



1.5.3 Patient Information Leaflet (PIL) or Package Insert

ZOLID (Linezolid Tablets 600mg)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What are Linezolid Tablets
2. What you need to know before you take Linezolid Tablets
3. How to take Linezolid Tablets
4. Possible side effects
5. How to store Linezolid Tablets
6. Contents of the pack and other information

1. What Are Linezolid Tablets

Linezolid Tablets is an antibiotic of the oxazolidinones group that works by stopping the growth of certain bacteria (germs) that cause infections. It is used to treat pneumonia and some infections in the skin or under the skin. Your doctor will have decided if Linezolid Tablets is suitable to treat your infection.



2. What You Need To Know Before You Take Linezolid Tablets

Do not take 'Linezolid Tablets' if you are:

- allergic (hypersensitive) to linezolid or any of the other ingredients of this medicine
- taking or have taken within the last 2 weeks any medicines known as monoamine oxidase inhibitors (MAOIs for example phenelzine, isocarboxazid, selegiline, moclobemide). These may be used to treat depression or Parkinson's disease.
- breastfeeding. This is because it passes into breast milk and could affect the baby.

Linezolid Tablets may not be suitable for you if you answer yes to any of the following questions. In this case tell your doctor as he/she will need to check your general health and your blood pressure before and during your treatment, or may decide that another treatment is better for you.

Ask your doctor if you are not sure whether these categories apply to you.

- Do you have high blood pressure?
- Have you been diagnosed with an overactive thyroid?
- Do you have a tumour of the adrenal glands (phaeochromocytoma) or carcinoid syndrome (caused by tumours of the hormone system with symptoms of diarrhoea, flushing of the skin, wheezing)?
- Do you suffer from manic depression, schizoaffective disorder, mental confusion or other mental problems?
- Are you taking any of the following medicines?

-decongestant cold or flu remedies containing pseudoephedrine or phenylpropanolamine

-medicines used to treat asthma such as salbutamol, terbutaline, fenoterol

-antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors) for example amitriptyline, cipramil, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine; sertraline

-medicines used to treat migraine such as sumatriptan and zolmitriptan

-medicines used to treat sudden, severe allergic reactions such as adrenaline (epinephrine)



-medicines which increase your blood pressure, such as noradrenaline (norepinephrine), dopamine and dobutamine

- medicines used to treat moderate to severe pain, such as pethidine

- medicines used to treat anxiety disorders, such as buspirone

- an antibiotic called rifampicin

Take special care with ‘Linezolid Tablets’

Tell your doctor before you take this medicine if you

- bruise and bleed easily
- are anaemic
- are prone to getting infections
- have a history of seizures
- have liver problems or kidney problems particularly if you have dialysis
- have diarrhoea

Tell your doctor immediately if during treatment you suffer from

- problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.
- You may develop diarrhoea while taking or after taking antibiotics, including Linezolid Tablets. If this becomes severe or persistent or you notice that your stools contain blood or mucus, you should stop taking Linezolid Tablets immediately and consult your doctor. In this situation, you should not take medicines that stop or slow bowel movement.
- recurrent nausea or vomiting, abdominal pain or over breathing

Taking other medicines

There is a risk that Linezolid Tablets may sometimes interact with certain other medicines to cause side effects such as changes in blood pressure, temperature or heart rate



Tell your doctor if you are taking or have taken within the last 2 weeks the following medicines as Linezolid Tablets must not be taken if you are already taking these medicines or have taken them recently. (See also Section 2 above ‘Do not take Linezolid Tablets’)

- monoamine oxidase inhibitors (MAOIs for example phenelzine, isocarboxazid, selegiline, moclobemide). These may be used to treat depression or Parkinson’s disease

Also tell your doctor if you are taking the following medicines. Your doctor may still decide to give you Linezolid Tablets, but will need to check your general health and your blood pressure before and during your treatment. In other cases, your doctor may decide that another treatment is better for you.

- Decongestant cold or flu remedies containing pseudoephedrine or phenylpropanolamine.
- Some medicines used to treat asthma such as salbutamol, terbutaline, fenoterol.
- Certain antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors). There are many of these, including amitriptyline, cipramil, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine, sertraline.
- Medicines used to treat migraine such as sumatriptan and zolmitriptan.
- Medicines used to treat sudden, severe allergic reactions such as adrenaline epinephrine).
- Medicines which increase your blood pressure, such as noradrenaline (norepinephrine) dopamine and dobutamine.
- Medicines used to treat moderate to severe pain, such as pethidine.
- Medicines used to treat anxiety disorders, such as buspirone.
- Medicines that stop blood clotting, such as warfarin

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking ‘Linezolid Tablets’ with food and drink

- You can take Linezolid Tablets either before, during or after a meal.



- Avoid eating large amounts of mature cheese, yeast extracts, or soya bean extracts e.g. soy sauce and drinking alcohol, especially draught beers and wine. This is because this medicine may react with a substance called tyramine which is naturally present in some foods to cause an increase in your blood pressure.
- If you develop a throbbing headache after eating or drinking, tell your doctor or pharmacist immediately.

Pregnancy and breast-feeding

The effect of Linezolid Tablets in pregnant women is not known. Therefore it should not be taken in pregnancy unless advised by your doctor. Tell your doctor if you are pregnant, think you may be pregnant or are trying to become pregnant.

You should not breastfeed when taking Linezolid Tablets because it passes into breast milk and could affect the baby.

Driving and using machines

Linezolid Tablets may make you feel dizzy or experience problems with your vision. If this happens, do not drive or operate any machinery. Remember that if you are unwell your ability to drive or operate machinery may be affected.

3. How to take Linezolid Tablets**Adults**

Always take Linezolid Tablets as your doctor has told you. If you are unsure ask your doctor or pharmacist. The usual dose is one tablet (600mg linezolid) twice daily (every twelve hours). Swallow the tablet whole with some water.

If you are on kidney dialysis, you should take Linezolid Tablets after dialysis.



A course of treatment usually lasts 10 to 14 days but can last up to 28 days. The safety and effectiveness of this medicine have not been established for treatment periods longer than 28 days. Your doctor will decide how long you should be treated.

While you are taking Linezolid Tablets, your doctor should perform regular blood tests to monitor your blood count.

Your doctor should monitor your eyesight if you take Linezolid Tablets for more than 28 days.

Children

Linezolid Tablets is not normally used to treat children and adolescents (under 18 years old).

If you take more Linezolid Tablets than you should?

Tell your doctor or pharmacist immediately.

If you forget to take Linezolid Tablets

Take the forgotten tablet as soon as you remember. Take the next tablet 12 hours after this and continue taking your tablets every 12 hours. Do not take twice as many tablets to make up for missing a dose.

If you stop taking Linezolid Tablets

Unless your doctor instructs you to stop treatment, it is important to continue taking Linezolid Tablets.

If you stop and your original symptoms come back tell your doctor or pharmacist immediately.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Linezolid Tablets can cause side-effects although not everybody gets them.

Tell your doctor, nurse or pharmacist immediately if you notice any of these side effects during your treatment with Linezolid Tablets:



- skin reactions such as red sore skin and flaking (dermatitis), rash, itching, or swelling, particularly around the face and neck. This may be the sign of an allergic reaction and it may be necessary for you to stop taking Linezolid Tablets.
- problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.
- severe diarrhoea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), which in very rare circumstances may develop into complications that are life-threatening.
- recurrent nausea or vomiting, abdominal pain or over breathing.
- fits or seizures have been reported with Linezolid Tablets. You should let your doctor know if you experience agitation, confusion, delirium, rigidity, tremor, in coordination and seizure while also taking antidepressants known as SSRI's (see section 2).

Numbness, tingling or blurred vision have been reported by patients who have been given Linezolid Tablets for more than 28 days. If you experience difficulties with your vision you should consult your doctor as soon as possible.

Other side effects include:

Common side-effects (likely to occur in less than 1 in 10 people):

- Fungal infections especially vaginal or oral "thrush"
- Headache
- Metallic taste in the mouth
- Diarrhoea, nausea or vomiting
- Changes in some blood test results including those measuring your kidney or liver function or blood sugar levels
- Unexplained bleeding or bruising, which may be due to changes in the numbers of certain cells in the blood which may affect blood clotting or lead to anaemia

Uncommon side-effects (likely to occur in less than 1 in 100 people):

- Inflammation of the vagina or genital area in women

- Changes in numbers of certain cells in the blood which may affect your ability to fight infection
- Difficulty in sleeping
- Dizziness, sensations such as tingling or feeling numb
- Blurred vision
- “Ringing” in the ears (tinnitus)
- Increased blood pressure, inflammation of the veins
- Indigestion, stomach pain, constipation
- Dry or sore mouth , swollen, sore, or discoloured tongue
- Skin rash
- A need to urinate more often
- Fever or chills, aches and pains
- Feeling tired or thirsty
- Inflammation of the pancreas
- Increased sweating
- Changes in proteins, salts or enzymes in the blood which measure kidney or liver function.
- Reduction in the numbers of cells in the blood which fight against infection.

Rare side-effects (likely to occur in less than 1 in 1000 people):

- Changes in heart rate (eg, increase rate)
- Transient ischaemic attacks (temporary disturbance of blood flow to the brain causing short term symptoms such as loss of vision, leg and arm weakness, slurring of speech and loss of consciousness),
- Kidney failure

The following side effects have also been reported frequency not known):

- Serotonin syndrome (symptoms include fast heart rate, confusion, abnormal sweating, hallucinations, involuntary movements chills and shivering)
- Lactic acidosis (symptoms include recurrent nausea and vomiting, abdominal pain,



overbreathing)

- Severe skin disorders
- Convulsions
- Superficial tooth discolouration, removable with professional dental cleaning (manual descaling)
- Alopecia (hair loss)
- Hyponatraemia (low blood sodium levels)
- Changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Linezolid Tablets

Keep out of the reach and sight of children.

There are no special storage conditions.

Do not use your tablets after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help us to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Linezolid Tablets 600mg contains

- The active substance in this medicine is called linezolid. Each tablet contains 600 mg linezolid
- The other ingredients are Lactose Monohydrate Hydroxy propyl methyl Cellulose Polacrillin Potassium, Magnesium stearate Colloidal silicon dioxide Hypromellose Polyethylene glycol Titanium dioxide Carnauba Wax

What Tenofovir Alafenamide 25 mg looks like and contents of the pack

ZOLID (Linezolid Tablets 600 mg)



Module 1 - Administrative information and prescribing information

White to off white, oval shaped, bevel edged, biconvex film-coated tablets debossed with "H" on one side with score line and "L" and "8" separated by a score line on the other side.

Linezolid Tablets are available in:

Blister pack: 1 x 10's Blister pack

Marketing Authorization Holder and Manufacturer

Marketing Authorisation Holder:

Name: Hetero Labs Limited

Business Address: 7-2-A2, Hetero Corporate,
Industrial Estates,
Sanath Nagar,
Hyderabad-500 018
Telangana.

Country: INDIA

Manufacturer:

Name: Hetero Labs Limited (Unit-V)

Address: SY. No.: 439, 440, 441 & 458, TSIIC Pharma SEZ,
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