

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

[TB307 trade name][†]
Pyrazinamide

*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 has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness seem 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 [TB307 trade name] is and what it is used for
2. What you need to know before you take [TB307 trade name]
3. How to take [TB307 trade name]
4. Possible side effects
5. How to store [TB307 trade name]
6. Contents of the pack and other information

1. What [TB307 trade name] is and what it is used for

[TB307 trade name] is a medicine used in children under 15 years of age to treat tuberculosis (TB), an infection caused by bacteria called *Mycobacterium tuberculosis*. It is always given together with other medicines to treat tuberculosis. Your health care provider has chosen the combination that is right for your condition.

[TB307 trade name] contains the active substance pyrazinamide and belongs to a group of antibiotics called antimycobacterials.

This medicine is intended for use in children. Safety information on use in adults is also provided.

2. What you need to know before you take [TB307 trade name]

Do not take [TB307 trade name] if you

- are allergic (hypersensitive) to pyrazinamide or any of the other ingredients in [TB307 trade name] (see section 6);
- have severe liver disease;
- have acute gout;
- have porphyria.

Talk to your health care provider before taking [TB307 trade name] if you

- have liver or kidney problems;

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

- have diabetes;
- have a history of gout;
- are allergic to ethionamide, isoniazid or niacin (nicotinic acid).

In case of impaired kidney function, your health care provider may decide to adjust the dose.

Your health care provider will check your blood for liver function and metabolic changes before starting therapy, and at regular intervals during treatment with [TB307 trade name].

If you are allergic to ethionamide, isoniazid or niacin (nicotinic acid), you should inform your health care provider, because you may also be allergic to [TB307 trade name].

Taking other medicines

Please tell your health care provider if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription. These may affect the action of [TB307 trade name], or [TB307 trade name] may affect their action.

In particular, tell your health care provider if you are taking:

- probenecid, sulfinpyrazone or allopurinol (medicines for treating gout);
- medicines that may affect your liver function such as rifampicin, isoniazid and ethionamide;
- oestrogen medicines for contraception since [TB307 trade name] may reduce their contraceptive effects.

Do not take [TB307 trade name] together with ofloxacin or levofloxacin, unless your health care provider tells you to do so.

Alcohol may increase the risk of liver disease. Avoid alcoholic drinks while using this medication.

Pyrazinamide may cause live bacterial vaccines (such as typhoid vaccine) to not work well. Tell your health care provider that you are using pyrazinamide before having any immunizations/vaccinations.

Taking [TB307 trade name] with food and drink

[TB307 trade name] is not affected by food and drink and may be taken with meals or in between meals.

Pregnancy and breastfeeding

If you become pregnant, or are planning to become pregnant, you must contact your health care provider to discuss the potential benefits and risks of your tuberculosis therapy to you and your child.

Pyrazinamide is excreted into breast milk. However, no negative effects have been reported in breastfed infants, whose mothers were receiving pyrazinamide.

[TB307 trade name] can be used during breastfeeding.

Driving and using machines

[TB307 trade name] is unlikely to affect the ability to drive and use machines.

[TB307 trade name] contains aspartame

This medicinal product contains aspartame, which is a source of phenylalanine and may be harmful for people with phenylketonuria, a rare genetic condition where phenylalanine may build up in the body.

3. How to take [TB307 trade name]

Always take [TB307 trade name] exactly as your health care provider has told you. You should check with your health care provider if you are not sure.

You can take [TB307 trade name] with meals or in between meals.

The dose, the interval between doses of [TB307 trade name] and the length of treatment is decided by your health care provider based on your body weight, your condition and the other medicines you are taking for treating tuberculosis.

In the case of tuberculous meningitis your healthcare provider may prescribe a different dosing regimen.

[TB307 trade name] is always given in combination with other antituberculosis medicines; please make sure to follow the instructions of your health care provider.

Recommended number of [TB307 trade name] dispersible tablets for patients less than 15 years of age (children and adolescents)

Weight	Daily dose
3 – <5 kg	0.5 tablet
5 – <7 kg	1 tablet
7 – <10 kg	2 tablets
10 – <16 kg	3 tablets
16 – <24 kg	5 tablets
24 – <30 kg	—*
30 – <36 kg	—*
36 – <46 kg	—*

* In these patients, other formulations containing higher amounts of pyrazinamide should be used.

If you have kidney disease your health care provider may tell you to take [TB307 trade name] three times per week instead of daily.

If you take more [TB307 trade name] than you should

If you accidentally take more tablets than you should, tell a health care provider or get medical advice straight away. Take the medicine pack with you. This is so the health care provider knows what you have taken. If you accidentally take too much medicine, you may result in increases in blood levels of uric acid and may cause liver damage.

If you forget to take [TB307 trade name]

If you forget to take a dose, take the missed dose as soon as you remember on the same day. If you do not remember on the same day, take the normal dose on the next day. Do not take a double dose to make up for forgotten dose. If you are unsure about what to do, ask your health care provider.

When you have to take [TB307 trade name] two or three times per week: In case you miss or forget to take a dose, then take the missed dose as soon as possible, unless the next regular dose is scheduled within 12 hours.

If you vomit within 1 hour of taking [TB307 trade name], then you should take an extra dose. If vomiting occurs more than an hour after taking the dose, then you do not need to take an extra dose and can take the next dose as usual when it is due.

If you stop taking [TB307 trade name]

It is important that you complete the course of treatment even if you begin to feel better. If you stop taking [TB307 trade name] too soon, your infection may not be completely cured and the infection may return or your condition may get worse. The bacteria causing the infection may become resistant to [TB307 trade name].

Taking this medicine

Disperse the required number of [TB307 trade name] tablets in approximately 50 ml water and the entire mixture should be swallowed. The mixture (tablets dispersed in water) should be used within 10 minutes. An additional volume of water should then be consumed immediately. When administering the dose to patients

weighing between 3 kg and 5 kg, only give half of the mixture prepared using 1 tablet. Discard any remaining mixture.

4. Possible side effects

Like all medicines, [TB307 trade name] can cause side effects, although not everybody gets them. When treating tuberculosis, it is not always possible to differentiate between unwanted effects caused by [TB307 trade name] 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 health care provider of any change in your health.

If you notice any of the following symptoms or side effects, **tell your health care provider immediately**:

- Nausea and vomiting
- Itching or yellowing of the skin
- joint pain (without signs of joint inflammation)
- Constipation or diarrhoea
- Muscle pain, tingling, numbness, weakness or paralysis
- Mental changes, such as anxiety, confusion, hallucinations, disorientation or paranoia.

Other side effects:

Tell your healthcare provider if you get any of the following side effects, especially if they get serious, or if you notice any other unexpected or unusual symptoms not listed in this leaflet.

Very common [may affect more than 1 in 10]:

- increased liver enzymes
- high levels of uric acid in the blood
- flushing

Common side effects [may affect up to 1 in 10 people]:

- nausea, vomiting

Uncommon side effects [may affect up to 1 in 100 people]:

- jaundice (yellowing of the skin and eye white)

Rare side effects [may affect up to 1 in 1,000 people]:

- liver failure
- pellagra (disease presenting with diarrhoea, skin inflammation and impaired brain function [dementia], caused by a lack of niacin, a certain vitamin), aggravated porphyria (disorder of certain enzymes in the synthesis pathway of the red blood pigment)
- rash, sensitivity to (sun-)light, hives

The following side effects have also been reported, but it is unknown how often they may occur:

- headache, dizziness, nervousness, difficulty sleeping
- abdominal cramps, loss of appetite
- inflammation of the kidney (interstitial nephritis)
- general aches and pains, fever, weight loss, allergic reactions
- low red blood cell count, low white blood cell count. If the number of red blood cells is reduced you may have symptoms of tiredness or breathlessness and a reduction in your white blood cell count can make you more prone to infections.
- decrease of platelets (blood cells important for blood clotting). If you have a low platelet count you may notice that you bruise more easily.
- gouty arthritis
- high blood pressure.

Reporting of side effects

If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help improve understanding about the safety of this medicine.

5. How to store [TB307 trade name]

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

Store below 30°C, in dry place. Protect from light.

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

Do not use this medicine if you notice visible signs of deterioration 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 [TB307 trade name] contains

- The active ingredient is pyrazinamide.
- The other ingredients of [TB307 trade name] are maize starch, sodium starch glycolate, povidone, microcrystalline cellulose, croscarmellose sodium, crospovidone, colloidal anhydrous silica, strawberry flavour, aspartame, purified talc, magnesium stearate

What [TB307 trade name] looks like and contents of the pack

White to off-white, circular, biconvex uncoated tablets having break line on one side and plain surface on other side.

The tablet cannot be divided into equal halves.

100 Tablets are packed in a triple laminated sachet and then placed in a round, white, HDPE container with PP closure.

Supplier and Manufacturer

Supplier

Macleods Pharmaceuticals Limited
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Andheri (East)
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Tel: +91-22-66762800
Fax: +91 -22-28216599
Email: vijay@macleodspharma.com
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Manufacturer

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Tehsil Baddi, District Solan
Himachal Pradesh – 174101
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Phone: +91 1795 661400
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For any information about this medicine, contact the local representative of the supplier:

This leaflet was last revised in September 2022.

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