Imacef Injection

Ceftriaxone

Presentation

Imacef 250 mg IM: Each vial contains Ceftriaxone 250 mg (as sterile Ceftriaxone Sodium USP).

Imacef 500 mg IM: Each vial contains Ceftriaxone 500 mg (as sterile Ceftriaxone Sodium USP).

Imacef 1 g IV/IM: Each vial contains Ceftriaxone 1 g (as sterile Ceftriaxone Sodium USP).

Imacef 2 g IV: Each vial contains Ceftriaxone 2 g (as sterile Ceftriaxone Sodium USP).

Indications

Imacef is indicated for the treatment of the following infections when caused by susceptible organisms :

- **Lower Respiratory Tract Infections** caused by *Streptococcus pneumoniae, Staphylococcus aureus, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, E. coli, Enterobacter aerogenes, Proteus mirabilis, Serratia marcescens.*
- **Acute Bacterial Otitis Media** caused by *Streptococcus pneumoniae, Haemophilus influenzae* (including beta-lactamase producing strains), *Moraxella catarrhalis* (including beta-lactamase producing strains).
- **Skin and Skin Structure Infections** caused *by Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pyogenes, Viridans group streptococci, E. coli, Enterobacter cloacae, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Morganella morganii, Pseudomonas aeruginosa, Serratia marcescens, Acinetobacter calcoaceticus, Bacteroides fragilis, Peptostreptococcus* species.
- **Urinary Tract Infections (complicated and uncomplicated)** caused by *E. coli, Proteus mirabilis, Proteus vulgaris, Morganella morganii, Klebsiella pneumoniae.*
- **Uncomplicated Gonorrhea (cervical, urethral, pharyngeal and rectal)** caused by *Neisseria gonorrhoeae* (including both penicillinase- and nonpenicillinase-producing strains) and pharyngeal gonorrhea caused by nonpenicilinase producing strains of *Neisseria gonorrhoeae.*
- **Pelvic Inflammatory Disease** caused by *Neisseria gonorrhoeae.*
- **Bacterial Septicemia** caused by *Staphylococcus aureus, Streptococcus pneumoniae. E.coli, Haemophilus influenzae, Klebsiella pneumoniae.*
- **Bone and Joint Infections** caused by *Staphylococcus aureus, Streptococcus pneumoniae, E. coli, Proteus mirabilis, Klebsiella pneumoniae, Enterobacter* species.
- **Intra-abdominal Infections** caused by *E. coli, Klebsiella pneumoniae, Bacteroides fragilis, Clostridium species, Peptostreptococcus species.*
- **Meningitis** caused by *Haemophilus influenzae, Neisseria meningitidis, Streptococcus pneumoniae.* Ceftriaxone has also been used successfully in a limited number of cases of meningitis and shunt infection caused by *Staphylococcus epidermidis and E. coli.*
- **Surgical Prophylaxis :** The preoperative administration of a single 1 g dose of Ceftriaxone may reduce the incidence of postoperative infections in patients undergoing surgical procedures classified as contaminated or potentially contaminated.

Dosage and Application

Adults

Usual daily dose is 1 to 2 g once a day (or in equally divided doses twice a day) depending on the type and severity of infection. Total daily dose should not exceed 4 g.

Uncomplicated gonococcal infections : A single dose of 250 mg IM is recommended.

Surgical prophylaxis : A single dose of 1 g IV, 30 minutes to 2 hour before surgery.

Children

To treat serious infections other than meningitis 50 to 75 mg/kg/day every 12 hours in divided doses is recommended. Dose should not exceed 4 g.

Meningitis-100 mg/kg/day is recommended. Dose should not exceed 4 g.

Skin & skin structure infection- 50 to 75 mg/kg once daily or in equally divided doses twice daily. Dose should not exceed 2 g.

The usual duration of therapy is 4 to 14 days; in complicated infections longer therapy may be required. Imacef therapy should be continued for at least 2 days after the sign and symptoms of infections have disappeared. No dosage adjustment is required for patients with renal or hepatic impairment.

Direction for use

Intramuscular Injection: For IM injection Imacef 250 mg or Imacef 500 mg is dissolved in 2 ml and Imacef 1 g in 3.5 ml of Lidocaine Hydrochloride 1% solution and administered by deep intragluteal injection. It is recommended that not more than 1 g be injected at one site. The Lidocaine solution must never be administrated intravenously. **Intravenous Injection:** For IV injection, Imacef 1 g is dissolved in 10 ml and Imacef 2 g in 20 ml of Water for Injections. The injection should be administrated over 2-4 minutes, directly into the vein or via the tubing of an intravenous infusion.

Side effects

Generally Ceftriaxone is well tolerated. However, few side effects including nausea, vomiting, diarrhea, dizziness and fever may occur.

Precautions

Ceftriaxone should be administered with caution to individuals with a history of gastrointestinal disease, particularly colitis.

Use in Pregnancy & Lactation

Pregnancy : The safety of Ceftriaxone in the treatment of infections during pregnancy has not been established. Ceftriaxone should only be used during pregnancy if the likely benefit outweighs the potential risk to the fetus and/or the mother.

Lactation : Ceftriaxone is excreted in breast milk at low concentrations. Therefore, caution should be exercised when Ceftriaxone is administered to a nursing mother.

Contraindications

Ceftriaxone is contraindicated in patients with known allergy to Ceftriaxone, other cephalosporins or penicillins.

Drug Interactions

No drug-drug interactions have been reported.

Stability and storage Recommendation

Ceftriaxone sterile powder should be stored in a cool and dry place, away from light. After reconstitution, protection from normal light is not necessary. The color of solution ranges from light yellow to amber, depending on the length of storage, concentration and diluent used. Reconstituted solutions retain their physical and chemical stability for 6 hours at room temperature and for 24 hours at 2°- 8° C. As a general rule, however the solutions should be used immediately after preparation.

Commercial Pack

Imacef 250 mg IM Injection : Pack of 1 vial containing 250 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by 1 ampoule of 2 ml Lidocaine Hydrochloride 1% USP for IM injection, a 3 ml sterile disposable syringe & a baby needle.

Imacef 500 mg IM Injection : Pack of 1 vial containing 500 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by 1 ampoule of 2 ml Lidocaine Hydrochloride 1% USP for IM injection, a 3 ml sterile disposable syringe & a baby needle.

Imacef 1 g IV/IM Injection : Pack of 1 vial containing 1 g Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by 1 ampoule of 10 ml of Water for Injections BP & 10 ml sterile disposable syringe for IV Injection and 1 ampoule of 3.5 ml Lidocaine Hydrochloride 1% USP & 5 ml sterile disposable syringe for IM injection.

Imacef 2 g IV Injection : Pack of 1 vial containing 2 g Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by 2 ampoules of 10 ml of Water for Injections BP, a 20 ml sterile disposable syringe, a butterfly needle & an alcohol pad for IV Injection.

Manufactured for:
general GENERAL Pharmaceuticals Ltd.
Gazipur, Bangladesh
by Popular Pharmaceuticals Ltd.
Tongi, Bangladesh