



Piperacillin and Tazobactam for Injection, USP

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

Wholesaler / Distributor Name	10 Single Dose Vials in a carton: NDC - 66794-216-41 Piperacillin and Tazobactam for Injection, USP (2.25 grams) Catalog numbers	10 Single Dose Vials in a carton: NDC - 66794-217-41 Piperacillin and Tazobactam for Injection, USP (3.375 grams) Catalog numbers	10 Single Dose Vials in a carton: NDC - 66794-218-41 Piperacillin and Tazobactam for Injection, USP (4.5 grams) Catalog numbers
AmerisourceBergen	10235162	10235165	10235163
Cardinal	5627369	5627377	5627385
McKesson	1530856	1530757	1530732
Morris & Dickson	901934	901942	901959

ABBREVIATED PRESCRIBING INFORMATION

PRODUCT NAME AND COMPOSITION: Piperacillin and Tazobactam for injection is a combination penicillin-class antibacterial and β -lactamase inhibitor. Supplied in 2.25 g, 3.375 g, and 4.5 g lyophilized powder for reconstitution in single-dose vials.

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

INDICATIONS: Treatment of Intra-abdominal infections, Skin and skin structure infections, Female pelvic infections, Community-acquired pneumonia, and Nosocomial pneumonia listed in the FPI. Piperacillin and Tazobactam for injection should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

DOSAGE AND ADMINISTRATION: See FPI for full details. The usual daily dose of piperacillin and tazobactam for injection for adults is 3.375 g every six hours totaling 13.5 g (12 g piperacillin/1.5 g tazobactam). Initial presumptive treatment of patients with nosocomial pneumonia should start with piperacillin and tazobactam for injection at a dosage of 4.5 g every six hours plus an aminoglycoside, totaling 18 g (16 g piperacillin/2 g tazobactam). Dosage in patients with renal impairment (≤ 40 mL/min of CRCL) and dialysis patients should be reduced, based on the degree of actual renal function impairment. For children with appendicitis and/or peritonitis the recommended piperacillin and tazobactam for injection dosage is 100 mg piperacillin/12.5 mg tazobactam per kilogram of body weight, every 8 hours in pediatric patients 9 months of age and older. For pediatric patients 2 to 9 months of age, the recommended dosage is 80 mg piperacillin/10 mg tazobactam per kilogram of body weight, every 8 hours. Piperacillin and Tazobactam for injection and aminoglycosides should be reconstituted, diluted, and administered separately. Co-administration via Y-site can be done under certain conditions.

CONTRAINDICATIONS: Piperacillin and Tazobactam for injection is contraindicated in patients with a history of allergic reactions to any of the penicillins, cephalosporins, or β -lactamase inhibitors.

COMMON SIDE EFFECTS: Most common side effects (incidence $>5\%$) treated with piperacillin and tazobactam for injection include: diarrhea, constipation, nausea, headache and insomnia.

See FPI for a complete list.

WARNINGS AND PRECAUTIONS: Serious hypersensitivity reactions (anaphylactic/anaphylactoid) reactions have been reported in patients receiving piperacillin and tazobactam. Discontinue piperacillin and tazobactam if a reaction occurs. Piperacillin and Tazobactam may cause severe cutaneous adverse reactions, such as Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms, and acute generalized exanthematous pustulosis. Discontinue piperacillin and tazobactam for progressive rashes. Hematological effects (including bleeding, leukopenia and neutropenia) have occurred. Monitor hematologic tests during prolonged therapy. Nephrotoxicity in

critically ill patients has been observed; the use of piperacillin and tazobactam was found to be an independent risk factor for renal failure and was associated with delayed recovery of renal function as compared to other beta-lactam antibacterial drugs in a randomized, multicenter, controlled trial in critically ill patients. Based on this study, alternative treatment options should be considered in the critically ill population. If alternative treatment options are inadequate or unavailable, monitor renal function during treatment with piperacillin and tazobactam. *Clostridium difficile* associated diarrhea: evaluate patients if diarrhea occurs. See FPI for full details.

OVERDOSAGE: There have been post-marketing reports of overdose with piperacillin/tazobactam. The majority of those events experienced, including nausea, vomiting, and diarrhea, have also been reported with the usual recommended dosages. Patients may experience neuromuscular excitability or convulsions if higher than recommended doses are given intravenously (particularly in the presence of renal failure). Treatment should be supportive and symptomatic according to the patient's clinical presentation. Excessive serum concentrations of either piperacillin or tazobactam may be reduced by hemodialysis. Following a single 3.375 g dose of piperacillin/tazobactam, the percentage of the piperacillin and tazobactam dose removed by hemodialysis was approximately 31% and 39%, respectively.

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 Piperacillin and Tazobactam for Injection, USP can be seen at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=876b22e3-de45-5ddc-e053-2a95a90ac886>.
- 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.”



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/>