

MYAMBUTOL®

Ethambutol tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MYAMBUTOL. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking MYAMBUTOL against the benefits this medicine is expected to have for you.

If you have any questions about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What MYAMBUTOL is used for

The name of your medicine is MYAMBUTOL. It contains the active ingredient ethambutol.

MYAMBUTOL is an antibiotic which is used to treat all forms of tuberculosis (including tuberculosis of the lung, skin, genital tract, urinary tract, bone and joint, eye and the brain). Importantly, MYAMBUTOL will not cure any other bacterial, viral or fungal diseases.

Your doctor may have prescribed MYAMBUTOL for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is available only with a doctor's prescription.

MYAMBUTOL is not addictive.

Before you take it

When you must not take it:

Do not take MYAMBUTOL if:

- **you have ever had an allergic reaction to ethambutol, or any of the ingredients listed at the end of this leaflet**
Some of the symptoms of an allergic reaction to an ethambutol may include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.
- **the expiry date (EXP) printed on the pack has passed.**
It may have no effect at all, or worse, an entirely unexpected effect, if you take it after the expiry date.
- **the packaging is torn or shows signs of tampering. If this is the case, take the tablets back to your pharmacist.**

Before you start to take it

You should notify your doctor if you have or have had any eye problems as MYAMBUTOL may affect your eyesight. If you feel your eyesight is being affected (for example your vision becomes blurred) please consult your doctor immediately.

If your daily dose is 15 mg/kg of bodyweight or more, you should arrange with your doctor to have monthly eye examinations.

You must tell your doctor if you have any other medical problems, especially kidney disease or gout.

The dose of MYAMBUTOL may need to be changed for you.

There is no evidence of any harmful effects to unborn babies when MYAMBUTOL is taken by pregnant women, however if you are pregnant you must inform your doctor.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

There may be interference between MYAMBUTOL and some other medicines. These medicines may be affected by MYAMBUTOL or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking MYAMBUTOL.

How to take it

MYAMBUTOL will be prescribed with other anti-tuberculosis drugs. Your doctor will decide on the best combination of drugs for you to take.

MYAMBUTOL tablets should be taken once every 24 hours with or without food.

The size of the dose to be taken will depend on whether you have previously received treatment for tuberculosis. It also depends on your bodyweight.

It can take up to 2 years of treatment with MYAMBUTOL to cure you of tuberculosis. It is important that you keep taking the medicine for the full time of treatment. Do not stop taking it if you start feeling better. You must have regular checkups.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

Initial Treatment

If you **have not** been treated for tuberculosis before, the usual dose is 15 mg/kg of bodyweight of MYAMBUTOL to be taken as a single dose once every 24 hours.

Re-Treatment

If you **have** been treated for tuberculosis before, the usual dose is 25 mg/kg of bodyweight of MYAMBUTOL to be taken as a single dose, once every 24 hours. After 60 days the dose will be lowered to 15 mg/kg of bodyweight.

These dosages may be changed by your doctor.

Take MYAMBUTOL tablets with a glass of water.

How long to take it

Continue taking it until your doctor tells you to stop.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

Do not try to make up for missed doses by taking more than one dose at a time.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken too much MYAMBUTOL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do:

If you are about to start taking any new medicines, tell your doctor or pharmacist that you are taking MYAMBUTOL.

If you become pregnant while taking MYAMBUTOL, tell your doctor immediately.

Things you must not do:

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use MYAMBUTOL to treat any other medical complaints unless told to by your doctor.

Things to be careful of:

Only use MYAMBUTOL at the times and doses recommended by your doctor.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MYAMBUTOL.

MYAMBUTOL is effective in most people, but may have unwanted side effects in some. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

About 3% of patients treated with MYAMBUTOL find that their vision becomes blurred. This effect however is generally reversible if the treatment is stopped promptly. If you feel you have had any deterioration in your eyesight since starting MYAMBUTOL please contact your doctor immediately.

MYAMBUTOL may cause allergic reactions, dermatitis, pain in the joints, loss of appetite, nausea, vomiting, upset stomach, fever, headache, dizziness, mental confusion, disorientation, possible hallucinations and numbness and tingling in the feet and hands. MYAMBUTOL may aggravate gout.

Medicines can have different effects on different people. The above list of side effects may be incomplete.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you do not understand anything in this list.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using it

Storage

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep MYAMBUTOL in a cool, dry place where it stays below 25°C. Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking MYAMBUTOL, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

MYAMBUTOL is supplied as either a 100 mg or 400 mg tablet in a white plastic bottle in two pack sizes; 56's and 100's.

What it looks like

MYAMBUTOL 100 mg tablets are round, glossy and yellow with no markings.

MYAMBUTOL 400 mg tablets are round and non-glossy white to off white with no markings.

Ingredients

MYAMBUTOL 100 mg tablets contain 100 mg of ethambutol hydrochloride as the active ingredient. It also contains:

- Sucrose
- Gelatin
- Sorbitol solution
- Magnesium stearate
- Stearic acid
- Shellac
- Purified talc
- Quinoline yellow CI47005
- Povidone
- Acetylated monoglyceride

MYAMBUTOL 400 mg tablets contain 400 mg of ethambutol hydrochloride as the active ingredient. It also contains:

- Calcium hydrogen phosphate
- Gelatin
- Sorbitol
- Magnesium Stearate
- Maize starch
- Ethyl cellulose

- Hypromellose
- Polyethylene glycol
- Titanium dioxide

Manufacturer

MYAMBUTOL is supplied in Australia by:

Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

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Australian Registration Numbers:

MYAMBUTOL 100 mg tablets - AUST R 47887

MYAMBUTOL 400 mg tablets - AUST R 147246