

Linlid[®]

Linezolid

COMPOSITION:

Linlid[®] 400 Tablet: Each film coated tablet contains Linezolid USP 400 mg.
Linlid[®] 600 Tablet: Each film coated tablet contains Linezolid USP 600 mg.
Linlid[®] Powder for Suspension: After reconstitution of suspension, each 5 ml contains Linezolid USP 100 mg.

PHARMACOLOGY:

Linlid[®] Tablet contains Linezolid, which is a synthetic antibacterial agent of the oxazolidinone class. Linlid[®] tablets for oral administration contain 400 mg or 600 mg Linezolid as film coated tablets. Linlid[®] for Oral Suspension is supplied as powder for reconstitution into a suspension for oral administration. Following reconstitution, each 5 ml contains 100 mg of Linezolid.

INDICATION:

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).

DOSE & ADMINISTRATION:

Indication	Dosage Recommended		
	Pediatric Patients (Birth through 11 years of age)	Adults and Adolescents (12 years and older)	Duration of Treatment (consecutive days)
Complicated skin and skin structure infections	10 mg/kg t.i.d	600 mg b.i.d	10 to 14
Community-acquired pneumonia, including concurrent bacteremia			
Nosocomial pneumonia			
Vancomycin-resistant <i>Enterococcus faecium</i> infections, including concurrent bacteremia	10 mg/kg t.i.d	600 mg b.i.d	14 to 28
Uncomplicated skin and skin structure infections	<5 Yrs: 10 mg/kg t.i.d, 5-11 Yrs: 10 mg/kg b.i.d	Adults: 400 mg b.i.d, Adolescents: 600 mg b.i.d	10 to 14

CONTRA-INDICATION:

Linlid[®] Tablet formulations are contraindicated for use in patients who have known hypersensitivity to Linezolid or any of the other product components of oxazolidone class of antibiotic.

WARNING AND PRECAUTION:

Myelosuppression, peripheral & optic neuropathy, serotonin syndrome, uncontrolled hypertension, pheochromocytoma, thyrotoxicosis, hypoglycemia etc.

SIDE EFFECTS:

Headache, nausea, diarrhea, vomiting, fungal infection, nerve problem, thrombocytopenia, myelosuppression etc.

USE IN PREGNANCY & LACTATION:

Pregnancy: There are no adequate and well-controlled studies in pregnant women. Linlid[®] Tablet 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 Linlid[®] is administered to a nursing woman.

USE IN CHILDREN & ADOLESCENTS:

For children and adolescents Linlid[®] Tablet may be used according to doctor advised.

DRUG INTERACTION:

Monoamine Oxidase [MAO] tablet Inhibitors: Linezolid is a reversible, nonselective inhibitor of monoamine oxidase. Therefore, Linezolid has the potential for interaction with adrenergic and serotonergic agents.

Adrenergic Agents: Some individuals receiving Linlid[®] Tablet may experience a reversible enhancement of the pressor 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.

Serotonergic Agents: Co-administration of Linezolid and serotonergic agents was not associated with serotonin syndrome in studies. Since there is limited experience with concomitant administration of Linezolid and serotonergic agents, physicians should be alert to the possibility of signs and symptoms of serotonin syndrome (e.g. hyperpyrexia and cognitive dysfunction) in patients receiving such concomitant therapy.

OVERDOSE:

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

STORAGE:

Store in a dry and cool place below 30^o C temperature and keep away from light and moisture. After reconstitution, the suspension should be used within 21 days. Keep out of reach of children.

PACKING:

Linlid[®] 400 Tablet: Each box contains 3 x 7's tablets in blister pack.
Linlid[®] 600 Tablet: Each box contains 2 x 7' s tablets in blister pack.
Linlid[®] Powder for Suspension: Each bottle containing dry powder for reconstitution into 100 ml suspension with a 10 ml measuring cup and a 5 ml dropper.



Manufactured by
Team Pharmaceuticals Ltd.
B 75-79, BSCIC, Rajshahi, Bangladesh

IST-0048