

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr **Sandoz Linezolid** **Linezolid tablets**

Read this carefully before you start taking Sandoz Linezolid and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Sandoz Linezolid.

What is Sandoz Linezolid used for?

Sandoz Linezolid is an antibiotic medicine. It is used to treat the following bacterial infections in adults:

- abdomen infections
- skin infections
- infections of system that carries urine out of body (urinary tract)
- lung infections (pneumonia)

Antibacterial drugs like Sandoz Linezolid treat only bacterial infections. They do not treat viral infections. Although you may feel better early in treatment, Sandoz Linezolid should be used exactly as directed. Misuse or overuse of Sandoz Linezolid could lead to the growth of bacteria that will not be killed by Sandoz Linezolid (resistance). This means that Sandoz Linezolid may not work for you in the future. Do not share your medicine.

How does Sandoz Linezolid work?

Sandoz Linezolid belongs to the class of medicines called oxazolidinones antibiotics. It works by stopping the growth of bacteria responsible for your infection.

What are the ingredients in Sandoz Linezolid?

Medicinal ingredient: Linezolid

Non-medicinal ingredients: Colloidal silica anhydrous, hydroxypropylcellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium starch glycolate, titanium dioxide.

Sandoz Linezolid comes in the following dosage forms:

Tablets: 600 mg

Do not use Sandoz Linezolid if you:

- are allergic to linezolid or any other ingredients of Sandoz Linezolid (see What are the ingredients in Sandoz Linezolid?).
- have uncontrolled high blood pressure
- have pheochromocytoma [a tumor of small part of the body, located on top of each kidney]

(adrenal gland)]

- have thyrotoxicosis (an overactive thyroid)
- have carcinoid syndrome (a condition caused by tumours of the hormone system with signs of diarrhea, skin flushing, rapid heartbeat, wheezing)
- have taken certain medications used for low mood (depression) like isocarboxazid, phenelzine or tranylcypromine or medications used for Parkinson's disease like selegiline or rasagiline in the last 14 days
- are taking any cold or flu medication containing pseudoephedrine or phenylpropanolamine*
- are taking epinephrine, a medication used for severe allergic reactions
- are taking any other medication that increases blood pressure like norepinephrine, dopamine or dobutamine
- are taking any medication known as selective serotonin re-uptake inhibitors (SSRI's) (e.g., citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline) or serotonin norepinephrine reuptake inhibitors (SNRIs) (e.g., desvenlafaxine, duloxetine, venlafaxine). These medications may be used for low mood (depression).
- are taking tricyclic antidepressants, medications for low mood such as amitriptyline, clomipramine, desipramine, doxepin, imipramine, nortriptyline
- are taking medications for migraine such as almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan
- are taking meperidine, a medication for pain
- are taking buspirone, a medication for anxiety

* phenylpropanolamine is no longer marketed in Canada

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Sandoz Linezolid. Talk about any health conditions or problems you may have, including if you:

- have a history of high blood pressure.
- have taken a drug for low mood (depression) within the last 2 weeks (14 days).
- have a history of anemia (low red blood cells), thrombocytopenia [(low cells in the blood that help the blood clot (platelets)], neutropenia (low white blood cells) or any other blood related problems.
- have a history of bleeding problems.
- have a history of seizures or convulsions.
- have diabetes. You will need to watch your blood sugar closely.
- are pregnant or trying to become pregnant.
- are breast-feeding.

Other warnings you should know about:

While taking Sandoz Linezolid

- Follow your doctor's instructions carefully.
- Do not stop taking your medicine until your doctor tells you to, even if you are feeling better. Sandoz Linezolid is not normally used in children and teenagers under 18 years

old.

- If you develop severe diarrhea during or over 2 months after treatment with Sandoz Linezolid, call your healthcare professional immediately (see What are possible side effects from using Sandoz Linezolid? section below).
- Do not use any medicine to treat your diarrhea without first checking with your doctor.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Sandoz Linezolid:

- All the medications listed under “Do not use Sandoz Linezolid if you” section above. Many other medications may also interact with Sandoz Linezolid. Tell your healthcare professional about all the medications you are taking, even those that do not appear on this list.
- Tyramine, a chemical naturally present in some pickled, smoked, or fermented foods or drinks like aged cheese and red wines. This interaction may cause a sudden increase in your blood pressure. If you develop a throbbing headache after eating or drinking, tell your healthcare professional. To prevent these problems, get a list of tyramine-rich foods to avoid from your healthcare professional while taking Sandoz Linezolid.

How to take Sandoz Linezolid:

You may take Sandoz Linezolid (tablets) with or without food.

Usual dose (adults, 18 years and older):

One tablet (600 mg) twice a day (every 12 hours) for 10 to 28 days.

Your healthcare professional will tell you how long you need to take Sandoz Linezolid.

Overdose:

If you think you have been given too much Sandoz Linezolid, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule as prescribed by your doctor.

Do not take double doses to make up for missing a dose.

What are possible side effects from using Sandoz Linezolid?

These are not all the possible side effects you may feel when taking Sandoz Linezolid. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Headache
- Diarrhea
- Nausea

- Vomiting
- Dizziness
- Change in taste
- Fungal infection
 - white patches in mouth, tongue or throat (oral thrush)
 - for women, vaginal yeast infection with itching and irritation in the vagina, pain or burning when urinating (peeing), vaginal discharge
- Tongue discoloration
- Fever
- Insomnia
- Constipation
- Rash
- Dry mouth
- Stomach discomfort
- Increased thirst
- High blood sugar (blurred vision, unusual thirst, increased frequency and amount of urination, a fruit-like breath odor, rapid breathing)
- Low blood sugar (dizziness, headache, feeling sleepy, feeling weak, shaking, a fast heartbeat, confusion, hunger, or sweating)
- Ringing in the ear
- High blood pressure (watch your blood pressure closely)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON Blood problems (decrease in the level of blood cells): Unusual bleeding or bruising, feeling very tired or weak shortness of breath, fever and chills, sore throat		√	
Vision problems: blurred vision, changes in colour vision, loss of vision		√	
Numbness, tingling, prickling sensations or burning pain		√	
Signs of too much lactic acid in the blood (lactic acidosis): feeling very tired or weak, feeling cold, severe nausea with or without vomiting, stomach pain, fast breathing, fast heartbeat, a heartbeat that does not feel normal, muscle pain			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
or cramps			
Allergic reactions: rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing; swelling of the mouth, face, lips, tongue, or throat			√
Clostridium difficile colitis (bowel inflammation): severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness			√
Serotonin syndrome (occur within several hours of starting a new medicine or increasing the dose of a drug you are already taking): severe headache, agitation, fever, fast heartbeat, flushing, seizures, shakiness, sweating a lot, change in balance, change in thinking clearly, severe upset stomach and throwing up, severe loose stools			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

Store at room temperature, 15°C to 30°C. Keep out of the reach and sight of children.

If you want more information about Sandoz Linezolid:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website \(https://www.canada.ca/en/health-canada.html\)](https://www.canada.ca/en/health-canada.html), the manufacturer's website www.sandoz.ca, or by calling at: 1-800-361-3062

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