

Linezolid APOTEX-600mg Tablets

Contains the active linezolid

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Linezolid APOTEX. It contains the active ingredient linezolid. Linezolid 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

Before you take this medicine

When you must not take it

Do not take this medicine if you:

- 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.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency Department at the nearest hospital.

- 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, scitalopram, 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 this medicine if

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

If you have any concerns about you taking this medicine speak to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you:

- 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 your doctor if you:

- are currently pregnant or you plan to become pregnant.
 - are currently breastfeeding or you plan to breastfeed.
- If you are pregnant or breast-feeding, the doctor may decide not to prescribe linezolid.

Tell your doctor if you are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

In particular, tell the doctor if you 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)
- pethidine, a medicine 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).

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

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with linezolid.

Also 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 to take this medicine

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

Follow all directions given by your doctor.

These instructions may be different to the information in this leaflet.

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

How much to take

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

Ask your doctor if you want more information about the dose of linezolid and how it is given.

When to take it

Take the dose as prescribed by your doctor.

Linezolid can be taken before, during or after meals.

How long to take it for

Continue taking linezolid until you finish the tablets unless your doctor recommends otherwise.

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

If you 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 to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

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

This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While you are taking this medicine

Things you must do

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

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

As part of the treatment, you 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 your 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 may need urgent medical care.

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

Tell the doctor if you get vaginal itching or discharge.

This may mean you 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.

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

Tell all doctors, dentists and pharmacists who are treating you that you are taking linezolid.

Things you must not do

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

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.

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

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

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

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

Things to be careful of

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

No effects on the ability to drive or use machines have been seen with linezolid. However, as with many other medicines, linezolid may cause dizziness or tiredness in some people.

Possible side effects

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

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 may not experience any of them.

While taking it

Tell your doctor 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.

See your doctor immediately and before you or your child take the next dose of linezolid 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, 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
- 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.

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 finishing it

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

- 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 normally harmless, to multiply and cause these 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.

After using it

Storage

Keep your tablets in the original container 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 this medicine in a cool dry place where the temperature stays below 25°C.

Do not store this medicine 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 linezolid 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 your medicine or the medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What Linezolid APOTEX- looks like

White coloured, oval shaped, biconvex, film coated tablets with "APO" engraved on one side and "LIN600" on the other side.

The tablets are available in blister packs of 10 tablets.

Ingredients

Each tablet contains 600mg of linezolid as the active ingredient.

It also contains the following inactive ingredients:

- methyl cellulose
- crospovidone
- silicon dioxide
- magnesium stearate
- hypromellose
- hydroxypropylcellulose
- macrogol 8000
- titanium dioxide.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

Linezolid APOTEX 600mg tablets

Blister packs of 10 tablets:

AUST R 207475.

Sponsor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

APO and APOTEX are registered trademarks of

Apotex Inc.

This leaflet was prepared in October 2016.