

PATIENT INFORMATION LEAFLET

ETHAMBUTOL* 400mg TABLETS (Ethambutol hydrochloride)

WHAT YOU SHOULD KNOW ABOUT ETHAMBUTOL TABLETS

This leaflet provides important information about your medicine. Please read it carefully before you start taking ETHAMBUTOL Tablets. If you have any questions, or there is anything you do not understand, ask your doctor or pharmacist (chemist). Keep this leaflet while you are taking ETHAMBUTOL Tablets, you may want to read it again.

WHAT IS IN ETHAMBUTOL TABLETS?

ETHAMBUTOL Tablets contain 400mg ethambutol hydrochloride in each film-coated tablet. ETHAMBUTOL belongs to a group called antituberculous drugs.

Other ingredients in ETHAMBUTOL Tablets are: Sucrose, gelatin 125 bloom, sorbitol solution 70%, magnesium stearate, stearic acid, polydextrose, hypromellose, macrogol 4000, titanium dioxide (E171), iron oxide yellow (E172) and iron oxide black (E172).

The licence holder is: Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland.

The manufacturer is: Wyeth Laboratories, New Lane, Havant, Hants PO9 2NG, England.

ETHAMBUTOL Tablets are licensed in bottles of 56, 100 and 500 grey film-coated tablets.

ETHAMBUTOL Tablets are supplied in bottles of 56 grey film-coated tablets.

WHAT CAN ETHAMBUTOL TABLETS BE USED TO TREAT?

ETHAMBUTOL Tablets are used for the treatment and prevention of tuberculosis, an infectious disease mainly affecting the lungs.

BEFORE TAKING THIS MEDICINE

If the answer to any of the following questions is **"YES"** you should talk to your doctor before taking any tablets as they may not be suitable for you:

- do you have sight problems?

- are you pregnant, breast feeding or trying for a baby ?
- have you ever had an allergic reaction to any of the ingredients in ETHAMBUTOL TABLETS (see “What is in ETHAMBUTOL TABLETS” above)?
- do you have kidney or liver problems ?
- are you taking any other medicines or tablets including any that you have bought without a prescription (like aspirin or an antacid)?
- do you have an intolerance to some sugars?

HOW AND WHEN TO TAKE ETHAMBUTOL TABLETS

Always take the number of tablets your doctor has told you to take. This information will also be on the pharmacist's label.

The dose of ETHAMBUTOL varies from person to person depending on your age, how much you weigh and whether it is for the treatment or prevention of tuberculosis.

The usual daily dosage for adults is 15 - 25 mg for each kilogram that you weigh given as a single dose.

The usual daily dosage for children is 20 (15-25) mg for each kilogram that you weigh given as a single dose.

Dosing in infants less than 3 months is not recommended.

ETHAMBUTOL Tablets are taken once daily. They should be swallowed whole with a drink of water; do not chew or crush the tablets. If you are not sure how many tablets to take or when to take them ask your pharmacist.

WHAT TO DO IF YOU FORGET TO TAKE A TABLET

If you do forget to take a tablet you should take it as soon as you remember. However, if this is within 2 hours of your next dose you should skip the missed tablet and carry on taking the rest of your tablets as usual. **Do not take a double dose of tablets to make up the missed dose.**

WHAT TO DO IF YOU TAKE TOO MANY TABLETS

If you have taken an overdose of ETHAMBUTOL Tablets (that is more tablets than the doctor has told you to) get medical help **immediately**, either by calling

your doctor or going to the nearest hospital casualty department. Remember to take the labelled medicine bottle with you, whether there are any ETHAMBUTOL Tablets left or not.

AFTER TAKING THIS MEDICINE

Like all medicines, ETHAMBUTOL may cause unwanted effects or side effects in some people. Most people do not get side effects when they take ETHAMBUTOL, but if you experience any of the symptoms described below or if you experience any symptoms not listed, please contact your doctor or pharmacist.

If you notice any changes or problems with your sight, contact your doctor immediately. Ethambutol has occasionally caused sight problems. In the majority of cases these will return to normal after stopping treatment. However in rare circumstances, the problem may take longer to heal or become permanent.

ATTENTION: Because ETHAMBUTOL occasionally causes sight problems you should not drive or use machinery, unless you are advised by your doctor that it is safe to do so.

Rarely ETHAMBUTOL can cause allergic reactions including skin rash and itching. Extremely rare is a severe allergic reaction known as an anaphylactoid reaction, which is characterised by difficulty in breathing, a flushed appearance, agitation or an irregular heartbeat. Rarely, ETHAMBUTOL can also cause a condition known as thrombocytopenia which may result in a purple rash, bruising and prolonged bleeding following injury. ETHAMBUTOL can also cause other blood disorders. You should consult your doctor if you develop a fever. If you experience shortness of breath, swelling or another symptom of a serious allergic reaction, contact your doctor immediately.

Other unwanted effects include: dizziness; numbness; burning or prickling feeling (pins and needles); skin problems including hard lumps, red patches often on the backs of arms and hands, and blisters or peeling; pain or swelling in your joints; gut and stomach problems such as loss of appetite, feeling sick, vomiting, and diarrhoea; and liver problems which may result in pale stools, blood in your urine, or make your skin or eyes look slightly yellow.

Extremely rarely, ETHAMBUTOL can affect the kidneys. If you have pain in your lower back, pain or burning when you pass urine, or difficulty in passing urine, you should contact your doctor.

STORING YOUR MEDICINE

