

Linezolid IV Infusion

Linezolid Intravenous Infusion I.P. 2mg/Infusion

Description

Linezolid Intravenous Infusion I.P. 2mg/Infusion is an intravenous (IV) formulation of the antibiotic Linezolid, a member of the oxazolidinone class. It is used for the treatment of serious bacterial infections caused by Gram-positive pathogens, including resistant strains such as methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Enterococcus faecium* (VRE). This IV formulation is suitable for patients who are unable to take oral medications or when rapid blood concentrations of the drug are necessary.

Composition

Each Linezolid Intravenous Infusion I.P. 2mg/Infusion contains:

- Linezolid: 2 mg
- Excipients: Sodium chloride, water for injection, and other stabilizing agents as required for preparation and stability.

The infusion is intended for use only in healthcare settings under the supervision of a healthcare professional.

Indications

Linezolid Intravenous Infusion is indicated for the treatment of the following serious bacterial infections:

- Community-acquired pneumonia (CAP) caused by susceptible organisms.

- Hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia.
 - Skin and soft tissue infections (SSTIs), including complicated skin infections.
 - Bacteremia caused by Gram-positive organisms, particularly MRSA and VRE.
 - Infections caused by multi-drug resistant organisms, when oral treatment is not an option.
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Dosage and Administration

- **Recommended Dose:**
The standard dosage for adults and pediatric patients (age ≥ 12 years) is:
 - 200 mg to 400 mg every 12 hours as an intravenous infusion.
The exact dose may vary depending on the severity of the infection and the patient's condition.
- **Infusion Rate:**
Linezolid IV infusion should be administered slowly over a period of 30 to 120 minutes. The infusion must not be injected directly or as a bolus to avoid complications.
 - For the 2 mg infusion, ensure that it is properly diluted according to the product instructions before administering.
- **Preparation:**
Linezolid intravenous infusion is ready to use when prepared according to the prescribed guidelines. It should be diluted in an appropriate IV solution, such as normal saline or 5% dextrose, before administration.
- **Monitoring:**
During therapy with Linezolid IV, patients should be monitored for potential side effects, including blood cell counts (due to the risk of myelosuppression), and any signs of serotonin syndrome or

peripheral neuropathy. In cases of prolonged use (more than 2 weeks), regular blood tests are recommended.

Contraindications

Linezolid Intravenous Infusion is contraindicated in:

- Hypersensitivity to Linezolid or any of the excipients.
 - Concurrent use of Monoamine Oxidase Inhibitors (MAOIs), or within 14 days after the discontinuation of an MAOI, due to the risk of severe drug interactions.
 - Severe uncontrolled hypertension or those with a history of hypertensive crises due to the potential for interaction with pressor agents or foods rich in tyramine.
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Warnings and Precautions

- **Serotonin Syndrome:** Linezolid may increase the risk of serotonin syndrome, especially when used concurrently with serotonergic drugs (SSRIs, SNRIs, tricyclic antidepressants, and certain migraine medications). Symptoms of serotonin syndrome include agitation, confusion, hallucination, fever, and tremors. If these symptoms occur, immediate medical intervention is required.
- **Myelosuppression:** Prolonged treatment with Linezolid can cause bone marrow suppression, including thrombocytopenia, anemia, and leukopenia. Blood counts should be monitored during therapy, especially for long durations (greater than 2 weeks).
- **Peripheral and Optic Neuropathy:** Prolonged use of Linezolid may cause peripheral neuropathy or optic neuropathy (visual disturbances). Patients on long-term therapy should be regularly monitored for symptoms such

as numbness, tingling, or changes in vision.

- **Liver and Kidney Function:** Caution is required in patients with hepatic or renal dysfunction. Dosage adjustments may be necessary in patients with severe hepatic impairment or renal failure. Regular liver and kidney function tests are recommended during treatment.
 - **Pregnancy and Lactation:** Linezolid should only be used during pregnancy if the benefits outweigh the risks. It is excreted in breast milk, and caution is recommended when administering the medication to breastfeeding women.
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Side Effects

Common side effects include:

- Diarrhea
- Headache
- Nausea and vomiting
- Fatigue and dizziness
- Rash

Serious adverse effects may include:

- Serotonin syndrome (especially when used with other serotonergic agents)
- Bone marrow suppression (low blood counts, including thrombocytopenia and anemia)
- Peripheral or optic neuropathy
- Severe allergic reactions, including anaphylaxis

If any of the serious side effects occur, stop treatment and seek immediate medical attention.

Drug Interactions

- **Monoamine Oxidase Inhibitors (MAOIs):** Do not use Linezolid in combination with MAOIs or within 14 days of stopping MAOI therapy.

- **Serotonergic Medications:** Co-administration of Linezolid with other drugs that affect serotonin levels (e.g., SSRIs, SNRIs, tricyclic antidepressants, or certain migraine medications) increases the risk of serotonin syndrome.
 - **Antihypertensive Drugs:** Linezolid may reduce the effectiveness of antihypertensive agents, and blood pressure should be monitored closely.
 - **Other Antibiotics:** There are no major interactions with other antibiotics, but caution should be taken when combining Linezolid with other medications that affect liver metabolism.
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Storage Instructions

- **Before reconstitution:** Store the product at 15°C to 25°C (59°F to 77°F).
 - **After preparation:** Store the infusion solution at room temperature (15°C to 25°C) and use immediately. Do not store reconstituted solutions for more than 4 hours.
 - **Do not freeze the solution.**
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Presentation

- **Form:** Intravenous infusion (ready-to-use)
 - **Strength:** 2 mg per infusion (single dose vial)
 - **Pack Size:** Available in single-dose vials, typically 100 mL for use in healthcare facilities.
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Conclusion

Linezolid Intravenous Infusion I.P. 2mg/Infusion is a potent antibiotic for treating serious infections caused by resistant Gram-positive bacteria, including MRSA and VRE. This formulation is suitable for patients who require intravenous therapy due to severe infections or

inability to take oral medications. It should be administered under the supervision of a healthcare professional, with close monitoring for side effects, particularly in patients receiving prolonged therapy. Always follow the prescribed dosing regimen and consult a healthcare provider for any concerns regarding its use.

Manufactured in India for:


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