

# Linezolid 2 mg/ml solution for infusion

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.
- 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 use 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 ARE TREATED WITH LINEZOLID**

**You should not be treated with 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 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 using 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 take any opioids?

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 before using 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**

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, have recently taken or might take 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 ‘**You should not be treated with 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 or certain medicines used to treat opioids dependence, such as buprenorphine. These medicines may interact with Linezolid and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor if you experience such symptoms.
- 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 e.g. 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 with food, drink and alcohol**

- You can use 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 used 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 you are treated with this medicine.

You should not breast-feed when you are treated with 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 Glucose**

This medicinal product contains 45.7 mg/ml (i.e. 13.7 g/300 ml) glucose. This should be taken into account in patients with diabetes mellitus.

**Sodium**

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

**3. HOW TO USE LINEZOLID**

**Adults**

Always use 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.

This medicine will be given to you through a drip (by infusion into a vein) by a doctor or healthcare professional. The recommended 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 treated with 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.

**The following information is intended for healthcare professionals only:**

**Linezolid 2 mg/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 intravenously (I.V.) 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 is as follows:

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

**Paediatric population:** There are insufficient data on the pharmacokinetics, safety and efficacy of linezolid in children and adolescents (< 18 years old) to establish dosage recommendations. Therefore, until further data are available, use of linezolid in this age group is not recommended.

**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 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.

While you are treated with Linezolid, your doctor should perform regular blood tests to monitor your blood count.  
Your doctor should monitor your eyesight if you are treated with 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 receive more Linezolid than you should

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

#### If you forget to use Linezolid

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:

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 using 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, 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 (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).
- 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
- Pain at and around the place where the infusion (drip) was given
- Inflammation of the veins (including where the infusion (drip) was given)
- A need to urinate more often
- Chills
- Feeling thirsty
- Increased sweating
- Hyponatraemia (low blood sodium levels)

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## Overdose

No specific antidote is known. No cases of overdose have been reported. However, the following information may prove useful: Supportive care is advised together with maintenance of glomerular filtration. Approximately 30% of a linezolid dose is removed during 3 hours of haemodialysis, but no data are available for the removal of linezolid by peritoneal dialysis or haemoperfusion.

## Instructions for use and handling

For single use only. Remove overwrap 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. Any unused medicinal product or waste material should be disposed of in accordance with local requirements. 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 sulfamethoxazole / trimethoprim. Additionally, it is chemically incompatible with ceftriaxone sodium.

## Shelf life

Before opening: 24 months

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.

## Special precautions for storage

Store in the original package (overwrap and carton) until ready to use in order to protect from light.

- Kidney failure
- Abdominal bloating
- Injection site pain
- 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 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)

## 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 Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. 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.

Store in the original package (overwrap and carton) until ready to use in order to protect from light.

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

Hospital Staff will make sure that Linezolid solution for infusion is not used after the 'EXP' 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 a 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 and out of the sight and reach of children until it is needed.

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.

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 1 ml of solution contains 2 mg linezolid. Each 300 ml infusion bag contains 600 mg linezolid.
- The other ingredients are glucose monohydrate, sodium citrate dihydrate, citric acid anhydrous, hydrochloric acid or sodium hydroxide for pH-adjustment and water for injections. See section 2 "Linezolid contains glucose and sodium."

### What Linezolid looks like and contents of the pack

Linezolid is presented as a clear solution in single infusion bags containing 300 ml of solution. The bags are supplied in boxes of 10 bags.

### The Marketing Authorisation Holder and Manufacturer

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