

Cefot[®]

Cefotaxime

Description

Cefot[®] is the preparation of cefotaxime sodium which is a semi synthetic, broad-spectrum third generation cephalosporin antibiotic for parenteral administration. The bactericidal activity of cefotaxime results from inhibition of cell wall synthesis. Cefotaxime has been shown to be activity against wide range of Gram-positive and Gram-negative organisms sensitive or resistant to first or second generation cephalosporin.

Indications

Cefot[®] is indicated for the treatment of patients with following serious infections, such as -

- Lower respiratory tract infections including pneumonia
- Genitourinary infections including urinary tract infections and also uncomplicated gonorrhoea (cervical/urethral and rectal)
- Gynecologic infections including pelvic inflammatory disease, endometritis and pelvic cellulitis
- Bacteremia and septicemia
- Skin and skin structure infections
- Intra-abdominal infections including peritonitis
- Bone and/or joint infections
- Central nervous system infections (e.g., meningitis and ventriculitis)

Dosage and administration

Dosage

Adults

Dosage and route of administration should be determined by susceptibility of the causative organisms, severity of the infection and the condition of the patient. **Cefot[®]** may be administered IM or IV after reconstitution. The maximum daily dosage should not exceed 12 g.

- **Life-threatening infections:** 12 g daily by IV injection every 4 hours in equal divided dosages (2 g per dose)

- **Moderate to severe infections (e.g., meningitis):** 3 to 6 g daily by IM or IV injection every 8 hours in equal divided dosages (1 to 2 g per dose)
- **Uncomplicated infections:** 2 g daily by IM or IV injection every 12 hours in equal divided dosages (1 g per dose)
- **Infections commonly needing antibiotics in higher dosage (e.g., septicemia):** 6 to 8 g daily by IV injection every 6 to 8 hours in equal divided dosages (2 g per dose)
- **Gonococcal urethritis/cervicitis in males and females:** 0.5 g as a single dose by IM injection
- **Rectal gonorrhea in females:** 0.5 g as a single dose by IM injection
- **Rectal gonorrhea in males:** 1 g as a single dose by IM injection

Cesarean section patients: The first dose of 1 g is administered intravenously as soon as the umbilical cord is clamped. The second and third doses should be given as 1 g intravenously or intramuscularly at 6 and 12 hours after the first dose.

Post-operative infection: Recommended dose is a single 1 g IM or IV administered 30 to 90 minutes prior surgery.

Infants and children (1 month to 12 years)

For body weights less than 50 kg, the recommended daily dose is 50 to 180 mg/kg IM or IV body weight divided into 4 to 6 equal doses. The higher dosages should be used for more severe or serious infections including meningitis.

For body weights 50 kg or more, the usual adult dosage should be used; the maximum daily dosage should not exceed 12 g.

Neonates (birth to 1 month)

0-1 week of age : 50 mg/kg per dose every 12 hours IV
1-4 weeks of age : 50 mg/kg per dose every 8 hours IV

Patients with renal impairment: If GFR is less than 5 ml/minute/1.73 m², initial dose of 1 g then use half of normal dose.

Geriatric use: The drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Care should be taken in dose selection.

Reconstitution procedure and administration

Reconstitution procedure

Cefot[®] IM injections: 250 mg IM with 2 ml water for injection, 500 mg IM with 2 ml water for injection, 1 g IM with 3 ml water for injection, 2 g IM with 5 ml water for injection.

Cefot[®] IV injections: 250 mg IV with 5 ml water for injection, 500 mg IV with 10 ml water for injection, 1 g IV with 10 ml water for injection, 2 g IV with 10 ml water for injection.

Cefot[®] IV infusion: **Cefot**[®] may be administered by IV infusion. 1 to 2 g are dissolved in 40-100 ml of water for injection or 50 ml or 100 ml of 0.9% Sodium Chloride injection or 5% Dextrose injection.

Administration

Cefot[®] IM injection: As with all IM preparations, **Cefot**[®] should be injected well within the body of a relatively large muscle, such as the upper outer quadrant of the buttock (i.e., gluteus maximus); aspiration is necessary to avoid inadvertent injection into a blood vessel. Individual IM doses of 2 g may be given if the dose is divided and is administered in different intramuscular sites.

Cefot[®] IV injection: For intermittent IV administration, a solution containing 1 or 2 g in 10 ml of sterile water for injection can be injected over a period of 3 to 5 minutes. Cefotaxime should not be administered over a period of less than 3 minutes.

Cefot[®] infusion: The prepared infusion should be administered over 20-60 minutes. **Cefot**[®] may also be given over a longer period of time through the tubing system by which the patients can receive other IV solutions. It is advisable to discontinue temporarily the administration of other solutions at the same site.

Compatibility and Stability

Use of freshly prepared solution is preferred. Reconstituted solution is stable up to 24 hours in refrigerator and 8 hours at room temperature.

Pregnancy and lactation

Cefotaxime is a drug of pregnancy category B. Cefotaxime should be avoided during pregnancy especially during the first trimester, without carefully weighing the expected benefit against possible risks. Cefotaxime is excreted in the milk and caution should be exercised when cefotaxime is administered to the nursing mother.

Side effects

Cefotaxime is generally well tolerated. The most common side effects are injection site inflammation with IV administration; pain, induration and tenderness after IM injection; hypersensitivity reactions have been reported, these include skin rash, pruritis, fever, eosinophilia; gastrointestinal reactions (such as colitis, diarrhea, nausea and vomiting); symptoms of pseudomembranous colitis can appear during or after antibiotic treatment. The less frequent side effects are potentially life-threatening arrhythmias following rapid (less than 60 seconds) bolus administration via central venous catheter has been observed; neutropenia, transient leukopenia, eosinophilia, thrombocytopenia and agranulocytosis, moniliasis, vaginitis, headache, transient elevations in SGOT, SGPT, serum LDH and serum alkaline phosphatase levels have been reported. As with some other cephalosporins, interstitial nephritis and transient elevations of BUN and creatinine have been occasionally observed with cefotaxime. As with other cephalosporins, isolated cases of erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported.

Contraindications

Cefotaxime is contraindicated in patients with known hypersensitivity to cefotaxime sodium or the cephalosporin group of antibiotics.

Drug interactions

Increased nephrotoxicity has been reported concomitant administration of cephalosporins and aminoglycoside antibiotics.

Overdosage

Most cases have shown no overt toxicity. The most frequent reactions are elevations of BUN and creatinine. Serum levels of cefotaxime may be reduced by peritoneal dialysis or haemodialysis. In the case of high doses, there is a risk of reversible encephalopathy.

Pharmaceutical precautions

Store in cool dry place, protected from light and heat.

Presentation

Cefot[®] 250 mg IM/IV injection : Pack of one vial contains Cefotaxime 250 mg as Sodium USP accompanied by an ampoule of 5 ml water for injection BP

Cefot[®] 500 mg IM/IV injection : Pack of one vial contains Cefotaxime 500 mg as Sodium USP accompanied by an ampoule of 10 ml water for injection BP

Cefot[®] 1 g IM/IV injection : Pack of one vial contains Cefotaxime 1 g as Sodium USP accompanied by an ampoule of 10 ml water for injection BP

Cefot[®] 2 g IM/IV injection : Pack of one vial contains Cefotaxime 2 g as Sodium USP accompanied by an ampoule of 10 ml water for injection BP

Package quantities

Cefot[®] 250 mg IM/IV injection : Box of 1 vial + 1 ampoule WFI (5 ml) + 1 Disposable syringe + 1 Alcohol pad + 1 Baby needle

Cefot[®] 500 mg IM/IV injection : Box of 1 vial + 1 ampoule WFI (10 ml) + 1 Disposable syringe + 1 Alcohol pad + 1 Baby needle

Cefot[®] 1 g IM/IV injection : Box of 1 vial + 1 ampoule WFI (10 ml) + 1 Disposable syringe + 1 Alcohol pad

Cefot[®] 2 g IM/IV injection : Box of 1 vial+ 1 ampoule WFI (10 ml) + 1 Disposable syringe + 1 Alcohol pad

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