CEFIZOX®

(Sterile Ceftizoxime sodium)

ACTION

Cefizox developed by Astellas 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. 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
- Intra-abdominal infections including biliary infections.
- Gynaecological infections
- Septicaemia

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:

Creatinine clearance (ml/min)	**Moderate infections**	**Severe or life threatening infections**
50 - 79	0.5 g every 8 hours	0.75 - 1.5 g every 8 hours
5 - 49	0.25 - 0.5 g every 12 hour	0.5 -1 g every 12 hours
0 -4 (dialysis patients)	0.25 g every 24 hour	0.5 g every 24 hours

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
1g	10 ml

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

- Sodium Chloride Injection
- Lactated ringer's Injection
- 5% or 10% Dextrose injection
- 5% Dextrose and 0.9%, 0.45%, 0.2% Sodium Chloride Injection
- 4% Sodium Bicarbonate in sterile water for injection
- 5% Dextrose in Lactated Ringer's Injection (only when reconstituted with 4% Sodium Bicarbonate 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
1g	4 ml	3 ml

- Inject into large muscle mass.

Note: In-use stability:
It is recommended that the solutions should be prepared right before use and administered right after their preparation. If any particular circumstances force the storage of the reconstituted solutions before use, the recommended storage times after reconstitution/dilution are summarized in the following table:

	Storage at Room Temperature	Storage at 2-8°C
After Reconstitution		
With Water for Injection	8 hours	12 hours
With 0.5% Lidocaine HCl Solution	4 hours	4 hours
After Dilution	6 hours	24 hours

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.

STORAGE

Don't store above 30ºC, store away from light.

PRESENTATION

Vials

CEFIZOX 500 IV: 500 mg Ceftizoxime as 528.66 mg ceftizoxime sodium
CEFIZOX 1000 IV: 1000 mg Ceftizoxime as 1057.33 mg ceftizoxime sodium
CEFIZOX 500 IM: 500 mg ceftizoxime as 528.66 mg ceftizoxime sodium + Lidocaine 0.5% ampoule
CEFIZOX 1000 IM: 1000 mg ceftizoxime as 1057.33 mg ceftizoxime sodium + Lidocaine 0.5% ampoule

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, the method of 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.

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Keep medicament out of the reach of children

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