

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.

Information for the patient

[TB406 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 [TB406 trade name] is and what it is used for
2. What you need to know before you take [TB406 trade name]
3. How to take [TB406 trade name]
4. Possible side effects
5. How to store [TB406 trade name]
6. Contents of the pack and other information

1. What [TB406 trade name] is and what it is used for

[TB406 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.

[TB406 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 [TB406 trade name]

Do not use [TB406 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 [TB406 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 [TB406 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

[TB406 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 [TB406 trade name].

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

Driving and using machines

[TB406 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 [TB406 trade name], you should not drive or use machines until you know how the medicine affects you.

3. How to take [TB406 trade name]

Take [TB406 trade name] exactly as your health care provider has told you. Always take [TB406 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 [TB406 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 [TB406 trade name].

If you have kidney disease your health care provider may tell you to take [TB406 trade name] three times per week instead of taking it daily.

Drug-susceptible tuberculosis

Children weighing less than 25 kg

Recommended doses of [TB406 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 [TB406 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 [TB406 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 [TB406 trade name] or you vomit after a dose

If you forget to take [TB406 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 [TB406 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 [TB406 trade name]

It is important that you complete the course of treatment even if you begin to feel better. If you stop taking [TB406 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 [TB406 trade name].

Taking this medicine

You can take [TB406 trade name] with food or in between meals. Try to take [TB406 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 [TB406 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, [TB406 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 [TB406 trade name]

Do not store above 30°C. Avoid excursion above 30°C.

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

Do not use this medicine after the expiry date stated on the label 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 [TB406 trade name] contains

- The active ingredient is ethambutol hydrochloride
- The other ingredients of [TB406 trade name] are silicified microcrystalline cellulose, polyvinyl pyrrolidone, crospovidone, aspartame, colloidal silicon dioxide, banana flavour and magnesium stearate

What [TB406 trade name] looks like and contents of the pack

[TB406 trade name] are white to light yellow, 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 a score line on the other side.

[TB406 trade name] are packed in

- aluminium foil on aluminium foil blister cards, each containing 10 tablets. Available in packs of 10 x 10 tablets
- aluminium foil strip packs, each containing 10 tablets. Available in packs of 10 x 10 tablets

Supplier and Manufacturer

Supplier

Cadila Pharmaceuticals Limited,
1389 Trasad Road,
Dholka– 382 225, District: Ahmedabad,
Gujarat, India
Phone: +91 2714-221481 / 221483 / 221484
Fax: +91 2714 220315
E-mail: pharmacovigilance@cadilapharma.com

Manufacturer

Cadila Pharmaceuticals Limited,
1389 Trasad Road,
Dholka– 382 225, District: Ahmedabad,
Gujarat, India
Tel: +91 2714-221481 / 221483 / 221484
Fax: +91 2714 220315
E-mail: pharmacovigilance@cadilapharma.com

For any information about this medicine, contact 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>*