

Composition

Zolivox<sup>™</sup> 400 Tablet: Each tablet contains Linezolid USP 400 mg.

Zolivox<sup>™</sup> 600 Tablet: Each tablet contains Linezolid USP 600 mg.

**Zolivox**<sup>TM</sup> Powder for Suspension: After reconstitution of suspension, each 5 ml contains Linezolid USP 100 mg.

**Zolivox**<sup>™</sup> is an antibiotic in the oxazolidinone class. **Zolivox**<sup>™</sup> is bacteriostatic with a unique mechanism of action. It inhibits protein synthesis by binding to a site on the bacterial 235 ribosomal RNA of the 505 subunit.

#### Indication

Zolivox<sup>IM</sup> is indicated in adults and children for the treatment of the following infections caused by susceptible Gram-positive bacteria: 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**

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

### Drug Interaction

Monoamine oxidase inhibitors and potential for interaction with adrenergic and serotonergic agents.

#### Side Effect

Most of the side effects reported with Linezolid are mild to moderate in intensity. The most common side effects in patients treated with Linezolid were diarrhoea, headache and nausea. Other side effects included oral moniliasis, vaginal moniliasis, hypertension, dyspepsia, localized abdominal pain, pruritus, and tongue discoloration.

### Contraindications

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

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: Monitor patients taking serotonergic agents, including antidepressants and opioids, for signs of serotonin syndrome. Patients taking serotonergic antidepressants should receive Linezolid only if no other therapies are available.

Clostridioides 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.

Hyponatremia and/or Syndrome of Inappropriate Antidiuretic Hormone Secretion (SIADH): Monitor serum sodium levels regularly in patients at risk of hyponatremia and/or SIADH.

#### Overdose

In the event of overdosage, hemodialysis may facilitate more rapid elimination of Linezolid.

#### 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.

Nursing Mothers: Linezolid and its metabolites are excreted in the milk of lactating rats. It is not known whether Linezolid is excreted in human milk. Caution should be exercised when Linezolid is administered to a nursing

# Storage

Zolivox<sup>™</sup> Tablet should be stored below 30° C. Protect from light & moisture. Keep out of children.

**Zolivox**<sup>™</sup> Powder for Suspension should be stored below 25°C, protect from light & moisture. After reconstitution, the suspension should be stored at normal temperature (below 25°C) and used within 21 days.

How Supplied
Zolivox<sup>TM</sup> 400 Tab: Each box contains 10 tablets in alu-alu blister pack.

Zolivox<sup>™</sup> 600 Tab: Each box contains 10 tablets in alu-alu blister pack.

Zolivox<sup>TM</sup> Powder for Suspension: Bottle containing dry powder to make 100 ml suspension with 5 ml spoon.



TM - Trade Mark

