CEFIZOX®
HIKMA PHARMACEUTICALS

(Sterile Ceftizoxime sodium)

Action
Cefizox developed by Fujisawa Research Laboratories is a semisynthetic, broad spectrum, Beta-lactamase resistant cephalosporin antibiotic for parenteral administration (IV, IM).

Indications
Cefizox is effective against a wide range of the following bacteria: Gram-positive bacteria: Staphylococcus aureus (including penicillinase and non-penicillinase producing strains); Staphylococcus epidermidis (including penicillinase and non-penicillinase producing strains), streptococcus agalactiae, Streptococcus pneumoniae, Streptococcus pyogenes. Gram-negative bacteria: acinetobacter, Enterobacter, Escherichia coli, Haemophilus influenzae (including ampicillin-resistant strains); Klebsiella pneumoniae, Morganella morganii; Neisseria gonorrhoeae; Proteus mirabilis, Proteus vulgaris, Providencia rettgeri, Serratia marcescens. Anaerobic bacteria Bacteroides species, Peptococcus, Peptostreptococcus, Eubacterium and clostridium species. Cefizox is usually active against the following organisms in vitro but the clinical significance is unknown: Corynobacterium diphtheriae, Aeromonous hydrophela, Citrobacter species, Moragsilla species, Neisseria meningitides, Pasteurella multicida, Providencia stuartii, Salmonella species, Shigella species, Yersinia enterocolitica, Actenomycis species, Bifidobacterium species, Clostridium Species, Eubacterium species, Fusobacterium species, Propionibacterium species, Veillonella species. Thus, Cefizox is indicated for the treatment of:

• Lower respiratory tract infections
• Skin and soft tissue infections
• Urinary tract infections
• Bone and joint infections
• Gonorrhea
• Meningitis

• Gynaecological infections
• Septicaemia
• Intra-abdominal infections including biliary infections
• Perioperative prophylaxis of infections
• Pelvic inflammatory infections

Dosage and administration
Usual adult dose: 1-2 g of Cefizox every 8-12 hours IM or IV.
Gonorrhea (uncomplicated): Single 1 g IM dose.
Urinary tract infections: 0.5-1 g every 12 hours IM or IV.
Septicaemia: 6-12 g/day may be given IV divided into 3 doses.
The maximum daily dose should not exceed 12 g.

Usual pediatric dose: (6 months of age and older): 50 mg/kg/body weight every 6-8 hours IM or IV.
Dosage may be increased to 200 mg/kg/day (not to exceed the maximum adult dose for serious infections).

Dosage in renal impairment: Modification of dosage is necessary in patients with impaired renal function. For an adult, following an initial loading dose of 0.5-1 g IM or IV, the maintenance dosing schedule should be as follows:

<table>
<thead>
<tr>
<th>Creatinine clearance (ml/min)</th>
<th>Moderate infections</th>
<th>Severe or life threatening infections</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-79</td>
<td>0.5g every 8 hours</td>
<td>0.75-1.5g every 8 hours</td>
</tr>
<tr>
<td>5-49</td>
<td>0.25-0.5g every 12 hours</td>
<td>0.5-1g every 12 hours</td>
</tr>
<tr>
<td>0-4 (dialysis patients)</td>
<td>0.25g every 24 hour</td>
<td>0.5g every 24 hours</td>
</tr>
</tbody>
</table>

Reconstitution
Intravenous injection: Reconstitute with sterile water for injection in volumes shown below and shake well. For direct intravenous use, inject slowly over 3-5 minutes.

Vial size Sterile water for injection
0.5 g 5 ml
1 g 10 ml
2 g 20 ml
HIKMA-CEFIZOX - p.2/2

For intravenous drip infusion: Dilute Cefizox reconstituted with water for injection in 50-100 ml of one of the following solutions:

- Sodium Chloride Injection
- Ringer’s Injection
- 5% or 10% Dextrose injection
- 5% Dextrose and 0.9%, 0.45%, 0.2% Sodium Chloride Injection
- Lactate Ringer’s Injection
- Invert sugar 10% in sterile water for injection
- 5% Sodium Bicarbonate in sterile water for injection

Intramuscular injection:
Reconstitute with the provided ampoules of lidocaine or with sterile water for injection and shake well.

Do not use lidocaine in patients hypersensitive to it. Do not inject intravenously when reconstituted with lidocaine HCl.

Vial size 0.5% lidocaine or sterile water for injection
500 mg 2 ml 2 ml
1 g 4 ml 3 ml
- Inject into large muscle mass.

Note: Cefizox should be used within 24 hours after reconstitution when stored at room temperature and within 96 hours if refrigerated. Solutions may vary in color from yellow to amber. This does not affect their potency. Parenteral drug products should be inspected visually for particulate matter prior to administration. If particulate matter is evident in reconstituted fluids, the drug solution should be discarded.

Warnings
Ceftizoxime should be given cautiously to penicillin-sensitive patients and patients with impaired renal function.

Contraindications
Ceftizoxime is contraindicated in patients with known allergy to cephalosporin antibiotics.

Precautions
Prolonged use of broad spectrum antibiotics may result in overgrowth of resistant bacteria. There are no adequate and well-controlled studies in pregnant women, therefore this drug should be used in pregnancy only if clearly needed. Ceftizoxime is excreted unchanged in breast milk, usually in low concentrations. However, problems in humans have not been documented to date.

Side effects
Ceftizoxime is generally well tolerated. The following side effects have been rarely reported: Hypersensitivity, transient elevation in SGOT, SGPT and alkaline phosphatase, diarrhea, nausea and vomiting.

Overdose
Serious acute hypersensitivity reactions may require adrenaline and other emergency measures.

Presentation
CEFIZOX 500 IV: Sterile Ceftizoxime (as sodium) USP 500 mg
CEFIZOX 1000 IV: Sterile Ceftizoxime (as sodium) USP 1000 mg
CEFIZOX 2000 IV: Sterile Ceftizoxime (as sodium) USP 2000 mg
CEFIZOX 500 IM: Sterile Ceftizoxime (as sodium) USP 500 mg with diluent ampoule (2 ml of 0.5% lidocaine HCl)
CEFIZOX 1000 IM: Sterile Ceftizoxime (as sodium) USP 1000 mg with diluent ampoule (4 ml of 0.5% lidocaine HCl)