Prescribing Information

For the use of Registered Medical Practitioner, Hospital or a Laboratory Only.

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Linezolid IV Injection (600mg/300ml)

AMERICAN

NEZOLID 600

Infusion

Composition :

Each 300 ml Contains:

Linezolid IP	600 mg
Dextrose Anhydrous IP	5% w/v
Water for Injections IP	q.s.

Description:
Linezolid is a oxazolidinone antibacterial agent representing the first approved antibiotic of a new structural class in 35 years.

Indications :
- Nosocomial Pneumonia
- Community Acquired Pneumonia
- Septicaemia
- Bacteremia of unknown origin.
- Endocarditis
- Prophylaxis during surgical procedures S.A.Cardiac valve replacement, total hip replacement.
- Patients with severe infections undergoing dental or upper RT surgery.
- Vancomycin resistant Enterococcus infections.
- Skin and Soft tissue infections.

Bacteriology :
Linezolid has been tested in vitro against Gram-positive organisms.
Linezolid has good activity against MSSA, MRSA, MRSE, Staph.epidermidis, Staphylococcus haemolyticus, Enterococcus faecalis, Enterococcus faecium, Sterptococcus pneumoniae and Streptococcus pyogens.
However Pseudomonas and Enterobacteriaceae are not susceptible to Linezolid.

Mechanism of Action :
Linezolid has a unique Mechanism of Action because of which cross resistance with other antibiotics is unlikely.
Linezolid selectively inhabits the bacterial ribosomal translation process.
Linezolid selectively binds to a site on the 23 S ribosomal RNA of the 50 S subunit, as a result Linezolid prevents the Initiation complex formation with the 70 S ribosomal subunit.

Absorption :
Maximum plasma concentrations are reached approximately 1-2 hours after dosing and the absolute Bioavailability is approximately 100 %.

Dosage and Administration :
Linezolid is given at a dose of 600 mg B.I.D. For 10-14 days.
In bacteremic infections due to Vancomycin Resistant Enterococci 600 mg B.I.D. For 14-28 days are given.

No dose adjustment is required for geriatric patients or patients with renal or hepatic impairment.

Pregnancy and Lactation :
No teratogenicity / carcinogenicity data is available, hence Linezolid should be used during pregnancy only if the potential benefits justifies the potential risk to the fetus.

Linezolid is selected in human breast milk, hence Linezolid should be avoided in lactating women.

Contra-indications :
Linezolid formulations are contra-indicated for use in patients who have known hypersensitivity to Linezolid or any of the other product compounds.

Precautions:
General : The use of antibiotics may promote the overgrowth of non susceptible organisms. Should super infection occur during therapy, appropriate measures should be taken.
Linezolid has not been studied in patients with uncontrolled hypertension, pheochromocytoma, carcinoid syndrome or untreated hyperthyroidism. The safety and efficacy of Linezolid formulations.

Given for longar than 28 days have not been evaluated in controlled clinical trials.

Thrombocytopenia : Thrombocytopenia has been reported in patients receiving Linezolid. Platelet counts should be monitored in patients who are at an increased risk for bleeding, who have pre existing Thrombocytopenia.
Because of Inhibition of MAO-A

A. Avoid foods with high tyramine content.
B. Avoid concomitant administration with adrenergic and serotonergic agents.
C. Avoid oral suspension containing phenylalanine.

Warnings:
Pseudomembranous-enterocolitis have been reported with nearly all antibacterial, including Linezolid. Therefore it is important to consider this diagnosis in patients who present diarrhoea subsequent to the administration of any antibacterial agent.

Instructions for use and handling:
Linezolid I.V. Injection is supplied in single-use, ready-to-use infusion. Protect from light on removal from the manufactur's original packing. Do not the solution if it contains visible solid particles.

The solution must be used immediately after the seal is first broken, if not used immediately storage times and conditions are the responsibility of the user.
Do not use in series connections. Do not introduce additives to this solution. Any unused solution must be discarded. Do not reconnect partially used containers.

Linezolid I.V. Injection should be administered by intravenous infusion over a period of 30-120 minutes.
If Linezolid I.V. Injection is to be given concomitantly with another drug, each drug should be given separately in accordance with the recommended dosage and route of administration for each product. In particular, physical incompatibilities resulted when Linezolid I.V. Injection was combined with the following drugs during simulated Y-site administration : Amphotericin B, chlorpromazine HCL, diazepam, pentamidine isethionate, erythromycin lactobionate, phenytoin sodium and trimethoprim - sulfamethoxazole. Additionally, chemical incompatibility resulted when Linezolid I.V. Injection was combined with ceftriaxone sodium.

If the same intravenous line is used for sequential infusion of several drugs, the line should be flushed before and after infusion of Linezolid I.V. Injection with an infusion solution compatible with Linezolid I.V. Injection and with any other drug(s) administered via this common line.

Compatible Intravenous Solutions :
5% dextrose Injection.
0.9 % sodium chloride injection.
Lactated ringer's injection.

Side Effects:
Allergic reactions like itching or hives swelling in hands and face, swelling or tingling in the mouth or throat, tightness in chest, trouble breathing.

Storage:
Linezolid I.V. Injection should be stored at temperature not exceeding 30° C. Protect from light.
Protect from-freezing Linezolid I.V. Injection may exhibit a yellow colour that can intensify over time without adversely affecting potency.
Keep out of reach of children.

Presentation :
Available in 100 ml / 300ml container sealed in paper foil over wrap and packed in a carton.

Marketed by:

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Care & Cure with Research

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