLite, Ciprofloxacin, Claritin (gliclazide), Clobetasol 0.05 percent cream (clobetasol propionate), Clonidine, Colace (docusate sodium), Compazine (prochlorperazine edisylate), Coumadin (warfarin sodium), Cozaar (losartan potassium), CSA, Cyclobenzaprine, Cyclosporin, Cytovene (ganciclovir), Cytoxan intravenous (IV), Dapsone, Decadron (dexamethasone) 0.5 ml Topical, Dilantin (phenytoin), Diovan (valsartan), Diphenoxylate, Diprolene ointment (betamethasone dipropionate), Doxazosin, Ecotrin (acetylsalicylic acid), Epinephrine, Epogen (epoetin alfa), Fentanyl, Ferrlecit (IV iron), Ferrous Sulfate, Flexeril, Flonase (fluticasone propionate), fluconazole (Diflucan), Folic Acid, Fosamax (alendronate sodium), Gentamicin drops, Halcion (Triazolam), Halog (halcinonide) cream 0.1 percent, Healon intraocular (hyaluronate sodium), Hectorol (doxercalciferol), Hexavitamin Tablets (kapasovit), Hismanal (astemizole), Hydrochlorothiazide, Imdur (isosorbide mononitrate), Imodium (loperamide hydrochloride), Imuran (azathioprine), Insulin, Interferon, Iopidine gtts (apracaclonidine), Iron, Kayexalate (sodium polystyrene sulfonate), Kaopectate (bismuth subsalicylate), K-Phos (potassium phosphate monobasic), Lactulose, Lasix (furosemide), Levsin (hyoscyamine sulfate), Lidocaine, Lipitor (atorvastatin calcium), Lopressor (metoprolol tartrate), Loratadine, Losartan Potassium, Miralax (macrogel), Multivitamin, Mycophenolic Acid, Nasonex (mometasone furoate), NebuPent (pentamidine isethionate), Nephrocaps (solvito N), Nephro-Vite (solvito N), Netilmicin, Nexium (esomeprazole magnesium), Niferex (ferroflycine sulfate complex), NitroQuick (glyceryl trinitrate), Norvasc (amlodipine besilate), Nystatin, OKT3 (muromonab CD-3), Os-Cal (calcium carbonate), Oxycodone, Paxil (paroxetine hydrochloride), Percocet, Persantine (dipyridamole), Phosphorus, Plaquenil (hydroxychloroquine phosphate), Potassium chloride, Prednisone, Prevacid (lansoprazole), Prilosec (omeprazole), Procardia (nifedipine), Procrit (epoetin alfa), Prograf (tacrolimus), Pyridoxine, Quinine, Renagel (sevelamer hydrochloride), Ribavirin, Rocaltrol (calcitriol), Saline nasal spray (sodium chloride), Seldane (terfenadine), Sestamibi, Simethicone, Sirolimus (Rapamune), Spironolactone (Aldactone), TAC (triamcinolone acetonide), Tacrolimus, TBEC (pantoprazole sodium), Temazepam (Restoril), Tetravisc Topical Gel (tetracaine hydrochloride), Timoptic gtts (timolol maleate), TriLyte Oral Solution (movicol), Tums (calcium carbonate), Valium (Diazepam), Vancomycin, Venofer and Iron Sucrose (saccharated iron oxide), Versed (midazolam hydrochloride), Vibramycin (doxycycline hyclate), Vicodin, Vioxx (rofecoxib), Vitamin B12 (cyanocobalin), Vitamin B6 (pyridoxine hydrochloride), Vitamin D (ergocalciferol), Vitamin E (tocopherol), WelChol (colesevelam hydrochloride), Zantac (ranitidine hydrochloride), Zemplar (paricalcitol), Zetia (ezetimibe), Zocor (simvastatin), and Zovirax.

On 12-May-1991, the patient received Magnevist solution for injection (dose not specified) via the intravenous route (IV) for a magnetic

resonance imaging (MRI) scan of the brain for the indications of headache and rule out central nervous system Lupus. The results showed slightly prominent sulci; otherwise, no abnormality was seen.

On 09-Feb-1998 or 1999 gadolinium (unspecified) was administered. Dose and indication not provided.

On (b) (6), the patient received her first cadaveric renal transplant.
On 08-Dec-1997, two spots on her right foot that were enlarging and trace trace edema were noted.

In (b) (6), her transplanted kidney was removed and in Apr-2008 she began peritoneal dialysis.

Relevant lab data on 21-Jun-1998 included glomerular filtration rate (GFR) of 3 mL/min/1.73m2 and creatinine of 15.2 (units and normal range not provided) (CKD stage 5).

On (b) (6), the patient experienced a questionable stroke and received Magnevist (dose not specified) IV for an MRI of the brain and a magnetic resonance imaging angiography (MRA) scan of the circle of willis for the questionable stroke. The results showed abnormally increased signal intensity within the sulci as demonstrated on the FLAIR images, likely related to the patients elevated cerebrospinal fluid (CSF) protein and abnormal signal intensity in the periventricular areas bilaterally, and the basal ganglia bilaterally in the right external capsule, likely related to small vessel ischemic disease. There was evidence of hemosiderin overlying the right superior frontal lobe and within the right basal ganglia likely related to previous lacunar infarcts. No evidence of the diffusion images to suggest an acute infarction. Magnetic resonance venography (MRV) images demonstrated flow in the visualized sinuses. The right transverse sinus appears hypoplastic. Mucoperioste al thickening involving the ethmoid sinuses. Addendum: An MRA of the right intracranial carotid artery demonstrated flow in the right intracranial carotid artery as well as flow in the visualized anterior cerebral artery and MI segment. There appeared to be narrowing of a right anterior temporal branch which was off the M2 segment. Evaluation of the left intracranial carotid artery demonstrated flow in the left intracranial portion of the internal carotid artery, the visualized MCA and ACA divisions. Evaluation of the posterior fossa demonstrated flow in the visualized vertebral arteries. The right vertebral artery appeared hypoplastic. Flow was demonstrated in the basilar artery. The patient was receiving peritoneal dialysis at this time however it was unknown if she received dialysis on the day of this scan.

On 06-Jul-1998, the patient received Magnevist (dose not specified) IV for an MRI of the cervical spine for the indication of spasmatic weakness. The results showed cervical
Spinal stenosis from cervical (C)3 through C7 due to a combination of mild degenerative disease and a congenitally narrow canal and cerebellar atrophy. The patient was receiving peritoneal dialysis around the time of the scan.

On 21-Jul-1998, it was reported the patient began to experience symptom onset of possible NSF which included painless lumps of the lower extremities. On an unknown date in (b) (6), she had a myocardial infarction.

On 14-Aug-1998, the patient had a skin punch biopsy of the right forearm and right upper back (violaceous firm indurated plaques). The

diagnosis was erythematous indurated nodule, consistent with scleroderma. The microscopics revealed both specimens to show essentially similar features in that there was a fibrocellular reaction in the dermis that extended from the papillary dermis to the lower reticular dermis and into the subcutaneous fat. Additional sections stained by the Periodic acid-Schiff (PAS)/Alcian blue technique revealed that there was an increase in ground substance within the dermis. These features could be seen in scleromyxedema. Fibrocellular reaction consistent with scleromyxedema in both sites. At this time, the clinical diagnosis was Lupus panniculitis. This biopsy did not confirm NSF.

On 09-Feb-1999, the patient received OMNISCAN 11 mL solution for injection (exact dose not specified) IV for an MRI of the neck and orbits for the indication of fullness in the right neck. The results showed an unremarkable study. The patient was receiving peritoneal dialysis around the time of the scan.

On 08-Apr-1999, it was reported the patient developed lumps that were painless on her legs that were present since Jul-1998. Initially, there were only a few lumps, now they had multiplied and were all over her legs. The lumps were non tender except for the area over her ischial tuberosity which was painful with sitting. Also, the skin over her left arm had tightened and hardened. At this time, she had good range of motion (ROM) of both the upper and lower extremities. On 14-Apr-1999, an edematous plaque on the shoulder was biopsied and showed a fibrohistiocytic infiltrate suspicious for scleromyxedema. The microscopic description revealed a bisected punch specimen that showed an interstitial infiltrate of small bland-appearing spindled cells within the papillary and reticular dermis. This also appeared to extend into the septae of the subcutaneous tissue. On these hand E-stained sections, this infiltrate appeared to be associated with an increase in mucinous ground substance; however, special stains were still pending. The histologic features were suspicious for scleromyxedema. The changes were not consistent with lupus panniculitis. Evaluation for a monoclonal gammapathy was recommended. On 18-May-1999 an addendum to the previous biopsy revealed features similar to those seen in the current specimen. The previous biopsy was perhaps slightly more cellular, and the changes did not extended as deeply into the dermis as the current biopsy specimen. The Alcian blue stain revealed an increase in mucinous ground substance in the current biopsy specimen. The features overall were consistent with scleromyxedema.

In Oct-1999, she experienced ESRD and was receiving peritoneal dialysis (relevant lab data was not provided). On 14-Oct-1999, antalgic gait noted and was suspected arthropathy from Lupus.

On 15-Sep-2000, there was regression of the plaque-like, non-pruritic skin lesions which had been present since 1998. A skin exam revealed well marginated, raised plaques over the forearms, low back and thighs. In Oct-2000, she experienced bilateral knee pain which was treated with injections of both Celestone and Lidocaine.

On (b) (6), she underwent a partial parathyroidectomy (secondary hyperparathyroidism), which subsequently grew back in 2003 and was overactive.

In Jun-2001, hard skin on the legs, posterior thighs, forearms and back was noted. She also had hyperpigmented, slightly raised plaques in the antecubital fossa.

## Case ID: 10035170

On (b) (6), she received her second cadaveric renal transplant. And on 05-Sep-2002, she was clinically diagnosed with nephrogenic fibrosing dermopathy (NFD).

On 10-Sep-2002, it was noted she still had a rash on her arms, shoulder, and back since Jul-1998. She also had joint stiffness, a skin rash on her hands and feet, sun sensitivity, multiple raised flat lesions on the low back and bilateral shoulders, and scleroderma-like linear lesions on the left forearm. As of Oct-2002, there was no deterioration in her stance or gait and muscle strength was intact.

In May-2003, infiltrative plaques were seen over the thighs, back and arms. Her gait remained normal. She appeared to have the newly described entity of NFD. Scleromyxedema was in the differential diagnosis.

On 10-Oct-2003, the patient received OMNISCAN solution for injection (dose not specified) IV for an MRI of the breast for the indication of left breast mass. The results showed no evidence of left breast mass.

Relevant lab data on 16-Oct-2003 included GFR of 57 mL/min/1.73m2 and creatinine of 1.2 (units and normal range not provided) (CKD stage 2).

As of Jun-2004, gait, stance and mobility were normal. However, in Oct-2004, there was a request for handicap parking due to severely limited ability to ambulate. She was unable to easily ambulate 100 feet without assistance reportedly due to her Lupus and arthritis.

In Jan-2005, her skin showed plaque-like lesions on the arms that were now longstanding. In Feb-2005, she was seen for lumbosacral and coccygeal pain. At this time, it was reported there was no change in her gait, stance or mobility. In May-2005, an exam revealed no peripheral edema, and musculoskeletal did not exhibit any evidence of inflammatory arthritis in the joints of her upper or lower extremities. She continued to experience the hyperpigmented papular skin rash over her right antecubital fossa, as well as her thighs, lower back, left arm and posterior aspect of her neck but there was no discharge, tenderness or erythema at these lesions. She appeared to be subtly improving. In Sep-2005, there was pain and weakness in her legs and nerve damage of her legs was questioned. Weakness and pain had been a chronic problem, since at least 2000. She could walk about a half of a block, but her thighs felt weak and achy. This improved with physical therapy (PT). Electromyography (EMG) between 1998 and 2002 showed a mild progression in sensory motor axonal polyneuropathy.

In Jan-2007, she experienced an infiltrative rash on her arms, which was slowly improving over the last several years (dermatology felt it might be due to gadolinium). There was no leg edema bilaterally. On 18-Jan-2007, she experienced chronic allograft nephropathy and in Sep-2007 was evaluated for a third renal transplant. On 10-Dec-2007, it was reported that she had a history of mild NSF and complained of increased spots on her trunk. An examination revealed no change in her rash and several indurated plaques. The impression was NSF (mild disease) suspected worsening secondary to increased creatinine (lab values not provided).

In Feb-2008, her skin rash was felt to be secondary to contrast dye. Her medical diagnoses were NSF, skin rash/MRI.

## Case ID: 10035170

Relevant lab data on 28-Mar-2008 included GFR of 15 mL/min/1.73m2 and creatinine of 3.8 (units and normal range not provided). She was in CKD stage 5.

On 07-Apr-2008, the patient received Gadolinium (unspecified) solution for injection (dose not specified) IV for an MRI of the abdomen for the indication of liver cancer. The results showed normal MRI of the abdomen. On 09-Apr-2008, no rash, no malar rash, no discoid rash, and no sclerodactyly were noted. In (b) (6) her second transplant failed and she was back on peritoneal dialysis 3-4 times weekly. In (b) (6) it was reported that she was walking into walls and falling for the past three months with a total of five falls (off balance when standing up); there was no injury. In Nov-2008, NSF reported as stable and very limited for many years.

In Feb-2009, the skin on all extremities was warm and dry, all joints ranged without pain and she was doing well from a balance standpoint. In May-2009, NSF skin changes were examined on both arms. She also had worsening fibrosis on the face (periorbital areas), arms, lower back, and medial thighs. In Sep-2009, her skin had no rash but her extremities had painful ROM on the right. In Oct-2009, she experienced some itching related to her NSF.

In Jan-2010, she complained of fatigue or pain like feeling in her legs and was tired when she walked. In Feb-2010, her skin was intact (no documentation of rash or lesions). In Apr-2010, there was no deterioration in gait, stance, tension signs, mobility or shoe wear. On 11-Aug-2010, she had indurated plaques on the antecubital fossa, and lower back that were more indurated than previously. Her upper inner arm had new induration with a positive groove sign. The medial thighs had slight erythema and increased induration from last year. The periorbital areas had slight hyperpigmentation of the lower lids but no discrete induration. The lower legs had indurated skin circumferentially around the calves which spared the feet. There were no contractures. NSF was reported as limited and stable for many years. She had actually improved on Absorbase only in the setting of improved renal function after her second kidney transplant. Now NSF was slowly getting worse.

It is to be noted, the patients most marked decline was noted between 14-Jun-2004 and 15-Oct-2004 and not associated with possible NSF. The patient herself apparently attributed her own decline at that time to her Lupus and arthritis.

The clinical outcome of the patients possible NSF at the time of reporting was not recovered.

The physicians responsible for the patient's possible NSF treatment did not evaluate her symptoms against the Cowper-Girardi criteria for NSF. No Cowper-Girardi score was applied.

**Relevant Medical History:**

| Disease/Surgical Procedure | Start Date | End Date | Continuing? |
|---|---|---|---|
| Lupus nephritis | 1984 | | NO |

## Case ID: 10035170

| | | |
|---|---|---|
| RENAL FAILURE CHRONIC | 1984 | NO |
| Hypertension | Sep-1984 | YES |
| Systemic lupus erythematosus | Sep-1984 | YES |
| Hepatitis C | 1995 | YES |
| Renal transplant | (b) (6) | NO |
| Removal of renal transplant | (b) (6) | NO |
| RENAL FAILURE CHRONIC | (b) (6) | YES |
| Myocardial infarction | (b) (6) | NO |
| CONVULSION | (b) (6) | NO |
| ENCEPHALITIS | (b) (6) | NO |
| Patellofemoral pain syndrome | Oct-2000 | NO |
| Parathyroidectomy | (b) (6) | NO |
| Diabetes mellitus | 2002 | YES |
| Renal transplant | (b) (6) | NO |
| Parathyroid disorder | 2003 | YES |
| CHRONIC ALLOGRAFT NEPHROPATHY | 18-Jan-2007 | NO |
| Transplant evaluation | Sep-2007 | NO |
| Transplant failure | (b) (6) | NO |
| Goitre | Sep-2010 | NO |
| Arthritis | | YES |
| Atrial fibrillation | | NO |
| Cytomegalovirus test | | YES |
| Gout | | YES |
| Hepatitis B | | YES |

## Case ID: 10035170

| | |
|---|---|
| Hyperparathyroidism secondary | YES |
| Nerve injury | YES |
| Osteoporosis | YES |
| Papilloma viral infection | YES |
| Peripheral sensory neuropathy | YES |
| Peritoneal dialysis | YES |
| Poor peripheral circulation | YES |
| ROTATOR CUFF SYNDROME | YES |
| Raynaud's phenomenon | YES |

| Medical History Product(s) | Start Date | End Date | Indications | Events |
|---|---|---|---|---|

### Relevant Laboratory Data:

| Test Name | Result | Unit | Normal Low Range | Normal High Range | Info Avail |
|---|---|---|---|---|---|
| GLOMERULAR FILTRATION RATE | 3 | mL/min/1.73m2 | | | N |
| skin biopsy | does not confirm NSF | (no units) | | | N |
| GLOMERULAR FILTRATION RATE | 57 | mL/min/1.73m2 | | | N |
| creatinine | 3.8 | (no units) | | | N |
| creatinine | 15.2 | (no units) | | | N |
| creatinine | 1.2 | (no units) | | | N |
| GLOMERULAR FILTRATION RATE | 15 | mL/min/1.73m2 | | | N |

### Concomitant Products:

| # | Product Name | Dose/ Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date | Interval 1st Dose to Event |
|---|---|---|---|---|---|---|---|---|
| 1 | ABSORBASE | | Topical | | | | | |

## Case ID: 10035170

| | Product Name | Dose/ Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date | Interval 1st Dose to Event |
|---|---|---|---|---|---|---|---|---|
| 2 | ACULAR LS | | Ophthalmic | | | | | |
| 3 | ACYCLOVIR | | | | | | | |
| 4 | AMBIEN | | | | | | | |
| 5 | AMIODARONE | | | | | | | |
| 6 | AMLODIPINE | | | | | | | |
| 7 | AMOXICILLIN | | | | | | | |
| 8 | AMPHOJEL | | | | | | | |
| 9 | ARANESP | | | | | | | |
| 10 | ASPIRIN | | | | | | | |
| 11 | ATARAX | | | | | | | |
| 12 | ATGAM | | | | | | | |
| 13 | AVAPRO | | | | | | | |
| 14 | BENADRYL | | | | | | | |
| 15 | BETADINE | | Ophthalmic | | | | | |
| 16 | BICITRA | | | | | | | |
| 17 | BISACODYL | | | | | | | |
| 18 | BUMEX | | | | | | | |
| 19 | CACLIUM GLUCONATE | | | | | | | |
| 20 | CALCI-MIX | | | | | | | |
| 21 | CALCITROL | | | | | | | |
| 22 | CALCIUM | | | | | | | |

## Case ID: 10035170

| | Product Name | Dose/ Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date | Interval 1st Dose to Event |
|---|---|---|---|---|---|---|---|---|
| 23 | CARDIZEM | | | | | | | |
| 24 | CARDURA | | | | | | | |
| 25 | CELESTONE | | | | | | | |
| 26 | CELLCEPT | | | | | | | |
| 27 | CEPHALEXIN | | | | | | | |
| 28 | CHOLECALCIFEROL | | | | | | | |
| 29 | CHOLESTYRAMINE LIGHT | | | | | | | |
| 30 | CIPROFLOXACIN | | | | | | | |
| 31 | CLARITIN | | | | | | | |
| 32 | CLOBETASOL 0.05% | | | | | | | |
| 33 | CLONIDINE | | | | | | | |
| 34 | COLACE | | | | | | | |
| 35 | COMPAZINE | | | | | | | |
| 36 | COUMADIN | | | | | | | |
| 37 | COZAAR | | | | | | | |
| 38 | CYCLOBENZAPRINE | | | | | | | |
| 39 | CYCLOSPORIN | | | | | | | |
| 40 | CYTOVENE IV | | | | | | | |
| 41 | CYTOXAN | | Intravenous (not otherwise specified) | | | | | |
| 42 | DAPSONE | | | | | | | |

## Case ID: 10035170

| | Product Name | Dose/ Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date | Interval 1st Dose to Event |
|---|---|---|---|---|---|---|---|---|
| 43 | DECADRON | | Topical | | | | | |
| 44 | DILANTIN | | | | | | | |
| 45 | DIOVAN | | | | | | | |
| 46 | DIPHENOXYLATE | | | | | | | |
| 47 | DIPROLENE | | | | | | | |
| 48 | DOXAZOSIN | | | | | | | |
| 49 | ECOTRIN | | | | | | | |
| 50 | EPINEPHRINE | | | | | | | |
| 51 | EPOGEN | | | | | | | |
| 52 | FENTANYL | | | | | | | |
| 53 | FERRLECIT | | Intravenous (not otherwise specified) | | | | | |
| 54 | FLONASE | | | | | | | |
| 55 | FLUCONAZOLE | | | | | | | |
| 56 | FOLIC ACID | | | | | | | |
| 57 | FOSAMAX | | | | | | | |
| 58 | GENTAMICIN | | | | | | | |
| 59 | HALCION | | | | | | | |
| 60 | HALOG | | | | | | | |
| 61 | HEALON | | Intraocular | | | | | |
| 62 | HECTOROL | | | | | | | |

## Case ID: 10035170

| | Product Name | Dose/ Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date | Interval 1st Dose to Event |
|---|---|---|---|---|---|---|---|---|
| 63 | HEXAVITAMIN | | | | | | | |
| 64 | HISMANAL | | | | | | | |
| 65 | HYDROCHLOROTHIAZIDE | | | | | | | |
| 66 | IMDUR | | | | | | | |
| 67 | IMODIUM | | | | | | | |
| 68 | IMURAN | | | | | | | |
| 69 | INSULIN | | | | | | | |
| 70 | INTERFERON NOS | | | | | | | |
| 71 | IOPIDINE | | | | | | | |
| 72 | IRON | | | | | | | |
| 73 | K-PHOS | | | | | | | |
| 74 | KAOPECTATE | | | | | | | |
| 75 | KAYEXALATE | | | | | | | |
| 76 | LACTULOSE | | | | | | | |
| 77 | LASIX | | | | | | | |
| 78 | LEVSIN | | | | | | | |
| 79 | LIDOCAINE | | | | | | | |
| 80 | LIPITOR | | | | | | | |
| 81 | LOPRESOR | | | | | | | |
| 82 | LORATADINE | | | | | | | |
| 83 | LOSARTAN | | | | | | | |

## Case ID: 10035170

| | Product Name | Dose/ Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date | Interval 1st Dose to Event |
|---|---|---|---|---|---|---|---|---|
| 84 | MIRALAX | | | | | | | |
| 85 | MULTIVITAMIN | | | | | | | |
| 86 | MUROMONAB-CD3 | | | | | | | |
| 87 | MYCOPHENOLIC ACID | | | | | | | |
| 88 | NASONEX | | | | | | | |
| 89 | NEBUPENT | | | | | | | |
| 90 | NEPHRO-VITE | | | | | | | |
| 91 | NEPHROCAPS | | | | | | | |
| 92 | NETILMICIN | | | | | | | |
| 93 | NEXIUM | | | | | | | |
| 94 | NIFEREX (POLYSACCHARIDE-IRON COMPLEX) | | | | | | | |
| 95 | NITROQUICK | | | | | | | |
| 96 | NORVASC | | | | | | | |
| 97 | NYSTATIN | | | | | | | |
| 98 | OS-CAL | | | | | | | |
| 99 | OXYCODONE | | | | | | | |
| ** | PANTOPRAZOLE SODIUM | | | | | | | |
| ** | PAXIL | | | | | | | |
| ** | PERCOCET | | | | | | | |
| ** | PERSANTINE | | | | | | | |

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| | Product Name | Dose/ Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date | Interval 1st Dose to Event |
|---|---|---|---|---|---|---|---|---|
| ** | PHOSPHORUS | | | | | | | |
| ** | PLAQUENIL | | | | | | | |
| ** | POTASSIUM CHLORIDE | | | | | | | |
| ** | PREDNISONE | | | | | | | |
| ** | PREVACID | | | | | | | |
| ** | PRILOSEC | | | | | | | |
| ** | PROCARDIA | | | | | | | |
| ** | PROCRIT | | | | | | | |
| ** | PROGRAF | | | | | | | |
| ** | PYRIDOXINE | | | | | | | |
| ** | QUININE | | | | | | | |
| ** | RENAGEL | | | | | | | |
| ** | RIBAVIRIN | | | | | | | |
| ** | ROCALTROL | | | | | | | |
| ** | SALINE | | Nasal | | | | | |
| ** | SELDANE | | | | | | | |
| ** | SIMETHICONE | | | | | | | |
| ** | SIROLIMUS | | | | | | | |
| ** | SPIRONOLACTONE | | | | | | | |
| ** | TAC | | | | | | | |
| ** | TACROLIMUS | | | | | | | |

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| | Product Name | Dose/ Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date | Interval 1st Dose to Event |
|---|---|---|---|---|---|---|---|---|
| ** | TEMAZEPAM | | | | | | | |
| ** | TETRAVISC | | Topical | | | | | |
| ** | TIMOPTIC | | Ophthalmic | | | | | |
| ** | TRILYTE | | Oral | | | | | |
| ** | TUMS | | | | | | | |
| ** | VALIUM | | | | | | | |
| ** | VANCOMYCIN | | | | | | | |
| ** | VENOFER | | | | | | | |
| ** | VERSED | | | | | | | |
| ** | VIBRAMYCIN | | | | | | | |
| ** | VICODIN | | | | | | | |
| ** | VIOXX | | | | | | | |
| ** | VITAMIN B-12 | | | | | | | |
| ** | VITAMIN B6 | | | | | | | |
| ** | VITAMIN D | | | | | | | |
| ** | VITAMIN E | | | | | | | |
| ** | WELCHOL | | | | | | | |
| ** | ZANTAC | | | | | | | |
| ** | ZEMPLAR | | | | | | | |
| ** | ZETIA | | | | | | | |
| ** | ZOCOR | | | | | | | |

# FDA - Adverse Event Reporting System (FAERS)

## FOIA Case Report Information

## Case ID: 10035170

| | Product Name | Dose/ Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date | Interval 1st Dose to Event |
|---|---|---|---|---|---|---|---|---|
| ** | ZOVIRAX | | Topical | | | | | |

**Reporter Source:**

**Study Report?:** No

**Sender Organization:** GE HEALTHCARE

**503B Compounding Outsourcing Facility?:**

**Literature Text:**