APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ETHAMBUTOL 400 mg PD film coated tablet

Ethambutol hydrochloride

Sugar free.

ETHAMBUTOL 100 mg ODT PD oral dispersible tablets

Ethambutol hydrochloride

Sugar free.

Contains sweetener (aspartame 20,0 mg per tablet).

This medicine is essentially ‘sodium-free’. It contains less than 1 mmol sodium (23 mg) per tablet.

Read all of this leaflet carefully before you start taking ETHAMBUTOL PD

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ETHAMBUTOL PD has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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What is in this leaflet

1. What ETHAMBUTOL PD is and what it is used for

The active ingredient in this medicine is ethambutol hydrochloride, which belongs to a group of medicines called anti-tuberculosis medicines.

ETHAMBUTOL PD is indicated for the treatment of tuberculosis in combination with other anti-tuberculosis medicines.

2. What you need to know before you take/use ETHAMBUTOL PD

Do not take ETHAMBUTOL PD:

- if you are hypersensitive (allergic) to ethambutol, or to any of the ingredients of ETHAMBUTOL PD (see section 6)
- if you have optic neuritis (inflammation of the nerve leading to the eye that may cause a complete or partial loss of vision)
- if you have severe kidney problems.

If you are caring for a child younger than 5 years of age, this child should not be administered ETHAMBUTOL PD.

Warnings and precautions

Take special care with ETHAMBUTOL PD:

- if you experience a decrease in sharpness of vision (visual acuity), tell your doctor about it, as it may be due to inflammation of the nerve leading to the eye (optic neuritis)
- if you experience changes in ability to see from one eye or both eyes, tell your doctor about it as this effect may be related to the dose and duration of treatment with ETHAMBUTOL PD. This effect is generally reversible when administration of ETHAMBUTOL PD is discontinued promptly. However, irreversible blindness has been reported. As a precaution, each eye must be tested separately and both eyes together
- if you are elderly and already suffering from impaired eyesight
- if you are the caregiver of a child, as testing of changes in sharpness of vision (visual acuity) in children may be difficult
- if you experience any changes in sharpness of vision or the ability to distinguish between colours when you start ETHAMBUTOL PD therapy for the first time or if you have been treated with ETHAMBUTOL PD for some time. Tests for sharpness of vision (visual acuity) and colour blindness (red-green discrimination) will be performed prior to the start of therapy and periodically thereafter. ETHAMBUTOL PD therapy will be stopped by your doctor, if your vision deteriorates
- if you have a history of gout, tell your doctor, as ETHAMBUTOL PD could cause gout attacks

- if you have kidney problems as your doctor may decide to adjust the dose of ETHAMBUTOL PD. 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
- 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 PD 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 PD

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

- tell your doctor if you are using any neurotoxic medicines (medicines that work on your brain)
- aluminium-containing antacids (to relieve heartburn or indigestion) interfere with the absorption of ETHAMBUTOL PD, making it less effective. Take ETHAMBUTOL PD, 4 hours after taking aluminium-containing antacids.

ETHAMBUTOL PD with food and drink

ETHAMBUTOL PD can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using ETHAMBUTOL PD.

Ethambutol is not recommended during pregnancy.

ETHAMBUTOL PD crosses the placenta and is excreted in breast milk. Breastfeeding is not recommended during ETHAMBUTOL PD treatment.

Driving and using machines

ETHAMBUTOL PD may cause visual disturbances including reduction in visual sharpness (acuity), tunnel vision (constriction of visual field), dark spots in the visual field and red-green colour blindness that may affect your ability to drive or use machines. You should not drive or operate machines if there is a change in your visual abilities.

Dizziness, disorientation, numbness and pins and needles are also among possible side effects that may affect your ability to drive or operate machinery.

It is not always possible to predict to what extent ETHAMBUTOL PD may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ETHAMBUTOL PD affects them.

3. How to take/use ETHAMBUTOL PD

Do not share medicines prescribed for you with any other person. Always use ETHAMBUTOL PD exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

ETHAMBUTOL PD comes as a tablet to be taken by mouth. It should not be used alone in initial treatment or in re-treatment.

Adults and children over 5 years of age:
Your 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.

Instructions for taking ETHAMBUTOL 100 mg ODT PD:

1. The required amount of drinking water should be poured into a small, clean drinking container such as a tumbler or cup
2. The required number of tablets should be added to the container.
3. The container should be swirled until tablets disperse completely, and the patient should drink the entire mixture immediately.

4. The container should be rinsed with an additional 10 mL of water, which the patient should drink to ensure that the entire dose is taken.

Children:

ETHAMBUTOL PD is not recommended for use in children

under 5 years.

Your doctor will tell you how long your treatment with ETHAMBUTOL PD will last. Do not stop treatment early because your condition may worsen.

If you have the impression that the effect of ETHAMBUTOL PD is too strong or too weak, tell your doctor or pharmacist.

If you take/use more ETHAMBUTOL PD than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- gastrointestinal disturbances, vomiting, fever, headache, loss of appetite, dizziness, hallucinations and/or visual disturbances.
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If you forget/use to take ETHAMBUTOL PD

If you forget to take ETHAMBUTOL PD, take as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ETHAMBUTOL PD can have side effects.

Not all side effects reported for ETHAMBUTOL PD are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while using ETHAMBUTOL PD, please consult your healthcare provider for advice.

If any of the following happens, stop using ETHAMBUTOL PD and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ETHAMBUTOL PD. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- blurred vision, unable to see the colours red and green (colour- blindness), sudden changes in vision, bleeding in the eye
- Stevens-Johnson syndrome or other serious skin disorders with blistering of the skin, mouth, eyelids and genitals, or peeling of the skin
- widespread rash, high body temperature and enlarged lymph nodes (DRESS

syndrome or drug hypersensitivity syndrome)

- jaundice - yellowing of the skin or whites of the eyes caused by liver or blood problems
- kidney problems with symptoms such as an increase or decrease in amount of urine, blood in the urine
- purple colour of skin, bleeding for a long time after injury or easy bruising, you easily pick up infections.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- gout (sudden burning pain, stiffness, swelling in a joint, usually a big toe)
- confusion about where you are (disorientation) and hallucinating
- headache, dizziness, numbness, weakness (hands and feet),

pain and tingling in the hands or feet, burning pain, feeling disorientated and tremors

- respiratory problems such as shortness of breath, cough, burning feeling in the chest
- nausea, vomiting, loss of appetite, stomach pain and diarrhoea, gas, metallic taste in mouth and upset stomach
- hives (rash with red itchy bumps), rash with small hard lesions caused by exposure to sunlight, blister-like eczema and skin eruptions (erythema

multiforme)

- joint pains
- fever and a sick feeling (malaise).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of ETHAMBUTOL PD. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store ETHAMBUTOL PD

Store all medicines out of reach of children.

Store at or below 30 °C.

Protect from heat and moisture.

Do not remove the blister from the outer carton until required for use.

HDPE containers: Keep well closed.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ETHAMBUTOL PD contains

ETHAMBUTOL 400 mg PD: The active ingredient is ethambutol hydrochloride 400 mg.

ETHAMBUTOL 100 mg ODT PD: The active ingredient is ethambutol hydrochloride 100 mg.

The other ingredients are:

ETHAMBUTOL 400 mg PD: Colloidal silicon dioxide, ethyl cellulose, hypromellose, lake of sunset yellow, magnesium stearate, maize starch, polyethylene glycol, povidone, propylene glycol, purified talc, titanium dioxide.

ETHAMBUTOL 100 mg ODT PD: Aspartame, colloidal silicon dioxide, croscarmellose sodium, crospovidone, flavour orange SD2912 (containing flavouring preparations, maltodextrin and gum acacia, and a nature-identical flavouring substance), low substituted hydroxy propyl cellulose, magnesium stearate, maize starch, microcrystalline cellulose, povidone, silicified microcrystalline cellulose and talc.

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What ETHAMBUTOL PD looks like and contents of the pack

ETHAMBUTOL 400 mg PD: Film coated tablets.

Light orange coloured, round, biconvex film coated tablets plain on both sides.

ETHAMBUTOL 100 mg ODT PD: Uncoated oral dispersible tablet

White to off-white, 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 are plain on the other side with characteristic odour.

The tablet can be divided into equal halves.

ETHAMBUTOL 400 mg PD:

Clear PVC/PVDC/aluminium blister strips of 10 tablets each, available in packs of 100 in an outer carton.

Clear PVC/PVDC/aluminium blister strips of 28 tablets, available in packs of 56 or 84 tablets in an outer carton.

Or

White round HPDE containers with a white HDPE cap containing 100 or 1 000 tablets.

ETHAMBUTOL 100 mg ODT PD:

Aluminium strip containing aluminium foil 0,04 mm as a base material and plain strip aluminium foil 0,04 mm as a lidding material.

Pack sizes: 10/30/60/90/100/120/180’s

Not all pack sizes are marketed.

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Holder of Certificate of Registration

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ETHAMBUTOL 400 mg PD:

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www.pharmadynamics.co.za

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