LordsLin
(Linezolid)

لارڈز لِن
(لینزولِڈ)

۶۰۰ ملی گرام گولیاں
۱۰۰ ملی گرام/۵ ملی لیٹر سسپنشن

COMPOSITION

LordsLin Dry Suspension 100mg/5ml
Each 5ml after reconstitution contains
Linezolid.....100mg
Product Specs. USP
LordsLin600mg Tablet
Each Film coated Tablet contains:
Linezolid..... 600mg
Product Specs. USP

DESCRIPTION

LordsLin for oral suspension contain linezolid, which is a synthetic antibacterial agent of the axazolidinone class.

MECHANISM OF ACTION

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 235 ribosomal RNA of the 505 subunit and prevents the formation of a functional 705 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.

INDICATIONS

LordsLin is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below.**LordsLin** is not indicated for the treatment of Gram-negative infections. It is critical that specific Gram-negative therapy be initiated immediately if a concomitant Gram-negative pathogen is documented or suspected

Pneumonia

Nosocomial pneumonia caused by Staphylococcus aureus (methicillin susceptible and resistant isolates) or Streptococcus pneumoniae Community-acquired pneumonia caused by Streptococcus pneumonie, including cases with concurrent bacteremia, or Staphylococcus aureus(methicillin-susceptible isolates only)

Skin and Skin Structure Infections

Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis caused by Staphylococcus aureus (methicillin-susceptible and resistant isolates), Streptococcus LordsLin has not been studied in pyogenes, or Streptococcus agalactiae. the treatment of decubitus ulcers. Uncomplicated skin and skin structure infections caused Staphylococcus aureus (methicillin-susceptible isolates only) or Streptococcus pyogenes.

Vancomycin-resistant Enterococcus faecium Infections

Includes cases with concurent bacteremia

DOSAGE AND ADMINISTRATION

The recommended dosage for LordsLin formulations for the treatment infections is described in table

Dosage Guidelines for LordsLin Due to the designated pathogens

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, Al neonatal patients should receive 10mg kg every 8 hours by 7 days of life

Reconstitution of Oral Suspension

To make 60ml suspension add 25ml freshly boiled and cooled water into the bottle with the help of measuring cup provided in the pack. Invert and shake lo-wet the powder in the bottle. Then add further 25ml water and invert to make suspension.

PHARMACOKINETICS

Absorption: Linezolid is extensively absorbed after oral dosing Maximum plasma concentrations are reached approximately 1 to 2 hours

Dosage and Route of Administration

Infection	Pediatric Patients (Birth through 11 Year of Age)	Adults and Adolescents (12 Year Older)	Recommended Duration of Treatment (Consecutive days)
Nosocomial Pneumonia Community-acquired pneumonia, including concurrent bacteremia Complicated skin and skin structure infections	10mg/kg oral every 8 hours	600mg oral every 12 hours	10 to 14
vancomycin-resistant Enterococcus faecium infections,including concurrent bacteremia	10mg/kg oral every 8 hours	600mg 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

after dosing, and the absolute bioavailability is approximately 100%. Therefore, linezolid may be given orally or intravenously without dose adjustment **Distribution:** Animal and human pharmacokinetic studies have demonstrated that linezolid readily distributes to well-perfused tissues.The plasma protein binding of linezolid is approximately 31% and isconcentration-independent. The volume of distribution of linezolid atsteady-state averaged 40 to 50 liters in healthy adult volunteers.

Metabolism: Linezolid is primarily metabolized by oxidation of the morpholine ring, which results in two inactive ring-opened carboxylic acid metabolites: the aminoethoxyacetic acid metabolite (A), and the hydroxyethyl glycine metabolite (B). Formation of metabolite A is presumed to be formed via an enzymatic pathway whereas metabolite B is mediated by a non-enzymatic chemical oxidation mechanism in vitro. In vitro studies have demonstrated that linezolid is minimally metabolized and may be mediated by human cytochrome P450. However, the metabolic pathway of linezolid is not fully understood.

Excretion: Non-renal clearance accounts for approximately 65% of the total clearance of linezolid. Under steady-state conditions, approximately 30% of the dose appears in the urine as linezolid, 40% as metabolite B, and 10% as metabolite A. The mean renal clearance of linezolid is 40 mL/min which suggests net tubular reabsorption. Virtually no linezolid appears in the feces, while approximately 6% of the dose appears in the feces as metabolite B, and 3% as metabolite A

WARNINGS AND PRECAUTIONS

Myelosuppression: Myelosuppression (including anemia, leukopenia, pancytopenia, and thrombocytopenia) has been reported in patients receiving linezolid. In cases where the outcome is known, when linezolid was discontinued., the affected hematologic parameters have risen toward pretreatment levels. Complete blood counts should be monitored weekly in patients who receive linezolid, particularly in those who receive linezolid for longer than two weeks.

Peripheral and Optic Neuropathy: Peripheral and optic neuropathies have been reported in patients treated with LordsLin primarily in those patients treated for longer than the maximum recommended duration of 28 days. In cases of optic neuropathy that progressed to loss of vision, patients were treated for extended periods beyond the maximum recommended duration. Visual blurring has been reported in some patients treated with for less than 28 days.

Serotonin Syndrome: Spontaneous reports of serotonin syndrome including fatal cases associated with the co-administration of LordsLin and serotonergic agents, including antidepressants such as selective serotonin reuptake inhibitors (SSRIs), have been reported.

Clostridium difficile Associated Diarrhea: Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including LordsLin, and may range in severity frommild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C.difficile.

Potential Interactions Producing Elevation of Blood Pressure: Unless patients are monitored for potential increases in blood pressure, linezolid should not be administered to patients with uncontrolled hypertension, pheochromocytoma, thyrotoxicosis and/or patients taking any of the following types of medications: directly and indirectly acting sympathomimetic agents (e.g. pseudoephedrine), vasopressive agents (eg. epinephrine, norepinephrine), dopaminergic agents (e.g. dopamine, dobutamine).

Lactic Acidosis: Lactic acidosis has been reported with the use of Linanti. In reported cases, patients experienced repeated episodes of nausea and vomiting. Patients who develop recurrent nausea or vomiting, unexplained acidosis, or a low bicarbonate level while receiving **LordsLin** should receive immediate medical evaluation.

Convulsions: 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.

Development of Drug-ResIstant Bacteria: Prescribing **LordsLin** in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

SIDE EFFECTS

The following adverse reactions have been identified during post approval use of Linezolid.Myelosuppression (including anemia, leukopenia, pancytopenia, and thrombocytopenia) has been reported during post-marketing use of **LordsLin**. Peripheral neuropathy, and optic neuropathy sometimes progressing to loss of vision, have been reported in patients freated with **LordsLin**, Lactic acidosis has been reported with the use of **LordsLin**.Although these reports have primarily been in patients treated for longer than the maximum recommended duration of 28 days, these events have also been reported in patients receiving shorter courses of therapy. Serotonin syndrome has been reported in patients receiving concomitant serotonergic agents, including antidepressants such as selective serotonin reuptake inhibitors (SSRIs) and **LordsLin**. Convulsions have been reported with the use of **LordsLin**. Anaphylaxis, angioedema, and bullous skin disorders such as those described as Stevens-Johnson syndrome have been reported. Superficial tooth discoloration and tongue discoloration have been reported with the use of linezolid. The tooth discoloration was removable with professional dental cleaning (manual descaling) in cases with known outcome. Hypoglycemia, including symptomatic episodes, has also been reported.

DRUG INTERACTIONS

Linezolid is a reversible, non selective inhibitor of monoamine oxidase. Therefore It has the potential for interaction with adrenergic andserotonergic agents,

FERTILITY, PREGNANCY AND LACTATION

Pregnancy: There are no adequate and well-controlled studies in pregnant women. **LordsLin** should be used during pregnancy only if thepotential benefit justifies the potential risk to the fetus. Nursing **Mothers:** It is not known whether linezolid is excreted in human milk. Because many drugs are excreted in human milk, caution should beexercised when **LordsLin** is administered to a nursing woman.

OVERDOSE

In the event o it of over dosage, supportive care is advised, with maintenance of glomerular filtration. Hemodialysis may facilitate more rapid elimination of linezolid. Clinical signs of acute toxicity in animals were decreased activity and ataxia in rats and vomiting and tremors in dogs treated with 3000 mg/kg/day and 2000 mg/kg/day, respectively.

CONTRAINDICATIONS

- **LordsLin** is contraindicated for use in patients who have known hypersensitivity to linezolid or any of the excipients.
- 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.

STORAGE & INSTRUCTIONS

Store below 30°C. Protect from heat, sunlight and moisture. Keep away from the reach of children. Store reconstituted suspension at room temperature and use within 14 days. To be sold on the prescription of a registered medical practitioner only.

PRESENTATION

LordsLin Dry Suspension 100mg/5ml in a pack of 60ml
LordsLin 600mg Tablet in a pack of 12's

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

ہدایات: دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

دھوپ اور نمی سے بچائیں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

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