

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

[TB334 trade name][†]
Ethambutol hydrochloride

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 [TB334 trade name] is and what it is used for
2. What you need to know before you take [TB334 trade name]
3. How to take [TB334 trade name]
4. Possible side effects
5. How to store [TB334 trade name]
6. Contents of the pack and other information

1. What [TB334 trade name] is and what it is used for

[TB334 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.

[TB334 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 [TB334 trade name]

Do not use [TB334 trade name] if you:

- are allergic (hypersensitive) to ethambutol, or to any of the other ingredients of this medicine (listed in section 6)
- if you have ever developed a severe skin rash or skin peeling, blistering, or mouth sores after taking ethambutol

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 health care provider may change how you take this medicine if your kidneys don't work well enough.

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

Tell your health care provider immediately if during treatment you get:

- liver problems. Some people get problems with their liver with [TB334 trade name] treatment.
Speak with your health care provider straightaway if you:
 - lose your appetite, or get nausea (feel sick), or feel tired all the time, or you have a rash *and you have any of the following*
 - belly pain, usually on the right side and near the chest
 - unexplained itching
 - yellowing of your skin or the white parts of your eyes, your nails or your skin
 - passing dark urine
 - passing stools that are very pale.Your health care provider will do blood tests to check how well your liver is working.
- severe skin reactions (see section 4. Possible side effects)

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 [TB334 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

[TB334 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 [TB334 trade name].

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

Driving and using machines

[TB334 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 [TB334 trade name], you should not drive or use machines until you know how the medicine affects you.

[TB334 trade name] contains aspartame

This medicine contains 20 mg of 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.

[TB334 trade name] contains propylene glycol

This medicine also contains 6.4 mg of propylene glycol in each tablet. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

3. How to take [TB334 trade name]

Take [TB334 trade name] exactly as your health care provider has told you. Always take [TB334 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 [TB334 trade name] depends on your weight and whether you have *drug-susceptible tuberculosis* or *drug-resistant tuberculosis*. Your health care provider will decide the right dose for you and how long you should continue taking [TB334 trade name].

If you have kidney disease your health care provider may tell you to take [TB334 trade name] three times per week instead of taking it daily.

Drug-susceptible tuberculosis

Children weighing less than 25 kg

Recommended doses of [TB334 trade name] for treating children with drug-susceptible tuberculosis are:

Patient's weight	Dose as 100-mg tablets
4 kg to less than 8 kg	1 tablet once daily
8 kg to less than 12 kg	2 tablets once daily
12 kg to less than 16 kg	3 tablets once daily
16 kg to less than 25 kg	4 tablets once daily

Adults and children weighing 25 kg or more

For patients weighing 25 kg or more, tablets containing higher amounts of ethambutol are more suitable.

Drug-resistant tuberculosis

Children weighing less than 24 kg

Recommended doses of [TB334 trade name] for treating children with drug-resistant tuberculosis are:

Patient's weight	Dose as 100-mg tablets
3 kg to less than 5 kg	½ tablet once daily
5 kg to less than 7 kg	1 tablet once daily
7 kg to less than 10 kg	2 tablets once daily
10 kg to less than 16 kg	3 tablets once daily
16 kg to less than 24 kg	4 tablets once daily

Adults and children weighing 24 kg or more

For patients weighing 24 kg or more, tablets containing higher amounts of ethambutol are more suitable.

If you take more [TB334 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 [TB334 trade name] or you vomit after a dose

If you forget to take [TB334 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 [TB334 trade name], then 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 [TB334 trade name]

It is important that you complete the course of treatment even if you begin to feel better. If you stop taking [TB334 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 [TB334 trade name].

Taking this medicine

You can take [TB334 trade name] with food or in between meals. Try to take [TB334 trade name] at about the same time each day.

Mix the tablets in drinking water before taking the dose. Use at least 10 mL water for each tablet but do not use more than 50 mL of water altogether.

Instructions for taking [TB334 trade name] dispersible tablets

1. Check how many tablets you need for your dose.
2. Pour drinking water (at least 10 mL for each tablet) into a small, clean cup or bowl
3. Add the tablets to the water.
4. Stir until the tablets break up completely and are fully mixed with the water.
5. Drink all the medicine mixture immediately.
6. Rinse the cup or bowl with a little more water and drink this water.

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

4. Possible side effects

Like all medicines, [TB334 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 reaction.
- severe skin reaction. Signs may include a severe rash that develops quickly, with blisters or peeling of the skin and possibly of mucous membranes (the lining of eyes, nose, mouth and genitals).

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)
- lose your appetite, or get nausea (feel sick), or feel tired all the time, or you have a rash
and you have any of the following
 - belly pain, usually on the right side and near the chest
 - unexplained itching
 - yellowing of the white parts of your eyes, your nails or your skin
 - passing dark urine
 - passing stools that are very pale

These are signs of a problem with your liver, which can become serious.

- develop pain in the lower back or you experience difficulty or pain in urinating. These may be signs of a kidney problem.
- notice any unusual bleeding, bruising or discoloured skin. These may be signs of a problem with your blood clotting.

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

Uncommon side effects (up to 1 in 100 people can get this side effect)

high levels of uric acid in the blood (hyperuricaemia) which may lead to gout (pain or swelling of the joints)

Rare side effects (up to 1 in 1000 people can get this side effect)

tingling, 'pins-and-needles' and numbness

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

Very rare side effects (up to 1 in 10 000 people can get this side effect)

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

blood tests showing reduced levels of some types of white blood cells

Other side effects (not known how often they can occur)

nausea (feeling sick), vomiting, loss of appetite, gas (flatulence), belly pain, diarrhoea, upset stomach shaking

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 [TB334 trade name]

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

Strip pack:

Do not store above 30°C. Store in a dry place, protected from light.

Blister pack:

Do not store above 30°C. Store in a dry place, protected from light. Avoid excursions over 30°C. Store tablets in the blisters in the provided carton

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 [TB334 trade name] contains

- The active ingredient is ethambutol hydrochloride.
- The other ingredients of [TB334 trade name] are colloidal silicon dioxide, microcrystalline cellulose, corn starch, sodium starch glycolate, croscarmellose sodium, aspartame, povidone, low-substituted hydroxypropyl cellulose, purified talc, silicified microcrystalline cellulose, orange flavour FTP (containing propylene glycol) and magnesium stearate.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [TB334 trade name] looks like and contents of the pack

[TB334 trade name] is a white to off-white, round uncoated tablets. They are flat on the top and bottom with a bevelled edge. The tablets have a break line on one side and are plain on the other side.

Strip pack

[TB334 trade name] is provided in a plain Alu-Alu strip pack containing 6 tablets. Available in cartons of 10 tablets.

[TB334 trade name] is provided in a plain Alu-Alu strip pack containing 10 tablets. Available in cartons of 8 tablets.

Blister pack

[TB334 trade name] is provided in an amber-coloured PVC/PE/PVdC-Alu blister card containing 10 tablets. Available in cartons of 10 tablets.

Supplier and Manufacturer

Supplier

Macleods Pharmaceuticals
Ltd 304 Atlanta Arcade
Marol Church Road
Andheri (East)
Mumbai 400 059
India
Tel: + 91 22 66762800
Fax: + 91 22 28216599
E-mail: vijay@macleodsPharma.com
sjadhav@macleodspharma.com
exports@macleodspharma.com

Manufacturer

Macleods Pharmaceuticals Ltd
Unit II
Plot No 25-27, Survey No 366
Premier Industrial Estate
Kachigam Daman 396 210
India
Tel: +91-22-66762800

Oxalis Labs
Village Theda, P.O. Lodhimajra
Tehsil: Baddi
Dist. Solan
Himachal Pradesh 174101
India
Tel: +91 01795350700
Email: arvind.yadav@macleodspharma.com

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>