Cefodox®
Cefpodoxime Proxetil

Composition

Cefodox® 100mg Tablet: Each tablet contains Cefpodoxime proxetil equivalent to 100mg cefpodoxime.
Cefodox® 200mg Tablet: Each tablet contains Cefpodoxime proxetil equivalent to 200mg cefpodoxime.
Cefodox® 50mg Dry Suspension: Each 5ml contains Cefpodoxime proxetil equivalent to 50mg cefpodoxime.
Cefodox® 100mg Dry Suspension: Each 5ml contains Cefpodoxime proxetil equivalent to 100mg 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 & 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 β lactamase producing strains)
Staphylococcus saprophyticus

G -ve Aerobes
Eschirechia coli
Haemophilus influenzae (including β lactamase producing strains)
Klebsiella pneumoniae
Moraxella (Branhamella) catarrhalis (including β lactamase producing strains)
Neisseria gonorrhea
Proteus mirabilis
**G +v Anaerobes**
Peptostreptococcus magnus

**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 & anorectal gonorrhea.

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

<table>
<thead>
<tr>
<th>Type of Infection</th>
<th>Total Daily Dose</th>
<th>Dose Frequency</th>
<th>Duration of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adults 12 years and older</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tonsillitis/Pharyngitis</td>
<td>200mg</td>
<td>100mg q 12 hours</td>
<td>5-10 days</td>
</tr>
<tr>
<td>Bronchitis and AECB</td>
<td>400mg</td>
<td>200mg q 12 hours</td>
<td>10 days</td>
</tr>
<tr>
<td>Acute community acquired Pneumonia</td>
<td>400mg</td>
<td>200mg q 12 hours</td>
<td>14 days</td>
</tr>
<tr>
<td>Skin and soft tissue infections</td>
<td>800mg</td>
<td>400mg q 12 hours</td>
<td>7-14 days</td>
</tr>
<tr>
<td>Uncomplicated urinary tract infections</td>
<td>200mg</td>
<td>100mg q 12 hours</td>
<td>7 days</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>400mg</td>
<td>200mg q 12 hours</td>
<td>10 days</td>
</tr>
<tr>
<td>Uncomplicated gonorrhea</td>
<td>200mg</td>
<td>Single dose</td>
<td></td>
</tr>
</tbody>
</table>

**Children (2 months to 12 years)**

<table>
<thead>
<tr>
<th>Type of Infection</th>
<th>Total Daily Dose</th>
<th>Dose Frequency</th>
<th>Duration of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tonsillitis/Pharyngitis</td>
<td>10mg/kg/day (Max 200mg/day)</td>
<td>5mg/kg/dose q 12 h (Max 100mg/dose)</td>
<td>5-10 days</td>
</tr>
</tbody>
</table>
**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 & efficacy in infants less than 2 months of age have not been established.

**Use in Geriatric**
No need to adjust the dose in elderly patients as no overall differences in effectiveness or safety were observed between elderly & 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 antibiotics.

**Side effects**
Cefodox® is generally well tolerated & possible encountered side effects are mild & 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.

**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 β-lactam antibiotic, renal excretion of cefpodoxime is inhibited by probencid 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.

**Overdosage**
In the event of serious toxic reaction from cefpodoxime proxetil overdosage, hemodialysis or peritoneal dialysis 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.

**Presentations**
- **Cefodox® 100mg Tablet:** 10 tablets per pack.
- **Cefodox® 200mg Tablet:** 10 tablets per pack.
- **Cefodox® 50mg Dry Suspension:** 50ml bottle.
- **Cefodox® 100mg Dry Suspension:** 50ml bottle.