

Package leaflet: Information for the user
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 tablet is and what it is used for
2. What you need to know before you take Linezolid tablets
3. How to take Linezolid tablets
4. Possible side effects
5. How to store Linezolid tablets
6. Contents of the pack and other information

1. What Linezolid tablet 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 tablets

Do not take Linezolid tablets:

- 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 medications may be used to treat depression or Parkinson's disease.
- if you are 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 tablets.

Linezolid tablets 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?
- 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
 - medicines 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 tablets

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 stools contains blood or mucus, you should stop taking Linezolid tablets 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 tablets

There is a risk that Linezolid tablets 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 tablets **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 tablets ’)

- 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 tablets, 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 pharmacist or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Linezolid tablets with food, drink and alcohol

- You can take Linezolid tablets 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.

Pregnancy, breast-feeding and fertility

The effect of this medicine 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 tablets because it passes into breast milk and could affect the baby.

Driving and using machines

Linezolid tablets 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 tablet contains soya lecithin. If you are allergic to soya, do not use this medicine.

3. How to take Linezolid tablets

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 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 tablets 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 tablets, your doctor should perform regular blood tests to monitor your blood count. Your doctor should monitor your eyesight if you take Linezolid tablets for more than 28 days.

Use in children and adolescents

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

If you take more Linezolid tablets than you should

Tell your doctor or pharmacist immediately.

If you forget to take Linezolid tablets

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 tablets

Unless your doctor instructs you to stop treatment, it is important to continue taking linezolid tablets.

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 tablets:

- 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 tablets.
- 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(IV only)
- 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 1000 people):

- Restricted field of vision.
- 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):

- 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 or 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 tablets

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 medicinal product does not require any special storage conditions.

HDPE bottle pack should be used within 90 days after first opening.

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 film-coated tablets contains

-The active substance in this medicine is called linezolid. Each tablet contains 600 mg linezolid

-The other ingredients are Microcrystalline cellulose, Hydroxypropyl cellulose -L, Sodium starch glycolate (Type A) and Magnesium stearate. The film coating contains Polyvinyl alcohol-part. hydrolyzed, Titanium dioxide (E171), Talc, Lecithin (soya) and Xanthan gum.

What Linezolid film-coated tablets looks like and contents of the pack

Linezolid 600 mg film-coated tablets are white to off-white, oval shaped biconvex and debossed "EQ1" on one side and plain on other side.

Tablets are available as Alu-Alu blister packed in a box or HDPE bottle pack.

HDPE bottles are fitted with white opaque polypropylene child resistant closure (with wad having induction sealing liner) and a desiccant disc.

Each box of Alu-Alu blister contains 1, 10, 20, 30, 50, 60 or 100 tablets.

Each HDPE bottle contains 10, 30 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Accord Healthcare Ireland Limited, Euro House, Euro Business Park, Little Island
Cork T45 K857, Ireland

Manufacturer

Wessling Hungary Kft.

Fóti út 56., Budapest 1047, Hungary

Accord Healthcare Polska Sp.z o.o.,

ul. Lutomiarska 50,95-200 Pabianice, Poland

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
Austria	Linezolid Accord 600 mg Filmtabletten
Cyprus	Linezolid Accord 600 mg Film-coated Tablets
Czech Republic	Linezolid Accord 600 mg potahované tablet

Germany	Linezolid Accord 600 mg Filmtabletten
Denmark	Linezolid Accord 600 mg filmovertrukne tabletter
Estonia	Linezolid Accord
Spain	Linezolid Accord 600 mg comprimidos recubiertos con película
Finland	Linezolid Accord 600 mg tabletti, kalvopäällysteinen
France	Linezolid Accord 600 mg comprimés pelliculés
Ireland	Linezolid 600 mg Film-coated Tablets
Italy	Linezolid Accord
Lithuania	Linezolid Accord 600 mg plėvele dengtos tabletės
Latvia	Linezolid Accord 600 mg apvalkotās tabletes
Malta	Linezolid 600 mg Film-coated Tablets
The Netherlands	Linezolid Accord 600 mg filmomhulde tabletten
Norway	Linezolid Accord
Poland	Linezolid Accord
Portugal	Linezolida Accord
Sweden	Linezolid Accord 600 mg filmdragerade tabletter
Slovenia	Linezolid Accord 600 mg filmsko obložene tablete
Slovak Republic	Linezolid Accord 600 mg filmom obalené tablety
United Kingdom	Linezolid 600 mg Film-coated Tablets

This leaflet was last approved in 07/2022