Lizolix™

Linezolid USP Film Coated Tablet

DESCRIPTION

Lizolix™ is a preparation of Linezolid. Linezolid is a synthetic antibacterial agent of a new class of antibiotics, the oxazolidinones, which has clinical utility in the treatment of infections caused by aerobic Gram-positive bacteria. The *in vitro* spectrum of activity of linezolid also includes certain Gram-negative bacteria and anaerobic 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. 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.

INDICATIONS

- Vancomycin-Resistant *Enterococcus faecium* infections, including cases with concurrent bacteremia.
- Nosocomial pneumonia caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant strains), or *Streptococcus pneumoniae* (penicillin-susceptible strains). Combination therapy may be clinically indicated if the documented or presumptive pathogens include Gram-negative organisms.
- Complicated skin and skin structure infections caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant strains), *Streptococcus pyogenes*, or *Streptococcus agalactiae*.
- Uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (methicillin-susceptible only) or *Streptococcus pyogenes*.
- Community-acquired pneumonia caused by *Streptococcus pneumoniae* (penicillin-susceptible strains only), including cases with concurrent bacteremia, or *Staphylococcus aureus* (methicillin-susceptible strains only).

DOSAGE AND ADMINISTRATION

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

Neonates <7 days: Most pre-term neonates <7 days of age (gestational age <34 weeks) have lower systemic linezolid clearance values and larger AUC values than many full-term neonates and older infants. These neonates should be initiated with a dosing regimen of 10 mg/kg every 12 hours. Consideration may be given to the use of 10 mg/kg every 8 hours regimen in neonates with a sub-optimal clinical response. All neonatal patients should receive 10 mg/kg every 8 hours by 7 days of life.

No dose adjustment is necessary when switching from intravenous to oral administration.

DRUG INTERACTION

- Linezolid is a reversible and nonselective inhibitor of monoamine oxidase.
- Linezolid has the potential for interaction with adrenergic and serotonergic agents.

SIDE EFFECTS

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. Other adverse events include oral moniliasis, vaginal moniliasis, hypertension, dyspepsia, localized abdominal pain, pruritus, and tongue discoloration.

PRECAUTION AND WARNING

- Myelosuppression: Monitor complete blood counts weekly. Consider discontinuation in patients who develop or have worsening myelosuppression.
- Peripheral and optic neuropathy: Reported primarily in patients treated for longer than 28 days. If patients experience symptoms of visual impairment, prompt ophthalmic evaluation is recommended.
- Serotonin syndrome: Patients taking serotonergic antidepressants should receive Linezolid only if no other therapies are available. Discontinue serotonergic antidepressants and monitor patients for signs and symptoms of both serotonin syndrome and antidepressant discontinuation.
- A mortality imbalance was seen in an investigational study in linezolid treated patients with catheter-related bloodstream infections.
- *Clostridium difficile* associated diarrhea: Evaluate if diarrhea occurs.
- Potential interactions producing elevation of blood pressure: monitor blood pressure.
- Hypoglycemia: Postmarketing cases of symptomatic hypoglycemia have been reported in patients with diabetes mellitus receiving insulin or oral hypoglycemic agents.

CONTRAINDICATIONS

- Hypersensitivity: Linezolid tablets are contraindicated for using in patients who have known hypersensitivity to linezolid.
- Monoamine Oxidase Inhibitors: 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.

USE IN PREGNANCY AND LACTATION

- 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.
- 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.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Lizolix™ 400 Tablet: Box containing 1 blister of 10 tablets. Each film-coated tablet contains Linezolid USP 400 mg.
Lizolix™ 600 Tablet: Box containing 1 blister of 10 tablets. Each film-coated tablet contains Linezolid USP 600 mg.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
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