

Package leaflet: Information for the use

Linezolid 600 mg film-coated tablets

For adults

Linezolid

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Linezolid is and what it is used for

Linezolid is an antibiotic of the oxazolidinones group that works by stopping the growth of certain bacteria (germs) that cause infections. It is used in adults to treat pneumonia and some infections in the skin or under the skin. Your doctor will have decided if Linezolid is suitable to treat your infection.

2. What you need to know before you take Linezolid

Do not take Linezolid :

- if you are allergic 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 medications may be used to treat depression or Parkinson's disease;
- if you are breastfeeding. This is because Linezolid passes into breast milk and could affect the baby.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Linezolid

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, fenoterol
 - antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors) for example amitriptyline, citalopram, 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
 - used to treat moderate to severe pain, such as pethidine
 - medicines used to treat anxiety disorders, such as buspirone
 - an antibiotic called rifampicin

Take special care with Linezolid

Tell your doctor before you take this medicine if you

- bruise and bleed easily
- are anaemic (have low red blood cells)
- are prone to getting infections
- have a history of seizures
- have liver problems or kidney problems particularly if you are on 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.
- loss of sensitivity in your arms or legs or a sensation of tingling or pricking in your arms or legs.
- recurrent nausea or vomiting, abdominal pain or rapid breathing
 - You may develop diarrhoea while taking or after taking antibiotics, including Linezolid . If this becomes severe or persistent or you notice that your stool 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.

Other medicines and Linezolid

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 Linezolid **must not** be taken if you are already taking these medicines or have taken them recently. (See also Section 2 above ‘Do not take Linezolid’.)

- 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 Linezolid, 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, citalopram, 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.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Linezolid with food, drink and alcohol

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

Pregnancy, breast-feeding and fertility

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 or breast feeding, 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 breastfeed 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.

Linezolid contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Linezolid contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take Linezolid

Adults

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The usual dose is one tablet (600 mg linezolid) twice daily (every twelve hours). Swallow the tablet whole with some water.

If you are on kidney dialysis, you should be given 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 Linezolid than you should

Tell your doctor or pharmacist immediately.

If you forget to take Linezolid

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 tablet.**

If you stop taking Linezolid

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 medicine, ask your doctor, pharmacist or nurse.

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 rare circumstances may develop into complications that are life-threatening.
- recurrent nausea or vomiting, abdominal pain or rapid 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
- Difficulty in sleeping
- Increased blood pressure
- Anaemia (low red blood cell)
- Changes in numbers of certain cells in the blood which may affect your ability to fight infection
- Skin rash
- Itching skin
- Dizziness
- Localised or general abdominal pain
- Constipation
- Indigestion
- Localised pain
- Fever

Uncommon: may affect up to 1 in 100 people

- Inflammation of the vagina or genital area in women
- Sensations such as tingling or feeling numb
- Blurred vision
- “Ringing” in the ears (tinnitus)
- Inflammation of the veins
- Dry or sore mouth, swollen, sore, or discoloured tongue
- A need to urinate more often
- Chills
- 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.
- Convulsions
- Hyponatraemia (low blood sodium levels)
- Kidney failure
- Reduction in platelets
- Abdominal bloating
- 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).
- Injection site pain
- Inflammation of the skin
- Increase in creatinine
- Stomach pain
- Changes in heart rate (e.g., increase rate)

Rare: may affect up to 1 in 1,000 people

- Restricted field of vision
- Superficial tooth discolouration, removable with professional dental cleaning (manual descaling)

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, rapid breathing)
- Severe skin disorders
- Sideroblastic anaemia (a type of anaemia (low red blood cells))
- Alopecia (hair loss)
- Changes in colour vision or difficulty in seeing detail
- Decrease of the blood cell count
- Weakness and/or sensory changes

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly:

For UK via:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

For IE via:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Linezolid

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

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

This medicine does not require any special storage conditions.

Shelf-life after first opening: 30 days.

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 us to protect the environment.

6. Contents of the pack and other information

What Linezolid contains

- The active substance in this medicine is linezolid. Each tablet contains 600 mg linezolid
- The other ingredients are lactose monohydrate, maize starch, hydroxypropyl cellulose, magnesium stearate and sodium starch glycolate (Type A). The film coating contains hypromellose, titanium dioxide (E171), macrogol and carnauba wax.

What Linezolid looks like and contents of the pack

Linezolid 600 mg Film-Coated Tablets are white to off white, oval shaped film-coated tablets debossed with 'H' on one side and 'L8' on the other side.

Linezolid tablets are available in:

Blister Pack: Alu-Alu

Pack sizes: 1, 10, 20, 30, 50, 60, 100 or 200 film-coated tablets

Container Pack: HDPE container with a childproof plastic cap and a silica gel.

Pack sizes: 20 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

For UK

Fresenius Kabi Ltd

Cestrian Court

Eastgate Way, Manor Park

Runcorn, Cheshire, WA7 1NT

United Kingdom

For IRL

Fresenius Kabi Deutschland GmbH

Else-Kröner-Straße 1,

61352 Bad Homburg v.d.Höhe
Germany

Manufacturer

Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park, Paola
Malta

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

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|----------------|--|
| France | Linezolide FRESENIUS KABI 600 mg, comprimé pelliculé |
| Germany | Linezolid Fresenius Kabi 600 mg Filmtabletten |
| Ireland | Linezolid 600 mg film-coated tablets |
| Italy | Linezolid Fresenius Kabi |
| Portugal | Linezolida Fresenius Kabi |
| Spain | Linezolid Fresenius Kabi |
| Romania | Linezolid Fresenius Kabi 600 mg comprimate filmate |
| United Kingdom | Linezolid 600 mg film-coated tablets |

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