

Linezolid APO Injection

Linezolid

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about linezolid. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you receiving linezolid against the benefits they expect it will have for you.

If you have any concerns about receiving this medicine, ask your doctor or pharmacist.

Keep this leaflet with you.

You may need to read it again..

What this medicine is used for

Linezolid is an antibiotic used to treat bacterial infections such as pneumonia, skin infections or blood infections. Depending on the type of bacteria, you may be given additional medicines.

Ask your doctor if you have any questions about why linezolid has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

Before you use this medicine

When linezolid must not be given

Do not receive linezolid if you have an allergy to:

- linezolid
- 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.

Do not receive linezolid if you have or have had any of the following medical conditions:

- uncontrolled high blood pressure
- pheochromocytoma (a type of tumour of the adrenal gland)
- thyrotoxicosis (an overactive thyroid gland)
- flushing or other symptoms caused by a carcinoid tumour

Do not receive linezolid if you are taking the following medicines:

- are taking or have taken in the last two weeks a monoamine oxidase inhibitor (e.g. moclobemide, phenelzine or tranylcypromine, selegiline)
- pseudoephedrine
- adrenaline

- medicines that increases blood pressure (e.g. noradrenaline, dopamine, dobutamine)
- serotonin re-uptake inhibitors (e.g. citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, sibutramine, venlafaxine)
- tricyclic antidepressants (e.g. amitriptyline, clomipramine, dothiepin, doxepin, imipramine, nortriptyline, trimipramine)
- migraine medicines (e.g. naratriptan, sumatriptan, zolmitriptan)
- pethidine
- buspirone

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell the doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell the doctor if you:

- have diarrhoea
- are anaemic or have had any abnormal blood test results (e.g. low haemoglobin or platelets)
- are diabetic (LINEZOLID APO injection contains glucose).

Tell your doctor if you are pregnant, plan to become pregnant or are breastfeeding.

Talk to the doctor if you have any concerns about receiving linezolid.

Taking other medicines

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

These medicines may include:

- 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, used to treat severe allergic reactions
- medicines that increase blood pressure (e.g. noradrenaline, dopamine, dobutamine)
- serotonin re-uptake inhibitor, used to treat mood disorders or obesity (e.g. citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, sibutramine, venlafaxine)
- tricyclic antidepressants, used to treat depression (e.g. amitriptyline, clomipramine, dothiepin, doxepin, imipramine, nortriptyline, trimipramine)
- some medicines to treat migraine (e.g., naratriptan, sumatriptan, zolmitriptan)
- pethidine, used to treat pain
- buspirone, used to treat anxiety
- rifampicin, used to treat infections
- any medicine that could reduce haemoglobin or platelet levels

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

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

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

How this medicine is given

Linezolid will be given to you by the doctor or nurse, usually in a hospital.

Linezolid is given by slow injection into the blood over a period of 30 to 120 minutes.

If you are on dialysis, linezolid should be given after dialysis.

You may be changed from the linezolid injection to an oral preparation of linezolid (such as tablets or oral suspension) to complete your course of treatment.

How much is given

Your doctor will decide on the dose of linezolid that you need, depending on your condition.

Treatment is usually given every day for 10 to 14 days, but may be given for up to 28 days.

In case of overdose

Overdose is unlikely as treatment will be given by the doctor or nurse. The possible effects of overdose are vomiting, tremors, unsteadiness or lack of coordination.

Tell the doctor or nurse immediately if you have any of these effects or if you feel worse during or after treatment with linezolid.

While being treated with this medicine

Things you must do

Follow all instructions given by the doctor.

In some cases, additional blood tests may be required.

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 linezolid unless

you are told otherwise by your doctor or pharmacist.

It is important to tell the doctor if you develop diarrhoea during or after treatment with linezolid. Do this even if it occurs several weeks after linezolid has been stopped. Do not take 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 during or soon after treatment with linezolid tell your 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 linezolid allows fungi to grow which causes the symptoms described above. Linezolid does not work against fungi.

Things you must not do

Do not take any medicine to treat diarrhoea without first checking with the doctor.

Diarrhoea may be caused by a serious condition affecting the bowel. You 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.

Linezolid 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.

Side effects

Tell the doctor or pharmacist as soon as possible if you do not feel well while receiving linezolid.

This medicine may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. Some side effects may require medical attention.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask the doctor or pharmacist to answer any questions you may have.

While using linezolid

Tell the 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.

Tell your doctor immediately if you notice any of the following:

- skin reactions (hives, rash or itching)
- visual disturbances or numbness or weakness of the arms and legs
- tiredness, headaches, being short of breath when exercising, dizziness, looking pale, fever and chills, sore throat or bruising (signs of a decrease in the level of your blood cells)
- sweating, feeling drunk and dizzy, muscle twitching, fever and shivering, confusion (signs of serotonin syndrome)

If any of the following happen, tell your doctor or nurse immediately:

- seizure
- 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 (signs of an allergic reaction) and bleeding in the lips, eyes, mouth, nose and genitals.
- Widespread painful red areas followed by blisters and ends with peeling of layers of skin. This may be accompanied by fevers and chills, aching muscles and generally feeling unwell.

These are serious side effects that may need urgent medical attention. These side effects are rare.

After finishing linezolid

Tell your doctor or pharmacist if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with LINEZOLID APO:

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

Linezolid can cause some bacteria, which are normally present in the bowel and usually harmless, to multiply and therefore cause the above symptoms. You 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.

Storage and Disposal

Storage

LINEZOLID APO will normally be stored in a hospital. It should be stored below 25°C and should be protected from light (kept in the box and foil wrapping before use).

Disposal

Hospital staff will make sure the medicine is not used after the expiry date printed on the bag.

Product description

What it looks like

A sterile, clear, colourless to yellow fluid for injection supplied as 300mL in infusion bags. Each bag is for single use only and is packaged in a foil overwrap contained within an outer carton. AUST R 235006

Ingredients

Each 1 mL of LINEZOLID APO injection contains 2 mg of linezolid as the active ingredient.

This medicine also contains:

- glucose
- sodium citrate (E331)
- citric acid anhydrous (E330)
- hydrochloric acid (E507) / sodium hydroxide (E524), and
- water for injections

Sponsor

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This leaflet was prepared in July 2020