

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[TB321 trade name][†]

Linezolid

*The warnings and instructions in this leaflet are intended for the person taking the medicine.
If you are a parent or carer responsible for giving the medicine to someone else such as a child,
you will need to apply the instructions accordingly.*

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 questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [TB321 trade name] is and what it is used for
2. What you need to know before you take [TB321 trade name]
3. How to take [TB321 trade name]
4. Possible side effects
5. How to store [TB321 trade name]
6. Contents of the pack and other information

1. What [TB321 trade name] is and what it is used for

[TB321 trade name] is a medicine used to treat tuberculosis (TB), an infection caused by bacteria called *Mycobacterium tuberculosis*. It is always given together with other medicines to treat tuberculosis. Your health care provider has chosen the combination that is right for your condition.

[TB321 trade name] contains the active substance linezolid and works by stopping the growth of bacteria that cause the infection.

2. What you need to know before you take [TB321 trade name]

Do not take [TB321 trade name] if you

- are allergic to linezolid or to any of the other ingredients of [TB321 trade name] (listed in section 6)
- are taking or have taken in the last 2 weeks a type of medicine known as a monoamine oxidase inhibitor, such as isocarboxazid, moclobemide, phenelzine or selegiline, which are used to treat depression or Parkinson's disease.

Warnings and precautions

Talk to your health care provider before taking [TB321 trade name] if you

- have high blood pressure, whether or not you are taking medicines for this
- have an overactive thyroid gland

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- have a condition of the adrenal glands called phaeochromocytoma (that can cause high blood pressure) or you have carcinoid syndrome (caused by tumours of the hormone system with symptoms of diarrhoea, flushing of the skin and wheezing)
- suffer from mental health problems such as manic depression, schizoaffective disorder, or acute mental confusion
- are taking any of the medicines listed under ‘Other medicines and [TB321 trade name]’

In these cases, [TB321 trade name] may not be right for you. Your health care provider 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 health care provider if you are not sure whether any of the above apply to you.

Take special care with [TB321 trade name]

Tell your health care provider before you take this medicine if you:

- bruise and bleed easily
- are anaemic (have low red blood cells)
- are prone to getting infections
- have ever had seizures (fits)
- have liver problems or kidney problems particularly if you are on dialysis
- have diarrhoea.

Tell your health care provider immediately if during treatment you get:

- severe skin reactions (see section 4. Possible side effects).
- problems with your vision (see section 4. Possible side effects).
- loss of sensitivity or a sensation of tingling or pricking in your arms or legs.
- severe or persistent diarrhoea or you notice that your stool contains blood or mucus. If this occurs, you should stop taking this medicine immediately and you should not take medicines that stop or slow bowel movement (see section 4. Possible side effects).
- recurrent nausea (feeling sick) or vomiting, abdominal (belly) pain or rapid breathing.
- tremor, fast heartbeat, rigidity, loss of muscle coordination, agitation, confusion, fever or abnormal sweating, or seizures (fits) when taking this medicine and antidepressants or medicines for migraine (see section 4. Possible side effects).
- extreme tiredness, abnormal bruising or bleeding, or signs of infection such as sore throat and high temperature (see section 4. Possible side effects).

Other medicines and [TB321 trade name]

There is a risk that linezolid may interact with certain other medicines and cause side effects such as changes in blood pressure, temperature or heart rate.

Make sure your health care provider knows if you are taking any of the medicines listed below:

- decongestant, cold or flu remedies containing pseudoephedrine or phenylpropanolamine
- cough medicines containing dextromethorphan
- medicines used to treat asthma such as salbutamol, terbutaline or fenoterol
- antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors), such as amitriptyline, citalopram, clomipramine, dosulepin (dothiepin), doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine or sertraline
- medicines used to treat migraine such as sumatriptan or zolmitriptan
- medicines used to treat sudden, severe allergic reactions such as adrenaline (epinephrine)
- medicines that increase your blood pressure, such as noradrenaline (norepinephrine), dopamine or dobutamine
- medicines used to treat moderate to severe pain, such as pethidine
- medicines used to treat anxiety disorders, such as buspirone

- an antibiotic called rifampicin
- medicines that stop blood clotting, such as warfarin
- the HIV medicine zidovudine.

Your health care provider may still decide to give you [TB321 trade name] if you are taking one of these medicines, but the health care provider may need to check your general health and your blood pressure before and during your treatment. In some cases, your health care provider may decide that another treatment is better for you.

Tell your health care provider if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

[TB321 trade name] with food and drink

- You can take your medicine with food or between meals.
- 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 increase your blood pressure.
- If you develop a throbbing headache after eating or drinking, tell your health care provider 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 health care provider for advice before taking this medicine.

The effect of linezolid in pregnant women is not known. You should, therefore, not take [TB321 trade name] while you are pregnant unless your health care provider has told you to.

Linezolid passes into breast milk and could affect the baby. Your health care provider will discuss with you about whether to stop breastfeeding.

Driving and using machines

[TB321 trade name] may make you feel dizzy or you may have problems with your vision. If they affect you in this way do not drive, operate machinery or do anything that requires you to be alert. Remember that if you are unwell your ability to drive or operate machinery may be affected.

3. How to take [TB321 trade name]

Always take [TB321 trade name] together with other medicines for treating tuberculosis. Your health care provider has chosen the right doses and combination of medicines to treat your tuberculosis

Always take this medicine exactly as your health care provider has told you. Check with your health care provider if you are not sure.

Your TB treatment may need to continue for many months. It is important to take the full course of treatment, even if you feel better.

Your healthcare provider will explain to you how to take your medicines and how long your treatment should last. Do not change the dose unless your health care provider tells you to.

Patients 14 years and older and weighing at least 46 kg

The usual recommended dose of [TB321 trade name] for adults and children weighing 46 kg or more is one tablet (600 mg) once daily.

Your health care provider may decrease the dose if you develop certain side effects.

Take the tablet with some water and swallow the tablet whole. You can take the tablets with food or between meals.

If you are on kidney dialysis, you should take [TB321 trade name] after your dialysis treatment.

Patients weighing from 5 kg up to 46 kg

[TB321 trade name] can be used in patients who weigh less than 46 kg if other suitable medicines are not available.

For a patient weighing less than 46 kg, mix the tablet with 10 mL of water and give a proportion of the mixture according to the patient's weight as shown below:

Patient's weight	How much mixture to give	Equivalent to a dose of
5 to less than 7 kg	1.25 mL daily	75 mg daily
7 to less than 16 kg	2.5 mL daily	150 mg daily
16 to less than 24 kg	4 or 5 mL daily (your health care provider will tell you which amount to give)	240 or 300 mg daily*
24 to less than 36 kg	5 mL daily	300 mg daily*
36 to less than 46 kg	7.5 mL daily	450 mg daily
*Children who need a 300-mg dose and who can swallow tablets can take half a tablet instead.		

For preparing this liquid mixture you need:

- Two small bowls
- drinking water
- a teaspoon and
- a 10-mL oral syringe, showing measurements of 0.5 mL.

The following steps should be followed:

1. Measure out 10 mL drinking water using the syringe and put it in the first bowl.
2. Add one linezolid 600-mg tablet.
3. Stir gently until the tablet disintegrates.
4. Look up the patient's weight in the above table (first column).
5. Then look under 'How much mixture to give', to find the right dose for the patient.
6. Use the syringe to draw up the correct amount of liquid mixture from the first bowl. Make sure there are no bubbles in the mixture you have drawn up.
7. Add a small amount of sweet food—no more than one teaspoon—to the second bowl. This helps to hide the unpleasant taste of the medicine.
8. Mix the sweet food and medicine mixture well.
9. Give the whole contents of the second bowl (medicine in the sweet food) to the patient straight away.
10. If there is anything left in the second bowl, rinse the bowl with a small amount of water and get the patient to drink it all. Use a spoon (or a bottle for an infant) to give the patient the remaining mixture. This is to make sure that the patient gets the full dose.
11. Give the patient something to drink after taking the medicine.
12. Throw away any liquid left in the first bowl.

Repeat these steps every time you need to give the medicine.

If you take more [TB321 trade name] than you should

Immediately contact your healthcare provider or your nearest hospital emergency department.

If you forget to take [TB321 trade name]

If you forget to take a dose and it is still less than 12 hours after you should have taken it, take the dose at once and take the next dose at the usual time.

If more than 12 hours have passed since you missed the dose, do not take the missed dose and instead take the next one at the usual time.

Do not take a double dose to make up for a missed dose.

If you are not sure what to do, ask your health care provider.

If you stop taking [TB321 trade name]

Unless your health care provider tells you to stop treatment, it is important to continue taking this medicine.

If you feel unwell again after you have stopped taking this medicine, speak to your health care provider at once to check that the tuberculosis has not come back.

If you have any questions on the use of this medicine, ask your health care provider.

4. Possible side effects

Like all medicines, [TB321 trade name] can cause side effects, although not everybody gets them.

If you notice any of the following symptoms or side effects, **tell your health care provider immediately**:

- skin reactions such as red sore skin and flaking (dermatitis), rash, itching, or swelling particularly around the face and neck. This may be the sign of an allergic reaction and it may be necessary for you to stop taking [TB321 trade name].
- problems with your vision such as blurred vision, changes in colour vision, difficulty seeing details or if your field of vision becomes restricted.
- severe diarrhoea containing blood or mucus, which may be signs of antibiotic-associated colitis and pseudomembranous colitis that may cause life-threatening complications in rare cases.
- recurrent nausea (feeling sick) or vomiting, abdominal (belly) pain or rapid breathing.
- fits or seizures
- agitation, confusion, fast heartbeat, abnormal sweating, rigidity, tremor, loss of muscle coordination and seizures while also taking medicines such as antidepressants known as SSRIs.
- extreme tiredness, abnormal bruising or bleeding or signs of infection, such as sore throat and high temperature. These may be signs of reduced activity of the bone marrow which leads to a severe decrease in:
 - red blood cells, which can make the skin pale and cause weakness and breathlessness (anaemia),
 - blood platelets (cells that help the blood to clot) and
 - white blood cells (cells that help the body to fight infections).

Numbness, tingling sensations or blurred vision may be more likely the longer you take the medicine.

Other side effects:

Tell your healthcare provider if you get any of the following side effects, especially if it gets serious, or if you notice any other unexpected or unusual symptoms not listed in this leaflet.

Common side effects (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 your kidney or liver function or blood sugar levels
- changes in the numbers of blood cells that affect blood clotting and ability to fight infections
- anaemia (low red blood cell count which can make skin pale and cause weakness or breathlessness)
- difficulty in sleeping
- increased blood pressure
- skin rash
- itching skin
- dizziness

- abdominal (belly) pain
- constipation
- indigestion
- fever

Uncommon side effects (may affect up to 1 in 100 people) are listed below:

- inflammation of the vagina or genital area in women
- sensations such as tingling or numbness
- blurred vision
- 'ringing' in the ears (tinnitus)
- dry or sore mouth, swollen, sore, or discoloured tongue
- loose stools
- a need to urinate more often
- chills
- feeling tired or thirsty
- inflammation of the pancreas (symptoms may include severe and persistent pain in the abdomen (belly) which might reach through to your back, as well as nausea and vomiting)
- increased sweating
- changes in proteins, salts or enzymes in the blood which measure kidney or liver function
- fits
- low blood sodium levels (hyponatraemia)
- kidney failure
- unexplained bleeding or bruising, which may be due to a reduction in certain cells in the blood that affect blood clotting
- abdominal bloating
- inflammation of the skin
- changes in heart rate (e.g. fast heartbeat)

Rare side effects (may affect up to 1 in 1,000 people) are listed below:

- restricted field of vision
- superficial tooth discolouration, removable with professional dental cleaning (manual descaling)
- 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)
- inflammation of part of the intestine (colitis)
- reduction of all blood cells

The following side effects have also been reported, but it is unknown how often they may occur:

- serotonin syndrome (symptoms include agitation, confusion, fast heartbeat, abnormal sweating, rigidity, tremor, loss of muscle coordination and seizures (fits))
- lactic acidosis (symptoms include recurrent nausea and vomiting, abdominal pain, rapid breathing)
- severe skin disorders
- sideroblastic anaemia (a particular type of anaemia (low red blood cells))
- hair loss
- changes in colour vision or difficulty in seeing details
- reduced production of new red or white blood cells in the bone marrow
- weakness and/or sensory changes
- severe allergic reactions (anaphylaxis)

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [TB321 trade name]

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Do not use this medicine after the expiry date stated on the label after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice description of the visible signs of deterioration that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 [TB321 trade name] contains

- The active ingredient is linezolid 600 mg.
- The other ingredients of [TB321 trade name] are:
Core tablet: corn starch, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose and sodium starch glycolate
Film coat: macrogol, polyvinyl alcohol-part hydrolysed, talc and titanium dioxide

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [TB321 trade name] looks like and contents of the pack

[TB321 trade name] are white to off-white, oval-shaped, biconvex, film-coated tablets, debossed with 'CL' on one side and a central break-line on the other side.

Bottles

[TB321 trade name] is available in a 40cc white HDPE bottle with a 33 mm white HDPE non-child resistant cap with Teckniplex® HS-130 liner.

Pack size: 20 tablets.

Blisters

[TB321 trade name] is available in white, opaque PVC-Aluminium blister packs.

Pack size: 2 X 10 tablets.

Supplier and Manufacturer

Supplier

Cipla Ltd.
Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg, Lower Parel
Mumbai: 400013
India
Tel. No.: 91-22-24826000
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Manufacturer

Cipla Limited
Unit IV, Plot no. 9 & 10
Pharma zone, Phase II
Indore special economic zone
Pithampur
Madhya Pradesh – 454 775
India

“For any information about this medicinal product, please contact the supplier”

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Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/pqweb/medicines>