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Linezolid 2 mg/ml
P1537613

Linezolid 2 mg/ml
P1537613

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 or 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 or 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

Linezolid is an antibiotic of the oxazolidinones group that works by stopping the growth of certain bacteria (germs) that cause infections. It is used in adults 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 use Linezolid

Do not use 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 breastfeeding. 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 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?

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 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 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
- feeling sick and unwell with muscle weakness, headache, confusion, and memory impairment which may indicate hyponatraemia (low blood sodium levels).

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.
- 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 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 breastfeed 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 glucose
Each 1 ml of Linezolid contains 45.7 mg glucose (13.7 g glucose in one bag).
This should be taken into account in patients with diabetes mellitus.

Linezolid contains sodium
Each 1 ml of Linezolid contains 0.38 mg sodium (114 mg sodium in one bag).
To be taken into consideration by patients on a controlled sodium diet.

3. How to use Linezolid

Adults

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist 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 given 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 use 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.

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.

Linezolid is not active against infections caused by Gram negative pathogens. Specific therapy against Gram negative organisms must be initiated concomitantly if co-infection with a Gram negative pathogen is documented or suspected.

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 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 recommendations for the solution for infusion 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 patients: 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

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Initiator: Vijay				
Artist: Vision Graphic Designers	Pharmacode: 37613			
Additional Information : Supersede item Code: P1535040				Sign / Date

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 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 SSRI's 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)
- Kidney failure
- Abdominal bloating
- Injection site pain
- Increase in creatinine
- Stomach pain
- Changes in heart rate (eg, 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)

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 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.

Hospital Staff will make sure that this medicine 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 clear solution, without particles will be used. They will also make sure that the solution is kept correctly in its original package in order to protect from light.

This medicine does not require any special temperature storage conditions.

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. 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 ml contains 2 mg linezolid.
  Each 300 ml infusion bag contains 600 mg linezolid.
- The other ingredients are: Glucose monohydrate, sodium citrate, citric acid monohydrate, hydrochloric acid (for pH-adjustment), sodium hydroxide (for pH-adjustment) and water for injection.

What Linezolid looks like and contents of the pack
Solution for infusion.

Linezolid solution for infusion is a isotonic, clear, colourless to slightly yellow colour solution, free from visible particles with pH range of 4.4-5.2.

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

The bags are supplied in boxes of 1, 5, 10 and 25 bags.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Milpharm Limited
Ares Block, Odyssey Business Park,
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Manufacturer
APL Swift Services (Malta) Limited,
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or

Milpharm Limited
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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 no pharmacokinetic data and limited clinical experience of Linezolid 2mg/ml solution for infusion in patients with severe hepatic insufficiency. Linezolid should be used with special caution in patients with severe hepatic insufficiency and only when the anticipated benefit is considered to outweigh the theoretical risk.

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. Do not reconnect partially used bags.

Linezolid 2 mg/ml 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).

For storage information, please refer to Section 5 How to store Linezolid.

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 2 mg/ml 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.

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