Anti-infective

Piramal Critical Care

Ceftriaxone for Injection, USP

Piramal's Ceftriaxone for Injection, USP is available through the wholesaler or distributor of your choice

Wholesaler / Distributor Name	25 Single Dose Vials in a carton: NDC - 66794-211-42 Ceftriaxone for Injection, USP (250 mg per vial) Catalog numbers	25 Single Dose Vials in a carton: NDC - 66794-212-42 Ceftriaxone for Injection, USP (500 mg per vial) Catalog numbers	25 Single Dose Vials in a carton: NDC - 66794-213-42 Ceftriaxone for Injection, USP (1 gram per vial) Catalog numbers	25 Single Dose Vials in a carton: NDC - 66794-214-42 Ceftriaxone for Injection, USP (2 grams per vial) Catalog numbers	1 Bottle in a carton: NDC - 66794-215-15 Ceftriaxone for Injection, USP (10 grams per bottle) Catalog numbers
AmerisourceBergen	10229458	10229489	10229377	10229551	10229552
Cardinal	5562442	5562459	5562467	5562475	5562483
McKesson	3979853	3979960	3979994	3979812	3979937
Morris & Dickson	778126	778142	778159	778167	778175

ABBREVIATED PRESCRIBING INFORMATION

PRODUCT NAME AND COMPOSITION: Ceftriaxone for Injection, an injectable antibacterial solution. Supplied in 250mg, 500mg, 1 and 2 grams vials.

Please refer to Full Prescribing Information (FPI) before prescribing.

INDICATIONS: Treatment of infections due to susceptible strains of the designated microorganisms in the conditions listed in the FPI.

DOSAGE AND ADMINISTRATION: See FPI for full details. Ceftriaxone for injection may be administered by either IV or IM routes. The recommended adult dosage of Ceftriaxone for injection is 1-2 grams once a day (or in equally divided doses twice a day) depending on the type and severity of infection. The total daily dose should not exceed 4 grams. If *Chlamydia trachomatis* is a suspected pathogen, appropriate antichlamydial coverage should be added, because Ceftriaxone sodium has no activity against this organism. For the treatment of uncomplicated gonococcal infections, a single intramuscular dose of 250 mg is recommended. For preoperative use (surgical prophylaxis), a single dose of 1 gram administered intravenously 1/2 to 2 hours before surgery is recommended. Generally, Ceftriaxone for injection therapy should be continued for at least 2 days after the signs and symptoms of infection have disappeared. The usual duration of therapy is 4 to 14 days; in complicated infections, longer therapy may be required. **Pediatric Patients** (2 months to 16 years): The recommended daily dose is 50 -75 mg per kg of body weight administered once a day (or in equally divided doses twice a day). The total daily dose should not exceed 2 grams. **Patients with Impaired Renal Function**: No dosage adjustment is necessary for patients with impairment of renal or hepatic function.

CONTRAINDICATIONS: Ceftriaxone for injection is contraindicated in patients who have shown immediate hypersensitivity reactions to Ceftriaxone or the cephalosporin class of antibiotics, penicillins or other beta-lactam antibiotics. Ceftriaxone for injection is also contraindicated in premature neonates.

COMMON SIDE EFFECTS: **Local**: Pain at IM injection site, pain at IV injection site (3%). **Systemic**: Rash (1.7%), diarrhea (2.7%), eosinophilia (6%), thrombocytosis (5.1%) and leukopenia (2.1%); elevations of aspartate aminotransferase (AST) (3.1%) or alanine aminotransferase (ALT) (3.3%). See FPI for a complete list.

WARNINGS AND PRECAUTIONS: To reduce the development of drug-resistant bacteria and maintain effectiveness of Ceftriaxone for injection and other antibacterial drugs, Ceftriaxone for injection should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy. See FPI for full details. Before therapy with Ceftriaxone for injection is instituted, careful inquiry should be made to determine whether the patient has had previous immediate hypersensitivity reactions to ceftriaxone, cephalosporins, penicillins, or other beta-lactams. Exercise caution if this product is to be given to penicillin-sensitive patients because cross-hypersensitivity among beta-lactam antibacterial drugs has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to Ceftriaxone for injection occurs, discontinue the drug

and institute appropriate supportive measures. Ceftriaxone must not be administered simultaneously with calcium-containing IV solutions, including continuous calcium-containing infusions such as parenteral nutrition via a Y-site. Precipitation of ceftriaxone-calcium can also occur when Ceftriaxone is mixed with calcium-containing solutions in the same IV administration line. *Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Ceftriaxone for injection, and may range in severity from mild diarrhea to fatal colitis. See FPI for full details.

OVERDOSAGE: Patients who receive an overdose should be carefully observed and given supportive treatment. 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.

For more information, please contact Piramal Customer Service at +1-800-414-1901 during business hours (8 a.m. EST to 5 p.m. EST) or e-mail at pcc.customerservice@piramal.com

- Full prescribing information of Ceftriaxone for Injection, USP can be seen at
  https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=88312fc0-35d5-2945-e053-2a95a90a34bd.
  https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=87a41e63-f29c-7082-e053-2995a90a1106.
- Adverse events should be reported to Piramal Critical Care at http://pcc-chex.force.com/SiteComplaintForm.
- You are encouraged to report adverse events of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.

"Saving and Improving Patients' Lives."

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Piramal Critical Care, Inc.
3950 Schelden Circle, Bethlehem, PA 18017, USA
Toll Free No.: +1-800-414-1901 www.piramalcriticalcare.com/us/

https://www.linkedin.com/company/piramal-critical-care/

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