

Arlin®

Linezolid

Tablet/Powder for Suspension/IV infusion

Description: Arlin® contains Linezolid, which is a synthetic antibacterial agent of the oxazolidinone class. Arlin tablets for oral administration contain 400 mg or 600 mg Linezolid as film-coated tablets. Arlin 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. Arlin 300 ml IV infusion contains 600 mg of Linezolid.

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).

Infection	Dosage and Route of Administration		Recommended Duration of Treatment (consecutive days)
	Pediatric Patients (Birth through 11 Years of Age)	Adults and Adolescents (12 Years and Older)	
Complicated skin and skin structure infections	10 mg/kg IV or oral t.i.d.	600 mg IV or oral 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 IV or oral t.i.d.	600 mg IV or oral b.i.d.	14 to 28
Uncomplicated skin and skin structure infections	< 5 yrs: 10 mg/kg oral t.i.d. 5-11 yrs: 10 mg/kg oral b.i.d.	Adults: 400 mg oral b.i.d. Adolescents: 600 mg oral b.i.d.	10 to 14

Contraindications

Arlin formulations are contraindicated for use in patients who have known hypersensitivity to Linezolid or any of the other product components.

Adverse Reactions

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

Use in Special Population

Pregnancy: There are no adequate and well-controlled studies in pregnant women. Arlin should be used during pregnancy only if the potential 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 be exercised when Arlin is administered to a nursing woman.

Drug Interactions

Monoamine Oxidase 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 Arlin 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.

Overdosage

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

Pharmaceutical Precautions

Store at temperature between 15°C and 30°C.

Commercial Pack

Arlin® 400 tablet : Box containing 20 tablets in 2 x 10's blister strips. Each film-coated tablet contains Linezolid INN 400 mg.

Arlin® 600 tablet : Box containing 20 tablets in 2 x 10's blister strips. Each film-coated tablet contains Linezolid INN 600 mg.

Arlin® Powder for Suspension : Dry Powder in amber glass bottle for reconstitution into 100 ml suspension. After reconstitution each 5 ml contains Linezolid INN 100 mg. Arlin® IV infusion: 300 ml IV infusion contains 600 mg of Linezolid (2mg/ml).

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

TONGI, BANGLADESH

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