Topcef™

Ceftriaxone

Composition

Topcef™ 250 mg IM Injection: Each vial contains dry substance equivalent to 250 mg Ceftriaxone (as sterile Ceftriaxone Sodium BP) with 2 ml Lidocaine Hydrochloride BP 1% Injection.

Topcef™ 500 mg IM/IV Injection: Each vial contains dry substance equivalent to 500 mg Ceftriaxone (as sterile Ceftriaxone Sodium BP) with 2 ml Lidocaine Hydrochloride BP 1% Injection for IM injection or 5 ml Water for Injection BP for IV injection.

Topcef™ 1 g IM/IV Injection: Each vial contains dry substance equivalent to 1 g Ceftriaxone (as sterile Ceftriaxone Sodium BP) with 3.5 ml Lidocaine Hydrochloride BP 1% Injection for IM injection or 10 ml Water for Injection BP for IV injection.

Topcef™ 2 g IV Injection: Each vial contains dry substance equivalent to 2 g Ceftriaxone (as sterile Ceftriaxone Sodium BP) accompanied by 2 ampoules each contains 10 ml water for injection.

Pharmacology

Ceftriaxone is a broad-spectrum cephalosporin for intravenous or intramuscular administration. Ceftriaxone is not absorbed after oral application. Ceftriaxone has bactericidal activity that results from the inhibition of bacterial cell wall synthesis. Ceftriaxone has a high degree of stability in the presence of β-lactamases produced by Gram-negative and Gram-positive bacteria.

Indication

Topcef™ is indicated in sepsis, meningitis, neurosyphillis, abdominal infections (peritonitis, infections of the biliary and gastrointestinal tracts), infections of the bones, joints, soft tissue, skin and of wounds, renal and urinary tract infections, respiratory tract infections, ear, nose and throat infections, genital infections, including gonorrhoea, perioperative prophylaxis of infections.

Dose and Administration

Adults and children over 12 years: The usual dose is 1-2 g of Topcef™ once daily (every 24 h). In severe cases, the dose may be raised to 4 g once daily. Neonates, infants and children up to 12 years: Neonates (up to 14 days): A daily dose of 20-50 mg/kg body weight, not to exceed 50 mg/kg. Infants and children (15 days to 12 years): A daily dose of 20-80 mg/kg. For children with body weights of 50 kg or more, the usual adult dose should be used. Elderly patients: The dosage recommended for adults require no modification in case of geriatric patients. Duration of therapy: 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. Meningitis: In bacterial meningitis in infants and children, treatment begins with dose of 100 mg/kg (not to exceed 4 g) once daily. Gonorrhoea: a single IM dose of 250 mg Topcef™ is recommended. Perioperative prophylaxis: a single dose of 1-2 g depending on the risk of infection of 30-90 minutes prior to surgery. In colorectal surgery, administration of Topcef™ with or without a 5-nitroimidazole, e.g. Ornidazole, has been proven effective. Impaired renal and hepatic function: In patients with impaired renal function, there is no need to reduce the dosage of Topcef™ provided hepatic function is intact. In patients with liver damage, there is no need for the dosage to be reduced provided renal function is intact **Or as directed by the physician**.

Directions for use

IM Injection: For IM injection, Topcef™ 250 mg or 500 mg is dissolved in 2 ml of 1% Lidocaine solution or 1 g Topcef™ in 3.5 ml of Lidocaine 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 administered intravenously. IV Injection: For IV injection, Topcef™ 500 mg is dissolved in 5 ml, Topcef™ 1 g in 10 ml & Topcef™ 2 g in 20 ml of sterile Water for Injection. Verify sensitivity with test dose before administering injection. The injection should be administered over 2-4 minutes, directly into the vein or via the tubing of an intravenous infusion.

Contraindication

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

Warning & Precaution

Ceftriaxone is excreted via both biliary and renal route. Patients with renal failure normally require no adjustment in dosage when usual doses of Ceftriaxone is administered but concentrations of drug in the serum should be monitored periodically. If evidence of accumulation exists, dosage should be decreased accordingly. Although transient elevations in BUN and serum creatinine have been observed at recommended dosage nephrotoxic potential of Ceftriaxone is similar to that of other cephalosporins. Dosage adjustments should not be necessary in patients with hepatic dysfunction; however, in patients with both hepatic dysfunction and significant renal disease, Ceftriaxone dosage should not exceed 2 gm daily without close monitoring of serum concentrations. If superinfection occurs during therapy, appropriate measures should be taken. Ceftriaxone should be prescribed with caution with a history of gastrointestinal disease, especially colitis.

Before administration of Ceftriaxone to patient, tolerability test should be done with test dose and administration should be continued for 2 to 4 minutes.

Side Effects

Systemic side effects- Convulsion, Diarrhoea, nausea, vomiting, stomatitis and glossitis, eosinophilia, leukopenia, granulocytopenia, hemolytic anemia, thrombocytopenia, exanthema, allergic dermatitis, pruritus, urticaria, edema, erythema multiforme, headache and dizziness, increase in liver enzymes, gallbladder sludge, oliguria, increase in serum creatinine, mycosis of the genital tract, shivering and anaphylactic or anaphylactoid reactions. Pseudomembranous enterocolitis and coagulation disorders have been reported as very rare side effects. Local side effects- In rare cases, phlebitic reactions occurred after IV administration. These may be minimized by slow (two to four minutes) injection. Intramuscular injection without Lidocaine solution is painful.

Use in Pregnancy and Lactation

Pregnancy: The safety of Ceftriaxone in the treatment of infections during pregnancy has not been established. It should only be used during pregnancy if the likely benefit out weighs the potential risk. Lactation: Ceftriaxone is excreted in breast milk at low concentrations. Caution should be exercised when Ceftriaxone is administered to a nursing mother.

Use in Children & Adolescents

In vitro studies have shown that Ceftriaxone, like some other cephalosporins, can displace bilirubin from serum albumin. Ceftriaxone should not be administered to hyperbilirubinemic neonates, especially prematures.

Drug Interaction

Two in vitro studies, one using adult plasma and the other neonatal plasma from umbilical cord blood have been carried out to assess interaction of ceftriaxone and calcium. Ceftriaxone concentrations up to 1mM (in excess of concentrations achieved in vivo following administration of 2 grams ceftriaxone infused over 30 minutes) were used in combination with calcium concentrations up to 12 mM (48 mg/dL). Recovery of ceftriaxone from plasma was reduced with calcium concentrations of 6 mM (24 mg/dL) or higher in adult plasma or 4 mM (16 mg/dL) or higher in neonatal plasma. This may be reflective of ceftriaxone-calcium precipitation.

Overdose

In the case of overdosage, drug concentration would not be reduced by hemodialysis or peritoneal dialysis. There is no specific antidote. Treatment of overdosage should be symptomatic.

Storage

Ceftriaxone sterile powder should be stored below 30°C and protected from light. Reconstituted solutions retain their physical and chemical stability for 6 hours at room temperature and for 24 hours at 5°C. As a general rule, however the solutions should be used immediately after preparation.

Packing

Topcef™ 250 mg IM Injection : Pack of 1 vial containing 250 mg Ceftriaxone (as sterile Ceftriaxone Sodium BP) accompanied by one ampoule of 2 ml Lidocaine Hydrochloride BP 1% Injection for IM injection, a sterile disposable syringe (5 ml) with an alcohol preparation pad, a strip bandage and a baby needle.

Topcef™ 500 mg IV Injection : Pack of 1 vial containing 500 mg Ceftriaxone (as sterile Ceftriaxone Sodium BP) accompanied by one ampoule of 5 ml Water for Injection BP for IV injection, a sterile disposable syringe (5 ml) with an alcohol preparation pad, a vein set and a strip bandage.

Topcef™ 500 mg IM Injection : Pack of 1 vial containing 500 mg Ceftriaxone (as sterile Ceftriaxone Sodium BP) accompanied by one ampoule of 2 ml Lidocaine Hydrochloride BP 1% Injection for IM injection, a sterile disposable syringe (5 ml) with an alcohol preparation pad and a strip bandage.

Topcef™ 1 g IV Injection : Pack of 1 vial containing 1 g Ceftriaxone (as sterile Ceftriaxone Sodium BP) accompanied by one ampoule of 10 ml Water for Injection BP for IV injection, a sterile disposable syringe (10 ml) with an alcohol preparation pad, a vein set and a strip bandage.

Topcef™ 1 g IM Injection : Pack of 1 vial containing 1 g Ceftriaxone (as sterile Ceftriaxone Sodium BP) accompanied by one ampoule of 3.5 ml Lidocaine Hydrochloride BP 1% Injection for IM injection, a sterile disposable syringe (5 ml) with an alcohol preparation pad and a strip bandage.

Topcef™ 2 g IV Injection : Pack of 1 vial containing 2 g Ceftriaxone (as sterile Ceftriaxone Sodium BP) accompanied by two ampoules of 10 ml Water for Injection BP, a sterile disposable syringe (20 ml) with vein set, alcohol preparation pad and a strip bandage.

Manufactured by:
Navana Pharmaceuticals Ltd.
Rupshi, Rupganj, Narayanganj, Bangladesh
NCLT0471_06-20_03

NAVANA PHARMA
JAHURUL ISLAM COMPANY