

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

[TB304 trade name][†]
Cycloserine

*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 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 [TB304 trade name] is and what it is used for
2. What you need to know before you take [TB304 trade name]
3. How to take [TB304 trade name]
4. Possible side effects
5. How to store [TB304 trade name]
6. Contents of the pack and other information

1. What [TB304 trade name] is and what it is used for

[TB304 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.

[TB304 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 [TB304 trade name]

Do not take [TB304 trade name]:

- if you are allergic to cycloserine or any of the other ingredients of [TB304 trade name] (see section 6, What [TB304 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.

Warnings and precautions

Your health care provider will carry out blood tests after starting [TB304 trade name] and regularly check how well your liver and kidneys are working.

[TB304 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 [TB304 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 [TB304 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 [TB304 trade name], or [TB304 trade name] may affect their action.

Use of [TB304 trade name] with isoniazid or ethionamide (other tuberculosis medicines) may make the side effects on the central nervous system worse. Your health care provider may adjust the dosage of your medicines and will regularly check for these side effects.

[TB304 trade name] with food, drink and alcohol

Do not take [TB304 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 [TB304 trade name] (see “Do not take [TB304 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. However, your baby should be given a vitamin B6 supplement if you breastfeed while taking [TB304 trade name]. 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

[TB304 trade name] may cause side effects such as dizziness or drowsiness, that can impair your ability to drive and to use machines safely.

3. How to take [TB304 trade name]

Your TB treatment will include other medicines as well as [TB304 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.

Adults:

The usual dose of [TB304 trade name] in adults varies with their weight but should not normally exceed 1000 mg. Typical doses by weight are:

Body weight	Daily dose	Number of capsules daily

30 to 45 kg	500 mg	2
46 kg or more	750 mg	3

However, your health care provider will prescribe the dose of [TB304 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

You will also be given pyridoxine (vitamin B6) to take with your other medicines, to help reduce the side effects of [TB304 trade name]. If you are breast feeding, your baby will also be given pyridoxine.

Children:

As in adults, the dose of [TB304 trade name] in children depends on their weight. Your health care provider will work out the dose of [TB304 trade name] appropriate for your child. Always use the dose recommended by your health care provider.

Small children may be prescribed a different cycloserine medicine to make it easier to give them the right dose. However, if [TB304 trade name] has been prescribed, your health care provider may recommend that the capsules be opened and made into a liquid mixture with 10 mL of water, part of which can be used to supply the child with the right dose.

Typical daily doses for children are included in the table below .

Child's weight	Daily dose	Total daily amount* of liquid mixture
3-4 kg	25 mg	1 mL
5-6 kg	50 mg	2 mL
7-9 kg	125 mg	5 mL
10-15 kg	250 mg	can be taken as a 250-mg capsule; for children who have difficulty swallowing, the capsule can be opened and dispersed in 10 mL of water, and the whole amount drunk
16 kg or more	500 mg	can be taken as 2 capsules of 250 mg; for children who have difficulty swallowing, each capsule can be opened and dispersed in 10 mL of water, and the whole amount drunk

*Your health care provider will advise you what amount to give, and how to split your child's dose if this is necessary

For preparing the liquid mixture you need:

- One small bowl
- drinking water
- a teaspoon and
- a 10-mL oral syringe (dispenser), showing measurements of 0.5 mL.

The following steps should be applied:

1. Measure out 10 mL drinking water using the dispenser and put it into the bowl.

2. Open one [TB304 trade name] capsule and empty contents into the bowl.
3. Stir gently until 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.

If you take more [TB304 trade name] than you should

If you have taken too many tablets 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 [TB304 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 [TB304 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, [TB304 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 [TB304 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 heart beat 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 characterized 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 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 [TB304 trade name]

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

Do not store above 25°C, store in tight container. Protect from moisture. Do not remove the desiccant canister from the bottle. Discard the product 30 days after initial opening of the bottle.

Do not use this medicine after the expiry date stated on the label and 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 [TB304 trade name] contains

- The active ingredient is 250 mg cycloserine.
- The other ingredients of [TB304 trade name] are :
Capsule fill: Talc.
Capsule shell: Gelatin, iron oxide red, iron oxide yellow and titanium dioxide.
Imprint ink: Shellac, propylene glycol, black iron oxide and potassium hydroxide.

What [TB304 trade name] looks like and contents of the pack

White to creamish pink powder, filled in hard shell gelatin capsules, with light orange opaque cap and white opaque body, axially imprinted with “MYLAN” over “CS250” in black ink on both the cap and body.

Bottle pack

[TB304 trade name] is provided in a round, wide mouth, white, HDPE bottle fitted with white opaque polypropylene screw cap with aluminium induction sealing liner and containing a silica gel desiccant canister.

Pack size: 100 capsules.

Blister pack

The primary packs are blister cards of 10 capsules (comprised of aluminium-aluminium foil).

One such blister or such 10 blisters are kept packed in a carton.

Pack size: 1 x 10 capsules and 10 x 10 capsules

Supplier and Manufacturer

Supplier

Mylan Laboratories Limited
Plot No.564/A/22,
Road No. 92, Jubilee Hills
Hyderabad – 500096
Telangana
India
Email: Imtiyaz.basade@viatris.com

Manufacturer

Mylan Laboratories Limited
Plot No. H-12 & H-13
MIDC, Waluj
Aurangabad - 431136
Maharashtra
India

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/pqweb/medicines>