Lizobest

Linezolid USP

Composition

Lizobest 400 Tablet: Each film coated tablet contains Linezolid USP 400 mg.
Lizobest 600 Tablet: Each film coated tablet contains Linezolid USP 600 mg.
Lizobest PFS 100 ml : After reconstitution according to direction, each 5 ml suspension contains Linezolid USP 100 mg.

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. The results of time-kill studies have shown Linezolid to be bacteriostatic against *enterococci* and *staphylococci*. For *streptococci*, Linezolid was found to be bactericidal for the majority of strains.

Indication

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

Dose and Administration

a) Route of administration: Oral

Dosage & Route of Administration			
Infection	**Pediatric Patients (Birth through 11 years of age)**	**Adults & Adolescents (12 years and older)**	**Duration (days)**
Nosocomial Pneumonia	10 mg/kg intravenous or oral every 8 hours	600 mg intravenous or oral every 12 hours	10 to 14 days
Community-acquired pneumonia, including concurrent bacteremia			
Complicated skin and skin structure infection			
Vancomycin-resistant *Enterococcus faecium* infections, including concurrent bacteremia	10 mg/kg intravenous or oral every 8 hours	intravenous or oral every 12 hours	14 to 28 days
Uncomplicated skin and skin structure infections	< 5 years: 10 mg/kg oral every 8 hours 5-11 years: 10 mg/kg oral every 12 hours	Adults: 400 mg oral every 12 hours Adolescents: 600 mg oral every 12 hours	10 to 14 days

Contra-indication

Known hypersensitivity to linezolid or any of the other product components. Patients taking any MAOI or within two weeks of taking an MAOI.

Warning & Precaution

Patients who develop recurrent nausea or vomiting, unexplained acidosis, or low bicarbonate level while receiving linezolid should receive immediate medical evaluation. Where administration of linezolid and concomitant serotonergic agents is clinically appropriate, patients should be closely observed for signs and symptoms of serotonin syndrome such as cognitive dysfunction, hyperpyrexia, hyper reflexia and incoordination. If signs or symptoms occur physicians should consider discontinuation of either one or both agents. If the concomitant serotonergic agent is withdrawn, discontinuation symptoms can be observed. 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. Convulsions have been reported in patients when treated with linezolid. In some of these cases, a history of seizures or risk factors for seizures was reported.

Side effects

a) Common: Most of the adverse events reported with linezolid were mild to moderate in intensity. The most common adverse events in patients treated with linezolid were diarrhea, headache and nausea.
b) Rare: Oral moniliasis, vaginal moniliasis, hypertension, dyspepsia, localized abdominal pain, pruritus, and tongue discoloration.

Use in Pregnancy and Lactation

a) Use in Pregnancy: Pregnancy category C. 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.
b) Use in 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 Children & Adolescent

Children: The safety and effectiveness of linezolid for the treatment of pediatric patients with the following infection have been established in a comparator-controlled study in pediatric patients ranging in age from 5 through 17 years.
Geriatric Use: The pharmacokinetics of linezolid are not significantly altered in elderly patients (65 years or older). Therefore, dose adjustment for geriatric patients is not necessary.

Drug Interaction

a) With Medicine: (1) Monoamine Oxidase Inhibitor: Linezolid is a reversible, nonselective inhibitor of monoamine oxidase. Therefore, linezolid has the potential for interaction with adrenergic and serotonergic agents. (2) Adrenergic Agents: Some individuals receiving linezolid may experience a reversible enhancement of the pressure response to indirect acting sympathomimetic agents, vasopressor or dopaminergic agents. Commonly used drugs such as phenylpropanolamine and pseudoephedrine have been specifically studied. Initial doses of adrenergic agents, such as dopamine or epinephrine, should be reduced and titrated to achieve the desired response. (3) Serotonergic Agents: Physicians should be alert to the possible signs and symptoms of serotonergic syndrome in patients receiving concomitant linezolid and serotonergic.
b) With food & other: There are no specific foods that must be exclude from diet when continous this medication.

Direction for reconstitution of suspension

First, shake the bottle to loosen powder. Then add 75 ml (with the help of given measuring cup) of boiled and cooled water. For the ease of preparation, add water in two portions. Shake well after each addition until all the powder is in suspension.

Overdose

No case of overdose has 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 hemodialysis. No data are available or hemoperfusion.

Storage

Store below 30°C. Protect from light and moisture. Keep all medicines out of reach of children. The reconstituted suspension should be stored in a cool and dry place. Use within 21 days after reconstitution.

Packing

Lizobest 400 Tablet: Each box contains 10 (1x 10's) tablet in Alu-Alu blister pack.
Lizobest 600 Tablet: Each box contains 10 (1x 10's) tablet in Alu-Alu blister pack.
Lizobest PFS 100 ml: Each amber glass bottle contains dry powder to make 100 ml suspension with a measuring cup.

Manufactured by
ONE PHARMA LTD.
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Bogura, Bangladesh

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