Anti-infective

Piramal Critical Care

Cefepime for Injection, USP

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

Wholesaler / Distributor Name	10 Single Dose Vials in a carton: NDC - 66794-209-41 Cefepime for Injection, USP (1 gram per vial) Catalog numbers	10 Single Dose Vials in a carton: NDC - 66794-210-41 Cefepime for Injection, USP (2 grams per vial) Catalog numbers
AmerisourceBergen	10221528	10221424
Cardinal	5535349	5535356
McKesson	3949476	3949450
Morris & Dickson	630335	630368

ABBREVIATED PRESCRIBING INFORMATION

PRODUCT NAME AND COMPOSITION: Cefepime for Injection, an injectable antibacterial solution. Supplied in 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. Cefepime for injection may be administered by either IV or IM routes. For intravenous administration, the dose can be given by slow intravenous injection over 30 minutes. The recommended adult dosage of Cefepime for injection is 1 to 2 grams every 8 to 12 hours for treatment duration of 7 to 10 days. **Pediatric Patients** (2 months to 16 years): The recommended daily dose is 50 mg per kg of body weight administered via intravenous infusion in equally divided doses every 8 to 12 hours. Pediatric patients weighing 40 kg or more should be dosed according to adult recommendations. **Patients with Impaired Renal Function**: The dose of Cefepime for injection in such patients should be adjusted to compensate for the slower rate of renal elimination, in accordance with the guidelines contained in the FPI. The same guidelines must be specifically followed for patients undergoing Hemodialysis and Continuous Ambulatory Peritoneal Dialysis (CAPD).

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

COMMON SIDE EFFECTS: Local: Pain at IM injection site, pain at IV injection site (3%), phlebitis (1.3%). Systemic: Rash (4%), diarrhea (3%), nausea (2%), vomiting (1%), pruritus (1%), fever (1%), and headache (1%).

See FPI for a complete list.

WARNINGS AND PRECAUTIONS: To reduce the development of drug-resistant bacteria and maintain effectiveness of Cefepime for injection and other antibacterial drugs, Cefepime 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 Cefepime for injection is instituted, careful inquiry should be made to determine whether the patient has had previous immediate hypersensitivity reactions to Cefepime, 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 Cefepime for injection occurs, discontinue the drug and institute appropriate supportive measures.

Serious and occasionally fatal neurotoxic reactions have been reported in patients on Cefepime therapy. These reactions include encephalopathy,

aphasia, myoclonus, seizures, and nonconvulsive status epilepticus. Most cases occurred in patients with renal impairment who did not receive appropriate dosage adjustment. If neurotoxicity associated with Cefepime therapy occurs, discontinue Cefepime and institute appropriate supportive measures. *Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Cefepime 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 presence of renal insufficiency, hemodialysis, not peritoneal dialysis, is recommended to aid in the removal of Cefepime from the body. Symptoms of overdose include encephalopathy (disturbance of consciousness including confusion, hallucinations, stupor, and coma), myoclonus, seizures, neuromuscular excitability and nonconvulsive status epilepticus.

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 Cefepime for Injection, USP can be seen at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=83d70378-012e-4ce3-e053-2991aa0a22be.
- 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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