

# LINEZOLID SANDOZ<sup>®</sup> FILM-COATED TABLETS 600MG

Linezolid(600mg)

## What is in this leaflet:

1. What Linezolid Sandoz is used for
2. How Linezolid Sandoz works
3. Before you use Linezolid Sandoz
4. How to use Linezolid Sandoz
5. While you are using it
6. Side effects
7. Storage and Disposal of Linezolid Sandoz
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

## What Linezolid Sandoz is used for

Linezolid Sandoz is used to treat pneumonia and some infections in the skin or under the skin.

Your doctor will decide if Linezolid Sandoz is suitable to treat your infection.

## How Linezolid Sandoz works

Linezolid Sandoz is an antibiotic of the oxazolidinones group that works by stopping the growth of certain bacteria (germs) that cause infections.

## Before you use Linezolid Sandoz

### - When you must not use it

Do not take Linezolid Sandoz if you are

- allergic 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.
- breast-feeding. This is because it passes into breast

milk and could affect the baby.

### - Before you start to use it

Consult your doctor or pharmacist before taking Linezolid Sandoz if you are having or have had the following conditions:

- high blood pressure
- diagnosed with an overactive thyroid
- diagnosed with 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)
- suffer from manic depression, schizoaffective disorder, mental confusion or other mental problems
- history of seizures
- kidney or liver problems

### - Taking other medicines

There is a risk that Linezolid Sandoz 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 Sandoz **must not** be taken if you are already taking these medicines or have taken them recently: 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 Sandoz, 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.
- 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.
- Selective serotonin reuptake inhibitor (SSRI) (antidepressant) for depression and triptans (for severe migraine), pethidine (pain killer) or buspirone (for anxiety disorder).
- Rifampicin (antibiotic for tuberculosis)
- Warfarin (blood thinning agent)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

## How to use Linezolid Sandoz

### - How much to use

#### Adults

Oral. Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose **for adults** is **one tablet** (600 mg linezolid) **twice daily** (every twelve hours).

A course of treatment usually lasts 10 to 14 days but can last up to 28 days. Your doctor will decide how long you should be treated.

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## Linezolid(600mg)

### - When to use it

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

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

### - How long to use it

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

If you stop taking Linezolid Sandoz and your original symptoms come back, tell your doctor or pharmacist immediately.

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

### - If you forget to use it

Take the forgotten tablet as soon as you remember.

Do not take a double dose to make up for a forgotten tablet.

### - If you use too much (overdose)

Contact your doctor or pharmacist immediately.

## **While you are using it**

### - Things you must do

Talk to your doctor or pharmacist if

- your red blood cell count, white blood cell count and platelet decreased
- you are anaemic or prone to getting infections
- you have diarrhea caused by antibiotic
- you have recurrent nausea or vomiting, abdominal pain, low bicarbonate level or hyperventilation (breathing rate is abnormally fast)
- neuropathy (nerve-related disease) for example changes in color vision,

blurred vision, visual defects, pain and numbness in hands and feet

- seizures

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

### - Things you must not do

#### **Pregnancy and breast-feeding**

The effect of Linezolid Sandoz in pregnant women is not known. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

You should not breast-feed when taking Linezolid Sandoz because it passes into breast milk and could affect the baby.

### - Things to be careful of

#### **Driving and using machines**

Linezolid Sandoz 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.

#### **Side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor, pharmacist or nurse immediately if you notice any of these side effects during your treatment with Linezolid Sandoz:

#### The serious side effects are:

- Severe skin disorder (not known), swelling particularly around the face and neck (not known), wheezing and/or difficulty breathing (not known). This may be the sign of an allergic reaction and it may be necessary for you to stop

taking Linezolid Sandoz. Skin reactions such as red sore skin and flaking (dermatitis) (uncommon), rash (common), itching (common).

- Problems with your vision such as blurred vision (uncommon), changes in colour vision (not known), difficulty in seeing details (not known) or if your field of vision becomes restricted (rare).
- Severe diarrhea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), which in rare circumstances may develop into complications that are life-threatening (rare).
- Recurrent nausea or vomiting, abdominal pain or rapid breathing (not known).
- Fits or seizures (uncommon) have been reported with linezolid. You should let your doctor know if you experience agitation, confusion, delirium, rigidity, tremor, incoordination and seizure while also taking antidepressants known as SSRIs (not known).
- 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 (common).
- Changes in numbers of certain cells in the blood which may affect your ability to fight infection (common). Some signs of infection include: any fever (common), sore throat (uncommon), mouth ulcers (uncommon) and tiredness (uncommon).
- Convulsions (uncommon).

# LINEZOLID SANDOZ<sup>®</sup> FILM-COATED TABLETS 600MG

## Linezolid(600mg)

- 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) (uncommon).
- “Ringing” in the ears (tinnitus) (uncommon).
- Inflammation of the pancreas (uncommon)

### Common side effects include:

- fungal infections especially vaginal or oral “thrush”
- anaemia
- difficulty in sleeping
- headache
- metallic taste
- dizziness
- high blood pressure
- diarrhea
- nausea, vomiting
- abdominal pain
- constipation
- indigestion
- abnormal liver and renal test
- itchy and rash
- fever
- localised pain

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my)

[Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### Storage and Disposal of Linezolid Sandoz

#### - Storage

Do not store above 30°C.

#### - Disposal

Return any unused or expired medicine to your doctor,

pharmacist or health care professional for safe disposal.

### Product Description

#### - What it looks like

White to off-white colored biconvex oval shaped film-coated tablet with “LZ600” debossed on one side and plain on the other side.

#### - Ingredients

##### - Active ingredient

Each film-coated tablet contains 600 mg of linezolid.

##### - Inactive ingredients

Excipients (core):

Microcrystalline cellulose  
Silica colloidal anhydrous  
Sodium starch glycolate type A  
Hydroxypropyl cellulose  
Magnesium stearate.

Excipients (coating):

Hypromellose (E464)  
Titanium dioxide (E171)  
Macrogol (E1521)

#### - MAL Number

MAL20016144ACZ

### Manufacturer

Novartis  
Pharmaceuticals  
S.R.L.  
Livezeni Street 7A  
540472 Targu Mures  
Mures County  
Romania

### Product Registration Holder

Sandoz Products Malaysia Sdn. Bhd.  
Unit 1202, Level 12, Uptown 1,  
No. 1, Jalan SS 21/58, Damansara Uptown,  
47400 Petaling Jaya, Selangor, Malaysia.

### Date of Revision

Oct 2025

### Serial Number

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