


ETHAMBUTOL TABLETS 400mg



GENUS PHARMACEUTICALS

Ethambutol Tablets 400mg

Each tablet contains 400mg
Ethambutol Hydrochloride BP

PIP 107 5969 56 tablets *Trademark

Ethambutol Tablets 400mg also
contain E171 and E172.
To be taken by mouth.
Use as directed by your doctor.

Keep out of the sight
and reach of children.
Store below 25°C in the original pack.

MA holder:
Genus Pharmaceuticals,
Linthwaite,
Huddersfield,
HD7 5QH,
UK.

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PL 17225/0005 PM/01/903

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ethambutol 400mg Tablets Ethambutol Hydrochloride

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. What Ethambutol Tablets are and what they are used for
2. Before you take Ethambutol Tablets
3. How to take Ethambutol Tablets
4. Possible side-effects
5. How to store Ethambutol Tablets

6. Further information

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. 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 under section 6)

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 functions tested.

Taking other medicines

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 any other medicines, including medicines obtained without a 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 for advice before taking this medicine.

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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 the Ingredients of Ethambutol Tablets.

This medicine contains sucrose and sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ETHAMBUTOL TABLETS

- Always take Ethambutol Tablets exactly as your doctor has told you to. 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 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 the forgotten tablet.

4. POSSIBLE SIDE-EFFECTS

Like all medicines, ethambutol 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.**

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), Stevens-Johnson syndrome (a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and/or genitals) • 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, 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

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

5. HOW TO STORE ETHAMBUTOL TABLETS

Keep out of the sight and reach of children.

Do not take Ethambutol Tablets after the expiry date which is printed on the pack. The expiry date refers to the last day of that month.

Ethambutol Tablets should be kept in the original package, in a safe, dry place at controlled room temperature (below 25°C). Return any unused tablets to your pharmacist. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What Ethambutol Tablets contain

The active substance in Ethambutol Tablets is ethambutol hydrochloride. Other ingredients are: sucrose; gelatin 125 bloom; sorbitol solution 70%; magnesium stearate; stearic acid; Aquapolish D grey (containing hydroxypropylmethylcellulose,

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hydroxypropylcellulose, cellulose, stearic acid, talcum, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172); deionised water.

What Ethambutol Tablets look like and the contents of the pack

Ethambutol Tablets 400mg are grey coated tablets. Each bottle contains 56 tablets.

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Marketing Authorisation Holder:

Genus Pharmaceuticals, Linthwaite, Huddersfield, HD7 5QH, UK.

Manufacturer:

Custom Pharmaceuticals Limited, Conway Street, Hove, East Sussex BN3 3LW, UK.

This leaflet was last revised in August 2017.



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