

LINZOLET

(Linezolid)

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(لینزولڈ)

Composition:

Each 5ml reconstituted suspension contains:

Linezolid 100mg

Each vial of 300ml contains:

Linezolid 600mg

(As per innovator's Specifications)

Classification : Antibiotic, Oxazolidinone

Pharmacology:

Linezole (Linezolid) is a synthetic antibacterial agent. It inhibits bacterial protein synthesis by binding to bacterial 23S ribosomal RNA of the 50S subunit. This prevents the formation of a functional 70S initiation complex that is essential for the bacterial translation process. Linezolid is bacteriostatic against enterococci and staphylococci and bactericidal against most strains of streptococci.

Pharmacokinetics:

Absorption: Rapidly and extensively absorbed after oral dosing. Maximum plasma concentrations are reached approximately 1 to 2 hours after dosing, and the absolute bioavailability is approximately 100%. Therefore, Linzole (Linezolid) may be given orally or intravenously without dose adjustment.

Distribution: Linzole (Linezolid) readily distributes to well-perfused tissues. The plasma protein binding of Linzole (Linezolid) is approximately 31% and is concentration-independent. The volume of distribution of Linzole (Linezolid) at steady-state averaged 40 to 50 liters in healthy adult volunteers.

Metabolism: Hepatic via oxidation of the morpholine ring, resulting in two inactive metabolites (aminoethoxyacetic acid, hydroxyethylglycine); does not involve CYP 450.

Bioavailability: 100%

Elimination: Half-life elimination in adults 4-5 hours. Time to peak plasma concentration by oral route in adults, is 1-2 hours.

Indications:

Vancomycin-Resistant *Enterococcus faecium* infections, including cases with concurrent bacteremia. Nosocomial pneumonia, complicated skin and skin structure infections, community acquired pneumonia including concurrent bacteremia.

Non-FDA approved indication: Treatment of mycobacterial infections. Linzole (Linezolid) has been used as a third-line regimen for the treatment of multidrug-resistant tuberculosis (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB).

Dosage and Administration:

Infection	Dosage and Route of Administration Adults and Adolescents (12 Years and Older)	Recommended Duration of Treatment (consecutive days)
Complicated skin and skin structure infections	600 mg IV or oral q 12h	10 to 14
Community-acquired pneumonia, including concurrent bacteremia		
Nosocomial pneumonia		
Vancomycin-resistant <i>Enterococcus faecium</i> infections, including concurrent bacteremia	600 mg IV or oral q 12h	14 to 28
Uncomplicated skin and skin structure infections	Adults: 400mg oral q12h Adolescents: 600mg oral q12h	10 to 14
Tuberculosis	600 mg IV or oral daily	Up to 2 yrs until sputum culture conversion if tolerated

Take with or without food. Avoid tyramine-containing foods/beverages.

Contraindications:

Linezole (Linezolid) formulations are contraindicated for use in patients who have known hypersensitivity to Linzole (Linezolid)

or any of the other product components.

Warnings/Precautions:

Myelosuppression has been reported and may be dependent on duration of therapy (generally >2 weeks of treatment); use with caution in patients with pre-existing myelosuppression, in patients receiving other drugs which may cause bone marrow suppression, or in chronic infection (previous or concurrent antibiotic therapy). Weekly CBC monitoring is recommended. Discontinue Linzole (Linezolid) in patients developing myelosuppression (or in whom myelosuppression worsens during treatment).

Lactic acidosis had been reported with use. Linzole (Linezolid) exhibits mild MAO inhibitor properties and has the potential to have the same interactions as other MAO inhibitors; use with caution in uncontrolled hypertension, pheochromocytoma, carcinoid syndrome, or untreated hyperthyroidism; avoid use with serotonergic agents such as TCAs, venlafaxine, trazodone, sibutramine, meperidine, dextromethorphan, and SSRIs; concomitant use has been associated with the development of serotonin syndrome. Unnecessary use may lead to the development of resistance to Linzole (Linezolid); consider alternatives before initiating outpatient treatment.

Peripheral and optic neuropathy has been reported in patients treated with Linzole (Linezolid), primarily those patients treated for longer than the maximum recommended duration of 28 days. Visual function should be monitored in all patients taking Linzole (Linezolid) for extended periods (> 3 months) and in all patients reporting new visual symptoms regardless of length of therapy with Linzole (Linezolid). Seizures have been reported; use with caution in patients with a history of seizures. Prolonged use may result in fungal or bacterial superinfection, including *C. difficile* associated diarrhea (CDAD) and pseudomembranous colitis. CDAD has been observed >2 months after antibiotic treatment.

Interactions:

Linezole (Linezolid) is a reversible, nonselective inhibitor of MAO. Serotonergic agents (e.g., TCA's, venlafaxine, trazodone, sibutramine, meperidine, dextromethorphan, and SSRIs) may cause a serotonin syndrome (eg, agitation, confusion, hallucinations, hyper-reflexia, myoclonus, shivering, tachycardia, hyperpyrexia, cognitive dysfunction) when used concomitantly. Adrenergic agents (eg, phenylpropanolamine, pseudoephedrine, sympathomimetic agents, vasopressor or dopaminergic agents) may cause hypertension. Tramadol may increase the risk of seizures when used concurrently with Linzole (Linezolid). Myelosuppressive medications may increase risk of myelosuppression when used concurrently with Linzole (Linezolid).

Dosage:

As directed by the physician.

Cautions:

Avoid freezing and injection should not be used if container is leaking, solution is cloudy or it contains un-dissolved particles.

Instructions:

Do not refrigerate or freeze at cool storage temperature. Store between (15-25)°C. Protect from heat & sunlight. Keep out of reach of children.

Presentation:

Linezole suspension is available in 60ml glass vial.

Linezole infusion is available in 300ml glass vial.

خوراک:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

تعمیر:

منجمد ہونے سے بچائیں اور انجکشن کے ایک ہونے یا اس میں کوئی غیر حل پذیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔

روشنی سے دور رکھیں اور مشعل جگہ پر ۱۵ سے ۲۵ ڈگری سینٹی گریڈ کے درمیان محفوظ کریں۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔

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Pvt Ltd

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ISO 9001, 14001 & 18001 CERTIFIED

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