Package leaflet: Information for the user

Linezolid Kalceks 2 mg/ml solution for infusion

linezolid

Read all of this leaflet carefully before you are given 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 Kalceks is and what it is used for

Linezolid Kalceks contains the active substance linezolid. 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 in adults. Your doctor will decide if this medicine is suitable to treat your infection.

2. What you need to know before you are given Linezolid Kalceks

You must not be given Linezolid Kalceks
- 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 or nurse before you are given Linezolid Kalceks.

Linezolid Kalceks 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 have 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 Kalceks can lead to serotonin syndrome, a potentially life-threatening condition (see section 2 “Other medicines and Linezolid Kalceks” and section 4).

Take special care with Linezolid Kalceks
Tell your doctor before you are given 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 using antibiotics, including Linezolid Kalceks. If this becomes severe or persistent or you notice that your stool contains blood or mucus, you should stop receiving this medicine 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.
- unexplained muscle pain, tenderness, or weakness, and/or dark urine. These can be signs of a serious condition called rhabdomyolysis (muscle breakdown), which can lead to kidney damage.
- feeling sick and unwell with muscle weakness, headache, confusion, and memory impairment which may indicate hyponatraemia (low blood sodium levels).

Other medicines and Linezolid Kalceks
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. There is a risk that Linezolid Kalceks may 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 Kalceks **must not** be given if you are already taking these medicines or have taken them recently (see also section 2 above “You must not be given Linezolid Kalceks”).
- 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 Kalceks, 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 Kalceks with food, drink and alcohol
- 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 Kalceks 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 or nurse **immediately**.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.
The effect of Linezolid Kalceks in pregnant women is not known. Therefore, it should not be given in pregnancy unless advised by your doctor.
Do not breast-feed when you are given this medicine because it passes into breast milk and could affect the baby.

Driving and using machines
This medicine 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 Kalceks contains glucose
Contains approximately 12 g glucose per dose (300 ml). This should be taken into account in patients with diabetes mellitus.

Linezolid Kalceks contains sodium
This medicine contains 114 mg sodium (main component of cooking/table salt) per dose (300 ml). This is equivalent to 5.7 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How Linezolid Kalceks is given

Adults
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 this medicine 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.

During treatment with Linezolid Kalceks, your doctor should perform regular blood tests to monitor your blood count.

Your doctor should monitor your eyesight if you are given this medicine for more than 28 days.

Use in children and adolescents
Linezolid Kalceks is not normally used to treat children and adolescents (under 18 years old).

If you are given more Linezolid Kalceks than you should
If you are concerned that you may have been given too much of this medicine, tell your doctor or a nurse at once.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor or nurse immediately if you notice any of these side effects during your treatment with Linezolid Kalceks:

The serious side effects (with frequency in brackets) are:
- **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 treatment with this medicine.
- **Severe skin reactions** such as a **raised purple rash** due to inflammation of the blood vessels (rare), a severe rash that develops quickly, with **blisters** or **peeling of the skin** (Stevens-Johnson syndrome and toxic epidermal necrolysis) (rare), **red sore skin and flaking** (dermatitis) (uncommon).
- Problems with your vision (uncommon) such as **blurred vision** (uncommon), **changes in colour vision** (not known**), difficulty in seeing detail** (not known), **loss of vision** (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).
- 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 (reduction in platelets or low red blood cell) (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).
- Rhabdomyolysis (rare): Signs and symptoms include unexplained **muscle pain, tenderness, or weakness, and/or dark urine**. These can be signs of a serious condition called rhabdomyolysis (muscle breakdown), which can lead to kidney damage.
- **Inflammation of the pancreas** (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 this medicine for more than 28 days. If you experience difficulties with your vision, you should **consult your doctor as soon as possible**.

Other side effects

Common (may affect up to 1 in 10 people)

- Fungal infections especially vaginal or oral “thrush”
- Difficulty in sleeping
- Headache
- Metallic taste in the mouth
- Dizziness
- Increased blood pressure
- Diarrhoea, nausea or vomiting, localised or general abdominal pain, constipation, indigestion
- Itching, rash
- Localised pain
- Changes in some blood test results including those measuring proteins, salts or enzymes which measure your kidney or liver function or blood sugar levels

Uncommon (may affect up to 1 in 100 people)
- Inflammation of the vagina or genital area in women
- Decrease of the blood cell count
- Hyponatraemia (low blood sodium levels)
- Hypoglycaemia (low blood sugar)
- Sensations such as tingling or feeling numb
- Weakness and/or sensory changes
- Changes in heart rate (e.g., increase rate)
- Inflammation of the veins (including where the infusion (drip) was given)
- Stomach pain (gastritis), abdominal bloating, dry mouth, swollen, sore, or discoloured tongue
- Hives
- Increased sweating
- Kidney failure, increase in creatinine, a need to urinate more often
- Chills, fatigue, pain at and around the place where the infusion was given
- Feeling thirsty

Rare (may affect up to 1 in 1 000 people)
- Superficial tooth discolouration, removable with professional dental cleaning (manual descaling)
- Red blood cell formation disorder (sideroblastic anaemia)
- Black discolouration of the tongue's surface, which appears hairy

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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Linezolid Kalceks

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 box, overwrap and bag after EXP. The expiry date refers to the last day of that month.

Do not store above 30 °C.
Store in the original package (overwrap and carton box) until ready to use in order to protect from light.

After opening:
Chemical and physical in-use stability has been demonstrated for 24 hours at 25 °C and 2 to 8 °C. 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 Kalceks contains
- The active substance is linezolid.

Each ml of solution contains 2 mg linezolid.
Each 300 ml infusion bag contains 600 mg linezolid.

- The other ingredients are glucose monohydrate, sodium citrate, citric acid, hydrochloric acid concentrated (for pH adjustment), sodium hydroxide (for pH adjustment), water for injections.

What Linezolid Kalceks looks like and contents of the pack
Linezolid Kalceks is a clear, colourless to yellowish solution for infusion, practically free from visible particles.
Linezolid Kalceks is available as 300 ml of solution in single use infusion bag sealed inside a foil laminate overwrap. The bags are packaged in a carton box.

Pack size: 1 or 10 infusion bags

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
[To be completed nationally]

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The following information is intended for healthcare professionals only:

IMPORTANT: Please refer to the Summary of Product Characteristics for full prescribing information.

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

Posology 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 infectious diseases specialist.

Linezolid solution for infusion may be used as initial therapy.

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 %.

Recommended dosage and duration of treatment 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 when administered for periods longer than 28 days have not been established.

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	600 mg twice daily	

Paediatric population: The safety and efficacy of linezolid in children aged (< 18 years old) has not been established. 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. CL_{CR} < 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: No dose adjustment is required. 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.

Method of administration: Intravenous use.
The recommended linezolid dosage should be administered intravenously twice daily.
The solution for infusion should be administered over a period of 30 to 120 minutes.

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 (see “Instructions for use and other handling” below).

Linezolid 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.

Instructions for use and other 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 medicinal product should be visually inspected prior to use. Only clear solutions free from 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 Kalceks solution for infusion is compatible with the following solutions:

- glucose 50 mg/ml (5 %) solution for infusion
- sodium chloride 9 mg/ml (0.9 %) solution for infusion
- Lactated Ringer’s solution (Hartmann’s solution).

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