

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

[TB353 trade name][†]

Protionamide

*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 [TB353 trade name] is and what it is used for
2. What you need to know before you take [TB353 trade name]
3. How to take [TB353 trade name]
4. Possible side effects
5. How to store [TB353 trade name]
6. Contents of the pack and other information

1. What [TB353 trade name] is and what it is used for

[TB353 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.

[TB353 trade name] contains the active substance protionamide. 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 [TB353 trade name]

Do not take [TB353 trade name]:

- if you are hypersensitive (allergic) to protionamide, ethionamide, isoniazid, or any of the ingredients of [TB353 trade name] (see section 6).
- if you have severe liver disease.

Warnings and precautions

Always take [TB353 trade name] together with other tuberculosis medicines that your health care provider has asked you to take.

Speak with your health care provider if you:

- lose your appetite
- get nausea (feel sick) or vomit

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

- have yellowing of your skin or the white parts of your eyes
- 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, mental changes such as depression, confusion or aggression, or swollen breasts (in men).

If you develop 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, your thyroid function and your vision during treatment with [TB353 trade name].

Your health care provider may ask you to take a vitamin, called pyridoxine (vitamin B6), during treatment with [TB353 trade name]. This medicine may reduce the risk of developing nerve damage, which is a side effect of [TB353 trade name].

Tell your health care provider about any unwanted effects even if you think they are not related to tuberculosis infection or your treatment.

Other medicines and [TB353 trade name]

Tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without prescription and natural health products. These may affect the action of [TB353 trade name], or [TB353 trade name] may affect their action.

[TB353 trade name] may make the side effects of isoniazid and rifampicin worse.

You should not drink alcohol during treatment with [TB353 trade name].

[TB353 trade name] with food and drink

You can take [TB353 trade name] with food or between meals. However, taking the tablets with food may reduce side effects on your gut.

Pregnancy and breast-feeding

You should not become pregnant while on treatment with [TB353 trade name]. If you become pregnant, or are planning to become pregnant, you must contact your health care provider to discuss any changes to your tuberculosis medicines.

Breast-feeding

Protonamide, the active substance in [TB353 trade name], may pass into human breast milk.

If you are interested in breast-feeding your baby, you should discuss the risks and benefits with your health care provider. While breast-feeding, you and your baby should take pyridoxine (vitamin B6). Ask your health care provider for more information.

Driving and using machines

[TB353 trade name] may cause side effects such as drowsiness or headache that can reduce your ability to drive and to use machines.

[HA353 trade name] contains lactose

Lactose is a source of glucose and galactose. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance. If, however, you have one of the rare genetic disorders galactosaemia, glucose-galactose intolerance or congenital lactase deficiency you must talk to your health care provider before taking this medicine.

3. How to take [TB353 trade name]

Always take [TB353 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 [TB353 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 [TB353 trade name] with food or between meals. Taking it with food may reduce stomach side effects.

Adults and patients weighing at least 46 kg

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 [TB353 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 5 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 | 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 |

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.

1. Place 1 tablet into the cup or glass and thoroughly crush the tablet.
2. Add 10 mL of drinking water to the cup or glass.
3. Stir the mixture thoroughly.
4. The amount of mixture to give to your child depends on the child's weight:

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

5. Use an oral syringe to 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 [TB353 trade name] (see Section 2).

Kidney disease

Talk to your health care provider if you have severe kidney problems. The health care provider will decide if your dose of [TB353 trade name] should be reduced.'

If you take more [TB353 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 [TB353 trade name]

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 more than 6 hours have passed since you should have taken the dose, then simply take your next dose when it is due. Do not take a double dose to make up for forgotten doses.

If you stop taking [TB353 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, [TB353 trade name] can cause side effects, although not everybody gets them. When treating tuberculosis, it is not always possible to say which side effects are caused by [TB353 trade name], and which are caused by any other medicines you may be taking at the same time. For this reason, it is important that you tell your health care provider of any change in your health.

Very common side effects (which may affect more than 1 in 10 people) are:

- metallic taste
- dry mouth or a lot of saliva in the mouth
- loss of appetite
- nausea (feeling sick).

Common side effects (which may affect more than 1 in 100 people) are:

- headache
- dizziness
- blood tests showing raised liver enzymes, a sign of liver problems.

Uncommon side effects (which may affect up to 1 in 100 people) are:

- vomiting
- heartburn
- belly pain
- feeling of fullness and flatulence (gas)
- diarrhoea or constipation
- mental problems such as confusion, poor concentration, depression, excitation and psychosis (seeing or hearing things that are not there or believing things that are not true).

Rare side effects (may affect up to 1 in 1,000 people) are:

- fits
- sleeping problems
- breast growth in men (gynaecomastia)

menstrual problems in women
thyroid gland not working well enough
low blood sugar levels
jaundice (yellowing of the skin or the whites of the eyes).

Other side effects that may occur in patients treated with protionamide. However, it is not known how often they occur:

low red blood cell counts and problems with blood coagulation
suicide attempts
pain and burning sensations in joints (algodystrophy)
low blood pressure after sitting up or standing up
swelling of the salivary glands
inflammation of the lining of the mouth
inflammation of the tongue (glossitis)
liver inflammation and liver not working well enough
skin rash (pellagra-like reactions)
skin reactions caused by light (photodermatoses)
skin cracking or fissures around the mouth (rhagades)
acne
hair loss
inflammation of the lips (cheilitis)
problems with vision (blurred or double vision, complete or partial loss of vision)
ear problems (hearing loss, ringing noises or tinnitus)
joint pain
joint inflammations
muscle weakness
bladder stones
coughing blood
allergic reactions

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 [TB353 trade name]

Do not store above 30°C. Store tablets in blisters in the provided carton to protect from light.

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

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

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

6. Contents of the pack and other information

What [TB353 trade name] contains

- The active ingredient is protionamide 250 mg.
- The other ingredients of [TB353 trade name] are croscarmellose sodium, crospovidone, copovidone, colloidal anhydrous silica, hypromellose, lactose monohydrate, microcrystalline cellulose, magnesium stearate, hypromellose, lactose monohydrate, titanium dioxide, macrogol, FD&C yellow #6 / Sunset yellow FCF (E110)

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

What [TB353 trade name] looks like and contents of the pack

[TB353 trade name] are orange coloured, round, biconvex film-coated tablets with a scoreline on one side.

[TB353 trade name] is packed in a clear PVC-aluminium blister card of 10 tablets.

Pack sizes:

- 5 blister cards are packed in a carton. (5 x 10 tablets)
- 10 blister cards are packed in a carton. (10 x 10 tablets)

Supplier and Manufacturer

Supplier

LEKHIM Joint Stock Company
23, Shota Rustaveli Street
Kyiv, 01033
Ukraine
Tel: +38-044 246 6312
e-mail: o.pechaeva@lekhim.ua

Manufacturer

Technolog Private Joint Stock Company
8, Stara prorizna street, Uman City
Cherkassy Region, 20300
Ukraine

For any information about this medicine, contact the supplier.

This leaflet was last revised in November 2023

Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>