KEPTRIX
Ceftriaxone

2 g IV Injection
1 g IV/IM Injection
500 mg IV/IM Injection
250 mg IV/IM Injection

DESCRIPTION

Keptrix (Ceftriaxone) has persuasive bactericidal activity against a broad range of gram-positive and especially gram-negative organisms. It is a third generation parenteral cephalosporin antibiotic which has excellent gram-negative activity. **Keptrix** (Ceftriaxone), like other cephalosporins and penicillins, kills bacteria by interfering bacterial cell wall synthesis. The spectrurm of activity includes both aerobic and some anaerobic species. It has considerable stability against degradation by most bacterial beta-lactamases particularly those produced by gram-negative organisms. **Keptrix** (Ceftriaxone) has relatively long plasma elimination half-life of approximately 8 hours, which offers single or once-daily dosage of the drug.

COMPOSITION

Keptrix Intravenous/ Intramuscular Injection
Active ingredient : Ceftriaxone Sodium USP.
Vials containing dry substance equivalent to 2 g, 1 g, 500 mg or 250 mg ceftriaxone (as sterile Ceftriaxone Sodium USP).
Solvent : Water for Injection BP or Lidocaine HCl 1% Solution.
Water for Injection: Each ampoule contains 10 ml or 5 ml sterile Water for Injection BP for reconstitution.
Lidocaine Solution: Each ampoule contains 3.5 ml or 2 ml of 1% Lidocaine injection for reconstitution.

INDICATION

Meningitis
Septicemia
Gonorrhoea
Bone and joint infections
Surgical prophylaxis
Typhoid fever
Urinary tract infections
Respiratory tract infections
Skin and soft tissue infections
Pelvic inflammatory diseases

DOSAGE AND ADMINISTRATION

Standard dosage
Adults and children over 12 years: The usual dosage is 1-2 g of Keptrix once daily (every 24 hours). In severe cases or in infections caused by moderately sensitive organisms, the dosage may be raised to 4 g, once daily.
Neonates, infants and children up to 12 years: The following dosage schedules are recommended for once daily administration:
Neonates (up to 14 days) : A daily dose of 20-50 mg/kg bodyweight, not to exceed 50 mg/kg, on account of the immaturity of the infant's enzyme systems. It is not necessary to differentiable between premature and term infants.
Infants and children (15 days to 12 years): A daily dose of 20-80 mg/kg.
For children with bodyweight of 50 kg or more, the usual adult dosage should be used.
Elderly patients: The dosages recommended for adults require no modification in the case of geriatric patients.
Duration of therapy
The duration of therapy varies according to the course of the disease. As with antibiotic therapy in general, administration of Keptrix should be continued for a minimum of 48-72 hours after the patient has become afebrile or evidence of bacterial eradication has been obtained.
Combination therapy
Synergy between Keptrix and aminoglycosides have been demonstrated with many gram-negative bacilli under experimental conditions. Although enhanced activity of such combinations is not always predictable, it should be considered in severe, life threatening infections due to microorganisms such as *Pseudomonas aeruginosa*. Because of physical incompatibility the two drugs must be administered separately at the recommended dosages.
Special dosage instructions
Meningitis: In bacterial meningitis in infants and children, treatment begins with doses of 100 mg/kg (not to exceed 4 g) once daily. As soon as the causative organism has been identified and its sensitivity determined, the dosage can be reduced accordingly. The best results have been found with the following duration of therapy :

Neisseria meningitidis 4 days
Haemophilus influenzae 6 days
Streptococcus pneumoniae 7 days
Susceptible Enterobacteriaceae 10-14 days

Lyme borreliosis: 50 mg/kg up to a maximum of 2 g in children and adults, once daily for 14 days.
Gonorrhoea (penicillinase-producing and nonpenicillinase-producing strains):
For the treatment, a single i.m. dose of 250 mg Keptrix 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 Keptrix 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 Keptrix provided hepatic function is intact. Only in cases of preterminal renal failure (creatinine clearance < 10ml/min) should the Keptrix dosage not exceed 2 g daily. In patients with liver damage, there is no need for the dosage to be reduced provided renal function is intact.
In patients with both severe renal and hepatic dysfunction, the plasma concentrations of ceftriaxone should be determined at regular intervals and if necessary the dose should be adjusted.
In patients undergoing dialysis no additional supplementary dosing is required following the dialysis. Plasma concentrations should, however, be monitored, to determine whether dosage adjustments are necessary, since the elimination rate in there patients may be altered.

OVERDOSE

Adverse reactions seen at dose levels up to 2 g in normal subjects did not differ from the profile seen in patients treated at the recommended doses.

EXCRETION

Total plasma clearance is 10 to 22 ml/min. Renal clearance is 5 to 12 ml/min. 50 to 60% of ceftriaxone is excreted unchanged in the urine, while 40 to 50% is excreted unchanged in the bile. The elimination half-life in adults is about 8 hours.

SIDE EFFECTS

Generally well tolerated after administration.
The mild side effects are as follows:
Local Reactions: pain, tenderness, phlebitis
Hypersensitivity: rash, pruritus, fever or chills.
Hematologic: eosinophilia, thrombocytosis and leukopenia. Less frequently occur anemia, hemolytic anemia, neutropenia, lymphopenia, thrombocytopenia and prolongation of the prothrombin time.
Gastrointestinal: diarrhea, nausea or vomiting, and dysgeusia.
Hepatic: elevations of SGOT or SGPT.
Renal: elevations of the BUN. Less frequently reported (<1%) were elevations of creatinine and the presence of casts in the urine.
Central Nervous System: headache or dizziness reported occasionally.
Genitourinary: moniliasis or vaginitis reported occasionally

PRECAUTION

Incompatibilities
Do not mix Ceftriaxone Injection with solutions containing calcium such as Hartmann's solution and Ringer's solution. Ceftriaxone is incompatible with amsacrine, vancomycin, fluconazole and aminoglycosides.
After dilution or reconstitution
24 hours when reconstituted in a recommended diluent. 48 hours when reconstituted in a recommended diluent and refrigerated.
Lactating mother
Low concentrations of ceftriaxone are excreted in human milk. Caution should be exercised when Ceftriaxone is administered to a nursing woman.

DRUG INTERACTION

No major drug interactions have been found.

CONTRAINDICATION

Ceftriaxone Injection is contraindicated in patients with known hypersensitivity to cephalosporin antibiotics.
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.

STORAGE CONDITION

Store the unopened medicine at or below 25°C. Protect from light. Protect from moisture.
Store the reconstituted medicine between 2 to 8°C.

DOSAGE FORMS & PACKS

Packs for i.v. injection containing:
1 vial with dry substance equivalent to 2 g ceftriaxone and 2 ampoules containing 10 ml of sterile Water for Injections each.
1 vial with dry substance equivalent to 1 g, 500 mg or 250 mg ceftriaxone, and 1 ampoule containing 10 ml or 5 ml of sterile Water for Injections.

Packs for i.m. injection containing:
1 vial with dry substance equivalent to 1 g, 500 mg or 250 mg ceftriaxone, and 1 ampoule containing 3.5 ml or 2 ml of 1% lidocaine solution.

Apex pharma

Manufactured by
Popular Pharmaceuticals Ltd. for
Apex Pharma Ltd.