Cefodox®

Cefpodoxime (Proxetil)

Composition

Cefodox® 100mg Tablet: Each tablet contains Cefpodoxime proxetil equivalent to 100 mg cefpodoxime.

Cefodox® 200mg Tablet: Each tablet contains Cefpodoxime proxetil equivalent to 200 mg cefpodoxime.

Cefodox® 50mg Dry Suspension: Each 5 ml contains Cefpodoxime proxetil equivalent to 50 mg cefpodoxime.

Cefodox® 100mg Dry Suspension: Each 5 ml contains Cefpodoxime proxetil equivalent to 100 mg cefpodoxime.

Pharmacological Properties

Cefodox® (Cefpodoxime proxetil) is an orally active, broad spectrum, semisynthetic third generation cephalosporin. Cefpodoxime proxetil is a prodrug that undergoes de-esterification to the active metabolite cefpodoxime. Cefpodoxime proxetil is rapidly absorbed after oral administration reaching peak plasma concentration within 2-3 hours. It is widely distributed to most body tissues. Cefpodoxime proxetil undergoes minimal metabolism and almost 33% of the dose is excreted unchanged renally.

Cefpodoxime proxetil inhibits bacterial cell wall synthesis and exerts a bactericidal activity against a wide range of gram positive and gram negative bacteria with a high stability in the presence of beta lactamase enzymes. It is usually active against the following organisms in vitro and in clinical infections.

G +ve Aerobes

Streptococcus pneumoniae
Streptococcus pyogenes
Staphylococcus aureus (including B lactamase producing strains)
Staphylococcus saprophyticus

G -ve Aerobes

Eschirechia coli
Haemophilus influenzae (including B lactamase producing strains)
Klebsiella pneumoniae
Moraxella (Branhamella) catarrhalis (including B lactamase producing strains)
Neisseria gonorrhea
Proteus mirabilis

G +ve Anaerobes

Peptostreptococcus magnus

Use in Geriatric

No need to adjust the dose in elderly patients as no overall differences in effectiveness or safety was observed between elderly and younger patients.

Patients with Renal Dysfunction

Dosing intervals should be increased to be every 24 hours in patients with severe renal impairment (<30 ml/min creatinine clearance).

Patients with Cirrhosis

No need to adjust the dose in cirrhotic patients with or without ascites as the pharmacokinetic of cefpodoxime proxetil is not affected.

Contraindications

Cefpodoxime proxetil is contraindicated in patients with known allergy to cefpodoxime proxetil or to the cephalosporin group of

Cefodox is generally well tolerated and most encountered side effects are mild and transient including: GIT upset, vaginal fungal infection, abdominal pain, rash, headache, nausea and vomiting. Similar to other broad spectrum antibiotics, pseudomembranous colitis may be expected although rarely reported.

Warnings and Precautions

Like other cephalosporins, Cefpodoxime proxetil should be administered with caution to patients receiving concurrent treatment with potent diuretic.

As with other antibiotics, prolonged administration of cefpodoxime proxetil may result in overgrowth of non-susceptible microorganisms. If super infection occurs during therapy, appropriate measures should be taken.

The total daily dose of cefpodoxime proxetil should be reduced in patients with transient or persistent renal insufficiency because of high and prolonged serum cefpodoxime concentration, which can occur in such individuals.

Like other cephalosporins, cefpodoxime is known to induce a positive direct coombs test, and transient changes in hepatic and hematologic laboratory results which are not clinically significant.

Indications

- Upper respiratory tract infections including pharyngitis, tonsillitis,sinusitis and otitis media
- Lower respiratory tract infections including acute exacerbation of chronic bronchitis and community acquired pneumonia.
- Skin and soft tissue infections
- Urinary tract infections
- Acute uncomplicated urethral, cervical and anorectal gonorrhea.

Dosage and Administration

Cefodox® tablet should be taken with food to enhance the absorption due to the effect of food in increasing the bioavailabilty of cefpodoxime proxetil. This effect is limited to the tablet dosage form only. **Cefodox®** suspension can be given without regard to food.

Type of Infection	Total Daily Dose	Dose Frequency	
Adults 12 years and older			
Tonsilitis/ Pharyngitis	200mg	100mg q 12 hours	5-10 days
Bronchitis and AECB	400mg	200mg q 12 hours	10 days
Acute community acquired Pneumonia	400mg	200mg q 12 hours	14 days
Skin and soft tissue infections	800mg	400mg q 12 hours	7-14 days
Uncomplicated urinary tract infections	200mg	100mg q 12	7 days
Sinusitis	400mg	200mg q 12	10 days
Uncomplicated gonorrhea	200mg	Single dose	
Children (2 months to 12 years)			
Tonsilitis/ Pharyngitis	10mg/kg/day (Max 200mg/day)	5mg/kg/dose q 12 h (Max 100mg/dose)	5-10 days
Otitis media	10mg/kg/day (Max 400mg/day)	5mg/kg q 12 h (Max 200mg/dose)	5 days
Sinusitis	10mg/kg/day (Max 400mg/day)	5mg/kg q 12 h (Max 200mg/dose)	10 days

Use in Pediatric

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

Drug Interactions

Concomitant administration with high doses of antacids or H2 blockers reduces peak plasma concentration by 24% to 42% and the extent of absorption by 27 to 32% but has no effect on the rate of absorption

As with other ß-lactam antibiotic, renal excretion of cefpodoxime is inhibited by probenecid resulting in 20% increase in peak plasma levels and 31% in AUC.

Close monitoring of renal function is advised when cefpodoxime proxetil is administered concomitantly with compounds of known nephrotoxic drugs.

Overdose

In the event of serious toxic reaction from cefpodoxime proxetil overdosage, hemodialy is or peritoneal dialy is are indicated particularly if renal function is compromised.

Use in Pregnancy and Lactation

Pregnancy category B :

No evidence of teratogenic effect is seen in animals at a dose up to 100mg/kg/day, however no adequate well controlled studies in pregnant women are available, thus cefpodoxime proxetil should be used during pregnancy only if clearly needed.

Nursing Mothers

Cefpodoxime proxetil, can be used by lactating women only if clearly needed according to physicians assessment to the importance of the drug to the nursing mother.

Presentation

Cefodox 100mg Tablet: 10 tablets per pack.
Cefodox® 2 mg Tablet: 10 tablets per pack
Cefodox 1 g Dry Suspension: 50 ml bottle.
Cefodox 100mg Dry Suspension: 50 ml bottle.

(This is a medicament - keep medicaments out of reach of children)

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, method for use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Pharma International

Rev. date June. 2007 I 021 02