

Package Leaflet: Information for the user

[Product name] <600 mg> <film-coated tablets>
Linezolid

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What [product name] is and what it is used for
2. What you need to know before you take [product name]
3. How to take [product name]
4. Possible side effects
5. How to store [product name]
6. Contents of the pack and other information

1. What [product name] is and what it is used for

[Product name] is a medicine containing an active substance called linezolid. [Product name] is an antibiotic of the oxazolidinones group that works by stopping the growth of certain bacteria (germs) that cause infections. It is used to treat pneumonia and some infections in the skin or under the skin. Your doctor will have decided if [Product name] is suitable to treat your infection.

2. What you need to know before you take [product name]

Do not take [product name]

- If you are **allergic (hypersensitive)** to linezolid or any of the other ingredients of this medicine (listed in section 6)
- If you are taking or have taken within the last 2 weeks any medicines known as monoamine oxidase inhibitors (MAOIs, for example phenelzine, isocarboxazid, selegiline, moclobemide). These may be used to treat depression or Parkinson's disease.
- If you are breastfeeding. This is because it passes into breast milk and could affect the baby.

Linezolid may not be suitable for you if you answer **yes** to any of the following questions. In this case tell your doctor as he/she will need to check your general health and your blood pressure before and during your treatment, or may decide that another treatment is better for you.

Ask your doctor if you are not sure whether these categories apply to you.

- Do you have **high blood pressure**?
- Have you been diagnosed with an **overactive thyroid**?
- Do you have a **tumour of the adrenal glands (phaeochromocytoma)** or **carcinoid syndrome** (caused by tumours of the hormone system with symptoms of diarrhoea, flushing of the skin, wheezing)?
- Do you suffer from **manic depression, schizoaffective disorder, mental confusion or other mental problems**?
- Are you taking any of the following medicines?

- **decongestant, cold or flu** remedies containing pseudoephedrine or phenylpropanolamine
- medicines used to treat **asthma** such as salbutamol, terbutaline orfenoterol
- antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors) for example amitriptyline, Cipramil, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine; sertraline
- medicines used to treat **migraine** such as sumatriptan and zolmitriptan
- medicines used to treat **sudden, severe allergic reactions** such as adrenalin (epinephrine)
- medicines which increase your **blood pressure**, such as noradrenaline (norepinephrine), dopamine and dobutamine
- medicines used to **treat moderate to severe pain**, such as pethidine
- medicines used to treat **anxiety disorders**, such as buspirone
- an antibiotic called rifampicin

Warnings and precautions

Talk to your doctor or pharmacist before taking [product name] if you

- **bruise and bleed easily**
- are **anaemic**
- are prone to getting **infections**
- have a history of **seizures**
- have **liver problems** or **kidney problems** particularly if you have dialysis
- have **diarrhoea**.

Tell your doctor immediately if during treatment you suffer from:

- problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.
- you may develop diarrhoea while taking or after taking antibiotics, including linezolid. If this becomes severe or persistent or you notice that your stools contains blood or mucus, you should stop taking linezolid immediately and consult your doctor. In this situation, you should not take medicines that stop or slow bowel movement.
- recurrent nausea or vomiting, abdominal pain or over breathing

Children and adolescents

Use of linezolid is not recommended for children and adolescents (under 18 years old).

Other medicines and [product name]

There is a risk that Linezolid may sometimes interact with certain other medicines to cause side effects such as changes in blood pressure, temperature or heart rate.

Tell your doctor if you are taking or have taken within the last 2 weeks the following medicines as [product name] **must not** be taken if you are already taking these medicines or have taken them recently. (See also Section 2 above ‘Do not use [product name]’).

- monoamine oxidase inhibitors (MAOIs, for example phenelzine, isocarboxazid, selegiline, moclobemide). These may be used to treat **depression** or **Parkinson’s disease**.

Also tell your doctor if you are taking the following medicines. Your doctor may still decide to give you [product name], but will need to check your general health and your blood pressure

before and during your treatment. In other cases, your doctor may decide that another treatment is better for you.

- **Decongestant cold or flu** remedies containing pseudoephedrine or phenylpropanolamine.
- Some medicines used to treat **asthma** such as salbutamol, terbutaline, fenoterol.
- Certain **antidepressants** known as tricyclics or SSRIs (selective serotonin reuptake inhibitors). There are many of these, including amitriptyline, Cipramil, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine, sertraline.
- Medicines used to treat **migraine** such as sumatriptan and zolmitriptan.
- Medicines used to treat **sudden, severe allergic reactions** such as adrenaline (epinephrine).
- Medicines which increase your **blood pressure**, such as noradrenaline (norepinephrine), dopamine and dobutamine.
- Medicines used to treat **moderate to severe pain**, such as pethidine.
- Medicines used to treat **anxiety disorders**, such as buspirone.
- Medicines that stop **blood clotting**, such as warfarin.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription.

[Product name] with food and drink

- You can take [product name] either before, during or after a meal.
- Avoid eating large amounts of mature cheese, yeast extracts, or soya bean extracts eg. soy sauce and drinking alcohol, especially draught beers and wine. This is because this medicine may react with a substance called tyramine which is naturally present in some foods to cause an increase in your blood pressure.
- If you develop a **throbbing headache** after eating or drinking, tell your doctor or pharmacist immediately.

Pregnancy and breast-feeding

The effect of linezolid in pregnant women is not known. Therefore it should not be taken in pregnancy unless advised by your doctor. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not breast-feed when taking linezolid because it passes into breast milk and could affect the baby.

Driving and using machines

Linezolid may make you feel dizzy or experience problems with your vision. If this happens, do not drive or operate any machinery. Remember that if you are unwell your ability to drive or operate machinery may be affected.

3. How to take [product name]

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet (600mg linezolid) twice daily (every twelve hours). Swallow the tablet whole with some water.

If you are on kidney dialysis, you should take linezolid after dialysis.

A course of treatment usually lasts 10 to 14 days but can last up to 28 days. The safety and effectiveness of this medicine have not been established for treatment periods longer than 28 days. Your doctor will decide how long you should be treated.

While you are taking linezolid, your doctor should perform regular blood tests to monitor your blood count.

Your doctor should monitor your eyesight if you take linezolid for more than 28 days.

Use in children and adolescents

Linezolid is not normally used to treat children and adolescents (under 18 years old).

If you take more [product name] than you should

Tell your doctor or pharmacist immediately.

If you forget to take [product name]

Take the forgotten tablet as soon as you remember. Take the next tablet 12 hours after this and continue taking your tablets every 12 hours. **Do not take a double dose to make up for a forgotten dose.**

If you stop taking [product name]

Unless your doctor instructs you to stop treatment, it is important to continue taking linezolid. If you stop and your original symptoms come back tell your doctor or pharmacist immediately.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor, nurse or pharmacist immediately if you notice any of these side effects during your treatment with linezolid:

- skin reactions such as red sore skin and flaking (dermatitis), rash, itching, or swelling, particularly around the face and neck. This may be the sign of an allergic reaction and it may be necessary for you to stop taking linezolid.
- problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.
- severe diarrhoea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), which in very rare circumstances may develop into complications that are life-threatening.
- recurrent nausea or vomiting, abdominal pain or over breathing.
- fits or seizures have been reported with linezolid. You should let your doctor know if you experience agitation, confusion, delirium, rigidity tremor, incoordination and seizure while also taking antidepressants known as SSRI's (see section 2).

Numbness, tingling or blurred vision have been reported by patients who have been given linezolid for more than 28 days. If you experience difficulties with your vision you should consult your doctor as soon as possible.

Other side effects include:

Common (may affect up to 1 in 10 people)

Fungal infections especially vaginal or oral 'thrush' • Headache • Metallic taste in the mouth • Diarrhoea, nausea or vomiting • Changes in some blood test results including those measuring your kidney or liver function or blood sugar levels • Unexplained bleeding or bruising, which may be due to changes in the numbers of certain cells in the blood which may affect blood clotting or lead to anaemia

Uncommon (may affect up to 1 in 100 people)

Inflammation of the vagina or genital area in women • Changes in numbers of certain cells in the blood which may affect your ability to fight infection • Difficulty in sleeping • Dizziness, sensations such as tingling or feeling numb • Blurred vision • "Ringing" in the ears (tinnitus) • Increased blood pressure, inflammation of the veins • Indigestion, stomach pain, constipation • Dry or sore mouth, swollen, sore or discoloured tongue • Skin rash • A need to urinate more often • Fever or chills, aches and pains • Feeling tired or thirsty • Inflammation of the pancreas • Increased sweating • Changes in proteins, salts or enzymes in the blood which measure kidney or liver function • Reduction in the numbers of cells in the blood which fight against infection.

Rare (may affect up to 1 in 1,000 people)

Changes in heart rate (eg, increase rate) • Transient ischaemic attacks (temporary disturbance of blood flow to the brain causing short term symptoms such as loss of vision, leg and arm weakness, slurring of speech and loss of consciousness) • Kidney failure

Not known (frequency cannot be estimated from the available data)

Serotonin syndrome (symptoms include fast heart rate, confusion, abnormal sweating, hallucinations, involuntary movements chills and shivering) • Lactic acidosis (symptoms include recurrent nausea and vomiting, abdominal pain, overbreathing) • Severe skin disorders • Convulsions • Superficial tooth discolouration, removable with professional dental cleaning (manual descaling) • Alopecia (hair loss) • Hyponatraemia (low blood sodium levels) • Changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via <to be completed nationally>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [product name]

Keep this medicine out of the sight and reach of children.

There are no special storage conditions.

Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [product name] contains

- The active substance is linezolid. Each tablet contains 600 mg linezolid
- The other ingredients are cellulose, microcrystalline (E460), crospovidone, hydroxypropylcellulose (E463), silica, colloidal anhydrous, magnesium stearate (E572). The film coating contains hypromellose (E464), titanium dioxide (E171), macrogol 400.

What [product name] looks like and contents of the pack

[Product name] are white to off-white, oblong, biconvex film coated tablets debossed with “L9II 600” on one side.

<Please refer to the procedure-specific annexes to this core PL for the procedure-specific contents of the pack.>

Not all package sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer(s)

[To be completed nationally]

<This medicinal product is authorised in the Member States of the EEA under the following names:>

<{Name of the Member State}> <{Name of the medicinal product}>

<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in {MM/YYYY}.

[To be completed nationally]