

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/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[TB385 trade name][†] Cycloserine

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

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 [TB385 trade name] is and what it is used for
2. What you need to know before you take [TB385 trade name]
3. How to take [TB385 trade name]
4. Possible side effects
5. How to store [TB385 trade name]
6. Contents of the pack and other information

1. What [TB385 trade name] is and what it is used for

[TB385 trade name] is used to treat tuberculosis (TB), an infection caused by bacteria called *Mycobacterium tuberculosis*. It is always given together with other medicines to treat tuberculosis and your health care provider has chosen the right combination for your condition.

[TB385 trade name] contains the active substance cycloserine, an antibiotic that stops the bacteria growing by interfering with their ability to make a protective wall around each cell.

2. What you need to know before you take [TB385 trade name]

Do not take [TB385 trade name]:

- if you are allergic to cycloserine or any of the other ingredients of [TB385 trade name] (see section 6, What [TB385 trade name] contains),
- if you have seizures (epilepsy),
- if you have a psychiatric disorder (e.g. depression or anxiety disorder),
- if you drink alcohol regularly.

Speak with your health care provider if you think you should not take this medicine.

Warnings and precautions

Your health care provider will carry out blood tests after starting [TB385 trade name] and regularly check how well your liver and kidneys are working.

[TB385 trade name] may severely affect your mind and nervous system (see “Possible side effects”). Your health care provider will regularly check for these symptoms. If you or your contacts notice you are feeling

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

very low or depressed or have other personality changes while you are taking cycloserine, report this immediately to your health care provider.

If you get a rash or yellowing of the skin and eyes (possible signs of an allergic reaction), tell your health care provider immediately.

Discuss the use of [TB385 trade name] with your health care provider if you have kidney disease. Your health care provider may need to adjust your dose.

It is important that your health care provider knows about all your symptoms even when you think they are not related to tuberculosis infection.

Other medicines and [TB385 trade name]

Tell your health care provider if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. These may affect the action of [TB385 trade name], or [TB385 trade name] may affect their action.

Use of [TB385 trade name] with isoniazid or ethionamide (other tuberculosis medicines) may make the side effects on the central nervous system worse. Use of [TB385 trade name] and delamanid (another tuberculosis medicine) might affect your mind or mood, causing confusion, fear, or seeing things that are not real. This is more likely to happen in children.

Your health care provider may adjust the dosage of your medicines and will regularly check for these side effects.

[TB385 trade name] with food, drink and alcohol

Do not take [TB385 trade name] with a high-fat meal as it may affect how well your body can absorb the medicine. This medicine should be taken without food if possible.

It can be taken with orange juice

Do **not** drink alcohol while you are being treated with [TB385 trade name] (see “Do not take [TB385 trade name]”, above). You are more likely to experience serious side effects such as seizures if you drink alcohol while taking this medicine and other side effects such as dizziness and drowsiness may be more severe.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, you must contact your health care provider to discuss the potential benefits and risks of your tuberculosis therapy to you and your child.

Cycloserine passes into the breast milk. No side effects have been reported in breast-fed-infants whose mothers were receiving cycloserine. It is important that you also continue to take the vitamin B6 supplement given to all patients who are prescribed this medicine.

Driving and using machines

[TB385 trade name] may cause side effects such as dizziness or drowsiness, that can impair your ability to drive and to use machines safely.

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[TB385 trade name] contains:

Each capsule of [TB385 trade name] contains the azo colouring agents sunset yellow FCF, tartrazine and ponceau 4R which may cause allergic reactions.

3. How to take [TB385 trade name]

Your health care provider will decide on the right doses and combination of medicines to treat your TB, based on your age, weight and condition, including whether your TB is resistant to standard treatments.

For the treatment of TB, [TB385 trade name] must be used with other medicines.

Always take [TB385 trade name] exactly as your health care provider has told you. Check with your health care provider if you are not sure.

Your TB treatment will include other medicines as well as [TB385 trade name] and may need to continue for many months. Your health care 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. It is important to take the full course of treatment recommended by your health care provider, even if you feel better.

Swallow [TB385 trade name] whole with water. For small children who cannot swallow the capsule, you may need to make up a mixture with [TB385 trade name] and some water, as instructed by your health care provider.

[TB385 trade name] is best taken on an empty stomach. It can also be taken with orange juice.

For information on how to take the other medicines you need for your TB treatment, discuss with your health care provider and see the leaflets that come with those medicines as well.

Adults:

The usual dose is given in the table below; however, always take this medicine as directed by your health care provider, and the daily dose should not normally exceed 1000 mg (4 capsules).

Body weight	Number of capsules daily
46 kg and more	3

However, your health care provider will prescribe the dose of [TB385 trade name] appropriate for you. If your prescribed dose is different, do not change it unless your health care provider tells you to do so.

This dose can be split up so you take part of it in the morning and part in the evening to reduce side effects. Your health care provider will advise you how to split your dose if this is necessary.

Children and adolescents weighing 30 kg to less than 46 kg

The usual dose is given in the table below; however, always take this medicine as directed by your health care provider, and the daily dose should not normally exceed 1000 mg (4 capsules).

Body weight	Number of capsules daily
30 to less than 46 kg	2

Children weighing 7 to less than 30 kg

The usual doses are given in the table below but always take the medicine as recommended by your health care provider, and the daily dose should not normally exceed 1000 mg (4 capsules).

Body weight	Number of capsules daily
7 to less than 10 kg	*
10 to less than 16 kg	1
16 to less than 30 kg	2

*In children weighing 7 to less than 10 kg, disperse one 250-mg capsule in 10 mL of water and give 5 mL daily; see instructions how to prepare a liquid mixture below

Children weighing 3 to less than 7 kg

A liquid mixture can be prepared by opening the capsule and dispersing the content of the capsule in 10 mL of water (see instructions below). The usual doses are given in the table below but always take the medicine as recommended by your health care provider.

Body weight	Daily volume of liquid mixture to be taken
3 to less than 5 kg	1 mL
5 to less than 7 kg	2 mL

Instructions on how to prepare a liquid mixture

For preparing the liquid mixture you need:

- One small bowl
- drinking water
- a teaspoon and
- a 10-mL oral syringe (dispenser), showing measurements of 1 mL, 2 mL and 5 mL

The following steps should be applied:

1. Open one [TB385 trade name] capsule and empty contents into the bowl.
2. Measure out 10 mL drinking water using the dispenser and put it into the bowl.
3. Stir gently with the spoon until the contents are fully dispersed.
4. **Use the dispenser to draw up the correct amount of liquid mixture from the bowl as instructed by your health care provider.** Make sure there are no bubbles in the mixture when you measure the amount drawn up.
5. Give the whole contents of medicine mixture in the dispenser to the child.
6. You may give the child a little milk or liquid after giving the medicine, this will help with removing bitter aftertaste
7. Throw away any remaining liquid left in the bowl.

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

Taking pyridoxine with [TB385 trade name]

Your health care provider may recommend that you also take pyridoxine (vitamin B6). Pyridoxine can help reduce the chance of getting peripheral neuropathy, a side effect of [TB385 trade name] that can affect nerves and cause tingling, pricking or numbness, especially of your hands and feet.

This vitamin is especially important if you are pregnant or breastfeeding, have HIV infection, malnutrition, alcohol dependence, kidney problems or diabetes.

Your health care provider will tell you how much pyridoxine to take – you should also read the patient information leaflet supplied with any pyridoxine tablets you are given.

If you take more [TB385 trade name] than you should

If you have taken too many capsules, you may develop headaches, dizziness, confusion, drowsiness, hyper-irritability, numbness or tingling in your hands or feet, slurred speech and personality changes (psychosis). You should immediately contact your health care provider or the nearest hospital emergency department for further advice.

If you forget to take [TB385 trade name]

If you usually take your medicine once a day, and you forget to take your dose at the usual time, then:

- If there are more than 12 hours to go until your next dose is due, take the missed dose as soon as possible.
- If there are less than 12 hours to go till your next dose, just skip the missed dose and take your next regular dose at the usual time.

If you usually split the daily dose and take your medicine twice a day (every 12 hours) and you forget to take a dose at the usual time, then:

- If there are more than 6 hours to go until your next dose is due, take the missed dose as soon as possible.
- If there are less than 6 hours to go till your next dose, just skip the missed dose and take your next regular dose at the usual time.

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

If you stop taking [TB385 trade name]

Do not stop treatment unless your health care provider tells you to, even if you are feeling better. If you stop the medicine too soon, your infection may not be completely cured.

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

4. Possible side effects

Like all medicines, [TB385 trade name] can cause side effects, although not everybody gets them. When treating tuberculosis, it is not always possible to differentiate between unwanted effects caused by [TB385 trade name], and those caused by any other medicines you may be taking at the same time, or by the disease itself.

For this reason, it is important that you inform your health care provider of any change in your health.

The most *commonly* reported (greater than 1 in every 10 patients treated) side effects are:

- confusion or abnormal behaviour,
- depression,
- lethargy (lack of energy),
- nervousness, anxiety,
- tremors (shaking),
- drowsiness,
- dizziness, vertigo (a spinning sensation)
- difficulty speaking,
- irritability,
- headache.

There are *rare* reports (between 1 in 10 000 and 1 in 1000 patients treated) of:

- allergic reactions (difficulty breathing; closing of your throat; swelling of your lips, tongue, or face; skin rash or hives, increased light sensitivity of the skin or inflammation of the liver).
- irregular heartbeat and sudden development of heart failure (your heart muscle doesn't pump blood as well as it should) in patients receiving 1 g or more per day.

Frequency estimates for the following effects are not available:

- vitamin B12 deficiency, folic acid deficiency, potentially leading to anaemia, which is characterised by many large immature and dysfunctional red blood cells (megaloblasts), other forms of anaemia.
- increased liver enzymes seen in blood tests, particularly in patients with pre-existing liver disease.
- involuntary rhythmic jerking movements of the arms and legs (clonic seizures), convulsion, coma, slight or partial paralysis, extremely high fever.

- skin rash, which can be life-threatening and also involve the mucous membranes (Stevens-Johnson syndrome).
- numbness or tingling in hands or feet.
- disorientation, memory loss, psychosis (irrational thoughts), feeling suicidal, aggression, character changes.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider as soon as possible. You can also report side effects directly via the local reporting system.

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 [TB385 trade name]

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

Do not store above 25°C, protect from moisture.

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 [TB385 trade name] contains

- The active ingredient is cycloserine
- The other ingredient(s) of [TB385 trade name] are excipients;
Capsule fill: Glyceryl behenate, Microcrystalline cellulose and Calcium carbonate
Capsule shell: gelatin, FD& C blue #1/brilliant blue FCF, erythrosine titanium dioxide, FD& C yellow #6/sunset yellow FCF, FD& C yellow #5/tartrazine, methyl paraben and propyl paraben
Printing ink: shellac, polysorbate, propylene glycol, ponceau 4R, red iron oxide and titanium dioxide

What [TB385 trade name] looks like and contents of the pack

[TB385 trade name] are hard gelatine capsules with an opaque with blue cap and opaque yellow body. The capsules are printed in white on the cap with 'Lupin' logo and the body imprinted with red ink with 'LUPIN'. They contain a white to pale pink granular powder.

[TB385 trade name] are packed with 10 capsules plain aluminium blister cards. Such one or 10 blister cards are packed in a carton and are available in pack sizes: 1 x 10's or 10 x 10's capsules

Supplier and Manufacturer

Supplier

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway,
Santacruz (East), Mumbai 400055,
India
Tel: 91-22-66402323
Fax: 91-22-266408128
E-mail: dsrm@lupin.com

Manufacturer

Lupin Limited
A-28/1, MIDC Area, Chikalthana
Chhatrapati Sambhajnagar 431210
Maharashtra State
India
Tel: 91 22406612444

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

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Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>