



CEFOTAXIME SODIUM INJECTION

CEFOTAXIME SODIUM INJECTION USP (vial)

Sterile Cefotaxime USP

eq. to Cefotaxime base 250 mg

Indications and Usage :

Treatment of infections of lower respiratory tract including pneumonia, urinary tract, skin and skin structures, bone and joints; treatment of bacteremia/septicemia, CNS infections, intra-abdominal infections including peritonitis, gynecological infections including pelvic inflammatory disease, endometritis and pelvic cellulitis caused by susceptible strains of specific microorganisms; perioperative prophylaxis.

Contraindications :

Hypersensitivity to cephalosporins.

Dosage and Administration :

Infection

Adults

IV/IM Up to 12 g/day in divided doses (from every 4 h for septicemia to every 12 h for uncomplicated infection) usually for 7 to 10 days. IV route is preferable for severe infections.

Children 1 mo to 12 yr of age (weighing less than 50 kg)

IV/IM 50 to 180 mg/kg/day in 4 to 6 divided doses.

Children 1 mo to 12 yr of age (weighing more than 50 kg)

Usual adult dose (max, 12 g/day).

Infants 1 to 4 wk of age

IV 50 mg/kg every 8 h.

Newborns younger than 1 wk of age

IV 50 mg/kg every 12 h.

Gonococcal Urethritis/Cervicitis in Men and Women

Adults

IM 0.5 g as single dose.

Rectal Gonorrhea

Adults

IM 0.5 g as single dose (women); 1 g as single dose (men).





Perioperative Prophylaxis

Adults

IV/IM 1 g 30 to 90 min prior to surgery.

Cesarean Section

Adults

IV 1 g as soon as umbilical cord is clamped; second and third dose IV/IM at 6- and 12-h intervals after first dose.

Dosage Adjustment for Renal Function Impairment

Reduce dose 50% in patients with Ccr less than 20 mL/min.

General Advice :

- * For IM or IV administration only. Not for intradermal, subcutaneous, or intra-arterial administration.
- * IV route preferred for severe or life-threatening infections, or for patients who may be poor risks because of lowered resistance.
- * Follow manufacturer's guidelines for reconstitution of sterile powder with respect to diluent volume, withdrawable volume, and approximate final concentration.
- * For IM administration, reconstitute vials with sterile water for injection or bacteriostatic water for injection.
- * For IV administration, reconstitute vials with at least 10 mL sterile water for injection; reconstitute infusion bottles with 50 or 100 mL sodium chloride 0.9% injection or dextrose 5% injection.
- * Shake to dissolve.
- * Thaw premixed frozen injection at room temperature or under refrigeration (at or below 41°F). Do not force thaw by immersion in water baths or microwave irradiation. Check container for minute leaks by squeezing container firmly. Discard container if leaks are detected. Do not use plastic containers in series connections because of risk of air embolism.
- * Reconstituted or thawed solution should be clear and pale to light yellow in color. Do not use if discolored, cloudy, or contains particulate matter.
- * Intermittent IV administration: solution containing 1 or 2 g cefotaxime in 10 mL sterile water for injection can be injected over a period of 3 to 5 min. Do not administer over a period of less than 3 min. Can also be administered via infusion system over longer period of time; temporarily discontinue administration of other solutions at same site during infusion of cefotaxime.
- * For continuous IV infusion, add solution of cefotaxime to IV bottles containing compatible fluids (sodium chloride 0.9% injection, dextrose 5% or 10% injection, dextrose 5% and sodium chloride 0.9%, 0.45%, or 0.2% injection, Ringer's lactate solution, sodium lactate injection, invert sugar 10% solution, Travasol 8.5% amino acid injection without electrolytes.
- * For IM administration. Dose of 2 g may be given if dose is divided and administered at different sites.

Storage/Stability :

Store vials and bottles of dry powder below 86°F. Protect from light and excessive temperature. Refer to manufacturer's guidelines for storage and stability recommendations for reconstituted solutions. Store premixed frozen injection in freezer capable of maintaining temperature of - 4°F. Thawed solution is stable for 10 days under refrigeration (at or below 41°F) or 24 h at or below 72°F. Do not refreeze thawed antibiotics.

For Information about Generic Medicines : genericmedicines@tajpharma.com

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According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries.

www.tajpharma.com

The company medicines are present in France, Georgia, Egypt and CIF countries.



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