

Composition

Traxef 250 mg IM Injection: Each vial contains Ceftriaxone Sodium USP equivalent to Ceftriaxone 250 mg.

Traxef 250 mg IV Injection: Each vial contains Ceftriaxone Sodium USP equivalent to Ceftriaxone 250 mg.

Traxef 500 mg IM Injection: Each vial contains Ceftriaxone Sodium USP equivalent to Ceftriaxone 500 mg.

Traxef 500 mg IV Injection: Each vial contains Ceftriaxone Sodium USP equivalent to Ceftriaxone 500 mg.

Traxef 1 gm IM Injection: Each vial contains Ceftriaxone Sodium USP equivalent to Ceftriaxone 1 gm.

Traxef 1 gm IV Injection: Each vial contains Ceftriaxone Sodium USP equivalent to Ceftriaxone 1 gm.

Traxef 2 gm IV Injection: Each vial contains Ceftriaxone Sodium USP equivalent to Ceftriaxone 2 gm.

Pharmacology

Ceftriaxone is a sterile, semisynthetic, broad-spectrum, 3rd generation cephalosporin antibiotic for intravenous or intramuscular administration. The bactericidal activity of Ceftriaxone results from inhibition of cell wall synthesis. Ceftriaxone has a high degree of stability in the presence of beta-lactamases both penicillinases and cephalosporinases of gram-negative and gram-positive bacteria.

Indications

Ceftriaxone 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 Gonorrhoea (cervical, urethral, pharyngeal and rectal) caused by *Neisseria gonorrhoeae*, including both penicillinase- and nonpenicillinase-producing strains, and pharyngeal gonorrhoea caused by nonpenicillinase-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 & shunt infection caused by *Staphylococcus epidermidis* & *E. coli*.
- Surgical Prophylaxis: The preoperative administration of a single 1 gm dose of Ceftriaxone may reduce the incidence of postoperative infections in patients undergoing surgical procedures classified as contaminated or potentially contaminated.

Dosage and Administration

To continue the administration of Ceftriaxone the tolerability of 1st dose must be monitored & Ceftriaxone IV injection should be administered slowly for 2 to 4 minutes.

Traxef may be administered intravenously or intramuscularly.

Adults: The usual adult daily dose is 1 to 2 gm given once a day (or in equally divided doses twice a day) depending on the type and severity of infection. The total daily dose should not exceed 4 gm.

For the treatment of uncomplicated gonococcal infections, a single intramuscular dose of 250 mg is recommended.

For preoperative use (surgical prophylaxis), a single dose of 1 gm administered intravenously 1/2 to 2 hours before surgery is recommended.

Pediatric Patients: For the treatment of skin and skin structure infections, the recommended total daily dose is 50 to 75 mg/kg given once a day (or in equally divided doses twice a day). The total daily dose should not exceed 2 gm.

For the treatment of acute bacterial otitis media, a single intramuscular dose of 50 mg/kg (not to exceed 1 gm) is recommended.

For the treatment of serious miscellaneous infections other than meningitis, the recommended total daily dose is 50 to 75 mg/kg, given in divided doses every 12 hours. The total daily dose should not exceed 2 gm.

In the treatment of meningitis, it is recommended that the initial therapeutic dose be 100 mg/kg (not to exceed 4 gm). Thereafter, a total daily dose of 100 mg/kg/day (not to exceed 4 gm daily) is recommended. The daily dose may be administered once a day (or in

equally divided doses every 12 hours). The usual duration of therapy is 7 to 14 days.

Generally, Traxef (Ceftriaxone) therapy should be continued for at least 2 days after the signs and symptoms of infection have disappeared. The usual duration of therapy is 4 to 14 days; in complicated infections, longer therapy may be required.

When treating infections caused by *Streptococcus pyogenes*, therapy should be continued for at least 10 days.

No dosage adjustment is necessary for patients with impairment of renal or hepatic function; however, blood levels should be monitored in patients with severe renal impairment (eg, dialysis patients) and in patients with both renal and hepatic dysfunctions.

Preparation of Solution:

Traxef 250 mg IM Injection: Add 2 ml of Lidocaine Hydrochloride BP 1% Injection to 250 mg vial and shake the vial well until the powder is dissolved properly.

Traxef 250 mg IV Injection: Add 5 ml of water for injection to Traxef 250 mg vial and shake the vial well until the powder is dissolved properly.

Traxef 500 mg IM Injection: Add 2 ml of Lidocaine Hydrochloride BP 1% Injection to 500 mg vial and shake the vial well until the powder is dissolved properly.

Traxef 500 mg IV Injection: Add 5 ml of water for injection to Traxef 500 mg vial and shake the vial well until the powder is dissolved properly.

Traxef 1 gm IM Injection: Add 3.5 ml of Lidocaine Hydrochloride BP 1% Injection to 1 gm vial and shake the vial well until the powder is dissolved properly.

Traxef 1 gm IV Injection: Add 10 ml of water for injection to Traxef 1 gm vial and shake the vial well until the powder is dissolved properly.

Traxef 2 gm IV Injection: Add 20 ml of water for injection to Traxef 2 gm vial and shake the vial well until the powder is dissolved properly.

Contraindications

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

Warning and Precautions

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

Side Effects

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

Use in Pregnancy & Lactation

Pregnancy: Pregnancy Category B. Reproductive studies have been performed in mice and rats at doses up to 20 times the usual human dose and have no evidence of embryotoxicity, fetotoxicity or teratogenicity.

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

Overdosage

There is no specific antidote. Treatment of overdosage should be symptomatic.

Storage

Store in a cool & dry place, away from light. Keep out of the reach of children.

Direction for reconstitution of powder

Use the solution immediately after reconstitution of powder. The reconstituted solution should be used within 6 hours if kept in room temperature or within 24 hours if refrigerated below 5°C temperature. Otherwise, the solution color will be changed from yellow to reddish color.

Packaging

Traxef 250 mg IM Injection: Each combipack contains 1 vial of Ceftriaxone 250 mg IM Injection, 1 ampoule of 2 ml Lidocaine Hydrochloride BP 1% Injection and 1 accessories pouch pack contains one 5 ml disposable syringe, 1 baby needle, 1 alcohol pad and 1 first aid band.

Traxef 250 mg IV Injection: Each combipack contains 1 vial of Ceftriaxone 250 mg IV Injection, 1 ampoule of 5 ml water for injection and 1 accessories pouch pack contains one 5 ml disposable syringe, 1 baby needle, 1 alcohol pad and 1 first aid band.

Traxef 500 mg IM Injection: Each combipack contains 1 vial of Ceftriaxone 500 mg IM Injection, 1 ampoule of 2 ml Lidocaine Hydrochloride BP 1% Injection and 1 accessories pouch pack contains one 5 ml disposable syringe, 1 baby needle, 1 alcohol pad and 1 first aid band.

Traxef 500 mg IV Injection: Each combipack contains 1 vial of Ceftriaxone 500 mg IV Injection, 1 ampoule of 5 ml water for injection and 1 accessories pouch pack contains one 5 ml disposable syringe, 1 baby needle, 1 alcohol pad and 1 first aid band.

Traxef 1 gm IM Injection: Each combipack contains 1 vial of Ceftriaxone 1gm IM Injection, 1 ampoule of 3.5 ml Lidocaine Hydrochloride BP 1% Injection and 1 accessories pouch pack contains one 5 ml disposable syringe, 1 baby needle, 1 alcohol pad and 1 first aid band.

Traxef 1 gm IV Injection: Each combipack contains 1 vial of Ceftriaxone 1 gm IV Injection, 1 ampoule of 10 ml water for injection and 1 accessories pouch pack contains one 10 ml disposable syringe, 1 butterfly needle, 1 alcohol pad and 1 first aid band.

Traxef 2 gm IV Injection: Each combipack contains 1 vial of Ceftriaxone 2 gm IV Injection, 2 ampoules of 10 ml water for injection and 1 accessories pouch pack contains one 20 ml disposable syringe, 1 butterfly needle, 1 alcohol pad and 1 first aid band.

Manufactured by

BEACON
CEPHALOSPORIN LIMITED
Bhaluka, Mymensingh, Bangladesh

