



Linezolid Injection

Piramal's Linezolid injection is available through the wholesaler or distributor of your choice

Wholesaler / Distributor Name	10 Single-Dose bags in a carton: NDC - 66794-219-43 Linezolid injection (600 mg/300mL per bag) Catalog numbers
AmerisourceBergen	10233071
Cardinal	5602446
McKesson	1508373
Morris & Dickson	890061

ABBREVIATED PRESCRIBING INFORMATION

PRODUCT NAME AND COMPOSITION: Linezolid injection is an oxazolidinone-class antibacterial solution. It is supplied in single-dose, ready-to-use flexible plastic infusion bags in a foil laminate overwrap.

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

INDICATIONS: Treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed in the FPI.

DOSAGE AND ADMINISTRATION: See FPI for full details. Linezolid injection should be administered by intravenous infusion over a period of 30 to 120 minutes. For nosocomial pneumonia, community-acquired pneumonia and complicated skin, skin structure infections and vancomycin-resistant *Enterococcus faecium* infections, including concurrent bacteremia, the recommended pediatric patients (birth through 11 years of age) dosage of Linezolid injection is 10 mg/kg intravenously every 8 hours for 10-14 days. For adults and adolescents (12 years and older), the recommended daily dose is 600 mg intravenously every 12 hours for the recommended duration of treatment (14-28 days). Maximum duration of treatment should be 28 days.

CONTRAINDICATIONS: Linezolid injection is contraindicated in patients who have known hypersensitivity to Linezolid or any of the other product components. Linezolid should not be used in patients taking any medicinal product which inhibits monoamine oxidases A or B (e.g., phenelzine, isocarboxazid) or within two weeks of taking any such medicinal product.

COMMON SIDE EFFECTS: Most common side effects (>5% of adult and/or pediatric patients) treated with Linezolid injection include: diarrhea, vomiting, headache, nausea, and anemia.

See FPI for a complete list.

WARNINGS AND PRECAUTIONS: Myelosuppression: Monitor complete blood counts weekly. Consider discontinuation in patients who develop or have worsening myelosuppression. Peripheral and optic neuropathy: Reported primarily in patients treated for longer than 28 days. If patients experience symptoms of visual impairment, prompt ophthalmic evaluation is recommended. Serotonin syndrome: Patients taking serotonergic antidepressants should receive Linezolid injection only if no other therapies are available. Discontinue serotonergic antidepressants and monitor patients for signs and symptoms of both serotonin syndrome and antidepressants discontinuation. A mortality imbalance was seen in an investigational study in Linezolid-treated patients with catheter-related bloodstream infections. Clostridium difficile associated diarrhea: Evaluate if diarrhea occurs. Potential interactions producing elevation of blood pressure: monitor blood pressure. Hypoglycemia: Post-marketing cases of symptomatic hypoglycemia have been reported in patients with diabetes mellitus receiving insulin or oral hypoglycemic agents.

See FPI for full details.

OVERDOSAGE: In patients who receive an overdose, supportive care is advised, with maintenance of glomerular filtration. Hemodialysis may facilitate more rapid elimination of Linezolid. In a Phase 1 clinical trial, approximately 30% of a dose of Linezolid was removed during a 3-hour hemodialysis session beginning 3 hours after the dose of Linezolid was administered. Data are not available for removal of Linezolid with peritoneal dialysis or hemoperfusion. Clinical signs of acute toxicity in animals were decreased activity and ataxia in rats, and vomiting and tremors in dogs treated with 3,000 mg/kg/day and 2,000 mg/kg/day 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 Linezolid Injection can be seen at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=95b8fd63-d018-8062-e053-2995a90ab96d>.
- 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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