

LINEVOX

Film Coated Tablets

linezolid

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before taking Linevox. This leaflet answers some common questions about Linevox.

It does not contain all the available information. It does not take the place of talking to your or your child's doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child taking Linevox against the expected benefits it will have.

Ask the doctor if you have any concerns about you or your child taking this medicine.

Keep this leaflet even after your treatment with Linevox is finished.

You may need to read it again.

What Linevox is used for

Linevox contains the active ingredient, linezolid.

Linevox is an antibiotic (an agent used to destroy certain types of bacteria).

It is used in the treatment of bacterial infections such as pneumonia, skin infections or blood infections.

Depending on the type of bacteria, you may be given additional medicines.

Your doctor, however, may prescribe Linevox for another purpose.

Ask your doctor if you have any questions about why Linevox has been prescribed for you or your child.

This medicine is not addictive.

Before taking Linevox

When you must not take it

Do not take Linevox or give Linevox to your child before you talk to your doctor or pharmacist if you or your child:

- are allergic to linezolid or any of the other ingredients listed at the end of this leaflet.
Some of the symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.
- have uncontrolled high blood pressure
- have pheochromocytoma (a type of tumour of the adrenal gland)
- have thyrotoxicosis (an overactive thyroid gland)
- have flushing or other symptoms caused by a carcinoid tumour
- are taking or have taken in the last two weeks any medicine that is a monoamine oxidase inhibitor (e.g., moclobemide, phenelzine or tranylcypromine to treat depression or selegiline to treat Parkinson's disease)
- any cold or flu medicine containing pseudoephedrine

- adrenaline, a medicine used to treat severe allergic reactions
- any other medicine that increases blood pressure (e.g., noradrenaline, dopamine, dobutamine)
- are taking any medicine that is an SSRI or serotonin re-uptake inhibitor, which are types of medicine to treat depression, anxiety, panic attacks, obsessive-compulsive disorders or obesity (e.g., citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, sibutramine, venlafaxine)
- tricyclic antidepressants, which are medicines to treat depression (e.g., amitriptyline, clomipramine, dothiepin, doxepin, imipramine, nortriptyline, trimipramine)
- some medicines to treat migraine (e.g. naratriptan, sumatriptan, zolmitriptan)
- pethidine, a medicine to treat pain.
- buspirone, a medicine to treat anxiety

Do not take Linevox if the packaging is torn or shows signs of tampering.

Do not take Linevox tablets after the expiry date printed on the pack has passed.

If you have any concerns about you or your child taking Linevox speak to your doctor or pharmacist.

Before you take Linevox

Tell the doctor if you or your child:

- have diarrhoea
- have allergies to any other medicines or substances, such as foods, preservatives or dyes
- are anaemic or have had any abnormal blood test results (e.g., low haemoglobin or platelets).

Tell the doctor if you:

- are pregnant or planning to become pregnant.
- are breastfeeding or intend to breastfeed

If you are pregnant or breastfeeding, the doctor may decide not to prescribe Linevox.

Talk to the doctor or pharmacist, if you have any concerns about you or your child being given Linevox.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, tell the doctor if you or your child have been treated with or are taking:

- any medicine that inhibits monoamine oxidase, (e.g., moclobemide, phenelzine or tranylcypromine to treat depression or selegiline to treat Parkinson's disease)
- any cold or flu medicine containing pseudoephedrine
- adrenaline, a medicine used to treat severe allergic reactions
- any other medicine that increases blood pressure (e.g., noradrenaline, dopamine, dobutamine)
- are taking any medicine that is an SSRI or serotonin re-uptake inhibitor, which are types of medicine to treat depression, anxiety, panic attacks, obsessive-compulsive disorders or obesity (e.g., citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, sibutramine, venlafaxine)

- tricyclic antidepressants, which are medicines to treat depression (e.g., amitriptyline, clomipramine, dothiepin, doxepin, imipramine, nortriptyline, trimipramine)
- some medicines to treat migraine (e.g., naratriptan, sumatriptan, zolmitriptan)
- any medicine that is an opioid, a medicine used to treat pain.
- buspirone, a medicine to treat anxiety
- rifampicin, a medicine to treat tuberculosis and some other infections
- any medicine that could reduce the levels of haemoglobin (the pigment in red blood cells which carries oxygen) or platelets (blood cells which help blood to clot)

These medicines may be affected by Linevox or may affect how well it works. You or your child may need different amounts of medicines, or may need to take different medicines.

Ask the doctor or pharmacist if you are not sure about this list of medicines.

Also tell the doctor if your or your child's diet contains a lot of mature cheese, yeast extracts, meat extracts, soya bean extracts (e.g., soy sauce), draught beers or wine.

Linevox may react with a substance which is naturally present in these foods.

How to take Linevox

It is recommended that treatment with Linevox begin in a hospital.

Follow all directions given by your or your child's doctor carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask the doctor or pharmacist for help.

When to take it

Take the dose as prescribed by your doctor.

Give the dose to your child as prescribed by your child's doctor.

Linevox can be taken before, during or after meals.

If you or your child are on dialysis, take Linevox after dialysis.

How much to take

Tablets

The recommended dose for adults and adolescents 12 years and older is one 600mg tablet twice daily (every 12 hours).

Oral Suspension*

The recommended dose for babies and children up to 12 years of age is 10mg/kg three times daily (every 8 hours).

*Oral Suspension formulations for this medicine are unavailable in Linevox brand but are available in other brands.

For babies and young children, the appropriate formulation of this medicine is the oral suspension preparation.

Ask your or your child's doctor if you want more information about the most appropriate dose and formulation of Linevox and how it is given.

How long to take it

Continue taking Linevox until you or your child finish the tablets unless your doctor recommends otherwise.

Do not stop taking Linevox unless your doctor tells you to, even if you feel better.

Do not stop giving Linevox to your child unless your child's doctor tells you to, even if your child feels better.

If you or your child do not complete the full course prescribed by the

doctor, the bacteria causing the infection may continue to grow and multiply. The infection may not clear completely or it may return.

A course of treatment usually lasts 10 to 14 days, but may be up to 28 days.

If you forget to take it

If it is almost time for your or your child's next dose, skip the missed dose and take the next dose when you or your child are meant to. Otherwise, take it or give it to your child as soon as you remember, and then go back to taking Linevox as you would normally.

Do not take a double dose or give a double dose to your child to make up for the dose that you missed.

If you have trouble remembering to take the medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or Poisons Information Centre (in Australia phone 13 11 26 and in New Zealand phone 0800 POISON or 0800 764 766) or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Linevox.

Do this even if there are no signs of discomfort or poisoning.

You or your child may need urgent medical attention.

Keep the telephone numbers for these places handy.

The possible effects of overdose are vomiting, tremors (shaking), unsteadiness or lack of coordination.

While taking Linevox

Things you must do

Follow all instructions given by your or your child's doctor. In some cases, additional blood tests may be required.

Tell all doctors, dentists and pharmacists who are treating you or your child that you are taking Linevox.

If you or your child are going to have surgery, tell the surgeon or anaesthetist that you or your child are taking this medicine.

It may affect other medicines used during surgery.

Tell your doctor immediately if you become pregnant while you are taking Linevox.

Keep all of your doctor's appointments so that you or your child's progress can be checked

Your doctor may do some blood test from time to time to make sure the medicine is working and to prevent unwanted side effects.

If the symptoms of the infection do not improve within a few days, or if they become worse, tell your or your child's doctor.

As part of the treatment, you or your child may be given other medicines including other antibiotics. It is important to keep taking these medicines as well as Linevox unless you are told otherwise by your or your child's doctor or pharmacist.

It is important to tell your or your child's doctor if you or your child develop diarrhoea during or after treatment with Linevox. Do this even if it occurs several weeks after Linevox has been stopped.

Do not take or give your child any medicine to treat diarrhoea without first checking with the doctor.

Diarrhoea may be caused by a serious condition affecting the bowel. You or your child may need urgent medical care.

If you or your child get a sore white mouth or tongue while taking or soon after stopping Linevox tell the doctor.

Tell the doctor if you or your child get vaginal itching or discharge.

This may mean you or your child have a fungal infection called thrush. Sometimes the use of Linevox allows fungi to grow which causes the symptoms described above. Linevox does not work against fungi.

Things you must not do

Do not take Linevox to treat any other complaint unless your doctor tells you to do so.

Do not give Linevox to anyone else, even if they seem to have the same condition as you.

Do not start taking any other medicines, prescription or not, without first telling your doctor or pharmacist.

Do not stop taking your medicine or lower the dosage without check with your doctor.

If you stop taking it suddenly, your condition may worsen.

Do not give your child any other medicines, prescription or not, without first telling your child's doctor or pharmacist.

Do not take or give your child any medicine to treat diarrhoea without first checking with the doctor.

Diarrhoea may be caused by a serious condition affecting the bowel. You or your child may need urgent medical care.

Avoid eating too much mature cheese, yeast extracts, meat extracts or soya bean extracts (e.g., soy sauce). Avoid drinking alcohol, especially draught beers and wine.

This is because Linevox may react with a substance which is naturally present in these foods.

If you or your child develop a throbbing headache after eating, tell your doctor or health care professional.

Things to be careful of

Be careful driving or operating machinery, until you know how Linevox affects you.

No effects on the ability to drive or use machines have been seen with Linevox. However, as with many other medicines, Linevox may cause dizziness or visual impairment in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful performing activities requiring attention such as riding bicycles or climbing.

Side effects

Tell your or your child's doctor or pharmacist as soon as possible if you or your child do not feel well while taking Linevox.

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Do not be alarmed by the following lists of side effects.

You or your child may not experience any of them.

Tell your or your child's doctor or pharmacist if you notice any of the following and they worry you:

- headache
- sore, white mouth or tongue (oral thrush)
- vaginal itching or discharge (vaginal thrush)
- pain, cramping or "bloating" of the abdomen
- nausea or vomiting
- metallic taste
- change in the colour of the tongue
- change in the colour of teeth. This may be reversible.

- Headache, difficulty concentrating, memory impairment, confusion, weakness and unsteadiness, which may lead to falls (these symptoms may indicate low sodium levels in the blood)

See your doctor immediately and before you or your child take the next dose of Linevox if you notice any of the following:

- skin reactions (hives, rash or itching)
- visual disturbances or numbness or weakness of the arms and legs (rare side effects that have been primarily reported in patients treated for longer than 28 days)
- tiredness, headaches, being short of breath when exercising, dizziness, looking pale, dark circles around the eyes, fever and chills, sore throat or bruising (these symptoms may indicate a decrease in the level of your blood cells)
- sweating, feeling drunk and dizzy, muscle twitching, fever and shivering, confusion. These may be symptoms of the serotonin syndrome, which is a rare but serious side effect.

If any of the following happen to you or your child, tell your or your child's doctor immediately or go to Accident and Emergency at your nearest hospital:

- Seizure
- Hallucination
- Fainting
- coma
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, severe itching or hives or blisters on the skin and bleeding in the lips, eyes, mouth, nose and genitals.
- Painful red/purple spots with/without blisters and peeling of skin.. This may be accompanied by fevers and

chills, aching muscles, joint pain, enlarged lymph nodes and generally feeling unwell.

These may be signs of a serious allergic reaction or side effect. You or your child may need urgent medical attention or hospitalisation. These side effects are rare.

After stopping your treatment

Tell your or your child's doctor or pharmacist if you or your child get any of the following side effects, particularly if they occur several weeks after stopping treatment with Linevox:

- severe stomach cramps
- watery and severe diarrhoea (which may be bloody), fever, in combination with one or both of the above.

Linevox can cause some bacteria, which are normally present in the bowel and normally harmless, to multiply and cause these symptoms. You or your child may need urgent medical attention.

Tell your doctor if you notice any other side effects.

Other side effects not listed above may also occur in some people.

After using Linevox

Storage

Keep your tablets in the original packaging, including outer carton, until it is time to take them.

If you take the medicine out of the pack it may not keep well.

Keep Linevox in a cool dry place where the temperature stays below 30°C.

Do not store Linevox or any other medicines in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Linevox where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Linevox or to stop giving Linevox to your child, or the medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

Australian Registration Numbers

AUST R 237304 (blister pack)

Date of preparation

This leaflet was revised in September 2022

Product description

What it looks like

Linevox tablets are white oval biconvex tablets, printed with '600' on one side. The tablets are available in blister packs of 10 tablets.

Ingredients

The active ingredient in Linevox is linezolid.

Linevox tablets contain 600mg of linezolid.

The tablets also contain:

- microcrystalline cellulose
- sodium starch glycollate type A
- magnesium stearate
- poloxamer
- povidone
- colloidal anhydrous silica
- lactose monohydrate
- talc
- OPADRY II Aqueous Film Coating YS-1-18202-A White
- Videojet InkSource 16-9000 Ink (blue printing ink)

This medicine contains lactose.

Supplier

Linevox is supplied in Australia by:

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel Street
Cremorne
Victoria 3121