

Linezolid AMNEAL

Linezolid

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Linezolid AMNEAL tablets. 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 taking Linezolid AMNEAL tablets 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 need to read it again.

What Linezolid AMNEAL is used for

Linezolid AMNEAL 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.

Your doctor may have prescribed it for another reason.

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

This medicine is not addictive.

Before You Take Linezolid AMNEAL

When you must not take it

Do not take Linezolid AMNEAL if you are allergic to linezolid or any of the 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 take Linezolid AMNEAL if you:

- 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)
- are taking any cold or flu medicine containing pseudoephedrine
- have recently received adrenaline, a medicine used to treat severe allergic reactions
- are taking any other medicine that increases blood pressure (e.g., noradrenaline, dopamine, dobutamine)

- are taking any medicine that is an SSRI (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)
- are taking tricyclic antidepressants, which are medicines to treat depression (e.g., amitriptyline, clomipramine, dothiepin, doxepin, imipramine, nortriptyline, trimipramine)
- are taking some medicines to treat migraine (e.g. naratriptan, sumatriptan, zolmitriptan)
- are receiving pethidine, a medicine to treat pain
- are taking buspirone, a medicine to treat anxiety.

Do not take this medicine if the expiry date (Exp.) printed on the pack has passed.

If it has expired return it to your pharmacist for disposal.

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

If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk 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 are pregnant or plan to become

pregnant. Tell your doctor if you are breastfeeding.

if you are pregnant or breastfeeding, the doctor may decide not to prescribe Linezolid AMNEAL.

Tell your doctor if you:

- have diarrhoea
- are anaemic or have had any abnormal blood test results (e.g., low haemoglobin or platelets).

If you have not told your doctor about any of the above, tell them before you start taking Linezolid AMNEAL.

Taking other medicines

Tell your doctor if you are taking any other medicines, including those that you buy without a prescription 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)
- any SSRI (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).

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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 Linezolid AMNEAL

It is recommended that treatment with Linezolid AMNEAL begin in a hospital.

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to take

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

The usual dose for children up to 12 years of age is 10 mg/kg three times daily (every 8 hours). An oral suspension of linezolid is available from other sponsors.

Ask your doctor or pharmacist for advice on the best formulation if the treatment is for your child.

When to take it

Linezolid AMNEAL tablets can be taken with or without food.

If you are on dialysis, take Linezolid AMNEAL after dialysis.

How long to take it

Continue taking Linezolid AMNEAL for as long as your doctor tells you. Do not stop taking your tablets because you are feeling better.

If you do not complete the full course prescribed by your doctor, the bacteria causing the infection may continue to grow and multiply. The infection may not clear completely or your symptoms may return.

A course of linezolid treatment (including any doses given by injection) 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 next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

If you have trouble remembering when 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), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Linezolid AMNEAL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep the telephone numbers for these places handy.

While you are taking Linezolid AMNEAL

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Linezolid AMNEAL.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Linezolid AMNEAL.

If you become pregnant while you are taking Linezolid AMNEAL, tell your doctor.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking Linezolid AMNEAL.

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

If you develop diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after you have stopped taking Linezolid AMNEAL.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any medications for diarrhoea without checking with your doctor or pharmacist.

If you get a sore, white mouth or tongue while taking or soon after stopping Linezolid AMNEAL, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes the use of Linezolid AMNEAL allows fungi to grow and the above symptoms to occur. Linezolid AMNEAL does not work against fungi.

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 your 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 AMNEAL 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 your Linezolid AMNEAL tablets to anyone else, even if they have the same condition as you.

Do not use Linezolid AMNEAL to treat other conditions unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Linezolid AMNEAL affects you.

No effects on the ability to drive or use medicines have been seen with Linezolid AMNEAL. However, as with many other medicines,

Linezolid AMNEAL may cause dizziness in some people.

Side Effects

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

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines have side effects. Sometimes they are serious, most of the time they are not. In serious cases, you may need medical attention.

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

You may not experience any of them.

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

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 (generally reversible).

See your doctor immediately and before you take the next dose of Linezolid AMNEAL 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.

Tell your doctor immediately, or go to the Accident and Emergency department at your nearest hospital if you notice any of the following:

- fits (seizures, convulsions)
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, severe itching, hives or blisters on the skin.

These may be signs of a serious allergic reaction or side effect. You may need urgent medical attention. These serious 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 AMNEAL:

- 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 occur in some people.

After taking Linezolid AMNEAL

Storage

Keep your tablets in the original packaging until it is time to take them.

If you take the tablets out of the box or the blister pack they may not keep well.

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

Do not store Linezolid AMNEAL or any other medicine in the bathroom, near a sink, or on a window sill. Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep your tablets where children cannot reach them. 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 Linezolid AMNEAL tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over. Return any unused medicine to your pharmacist.

Product description

What it looks like

Linezolid AMNEAL tablets are white to off white, oval shaped, film coated tablets, debossed with AI006 on one side and plain on the other side.

Linezolid AMNEAL tablets are presented in the following packs:

- PVC-PVdC/Aluminium blister packs containing 10* or 30 tablets (AUST R 247236)
- HDPE bottles containing 10 or 30 tablets (AUST R 247237)

*Commercially available

Ingredients

The active ingredient in Linezolid AMNEAL is linezolid. Each tablet contains 600 mg of linezolid.

The tablets also contain:

- microcrystalline cellulose
- croscarmellose sodium
- povidone
- silicon dioxide
- magnesium stearate

The film coating contains:

- hypromellose
- diethyl phthalate
- purified talc
- ethylcellulose
- titanium dioxide

Name and Address of the Sponsor

Amneal Pharma Australia Pty Ltd
12 River St
South Yarra
VIC – 3141
Australia

Date of Preparation

July 2015