Linezolid Tablets

COMPOSITION

LINXO 600 mg Tablets

Each film-coated tablet contains:
Linezolid …… 600 mg

INDICATIONS

LINXO -600 are indicated in the treatment of the following infections caused by susceptible strains of the designated microorganisms:

- **Vancomycin-resistant *Enterococcus faecium* infections,** including cases with concurrent bacteremia.
- **Nosocomial pneumonia** caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant strains), or *Streptococcus pneumoniae*(including multi-drug resistant strains [MDRSP]).
- **Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis,** caused by*Staphylococcus aureus* (methicillin-susceptible and -resistant strains), *Streptococcus pyogenes,* or *Streptococcus agalactiae.* Linezolid has not been studied in the treatment of decubitus ulcers. Combination therapy may be clinically indicated if the documented or presumptive pathogens include Gram-negative organisms.
- **Uncomplicated skin and skin structure infections** caused by *Staphylococcus aureus* (methicillin-susceptible only) or *Streptococcus pyogenes.*
- **Community-acquired pneumonia** caused by *Streptococcus pneumoniae* (including multi-drug resistant strains [MDRSP]), including cases with concurrent bacteremia, or *Staphylococcus aureus* (methicillin-susceptible strains only).

To reduce the development of drug-resistant bacteria and maintain the effectiveness of linezolid and other antibacterial drugs, linezolid should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.
When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

DOSAGE AND ADMINISTRATION

Dosage Guidelines for LINXO I.V.Injection and Tablets/DT

Infection *	Dosage and Route of Administration		Recommended Duration of Treatment (consecutive days)
	Pediatric Patients **/* (from newborns to 11 years of age)	Adults and Adolescents (aged 12 years and older)	
Complicated skin and skin structure infections	10 mg/kg oral & q8 hours	600 mg oral & q12 hours	10–14
Community-acquired pneumonia, including			

concurrent bacteremia			
Nosocomial pneumonia			
Vancomycin-resistant *Enterococcus faecium* infections, including concurrent bacteremia	10 mg/kg oral & q8 hours	600 mg oral & q12 hours	14–28
Uncomplicated skin and skin structure infections	**<5 years** 10 mg/kg oral & q8 hours **5–11 years** 10 mg/kg oral & q12 hours	**Adults** 400 mg oral & q12 hours **Adolescents** 600 mg oral & q12 hours	10–14

* 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 q12 hours. Consideration may be given to the use of 10 mg/kg q8-hours regimen in neonates with a sub-optimal clinical response. All neonatal patients should receive 10 mg/kg q8 hours by 7 days of birth.

& Oral dosing, using either LINXO t ablets

Adult patients with infection due to MRSA should be treated with linezolid 600 mg q12 hours.

As oral bioavailability is approximately 100%, no dose adjustment is necessary. Thus,

LINXO Tablets Administration
Tablets should be swallowed whole without chewing. **LINXO Tablets** may be taken with or without food.

CONTRAINDICATIONS

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

Monoamine Oxidase Inhibitors:
Linezolid should not be used in patients taking any medicinal product that inhibits monoamine oxidases A or B (eg, phenelzine, isocarboxazid) or within 2 weeks of taking any such medicinal product.

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 (eg, pseudoephedrine), vasopressive agents (eg, epinephrine, norepinephrine), dopaminergic agents (eg, dopamine, dobutamine).

Potential Serotonergic Interactions
Unless patients are carefully observed for signs and/or symptoms of serotonin syndrome, 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, or buspirone.

PACKAGING INFORMATION

LINXO 600 mg Tablets…….. Strip pack of 4 tablets


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