

PACKAGE LEAFLET: INFORMATION FOR THE USER

Linezolid 2 mg/ml solution for infusion 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.
- 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 infusion is and what it is used for
2. What you need to know before you use Linezolid infusion
3. How to use Linezolid infusion
4. Possible side effects
5. How to store Linezolid infusion
6. Contents of the pack and other information

1. What Linezolid infusion is and what it is used for

Linezolid infusion 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 infusion is suitable to treat your infection.

2. What you need to know before you use Linezolid infusion

Do not take Linezolid infusion:

- 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 infusion passes into breast milk and could affect the baby.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Linezolid infusion.

Linezolid infusion 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?
- Have you had hyponatraemia in the past (low blood sodium levels) or have you used medicines that lower blood sodium levels, e.g. some diuretics (also known as “water tablets”) such as hydrochlorothiazide?
- Are you using opioids?

The use of some medicines, including antidepressants and opioids, in combination with Linezolid infusion, may lead to serotonin syndrome, a potentially life-threatening disorder (see section 2 “Other medicines and Linezolid infusion” and section 4).

Take special care with Linezolid infusion

Tell your doctor before you are treated with 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 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.
- loss of sensitivity in your arms or legs or a sensation of tingling or pricking in your arms or legs.
- diarrhoea; you may develop diarrhoea while taking or after taking antibiotics, including Linezolid infusion. If this becomes severe or persistent or you notice that your stool contains blood or mucus, you should stop taking Linezolid infusion 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
- feel sick and unwell with muscle weakness, headache, confusion and memory loss, which may indicate hyponatraemia (low blood sodium levels).

Other medicines and Linezolid infusion

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

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Tell your doctor if you are using or have used within the last 2 weeks the following medicines as Linezolid infusion **must not** be used if you are already using these medicines or have used them recently (see also Section 2 above “Do not use Linezolid infusion”).

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

Also tell your doctor if you are using the following medicines. Your doctor may still decide to give you Linezolid infusion, 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 tricyclic antidepressants or SSRIs (selective serotonin reuptake inhibitors). There are many types 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
- Opioids such as pethidine used to treat moderate to severe pain.
- Medicines used to treat anxiety disorders, such as buspirone.
- Medicines that stop blood clotting, such as warfarin.
- An antibiotic called rifampicin.

Linezolid infusion with food and drink

- You can take Linezolid infusion 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 to 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 infusion 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 using Linezolid infusion because it passes into breast milk and could affect the baby.

Driving and using machines

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

Linezolid infusion contains

Glucose

Contains 13.7 g glucose per dose. This should be taken into account in patients with diabetes mellitus.

Sodium

This medicine contains 114 mg sodium (main component of cooking/table salt) in each unit volume. This is equivalent to 5.7% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Linezolid infusion

Adults:

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

This medicine will be given to you through a drip (by infusion into a vein) by a doctor or healthcare professional. The usual dose for adults (18 years and older) is 300 ml (600 mg linezolid) twice daily which is given directly into the blood stream (intravenously) by a drip over a period of 30 to 120 minutes.

If you are on kidney dialysis, you should be given Linezolid infusion after 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 infusion, your doctor should perform regular blood tests to monitor your blood count.

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

Use in children and adolescents

is not recommended in children and adolescents (under 18 years old).

If you use more Linezolid infusion than you should

If you are concerned that you may have been given too much Linezolid infusion, tell your doctor or a nurse at once.

If you forget to use Linezolid infusion

As you will be given this medicine under close supervision, it is very unlikely that you will miss a dose. If you think that you have missed a dose of treatment, tell a doctor or nurse at once. Do not take a double dose to make up for a forgotten dose.

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 infusion:

The serious side effects (with frequency in brackets) of Linezolid infusion 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 infusion. 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 infusion. Serotonin syndrome (not known): if you are taking antidepressants known as SSRIs (selective serotonin reuptake inhibitors) or opioids in addition to Linezolid infusion (see section 2) and you notice agitation, confusion, delirium, stiffness, tremor, lack of coordination, seizures, rapid heartbeat, severe breathing problems and diarrhoea (which may indicate serotonin syndrome), tell your doctor. 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: 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 infusion 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, salt or enzymes that measure your kidney or liver function or blood sugar levels
- Difficulty in sleeping
- Increased blood pressure
- Anaemia (low red blood cells)
- Dizziness
- Localised or general abdominal pain
- Constipation
- Indigestion
- Localised pain
- Reduction in the number of 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
- Pain at and around the place where the infusion was given
- Inflammation of the veins (including where the infusion was given)
- A need to urinate more often
- Chills
- Feeling thirsty
- Abnormal sweating
- Hyponatraemia (low blood sodium levels)
- Kidney failure
- Abdominal bloating
- Injection site pain
- Increase in creatinine
- Stomach pain
- Changes in heart rate (e.g, increased rate)
- Reduction in the number of blood cells
- Sensory weakness and/or changes

Rare (may affect up to 1 in 1000 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)

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

HPRAs 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 infusion

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, bags and overpouch after 'EXP'. The expiry date refers to the last day of that month.

Store in the original package until ready to use in order to protect from light.

Hospital Staff will make sure that Linezolid infusion is not used after the expiry date printed on the bag and that it is given to you as soon as the seal is broken. They will also visually inspect the solution prior to use and only clear solution, without particles will be used. They will also make sure that the solution is kept correctly in its box and foil wrapping in order to protect from light until it is needed.

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 2 mg/ml solution for infusion contains

-The active substance is linezolid. Each 1ml of solution contains 2 mg linezolid. Each 300 ml infusion bag contains 600 mg linezolid.

-The other ingredients are glucose monohydrate (a type of sugar), sodium citrate dihydrate (E331), citric acid monohydrate (E330), hydrochloric acid (E507) (for pH adjustment), sodium hydroxide (E524) (for pH adjustment) and water for injections.

What Linezolid 2 mg/ml solution for infusion looks like and contents of the pack

Linezolid infusion is presented as a clear solution in single infusion bags containing 300 ml (600mg linezolid) of solution.

The bags are supplied in boxes of 10 bags.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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

Manufacturer

Accord Healthcare Limited
Sage House, 319 Pinner Road,
North Harrow, Middlesex, HA1 4HF,
United Kingdom

Demo S.A. Pharmaceutical Industry
21st km National Road Athens-Lamia
Krioneri Attiki, 145 68, Greece

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 2mg/ml infusionslösung
Belgium	Linezolid Accord 2 mg/ml oplossing voor infusie/solution pour perfusion/Infusionslösung
Croatia	Linezolid Accord 2 mg/ml solution for infusion

Cyprus	Linezolid Accord 2 mg/ml solution for infusion
Czech Republic	Linezolid Accord
Denmark	Linezolid Accord 2 mg/ml solution for infusion
Estonia	Linezolid Accord
Finland	Linezolid Accord 2mg/ml infuusioneste, liuos
Germany	Linezolid Accord 2mg/ml Infusionslösung
Ireland	Linezolid 2 mg/ml solution for infusion
Italy	Linezolid Accord Healthcare
Latvia	Linezolid Accord 2 mg/ml šķīdums infūzijām
Lithuania	Linezolid Accord 2 mg/ml infuzinis tirpalas
Malta	Linezolid 2 mg/ml solution for infusion
Norway	Linezolid Accord
Poland	Linezolid Accord
Romania	Linezolid Accord 2 mg/ml solutie perfuzabila
Slovakia	Linezolid Accord 2 mg/ml infúzny roztok
Slovenia	Linezolid Accord 2 mg/ml raztopina za infundiranje
Sweden	Linezolid Accord 2 mg/ml solution for infusion
United Kingdom	Linezolid 2 mg/ml solution for infusion
Portugal	Linezolida Accordpharma
Spain	Linezolid Accordpharma 2 mg/ml solución para perfusión EFG

This leaflet was last revised in 08/2023.

The following information is intended for healthcare professionals only:

Linezolid 2mg/ ml solution for infusion

Linezolid

IMPORTANT: Refer to Summary of Product Characteristics before prescribing.

Dosage and Method of Administration

Linezolid should only be initiated in a hospital environment and after consultation with a relevant specialist such as a microbiologist or an infectious diseases specialist.

Patients who commence treatment on the parenteral formulation may be switched to either oral presentation when clinically indicated. In such circumstances, no dose adjustment is required as linezolid has an oral bioavailability of approximately 100 %.

The solution for infusion should be administered over a period of 30 to 120 minutes.

The recommended linezolid dosage should be administered IV or orally twice daily.

Recommended dosage and duration for adults:

The duration of treatment is dependent on the pathogen, the site of infection and its severity, and on the patient's clinical response.

The following recommendations for duration of therapy reflect those used in the clinical trials. Shorter treatment regimens may be suitable for some types of infection but have not been evaluated in clinical trials.

The maximum treatment duration is 28 days. The safety and effectiveness of linezolid have not yet been established for treatment periods longer than 28 days.

No increase in the recommended dosage or duration of treatment is required for infections associated with concurrent bacteraemia. The dose recommendation for the solution for infusion and the tablets/granules for oral suspension are identical and are as follows:

Infections	Dosage and route for twice daily administration	Duration of treatment
Nosocomial pneumonia	600 mg twice daily	10-14 Consecutive Days
Community acquired pneumonia		
Complicated skin and soft tissue infections	600 mg twice daily	

Paediatric population: The safety and efficacy of linezolid in children aged (< 18 years old) has not been established. Currently available data are described in section 4.8, 5.1, and 5.2 of the SmPC but no recommendation on a posology can be made.

Elderly: No dose adjustment is required.

Renal impairment: No dose adjustment is required.

Severe renal impairment (i.e. CLCR < 30 ml/min): No dose adjustment is required. Due to the unknown clinical significance of higher exposure (up to 10-fold) to the two primary metabolites of linezolid in patients with severe renal insufficiency, linezolid should be used with special caution in these patients and only when the anticipated benefit is considered to outweigh the theoretical risk.

As approximately 30 % of a linezolid dose is removed during 3 hours of haemodialysis, LINEZOLID infusion should be given after dialysis in patients receiving such treatment. The primary metabolites of

linezolid are removed to some extent by haemodialysis, but the concentrations of these metabolites are still very considerably higher following dialysis than those observed in patients with normal renal function or mild to moderate renal insufficiency. Therefore, linezolid should be used with special caution in patients with severe renal insufficiency who are undergoing dialysis, and only when the anticipated benefit is considered to outweigh the theoretical risk.

To date, there is no experience of linezolid administration to patients undergoing continuous ambulatory peritoneal dialysis (CAPD) or alternative treatments for renal failure (other than haemodialysis).

Hepatic impairment: Patients with mild to moderate hepatic insufficiency (Child-Pugh class A or B): No dose adjustment is required.

Severe hepatic impairment (Child-Pugh class C): As linezolid is metabolised by a non-enzymatic process, impairment of hepatic function would not be expected to significantly alter its metabolism and, therefore, no dose adjustment is recommended. However, there are limited clinical data and it is recommended that linezolid should be used in such patients only when the anticipated benefit is considered to outweigh the theoretical risk (see sections 4.4 and 5.2).

Special precautions for disposal and other handling

For single use only. Remove overpouch only when ready to use, then check for minute leaks by squeezing the bag firmly. If the bag leaks, do not use as sterility may be impaired. The solution should be visually inspected prior to use and only clear solutions, without particles should be used. Do not use these bags in series connections. Any unused solution must be discarded. Do not reconnect partially used bags.

LINEZOLID Solution for Infusion is compatible with the following solutions: 5 % glucose intravenous infusion, 0.9 % sodium chloride intravenous infusion, Ringer-lactate solution for injection (Hartmann's solution for injection).

Incompatibilities

Additives should not be introduced into this solution. If linezolid is to be given concomitantly with other drugs, each drug should be given separately in accordance with its own directions for use. Similarly, if the same intravenous line is to be used for sequential infusion of several drugs, the line should be flushed prior to and following linezolid administration with a compatible infusion solution.

LINEZOLID Solution for Infusion is known to be physically incompatible with the following compounds: amphotericin B, chlorpromazine hydrochloride, diazepam, pentamidine isethionate, erythromycin lactobionate, phenytoin sodium and sulphamethoxazole / trimethoprim. Additionally, it is chemically incompatible with ceftriaxone sodium.

Shelf Life

After opening: From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.