

PACKAGE LEAFLET

Package leaflet: Information for the user

Ethambutol Hydrochloride 100mg and 400mg Film-coated Tablets

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 serious, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ethambutol Tablets

- 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 functions tested.

- 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 Tablet treatment. Stop taking Ethambutol Tablet and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Ethambutol Tablets with food and drink

Ethambutol Tablets may be taken with or without food.

Pregnancy and breast-feeding

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.

Important information about Ethambutol Tablets

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Ethambutol Tablets

Always take Ethambutol Tablets exactly as your doctor has told you. You should 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 treatment for the first time:

The usual dose of ethambutol for adults for prevention of tuberculosis or first time treatment of 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 it 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 it 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 carton and blister pack with you, whether there are any Ethambutol Tablets left or not.

If you forget to take Ethambutol Tablets

If you forget to take 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 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

Keep taking the medicine for as long as your doctor has told you, even if you are feeling better. If you stop the medicine too soon, your infection may not be completely cured. You should not stop treatment unless your doctor or health care provider tells you to.

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

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). **If this occurs, stop taking this medicine and contact your doctor immediately.**
- Eye problems (e.g. colour blindness, loss of vision or visual acuity).

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

Skin and subcutaneous skin disorders:

Stop using Ethambutol Tablets and tell your doctor immediately if you notice any of the following symptoms:

- 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).

Other possible side effects include:

- High levels of uric acid in the blood (hyperuricaemia) and gout (a symptom of these conditions is joint inflammation)
- Thrombocytopenia (which may result in bruising, nosebleeds, pinpoint red spots, prolonged bleeding after injury) and other blood disorders such as leucopenia and neutropenia
- Minor allergic reactions such as rashes, itching and hives
- Muscle weakness and wasting, pain, numbness, pins and needles sensations
- Headache, dizziness, disorientation
- Mental confusion, hallucinations
- Generally feeling unwell, fever
- Shortness of breath, chest pains
- Blisters or peeling skin (Inc. following exposure to sunlight).
- Kidney problems (lower back pain, pain or burning when passing urine, difficulty passing urine)
- Other potential unwanted effects include loss of appetite, feeling sick, being sick, stomach pain/upsets, diarrhoea and liver problems (which may result in pale stools, blood in your urine or yellowing of the skin and/or eyes).

If any of the side-effects get serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

UK

The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for "MHRA Yellow Card" in the Google Play or Apple App Store

Ireland

HPRa Pharmacovigilance
 Earlsfort Terrace, IRL - Dublin 2
 Tel: +353 1 6764971, Fax: +353 1 6762517
 Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

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 carton and blister. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ethambutol Tablets contain

- The active substance is ethambutol hydrochloride. Each tablet contains either 100mg or 400mg of ethambutol hydrochloride.
- The other ingredients are

Core Tablet:

Magnesium stearate, maize starch, microcrystalline cellulose, povidone, silica colloidal anhydrous, sodium starch glycolate.

Film Coating:

Hypromellose 15cP, polydextrose, polyethylene glycol 4000, titanium dioxide.

The tablets also contain the following colourants:

100mg - Iron oxide yellow (E172).

400mg- Iron oxide black (E172), iron oxide yellow (E172).

What Ethambutol Tablets look like and contents of the pack

Ethambutol 100mg Tablets are yellow, circular biconvex film-coated tablets, plain on both sides. Ethambutol 400mg Tablets are grey circular biconvex film-coated tablets, plain on both sides. Both tablets are supplied in blister packs of 10, 14, 20, 28, 30, 56, 60, 84, 90 and 112 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Aspire Pharma (Malta) Limited
Trident Park, Notabile Gardens
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Manufacturer

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