

# LINEZOLID KABI

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I being given LINEZOLID KABI?

LINEZOLID KABI contains the active ingredient linezolid. LINEZOLID KABI is used to treat bacterial infections such as pneumonia, skin infections or blood infections.

For more information, see Section [1. Why am I using LINEZOLID KABI?](#) in the full CMI.

### 2. What should I know before being given LINEZOLID KABI?

Do not use if you have ever had an allergic reaction to LINEZOLID KABI or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before being given LINEZOLID KABI?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with LINEZOLID KABI and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How will I be given LINEZOLID KABI?

It is recommended that treatment with LINEZOLID KABI begin in a hospital. LINEZOLID KABI is a liquid which is given by slow injection into the blood (known as an intravenous infusion or “drip”) by a doctor or a nurse.

If you or your child is on dialysis, LINEZOLID KABI should be given after dialysis.

You or your child may be changed from LINEZOLID KABI to an oral preparation of linezolid to complete your course of treatment.

More instructions can be found in Section [4. How will I be given LINEZOLID KABI?](#) in the full CMI.

### 5. What should I know while being given LINEZOLID KABI?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell your doctor if the symptoms of the infection do not improve within a few days, or if they become worse; you or your child have severe diarrhoea, a sore white mouth or tongue; you have vaginal itching or discharge; or if are pregnant or plan to become pregnant.</li><li>• Remind any doctor, dentist or pharmacist that you visit that you are using LINEZOLID KABI.</li><li>• For more information on “Things you should do” refer to Section 5 in the full CMI.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine or lower the dosage without checking with your doctor.</li><li>• Do not use LINEZOLID KABI to treat any other medical complaints unless your doctor tells you to.</li><li>• Do not start taking any other medicines without first telling your doctor or pharmacist.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how LINEZOLID KABI affects you.</li><li>• This medicine may cause dizziness and visual impairment in some people. Children should be careful performing activities requiring attention such as riding bicycles or climbing.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Avoid drinking alcohol, especially draught beers and wine.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• LINEZOLID KABI injection is stored in the pharmacy or on the hospital ward at below 25°C and should be stored in its carton before being used.</li></ul>

For more information, see Section [5. What should I know while using LINEZOLID KABI?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects of LINEZOLID KABI include headache, diarrhoea, nausea and vomiting.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# LINEZOLID KABI

Active ingredient: *Linezolid*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using LINEZOLID KABI. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LINEZOLID KABI.**

Where to find information in this leaflet:

- [1. Why am I being given LINEZOLID KABI?](#)
- [2. What should I know before I am given LINEZOLID KABI?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given LINEZOLID KABI?](#)
- [5. What should I know while being given LINEZOLID KABI?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being given LINEZOLID KABI?

**LINEZOLID KABI contains the active ingredient linezolid.** LINEZOLID KABI is an antibiotic (an agent used to destroy certain types of bacteria). It is used in the treatment of bacterial infections such as pneumonia, skin infections or blood infections.

Depending on the type of bacteria, you may be given additional medicines.

Your doctor, however, may have prescribed LINEZOLID KABI for another purpose. **Ask your doctor if you have any questions about why LINEZOLID KABI has been prescribed for you or your child.**

## 2. What should I know before I am given LINEZOLID KABI?

### Warnings

**Do not use LINEZOLID KABI if you or your child have the following medical conditions:**

- you are allergic to linezolid, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.

- Uncontrolled high blood pressure
- Pheochromocytoma (a type of tumour of the adrenal gland)
- Thyrotoxicosis (an overactive thyroid gland)

- Flushing or other symptoms caused by a carcinoid tumour.

**Do not use LINEZOLID KABI if you or your child are taking any of the following medicines:**

- Are taking or have taken in the last two weeks any medicine that is a monoamine oxidase inhibitor (e.g. moclobemide, phenelzine or tranylcypromine to treat depression or selegiline to treat Parkinson's disease)
- Any medicines listed in Section [3. What if I am taking other medicines?](#)

**Do not use LINEZOLID KABI**

- The packaging is torn or shows signs of tampering
- The expiry date printed on the pack has passed have any other medical conditions

**Check with your doctor if you or your child:**

- Have diarrhoea
- Have phenylketonuria
- Are anemic or have had any abnormal blood test results (e.g. low haemoglobin or platelets)
- Are diabetic
- Have kidney or liver problems
- Have any other medical conditions
- Have allergies to any other medicines, foods, preservatives or dyes
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

**LINEZOLID KABI injection contains glucose.**

LINEZOLID KABI is not addictive.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with LINEZOLID KABI and affect how it works. These include:**

- any medicine that inhibits monoamine oxidase (e.g. moclobemide, phenelzine or tranylcypromine to treat depression or selegiline to treat Parkinson's disease)
- are taking any medicine that is an SSRI or serotonin re-uptake inhibitor, which are types of medicine to treat depression, anxiety, panic attacks, obsessive compulsive disorders or obesity (e.g. citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, sibutramine, venlafaxine)
- tricyclic antidepressants, which are medicines to treat depression (e.g. amitriptyline, clomipramine, dothiepin, doxepin, imipramine, nortriptyline, trimipramine)
- buspirone, a medicine to treat anxiety
- some medicines to treat migraine (e.g. naratriptan, sumatriptan, zolmitriptan)
- any medicine that is an opioid, a medicine to treat pain
- any cold or flu medicine containing pseudoephedrine
- adrenaline, a medicine used to treat severe allergic reactions
- any other medicine that increases blood pressure (e.g. noradrenaline, dopamine, dobutamine)
- rifampicin, a medicine to treat tuberculosis and some other infections
- any medicine that could reduce the levels of haemoglobin (the pigment in red blood cells which carries oxygen) or platelets (blood cells which help blood to clot).

These medicines may be affected by LINEZOLID KABI or may affect how well it works. You or your child may need different amounts of medicines or may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

**Tell the doctor if your or your child's diet contains a lot of mature cheese, yeast extracts, meat extracts, soya bean extracts (e.g. soy sauce), draught beers or wine.**

LINEZOLID KABI may react with a substance which is naturally present in these foods.

#### 4. How will I be given LINEZOLID KABI?

##### How it is given

It is recommended that treatment with LINEZOLID KABI begin in a hospital.

LINEZOLID KABI will be given to you or your child by a doctor or nurse.

LINEZOLID KABI is a liquid which is given by a slow injection into the blood (known as an intravenous infusion or "drip").

You or your child may be changed to an oral preparation to complete your course of treatment.

The recommended dose for adults and adolescents 12 years and older is 600 mg twice daily (every 12 hours)

The recommended dose for babies and children up to 12 years of age is 10 mg/kg three times daily (Every 8 hours).

These doses are given intravenously by a "drip" over a period of 30 to 120 minutes.

Treatment is usually given every day for 10 to 14 days but may be given for up to 28 days.

**Ask the doctor if you want more information about the dose of LINEZOLID KABI and how it is given.**

##### When it is given

LINEZOLID KABI can be taken before, during or after meals.

**If you or your child is on dialysis, take LINEZOLID KABI after dialysis.**

##### If you forget to use LINEZOLID KABI

LINEZOLID KABI should be used regularly at the same time each day. If you miss your dose at the usual time, ask your doctor or pharmacist for advice.

##### If you are given too much LINEZOLID KABI

As this product is administered by a doctor or healthcare professional, it is unlikely you will be given too much LINEZOLID KABI.

**However, if you have any concerns, you should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

#### 5. What should I know while being given LINEZOLID KABI?

##### Things you should do

**If you or your child are about to be started on any new medicine, remind your doctor and pharmacist that you or your child are taking LINEZOLID KABI.**

**Tell any other doctors, dentists and pharmacists who are treating you or your child that you are taking LINEZOLID KABI.**

**If you or your child are going to have surgery, tell the surgeon or anaesthetist that you or your child are taking this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant while you are being treated with LINEZOLID KABI, tell your doctor immediately.**

**Keep all of your doctor's appointments so that yours or your child's progress can be checked.**

Your doctor may do some blood tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

**If the symptoms of the infection do not improve within a few days, or if they become worse, tell your or your child's doctor.**

As part of the treatment, you or your child may be given other medicines including other antibiotics. It is important to keep taking these medicines as well as LINEZOLID KABI unless you are told otherwise by your doctor or pharmacist.

**It is important to tell the doctor if you develop diarrhoea during or after treatment with LINEZOLID KABI. Do this even if it occurs several weeks after LINEZOLID KABI has been stopped.**

**Do not take any medicine to treat diarrhoea without first checking with the doctor.**

Diarrhoea may be caused by a serious condition affecting the bowel. You or your child may need urgent medical care.

**If you or your child get a sore white mouth or tongue during or soon after treatment with LINEZOLID KABI tell your doctor.**

**Tell the doctor if you or your child get vaginal itching or discharge.**

This may mean you or your child have a fungal infection called thrush. Sometimes the use of LINEZOLID KABI allows fungi to grow which causes the symptoms described above. LINEZOLID KABI does not work against fungi.

### **Things you should not do**

**Do not take LINEZOLID KABI to treat other complaints unless your doctor tells you to do so.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

If you stop taking it suddenly, your condition may worsen.

**Do not start taking any other medicines, prescription or not, without first telling your doctor or pharmacist.**

**Do not take any medicine to treat diarrhoea without first checking with the doctor.**

**Avoid eating too much mature cheese, yeast extracts, meat extracts or soya bean extracts (e.g. soy sauce).**

This is because LINEZOLID KABI may react with a substance which is naturally present in these foods.

**If you or your child develop a throbbing headache after eating, tell your doctor or your healthcare professional.**

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how LINEZOLID KABI affects you.**

This medicine may cause dizziness and visual impairment in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful performing activities requiring attention such as riding bicycles or climbing.

### **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

**Avoid drinking alcohol, especially draught beers and wine.**

This is because LINEZOLID KABI may react with a substance which is naturally present in these foods.

### **Looking after your medicine**

It is unlikely you will be asked to store LINEZOLID KABI yourself. It will usually be stored in the pharmacy or on the hospital ward. It should be stored below 25°C and should be kept in its carton before being used.

Hospital staff will make sure the medicine is not used after the expiry date printed on the infusion bag or the infusion bottle.

### **Getting rid of any unwanted medicine**

A doctor, nurse or pharmacist will dispose of any unused LINEZOLID KABI.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<b>Nervous system disorders:</b> <ul style="list-style-type: none"><li>• Headache</li><li>• Taste perversion – metallic taste</li><li>• Difficulty concentrating, memory impairment, confusion, weakness and unsteadiness, which may lead to falls (these symptoms may indicate low sodium levels in the blood)</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>
<b>Infections and Infestations:</b> <ul style="list-style-type: none"><li>• Sore, white mouth or tongue (oral thrush)</li><li>• Vaginal itching or discharge (vaginal thrush)</li></ul>	
<b>Gastrointestinal disorders:</b> <ul style="list-style-type: none"><li>• Nausea or vomiting</li><li>• Pain, cramping or bloating of the abdomen</li></ul>	
<b>Other:</b> <ul style="list-style-type: none"><li>• Change in the colour of the tongue</li><li>• Change in the colour of teeth. This may be reversible</li></ul>	

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• Skin reactions (hives, rash or itching)</li><li>• Visual disturbances or numbness or weakness of the arms and legs (rare side effects that have been primarily reported in patients treated for longer than 28 days)</li><li>• Tiredness, headaches, being short of breath when exercising, dizziness, looking pale, dark circles around the eyes, fever and chills, sore throat or bruising (these symptoms may indicate a decrease in the level of your blood cells)</li><li>• Sweating, feeling drunk and dizzy, muscle twitching, fever and shivering, confusion</li></ul> <p>These may be symptoms of the serotonin syndrome, which is a rare but serious side effect.</p> <ul style="list-style-type: none"><li>• Seizure</li><li>• Hallucination</li><li>• Fainting</li><li>• Coma</li><li>• Shortness of breath</li><li>• Wheezing or difficulty breathing</li><li>• Swelling of the face, lips, tongue or other parts of the body.</li><li>• Rash, severe itching or hives or blisters on the skin and bleeding in the lips, eyes, mouth, nose and genitals.</li><li>• Painful red/purple spots with/without blisters and peeling of skin. This may be accompanied by fevers and chills, aching muscles, joint pain, enlarged lymph nodes and generally feeling unwell.</li></ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

These are serious side effects. You may need urgent medical attention or hospitalization. These side effects are rare.

## After finishing LINEZOLID KABI treatment

**Tell your or your child's doctor or pharmacist if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with LINEZOLID KABI:**

- Severe stomach cramps
- Watery and severe diarrhoea (which may be bloody), fever, in combination with one or both of the above.

LINEZOLID KABI can cause some bacteria, which are normally present in the bowel and normally harmless, to multiply and therefore cause the above symptoms. You may need urgent medical attention.

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What LINEZOLID KABI contains

<b>Active ingredient (main ingredient)</b>	Linezolid
<b>Other ingredients (inactive ingredients)</b>	glucose monohydrate sodium citrate citric acid hydrochloric acid/sodium hydroxide water for injections.

**Do not take this medicine if you are allergic to any of these ingredients.**

### What LINEZOLID KABI looks like

Linezolid Kabi is a sterile, clear, colourless to yellow fluid (solution) for injection, supplied as 300mL in an infusion bag or an infusion bottle. Each bag or bottle is for single use only and is packaged within a carton

LINEZOLID KABI linezolid 600 mg/300 mL solution for injection infusion bottle (AUST R 277697).

LINEZOLID KABI linezolid 600 mg/300 mL solution for injection infusion bag (AUST R 277696).

### Who distributes LINEZOLID KABI

Fresenius Kabi Australia Pty Limited

Level 2, 2 Woodland Way

Mount Kuring-gai NSW 2080

Telephone: 1300 732 001

This leaflet was prepared in October 2022.