Package leaflet: Information for the patient

Linezolid 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, 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 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)
- 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.
- breast-feeding. This is because it 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, whether or not you are taking medicines for this?
- 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?
- Do you have a history of hyponatraemia (low blood sodium levels) or do you take medicines that lower blood sodium levels e.g. certain diuretics (also called "water tablets") such as hydrochlorothiazide?
- Do you take any opioids?
- 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, 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, buprenorphine
  - medicines used to treat anxiety disorders, such as buspirone
  - an antibiotic called rifampicin.

The use of certain medicines, including antidepressants and opioids, together with Linezolid can lead to serotonin syndrome, a potentially life-threatening condition (see section 2 "Other medicines and Linezolid" and section 4).

Take special care with Linezolid

Tell your doctor, pharmacist or nurse before taking this medicine if you
- are elderly
- 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
- 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.
- unexplained muscle pain, tenderness, or weakness, and/or dark urine. These can be signs of a serious condition called rhabdomyolysis (muscle breakdown), which can lead to kidney damage.
- feeling sick and unwell with muscle weakness, headache, confusion and memory impairment which may indicate hyponatraemia (low blood sodium levels).

Children and adolescents

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

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 or pharmacist if you are taking or have recently taken any other medicines.

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 - opioids such as pethidine, buprenorphine.
- medicines used to treat anxiety disorders, such as buspirone.
- medicines that stop blood clotting, such as warfarin.
- an antibiotic called rifampicin.

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 this medicine 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.

See also section 3 "Method of use" for further information.

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 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.

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

3. How to take Linezolid

Adults
Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The recommended dose **for adults** is **one tablet** (600 mg linezolid) **twice daily** (every twelve hours).

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).

Method of use
Swallow the tablet whole with some water.
You can take Linezolid either before, during or after a meal.

If you are on kidney dialysis, you should take Linezolid after your dialysis treatment.

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 taking Linezolid 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, pharmacist or nurse immediately if you notice any of these side effects during your treatment with Linezolid:

The serious side effects (with frequency in brackets) of Linezolid are:

- severe skin disorder (uncommon), swelling particularly around the face and neck (uncommon), wheezing and/or difficulty breathing (rare). This may be the sign of an allergic reaction and it may be necessary for you to stop taking Linezolid. Skin reactions such as a raised purple rash due to inflammation of the blood vessels (rare), red sore skin and flaking (dermatitis) (uncommon), rash (common), itching (common).
- problems with your vision (uncommon) such as blurred vision (uncommon), changes in colour vision (not known), difficulty in seeing detail (not known) or if your field of vision becomes restricted (rare)
- 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 (uncommon)
- recurrent nausea or vomiting, abdominal pain or rapid breathing (rare)
- fits or seizures (uncommon) have been reported with Linezolid
- serotonin syndrome (not known): You should let your doctor know if you experience agitation, confusion, delirium, rigidity, tremor, incoordination, seizure, rapid heartbeat, severe breathing problems, and diarrhoea (suggestive of serotonin syndrome) while also taking antidepressants known as SSRIs or opioids (e.g. buprenorphine) (see section 2).
- 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 (common)
- changes in numbers of certain cells in the blood which may affect your ability to fight infection (uncommon) some signs of infection include: any fever (common), sore throat (uncommon), mouth ulcers (uncommon) and tiredness (uncommon)
- rhabdomyolysis (rare): Signs and symptoms include unexplained muscle pain, tenderness, or weakness, and/or dark urine. These can be signs of a serious condition called rhabdomyolysis (muscle breakdown), which can lead to kidney damage.
- inflammation of the pancreas (uncommon).
- convulsions (uncommon)
- 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) (uncommon)
- "ringing" in the ears (tinnitus) (uncommon).

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 proteins, salts or enzymes which measure your kidney or liver function or blood sugar levels
- difficulty in sleeping
- increased blood pressure
- anaemia (low red blood cell)
- dizziness

- localised or general abdominal pain
- constipation
- indigestion
- localised pain
- reduction in platelets.

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
- swollen, sore, or discoloured tongue
- dry mouth
- a need to urinate more often
- chills
- feeling thirsty
- increased sweating
- hyponatraemia (low blood sodium levels)
- hypoglycaemia (low blood sugar)
- kidney failure
- abdominal bloating
- increase in creatinine
- stomach pain
- changes in heart rate (e.g. increase rate)
- decrease of the blood cell count
- weakness and/or sensory changes.

Rare (may affect up to 1 in 1000 people):
- superficial tooth discolouration, removable with professional dental cleaning (manual descaling)
- black discolouration of the tongue's surface, which appears hairy.

The following side effects have also been reported (**Not known:** frequency cannot be estimated from the available data):
- alopecia (hair loss).

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 via the national reporting system: 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 carton and blister after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Linezolid contains

- The active substance is linezolid. Each film-coated tablet contains 600 mg of linezolid.
- The other ingredients are cellulose microcrystalline, silica colloidal anhydrous, sodium starch glycolate type A, hydroxy propyl cellulose, magnesium stearate in the core; hypromellose (E464), titanium dioxide (E171), macrogol (E1521) in the film coating.

What Linezolid looks like and contents of the pack

Linezolid 600 mg film-coated tablets are white to off white coloured biconvex oval shaped film-coated tablet, 18.8 mm long, 9.9 mm wide and 6.4 mm thick with "LZ600" debossed on one side and plain on the other side.

Linezolid 600 mg film-coated tablets are available as blister in packs containing:

10, 10 (10x1), 20, 28, 30, 50, 60, 100 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.
Novartis Pharmaceuticals S.R.L., Str. Livezeni nr. 7A, RO-540472 Targu-Mures, Romania.
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria	Linezolid Sandoz 600 mg – Filmtabletten
Belgium	Linezolid Sandoz 600 mg filmomhulde tabletten
Czechia	Linezolid Sandoz 600 mg
Denmark	Linezolid "Sandoz"
Finland	Linezolid Sandoz 600 mg kalvopäällysteise t tabletit
Germany	Linezolid – 1 A Pharma 600 mg Filmtabletten
Ireland	Linezolid 600 mg film-coated tablets
Luxembourg	Linezolid Sandoz 600 mg comprimés pelliculés
Netherlands	Linezolid Sandoz 600 mg, filmomhulde tabletten
Norway	Linezolid Sandoz
Romania	Linezolid Sandoz 600 mg comprimate filmate
Slovakia	Linezolid Sandoz 600 mg filmom obalené tablety
Spain	Linezolid Sandoz 600 mg comprimidos recubiertos con película EFG
Sweden	Linezolid Sandoz 600 mg filmdragerade tabletter
United Kingdom (Northern Ireland)	Linezolid 600 mg Film-coated tablets

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