

CEFTRIAZONE FOR INJECTION USP 1 GM

POM

COMPOSITION:

Each vial contains:
Ceftriaxone Sodium USP (Sterile)
Eq. to Anhydrous Ceftriaxone 1 gm

PHARMACOLOGICAL CLASSIFICATION:

Third generation cephalosporin antibiotic

PHARMACOLOGICAL ACTION:

Ceftriaxone is a third generation cephalosporin inhibits bacterial cell wall synthesis by binding to one or more of the penicillin-binding proteins (PBPs) which in turn inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell walls, thus inhibiting cell wall biosynthesis. Bacteria eventually lyse due to ongoing activity of cell wall autolytic enzymes (autolysins and murein hydrolases) while cell wall assembly is arrested.

Pharmacokinetic:

Absorption: Well absorbed

Distribution: Vd: 6-14 L; widely throughout the body including gallbladder, lungs, bone, bile, CSF (higher concentrations achieved when meninges are inflamed)

Protein binding: 85% to 95%

Half-life elimination: Normal renal and hepatic function: 5-9 hours; Renal impairment (mild-to-severe): 12-16 hours

Time to peak, serum: 2-3 hours

Excretion: Urine (33% to 67% as unchanged drug); feces (as inactive drug)

INDICATIONS:

Ceftriaxone Injection is indicated for Lower respiratory tract infections and community-acquired pneumonia; Acute bacterial otitis media; Skin and skin structure infections; Urinary tract infections; Uncomplicated gonorrhoea; Pelvic inflammatory disease; Bacterial septicemia; Bone and joint infections; Intra-abdominal infections; Bacterial meningitis; Perioperative prophylaxis of infections associated with surgery.

CONTRAINDICATIONS:

Ceftriaxone Injection is contraindicated in

Patient with Hypersensitivity to cephalosporin and beta-lactamase inhibitors.

Neonates with jaundice, hypoalbuminaemia, acidosis or impaired bilirubin binding.

Concomitant treatment with calcium in children: risk of precipitation in urine and lungs of neonates (and possibly infants and older children).

SPECIAL PRECAUTIONS AND WARNINGS:

Use with caution in patients with a history of penicillin allergy, especially IgE-mediated reactions (e.g. anaphylaxis, angioedema, urticaria). Abnormal gallbladder sonograms have been reported, possibly due to ceftriaxone-calcium precipitates; discontinue in patients with signs and symptoms of gallbladder disease. Use with caution in patients with a history of GI disease, especially colitis.

Prolonged use may result in fungal or bacterial superinfection, including *C. difficile*-associated diarrhea (CDAD) and pseudomembranous colitis; CDAD has been observed >2 months post-antibiotic treatment.

Renal/hepatic impairment: Use with caution in patients with concurrent hepatic dysfunction and significant renal disease; dosage should not exceed 2 g/day.

Pregnancy: The pharmacokinetics of ceftriaxone in the third trimester is similar to those of nonpregnant patients, with the possible exception of lower peak concentrations during labor. Ceftriaxone crosses the placenta and distributes to amniotic fluid. Ceftriaxone is recommended for use in pregnant women for the treatment of gonococcal infections.

Lactating women: It passes into breast milk so use with caution in Lactating women

Neonates: Use extreme caution in neonates due to risk of hyperbilirubinemia, particularly in premature infants (contraindicated in hyperbilirubinemic neonates).

ADVERSE EFFECTS:

Rash, Diarrhoea, Eosinophilia, thrombocytosis, leukopenia, elevation of hepatic enzymes, tenderness at injection site, pain elevation of blood urea nitrogen (BUN), local reaction on I.M administration (e.g. Induration, warmth, tightness).

DOSAGE AND DIRECTIONS FOR USE:

Adult: 1-2 g every 12-24 hours or as directed by physician depending on the type and severity of infection

Pediatric: Mild-to-moderate infections: 50-75 mg/kg/day in 1-2 divided doses every 12-24 hours (maximum: 2 g/day); continue until at least 2 days after signs and symptoms of infection have resolved

Serious infections: 80-100 mg/kg/day in 1-2 divided doses (maximum: 4 g/day)

Directions for Use: Do not use diluents containing calcium, such as Ringer's solution or Hartmann's solution.

Intramuscular Administration: Reconstitute Ceftriaxone powder with sterile water for injection. Inject sterile water for injection into vial, shake vial thoroughly to form solution. Withdraw entire contents of vial into syringe to equal total labeled dose. After reconstitution, each 1 mL of solution contains approximately 250 mg or 350 mg equivalent of ceftriaxone according to the amount of sterile water for injection indicated below. If required, more dilute solutions could be utilized.

Vial Dosage Size	Amount of sterile water for injection to be Added	
1 gm	250 mg/m	350 mg/ml
	3.6 ml	2.1 ml

As with all intramuscular preparations, it should be injected well within the body of a relatively large muscle; aspiration helps to avoid unintentional injection into a blood vessel.

Intravenous Administration: Ceftriaxone should be administered intravenously by infusion over a period of 30 minutes. Concentrations between 10 mg/mL and 40 mg/mL are recommended; however, lower concentrations may be used if desired. Reconstitute vials with sterile water for injection.

Vial Dosage Size	Amount of sterile water for injection to be Added
1 gm	9.6 ml

After reconstitution, each 1 mL of solution contains approximately 100 mg equivalent of ceftriaxone. Withdraw entire contents and dilute to the desired concentration with sterile water for injection.

OVERDOSAGE:

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.

DRUG INTERACTIONS:

Ceftriaxone Antibiotics may diminish the therapeutic effect of BCG Typhoid Vaccine. Calcium Salts (Intravenous) may enhance the adverse/toxic effect of Ceftriaxone. Ceftriaxone binds to calcium forming an insoluble precipitate. Probenecid may increase the serum concentration of Ceftriaxone. Ceftriaxone may enhance the anticoagulant effect of Vitamin K.

PRESENTATION:

Vial Pack

STORAGE INSTRUCTIONS:

Store below 30°C. Protect from light & moisture.

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