Zolidon

Tablet & Powder for Suspension/ IV Infusion

L= 240 mm
H= 200 mm

Linezolid USP

COMPOSITION

Zolidon 400 Tablet: Each film-coated tablet contains Linezolid USP 400 mg.
Zolidon 600 Tablet: Each film-coated tablet contains Linezolid USP 600 mg.
Zolidon 600 IV Infusion: Each 300 ml sterile solution contains Linezolid USP 600 mg (2 mg/ml).
Zolidon Powder for Suspension: After reconstitution, according to direction, each 5 ml suspension contains Linezolid USP 100 mg.

PHARMACOLOGY

Linezolid is a synthetic antibiotic of the Oxazolidinone class. It is active against most Gram-positive bacteria that cause disease including *Streptococci,* Vancomycin-Resistant *Enterococci* (VRE) and Methicillin-Resistant *Staphylococcus aureus* (MRSA). Linezolid works by inhibiting bacterial protein synthesis.

INDICATIONS

Zolidon is indicated for the treatment of infections caused by Gram-positive bacteria listed below. Zolidon is not indicated for the treatment of Gram-negative infections.

- Nosocomial pneumonia caused by *Staphylococcus aureus* (methicillin-susceptible and resistant isolates) or *Streptococcus pneumonia*.
- Community-acquired pneumonia caused by *Streptococcus pneumonia* or *Staphylococcus aureus* (methicillin-susceptible isolates only).
- Complicated skin and skin structure infections (including diabetic foot infections, without concomitant osteomyelitis) caused by *Staphylococcus aureus* (methicillin-susceptible and-resistant isolates), *Streptococcus pyogenes* or *Streptococcus agalactiae*.
- Uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (methicillin-susceptible isolates only) or *Streptococcus pyogenes*.
- Vancomycin-resistant *Enterococcus faecium* infections, including cases with concurrent bacteremia.

DOSAGE & ADMINISTRATION

Infection	Pediatric Patients	Adults and Adolescents	Duration (days)
Nosocomial pneumonia	10 mg/kg IV or oral every 8 hours	600 mg IV or oral every 12 hours	10-14
Community-acquired pneumonia, including concurrent bacteremia			
Complicated skin and skin structure infections			
Vancomycin-resistant *Enterococcus faecium* infections, including concurrent bacteremia	10 mg/kg IV or oral every 8 hours	600 mg IV or oral every 12 hours	14-28
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	10-14

Neonates (<7 days): Neonates should be initiated with a dose 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 neonates should receive dose of 10 mg/kg every 8 hours by 7 days of life. No dose adjustment is necessary when switching from IV to oral administration.
Hepatic Impaired patients: No dose adjustment is recommended for patients with mild-to-moderate hepatic impairment.
Zolidon 600 IV Infusion should be administered over a period of 30 to 120 minutes. May exhibit a yellow color that can intensify over time without adversely affecting potency. Should be inspected visually for particulate matter prior to administration.

CONTRAINDICATION

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 A or B (e.g. phenelzine, isocarboxazid) or within two weeks of taking any such medicinal product.

WARNINGS AND PRECAUTIONS

- Myelosuppression (including anemia, leukopenia, pancytopenia and thrombocytopenia) has been reported in patients receiving Linezolid. Discontinuation of therapy with Linezolid should be considered in such cases
- Peripheral and optic neuropathies have been reported. The continued use of Linezolid in these patients should be weighed against the potential risks.
- Serotonin syndrome have been reported. Unless clinically appropriate, Linezolid should not be administered to patients with carcinoid syndrome and/or patients taking any of the following medications: serotonin re-uptake inhibitors, tricyclic antidepressants, serotonin 5-HT1 receptor agonists (triptans), meperidine, bupropion or buspirone.
- Linezolid is not approved and should not be used for the treatment of patients with catheter-related bloodstream infections or catheter-site infections.
- Clostridium Difficile Associated Diarrhea (CDAD) has been reported. If CDAD is suspected or confirmed, ongoing antibiotic use may need to be discontinued.
- Linezolid should not be administered to patients with uncontrolled hypertension, pheochromocytoma, thyrotoxicosis
- Lactic acidosis has been reported, if occur patient should receive immediate medical evaluation.
- Convulsions have been reported in patients when treated with Linezolid.
- Hypoglycemia have been reported in patients with diabetes mellitus receiving insulin or oral hypoglycemic agents when treated with Linezolid. Diabetic patients should be cautioned when treated with Linezolid.

SIDE EFFECT

Common Side Effects: The most common side effects include Headache, Diarrhea, Nausea, Vomiting, Dizziness, Rash and Anemia.
Rare Side Effects: Taste alteration, Vaginal/Oral moniliasis, Abnormal liver function, Fungal infection, Tongue discoloration and Abdominal pain may occur.

USE IN PREGNANCY AND LACTATION

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.
Lactation: It is not known whether Linezolid is excreted in human milk. Caution should be exercised when Linezolid is administered to a nursing woman.

USE IN CHILDREN & ADOLESCENTS

Linezolid can be prescribed to pediatric patients ranging in age from birth through 11 years (Except in case of uncomplicated skin and skin structure infections; ranging in age from 5 through 17 years).

USE IN GERIATRIC

No significant differences were found between the elderly and younger patients regarding the safety, effectiveness and clinical response of Linezolid.

DRUG INTERACTIONS

With medicine: Linezolid is a reversible, nonselective monoamine oxidase inhibitor. Linezolid has the potential for interaction with adrenergic and serotonergic agents.
With food & others: Linezolid may be taken with or without food. Large quantities of foods or beverages with high tyramine content should be avoided while taking Linezolid.

OVERDOSE

In the event of overdose, supportive care is advised with maintenance of glomerular filtration. Hemodialysis may facilitate more rapid elimination of Linezolid.

STORAGE

Store below 30° C temperature and dry place, protected from light.
Keep all medicines out of reach of children.

PACKING

Zolidon 400 Tablet: Each box contains 1x10 tablets in Alu-Alu blister strips.
Zolidon 600 Tablet: Each box contains 1x10 tablets in Alu-Alu blister strips.
Zolidon 600 IV Infusion: Each box contains 300 ml IV infusion (within a PP bottle) along with Infusion Set, Alcohol Pad & First Aid Bandage.
Zolidon Powder for Suspension: After reconstitution, according to direction, each bottle contains 100 ml suspension.

***Further information is available on request**

Manufactured by:
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For Health, Vigour and Happiness
21005281/01