

Package leaflet: Information for the user

Ethambutol 400 mg film-coated tablets (Ethambutol hydrochloride)

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 any further questions, ask your doctor or pharmacist.
- 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 are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Ethambutol Tablets are and what they are used for

The name of your medicine is Ethambutol Tablets. Ethambutol belongs to a group called antituberculosis drugs and is used for the treatment and prevention of tuberculosis, an infectious disease mainly affecting the lungs.

2. What you need to know before you take Ethambutol Tablets

Do not take Ethambutol Tablets:

- If you have sight problems
- If you are allergic (hypersensitive) to Ethambutol Hydrochloride, or 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 and/or mouth sores after taking ethambutol.

Warnings and precautions

Take special care with ethambutol:

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with ethambutol treatment. Stop taking ethambutol and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Problems with your sight

You should have your eyesight checked before taking these tablets, and if you notice any changes to your vision whilst taking these tablets, you should stop taking them and notify your doctor immediately. In the majority of cases, any changes to vision will return to normal within a few weeks/months after stopping treatment however, in rare cases, it may take longer for eyesight to recover or the changes may become permanent.

Take special care with Ethambutol if you have a history of kidney problems. Before treatment with Ethambutol you should have your kidneys checked.

If you develop symptoms suggestive of hepatitis (e.g. abdominal pain, fever, loss of appetite) or feel generally unwell, you may need your liver function tested.

Other medicines and Ethambutol Tablets

You should not take Ethambutol tablets at the same time as antacid medicine containing aluminium hydroxide (Used to treat heartburn and indigestion) as this can make Ethambutol less effective.

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without prescription

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Ethambutol occasionally causes sight problems and may present symptoms which affect the ability to drive or use machinery (e.g. numbness or paraesthesia (abnormal sensation like pins and needles) of the furthest parts of your body, disorientation). After taking your medicine you should not drive or use machinery until you know how Ethambutol affects you.

3. How to take Ethambutol Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The dosage of Ethambutol varies from person to person depending on your age, how much you weigh and whether it is being used for the treatment or for the prevention of tuberculosis.
- Patients who have Kidney problems may need blood tests so that their doctor can reduce the dose in some cases.
- Ethambutol tablets should be taken once daily.
- They should be swallowed whole with a drink of water; do not chew or crush the tablets.
- If you are not sure how many tablets to take, or when to take them, ask your pharmacist.

Adults:

- **Prevention and first time treatment:** The usual dose of Ethambutol for adults for prevention of tuberculosis or for first time treatment for tuberculosis is 15mg per kg of body weight per day.
- **Second time (or subsequent) treatment:** The usual dose of Ethambutol for adults for second time (or subsequent) treatment of tuberculosis is 25mg per kg of body weight per day for the first 60 days, reducing to 15mg per kg of body weight per day for as long as the doctor considers necessary.

Children:

- **Prevention:** The usual dose of Ethambutol for children for prevention of tuberculosis is 15mg per kg of body weight per day.
- **First, second time (or subsequent) treatment:** The usual dose of Ethambutol for children for first time treatment, second time treatment or subsequent treatment of tuberculosis is 25mg per kg of body weight per day for the first 60 days, reducing to 15mg per kg of body weight per day for as long as the doctor considers necessary.

If you take more Ethambutol Tablets than you should

If you have taken an overdose of Ethambutol tablets (that is more than the doctor has told you to) get medical help immediately, either by calling your doctor or going to the nearest hospital casualty department. Remember to take the labelled medicine bottle with you, whether there are any Ethambutol tablets left or not.

If you forget to take Ethambutol Tablets

If you forget to take a tablet you should take it as soon as you remember. However, if this is within 2 hours of your next dose you should skip the missed tablet and carry on taking the rest of your tablets as usual.

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

If you stop taking Ethambutol Tablets

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any of the following symptoms, tell your doctor immediately:

- Severe allergic reaction (e.g. difficulty in breathing, flushed appearance, agitation or an irregular heartbeat).
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

If this occurs, stop taking this medicine and contact your doctor immediately.

-Eye problems (e.g. colour blindness, eye pain, loss of vision or visual acuity).

If you notice any changes or problems with your sight, contact your doctor immediately.

Other possible side effects include:

Uncommon (may affect up to 1 in 100 people)

- High levels of uric acid in the blood (hyperuricaemia).
- Eye problems (e.g. colour blindness, eye pain, loss of vision or visual acuity).

Rare (may affect up to 1 in 1,000 people)

- Thrombocytopenia (which may result in bruising, nosebleeds, pinpoint red spots, prolonged bleeding after injury).
- Minor allergic reactions such as rashes, itching, and hives.
- Muscle weakness and wasting, pain, numbness, pins and needles sensation.

Very rare (may affect up to 1 in 10,000 people)

- Severe allergic reaction (e.g. difficulty in breathing, flushed appearance, agitation, or an irregular heartbeat).
- Blood disorders such as leucopenia, and neutropenia.
- Gout (a symptom of these conditions is joint inflammation), joint pains.
- Headache, dizziness, disorientation.
- Mental confusion, Hallucinations.
- Shortness of breath, chest pain, generally feeling unwell, fever.
- Liver failure.

- Kidney problem (lower back pain, pain or burning when passing urine, difficulty passing urine)

Not known (frequency cannot be estimated from the available data)

- Loss of appetite, feeling sick, being sick, stomach pain/upsets, diarrhoea. Liver problems (which may result in pale stools, blood in your urine or yellowing of the skin and/ or eyes).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ethambutol Tablets

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

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

100 mg:

Do not store above 25°C

400 mg:

Do not store above 25°C

Use within 60 days after first opening the HDPE bottle.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist 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 Ethambutol tablets contain

The active substance is Ethambutol. Each film-coated tablet contains 100 mg/400 mg of Ethambutol (as Ethambutol hydrochloride).

The other ingredients are:

Tablet core: Povidone, microcrystalline cellulose, crospovidone, croscarmellose sodium, colloidal anhydrous silica, purified talc, magnesium stearate, hydroxypropyl methylcellulose.

Tablet Film-coat:

100mg: Opadry AMB II White 88A180040 containing

Polyvinyl alcohol-part. Hydrolysed, talc, titanium dioxide, Glycerol esters of fatty acids, sodium lauryl sulphate.

400 mg: Opadry AMB II Grey 88A575002 containing

Polyvinyl alcohol-part. Hydrolysed, talc, titanium dioxide, mono and diglycerides, sodium lauryl sulphate, black iron oxide, brilliant blue FCF aluminum lake.

What Ethambutol tablets looks like and contents of the pack

Ethambutol 100 mg film-coated tablets are White to off-white, circular, biconvex, coated tablets plain on both sides with an approximate diameter of 7.60 mm.

Ethambutol 400 mg film-coated tablets are grey, circular, biconvex, coated tablets plain on both sides with an approximate diameter of 12.60 mm.

Ethambutol tablets are available in blister pack 10, 14, 20, 28, 30, 56, 60, 84, 90, 100 and 112 tablets and HDPE bottle pack of 1000 tablets.

Not all pack sizes may be marketed.

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