Linzo

Linezolid

Composition : Linzo-400: Each film coated tablet contains Linezolid USP 400mg.
Linzo-600: Each film coated tablet contains Linezolid USP 600mg.
Linzo Suspension: Each 5ml reconstituted suspension contains Linezolid USP 100mg.

Pharmacology : Linezolid is a synthetic, antibacterial agent belonging to a new class of antibiotics, the oxazolidinones, with in vitro activity against Gram positive aerobic bacteria, some Gram positive anaerobic bacteria and certain Gram negative bacteria. It selectively inhibits bacterial protein synthesis via a mechanism of action different from that of other antibacterial agents. Linezolid binds to the 23S ribosomal RNA of the 50S subunit of the bacterial ribosome and prevents the formation of a functional 70S initiation complex which is an essential component of the bacterial translation process.

Indication : Linezolid is indicated for the treatment of: • Nosocomial pneumonia • Community-acquired pneumonia • Complicated skin and skin structure infection including diabetic foot infections • Uncomplicated skin and skin structure infections • Vancomycin-resistant Enterococcus faecium infections.

Dosage and Administration:

Infection	**Dosage, route and frequency of administration**		
	Pediatric patients* (birth through 11 years of age)	**Adults and adolescent (12 years and older)**	**Recommended duration of treatment (consecutive days)**
Nosocomial pneumonia	10 mg/kg every 8 hours	600 mg every 12 hours	10 to 14
Community-acquired pneumonia, including concurrent bacteremia			
Complicated skin and skin structure infections			
Vancomycin-resistant Enterococcus faecium infections, including concurrent bacteria	10 mg/kg every 8 hours	600 mg every 12 hours	14 to 28
Uncomplicated skin and skin structure infections	**less than 5 years:** 10 mg/kg orally every 8 hours. **5-11 years:** 10 mg/kg orally every 12 hours	**Adults:** 400 mg orally every 12 hours. **Adolescents:** 600 mg orally every 12 hours	10 to 14

Contraindication : It is contraindicated for using 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.

Precaution : CBC should be monitored weekly in patients who receive Linezolid, particularly in those who receive Linezolid for longer than two weeks, those with pre-existing myelosuppression or those with a chronic infection who have received previous or concomitant antibiotic therapy. If patients experience symptoms of visual impairment, such as changes in visual acuity, changes in color vision, blurred vision, or visual field defect, prompt ophthalmic evaluation is recommended. Linezolid should not be used for the treatment of patients with catheter-related bloodstream infections or catheter-site infections. Over two months after antibiotic administration if *Clostridium difficile* associated Diarrhea (CDAD) is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Linezolid should not be administered to patients with uncontrolled hypertension, pheochromocytoma, thyrotoxicosis and/or patients taking medications: sympathomimetic agents, vasopressive agents, dopaminergic agents. If hypoglycemia occurs, a decrease in the dose of insulin or oral hypoglycemic agent, or discontinuation of oral hypoglycemic agent, insulin, or Linezolid may be required.

Side effects: The most common side effects are diarrhea, vomiting, headache, nausea, anemia, eosinophilia, taste disturbance.

Use in pregnancy and Lactation : Pregnancy : Available data with Linezolid use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Linezolid should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Lactation:** It is not known whether Linezolid is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Linezolid is administered to a nursing woman.

Use in child : There is no data available.

Drug Interaction : Linezolid is a reversible, nonselective inhibitor of monoamine oxidase. Therefore, Linezolid has the potential for interaction with adrenergic and serotonergic agents.

Overdose : No cases of overdose have been reported. Symptomatic and supportive care is advised together with maintenance of glomerular filtration. Approximately 30% of a Linezolid dose is removed during 3 hours of haemodialysis. No data are available for the removal of Linezolid by peritoneal dialysis or haemoperfusion.

Storage : Store below 30°C in a cool and dry place. Protect from light and moisture. Keep out of reach of children.

Packing : Linzo-400 Tablet: Each box contains 10's tablets in blister pack.

Linzo-600 Tablet: Each box contains 10's tablets in blister pack.

Linzo Suspension: Each bottle contains dry powder for preparation of 100ml suspension.

Manufactured by
DRUG INTERNATIONAL LTD.
Tongi, Gazipur, Bangladesh

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