

## Linezolid APOTEX-Tablets

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 using this medicine against the benefits they expect it will have for you.

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

**Keep this leaflet with the medicine.**

You may want 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 need 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.

This medicine is not addictive.

#### Before you take this medicine

##### When you must not take it

**Do not take this medicine 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.

**Tell your doctor if you have or have had 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

**Tell your doctor if you are taking the following medications:**

- monoamine oxidase inhibitor (currently taking or have taken in the last two weeks)
- pseudoephedrine
- adrenaline
- medicines that increase blood pressure
- serotonin re-uptake inhibitor
- tricyclic antidepressants
- migraine medicines
- pethidine
- buspirone

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**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 allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have:**

- diarrhoea
- anaemia or abnormal blood test results (e.g. low haemoglobin or platelets).

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

Your doctor can discuss with you the risks and benefits involved.

**If you have not told your doctor about any of the above, tell them before you start taking this medicine.**

**Taking other medicines**

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

In particular, tell the doctor if you are taking:

- any medicine that inhibits monoamine oxidase (e.g. moclobemide, phenelzine or tranlycypromine 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 some 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)

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.

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).

##### 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.**

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

**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.

##### 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.

##### If you take too much (overdose)

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to the Emergency department at your nearest hospital if you think that you or anyone else may have taken too much of this medicine. 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

**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.**

**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.

**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.**

**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.

*Things you must not do*

**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.**

**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.**

*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, linezolid may cause dizziness or tiredness in some people.

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## Side effects

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**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. Some side effects 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 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

- tiredness, headaches, being short of breath when exercising, dizziness, looking pale, fever and chills, sore throat or bruising (may indicate a decrease in the level of your blood cells)

**If any of the following happen to you, tell your doctor immediately or go to the Emergency department at your nearest hospital:**

- seizure
- sweating, feeling drunk and dizzy, muscle twitching, fever and shivering, confusion (may indicate serotonin syndrome)
- rash, severe itching or hives or blisters on the skin and bleeding in the lips, eyes, mouth, nose and genitals
- 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 a serious allergic reaction).

The above list includes serious side effects that may need urgent medical attention. 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.

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## After using it

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### Storage

**Keep your tablets in its pack, 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 expiry date has passed, ask your pharmacist what to do with any that is left over.

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## Product description

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### What it looks like

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

Available in blister packs of 10 tablets.

AUST R 207475.

### Ingredients

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

It also contains the following:

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

This medicine does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

### Sponsor

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