

PHARMACOR LINEZOLID

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 using PHARMACOR LINEZOLID?

PHARMACOR LINEZOLID contains the active ingredient linezolid. It is used in the treatment of bacterial infections such as pneumonia, skin infections or blood infections. For more information, see Section [1. Why am I using PHARMACOR LINEZOLID?](#) in the full CMI.

2. What should I know before I use PHARMACOR LINEZOLID?

Do not use if you or your child have ever had an allergic reaction to PHARMACOR LINEZOLID 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 I use PHARMACOR LINEZOLID?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PHARMACOR LINEZOLID 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 do I use PHARMACOR LINEZOLID?

Your doctor will give you instruction on how to take PHARMACOR LINEZOLID.

More instructions can be found in Section [4. How do I use PHARMACOR LINEZOLID?](#) in the full CMI.

5. What should I know while using PHARMACOR LINEZOLID?

Things you should do	<ul style="list-style-type: none">• 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 you are pregnant, or plan to become pregnant.• Tell any other doctor or dentist you visit that you or your child are using PHARMACOR LINEZOLID.• For more information on "Things you should do" can be found in Section 5 in the full CMI.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or lower the dosage without checking with your doctor.• Do not use PHARMACOR LINEZOLID to treat any other medical complaints unless your doctor tells you to.• Do not start taking any other medicines without first telling your doctor or pharmacist.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how PHARMACOR LINEZOLID affects you.• 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.
Drinking alcohol	<ul style="list-style-type: none">• Avoid drinking alcohol, especially draught beers and wine.
Looking after your medicine	<ul style="list-style-type: none">• Store PHARMACOR LINEZOLID in a cool dry place where the temperature stays below 25°C.• Do not store PHARMACOR LINEZOLID or any other medicines in a bathroom or near a sink.• Do not leave it in the car or on window sills.• Keep PHARMACOR LINEZOLID and all other medicines where children cannot reach them.

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

6. Are there any side effects?

Side effects of this medicine may include headache; sore white mouth or tongue; vaginal itching or discharge; abdominal pain or bloating; nausea; vomiting; metallic taste; change in colour of tongue or teeth; difficulty concentrating; memory or visual impairment; confusion; tiredness; dizziness; rash, itching or hives or blisters on skin; numbness or weakness of arms or legs; shortness of breath; sweating; seizure; fainting; coma; swelling of face or lips; bleeding in lips, eyes, mouth, nose and genitals; painful red/purple spots with/without blisters and peeling of skin, may be accompanied by fevers, chills, aching muscles, dehydration, dark urine, reduced urine, no urine, joint pain, enlarged lymph nodes and generally feeling unwell. 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.

PHARMACOR LINEZOLID

Active ingredient(s): [Linezolid]

Consumer Medicine Information (CMI)

This leaflet provides important information about using PHARMACOR LINEZOLID. **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 PHARMACOR LINEZOLID.**

Where to find information in this leaflet:

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

1. Why am I using PHARMACOR LINEZOLID?

PHARMACOR LINEZOLID contains the active ingredient Linezolid. It is 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 may have prescribed it for another reason.

Ask your doctor if you have any questions about why PHARMACOR LINEZOLID has been prescribed for you or your child.

2. What should I know before I use PHARMACOR LINEZOLID?

Warnings

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

- 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 PHARMACOR LINEZOLID 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 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)
- bupirone, a medicine to treat anxiety
- some medicines to treat migraine (e.g. naratriptan, sumatriptan, zolmitriptan)
- pethidine, 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).

Do not use PHARMACOR LINEZOLID if:

- the packaging is torn or shows signs of tampering
- the expiry date printed on the pack has passed.

Tell your doctor if you or your child have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you or your child:

- have diarrhoea
- have phenylketonuria
- are anaemic or have had any abnormal blood test results (e.g. low haemoglobin or platelets)
- are diabetic

- have kidney or liver problems.

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.

Important information about some of the ingredients in PHARMACOR LINEZOLID which contains:

- sodium may be harmful in a low-sodium diet. Each tablet contains sodium as Sodium stearyl fumarate (18 mg).

PHARMACOR LINEZOLID 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 that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and PHARMACOR LINEZOLID may interfere with each other. 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, obsessivecompulsive 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 PHARMACOR LINEZOLID 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.

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

4. How do I use PHARMACOR LINEZOLID?

How much is given

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

Continue taking PHARMACOR LINEZOLID until you or your child finish the tablets unless your doctor recommends otherwise.

Do not stop taking PHARMACOR LINEZOLID unless your doctor tells you to, even if you feel better.

Do not stop giving PHARMACOR LINEZOLID to your child unless your child's doctor tells you to, even if your child feels better.

If you or your child do not complete the full course prescribed by the doctor, the bacteria causing the infection may continue to grow and multiply. The infection may not clear completely or it may return. A course of treatment usually lasts 10 to 14 days but may be up to 28 days.

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

How PHARMACOR LINEZOLID is given

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

Follow all directions given by your or your child's doctor carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask the doctor or pharmacist for help.

When to take PHARMACOR LINEZOLID

PHARMACOR LINEZOLID can be taken before, during or after meals. If you or your child is on dialysis, take PHARMACOR LINEZOLID after dialysis.

If you forget to take PHARMACOR LINEZOLID

PHARMACOR LINEZOLID should be taken 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 use too much PHARMACOR LINEZOLID

If you think that you or your child have used too much PHARMACOR LINEZOLID, you may need urgent medical attention.

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.

Symptoms of an overdose are vomiting, tremors (shaking), unsteadiness or lack of coordination.

5. What should I know while using PHARMACOR LINEZOLID?

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 PHARMACOR LINEZOLID.

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

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 PHARMACOR LINEZOLID, tell your doctor immediately.

Keep all of your doctor's appointments so that your 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 PHARMACOR LINEZOLID 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 PHARMACOR LINEZOLID. Do this even if it occurs several weeks after PHARMACOR LINEZOLID 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 PHARMACOR LINEZOLID 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 PHARMACOR LINEZOLID allows fungi to grow which causes the symptoms described above. PHARMACOR LINEZOLID does not work against fungi.

Things you should not do

Do not take PHARMACOR LINEZOLID 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 give your child any other medicines, prescription or purchased from a health food shop, pharmacy or supermarket 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).

Avoid drinking alcohol, especially draught beers and wine.

This is because PHARMACOR LINEZOLID 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 health care professional.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PHARMACOR LINEZOLID 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

Avoid drinking alcohol, especially draught beers and wine.

Looking after your medicine

Keep your tablets in the original packaging, including outer carton, until it is time to take them.

If you take the medicine out of the pack it may not keep well.

Do not take PHARMACOR LINEZOLID if the packaging is torn or shows signs of tampering.

Do not take PHARMACOR LINEZOLID if the expiry date (EXP) printed on the pack has passed.

Keep PHARMACOR LINEZOLID in a cool dry place where the temperature stays below 25°C.

Store PHARMACOR LINEZOLID in a cool dry place away from moisture, heat or sunlight; for example, do not store PHARMACOR LINEZOLID in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep PHARMACOR LINEZOLID where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

Tell the doctor or pharmacist as soon as possible if you or your child do not feel well while you are being treated with PHARMACOR LINEZOLID.

This medicine helps most people, but it may have unwanted side effects in a few people. 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.

Do not be alarmed by the following lists of side effects.

You or your child may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • headache • sore, white mouth or tongue (oral thrush) • vaginal itching or discharge (vaginal thrush) • pain, cramping or bloating of the abdomen • nausea or vomiting • metallic taste • change in the colour of the tongue • change in the colour of teeth. This may be reversible • difficulty concentrating, memory impairment, confusion, weakness and unsteadiness, which may lead to falls (these symptoms may indicate low sodium levels in the blood). 	<p>Speak to your doctor if you have notice any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • seizure • hallucination • fainting • coma • shortness of breath • wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body • rash, severe itching or hives or blisters on the skin and bleeding in the lips, eyes, mouth, nose and genitals. • 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. • muscle aching or swelling • lack of consciousness • dehydration • dark red or brown urine, or • reduced or no urine 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • skin reactions (hives, rash or itching) • 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) • 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) • sweating, feeling drunk and dizzy, muscle twitching, fever and shivering, confusion <p>These may be symptoms of the serotonin syndrome, which is a rare but serious side effect.</p>	<p>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.</p>

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

After finishing PHARMACOR LINEZOLID 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 PHARMACOR LINEZOLID:

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

PHARMACOR LINEZOLID 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. 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 PHARMACOR LINEZOLID contains

Active ingredient (main ingredient)	PHARMACOR LINEZOLID contains 600 mg of active linezolid
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Pre-gelatinised starch (lycatab c)• Mannitol (pearlitol 160c)• Colloidal silicon dioxide• Copovidone (plasdone s 630)• Sodium stearyl fumarate <p>The film coating contains:</p> <ul style="list-style-type: none">• Opadry White YS-1-18202-A• Water

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

What PHARMACOR LINEZOLID looks like

PHARMACOR LINEZOLID Tablets are off white capsule shape film coated tablet debossed with "LIN 600" on one side, plain on other side.

The PHARMACOR LINEZOLID Tablets are packed in:

- Blister packs: 10's and 30's tablets
- HDPE bottle packs: 20's and 100's tablets

* Not all pack sizes may be available.

Who distributes PHARMACOR LINEZOLID

Pharmacor Pty Ltd.
CHATSWOOD, NSW 2067,
Australia
www.pharmacor.com.au

Australian Registration Numbers

PHARMACOR LINEZOLID Tablets:

Bottle: AUST R 296542

Blister: AUST R 296543

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