

# CEFIZOX<sup>®</sup>

(Sterile Cefizoxime 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:

| <b>Creatinine clearance</b> | <b>Moderate infections</b> | <b>Severe or life threatening infections</b> |
|-----------------------------|----------------------------|----------------------------------------------|
| <b>(ml/min)</b>             |                            |                                              |
| 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.

| <b>vial size</b> | <b>0.5% lidocaine</b> | <b>or sterile water for injection</b> |
|------------------|-----------------------|---------------------------------------|
| 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 |
|----------------------------------|-----------------------------|------------------|
| <b>After Reconstitution</b>      |                             |                  |
| With Water for Injection         | 8 hours                     | 12 hours         |
| With 0.5% Lidocaine HCl Solution | 4 hours                     | 4 hours          |
| <b>After Dilution</b>            | 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 30°C, 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  
Rev-12/2015