

Lizox

Linezolid USP

COMPOSITION

Lizox 400 Tablet: Each film coated tablet contains linezolid USP 400 mg.

Lizox 600 Tablet: Each film coated tablet contains linezolid USP 600 mg.

PHARMACOLOGY

Linezolid is a synthetic antibacterial agent belonging to the oxazolidinones class, which has clinical utility in the treatment of infections caused by aerobic gram-positive bacteria. Linezolid inhibits bacterial protein synthesis through a mechanism of action different from that of other antibacterial agents; therefore, cross resistance between Linezolid and other classes of antibiotics is unlikely. Linezolid binds to a site on the bacterial 23S ribosomal RNA of the 50S subunit and prevents the formation of a functional 70S initiation complex, which is an essential component of the bacterial translation process.

INDICATIONS

Linezolid is indicated for the treatment of- Nosocomial pneumonia, Community-acquired pneumonia, Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis, Uncomplicated skin and skin structure infections, Vancomycin-resistant *Enterococcus faecium* infections.

DOSAGE AND ADMINISTRATION

Dosage, Route & Frequency of administration			
Indication	Pediatric (Birth through 11 years of Age)	Adults and Adolescents (12 years and Older)	Duration (days)
Nosocomial pneumonia	10 mg/kg every 8 hours	600 mg every 12 hours	10-14
Community- acquired pneumonia, including concurrent bacteremia			
Complicated skin and skin structure infections			
Vancomycin-resistant <i>Enterococcus faecium</i> infections, including concurrent bacteremia	10 mg/kg every 8 hours	600 mg every 12 hours	14-28
Uncomplicated skin and skin structure infections	less than 5 years: 10 mg/kg every 8 hours 5–11 years: 10 mg/kg every 12 hours	Adults: 400 mg every 12 hours Adolescents: 600 mg every 12 hours	10-14

CONTRAINDICATIONS

It is contraindicated for use 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 (e.g., phenelzine, isocarboxazid) or within two weeks of taking any such medicinal product.

PRECAUTIONS

The safety and efficacy of Linezolid formulation given for longer than 28 days have not been evaluated in controlled clinical trials. Thrombocytopenia has been reported in patients receiving Linezolid. Platelet counts should be monitored in patients who are at an increased risk of bleeding and have pre-existing thrombocytopenia.

SIDE-EFFECTS

Common side effects include: diarrhea, vomiting, headache, nausea, anemia, eosinophilia, taste disturbances.

USE IN SPECIAL GROUPS

Pregnancy: There are no adequate and well-controlled studies in pregnant women. Linezolid should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing mothers: Linezolid is present in breast milk, so caution should be exercised when Linezolid is administered to a nursing woman.

Pediatric patients: Linezolid was safe and well-tolerated in pediatric patients.

Geriatric patients: Linezolid is effective and safe for the elderly with gram-positive bacterial infection.

DRUG INTERACTIONS

Monoamine oxidase inhibitors, adrenergic and serotonergic agents have the potentiality for interaction with Linezolid.

STORAGE

- Store below 30°C, keep in dry place & protect from light.
- Keep out of reach of children.

PACKING

Lizox 400 Tablet: Each box contains 10 tablets in Alu-Alu blister pack.

Lizox 600 Tablet: Each box contains 10 tablets in Alu-Alu blister pack.

Manufactured by:
 **ARISTOPHARMA LTD.**
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