APPROVED CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DYNA ETHAMBUTOL 400 mg film coated tablet

Ethambutol hydrochloride

DYNA ETHAMBUTOL 400 mg is sugar-free

Read all of this leaflet carefully before you start taking DYNA ETHAMBUTOL 400 mg

- 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.
- DYNA ETHAMBUTOL 400 mg 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.

What is in this leaflet

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1. What DYNA ETHAMBUTOL 400 mg 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.

DYNA ETHAMBUTOL 400 mg is indicated for the treatment of tuberculosis in combination with other anti-tuberculosis medicines in adults and children over 12 years of age.

2. What you need to know before you take/use DYNA ETHAMBUTOL 400 mg

Do not take DYNA ETHAMBUTOL 400 mg:

- if you are hypersensitive (allergic) to ethambutol, or to any of the ingredients of DYNA ETHAMBUTOL 400 mg (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 are caring for a child younger than 5 years of age, this child should not be administered DYNA ETHAMBUTOL 400 mg.

Warnings and precautions

Take special care with DYNA ETHAMBUTOL 400 mg:

- 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

DYNA ETHAMBUTOL 400 mg. This effect is generally reversible when administration of DYNA ETHAMBUTOL 400 mg 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 DYNA ETHAMBUTOL 400 mg therapy for the first time or if you have been treated with DYNA ETHAMBUTOL 400 mg 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. DYNA ETHAMBUTOL 400 mg therapy will be stopped by your doctor, if your vision deteriorates.
- if you have a history of gout, tell your doctor, as DYNA ETHAMBUTOL 400 mg could cause gout attacks.
- if you have kidney problems as your doctor may decide to adjust the dose of DYNA ETHAMBUTOL 400 mg. 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 DYNA ETHAMBUTOL 400 mg

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 DYNA ETHAMBUTOL 400 mg, making it less effective. Take DYNA ETHAMBUTOL 400 mg, 4 hours after taking aluminium containing antacids.

DYNA ETHAMBUTOL 400 mg with food and drink

DYNA ETHAMBUTOL 400 mg 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 DYNA ETHAMBUTOL 400 mg.

Safety in pregnancy and breastfeeding has not been established.

DYNA ETHAMBUTOL 400 mg crosses the placenta and is excreted in breast milk.

Driving and using machines

DYNA ETHAMBUTOL 400 mg 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 DYNA ETHAMBUTOL 400 mg 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 DYNA ETHAMBUTOL 400 mg affects them.

3. How to take/use DYNA ETHAMBUTOL 400 mg

Do not share medicines prescribed for you with any other person. Always use DYNA ETHAMBUTOL 400 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

DYNA ETHAMBUTOL 400 mg 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 12 years:
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.

Children:

DYNA ETHAMBUTOL 400 mg is not recommended for use in children under 5 years.

Your doctor will tell you how long your treatment with DYNA ETHAMBUTOL 400 mg will last. Do not stop treatment early because your condition may worsen.
If you have the impression that the effect of DYNA ETHAMBUTOL 400 mg is too strong or too weak, tell your doctor or pharmacist.

If you take/use more DYNA ETHAMBUTOL 400 mg 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.

If you forget/use to take DYNA ETHAMBUTOL 400 mg

If you forget to take DYNA ETHAMBUTOL 400 mg, 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

DYNA ETHAMBUTOL 400 mg can have side effects.

Not all side effects reported for DYNA ETHAMBUTOL 400 mg are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while using DYNA ETHAMBUTOL 400 mg, please consult your healthcare provider for advice.

If any of the following happens, stop using DYNA ETHAMBUTOL 400 mg 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 DYNA ETHAMBUTOL 400 mg. 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

- 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) and joint pain
- 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
- low blood pressure (feeling lightheaded, dizzy and faint)
- respiratory problems such as shortness of breath, cough, burning feeling in the chest
- nausea, vomiting, loss of appetite, stomach pain and diarrhoea
- 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 pain
- fever and a sick feeling (malaise).

The following side effects have been reported but the frequency for them to occur is not known:

- tremors
- flatulence (farting), metallic taste, loss of appetite, upset stomach

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 online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8.

An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

By reporting side effects, you can help provide more information on the safety of DYNA ETHAMBUTOL 400 mg.

5. How to store DYNA ETHAMBUTOL 400 mg

Store all medicines out of reach of children.

Store at or below 30 °C

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 DYNA ETHAMBUTOL 400 mg contains

The active ingredient is ethambutol hydrochloride 400 mg.

The other ingredients are:

Colloidal silicon dioxide, ethyl cellulose, hypromellose, lake of sunset yellow, magnesium stearate, maize starch, polyethylene glycol, Povidone, propylene glycol, purified talc, titanium dioxide.

What DYNA ETHAMBUTOL 400 mg looks like and contents of the pack

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

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.

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Holder of Certificate of Registration

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