

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[TB242 trade name][†]
Ethionamide

*The warnings and instructions in this leaflet are intended for the person taking the medicine.
If you are a parent or carer responsible for giving the medicine to someone else such as a child,
you will need to apply the instructions accordingly.*

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 questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours..
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [TB242 trade name] is and what it is used for
2. What you need to know before you take [TB242 trade name]
3. How to take [TB242 trade name]
4. Possible side effects
5. How to store [TB242 trade name]
6. Contents of the pack and other information

1. What [TB242 trade name] is and what it is used for

[TB242 trade name] is a medicine used to treat tuberculosis (TB), an infection caused by bacteria called *Mycobacterium tuberculosis*. It is always given together with other medicines to treat tuberculosis. Your healthcare provider has chosen the combination that is right for your condition.

[TB242 trade name] contains the active substance ethionamide. It stops the bacteria multiplying and can kill them by preventing the bacteria from building their cell wall.

2. What you need to know before you take [TB242 trade name]

Do not take [TB242 trade name]:

- if you are hypersensitive (allergic) to ethionamide, to protionamide or any of the other ingredients of [TB242 trade name] (see section 6, “What [TB242 trade name] contains”).
- if you have severe liver disease.

Warnings and precautions:

Always take [TB242 trade name] together with other tuberculosis medicines that your health care provider has asked you to take.

Speak with your health care provider straightaway if you:

- lose your appetite
- get nausea (feel sick)
- have yellowing of your skin or the white parts of your eyes

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- pass dark urine
- pass stools that are clay-coloured (or are red or black)
- have belly pain, usually on the right side and near the chest

These are signs of a problem with your liver, which can become serious.

Speak with your health care provider straightaway if you get problems with your eyes (such as eye pain, blurred vision, colour blindness or trouble seeing), numbness, tingling or pain in your hands or feet, unusual bruising or bleeding, swollen breasts (in men), mental changes such as depression, confusion or feeling angry or irritable.

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

Your health care provider will regularly check your blood sugar, blood tests for your thyroid function and your vision during treatment with [TB242 trade name].

Your health care provider may ask you to take pyridoxine (vitamin B6) during treatment with [TB242 trade name]. This vitamin can prevent nerve damage, which is a side effect of [TB242 trade name]. Suggested dose of pyridoxine for adults is 100 mg daily and the dose for children is usually between 10 and 50 mg daily, depending on their weight.

Tell your health care provider about all your symptoms even if you think they are not caused by the tuberculosis infection or your treatment.

Other medicines and [TB242 trade name]

Tell your health care provider if you are taking or have recently taken any medicines, including medicines obtained without prescription. Some medicines can change how well [TB242 trade name] works, or [TB242 trade name] may change the effect of other medicines you take.

[TB242 trade name] may make the side effects of isoniazid and rifampicin worse.

Do not drink large amounts of alcohol during your treatment with [TB242 trade name].

[TB242 trade name] with food and drink

You can take [TB242 trade name] with food or between meals. However, taking it with food may reduce side effects on your gut.

Pregnancy and breast-feeding

You should not become pregnant while on treatment with [TB242 trade name]. If you become pregnant, or are planning to become pregnant, you must contact your health care provider to discuss the effect on your treatment for tuberculosis and on your baby.

It is not known if ethionamide passes into your milk if you are breast feeding. Your baby should have regular checks for ethionamide side effects if you need to breast-feed during [TB242 trade name] treatment.

Driving and using machines

Ethionamide may cause side effects, such as drowsiness and headache, that can interfere with driving and using machines.

Important information about some of the ingredients of [TB242 trade name]

Each tablet contains FD&C yellow #6/sunset yellow FCF aluminium lake, which may cause allergic reactions.

3. How to take [TB242 trade name]

Always take [TB242 trade name] exactly as your health care provider has told you. Check with your health care provider if you are not sure.

Your health care provider has worked out the right dose of [TB242 trade name] for you. The following information includes the usual doses of this medicine. If your dose is different, do not change it unless your health care provider tells you to do so.

You can take [TB242 trade name] with food or between meals.

Adults

For adults, the usual daily dose is 3 to 4 tablets (750 to 1000 mg daily), depending on your weight and any side effects you get.

You can take the dose once a day. However, if you get certain side effects, check with your health care provider if you can split the dose into two doses over the day or if you can take [TB242 trade name] at a different time to your other medicines.

Your health care provider may start your treatment with 1 tablet on the first day and then gradually increase the dose over a few days, until you reach the dose that is right for you.

Children

The health care provider will work out the right dose for your child. The daily dose depends on the child's weight. The following doses are recommended for children who weigh 7 kg or more:

Child's weight	Dose of 250-mg tablets
5 kg to less than 7 kg	See instructions for mixing the tablets for children weighing less than 10 kg
7 kg to less than 10 kg	½ tablet daily (See Instructions for mixing the tablets for children weighing less than 10 kg)
10 kg to less than 16 kg	1 tablet daily*
16 kg to less than 46 kg	2 tablets daily*
Over 46 kg	As for adults
* If your child gets certain side effects, check with the health care provider about splitting the dose into two doses over the day or giving the dose at a different time to the other medicines.	

Instruction for mixing the tablets for children weighing less than 10 kg

You will need:

- a clean cup or glass
- drinking water
- an oral syringe to measure out the mixture you give to your child.
- Place 1 tablet into the cup or glass and thoroughly crush the tablet.
- Add 10 mL of drinking water to the cup or glass.
- Stir the mixture thoroughly.
- The amount of mixture to give to your child depends on the child's weight:

Child's weight	Amount of mixture to give
5 to less than 7 kg	3 mL daily
7 to less than 10 kg	5 mL daily

- Using an oral syringe, measure out the right amount of mixture for your child and have the child drink all of it straightaway.

Liver disease

If you have severe liver disease, you must not take [TB242 trade name] (see ‘Do not take [TB242 trade name]’).

If you take more [TB242 trade name] 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 health care provider or the nearest hospital emergency department for advice.

If you forget to take [TB242 trade name]

If you miss a dose and notice within 6 hours, take the missed dose as soon as possible. Take the next regular dose as scheduled. If more than 6 hours have passed since you should have taken the dose, then simply wait to take your next dose when it is due. Do not take a double dose to make up for a forgotten dose.

If you stop taking [TB242 trade name]

Keep taking the medicine for as long as your health care provider has told you, even if you are feeling better. If you stop the medicine too soon, your infection may not be completely cured and may make future treatment difficult.

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

If you have any questions about this medicine, ask your health care provider.

4. Possible side effects

Like all medicines, [TB242 trade name] can cause side effects, although not everybody gets them. It is not always possible to say which unwanted effects are caused by [TB242 trade name] and which are caused by any other medicines you may also be taking.

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

The *most common* side effects (which can occur in more than 1 person in 10 who take the medicine) are stomach discomfort, abdominal (belly) pain, loss of appetite, vomiting, diarrhoea, and nausea (feeling sick). How often these side effects occur depends on the dose and duration of therapy.

Blood tests that show stress on the liver (increased liver enzymes called serum transaminases) can also occur very commonly in people taking [TB242 trade name].

Other *common* side effects (which can occur in more than 1 person in every 100 who take the medicine) 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 can occur in people treated with ethionamide. However, it is not known how often they occur:

- decrease of platelets (blood cells important for blood clotting);
- metallic taste and sulphurous belching;
- increased salivation;
- taste changes;
- so-called Pellagra-like syndrome (with diarrhoea, skin inflammation and problems with brain function, caused by a lack of niacin, a type of vitamin);
- reduced thyroid function;
- raised sugar in the blood;
- psychotic reactions (hallucinations, abnormal thinking, personality changes);
- low blood pressure (especially after standing up);

- altered brain function and brain disorder (encephalopathy);
- tingling in the arms and legs;
- altered sense of smell;
- rash (red, raised or itchy), red or purple discolouration on the skin (purpura), itchy rash (urticaria), acne;
- sensitivity to light (photosensitivity);
- inflammation of mucous lining (cheeks, gums, tongue, lips, throat);
- hair loss;
- breast enlargement in men;
- 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);
- fever.

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

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [TB242 trade name]

Do not store above 30°C.

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

Do not use this medicine after the expiry date stated on the label. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 [TB242 trade name] contains

- The active ingredients is ethionamide. Each coated tablet contains 250 mg ethionamide.
- The other ingredients of [TB242 trade name] 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.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [TB242 trade name] looks like and contents of the pack

Orange-coloured, circular, biconvex film-coated tablets plain on both sides. The tablets should not be divided.

Blister pack

White opaque PVDC/PVC/Alu blisters. 10 tablets per blister. 10 blisters are packed in one outer carton.

Bottle

White round HDPE bottle with CRC cap. 100 tablets per bottle.

Supplier and Manufacturer

Supplier

Micro Labs Limited
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Manufacturer

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Tel: +91-4344-276618, 277261
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For any information about this medicine, contact the supplier.

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Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/pqweb/medicines>