PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ETHAMBUTOL 400 mg PHARMA-Q tablets

Ethambutol hydrochloride

Contains sugar: sorbitol

Read all of this leaflet carefully before you take ETHAMBUTOL 400 mg PHARMA-Q

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ETHAMBUTOL 400 mg PHARMA-Q 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

1. What ETHAMBUTOL 400 mg PHARMA-Q is and what it is used for

ETHAMBUTOL 400 mg PHARMA-Q contains the active substance ethambutol which belongs to a group of medicines called anti-tuberculosis medicines.

ETHAMBUTOL 400 mg PHARMA-Q is used to treat tuberculosis (TB) together with other medicines.

2. What you need to know before you take ETHAMBUTOL 400 mg PHARMA-Q

Do not take ETHAMBUTOL 400 mg PHARMA-Q:

- if you are hypersensitive (allergic) ethambutol or any of the other ingredients of ETHAMBUTOL 400 mg PHARMA-Q (listed in section 6).
- if you have kidney problems.
- if you have eye disorder caused by inflammation of nerves in your eye (optic neuritis, retrobulbar neuritis).

Children and adolescents

ETHAMBUTOL 400 mg PHARMA-Q is not recommended for children under 13 years of age.

Warnings and precautions

Take special care with ETHAMBUTOL 400 mg PHARMA-Q:

- If you experience a decrease in sharpness of vision (vision acuity) tell your doctor about it, as it may be due 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 the treatment with ETHAMBUTOL 400 mg PHARMA-Q. This effect is generally reversible when administration of the medicine 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 the caregiver of a child, as testing of changes in sharpness of vision (vision 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 400 mg PHARMA-Q, therapy will be stopped by your doctor, if your vision deteriorates.
- Your doctor will check your kidney function and uric acid levels before starting your treatment with ETHAMBUTOL 400 mg PHARMA-Q.

Other medicines and ETHAMBUTOL 400 mg PHARMA-Q

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

Tell your doctor if you are taking any of the following:

- Antacid medicines that contain aluminium hydroxide. ETHAMBUTOL 400 mg PHARMA-Q should be taken 4 hours before or 4 hours after taking antacid.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ETHAMBUTOL 400 mg PHARMA-Q.

Pregnancy

ETHAMBUTOL 400 mg PHARMA-Q is not recommended in pregnancy.

Breastfeeding

Ethambutol passes into breastmilk. If you are breastfeeding, you must not take ETHAMBUTOL 400 mg PHARMA-Q.

Driving and using machines

ETHAMBUTOL 400 mg PHARMA-Q may cause problems with eyesight, dizziness, disorientation or tingling or numbness in the hands and feet. They can affect the ability to drive and to use machines.

It is not always possible to predict to what extent ETHAMBUTOL 400 mg PHARMA-Q may interfere with your daily activities. After taking ETHAMBUTOL 400 mg PHARMA-Q, you should not drive or use machinery until you know how ETHAMBUTOL 400 mg PHARMA-Q affects you.

ETHAMBUTOL 400 mg PHARMA-Q contains sorbitol

ETHAMBUTOL 400 mg PHARMA-Q contains sorbitol.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take ETHAMBUTOL 400 mg PHARMA-Q.

3. How to take ETHAMBUTOL 400 mg PHARMA-Q

Do not share medicines prescribed for you with any other person.

Always take ETHAMBUTOL 400 mg PHARMA-Q exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Usual dosage:

The dose of ETHAMBUTOL 400 mg PHARMA-Q depends on your weight and your health care provider will work out your dose.

The duration of treatment depends on the combination of medicines used together with ETHAMBUTOL 400 mg PHARMA-Q.

Kidney disease

If you have a kidney disease, your health care provider may change the dose of ETHAMBUTOL 400 mg PHARMA-Q.

If you have the impression that the effect of ETHAMBUTOL 400 mg PHARMA-Q is too strong or too weak, tell your doctor or pharmacist.

If you take more ETHAMBUTOL 400 mg PHARMA-Q than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Remember to take the pack and any remaining tablets with you.

If you miss a dose of ETHAMBUTOL 400 mg PHARMA-Q

If you miss a dose, you should take it as soon as you remember. However, if it is nearly time for the next dose, you should skip the missed dose and take your next dose at the usual time. A dose should not be doubled to make up for a missed dose.

If you stop taking ETHAMBUTOL 400 mg PHARMA-Q

You should keep taking the medicine for as long as your health care provider tells you to do so, even if you feel better. If the medicine is stopped too soon, the infection may not be completely cured. Treatment should not be stopped unless your health care provider says so.

4. Possible side effects

ETHAMBUTOL 400 mg PHARMA-Q can have side effects.

Not all side effects reported for ETHAMBUTOL 400 mg PHARMA-Q are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ETHAMBUTOL 400 mg PHARMA-Q, please consult your health care provider for advice.

If any of the following happens, stop taking ETHAMBUTOL 400 mg PHARMA-Q and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, lips, mouth or throat which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting;
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS).

These are all very serious side effects. If you have them, you may have had a serious reaction to ETHAMBUTOL 400 mg PHARMA-Q. 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, inability to see red-green, sudden changes in vision, bleeding in the eye;
- kidney problems with symptoms of lower back pain, burning or difficulty when you pass urine or blood in your urine, deterioration of kidney function (interstitial nephritis, nephrotoxicity);
- liver problems which may result in pale stools, dark urine, or make your skin or eyes look slightly yellow (jaundice).

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

Tell your doctor if you notice any of the following:

Less frequent

- Thrombocytopenia, leucopenia, neutropenia,
- reduced levels of platelets and white blood cells in the body (eosinophilia),
- high levels of uric acid in the blood (hyperuricaemia),
- a result of damage to the nerves outside of the brain and spinal cord (peripheral

neuropathy), numbness, headache, dizziness,

- tingling, 'pins-and-needles' and numbness,
- rash and prickling (paraesthesia) weakness (hands and feet), burning pains, disorientation, involuntary body movements (tremor),
- decreased visual acuity, loss of vision, scotoma, colour blindness, visual disturbance, visual field defect, eye pain,
- inflammation of the lungs (pneumonitis, pulmonary infiltrates, with or without eosinophilia),
- decreased/loss of appetite (anorexia), nausea, vomiting, abdominal pain, diarrhoea,
- excess amount of air/gas in the stomach (flatulence), metallic taste,
- hepatic reactions with hepatitis, yellowing pigmentation of skin and eyes (jaundice),
- abnormal liver function test values, and very rarely hepatic failure,
- joint pains,
- general feeling of discomfort, illness (malaise), raised body temperature or fever (pyrexia).

Frequency unknown

- Pain or swelling in your joints (especially big toe) with tender hot skin over effected joints (gout),
- mental confusion, disorientation, seeing or hearing things that are not really there (hallucinations).

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, pharmacist or nurse. You can also report

adverse reactions 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 400 mg PHARMA-Q.

5. How to store ETHAMBUTOL 400 mg PHARMA-Q

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Keep the blister in the outer carton until required for use.
- Do not use after the expiry date stated on the label OR 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 400 mg PHARMA-Q contains

- The active substance is ethambutol. Each ETHAMBUTOL 400 mg PHARMA-Q film-coated tablet contains ethambutol hydrochloride 400 mg.

  Contains sugar: sorbitol 2,8 mg per tablet.
- The other ingredients are:

  Core: Dibasic calcium phosphate, gelatin, magnesium stearate, maize starch and sorbitol.

  Coating: Ethyl cellulose, hydroxypropyl methylcellulose, macrogol/PEG and titanium dioxide.

What ETHAMBUTOL 400 mg PHARMA-Q looks like and contents of the pack

ETHAMBUTOL 400 mg PHARMA-Q tablets are white to off white, smooth, round, biconvex, film-coated tablets, plain on both sides.

ETHAMBUTOL 400 mg PHARMA-Q tablets are packed in PVC-PVDC/Alu blister packs in a cardboard carton.

Pack size: 1 blister of 28 tablets or multiple blisters may be packed in a carton (24 blisters of 28 tablets).

Holder of Certificate of Registration

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Access to the corresponding Professional Information

https://www.pharmaq.co.za