Only for the use of Medical Professionals

Cefdox®

Cefpodoxime

Description

Cefdox® is the preparation of Cefpodoxime Proxetil, an orally administered extended spectrum, semi-synthetic 3rd generation antibiotic of Cephalosporin class. Like other β-lactam antibiotics it is a bactericidal drug that acts by inhibition of bacterial cell wall synthesis.

Indication

Cefdox® is indicated in the following diseases-

- Lower respiratory tract infections: Acute community acquired pneumonia, acute bacterial exacerbation of chronic bronchitis
- Upper respiratory tract infections: Acute otitis media, acute maxillary sinusitis, pharyngitis, tonsillitis.
- Sexually transmitted diseases: Acute uncomplicated urethral & cervical gonorrhea, acute ano-rectal infection in women caused by *N. gonorrhea.*
- Uncomplicated urinary tract infections: Cystitis, Pyuria.
- Skin and soft tissue infections: Furuncle, cellulitis, subcutaneous abscess, infectious atheroma & periproctal abscess.

Dosage & Administration

Cefdox® capsule should be administered orally with food. **Cefdox®** suspension and pediatric drops may be given regardless of food

Adults

- Upper respiratory tract infections (but in Pharyngitis and tonsillitis reserved for infections which are recurrent, chronic or resistant to other antibacterials): 100mg twice daily (200mg twice daily in sinusitis)
- Lower respiratory tract infections (including bronchitis and pneumonia): 100-200mg twice daily
- Skin and soft tissue infections: 200mg twice daily
- Uncomplicated urinary tract infections: 100mg twice daily (200mg twice daily in uncomplicated upper urinary tract infections)
- Uncomplicated gonorrhea: 200mg as a single dose

Children

The recommended doses in children for 5-14 days according to the severity of the infection are as follows:

- 15 days – 6 months : 4mg/kg every 12 hours
- 6 months – 2 years : 40mg every 12 hours
- 3 – 8 years : 80mg every 12 hours
- Over 9 years : 100mg every 12 hours

Patients with renal dysfunction: For patients with severe renal impairment (creatinine clearance <30ml/min) the dosing intervals should be increased to 24 hourly.

Patients with liver cirrhosis: Pharmacokinetics of Cefpodoxime Proxetil in cirrhotic patients is similar to those in healthy subjects. Dose adjustment is not necessary in this population.

Use in pregnancy and lactation

Cefpodoxime was neither teratogenic nor embryocidal in animal trial. There is however, no adequate and well controlled study of Cefpodoxime Proxetil use in pregnant woman. The

drug should be used during pregnancy only if clearly needed. Because Cefpodoxime is excreted in human milk & there is potential risk of serious reactions in nursing infants, a decision should be made whether to discontinue breast-feeding or to discontinue the drug.

Precautions
In patients with transient or persistent reduction in urinary output due to renal insufficiency, the total daily dose of Cefpodoxime Proxetil should be reduced. Cefpodoxime, like other Cephalosporins, should be administered with caution to patients receiving concurrent treatment with potent diuretics. As with other broad spectrum antibiotics, prolonged use of Cefpodoxime Proxetil may result in overgrowth of non-susceptible organisms. Repeated evaluation of the patient's condition is essential.

Side effects
Cefpodoxime Proxetil has very few side effects. The side effects include diarrhea, nausea, skin & vaginal fungal infection, abdominal pain, headache, chest pain, myalgia, dyspepsia, dizziness, vertigo, cough etc. In children incidence of fungal skin rash is more than in adults.

Contraindications
Cefpodoxime Proxetil is contraindicated in patients with known hypersensitivity to Cefpodoxime or to the Cephalosporin group of antibiotics.

Over dosage
Over dosage may cause toxic reaction. Toxic symptoms include nausea, vomiting, epigastric distress and diarrhea.

Drug Interactions
Antacids: Concomitant administration of high doses of antacids (sodium bicarbonate and aluminium hydroxide) or H2 blockers reduce peak plasma level by 24% to 42% and the extent of absorption by 27% to 32%, respectively
Probenecid: Renal excretion of Cefpodoxime was inhibited by probenecid and resulted in an approximately 31% increase in AUC.
Nephrotoxic drugs: Close monitoring of renal function is advised when Cefpodoxime Proxetil is administered concomitantly with compounds of known nephrotoxic potential

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

Presentation
Cefdox® 100mg capsule **:** White body and white cap capsule. Each capsule contains Cefpodoxime 100mg as Proxetil USP.
Cefdox® Powder for Suspension **:** Light yellow colored, mint and banana flavored dry powder for suspension. When reconstituted each 5ml suspension contains Cefpodoxime 40mg as Proxetil USP
Cefdox® DS Powder for Suspension**:** Light yellow colored, mint and banana flavored dry powder for suspension. When reconstituted each 5ml suspension contains Cefpodoxime 80mg as Proxetil USP
Cefdox® Pediatric Drops **:** Light yellow colored, banana and mango flavored drops. When reconstituted each ml contains Cefpodoxime 20mg as Proxetil USP

Direction for reconstitution
<u>50ml suspension</u>

Shake the bottle well to loosen the powder. Add 30ml (6 tea spoonfuls) of boiled and cooled water to the dry mixture in the bottle. For ease of preparation add water to the bottle in two portions. Shake the bottle well after each addition until all the powder is mixed in the suspension

50ml DS suspension

Shake the bottle well to loosen the powder. Add 32.5ml (6.5 tea spoonfuls) of boiled and cooled water to the dry mixture in the bottle. For ease of preparation add water to the bottle in two portions. Shake the bottle well after each addition until all the powder is mixed in the suspension

15ml Pediatric drop

Shake the bottle well to loosen the powder. Add 10ml (2 tea spoonfuls) of boiled and cooled water to the dry mixture in the bottle. For ease of preparation add water to the bottle in two portions. Shake the bottle well after each addition until all the powder is mixed in the pediatric drops

Note

Shake the suspension and pediatric drops well before each use. Keep the bottle tightly closed. The reconstituted suspension and pediatric drops should be stored in a cool and dry place, preferably in refrigerator and unused portion should be discarded after 10 days.

Package quantities

Cefdox® 100mg capsule	: Carton of 6 capsules in Alu-Alu blister.
Cefdox® Powder for Suspension	: Bottle of 50ml.
Cefdox® DS Powder for Suspension	: Bottle of 50ml.
Cefdox® Paediatric Drops	: Bottle of 15ml.

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code no.3215/C