

CEFOCEF

Composition

Each vial of **CEFOCEF Injection** contains:

Ceftriaxone sodium

250 mg / 1 g

Pharmacology

CEFOCEF is a semisynthetic, broad-spectrum third generation cephalosporin antibiotic for intravenous (IV) or intramuscular (IM) administration. Its bactericidal activity results from inhibition of cell wall synthesis. **CEFOCEF** has a high degree of stability in the presence of beta-lactamases, both penicillinases and cephalosporinases of Gram-negative and Gram-positive bacteria.

The antibacterial spectrum of **CEFOCEF** includes *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, Viridans group streptococci, *Acinetobacter calcoaceticus*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Escherichia coli*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Moraxella catarrhalis*, *Morganella morganii*, *Neisseria gonorrhoeae*, *Neisseria meningitidis*, *Proteus mirabilis*, *Proteus vulgaris*, *Serratia marcescens*, *Salmonella species* (including *S. typhi*) and *Shigella* species.

CEFOCEF is also active against many strains of *Pseudomonas aeruginosa*. Many strains of the above organisms that are multiply resistant to other antibiotics, including penicillins, cephalosporins and aminoglycosides, are susceptible to ceftriaxone. **CEFOCEF** is also active against a variety of anaerobes including *Bacteroides fragilis*, *Clostridium* species and *Peptostreptococcus species*.

Ceftriaxone is completely absorbed following IM administration with mean peak plasma concentrations occurring between 2 and 3 hours post-dosing. Thirty-three to 67% of administered dose is excreted in the urine as unchanged drug and the remainder in the bile. The elimination half-life of **CEFOCEF** ranges from 5.8-8.7 hours. Ceftriaxone reversibly binds to plasma proteins.

Indications

CEFOCEF is indicated for the treatment of the following infections when caused by susceptible microorganisms,

- Lower respiratory tract infections
- Acute bacterial otitis media
- Skin and skin structure infections
- Urinary tract infections
- Uncomplicated gonorrhea
- Pelvic inflammatory disease
- Bacterial septicemia
- Bone and joint infections
- Intra-abdominal infections
- Meningitis
- Typhoid
- Surgical prophylaxis

Before instituting treatment with **CEFOCEF**, appropriate specimens should be obtained for isolation of the causative organism and for determination of its susceptibility to the drug. Therapy with **CEFOCEF** may be instituted prior to obtaining results of susceptibility testing.

Contraindications

CEFOCEF is contraindicated in patients with known allergy to the cephalosporin class of antibiotics.

CEFOCEF should not be administered to hyperbilirubinemic neonates, especially prematures.

Precautions

Before initiating therapy with **CEFOCEF**, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins or penicillins. This product should be given cautiously to penicillin-sensitive patients.

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including ceftriaxone. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of **CEFOCEF**.

Alterations in prothrombin times have occurred rarely in patients treated with ceftriaxone. Patients with either impaired synthesis or low vitamin K stores (e.g., chronic hepatic disease and malnutrition) may require monitoring of prothrombin time during **CEFOCEF** treatment. Vitamin K administration (10 mg weekly) may be necessary if the prothrombin time is prolonged before or during therapy.

CEFOCEF should be prescribed with caution in individuals with a history of colitis.

Pregnancy & Lactation

There are no adequate and well-controlled studies with **CEFOCEF** in pregnant women. Therefore, this drug should be used during pregnancy only if clearly needed.

Low concentrations of **CEFOCEF** are excreted in human milk. Caution should be exercised when it is administered to a nursing woman.

Adverse Reactions

CEFOCEF is generally well tolerated. Commonly observed adverse events include pain, indurations and tenderness at the site of administration, rash, pruritus, fever or chills, diarrhea, nausea and vomiting. Headache, dizziness, diaphoresis and flushing are also reported occasionally. Other less frequently reported adverse events include eosinophilia, thrombocytosis, leukopenia, anemia and prolongation of the prothrombin time.

Dosage & Administration

CEFOCEF can be administered IV or IM.

The usual adult dose of **CEFOCEF** is 1-2g once a day (or in equally divided doses *bid*) depending on the severity of infection. The total daily dose of **CEFOCEF** should not exceed 4g. For the treatment of uncomplicated gonococcal infections, a single IM dose of 250 mg is recommended. For surgical prophylaxis, a single dose of 1g administered IV 30 minutes to 2 hours before surgery is recommended.

Safety and effectiveness of ceftriaxone in neonates, infants and children has been established.

In children, the recommended total daily dose of **CEFOCEF** is 50-75 mg/kg once a day (or in equally divided doses *bid*). The total daily doses of **CEFOCEF** should not exceed 2g. For the treatment of acute bacterial otitis media, a single IM dose of 50 mg/kg (not to exceed 1g) is recommended.

In the treatment of meningitis, it is recommended that the initial therapeutic dose of **CEFOCEF** be 100 mg/kg (not to exceed 4g). Thereafter, a total daily dose of 100 mg/kg/day (not to exceed 4g daily) is recommended. The daily dose may be administered once a day or in equally divided doses *bid*. The usual duration of **CEFOCEF** therapy is 7-14 days.

Dosage adjustments should not be necessary in patients with hepatic dysfunction; however, in patients with both hepatic dysfunction and significant renal disease, **CEFOCEF** dosage should not exceed 2g daily without close monitoring of serum concentrations.

Presentation

CEFOCEF is available in a vial of 250 mg and 1 g alongwith water for injection.