Package Leaflet: Information for the user

Ethambutol Atb 250 mg film-coated tablets
Ethambutol hydrochloride

Ethambutol Atb 400 mg film-coated tablets
Ethambutol hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Ethambutol Atb is and what it is used for

Ethambutol Atb is used in the treatment of tuberculosis. Tuberculosis is a contagious infectious disease caused by *Mycobacterium tuberculosis*, also known as Koch's bacillus.
Ethambutol is indicated in the following forms of tuberculosis:
- pulmonary tuberculosis (symptoms: fever, predominantly evening rise of temperature, fatigue,
- weight loss, night sweats, cough with or without sputum, sometimes bloody sputum, shortness of breath, especially with exertion);
- extra-pulmonary tuberculosis (the infection spreads outside the lungs);
- tuberculous meningitis (affecting the meninges).

Ethambutol should only be used in conjunction with other antituberculosis agents and antibacterial chemotherapy for tuberculosis (germs develop resistance after monotherapy), both in the primary treatment and re-treatment.

Ethambutol is included in first-time re-treatment therapy.

2. What you need to know before you take Ethambutol Atb

Do not take Ethambutol Atb
- if you are hypersensitive (allergic) to ethambutol or any of the other ingredients of Ethambutol Atb (see section 6).

- if you have an inflammation of the optic nerve (optic neuritis).

Warnings and precautions
Talk to your doctor or pharmacist before taking Ethambutol Atb.
Ophthalmological examination should be performed prior to therapy with ethambutol - visual acuity, vision field, colour vision, optic fundus; ophthalmological examination will be effected at regular intervals during the treatment. Notify your doctor immediately if visual disturbances occur during the treatment with ethambutol. Tell your doctor if:
- you suffer from kidney disease (dose should be adjusted). If renal function cannot be monitored, it is recommended to avoid ethambutol administration.
- you have ocular lesions or in case of other risk situations – alcoholics, tobaccos, diabetics, concomitant use of toxic medicines for retina.
- increased serum concentration of uric acid or symptoms of gout.

Children
Ethambutol is not recommended at young ages as children might be less likely to report ocular toxicity. The usual dose of ethambutol for children over 5 years old is 15 mg per kg of body weight per day.

Other medicines and Ethambutol Atb
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Notify your doctor if you take: aluminium hydroxide, other medicines with toxic risk for optic nerve and retina: chlorpromazine, phenothiazine, and other thiazines, digitalis, chloramphenicol.
Concomitant use of disulfiram increases the risk of ocular toxicity.

Ethambutol Atb with food, drink and alcohol
Avoid alcoholic beverages while using ethambutol.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
During pregnancy and breast-feeding the doctor will consider the benefit of treating you with ethambutol against the risk to your baby.

Driving and using machines
Ethambutol may cause side effects that can impair your ability to drive and to use machines.

3. How to take Ethambutol Atb

Always take this medicine exactly as your doctor or pharmacist told you. You should check with your doctor or pharmacist if you are not sure.

Tuberculosis treatment is planned as recommended by the national therapeutic programs. Ethambutol Atb is orally administered.

Use in adults:
The usual dose of ethambutol is of 15- 25 mg per kg of bodyweight per day (not more than 1.6 g/day), 7 times a week, or 30-50 mg per kg of bodyweight per day (not more than 2 g/day), 3 times a week.

Use in children:
Ethambutol will be administered only after close evaluation of risk/benefit ratio in patients whose side effects on visual acuity cannot be accurately determined (see section Warnings and precautions).

The usual dose of ethambutol is of 15 - 25 mg per kg of bodyweight daily. The product shall be administered orally, as single dose.

Renal failure
Caution is recommended in patients with renal failure.

Hepatic failure
It is not necessary to adjust doses in patients with hepatic failure.

Method of administration
Film-coated tablets will be administered orally, in a single dose, under direct medical monitoring within treatment period.
The duration of antituberculous therapy depends on the regimen chosen, the patient's clinical and radiographical responses, smear and culture results, and susceptibility studies of *Mycobacterium tuberculosis* isolated from the patient.
If therapy is discontinued, the treatment schedule should be extended to a later completion date depending on the length of the interruption, the time during therapy or the patient's status.

If you take more Ethambutol Atb than you should

If you have accidentally taken too many film-coated tablets of Ethambutol Atb, more than recommended or if someone accidentally swallows your medicines, immediately contact your doctor or the nearest hospital emergency department for further advice. Remember to take the rest of filmcoated tablets with you.

If you forget to take Ethambutol Tablets

Do not take a double dose to make up for a forgotten dose.

If you stop taking Ethambutol Atb

Keep taking Ethambutol Atb even if you are feeling better, only your doctor recommended you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common: visual disturbances due to optic neuritis (retrobulbar neuritis). They can be unilateral or bilateral. Typical initial signs include impairment of colour vision (red-green blindness) and constriction of visual field (central or peripheral scotoma). These changes are often reversible upon discontinuation of therapy. To avoid development of irreversible optic atrophy, visual acuity should be regularly monitored.
Uncommon: increased plasmatic concentration level of uric acid Rare:
transient skin rash, itching, urticaria
Very rare: thrombocytopenia, leukopenia (allergic), neutropenia with eosinophilia, hypersensitivity reactions, anaphylactic reactions, gout, photosensitive lichenoid eruptions, bullous dermatitis, StevensJohnson syndrome, epidermal necrolysis, interstitial nephritis.

Not known: confusion, disorientation, hallucination, sensation of tingling of the skin, especially in the legs, dizziness, headache, tremor, pneumonia, extrinsic allergic alveolitis, nausea, vomiting, loss of appetite, flatulence, abdominal pain, diarrhoea, hepatitis, jaundice, transient increases in liver enzymes, hepatic failure, fever, and malaise.

Frequency categories are derived according to the following conventions:
Very common: may affect more than 1 user in 10 Common:
may affect less than 1 in 10 users
Uncommon: may affect less than 1 in 100 users
Rare: may affect less than 1 in 1,000 users
Very rare: may affect less than 1 in 10,000 users
Not known: cannot be estimated from the available data

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system whose details are published on website of National Agency for Medicines and Medical Devices http://www.anm.ro. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ethambutol Atb

Keep out of the sight and reach of children.

Store below 25 °C, in the original package.

Do not take Ethambutol Atb after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ethambutol Atb contains

- Active substance is ethambutol hydrochloride. Each film-coated tablet contains 250 mg of ethambutol hydrochloride.
- The other ingredients are: *core*: microcrystalline cellulose type 101, povidone, microcrystalline cellulose type 102, partially pregelatinized maize starch, colloidal anhydrous silica, magnesium stearate; *film*: partially hydrolysed polyvinyl alcohol, titanium dioxide (E 171), macrogol (PEG 3350), talc, iron oxide, red (E 172).

- Active substance is ethambutol hydrochloride. Each film-coated tablet contains 400 mg of ethambutol hydrochloride.
- The other ingredients are: *core:* microcrystalline cellulose type 101, povidone, microcrystalline cellulose type 102, partially pregelatinized maize starch, colloidal anhydrous silica, magnesium stearate; *film:* partially hydrolysed polyvinyl alcohol, titanium dioxide (E 171), macrogol (PEG 3350), talc.

What Ethambutol Atb looks like and contents of the pack
Pink, round, biconvex film-coated tablets with 12 mm diameter.
White, round, biconvex film-coated tablets with 13 mm diameter.

It is available in folding carton with 2 PVC/Al or cardboard box with 150 PVC/Al blisters of 10 film-coated tablets.

Marketing Authorisation Holder and Manufacturer
Antibiotice SA
1 Valea Lupului Street, 707410 Iaşi, Romania

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:
Romania
ANTIBIOTICE SA

This leaflet was last revised in June 2015.

Detailed information on this medicine is available on the web site of National Agency for Medicines and Medical Devices http://www.anm.ro