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CEFOPROX Tablets/DT/Powder for Oral Suspension (Cefpodoxime proxetil)

Composition

CEFOPROX-200 Tablets
Each film-coated tablet contains:
Cefpodoxime proxetil IP equivalent to
Cefpodoxime ..... 200 mg
Colour: Sunset Yellow FCF, Ponceau 4R & Titanium dioxide
CEFOPROX-50 Oral suspension
Each 5 ml (after reconstitution) contains:
Cefpodoxime proxetil IP equivalent to
Cefpodoxime..... 50 mg
In a flavoured base
CEFOPROX-100 Oral suspension
Each 5 ml (after reconstitution) contains:
Cefpodoxime proxeti lP equivalent to
Cefpodoxime..... 100 mg
In a flavoured base
CEFOPROX-100 DT
Each dispersible uncoated tablet contains:
Cefpodoxime proxetil IP equivalent to
Cefpodoxime.....100 mg
In a flavoured base
Colour : Lake Quinoline Yellow WS

Dosage Form/s

Film-coated tablet, powder for oral suspension and dispersible tablet.

Pharmacology

▶ Pharmacodynamics

Cefpodoxime proxetil is an orally administered, extended-spectrum, semi-synthetic antibiotic of the cephalosporin class. Cefpodoxime is a bactericidal agent that acts by inhibition of bacterial cell wall synthesis.
Cefpodoxime has activity in the presence of some beta-lactamases, both penicillinases and cephalosporinases, of Gram-negative and Gram-positive bacteria.
Microbiology

The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infections is questionable.

Antibacterial Spectrum

Commonly Susceptible Species

Aerobic Gram Positive Organisms:

Staphylococcus aureus (Methicillin susceptible)

Streptococcus pyogenes

Aerobic Gram Negative Organisms*:*

Haemophilus influenzae

Moraxella catarrhalis

Proteus mirabilis+

Species for which Acquired Resistance may be a Problem

Aerobic Gram Positive Organisms

Streptococcus pneumoniae

Aerobic Gram Negative Organisms

*Citrobacter freundi**

*Enterobacter cloacae**

Escherichia coli+

Klebsiella pneumoniae+

*Serratia marcescens**

Inherently Resistant Organisms

Aerobic Gram Negative Organisms

Morganella morganii

Pseudomonas aeruginosa.

Aerobic Gram Positive Organisms

Staphylococcus aureus (methicillin resistant)

Enterococcus spp.

Others

Chlamydia spp.

Chlamydophila spp.

Legionella pneumophila

Mycoplasma spp.

Note:

* natural intermediate susceptibility

+ ESBL producing species are always resistant

▶ Pharmacokinetics

Cefpodoxime proxetil is a prodrug that is absorbed from the gastrointestinal tract and de-esterified to its active metabolite, cefpodoxime. Following oral administration of 100 mg of cefpodoxime proxetil to fasting subjects, approximately 50% of the administered cefpodoxime dose was absorbed systemically. A 100 mg dose of oral suspension produced an average peak cefpodoxime concentration of approximately 1.5 mcg/mL.

When a 200 mg dose of the suspension was taken with food, the extent of absorption (mean AUC) and mean

peak plasma concentration in fed subjects were not significantly different from fasted subjects, but the rate of absorption was slower with food (48% increase in T_{max}). The volume of distribution is 32.3 L and peak levels of cefpodoxime occur 2 to 3 hrs after dosing. The maximum plasma concentration is 1.2 mg/L and 2.5 mg/L after doses of 100 mg and 200 mg respectively. Protein binding of cefpodoxime ranges from 22% to 33% in serum and from 21% to 29% in plasma. Concentrations of cefpodoxime in excess of the minimum inhibitory levels (MIC) for common pathogens can be achieved in lung parenchyma, bronchial mucosa, pleural fluid, tonsils, interstitial fluid and prostate tissue.

As the majority of cefpodoxime is eliminated in the urine, the concentration is high. (Concentrations in 0-4, 4-8, 8-12 hr fractions after a single dose exceed MIC_{90} of common urinary pathogens). Good diffusion of cefpodoxime is also seen into renal tissue, with concentrations above MIC_{90} of the common urinary pathogens, 3-12 hrs after an administration of a single 200 mg dose (1.63.1µg/ g). Concentrations of cefpodoxime in the medullary and cortical tissues is similar.

Studies in healthy volunteers show median concentrations of cefpodoxime in the total ejaculate 6-12 hrs following administration of a single 200 mg dose to be above the MIC_{90} of *N. gonorrhoeae*. The main route of excretion is renal, 80% is excreted unchanged in the urine, with an elimination half-life of approx 2.4 hours. Over the recommended dosing range (100–400 mg), approximately 29–33% of the administered cefpodoxime dose was excreted unchanged in the urine in 12 hours. There is minimal metabolism of cefpodoxime *in vivo.*

Special Population

Renal Impairment

Elimination of cefpodoxime is reduced in patients with moderate to severe renal impairment (<50 mL/min creatinine clearance). In subjects with mild impairment of renal function (50 to 80 mL/min creatinine clearance), the average plasma half-life of cefpodoxime was 3.5 hours. In subjects with moderate (30 to 49 mL/min creatinine clearance) or severe renal impairment (5 to 29 mL/min creatinine clearance), the half-life increased to 5.9 and 9.8 hours, respectively. Approximately 23% of the administered dose was cleared from the body during a standard 3-hour hemodialysis procedure.

Hepatic Impairment

Absorption was somewhat diminished and elimination unchanged in patients with cirrhosis. The mean cefpodoxime T1/2 and renal clearance in cirrhotic patients were similar to those derived in studies of healthy subjects. Ascites did not appear to affect values in cirrhotic subjects. No dosage adjustment is recommended in this patient population.

Geriatrics

Elderly subjects do not require dosage adjustments unless they have diminished renal function.

Indications

CEFOPROX Tablets/Oral Suspension/DT are indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the conditions listed below:

Acute otitis media caused by *Streptococcus pneumoniae*, (excluding penicillin-resistant strains), *Streptococcus pyogenes, Haemophilus influenzae* (including beta-lactamase-producing strains), or *Moraxella (Branhamella) catarrhalis* (including beta-lactamase-producing strains).

Pharyngitis and/or tonsillitis caused by *Streptococcus pyogenes.* NOTE: Only penicillin by the intramuscular route of administration has been shown to be effective in the prophylaxis of rheumatic fever. Cefpodoxime proxetil is generally effective in the eradication of streptococci from the oropharynx. However, data establishing the efficacy of cefpodoxime proxetil for the prophylaxis of

subsequent rheumatic fever are not available.
Community-acquired pneumonia caused by *Streptococcus pneumoniae* or *Haemophilus influenzae* (including beta-lactamase-producing strains).
Acute bacterial exacerbation of chronic bronchitis caused by *Streptococcus pneumoniae, Haemophilus influenzae* (non-beta-lactamase-producing strains only), or *Moraxella catarrhalis*. Data are insufficient at this time to establish efficacy in patients with acute bacterial exacerbations of chronic bronchitis caused by beta-lactamase-producing strains of *Haemophilus influenzae*.
Acute, uncomplicated urethral and cervical gonorrhea caused by *Neisseria gonorrhoeae* (including penicillinase-producing strains).
Acute, uncomplicated ano-rectal infections in women due to *Neisseria gonorrhoeae* (including penicillinase-producing strains).

> NOTE: The efficacy of cefpodoxime in treating male patients with rectal infections caused by *Neisseria gonorrhoeae* has not been established. Data do not support the use of cefpodoxime proxetil in the treatment of pharyngeal infections due to *Neisseria gonorrhoeae* in men or women.

Uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (including penicillinase-producing strains) or *Streptococcus pyogenes.* Abscesses should be surgically drained as clinically indicated.

> NOTE: In clinical trials, successful treatment of uncomplicated skin and skin structure infections was dose-related. The effective therapeutic dose for skin infections was higher than those used in other recommended indications.

Acute maxillary sinusitis caused by *Haemophilus influenzae* (including beta-lactamase-producing strains), *Streptococcus pneumoniae,* and *Moraxella catarrhalis*.
Uncomplicated urinary tract infections (cystitis) caused by *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis*, or *Staphylococcus saprophyticus*. NOTE: In considering the use of cefpodoxime proxetil in the treatment of cystitis, the lower bacterial eradication rates of cefpodoxime proxetil should be weighed against the increased eradication rates and different safety profiles of some other classes of approved agents.

Dosage And Administration

The tablets should be taken with food to enhance absorption.
The recommended dosages, durations of treatment, and applicable patient population are as described in the following chart:

▶ Patients with normal Renal Function (Tablets and Granules for Oral Suspension)

Adults and adolescents (aged 12 years and older)			
Type of Infection	Total Daily Dose	Dose Frequency	Duration
Pharyngitis and/or tonsillitis	200 mg	100 mg Q12 hours	5–10 days
Acute community-acquired pneumonia	400 mg	200 mg Q 12 hours	14 days
Acute bacterial exacerbations of chronic bronchitis	400 mg	200 mg Q 12 hours	10 days

Uncomplicated gonorrhea (men and women) and rectal gonococcal infections (women)	200 mg	single dose	
Skin and skin structure	800 mg	400 mg Q 12 hours	7–14 days
Acute maxillary sinusitis	400 mg	200 mg Q 12 hours	10 days
Uncomplicated urinary tract infection	200 mg	100 mg Q12 hours	7 days

Granules for Oral Suspension

Oral suspension may be given without regard of food. The recommended dosages, durations of treatment and applicable patient populations are as described in the following chart.

Infants and pediatric patients (age 2 months through 12 years)			
Type of Infection	Total Daily Dose	Dose Frequency	Duration
Acute otitis media	10 mg/kg/day (Max 400 mg/day)	5 mg/kg Q12 hours (Max 200 mg/dose)	5 days
Pharyngitis and/or tonsillitis	10 mg/kg/day (Max 200 mg/day)	5 mg/kg Q 12 hours (Max 100 mg/dose)	5–10 days
Acute maxillary sinusitis	10 mg/kg/day (Max 400 mg/day)	5 mg/kg Q 12 hours (Max 200 mg/dose)	10 days

Patients with Impaired Renal Function

Adults

The dosage of CEFOPROX Tablets/Oral Suspension/DT does not require modification if creatinine clearance exceeds 40 $ml.min^{-1}/1.73m^2$.

Below this value, pharmacokinetic studies indicate an increase in the plasma elimination half-life and the maximum plasma concentrations; hence, the dosage should be adjusted appropriately.

Creatinine Clearance (mL/min)	
39–10	Unit dose[1] administered as a single dose every 24 hours (ie, half of the usual adult dose).
<10	Unit dose[1] administered as a single dose every 48 hours (ie, quarter of the usual adult dose).
Hemodialysis patients	Unit dose[1] administered after each dialysis session. The dose frequency should be three times/week after hemodialysis

NOTE: [1]The unit dose is either 100 mg or 200 mg, depending on the type of infection.

When only the serum creatinine level is available, the following formula (based on sex, weight, and age of the patient) may be used to estimate creatinine clearance (mL/min). For this estimate to be valid, the serum creatinine level should represent a steady state of renal function.

Males (mL/min)	Weight (kg) x (140 – age) 72 x serum creatinine (mg/100 mL)
Females (mL/min)	0.85 x above value

▶ Pediatrics Use

There is no data available in the case of pediatric patients with impaired renal function.

▶ Patients with Cirrhosis

Cefpodoxime pharmacokinetics in cirrhotic patients (with or without ascites) are similar to those in healthy subjects. Dose adjustment is not necessary in this population.
CEFOPROX tablets should be swallowed whole without chewing.
CEFOPROX Oral Suspension is provided in the form of a dry powder for reconstitution. Tap the bottle to loosen the powder. Add two-thirds of the sterile water (provided with the pack) and shake the bottle vigorously. Add more water up to the mark on the bottle and shake well. Allow the suspension to stand for 5 minutes. After mixing, the suspension should be stored in a refrigerator, 2–8°C (36–46°F). Shake well before using. Keep the container tightly closed. The mixture may be used for 14 days. Discard the unused portion after 14 days.
CEFOPROX DT should be dispersed in a teaspoonful (5 ml) of boiled and cooled water before administration.

Contraindications

Cefpodoxime proxetil is contraindicated in patients with a known allergy to cefpodoxime or to the cephalosporin group of antibiotics or to any of the excipients.
It is also contraindicated in patients with previous history of immediate and / or severe hypersensitivity reaction (anaphylaxis) to penicillin or other betalactam antibiotic.

Warnings And Precautions

Cefpodoxime is not a preferred antibiotic for the treatment of staphylococcal pneumonia and should not be used in the treatment of atypical pneumonia caused by organisms such as *Legionella, Mycoplasma* and *Chlamydia*. Cefpodoxime is not recommended for the treatment of pneumonia due to *S. pneumoniae*
As with all beta-lactam antibacterial agents, serious and occasionally fatal hypersensitivity reactions have been reported. In case of severe hypersensitivity reactions, treatment with cefpodoxime must be discontinued immediately and adequate emergency measures must be initiated.
Before therapy with cefpodoxime proxetil is instituted, a detailed inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cefpodoxime, other cephalosporins, penicillins, or other drugs. If cefpodoxime is to be administered to penicillin-sensitive patients, caution should be exercised because cross-hypersensitivity among beta-lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. As with all beta-lactam antibacterial agents, serious and occasionally fatal hypersensitivity reactions have been reported. In case of severe hypersensitivity reactions, treatment with cefpodoxime must be discontinued immediately and adequate emergency measures must be initiated. Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen, intravenous fluids,

intravenous antihistamine, and airway management, as clinically indicated. Caution should be used if cefpodoxime is given to patients with a history of non-severe hypersensitivity to other beta-lactam agents.
Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Cefpodoxime proxetil, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.
C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.
If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.
A concerted effort to monitor for *C. difficile* in cefpodoxime-treated patients with diarrhea was undertaken because of an increased incidence of diarrhea associated with *C. difficile* in early trials in normal subjects. *C. difficile* organisms or toxin was reported in 10% of the cefpodoxime-treated adult patients with diarrhea; however, no specific diagnosis of pseudomembranous colitis was made in these patients.
Pseudomembranous colitis has been reported with nearly all antibacterial agents, including cefpodoxime, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of cefpodoxime proxetil.
Discontinuation of therapy with cefpodoxime and the administration of specific treatment for *Clostridium difficile* should be considered. Medicinal products that inhibit peristalsis should not be given. In post-marketing experience outside the United States, reports of pseudomembranous colitis associated with the use of cefpodoxime proxetil have been received.
In patients with transient or persistent reduction in urinary output due to renal impairment, the total daily dose of cefpodoxime proxetil should be reduced because high and prolonged serum antibiotic concentrations can occur in such individuals following usual doses. Cefpodoxime, like other cephalosporins, should be administered with caution to patients receiving concurrent treatment with potent diuretics. Discontinuation of therapy with cefpodoxime and the administration of specific treatment for Clostridium difficile should be considered. Medicinal products that inhibit peristalsis should not be given.
Cefpodoxime should always be prescribed with caution in patients with a history of gastrointestinal disease, particularly colitis.
As with all beta-lactam antibiotics, neutropenia and more rarely agranulocytosis may develop particularly during extended treatment. For cases of treatment lasting longer than 10 days, the blood count should be monitored and treatment discontinued if neutropenia is found.
Cephalosporins may be absorbed onto the surface of red cell membranes and react with antibodies directed against the drug. This can produce a positive Coomb's test and very rarely, haemolytic anaemia. Cross-reactivity may occur with penicillin for this reaction.
Changes in renal function have been observed with cephalosporin antibiotics, particularly when given concurrently with potentially nephrotoxic drugs such as aminoglycosides and/or potential diuretics. In such cases, renal function should be monitored.
In cases of severe renal insufficiency it may be necessary to reduce the dosage regimen dependent on the creatinine clearance.
As with other antibiotics, prolonged use of cefpodoxime may result in the overgrowth of non-susceptible organisms (candida and Clostridium difficile), which may require interruption of treatment. Repeated

evaluation of the patient's condition is essential. If superinfection occurs during therapy, appropriate measures should be taken.
Prescribing cefpodoxime proxetil in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

▶ Information for Patients

Patients should be counseled that antibacterial drugs including cefpodoxime proxetil should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When cefpodoxime proxetil is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by cefpodoxime proxetil or other antibacterial drugs in the future.
Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

▶ Drug Interactions

Antacids: Concomitant administration of high doses of antacids (sodium bicarbonate and aluminum hydroxide) or H_2 blockers reduces peak plasma levels by 24–42% and the extent of absorption by 27–32%, respectively. The rate of absorption is not altered by these concomitant medications. Oral anti-cholinergics (eg, propantheline) delay peak plasma levels (47% increase in T_{max}), but do not affect the extent of absorption (AUC).
Probenecid: As with other beta-lactam antibiotics, renal excretion of cefpodoxime was inhibited by probenecid and resulted in an approximately 31% increase in AUC and a 20% increase in peak cefpodoxime plasma levels.
Nephrotoxic Drugs: Although nephrotoxicity has not been noted when cefpodoxime proxetil was given alone, close monitoring of renal function is advised when cefpodoxime proxetil is administered concomitantly with compounds of known nephrotoxic potential.
Oral Anticoagulants: Simultaneous administration of cefpodoxime with warfarin may augment its anticoagulant effects. There have been many reports of increases in oral anticoagulant activity in patients receiving antibacterial agents, including cephalosporins. The risk may vary with the underlying infection, age and general status of the patient so that the contribution of the cephalosporins to the increase in INR (international normalised ratio) is difficult to assess. It is recommended that the INR should be monitored frequently during and shortly after coadministration of cefpodoxime with an oral anticoagulant agent.
Studies have shown that bioavailability is decreased by approximately 30% when cefpodoxime is administered with drugs which neutralise gastric pH or inhibit acid secretions. Therefore, such drugs as antacids of the mineral type and H2 blockers such as ranitidine, which can cause an increase in gastric pH, should be taken 2 to 3 hours after Cefpodoxime administration.
Cephalosporins potentially enhance the anticoagulant effect of coumarins and reduce the contraceptive effect of oestrogens.
Drug/Laboratory Test Interactions
Interaction with Laboratory tests
A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with

copper sulphate test tablets, but not with tests based on enzymatic glucose oxidase reactions.
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Sunset yellow (E110) may cause allergic reactions.
Cephalosporins, including cefpodoxime proxetil, are known to occasionally induce a positive direct Coombs' test.

▶ Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal carcinogenesis studies of cefpodoxime proxetil have not been performed. Mutagenesis studies of cefpodoxime, including the Ames test both with and without metabolic activation, the chromosome aberration test, the unscheduled DNA synthesis assay, mitotic recombination and gene conversion, the forward gene mutation assay and the *in vivo* micronucleus test, were all negative. No untoward effects on fertility or reproduction were noted when 100 mg/kg/day or less (2 times the human dose based on mg/m^2) was administered orally to rats.

▶ Pregnancy

Pregnancy Category B
There are no adequate and well-controlled studies of cefpodoxime proxetil use in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. CEFOPROX Tablets/Oral Suspension/DT should be used during pregnancy only if clearly needed.

▶ Lactation

Because of the potential for serious reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Cefpodoxime is excreted in breast milk in small amounts. Cefpodoxime may be used during breastfeeding. Continuation of breastfeeding should be questioned in case of diarrhoea or mucosal fungus infection in the breastfed infant. The possibility of sensitisation should be borne in mind.

▶ Pediatric use

Safety and efficacy in infants less than 2 months of age have not been established.

▶ Geriatric Use

Dose adjustment in elderly patients with normal renal function is not necessary.

▶ Effects on Ability to Drive and Use Machines

Dizziness has been reported during treatment with cefpodoxime and may affect the ability to drive and use machines.

Undesirable Effects

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 with diarrhea, 10% had *C. difficile* organism or toxin in the stool. (See WARNINGS AND PRECAUTIONS.)
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:

Body: fungal infections, abdominal distention, malaise, fatigue, asthenia, fever, chest pain, back pain, chills, generalized pain, abnormal microbiological tests, moniliasis, abscess, allergic reaction, facial edema, bacterial infections, parasitic infections, localized edema, localized pain.
Cardiovascular: congestive heart failure, migraine, palpitations, vasodilation, hematoma, hypertension, hypotension.
Digestive: vomiting, dyspepsia, dry mouth, flatulence, decreased appetite, constipation, oral moniliasis, anorexia, eructation, gastritis, mouth ulcers, gastrointestinal disorders, rectal disorders, tongue disorders, tooth disorders, increased thirst, oral lesions, tenesmus, dry throat, toothache.
Hemic and Lymphatic: anemia.
Metabolic and Nutritional: dehydration, gout, peripheral edema, weight increase.
Musculo-skeletal: myalgia.
Nervous: dizziness, insomnia, somnolence, anxiety, shakiness, nervousness, cerebral infarction, change in dreams, impaired concentration, confusion, nightmares, paresthesia, vertigo.
Respiratory: asthma, cough, epistaxis, rhinitis, wheezing, bronchitis, dyspnea, pleural effusion, pneumonia, sinusitis.
Skin: urticaria, rash, pruritus non-application site, diaphoresis, maculopapular rash, fungal dermatitis, desquamation, dry skin non-application site, hair loss, vesiculobullous rash, sunburn.
Special Senses: taste alterations, eye irritation, taste loss, tinnitus.
Urogenital: hematuria, urinary tract infections, metrorrhagia, dysuria, urinary frequency, nocturia, penile infection, proteinuria, vaginal pain.
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 as follows:

▶ 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%

Body: Localized abdominal pain, abdominal cramp, headache, monilia, generalized abdominal pain, asthenia, fever, fungal infection.
Digestive: Nausea, monilia, anorexia, dry mouth, stomatitis, pseudomembranous colitis. *Hemic & Lymphatic:* Thrombocythemia, positive direct Coombs' test, eosinophilia, leukocytosis, leukopenia, prolonged partial thromboplastin time, thrombocytopenic purpura.

Metabolic & Nutritional: Increased SGPT.
Musculo-Skeletal: Myalgia.
Nervous: Hallucination, hyperkinesia, nervousness, somnolence.
Respiratory: Epistaxis, rhinitis.
Skin: Skin moniliasis, urticaria, fungal dermatitis, acne, exfoliative dermatitis, maculopapular rash.
Special Senses: Taste perversion.
Metabolic and Nutritional: Increased SGPT,
Nervous: Hallucination, hyperkinesia, nervousness, somnolence, Headache, paraesthesia,dizziness,
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%

Nervous sSystem: Dizziness, headache, syncope
Dermatologic: Rash.
Genital: Vaginitis.
Gastrointestinal: Abdominal pain.
Psychiatric: Anxiety.
The additional adverse events as per the EMC data were as follows:
Gastrointestinal disorders
Common: Gastric pressure bloody diarrhea can occur as a symptom of enterocolitis.
Bloody diarrhea can occur as a symptom of enterocolitis.
Metabolism and nutrition disorders:Common: Loss of appetite
Immune system disorders: Hypersensitivity reactions of all degrees of severity have been observed. Very rare immune system disorders include; anaphylactic reactions, bronchospasm, purpura and angioedema
Hepato-biliary disorders
Rare: Transient moderate elevations of ASAT, ALAT and alkaline phosphatase and/or bilirubin. These laboratory abnormalities which may be explained by the infection, may rarely exceed twice the upper limit of the named range and elicit a pattern of liver injury, usually cholestatic and most often asymptomatic.
Very rare: liver damage
Skin and subcutaneous tissue disorders:
Very rare: Stevens- Johnson syndrome, toxic epidermal necrolysis and erythema multiforme

▶ 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:
Adverse Reactions and Abnormal Laboratory Tests: Renal dysfunction, toxic nephropathy, hepatic dysfunction including cholestasis, aplastic anemia, hemolytic anemia, serum sickness-like reaction, hemorrhage, agranulocytosis, and pancytopenia.
Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced. If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.
If you experience any side-effects, talk to your doctor or pharmacist or write to drugsafety@cipla.com. You can also report side effects directly via the national pharmacovigilance program of India by calling on 1800 180 3024.
By reporting side-effects, you can help provide more information on the safety of this product.

Overdosage

In the event of serious toxic reaction from overdosage, hemodialysis or peritoneal dialysis may aid in the removal of cefpodoxime from the body, particularly if renal function is compromised. The toxic symptoms following an overdose of beta-lactam antibiotics may include nausea, vomiting, epigastric distress, and diarrhea. In cases of overdosage, particularly in patients with renal insufficiency, encephalopathy may occur. The encephalopathy is usually reversible once cefpodoxime plasma levels have fallen.

Storage And Handling Instructions

Store in a cool, dry place.
Protect from light.

Special Precautions For Disposal And Other Handling

Any unused product or waste material should be disposed off in accordance with local requirements.

Packaging Information

CEFOPROX-200 Tablets
Strip pack of 10 tablets
CEFOPROX-50/CEFOPROX-100 Oral suspension
Bottle of 30 ml
CEFOPROX-100 DT
Strip pack of 10 tablets

Last updated: Oct 2018
Last reviewed: Oct 2018

CEFOPROX Tablets/DT/Powder for Oral Suspension