CEFUMAX

Cefuroxime sodium

Vials (For IV or IM injection)

Broad Spectrum Antibiotic

COMPOSITION

Each vial contains :
Cefuroxime sodium equivalent to 250 mg, 750 mg or 1.5 g cefuroxime.

PROPERTIES

CEFUMAX (cefuroxime sodium) is a broad spectrum semisynthetic second-generation cephalosporin for parenteral (IV or IM) administration. **CEFUMAX** possesses potent bactericidal activity against a wide range of Gram-positive and Gram-negative bacteria, including ß-lactamase-producing strains. **CEFUMAX** irreversibly inhibits bacterial cell wall synthesis resulting in rapid and complete eradication of sensitive bacteria. Cefuroxime exerts a broader spectrum of activity against Gram-negative bacteria compared to the first-generation cephalosporins and most penicillins. Clinically, **CEFUMAX** cures various severe and moderately severe infections, including those caused by Gram-negative bacteria. This efficacy, besides safety and excellent tolerability, demonstrate the superiority of parenteral **CEFUMAX** for treatment of a wide variety of local and systemic bacterial infections.

PHARMACOKINETICS

Peak plasma concentrations of cefuroxime are achieved within 5 minutes of IV and 45 minutes after IM administration of **CEFUMAX.** Up to 50% of the drug is bound to plasma proteins. Cefuroxime is widely distributed into most body fluids and tissues reaching concentrations higher than the minimum inhibitory concentrations (MICs) of susceptible bacteria. Effective penetration into the CSF occurs with meningeal inflammation. The drug is excreted unchanged mainly in the urine with a small amount eliminated in bile. Plasma half-life is about 1.5 hours.

ANTIMICROBIAL SPECTRUM

CEFUMAX is highly active against a wide range of pathogenic ß-lactamase-and non-ß-lactamase-producing organisms :

GRAM-POSITIVE BACTERIA :

Aerobes : Staphylococcus aureus, Staph. epidermidis, Streptococcus pyogenes (group A beta-hemolytic streptococci), S. agalactiae (group B beta-hemolytic streptococci) and S. pneumoniae.

Anaerobes : Clostridium, Peptococcus and Peptostreptococcus species.

GRAM-NEGATIVE BACTERIA :

Aerobes : Haemophilus influenzae, Neisseria gonorrhoeae, N. meningitidis, Escherichia coli, Proteus mirabilis, P. vulgaris, Morganella morganii, Providencia rettgeri, Providencia stuartii and Klebsiella, Citrobacter, Enterobacter and Serratia species.

Anaerobes: Fusobacterium species.

INDICATIONS

CEFUMAX is indicated for treatment of severe and moderately severe infections caused by cefuroxime-susceptible bacteria :

- **Lower respiratory tract infections :** severe bronchitis , pneumonia , bronchopneumonia, bronchiectasis, lung abscess and empyema.
- **Urinary tract infections :** pyelonephritis, cystitis and urethritis.
- **Bone and joint infections :** osteomyelitis, bone abscess and septic arthritis.
- **CNS infections :** meningitis.
- **Septicemia, bacteremia and bacterial endocarditis.**
- **Abdominal infections:** cholecystitis, cholangitis, peritonitis and other intra-abdominal infections.
- **Gynecologic and obstetric infections :** oophoritis , salpingo-oophoritis , pelvic abscess and cellulitis, endometritis, puerperal sepsis and septic abortion .
- **Male genital tract infections :** prostatitis, orchitis and epididymo-orchitis.
- **Venereal diseases :** gonorrhea.
- **Skin and soft tissue infections :** cellulitis, abscesses, pyoderma and infected burns, traumatic and postoperative wounds.
- **ENT infections:** otitis media, tonsillitis and sinusitis.
- **Perioperative prophylaxis.**

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CONTRAINDICATIONS

Hypersensitivity to cephalosporins.

ADVERSE EFFECTS

CEFUMAX is safe and well tolerated. Mild diarrhea, skin rash and urticaria may rarely occur. Transient elevation of serum transaminases and transient leucopenia may occur during therapy.

PRECAUTIONS

Penicillin - hypersensitive patients may be also hypersensitive to cephalosporins (cross-sensitivity). Treatment should be stopped if allergic reaction occurs. Although there is no evidence of teratogenic or harmful effects, the drug, as with other antibiotics, should not be used during pregnancy or lactation unless strictly indicated.

INTERFERENCE WITH LABORATORY TESTS

During cephalosporin treatment, false positive results may be obtained for urinary glucose if it is determined by reduction methods; this can be avoided by using enzymatic methods. Also, direct Coombs' test may give false positive results.

DOSAGE

The dose of **CEFUMAX** and route of administration (IV or IM) depend on the age of the patient, renal function and severity of infection. IV injection should be done slowly over 3-5 minutes. Unless otherwise prescribed by the physician the following doses are recommended :

- **Neonates (up to 1 month):** 30-60 mg/kg/day , in equally divided doses every 8 hours (IV) or 12 hours (IM). **In severe infections and meningitis :** 100 mg/ kg/ day (IV), in equally divided doses, every 6-8 hours.
- **Infants and children (up to 12 years) :** 30-60 mg/kg/day, in equally divided doses every 6 hours (IV) or 8 hours (IM). **In severe infections:** up to 100 mg/kg/day (IV), in equally divided doses every 6-8 hours. **In meningitis:** 200-240 mg/kg/day (IV), in equally divided doses every 6-8 hours.
- **ADULTS :** 750 mg (IV or IM) every 8 hours. **In severe infections:** 1.5 g (IV) every 6 -8 hours. **In meningitis:** up to 3 g (IV) every 8 hours.
- **Uncomplicated gonorrhea :** a single dose of 1.5 g (IM), given at 2 different injection sites, together with 1 g oral probenecid.
- **Perioperative prophylaxis :** 1.5 g (IV) half an hour before surgery followed by 750 mg (IV or IM) every 8 hours for up to 24 - 48 hours.

Dosage in renal impairment : In patients with renal insufficiency, a dose of 750 mg is given at different time intervals according to creatinine clearance :

Creatinine Clearance (ml/min./1.73 m^2)	Time interval (hours)
Less than 10	24
From 10-20	12
Over 20	8

RECONSTITUTION OF CEFUMAX POWDER :

- **For IM injection :**

Add 1 ml water for injection to 250 mg **CEFUMAX** or 3 ml water for injection to 750 mg **CEFUMAX**. Shake gently to produce an opaque suspension.

- **For IV injection :**

Dissolve **CEFUMAX** in water for injection using at least 2 ml for 250 mg, at least 6 ml for 750 mg or 15 ml for 1.5 g

For short intravenous infusion (up to 30 min.) 1.5 g may be dissolved in 50 ml water for injection.

- For infusion , the reconstituted solution of **CEFUMAX** is added to a suitable infusion solution, e.g. isotonic sodium chloride, 5% dextrose or M/6 sodium lactate.
- Reconstituted solutions for IV or IM should be used immediately or within 24 hours if kept at room temperature (15 - 30° C) or within 48 hours if kept under refrigeration (at 5° C).

PACKING :

A box containing 1 vial (powder equivalent to 250 mg, 750 mg or 1.5 g cefuroxime)

STORAGE :

Keep at room temperature (15 - 30° C)
Keep out of the reach of children.