

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

[TB008 trade name][†]
Ethambutol hydrochloride

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 [TB008 trade name] is and what it is used for
2. What you need to know before you take [TB008 trade name]
3. How to take [TB008 trade name]
4. Possible side effects
5. How to store [TB008 trade name]
6. Contents of the pack and other information

1. What [TB008 trade name] is and what it is used for

[TB008 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.

[TB008 trade name] contains the active substance ethambutol. It works by stopping the bacteria from multiplying in the body.

2. What you need to know before you take [TB008 trade name]

Do not use [TB008 trade name] if you:

- are allergic (hypersensitive) to ethambutol, or to any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your health care provider if you have:

- problems with eyesight. Contact your health care provider at once if you notice any changes with your vision, blurring, difficulty telling colours apart, trouble seeing, or eye pain. Your health care provider will check your vision before treatment and also during treatment.

- kidney disease. Your healthcare provider may change how you take this medicine if your kidney don't work well enough.

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

Taking other medicines

Tell your health care provider if you are taking, have recently taken or might take any other medicines.

You should not take [TB008 trade name] at the same time as stomach medicines that contain aluminium hydroxide (used to relieve heartburn and indigestion), as this can make ethambutol less effective.

Pregnancy

[TB008 trade name] can be used during pregnancy for treating tuberculosis.

Tuberculosis can be particularly dangerous in pregnancy and it is important that you get the right treatment.

Breast-feeding

You can breast-feed your baby during treatment with [TB008 trade name].

Ethambutol passes into breast milk but it is not likely to have any unwanted effects on your baby.

Driving and using machines

[TB008 trade name] may cause eyesight problems or tingling or numbness in the hands and feet. Very rarely, the medicine can also cause dizziness and disorientation. These side effects can affect how well you can drive or use machines.

After taking [TB008 trade name], you should not drive or use machines until you know how the medicine affects you.

3. How to take [TB008 trade name]

Take [TB008 trade name] exactly as your health care provider has told you. Always take [TB008 trade name] with other tuberculosis medicines. Your health care provider will choose the right combination of medicines for you.

Check with your health care provider if you are not sure.

The dose of [TB008 trade name] depends on your weight and whether you have *drug-sensitive tuberculosis* or *drug-resistant tuberculosis*. Your health care provider will decide the right dose for you and how long you should continue taking [TB008 trade name].

If you have kidney disease your health care provider may tell you to take [TB008 trade name] three times a week instead of taking it daily.

Drug-susceptible tuberculosis

Adults and adolescents weighing over 30 kg

Recommended doses of [TB008 trade name] for treating drug-susceptible tuberculosis are:

Patient's weight	Dose as 400-mg tablets
30 kg to less than 35 kg	2 tablets once daily
35 kg to less than 65 kg	3 tablets once daily
65 kg or more	4 tablets once daily

Children and adolescents weighing less than 30 kg

For patients weighing less than 30 kg, tablets containing lower amounts of ethambutol are more suitable.

However, [TB008 trade name] may be used for patients who weigh less than 30 kg if a more suitable medicine is not available. In such cases, [TB008 trade name] is mixed with drinking water and the patient takes a proportion of the mixture. See below ('[TB008 trade name] for children and adolescents weighing less than 30 kg') for recommended doses and how to make the mixture and how much of the mixture the patient should take.

Drug-resistant tuberculosis

Adults and adolescents weighing over 30 kg

The dose of ethambutol depends on the patient's weight and is around 15–25 mg/kg once daily.

Recommended doses of [TB008 trade name] for treating drug-resistant tuberculosis are shown below:

Patient's weight	Dose as 400-mg tablets
30 kg to less than 46 kg	2 tablets once daily
46 kg to less than 70 kg	3 tablets once daily
70 kg or more	4 tablets once daily

Children and adolescents weighing less than 30 kg

For patients weighing less than 30 kg, tablets containing lower amounts of ethambutol are more suitable.

However, [TB008 trade name] may be used for patients who weigh less than 30 kg if a more suitable medicine is not available. In such cases, [TB008 trade name] is mixed with drinking water and the patient takes a proportion of the mixture. See below ('[TB008 trade name] for children and adolescents weighing less than 30 kg') for recommended doses and how to make the mixture and how much of the mixture the patient should take.

If you take more [TB008 trade name] than you should

If you accidentally take more tablets than you should, tell a health care provider or get medical advice straight away. Take the medicine pack with you so the health care provider knows what you have taken.

If you forget to take [TB008 trade name] or you vomit after a dose

If you forget to take [TB008 trade name] at the usual time and:

- it is less than 6 hours since the usual time you take the dose, take the dose straight away and then take the next one at the usual time the next day
- if it is more than 6 hours since the usual time you take the dose, skip the missed dose and take the next one at the usual time the next day.

Do not take a double dose to make up for the forgotten dose. If you are unsure about what to do, ask your health care provider.

If you vomit within 1 hour of taking [TB008 trade name], then you should take another dose. If you vomit more than an hour after taking the dose, then you do not need to take another dose and you can take the next dose as usual on the next day.

If you stop taking [TB008 trade name]

It is important that you complete the course of treatment even if you begin to feel better. If you stop taking [TB008 trade name] too soon, your infection may not be completely cured and the infection may return or your condition may get worse. The bacteria causing the infection may become resistant to [TB008 trade name].

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

[TB008 trade name] for children and adolescents weighing less than 30 kg

[TB008 trade name] should be used **only** if a medicine suitable for children is not available.

Drug-susceptible tuberculosis

Recommended doses for treating children and adolescents with **drug-susceptible tuberculosis** are:

Patient's weight	Dose in mg
4 kg to less than 8 kg	100 mg once daily
8 kg to less than 12 kg	200 mg once daily
12 kg to less than 16 kg	300 mg once daily
16 kg to less than 25 kg	400 mg once daily
25 kg to less than 30 kg	600 mg once daily

See below for instructions on making a mixture of [TB008 trade name] and how much mixture the patient should take.

Drug-resistant tuberculosis

Recommended doses for treating children and adolescents with **drug-resistant tuberculosis** are:

Patient's weight	Dose in mg
3 kg to less than 5 kg	60 mg once daily
5 kg to less than 7 kg	120 mg once daily
7 kg to less than 10 kg	160 mg once daily
10 kg to less than 16 kg	240 mg once daily
16 kg to less than 24 kg	400 mg once daily
24 kg to less than 30 kg	600 mg once daily

See below for instructions on making a mixture of [TB008 trade name] and how much mixture the patient should take.

Instructions on making a mixture of [TB008 trade name] and how much mixture the patient should take To make a mixture of [TB008 trade name], you need:

- [TB008 trade name] – either one or two tablets, according to the dose, see table below
- Cool drinking water
- Two small, clean, dry bowls
- 10-mL oral syringe
- Small amount of flavoured liquid or semi-solid food to mask the medicine's taste

Steps to make the medicine mixture and taking it:

1. Place one [TB008 trade name] tablet (or two tablets if the dose is more than 400 mg) in a small bowl.
2. Using an oral syringe, measure 10 mL of drinking water for each tablet and add this to the bowl. Swirl or stir the liquid until the tablet breaks up completely.
3. Use the oral syringe to measure a proportion of the mixture according to the patient's dose (see table below). Throw away the mixture that remains in the bowl.

4. Squirt the measured dose into the other clean bowl and add a small amount of flavoured liquid or semi-solid food and mix thoroughly.
5. The patient should immediately take this. Rinse the bowl with a small amount of water and the patient should drink this also.
6. The patient may take a little milk or liquid after taking the medicine to help wash away the medicine's taste.

Dose of [TB008 trade name] mixture – see above for recommended doses for patients weighing less than 30 kg

Recommended dose in mg	Mixture to be prepared	Amount of mixture to take (measured using an oral syringe)
60 mg once daily	One 400-mg tablet mixed in 10 mL water	1.5 mL once daily
100 mg once daily		2.5 mL once daily
120 mg once daily		3 mL once daily
160 mg once daily		4 mL once daily
200 mg once daily		5 mL once daily
240 mg once daily		6 mL once daily
300 mg once daily		7.5 mL once daily
400 mg once daily ¹		10 mL once daily
600 mg once daily	Two 400-mg tablets mixed in 20 mL water	15 mL once daily
1. For the 400-mg dose, it is preferable for the patient to swallow the 400-mg tablet, rather than mixing it with water.		

4. Possible side effects

Like all medicines, [TB008 trade name] can cause side effects, but not everybody gets them. It is important that you tell the health care provider of any change in your health.

You should ask for medical help immediately if you have:

- sudden problems with breathing, wheeziness, swelling of the face, eyes, lips or throat, flushed appearance or irregular heartbeat. These may be symptoms of a severe allergic reactions

Speak with your health care provider straightaway if you have:

- changes in vision, including blurred vision, eye pain or not being able to see colours properly (colour blindness)

The following side effects can also occur in patients treated with ethambutol:

Uncommon side effects (may affect more than 1 in 1000 people) high levels of uric acid in the blood (hyperuricaemia) which may lead to gout (pain or swelling of the joints)

Rare side effects (may affect up to 1 in 10 000 people)

tingling, 'pins-and-needles' and numbness rash,

itchiness, hives (red, itchy bumps on the skin)

blood tests showing reduced blood platelets (which can cause bleeding and bruising)

Very rare side effects (may affect fewer than 1 in 10 000 people) dizziness, headache and

disorientation mental confusion, hallucination (seeing or hearing things that are not there) liver problems (hepatic failure) kidney problems (lower back pain, pain or burning when passing urine, difficulty passing urine) feeling ill, joint pains, fever lung damage causing breathing

difficulty skin allergy to bright light, severe skin rashes with blistering and skin peeling blood tests showing reduced levels of some types of white blood cells

Frequency of side effects not known nausea (feeling sick), vomiting, loss of appetite, gas (flatulence), belly pain, diarrhoea, upset stomach inflammation of the liver, jaundice (yellowing of the skin and/or eyes), blood tests suggesting liver problems

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your healthcare provider as soon as possible.

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 [TB008 trade name]

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

Store below 30°C. Protect from light.

Do not use this medicine after the expiry date stated on the carton, blister or bottle, after “EXP”. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration or 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 [TB008 trade name] contains

- The active ingredient is 400 mg of ethambutol hydrochloride.
- The other ingredients of [TB008 trade name] are:
 - *Core tablet*
 - Dibasic calcium phosphate
 - Gelatin
 - Sorbitol
 - Maize starch
 - Magnesium stearate
 - *Film-coat*
 - Ethylcellulose
 - Hydroxypropylmethyl cellulose
 - Polyethylene glycol
 - Titanium dioxide

What [TB008 trade name] looks like and contents of the pack

[TB008 trade name] is a white to off-white, smooth, round, biconvex, film-coated tablet, with break-line on one side and plain on other side. The break line can be used to divide [TB008 trade name] into equal doses.

[TB008 trade name] tablets are available in:

Alu/PVC blister pack

Blister card of 10 tablets (comprised of clear, transparent PVC blisters sealed with aluminium foil). Such 10 blister cards are packed into a carton.

Pack size: 10 x 10 tablets

Alu/PVC/ PVdC blister pack

Blister card of 28 tablets (comprised of orange, transparent PVC/PVDC blisters sealed with aluminium foil).
Such 24 blisters are packed into a carton.

Pack size: 24 x 28 tablets

HDPE bottle pack

A round, white, opaque, HDPE bottle fitted with a white LDPE lid and white polypropylene screw cap. Pack
size: 1000 tablets

Supplier

Cadila Pharmaceuticals Limited
1389, Dholka – 382225
District: Ahmedabad
Gujarat, India

Tel. No.: +91 2714-221481 / 221483 / 221484

Email: pharmacovigilance@cadilapharma.com

Manufacturer

Cadila Pharmaceuticals Limited
Main Pharma Block, 1389
Trasad Road, Dholka –382 225
District: Ahmedabad, Gujarat, India

Tel. No.: +91 2714-221481 / 221483 / 221484

Email: pharmacovigilance@cadilapharma.com

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

This leaflet was last revised in October 2023.

Section 6 was updated in November 2024.

*Detailed information on this medicine is available on the World Health Organization (WHO)
website:*

<https://extranet.who.int/pqweb/medicines>