

LINEZOLID SANDOZ® FILM-COATED TABLETS 600MG

Linezolid (600mg)

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What Linezolid Sandoz is used for

Linezolid Sandoz is an antibiotic. It is used to treat pneumonia, skin infections, and some bacterial infections that are resistant to other antibiotics.

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.
 - are taking or have taken within the last 2 weeks any medicines known as

monoamine oxidase inhibitors (MAOIs for example phenelzine, isocarboxazid).

- have uncontrolled hypertension (high blood pressure)
- have pheochromocytoma (adrenal gland tumor)
- have thyrotoxicosis (excessive thyroid hormone)
- have carcinoid syndrome (signs and symptoms that occur secondary to carcinoid tumours)
- If you are taking any of the following medicines
 - pseudoephedrine
 - phenylpropanolamine
 - epinephrine
 - norepinephrine
 - dopamine
 - dobutamine
 - serotonin re-uptake inhibitors
 - tricyclic antidepressants
 - serotonin 5-HT₁ receptor agonists
 - meperidine
 - buspirone

Pregnancy and lactation

The effect of Linezolid in pregnant women is not known. Therefore, it should not be taken in pregnancy unless advised by your doctor.

It is not known if linezolid is excreted in human milk. Therefore, Linezolid Sandoz should be taken with caution in nursing women.

Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Consult your doctor or pharmacist before taking Linezolid Sandoz if you:

- are at increased risk for bleeding
- have a pre-existing condition called myelosuppression in which your bone marrow activity is decreased
- are on medications that may decrease hemoglobin levels or platelet count
- have a history of seizures or have risk factors for seizures
- are taking any serotonergic agents, including antidepressants such as selective serotonin reuptake inhibitors (SSRIs) and opioids
- have Hyponatremia and/or Syndrome of Inappropriate Antidiuretic Hormone Secretion (SIADH)
- are at high risk for life threatening systemic infections, such as those with infections related to central venous catheters in intensive care units

- Taking other medicines

Linezolid Sandoz should not be taken with the following medicines:

- Monoamine oxidase inhibitors (e.g. phenelzine,

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isocarboxazid) in the last two weeks

- Sympathomimetic agents (e.g. pseudoephedrine, phenylpropanolamine)
- Vasopressive agents (e.g. epinephrine, norepinephrine)
- Dopaminergic agents (e.g. dopamine, dobutamine)
- Rifampin
- Serotonin re-uptake inhibitors
- Tricyclic antidepressants
- Serotonin 5-HT₁ receptor agonists
- Meperidine or buspirone

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.

- 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.

If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose.

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

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Linezolid Sandoz.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Linezolid Sandoz to anyone else, even if they have the same symptoms or condition as you.

- 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.

If signs or symptoms of rhabdomyolysis (breakdown of damaged muscle) are observed, you should stop using Linezolid Sandoz and tell your doctor immediately.

Side effects

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Like all medicines, this medicine can cause side effects, although not everybody gets them.

You may develop diarrhoea while taking or after taking Linezolid Sandoz. If this becomes severe or persistent or you notice that your stool contains blood or mucus, you should stop taking Linezolid Sandoz immediately and consult your doctor.

If you take Linezolid Sandoz for longer periods you may get problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.

Other side effects some patients have experienced while taking linezolid are:

- Abdominal pain/cramps/distension
- Nausea
- Vomiting
- Moniliasis (yeast infection)
- Abnormal blood tests
- Abnormal liver function tests
- Headache
- Taste alteration
- Reversible anemia
- Sideroblastic anaemia (a form of anemia in which the bone marrow produces ringed sideroblasts)
- Leucopenia (decreased number of white blood cells)

- Thrombocytopenia (decreased number of platelets)
- Pancytopenia (decreased number of red blood cells, white blood cells and platelets)
- Optic neuropathy (loss of vision due to damage to the optic nerve)
- Anaphylaxis (serious allergic reaction)
- Lactic acidosis
- Peripheral neuropathy
- Convulsions
- Rash
- Angioedema (swelling of the skin and mucous membranes)
- Tongue discoloration
- Bullous skin disorders (e.g. Stevens Johnson syndrome, toxic epidermal necrolysis)
- Superficial tooth discoloration.
- Rhabdomyolysis (breakdown of damaged muscle) - muscle pain, tenderness or weakness and dark urine

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website

npa.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

Medicines should not be disposed of via wastewater or household waste.

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

LINEZOLID SANDOZ[®] FILM-COATED TABLETS 600MG

Linezolid (600mg)

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Product Registration Holder

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