

Package leaflet: Information for the user

Linezolid Pfizer 100 mg/5 ml granules for oral suspension

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 Pfizer 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 Pfizer

Do not take Linezolid Pfizer:

- 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 breast-feeding. 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, 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?

Take special care with Linezolid Pfizer

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.
- 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.
- recurrent nausea or vomiting, abdominal pain or rapid breathing.

Other medicines and Linezolid Pfizer

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 Pfizer’).

- 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.
- An antibiotic called rifampicin.

Linezolid Pfizer 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 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 Pfizer contains

Aspartame

Aspartame, a sweetening agent, is partly converted into phenylalanine in the body. This may be harmful for people with phenylketonuria.

Sucrose, sorbitol, mannitol and fructose

This medicine contains sucrose, mannitol, sorbitol and fructose. If you have been told that you have an intolerance to some sugars contact your doctor before taking this medicine. Sucrose and fructose may also be harmful to the teeth.

Sodium

When made up into a suspension this medicine contains 51 mg of sodium per dose (8.5 mg per 5 ml). This should be taken into consideration if you are on a controlled sodium diet.

Ethanol

This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per 5 ml dose.

3. How to take Linezolid Pfizer

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.

Linezolid comes as granules which will be made up exclusively by a healthcare professional to make a suspension for you to take.

The recommended dose of Linezolid suspension is six 5 ml spoonfuls (600 mg linezolid) twice daily (every 12 hours).

Before using, gently turn the the bottle upside down a few times. DO NOT SHAKE.

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

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 Pfizer than you should

Tell your doctor or pharmacist immediately.

If you forget to take Linezolid Pfizer

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

If you stop taking Linezolid Pfizer

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:

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

- Severe skin disorder (not known), swelling particularly around the face and neck (not known), wheezing and/or difficulty breathing (not known). This may be the sign of an allergic reaction and it may be necessary for you to stop taking Linezolid. Skin reactions such as red sore skin and flaking (dermatitis) (uncommon), rash (common), itching (common).
- Problems with your vision 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 (rare).
- Recurrent nausea or vomiting, abdominal pain or rapid breathing (not known).
- Fits or seizures (uncommon) 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 SSRIs (see section 2) (not known).
- 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 (common) some signs of infection include: any fever (common), sore throat (uncommon), mouth ulcers (uncommon) and tiredness (uncommon).
- 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 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

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
- Inflammation of the veins (IV only)
- Swollen, sore, or discoloured tongue
- A need to urinate more often
- Chills
- Feeling thirsty
- Increased sweating
- Changes in proteins, salts or enzymes in the blood which measure kidney or liver function
- Hyponatraemia (low blood sodium levels)
- Kidney failure
- Reduction in platelets
- Abdominal bloating
- Injection site pain
- Increase in creatinine
- Stomach pain
- Changes in heart rate (e.g, increase rate)

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

- Superficial tooth discolouration, removable with professional dental cleaning (manual descaling)

The following side effects have also been reported (Not known: frequency cannot be estimated from the available data):

- Alopecia (hair loss)
- 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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Linezolid Pfizer

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

Keep the bottle in the outer carton in order to protect from light.

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

Any remaining, unused suspension should be discarded within 21 days of reconstitution.

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 Pfizer contains

- The active substance is linezolid. After reconstitution each 5 ml of suspension contains 100 mg linezolid.
- The other ingredients are sucrose, mannitol, microcrystalline cellulose (E460), carboxymethylcellulose sodium (E466) aspartame, anhydrous colloidal silica (E551), sodium citrate, xanthan gum, sodium benzoate, citric acid anhydrous, sodium chloride, sweeteners (fructose, maltodextrin (corn derived), monoammonium glycyrrhizinate, sorbitol). Flavourings are orange flavour, peppermint flavour, vanilla flavour and orange cream flavour.

What Linezolid Pfizer looks like and contents of the pack

Linezolid granules for oral suspension are supplied in a brown bottle containing white to light yellow orange flavoured granules which may contain lumps providing a white to yellow orange-flavoured liquid (suspension) when made up with water. Each bottle is packaged in a carton with a 2.5 ml/5 ml measuring spoon.

The Marketing Authorisation Holder

Pfizer Healthcare Ireland,
9 Riverwalk,
National Digital Park,
City West Business Campus,
Dublin 24,
Ireland

Manufacturer

Pfizer Manufacturing Belgium NV, Rijksweg 12, B-2870 Puurs, Belgium or Pfizer Service Company, BVBA, Hoge Wei 10, 1930 Zaventem, Belgium.

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

Austria	Linezolid Pfizer
France	Linezolid Pfizer 100mg/5ml granulés pour suspension buvable
Germany	Linezolid Pfizer 100mg/5ml Granulat zur Herstellung einer Suspension zum Einnehmen
Ireland	Linezolid Pfizer 100mg/5ml Granules for Oral Suspension
Italy	Linezolid Pfizer
Netherlands	Linezolid Pfizer 100mg/5ml Granulaat voor orale suspensie
Portugal	Linezolid Pfizer
United Kingdom	Linezolid Pfizer 100mg/5ml Granules for Oral Suspension

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The following information is intended for healthcare professionals only:

Instructions for preparation of the oral suspension:

Linezolid comes as granules which will be made up exclusively by the a healthcare professional.

Loosen the granules and reconstitute using 123 ml water in two approximately equal aliquots to produce 150 ml oral suspension. The suspension should be vigorously shaken between each addition of water. The appearance after reconstitution is a white to yellow-orange suspension.

Before using, gently turn the the bottle upside down a few times. DO NOT SHAKE.

The usual dose of Linezolid Pfizer suspension is six 5 ml spoonfuls (600 mg linezolid) twice daily (every 12 hours).

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

See also Section 3 above 'How to take Linezolid Pfizer'.