

VOLINZA

COMPOSITION:

VOLINZA 400mg Tablets

Each film coated tablet contains:

Linezolid (M.S)400mg

VOLINZA 600mg Tablets

Each film coated tablet contains:

Linezolid (M.S)600mg

VOLINZA 100mg/5ml Suspension

Each 5ml contains:

Linezolid (M.S)100mg

Product conforms to Manufacturer's Specifications.

DESCRIPTION:

Mechanism of action:

Esomeprazole works by binding irreversibly to the H⁺/K⁺ ATPase in the proton pump. Because the proton pump is the final pathway for secretion of hydrochloric acid by the parietal cells in the stomach, its inhibition dramatically decreases the secretion of hydrochloric acid into the stomach and alters gastric pH.

MECHANISM OF ACTION:

Linezolid is a synthetic antibacterial agent of the oxazolidinone class, 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 binds to a site on the bacterial 23S ribosomal RNA of the 50S subunit and prevents the formation of a functional 70S initiation complex, which is essential for bacterial reproduction.

The results of time-kill studies have shown Linezolid to be bacteriostatic against enterococci and staphylococci. For streptococci, Linezolid was found to be bactericidal for the majority of isolates.

MICROBIOLOGY:

Mechanisms of Resistance

Point of mutations in the 23S rRNA are associated with linezolid resistance. Organisms resistant to oxazolidinones via mutations in chromosomal genes encoding 23S rRNA or ribosomal proteins are generally cross-resistant to linezolid. Also linezolid resistance in staphylococci mediated by the enzyme methyltransferase has been reported. This resistance is mediated by the cfr (chloramphenicol-florfenicol) gene located on a plasmid which is transferable between staphylococci.

Linezolid has been shown to be active against most isolates of the following microorganisms:

Gram-Positive Bacteria

Enterococcus faecium (vancomycin-resistant isolates only)

Staphylococcus aureus (including methicillin-resistant isolates)

Streptococcus agalactiae



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Streptococcus pneumoniae
Streptococcus pyogenes
Gram-Negative Bacteria
Pasteurella multocida

PHARMACOKINETIC:

Linezolid metabolized to form inactive derivatives.

Plasma protein binding is about 31% and is not concentration dependent.

Linezolid concentrations have been determined in various fluids. The ratio of linezolid in saliva and sweat relative to plasma was 1.2:1.0 and 0.55:1.0, respectively.

Linezolid is primarily metabolized by oxidation of the morpholine ring resulting mainly in the formation of two inactive open-ring carboxylic acid

derivatives; the aminoethoxyacetic acid metabolite and the hydroxyethyl glycine metabolite. The hydroxyethyl glycine metabolite is the

predominant human metabolite and is believed to be formed by a non-enzymatic process. The aminoethoxyacetic acid metabolite is less

abundant. In patients with normal renal function or mild to moderate renal insufficiency, linezolid is primarily excreted under steady-state

conditions in the urine (40%), parent drug (30%). Virtually no parent drug is found in the faeces.

Non-renal clearance accounts for approximately 65% of the total clearance of linezolid. A small degree of non-linearity in clearance is observed

with increasing doses of linezolid. This appears to be due to lower renal and non-renal clearance at higher linezolid concentrations.

INDICATIONS:

VOLINZA is not indicated for the treatment of Gram-negative infections. VOLINZA (Linezolid) is indicated for the treatment of infections caused

by susceptible strains of the designated microorganisms in the specific conditions listed below.

Pneumonia

Nosocomial pneumonia caused by Staphylococcus aureus (methicillin-susceptible and -resistant isolates) or Streptococcus pneumoniae.

Community-acquired pneumonia caused by Streptococcus pneumoniae, 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 pyogenes, or Streptococcus agalactiae.

Uncomplicated skin and skin structure infections caused by Staphylococcus aureus (methicillin-susceptible isolates only) or Streptococcus

pyogenes.



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DOSAGE AND ADMINISTRATION:

The recommended dosage for VOLINZA formulations for the treatment of infections is described in Table.

Table 1: Dosage Guidelines for Linezolid (Volinza)

	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)	
Nosocomial pneumonia	10 mg/kg I.V. or oral every 8 hours	600 mg I.V. or oral every 12 hours	10 to 14
Community-acquired pneumonia			
Complicated skin and skin structure infections			
Vancomycin-resistant Enterococcus faecium infections	10 mg/kg I.V. or oral every 8 hours	600 mg I.V. or every 12 hours	14 to 28
Uncomplicated skin and skin structure infections	Less than 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 orally every 12 hours	10 to 14

CONTRAINDICATIONS:

Hypersensitivity

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

WARNINGS AND PRECAUTIONS:

Take special care with Linezolid if you are: bruise and bleed, anaemic, prone to getting infections, have a history of seizures, have liver problems or kidney problems particularly if you are on dialysis, have diarrhea, recurrent nausea or vomiting, abdominal pain or rapid breathing.

PREGNANCY AND LACTATION:

Teratogenic Effects – Pregnancy Category C

Linezolid and its metabolites are excreted in the milk. Concentrations in milk were similar to those in maternal plasma.



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DRUG-DRUG INTERACTIONS:

Monoamine oxidase inhibitors

Linezolid is a reversible, non-selective inhibitor of monoamine oxidase (MAOI).

Potential interactions producing elevation of blood pressure

Linezolid enhanced the increases in blood pressure caused by pseudoephedrine and phenylpropanolamine hydrochloride.

Co-administration of linezolid with either pseudoephedrine or phenylpropanolamine resulted in mean increases in systolic blood pressure of the order of 30-40 mmHg, compared with 11-15 mmHg increases with linezolid alone.

Potential serotonergic interactions

Linezolid with serotonergic agents, including antidepressants such as selective serotonin reuptake inhibitors (SSRIs), cases of serotonin syndrome have been reported. Therefore, while co-administration is contraindicated, management of patients for whom treatment with linezolid and serotonergic agents is essential.

Drugs metabolised by cytochrome P450

Linezolid is not detectably metabolised by the cytochrome P450 (CYP) enzyme system and it does not inhibit any of the clinically significant human CYP isoforms (1A2, 2C9, 2C19, 2D6, 2E1, 3A4).

Rifampicin

Rifampicin decreased the linezolid C_{max} and AUC by a mean 21% [90% CI] and a mean 32% [90% CI], respectively.

SIDE EFFECTS:

Diarrhea.

Nausea.

Vomiting.

Headache.

Sleep Problems (insomnia).

Constipation.

Dizziness.

Discolored Tongue.

Unusual Or Unpleasant Taste In The Mouth.

Vaginal Itching Or Discharge.

Yeast Infection In The Mouth (oral Thrush).

Fungal Infections.

Low Platelet Count (thrombocytopenia).

Myelosuppression.

Serotonin Syndrome.

Nerve Problems.

Skin Swelling (angioedema).

Fever, Chills, Body Aches, Flu Symptoms, Sores In Your Mouth And Throat.



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Easy Bruising Or Bleeding, Pale Skin, Lightheadedness, Shortness Of Breath, Rapid Heart Rate, Trouble Concentrating.

Blurred Vision, Trouble Seeing Color.

Numbness, Burning Pain, Or Tingly Feeling In Your Hands Or Feet.

Seizures (convulsions).

Low Blood Sugar (headache, Hunger, Weakness, Sweating, Confusion, Irritability, Dizziness, Fast Heart Rate, Or Feeling Jittery).

OVERDOSE:

In the event of over dosage, supportive care is advised, with maintenance of glomerular filtration. Hemodialysis may facilitate more rapid elimination of VOLINZA (Linezolid). Clinical signs of acute toxicity were decreased activity and ataxia and vomiting and tremors.

INSTRUCTIONS:

For Injection:

Keep out of reach of children.

Avoid exposure to heat, light, and freezing.

Store between 15 to 30°C

Improper storage may deteriorate the medicine.

For Tablets and Suspension:

Store in a cool & dry place below 25°C.

Protect from light, heat and moisture.

Keep out of reach of children.

PRESENTATION:

VOLINZA Infusion 2mg/ml is available in pack size of 1's.

VOLINZA Tablet 400mg is available in blister pack of 12's.

VOLINZA Tablet 600mg is available in blister pack of 12's.

