

Cerox-A[®]

Cefuroxime

Description

Cerox-A[®] is a preparation of Cefuroxime. It is a semi synthetic, broad spectrum Cephalosporin antibiotic for oral and parenteral administration; which is active against a wide range of gram-positive and gram-negative organisms including many β -lactamase producing strains.

Indications and Uses

Cerox-A[®] is indicated for:

- ❖ Upper respiratory tract infections including otitis media, sinusitis, tonsillitis and pharyngitis
- ❖ Lower respiratory tract infections including acute and chronic bronchitis and pneumonia
- ❖ Genito-urinary tract infections including pyelonephritis, cystitis and urethritis, gonorrhea, acute uncomplicated gonococcal urethritis and cervicitis
- ❖ Skin and soft tissue infections including furunculosis, pyoderma and impetigo
- ❖ Early lyme disease including erythema & marginatum
- ❖ Bone and joint infections
- ❖ Meningitis
- ❖ Septicemia
- ❖ Prophylaxis against infections in abdominal, pelvic, orthopedic, cardiac, pulmonary, esophageal and vascular surgery

Dosage & Administration

Oral

Infections	Dosage	Duration (Days)
Tablet: Adolescents and adults (13 years of age and above)		
Pharyngitis, Tonsillitis	250 mg b.i.d	5-10
Acute bacterial maxillary sinusitis	250 mg b.i.d	10
Acute bacterial exacerbation of chronic bronchitis	250-500 mg b.i.d	10
Secondary bacterial infections of acute bronchitis	250-500 mg b.i.d	5-10
Uncomplicated skin and skin-structure infections	250-500 mg b.i.d	10
Uncomplicated urinary tract infections	125-250 mg b.i.d	7-10
Uncomplicated gonorrhea	1000 mg once	1
Lyme disease	500 mg b.i.d	20
Tablet: Pediatric Patients up to 12 years (Who can swallow tablets)		
Pharyngitis, Tonsillitis	125 mg b.i.d	5-10
Acute otitis media	250 mg b.i.d	10
Acute bacterial maxillary sinusitis	250 mg b.i.d	10
Suspension: Paediatric patients (3 months – 12 years)		
Pharyngitis, Tonsillitis	20 mg/kg/day in 2 divided doses	5-10
Acute otitis media	30 mg/kg/day in 2 divided doses	10
Acute bacterial maxillary sinusitis	30 mg/kg/day in 2 divided doses	10

Injection

Adults

Usual dose is 750mg three times daily by intramuscular or intravenous injection for 5-10 days. For more severe infections this dose should be increased to 1.5g three times daily intravenously. The frequency of dosage may be increased to six-hourly injections, intramuscular or intravenous, giving total daily doses of 3g to 6g.

Pre-operative prophylaxis: For clean-contaminated or potentially contaminated surgical procedures, a 1.5 g dose administered intravenously just before surgery (approximately one-half to 1 hour before the initial incision) is recommended. Thereafter, 750 mg intravenously every 8 hourly when the procedure is prolonged.

Open heart surgery: For preventive use, a 1.5 g dose administered intravenously at the induction of anesthesia and every 12 hourly thereafter for a total of 6 g is recommended.

Bone and joint infections: 1.5 g dose every 8 hourly is recommended. Oral therapy is administered when appropriate, following the completion of parenteral administration of Cefuroxime.

Life-threatening infections: 1.5 g every 6 hourly may be required. In bacterial meningitis, the dosage should not exceed 3 grams every 8 hourly.

Gonorrhea: 1.5g should be given as a single dose (Two 750 mg injections into 2 different sites)

Infants and children (Above 3 months of age)

Usual dose is 30-100mg/kg/day given in three or four divided doses. A dose of 60 mg/kg/day will be appropriate for most infections.

Neonates: Usual dose is 30-100mg/kg/day given in two or three divided doses.

Bone and joint infections: 150 mg/kg/day is recommended in equally divided doses every 8 hourly.

Bacterial meningitis: 200-240 mg/kg/day intravenously in divided doses every 6-8 hourly.

Preparation of solution for Injection

Cerox-A [®] 1.5g IV Injection	To be constituted with 16.0 ml of water for injection
Cerox-A [®] 750mg IV Injection	To be constituted with 8.0 ml of water for injection
Cerox-A [®] 750mg IM Injection	To be constituted with 3.0 ml of water for injection
Cerox-A [®] 250mg IV Injection	To be constituted with 2.0 ml of water for injection
Cerox-A [®] 250mg IM Injection	To be constituted with 1.0 ml of water for injection

Preparation of Powder for suspension

Shake the bottle well to loosen the powder. Add 40ml (8 Spoonfuls) of boiled and cooled water in two portions to the dry mixture in the bottle. Shake the bottle vigorously until all the powder dissolve to make a suspension

Note

Shake the bottle vigorously before use. Keep the bottle tightly closed. The reconstituted suspension should be stored in a cool and dry place, preferably in refrigerator and used within 14 days after reconstitution. Use the supplied spoon for water measurement

Contraindications

Cefuroxime is contraindicated in patients with known hypersensitivity to Cephalosporins & patients with pseudomembraneous colitis.

Precautions

As with other antibiotics, prolonged use of Cefuroxime may result in the over growth of non-susceptible organisms (e. g. *Candida*, *Enterococci*, *Clostridium difficile*), which may require interruption of treatment. Pseudomonous colitis has been reported with the use of broad-spectrum antibiotics; therefore, it is important to consider its diagnosis in patients who develop serious diarrhea during or after antibiotic use.

Drug Interactions

Drug interaction is common with other antibiotics. Cefuroxime may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined estrogen /progesterone oral contraceptives.

Side effects

Generally Cefuroxime is well tolerated; however a few side effects like nausea, vomiting, diarrhea, abdominal discomfort, or pain may occur. As with other broad-spectrum antibiotics prolonged administration of Cefuroxime may result in overgrowth of non susceptible microorganisms.

Over dosage

Over dosage of Cefuroxime can cause cerebral irritation leading to convulsions. Serum levels of Cefuroxime can be reduced by haemodialysis and peritoneal dialysis.

Use in pregnancy and lactation

While all antibiotics should be avoided in the first trimester if possible, Cefuroxime has been safely used in later pregnancy to treat urinary and other infections. Cefuroxime is excreted in human milk, and consequently caution should be exercised when Cefuroxime is administered to a nursing mother

Pharmaceutical precautions

Store in a cool dry place. Protect from light.

Presentation

Cerox-A[®] 250mg tablet : White, oblong, film coated tablet. Each tablet contains Cefuroxime 250mg as Axetil USP.

Cerox-A[®] 500mg tablet : Light yellow colored, oval shaped film coated tablet. Each tablet contains Cefuroxime 500mg as Axetil USP

Cerox-A[®] Powder for suspension (70ml) : Each 5ml contains 125mg of Cefuroxime as Axetil USP

Cerox-A[®] 250mg IM/IV Injection : Pack of one vial contains Cefuroxime 250mg as Sodium USP accompanied by an ampoule of 5ml water for injection & a disposable syringe.

Cerox-A[®] 750mg IM/IV Injection : Pack of one vial contains Cefuroxime 750mg as Sodium USP accompanied by an ampoule of 10ml water for injection & a disposable syringe.

Cerox-A[®] 1.5g IV Injection : Pack of one vial contains Cefuroxime 1.5g as Sodium USP accompanied by an ampoule of 20ml water for injection & a disposable syringe.

Package quantities

Cerox-A[®] 250mg Tablet : Carton of 16 tablets in Alu-Alu blister.

Cerox-A[®] 500mg Tablet : Carton of 8 tablets in Alu-Alu blister.

Cerox-A[®] Powder for Suspension : Bottle of 70ml.

Cerox-A[®] 250mg Injection (IM/IV) : Pack of 1 vial with a 5ml ampoule of water for injection & a disposable syringe.

Cerox-A[®] 750mg Injection (IM/IV) : Pack of 1 vial with a 10ml ampoule of water for injection & a disposable syringe.

Cerox-A[®] 1.5g Injection (IV) : Pack of 1 vial with a 20ml ampoule of water for injection, a disposable syringe, first aid bandage, alcohol pad & butterfly needle.

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