

## Information for the patient

[TB350 trade name]<sup>†</sup>

Linezolid

**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 has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness seem 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 [TB350 trade name] is and what it is used for
2. What you need to know before you take [TB350 trade name]
3. How to take [TB350 trade name]
4. Possible side effects
5. How to store [TB350 trade name]
6. Contents of the pack and other information

#### 1. What [TB350 trade name] is and what it is used for

[TB350 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.

[TB350 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 [TB350 trade name]

##### Do not take [TB350 trade name] if you

- are allergic to linezolid or any of the other ingredients of [TB350 trade name] (listed in section 6)
- are taking or have taken in the last 2 weeks any medicines known as monoamine oxidase inhibitors, such as phenelzine, isocarboxazid, selegiline or moclobemide, which are used to treat depression or Parkinson's disease.
- are breast-feeding. This is because linezolid passes into breast milk and could affect the baby.

### Warnings and precautions

#### Talk to your health care provider before taking [TB350 trade name] if you

- have high blood pressure, whether or not you are taking medicines for this
- have been diagnosed with an overactive thyroid
- 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 and wheezing)
- suffer from manic depression, schizoaffective disorder, mental confusion or other mental problems
- are taking any of the following:

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<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- decongestant, cold or flu remedies containing pseudoephedrine or phenylpropanolamine
- 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, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine or setraline
- 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.

In these cases, [TB350 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 the above categories apply to you.

#### **Take special care with [TB350 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 a history of 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 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 [TB350 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 under **Warnings and precautions**. Your health care provider may still decide to give you [TB350 trade name], but will need to check your general health and your blood pressure before and during your treatment. In other 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.

### **[TB350 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 cause an increase in 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 [TB350 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**

[TB350 trade name] may make you feel dizzy or experience 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.

### **[TB350 trade name] contains the sugar lactose**

If you have been told by your health care provider that you have an intolerance to some sugars, contact your health care provider before taking this medicine

## **3. How to take [TB350 trade name]**

Your TB treatment will include other medicines as well as [TB350 trade name] and may need to continue for many months. Your healthcare provider will explain to you how to take your medicines and how long your treatment should last.

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

### **Patients 14 years and older and weighing at least 45 kg**

The usual recommended dose of [TB350 trade name] for the long term treatment of drug resistant tuberculosis in adults and children weighing 45 kg or more is one tablet (600 mg) once daily.

Your healthcare 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 [TB350 trade name] after your dialysis treatment.

While you are taking [TB350 trade name], your healthcare provider should perform regular blood tests to monitor your blood count. Your healthcare provider should also monitor your eyesight.

Some patients may be given a shorter treatment (6 to 9 months) with [TB350 trade name] and two other medicines, bedaquiline and pretomanid. The starting dose of [TB350 trade name] in this combination is two tablets (1200 mg) once daily. Your healthcare provider may decrease the dose if you develop certain side effects.

### **Use in younger patients weighing from 5 kg up to 45 kg**

[TB350 trade name] is not for use in children with a body weight less than 5 kg.

Patients weighing from 5 up to 45 kg should preferably be given a different version of the medicine, e.g. oral suspension or dispersible tablets containing lower amounts of the active substance linezolid.

If these formulations are not available, a tablet of [TB350 trade name] can be made up into a liquid mixture with water to supply a child with the right daily dose for their weight as follows:

<b>Child's weight</b>	<b>How much mixture to draw up</b>	<b>Equivalent to a dose of</b>
5 to 15 kg	2.5 mL	150 mg
16 to 34 kg	5 mL*	300 mg
35 to 45 kg	7.5 mL	450 mg

\*For children weighing between 16 and 34 kg who are able to swallow tablets, the 600 mg tablets can be split and 1/2 tablet be given per day instead.

For preparing this formulation 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 child's weight on in the above table (left-hand column).
5. Then look under "How much mixture to draw up", which shows how much of the liquid mixture you need to draw up.
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 when you measure the amount drawn up.
7. Add a small amount of sweet food—no more than one teaspoon—to the second bowl. This is to hide the unpleasant taste of the medicine.
8. Mix the sweet food and medicine-containing liquid well.
9. Give the whole contents of the second bowl (medicine in the sweet food) to the child straight away.
10. If there is anything left in the second bowl, rinse the bowl with a small amount of water and get the child to drink it all. If the child cannot drink from the bowl, use a spoon or use a bottle to feed the child the remaining liquid. This is to make sure that the child gets the full dose.
11. Give the child 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 [TB350 trade name] than you should**

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

#### **If you forget to take [TB350 trade name]**

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember. Take the next tablet 24 hours after this and continue taking your tablets every 24 hours.

#### **If you stop taking [TB350 trade name]**

Unless your healthcare provider instructs you to stop treatment, it is important to continue taking this medicine.

If you stop and your original symptoms come back tell your healthcare provider immediately.

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

#### **4. Possible side effects**

Like all medicines, [TB350 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 [TB350 trade name].
- problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing details or if your field of vision becomes restricted.
- 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.
- recurrent nausea (feeling sick) or vomiting, abdominal (belly) pain or rapid breathing.
- fits or seizures, which have been reported with [TB350 trade name]. You should let your health care provider know if you experience agitation, confusion, fast heartbeat, abnormal sweating, rigidity, tremor, loss of muscle coordination and seizures while also taking 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] are listed below:

- 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 certain cells in the blood that affect blood clotting
- anaemia (low red blood cell count which can make skin pale and cause weakness or breathlessness)
- changes in numbers of certain cells in the blood which may affect your ability to fight infection
- difficulty in sleeping
- increased blood pressure
- skin rash
- itching skin
- dizziness
- localised or general abdominal 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 feeling numb
- blurred vision
- “ringing” in the ears (tinnitus)
- dry or sore mouth, swollen, sore, or discoloured tongue
- 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
- 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 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)
- inflammation of part of the intestine (colitis)

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 any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help improve understanding about the safety of this medicine.

### **5. How to store [TB350 trade name]**

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

Do not store above 30°C. Protect from moisture. Store in the original pack.

Do not use this medicine after the expiry date stated on the carton 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 [TB350 trade name] contains**

- The active ingredient is linezolid. Each table contains 600mg of linezolid.
- The other ingredients of [TB350 trade name] are lactose monohydrate, polacrillin potassium, hypromellose, colloidal silicon dioxide, magnesium stearate, hydroxypropyl methylcellulose, polyethylene glycol and titanium dioxide

**What [TB350 trade name] looks like and contents of the pack**

[TB350 trade name] are white to off-white coloured, oval, biconvex film-coated tablets with bevelled edges, having a score line on one side and plain on the other side.

[TB350 trade name] is available in clear PVC/PVDC-aluminium or PVC-aluminium blister packs. Each carton pack contains 10 x 10's tablets.

**Supplier and Manufacturer**

***Supplier***

Lupin Limited  
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Tel.: +91-22-66402323  
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***Manufacturer***

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Fax: +91-1923-220177  
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For any information about this medicine, contact the local representative of the supplier.

**This leaflet was last revised in December 2021**

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