Skip to main content

Cefpodoxmine Proxetil (Vantin)

??? ??????: 30 ??????/?????? 2017

Clinical Trials

Film-coated Tablets (Multiple dose)

of cefpodoxime proxetil film-coated tablets, 4696 patients were treated with the recommended dosages of cefpodoxime (100 to **multiple doses** In clinical trials using 400 mg Q 12 hours). There were no deaths or permanent disabilities thought related to drug toxicity. One-hundred twenty-nine (2.7%) patients discontinued medication due to adverse events thought possibly or probably related to drug toxicity. Ninety-three (52%) of the 178 patients who discontinued therapy (whether -thought related to drug therapy or not) did so because of gastrointestinal disturbances, nausea, vomiting, or diarrhea. The percentage of cefpodoxime proxetil treated patients who discontinued study drug because of adverse events was significantly greater at a dose of 800 mg daily than at a dose of 400 mg daily or at a dose of 200 mg daily. Adverse events thought possibly or probably related to cefpodoxime in multiple-dose clinical trials (N=4696 cefpodoxime-treated patients) were:

Incidence Greater Than 1%

Diarrhea 7.0%

Diarrhea or loose stools were dose-related: decreasing from 10.4% of patients receiving 800 mg per day to 5.7% for those receiving 200 mg per day. Of patients .)**WARNINGS** organism or toxin in the stool. (See *C. difficile*with diarrhea, 10% had

Nausea 3.3%
Vaginal Fungal Infections 1.0%
Vulvovaginal Infections 1.3%
Abdominal Pain 1.2%
Headache 1.0%

Incidence Less Than 1%: By body system in decreasing order

Clinical Studies

Adverse events thought possibly or probably related to cefpodoxime proxetil that occurred in less than 1% of patients (N=4696)

fungal infections, abdominal distention, malaise, fatigue, asthenia, fever, chest pain, back pain, chills, generalized pain, abnormal microbiological tests, **Body -** moniliasis, abscess, allergic reaction, facial edema, bacterial infections, parasitic infections, localized edema, localized pain.

congestive heart failure, migraine, palpitations, vasodilation, hematoma, hypertension, hypotension. **Cardiovascular -**

vomiting, dyspepsia, dry mouth, flatulence, decreased appetite, constipation, oral moniliasis, anorexia, eructation, gastritis, mouth ulcers, gastrointestinal **Digestive -** disorders, rectal disorders, tongue disorders, tooth disorders, increased thirst, oral lesions, tenesmus, dry throat, toothache.

anemia. **Hemic and Lymphatic -**

dehydration, gout, peripheral edema, weight increase. **Metabolic and Nutritional -**

myalgia. **Musculo-skeletal -**

dizziness, insomnia, somnolence, anxiety, shakiness, nervousness, cerebral infarction, change in dreams, impaired concentration, confusion, nightmares, **Nervous -** paresthesia, vertigo.

asthma, cough, epistaxis, rhinitis, wheezing, bronchitis, dyspnea, pleural effusion, pneumonia, sinusitis. **Respiratory -**

urticaria, rash, pruritus non-application site, diaphoresis, maculopapular rash, fungal dermatitis, desquamation, dry skin non-application site, hair loss, **Skin -** vesiculobullous rash, sunburn.

taste alterations, eye irritation, taste loss, tinnitus. **Special Senses -**

hematuria, urinary tract infections, metrorrhagia, dysuria, urinary frequency, nocturia, penile infection, proteinuria, vaginal pain. **Urogenital -**

Granules for Oral Suspension (Multiple dose)

In clinical trials using multiple doses of cefpodoxime proxetil granules for oral suspension, 2128 pediatric patients (93% of whom were less than 12 years of age) were treated with the recommended dosages of cefpodoxime (10 mg/kg/day Q 24 hours or divided Q 12 hours to a maximum equivalent adult dose). There were no deaths or permanent disabilities in any of the patients in these studies. Twenty-four patients (1.1%) discontinued medication due to adverse events thought possibly or probably related to study drug. Primarily, these discontinuations were for gastrointestinal disturbances, usually diarrhea, vomiting, or rashes.

Adverse events thought possibly or probably related, or of unknown relationship to cefpodoxime proxetil for oral suspension in multiple-dose clinical trials (N=2128 patients treated with cefpodoxime) were:

Incidence Greater Than 1%

Diarrhea 6.0%

The incidence of diarrhea in infants and toddlers (age 1 month to 2 years) was 12.8%.

Diaper rash/Fungal skin rash 2.0% (includes moniliasis)

The incidence of diaper rash in infants and toddlers was 8.5%.

Other skin rashes 1.8%

Vomiting 2.3%

Incidence Less Than 1%

Localized abdominal pain, abdominal cramp, headache, monilia, generalized abdominal pain, asthenia, fever, fungal infection. **Body:**

Nausea, monilia, anorexia, dry mouth, stomatitis, pseudomembranous colitis. **Digestive:**

Thrombocythemia, positive direct Coombs' test, eosinophilia, leukocytosis, leukopenia, prolonged partial thromboplastin time, **Hemic & Lymphatic:** thrombocytopenic purpura.

Increased SGPT. **Metabolic & Nutritional:**

Myalgia. **Musculo-Skeletal:**

Hallucination, hyperkinesia, nervousness, somnolence. **Nervous:**

Epistaxis, rhinitis. **Respiratory:**

Skin moniliasis, urticaria, fungal dermatitis, acne, exfoliative dermatitis, maculopapular rash. **Skin:**

Taste perversion. **Special Senses:**

Film-coated Tablets (Single dose)

In clinical trials using a single dose of cefpodoxime proxetil film-coated tablets, 509 patients were treated with the recommended dosage of cefpodoxime (200 mg). There were no deaths or permanent disabilities thought related to drug toxicity in these studies.

Adverse events thought possibly or probably related to cefpodoxime in single-dose clinical trials conducted in the United States were:

Incidence Greater Than 1%

Nausea 1.4%

Diarrhea 1.2%

Incidence Less Than 1%

Dizziness, headache, syncope. **Central Nervous System:**

Rash. **Dermatologic:**

Vaginitis. **Genital:**

Abdominal pain. **Gastrointestinal:**

Anxiety. **Psychiatric:**

Laboratory Changes

Significant laboratory changes that have been reported in adult and pediatric patients in clinical trials of cefpodoxime proxetil, without regard to drug relationship, were:

Transient increases in AST (SGOT), ALT (SGPT), GGT, alkaline phosphatase, bilirubin, and LDH. ***:Hepatic***

Eosinophilia, leukocytosis, lymphocytosis, granulocytosis, basophilia, monocytosis, thrombocytosis, decreased hemoglobin, decreased hematocrit, ***:Hematologic*** leukopenia, neutropenia, lymphocytopenia, thrombocytopenia, thrombocythemia, positive Coombs' test, and prolonged PT, and PTT.

Hyperglycemia, hypoglycemia, hypoalbuminemia, hypoproteinemia, hyperkalemia, and hyponatremia. ***:Serum Chemistry***

Increases in BUN and creatinine. ***:Renal***

Most of these abnormalities were transient and not clinically significant.

Post-marketing Experience

The following serious adverse experiences have been reported: allergic reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme and serum sickness-like reactions, pseudomembranous colitis, bloody diarrhea with abdominal pain, ulcerative colitis, rectorrhagia with hypotension, anaphylactic shock, acute liver injury, in utero exposure with miscarriage, purpuric nephritis, pulmonary infiltrate with eosinophilia, and eyelid dermatitis.

One death was attributed to pseudomembranous colitis and disseminated intravascular coagulation.

Cephalosporin Class Labeling

In addition to the adverse reactions listed above which have been observed in patients treated with cefpodoxime proxetil, the following adverse reactions and altered laboratory tests have been reported for cephalosporin class antibiotics:

Renal dysfunction, toxic nephropathy, hepatic dysfunction including cholestasis, aplastic anemia, hemolytic ***:Adverse Reactions and Abnormal Laboratory Tests*** anemia, serum sickness-like reaction, hemorrhage, agranulocytosis, and pancytopenia.

DOSAGE Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced. (See .) If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be **OVERDOSAGE** and **AND ADMINISTRATION** given if clinically indicated.