

ETHAMBUTOL 100 MG TABLETS
ETHAMBUTOL 400 MG 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 your pharmacist.**
- **This medicine has been prescribed for you only. Do not pass it on to others; it may harm them, even if their symptoms are the same as yours.**
- **If you get any of the side effects, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.**

WHAT IS IN THIS LEAFLET

1. What Ethambutol Tablets are and what they are used for
2. What you need to know before you take Ethambutol Tablets
3. How to take Ethambutol Tablets
4. Possible side effects
5. How to store Ethambutol Tablets
6. Contents of the pack and other information

1. WHAT ETHAMBUTOL TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredient in your tablets is ethambutol hydrochloride, which belongs to a group of medicines called anti-tuberculosis drugs. These are used to treat and prevent tuberculosis which is an infectious disease mainly affecting the lungs.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ETHAMBUTOL TABLETS**Do not take these tablets if you:**

- **are allergic (hypersensitive)** to ethambutol, or to any of the **other ingredients** (these are listed in section 6, other information)
- have problems with your eyes or your eyesight (unless your doctor has decided it is essential).

Warnings and precautions:

Talk to your doctor or pharmacist before taking Ethambutol Tablets if you have

- **problems with your eyesight** - You should have your eyesight checked before you start taking this medicine. If you notice any changes to your vision whilst taking this medicine, you should stop taking them and you **MUST** inform your doctor straight away. In 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. Young children or people with communication difficulties should be closely monitored by their parents or carers for any signs of problems with their eyesight.

- **kidney problems** as your doctor may decide to adjust the dose of Ethambutol Tablets. Special care should be taken with Ethambutol if you have a history of kidney problems and 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.

Other medicines and Ethambutol Tablets

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

Ethambutol Tablets should not be taken at the same time as antacid medicines containing aluminium hydroxide (used to relieve heartburn and indigestion), as this can make ethambutol less effective.

Although ethambutol is not known to be affected itself by any other drugs or to affect other drugs, make sure your doctor knows if you are taking any other medicines.

Pregnancy, breast-feeding and fertility

You should not take this medicine if you are pregnant or breast-feeding, or if you are trying for a baby, unless your doctor considers it essential. Speak to your doctor before taking the tablets.

Driving and using machinery

Ethambutol can cause problems with eyesight, dizziness, disorientation or tingling/numbness in hands or feet. You should not drive or operate machinery if it has this effect on you.

This medicine contains less than 1mmol sodium (23 mg) per 100 mg and 400 mg tablet, that is to say essentially 'sodium free'.

3. HOW TO TAKE ETHAMBUTOL TABLETS

The tablets should be swallowed whole with a drink of water. They should be taken as a single dose once a day.

The doctor will decide what dose of tablets you need to take. The dose varies from person to person depending on age, weight and whether it is being used for treatment or prevention of tuberculosis.

If you suffer from any kidney problems your doctor may do blood tests to check whether you need to take a lower dose than usual.

Always take the tablets exactly as the doctor has told you. The dose will be on the pharmacist's label. If you are not sure, ask your doctor or pharmacist. Carry on

taking them for as long as you have been told unless you have any problems in which case, check with your doctor.

Adults:

For prevention and first time treatment of tuberculosis: The usual dose is 15 mg per kg of body weight each day.

Second time (or subsequent) treatment of tuberculosis: The usual dose is 25 mg per kg of body weight each day for the first 60 days, reducing to 15 mg per kg of body weight each day for as long as necessary.

Children:

For prevention of tuberculosis: The usual dose is 15 mg per kg of body weight each day.

First time, second time (or subsequent) treatment of tuberculosis: The usual dose is 25 mg per kg of body weight each day for the first 60 days, reducing to 15 mg per kg of body weight each day for as long as necessary.

Elderly:

The same dosages as for adults are usually used although reduced doses may be required in the elderly who have kidney problems; in these patients the doctor will carry out blood tests to determine the dose required.

If you take more tablets than you should

If you have accidentally taken more than the prescribed dose, contact your nearest hospital casualty department or tell your doctor or pharmacist **immediately**. Remember to take the pack and any remaining tablets with you. Symptoms of overdose include: Gastrointestinal disturbances, vomiting, fever, headache, loss of appetite, dizziness, hallucinations and/or visual disturbances.

If you forget to take a dose of Ethambutol Tablets

If you forget to take a dose, take it as soon as you remember, however, if this is within a few hours of when your next dose is due, skip the missed dose and just carry on with the normal routine. Do not take a double dose to make up for the forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

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

Some side effects can be serious.

Stop taking Ethambutol Tablets and tell your doctor straightaway if you notice the following effects:

- **sudden wheeziness, difficulty breathing, swelling of the face, eyes, lips or throat, flushed appearance, irregular heartbeat.** (These may be symptoms of a severe allergic reaction)
- **any changes or problems with your eyesight including** loss of vision, blurred vision, eye pain or colour blindness. Usually sight will return to normal after stopping treatment with ethambutol, but in rare cases the problem may take longer to return to normal or become permanent.
- **blisters or peeling of skin (including following exposure to sunlight), red or purple rash**
If you notice any changes or problems with your sight, contact your doctor immediately.

Tell your doctor straightaway if you notice any of the following effects:

- **skin rash and itching**, a condition known as Stevens-Johnson syndrome which involves a skin rash, possibly with peeling and blistering and a sore mouth; other skin problems including hard lumps, red patches often on the backs of arms and hands and blisters or peeling
- you have pale stools or your skin or whites of your eyes become yellow (as these may be signs of a liver problem)
- you develop pain in the lower back or you experience difficulty or pain in urinating (as these may be signs of a kidney problem)
- you notice any unusual bleeding, bruising or discoloured skin (as these may be signs of a blood disorder)

- you notice any changes to your vision

The following other side effects have also been reported:

Common (may affect up to 1 in 10 people)

- eye problems; inflammation of the optic nerve, loss of the sharpness of vision

Uncommon (may affect up to 1 in 100 people)

- high levels of uric acid in the blood (hyperuricaemia)

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

- numbness, pins and needles sensation
- low blood platelet count (which may result in nosebleeds, pinpoint red spots, prolonged bleeding after injury)
- minor allergic reactions such as rashes, itching and swollen, pale red bumps or plaques (wheals) on the skin

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

- hypersensitivity or anaphylactic reaction
- blood disorders such as reduction in the number of white cells in the blood and low level of neutrophils, a type of white blood cell
- dizziness, confusion, disorientation, hallucinations, headache, fever, generally feeling unwell
- joint pains, burning pain, weakness in hands and feet
- fluid in the lungs or inflammation of the lungs which may cause breathlessness, cough and raised temperature
- gout (which results in warmth, swelling, reddish discoloration, and marked tenderness of joint especially common to affect big toe)
- liver failure

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

- shaking
- stomach problems, including loss of appetite, feeling or being sick, diarrhoea, flatulence (wind), stomach pain, metallic taste and weight loss
- hepatitis, jaundice, transient increase in liver enzymes, abnormal liver function tests in patients on multiple medications

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 Yellow Card Scheme, Website: 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 out of the sight and reach of children.

Do not store above 25°C. Keep your medicine in the pack in which it was given to you. Do not transfer your medicine to another container.

Do not take this medicine after the expiry date (Exp.) stated. The expiry date refers to the last day of that month.

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

Ethambutol Tablets are available in two strengths containing either 100 mg or 400 mg ethambutol hydrochloride as the active ingredient.

The other ingredients are sodium starch glycolate, maize starch, povidone, colloidal anhydrous silica, microcrystalline cellulose, magnesium stearate and colours containing polydextrose, hypromellose, titanium dioxide (E171), macrogol and yellow iron oxide (E172); the 400 mg tablets also contain black iron oxide (E172).

What the medicine looks like and contents of the pack

Ethambutol 100 mg Tablets are yellow, round, film-coated tablets.

Ethambutol 400 mg Tablets are grey, round, film-coated tablets.

Each pack contains 56 tablets.

Marketing Authorisation Holder:

Kent Pharma UK Limited,
2nd Floor,
Connect 38,
1 Dover Place,
Ashford, Kent,
England,
TN23 1FB.

Manufacturer responsible for batch release:

Kent Pharmaceuticals Limited,
Repton Road,
Measham,
DE12 7DT,
U.K.

Date leaflet revised: 03/2023

If you would like this leaflet in a different format, please contact the licence holder at the above address.

Customer: Cadila	Designer: ABC (AWG)	Colours
Product: Ethambutol 100mg and 400mg Tablets		
Dimensions: 240mm x 320mm		
Item Code: CP.ETL.JNT.T.CD.V7P1		
Proof No and Date: 1 20 Dec 22		
Revision: MAH & Br site removal updates		
ARTWORK FOR SUBMISSION		
Supersedes: V6P2		