

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Ethionamide 250 mg Tablets*

Read all of this leaflet carefully before you start taking 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, health care provider 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, health care provider or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Ethionamide 250 mg Tablets is and what it is used for.
2. What you need to know before you take Ethionamide 250 mg Tablets.
3. How to take Ethionamide 250 mg Tablets.
4. Possible side effects.
5. How to store Ethionamide 250 mg Tablets.
6. Contents of the pack and other information.

1. WHAT ETHIONAMIDE 250 MG TABLETS IS AND WHAT IT IS USED FOR

Ethionamide is used in combination with other antituberculosis agents for the treatment of all forms of tuberculosis caused by *Mycobacterium tuberculosis*.

Ethionamide is only used as a second line antimycobacterial drug when resistance to or toxicity from first-line drugs has developed.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ETHIONAMIDE 250 MG TABLETS

Do not take Ethionamide 250 mg Tablets:

- if you are hypersensitive (allergic) to ethionamide or any of the other ingredients of Ethionamide 250 mg Tablets (see section 6. What Ethionamide 250 mg Tablets contains),
- if you have severe liver disease.

Warnings and precautions:

Always take Ethionamide 250 mg Tablets together with other antituberculosis drugs that your doctor or health care provider prescribes you.

If you develop clinical symptoms suggesting an injury of the liver, such as loss of appetite, nausea, jaundice (yellowing of the skin and eye white), dark urine, discoloured stools, pain and tenderness in the upper right abdomen, tell your doctor immediately.

If you experience rash or fever (possible signs of an allergic reaction), tell your doctor or health care provider immediately.

* Trade names are not prequalified by WHO. This is under local drug regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Your doctor or health care provider will regularly monitor your blood sugar, your thyroid function and your visual acuity throughout therapy with Ethionamide 250 mg Tablets because ethionamide may lead to alterations (see “Undesirable effects”).

Your doctor may prescribe a certain vitamin, called pyridoxine, for you to be taken concomitantly with Ethionamide 250 mg Tablets. This medicine may reduce the risk of developing nerve damage.

It is important that your doctor or health care provider knows about all your symptoms even when you think they are not related to tuberculosis infection.

Other medicines and Ethionamide 250 mg Tablets

Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. These may affect the action of Ethionamide 250 mg Tablets, or Ethionamide 250 mg Tablets may affect their action.

Ethionamide may interact with isoniazid and rifampicin and may make side effects worse.

Ethionamide 250 mg Tablets should not be taken with large amounts of alcohol.

Ethionamide 250 mg Tablets with food and drink

Ethionamide 250 mg Tablets may be taken with or without food. Intake with food may reduce gastrointestinal side effects.

Pregnancy and breast-feeding

You should avoid becoming pregnant while on treatment with Ethionamide 250 mg Tablets. If you become pregnant, or are planning to become pregnant, you must contact your doctor or health care provider to discuss the potential benefits and risks of your tuberculosis therapy to you and your child.

It is not known whether ethionamide is excreted into human milk. If continuation of breast-feeding during Ethionamide 250 mg Tablets treatment is deemed necessary, your baby should be closely monitored for side effects of ethionamide (see section 4.8).

Driving and using machines

Ethionamide may cause side effects such as drowsiness or headache, that can impair your ability to drive and to use machines.

3. HOW TO TAKE ETHIONAMIDE 250 MG TABLETS

Always take Ethionamide 250 mg Tablets exactly as your doctor or health care provider told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

Your doctor will assign the dose of Ethionamide 250 mg Tablets appropriate for you. The following information includes only the average doses of this medicine. If your prescribed dose is different, do not change it unless your doctor or health care provider tells you to do so.

For adults the usual daily dose is two to four tablets (500 mg to 1 g daily), depending on body weight and tolerance. The daily dose can be taken either at a single occasion or split up in two doses over the day to improve tolerability. Your doctor may instruct you to take one tablet on the first day and then gradually increase the dose over a number of days, until you reach the target dose. Ethionamide 250 mg Tablets may be taken with or without food. Intake with food may improve gastrointestinal tolerability.

Children:

For children the dose must be determined by the doctor that prescribes the drug. Doses of 15-20 mg/kg of body weight per day have been recommended. The dose can be taken either at a single occasion or split up in two doses over the day to improve tolerability.

If you have severe liver disease you must not take ethionamide (see “Do not take Ethionamide 250 mg Tablets”).

No dose adjustment is necessary if you have a kidney disease.

If you take more Ethionamide 250 mg Tablets than you should

If you have taken too many tablets or if someone accidentally swallows some, there is no immediate danger. However, you should contact your doctor, health care provider or the nearest hospital emergency department for further advice.

If you forget to take Ethionamide 250 mg Tablets

If you accidentally miss a dose and notice within 6 hours take the missed dose as soon as possible. Take the next regular dose as scheduled. If you notice later, then simply take your normal dose when the next one is due. Do not take a double dose to make up for forgotten individual doses.

If you stop taking Ethionamide 250 mg Tablets

Keep taking the medicine for as long as your doctor has told you, even if you are feeling better. If you stop the medicine too soon, your infection may not be completely cured.

You should not stop treatment unless your doctor or health care provider tells you to.

If you have any further questions on the use of this product, ask your doctor or health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ethionamide 250 mg Tablets can cause side effects, although not everybody gets them. When treating tuberculosis, it is not always possible to differentiate between unwanted effects caused by Ethionamide 250 mg Tablets, or those caused by any other medicines you may be taking at the same time.

For this reason, it is important that you inform your doctor or health care provider of any change in your health.

The *most commonly* reported side effects (greater than 1 in 10 patients treated) are stomach discomfort, abdominal pain, loss of appetite, vomiting, diarrhoea, and nausea. The frequency depends on the dose and duration of therapy.

Furthermore, increased liver enzymes measured in the blood (serum transaminases) have been reported very commonly.

Other *common* side effects (greater than 1 in every 100 patients treated) are headache, dizziness, drowsiness, general weakness, feeling of pins and needles (paraesthesia), inflammation of the liver (hepatitis) and yellowing of the skin.

The following side effects have been reported in patients treated with ethionamide. However, frequency estimates for these effects are not available:

Decrease of platelets (blood cells important for blood clotting), metallic taste and sulphurous belching, increased salivation, taste disorders, a so called Pellagra-like syndrome (a condition presenting with diarrhoea, skin inflammation and impaired brain function, caused by a lack of niacin, a certain vitamin), thyroid underfunction, raised sugar in the blood, psychotic reactions (hallucinations, abnormal thinking, personality changes), low blood pressure (especially after standing up), altered brain function and/or structure (encephalopathy), tingling in the limbs, altered sense of smell, rash (red, raised or itchy), urticaria, acne, sensitivity to light (photosensitivity), inflammation of mucous lining (cheeks, gums, tongue, lips, throat), hair loss, red or purple discolouration on the skin (purpura), breast enlargement in male patients, menstrual disturbance, impotence, visual disturbance (blurred or double vision, complete or partial loss of vision), damage to the ear (e.g. dizziness, hearing loss, tinnitus), rash and fever.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or health care provider or pharmacist as soon as possible.

5. HOW TO STORE ETHIONAMIDE 250 MG TABLETS

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Do not use Ethionamide 250 mg Tablets after the expiry date which is stated on the label 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 Ethionamide 250 mg Tablets contains

The active ingredient is 250 mg ethionamide.

The other ingredients are:

Core tablet: Colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose, polysorbate 80, povidone and sodium starch glycolate.

Seal coating: Hypromellose and polyethylene glycol.

Film coating (Opadry 02F83057 Orange): FD&C yellow #6/sunset yellow FCF aluminium lake, hypromellose, polyethylene glycol, talc and titanium dioxide.

What Ethionamide 250 mg Tablets looks like and contents of the pack

Orange coloured, circular, biconvex film-coated tablets plain on both sides.

The tablets should not be divided.

Supplier

Micro Labs Limited
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Bangalore 560 001
Karnataka
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and Manufacturer

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This leaflet was prepared in. July 2013.

Section 6 was updated in April 2020.

Detailed information on this medicine is available on the World Health Organization (WHO) web site:
<https://extranet.who.int/prequal/>.