

Cefotaxime

Introduction: Cefotaxime is in a group of drugs called cephalosporin antibiotics. Cefotaxime injection is used to treat many kinds of bacterial infections, including severe or life-threatening forms. Cefotaxime is also used to prevent infections in people having surgery.

Mechanism of action: 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.

Pharmacology:

Distribution: Widely to body tissues and fluids including aqueous humor, ascitic and prostatic fluids, bone; penetrates CSF best when meninges are inflamed; crosses placenta; enters breast milk.

Metabolism: Partially hepatic to active metabolite, desacetylcefotaxime

Half-life elimination: Premature neonates <1 week: 5-6 hours; Full-term neonates <1 week: 2-3.4 hours; Adults: 1-1.5 hours; prolonged with renal and/or hepatic impairment

Time to peak, serum: I.M.: Within 30 minutes

Excretion: Urine (as unchanged drug and metabolites)

Indications: Cefotaxime is indicated for the treatment of patients with serious infections caused by susceptible strains of the designated microorganisms in the diseases listed below:

- **Lower respiratory tract infections:** including pneumonia, caused by *Streptococcus pneumoniae*, *Streptococcus pyogenes* and other streptococci, *Staphylococcus aureus*, *Escherichia coli*, *Klebsiella* species, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Proteus mirabilis*, *Serratia marcescens*, *Enterobacter* species, indole positive *Proteus* and *Pseudomonas* species.
- **Genitourinary infection:** Urinary tract infections caused by *Enterococcus* species, *Staphylococcus epidermidis*, *Staphylococcus aureus*, *Citrobacter* species, *Enterobacter* species, *Escherichia coli*, *Klebsiella* species, *Proteus mirabilis*, *Proteus vulgaris* *, *Providencia stuartii*, *Morganella morganii* *, *Providencia rettgeri* *, *Serratia marcescens* and *Pseudomonas* species. Also, uncomplicated gonorrhoea caused by *Neisseria gonorrhoeae*, including penicillinase producing strains.
- **Gynecologic infections,** including pelvic inflammatory disease, endometritis and pelvic cellulitis caused by *Staphylococcus epidermidis*, *Streptococcus* species, *Enterococcus* species, *Enterobacter* species *, *Klebsiella* species *, *Escherichia coli*, *Proteus mirabilis*, *Bacteroides* species, *Clostridium* species, and anaerobic cocci and *Fusobacterium*

species. Cefotaxime, like other cephalosporins, has no activity against *Chlamydia trachomatis*. Therefore, when cephalosporins are used in the treatment of patients with pelvic inflammatory disease and *C. trachomatis* is one of the suspected pathogens, appropriate antichlamydial coverage should be added.

- **Bacteremia/Septicemia** caused by *Escherichia coli*, *Klebsiella* species, and *Serratia marcescens*, *Staphylococcus aureus* and *Streptococcus* species (including *S. pneumoniae*).
- **Skin and skin structure infections** caused by *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pyogenes* and other streptococci, *Enterococcus* species, *Acinetobacter* species *, *Escherichia coli*, *Citrobacter* species, *Enterobacter* species, *Klebsiella* species, *Proteus mirabilis*, *Proteus vulgaris* *, *Morganella morganii*, *Providencia rettgeri* *, *Pseudomonas* species, *Serratia marcescens*, *Bacteroides* species, and anaerobic cocci.
- **Intra-abdominal infections** including peritonitis caused by *Streptococcus* species *, *Escherichia coli*, *Klebsiella* species, *Bacteroides* species, and anaerobic cocci *Proteus mirabilis* *, and *Clostridium* species *.
- **Bone and/or joint infections** caused by *Staphylococcus aureus* (penicillinase and non-penicillinase producing strains), *Streptococcus* species (including *S. pyogenes* *), *Pseudomonas* species (including *P. aeruginosa* *), and *Proteus mirabilis* *.
- **Central nervous system infections**, e.g., meningitis and ventriculitis, caused by *Neisseria meningitidis*, *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Klebsiella pneumoniae* * and *Escherichia coli* *.

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 (see table for dosage guideline). The maximum daily dosage should not exceed 12 grams.

DOSAGE OF Cefotaxime		
Type of Infection	Daily Dose (grams)	Frequency and Route
Gonococcal urethritis/ cervicitis in males and females	0.5	0.5 gram IM (single dose)
Rectal gonorrhoea in females	0.5	0.5 gram IM (single dose)
Rectal gonorrhoea in males	1	1 gram IM (single dose)
Uncomplicated infections	2	1 gram every 12 hours IM or IV (dose)
Moderate to severe infections	3-6	1-2 grams every 8 hours IM or IV
Infections commonly needing antibiotics in higher dosage (e.g., septicemia)	6-8	2 grams every 6-8 hours IV
Life-threatening infections	up to 12	2 grams every 4 hours IV

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

Neonates, Infants, and Children: The following dosage schedule is recommended:

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

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 four to six 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 grams.

Side effects:

- diarrhea that is watery or bloody;
- severe pain, irritation, or skin changes where the needle was placed;
- skin rash, bruising, severe tingling, numbness, pain, muscle weakness;
- uneven heartbeats;
- fever, chills, body aches, flu symptoms;
- easy bruising or bleeding, unusual weakness;
- fever, sore throat, and headache with a severe blistering, peeling, and red skin rash;
- seizure (black-out or convulsions); or
- jaundice (yellowing of the eyes or skin).
- pain, irritation, or hardening where the injection was given;
- stomach pain, nausea, vomiting;
- headache; or
- vaginal itching or discharge.

Precautions: Cefotaxime should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis. As with other beta-lactam antibiotics, granulocytopenia and, more rarely, agranulocytosis may develop during treatment with Cefotaxime, particularly if given over long periods. For courses of treatment lasting longer than 10 days, blood counts should therefore be monitored. Cefotaxime, like other parenteral anti-infective drugs, may be locally irritating to tissues. In rare instances, extensive perivascular extravasation Cefotaxime may result in tissue damage and require surgical treatment. To minimize the potential for tissue inflammation, infusion sites should be monitored regularly and changed when appropriate.

Pregnancy: There are no well-controlled studies in pregnant women; the drug should be used during pregnancy only if clearly needed.

Nursing mothers: Cefotaxime is excreted in human milk in low concentrations. Caution should be exercised when Cefotaxime is administered to a nursing woman.

Pediatric use: To prevent unintentional overdose, this product should not be used in pediatric patients who require less than the full adult dose of cefotaxime.

Geriatric use: This 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. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Contraindications: Cefotaxime for Injection is contraindicated in patients who have shown hypersensitivity to cefotaxime sodium or the cephalosporin group of antibiotics.

How supplied: Customized as per request.