

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

[TB391 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 [TB391 trade name] is and what it is used for
2. What you need to know before you take [TB391 trade name]
3. How to take [TB391 trade name]
4. Possible side effects
5. How to store [TB391 trade name]
6. Contents of the pack and other information

1. What [TB391 trade name] is and what it is used for

[TB391 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.

[TB391 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 [TB391 trade name]

Do not take [TB391 trade name] if you

- are allergic to linezolid or to any of the other ingredients of [TB391 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 [TB391 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 [TB391 trade name]’

In these cases, [TB391 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 [TB391 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 [TB391 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 [TB391 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.

[TB391 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 [TB391 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

[TB391 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.

Other ingredients of [TB391 trade name]

This medicine contains 30 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicinal product contains 32.46 mg sodium per tablet, equivalent to 1.6% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

3. How to take [TB391 trade name]

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

This medicine is used as part of tuberculosis treatment in children weighing up to 46 kg. The treatment will include other medicines as well as [TB391 trade name] and may need to continue for many months. Your healthcare provider will explain to you how to take the medicines and how long treatment should last. It is important to take the full course of treatment, even if you feel better.

The daily dose depends on the patient's weight. Usual doses are as follows:

| Child's weight | Number of 150-mg dispersible tablets | Amount of water to make up the dose (see Instructions for mixing the tablets, below) |
|-----------------------|---|---|
|-----------------------|---|---|

| | | |
|---|---|-------------------------------------|
| 3 to less than 5 kg | See Instructions for mixing the tablets, below, to give a proportion of the mixture | |
| 5 to less than 7 kg | See Instructions for mixing the tablets, below, to give a proportion of the mixture | |
| 7 to less than 16 kg | 1 tablet daily | 10 mL (2 teaspoonfuls) [†] |
| 16 to less than 24 kg | 2 tablets daily* | 20 mL (4 teaspoonfuls) |
| 24 to less than 36 kg | 2 tablets daily | 20 mL (4 teaspoonfuls) |
| 36 to less than 46 kg | 3 tablets daily | 30 mL (6 teaspoonfuls) |
| [†] If your health care provider feels it is better to use less than 10 mL, then the health care provider will explain how to make up the mixture and how much of it is needed. You may be given an oral syringe to measure out the right amount of water. | | |
| * Your health care provider may decide that a smaller dose of 225 mg is right for you. To do this, use the Instructions for mixing the tablets when a proportion of the mixture needs to be given, below. | | |

[TB391 trade name] is not recommended in children who weigh less than 3 kg or weigh more than 46 kg.

Your healthcare provider may decrease the dose if you get certain side effects.

You can take the tablets with food or between meals.

If you are on kidney dialysis, you should take [TB391 trade name] after your dialysis treatment.

Instructions for mixing the tablets when the entire mixture needs to be given

The table above tells you how much water and how many tablets you need for the daily dose.

Measure out the water in a cup or a bowl and place the right number of [TB391 trade name] tablets in it.

Make sure that the tablets break down completely in the water. The child should take all the mixture at once.

Add a little more water to the cup or bowl and gently rinse it around to collect any medicine left, then get your child to drink it so that they get the full dose of the medicine.

Instructions for mixing tablets to give a proportion of the mixture for children weighing 3 to less than 7 kg

- To prepare the daily dose, use an oral syringe to measure 10 mL water into a cup or a bowl
- Add 1 tablet of [TB391 trade name] to the water and make sure it breaks down completely
- The child should take a proportion of the mixture, depending on their weight:
 - If your child weighs **3 to less than 5 kg**, use the oral syringe to give them 2.5 mL of the mixture
 - If your child weighs **5 to less than 7 kg**, use the oral syringe to give them 5 mL of the mixture

Instructions for mixing tablets for children weighing 16 to less than 24 kg

- To prepare the daily dose, use an oral syringe to measure 20 mL water into a cup or a bowl
- Add 2 tablets of [TB391 trade name] to the water and make sure they break down completely
- Use the oral syringe to give the child 15 mL of the mixture

If you take more [TB391 trade name] than you should

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

If you forget to take [TB391 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 [TB391 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, [TB391 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 [TB391 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 [TB391 trade name]

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

Store below 30°C in a dry place, avoid excursions over 30°C.

Do not use this medicine after the expiry date stated on the carton and alu/alu strips after EXP. The expiry date refers to the last day of that month.

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 [TB391 trade name] contains

- The active ingredient is linezolid.
- The other ingredients of [TB391 trade name] are hydroxypropyl cellulose, ethyl cellulose, polyethylene glycol, microcrystalline cellulose, crospovidone, mannitol, sodium chloride, sodium citrate dihydrate, aspartame, saccharin sodium, powderome peppermint premium, powderome strawberry premium, flavour peppermint and magnesium stearate.

What [TB391 trade name] looks like and contents of the pack

White to off-white coloured, capsule shaped, biconvex uncoated tablet with a score line on one side and plain on the other side.

The score line is intended for subdivision of tablets when half a tablet dose is to be administered.

Alu/Alu strip. Each strip contains 10 tablets. Such 8 or 10 strips are packed in a carton along with a patient information leaflet. Pack sizes: 8 x 10's and 10 x 10's tablets.

Supplier and Manufacturer

Supplier

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church road
Andheri (East)
Mumbai – 400 059, India.
Tel: +91-22-66762800
Fax: +91 -22-28216599
Email: exports@macleodspharma.com
vijay@macleodspharma.com
sjadhav@macleodspharma.com

Manufacturer

Macleods Pharmaceuticals Limited
Plot No.50 to 54A
SEZ, Phase II
Pithampur,Dist.: Dhar
Madhya Pradesh, 454774
India
Tel: 07292-350600 / 07292-3506601
Fax: 07292-350603
Email: nishata@macleodspharma.com

For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in May 2023

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