

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/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[TB302 trade name][†]

Isoniazid/rifampicin

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

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 [TB302 trade name] is and what it is used for
2. What you need to know before you take [TB302 trade name]
3. How to take [TB302 trade name]
4. Possible side effects
5. How to store [TB302 trade name]
6. Contents of the pack and other information

1. What [TB302 trade name] is and what it is used for

[TB302 trade name] is a medicine used in children to treat tuberculosis (TB), an infection caused by bacteria called *Mycobacterium tuberculosis*.

[TB302 trade name] is also used to prevent TB if there is a high chance you could catch tuberculosis.

[TB302 trade name] contains two tuberculosis medicines, rifampicin and isoniazid. These are antibiotics that work in different ways to kill the bacteria that cause TB.

Although this medicine is intended for use in children, information from its use in adults is also included to give a fuller picture of the medicine's effects.

2. What you need to know before you take [TB302 trade name]

Do not take [TB302 trade name] if you:

- are allergic (hypersensitive) to isoniazid or rifampicin, or any of the other ingredients of [TB302 trade name] (see section 6, *What [TB302 trade name] contains*)
- have current liver disease, including yellowing of the skin and eyes (jaundice) or severely reduced liver function
- have had liver problems after taking isoniazid or rifampicin before
- have had severe side effects with isoniazid or rifampicin before that include fever, chills or inflammation of the joints
- are taking certain medicines:
 - voriconazole (a medicine used to treat fungal infections)

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

- HIV medicines: atazanavir, darunavir, doravirine, elvitegravir/cobicistat, etravirine, fosamprenavir, lopinavir, nevirapine, rilpivirine, ritonavir, tipranavir
- chronic hepatitis C medicines: daclatasvir, elbasvir/grazoprevir, glecaprevir/pibrentasvir, ledipasvir/sofosbuvir, ombitasvir/paritaprevir/ritonavir, sofosbuvir
- lurasidone (a medicine for mental problems)

Check with your health care provider if you are not sure whether your medicine is included.

Speak to your health care provider if you think you should not take this medicine.

Warnings and precautions

Talk to your health care provider before taking [TB302 trade name]. Tell your health care provider before starting the medicine if you have:

- liver problems such as long-term liver disease
- kidney problems
- diabetes
- epilepsy
- porphyria
- mental problems (psychosis)
- damage to your nerves (peripheral neuropathy) that causes a sensation of tingling in the hands or feet
- HIV infection
- malnutrition
- been told you are a ‘slow acetylator’ (your body breaks down certain medicines more slowly than usual)

Also tell your health care provider if you are allergic to the medicines ethionamide, pyrazinamide, or niacin (nicotinic acid) – this may make it more likely that you will also be allergic to [TB302 trade name].

If any of these apply, your health care provider will discuss your treatment with you, and explain whether you will need additional checks in case you get side effects.

While taking [TB302 trade name] your health care provider will regularly check for any problems with your liver. Speak with your health care provider straightaway if you get **symptoms that might suggest liver damage**, especially if you:

- lose your appetite, or get nausea (feel sick), or feel tired all the time, or you have a rash

and you have any of the following:

- belly pain, usually on the right side and near the chest
- unexplained itching
- yellowing of the white parts of your eyes, your nails or your skin
- passing dark urine
- passing stools that are very pale.

You may be at higher risk of liver problems if:

- you are older than 35 years
- you drink alcohol daily (see “Taking [TB302 trade name] with food and drink”)
- you have a long-term liver disease
- you use recreational drugs by injection (e.g. heroin).

If any of these apply to you, your health care provider will test for liver problems more often. If serious liver problems develop your health care provider may change your treatment and ask you to stop taking [TB302 trade name].

If you get flu-like symptoms such as fever, headache and muscle aches, you should report this to your health care provider, since [TB302 trade name] may be the cause.

Serious skin reactions (often with other symptoms like chills and fever) may happen in some people taking [TB302 trade name]. Stop taking [TB302 trade name] and tell your health care provider right away if you have any of the following symptoms: rash; red and painful skin; blistered, peeling or bleeding skin; sores or blisters on the inside of your mouth or lips or on your genitals; swollen face, lips, mouth, tongue or throat; flu-like symptoms.

Tingling, pricking or numbness in the hands and feet (**peripheral neuropathy**) is the most common side effect of isoniazid, one of the active substances in [TB302 trade name] (see “Possible side effects”). If you have kidney or liver problems, you may be at higher risk of isoniazid side effects including peripheral neuropathy. You are also more likely to get peripheral neuropathy if you are malnourished, have diabetes, are dependent on alcohol, have HIV infection, or are pregnant or breastfeeding. Your health care provider will check on you regularly if any of these apply. Speak with your health care provider right away if you get tingling in your hands and feet.

Your health care provider may recommend that you take vitamin B6 (pyridoxine) if you are more likely to develop peripheral neuropathy.

Tell your health care provider if you get new or worsening **cough and breathlessness** after starting treatment with [TB302 trade name] or if other TB symptoms (e.g. tiredness, headache, loss of appetite, weight loss, or weakness) seem to get worse.

If you are taking cortisone or any cortisone-like drug, you should report this to your health care provider, since the cortisone dose may have to be increased while taking [TB302 trade name].

[TB302 trade name] may cause a reddish orange discoloration of body fluids such as urine, sputum and tears. This is due to rifampicin, and does not require medical attention. Also, contact lenses or dentures may become stained due to [TB302 trade name].

Tell your health care provider about any illness you get, even if you think it is not related to tuberculosis infection or your medicine.

Other medicines and [TB302 trade name]

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 [TB302 trade name], or [TB302 trade name] may affect their action. Side effects of either medicine may become worse and/or the medicines may become less effective.

Medicines you must not take with [TB302 trade name]

- **You must not take [TB302 trade name] with** certain medicines (see the full list of these medicines above under ‘*Do not take [TB302 trade name] if you*’).

This is because [TB302 trade name] may significantly decrease the amount of these medicines in your blood, preventing them from working well enough.

Check with your health care provider if you are not sure you can take your medicines with this one.

Other medicines that can interfere with [TB302 trade name]

You should avoid using antacids (for heartburn or indigestion) that contain aluminium hydroxide as it can interfere with your body’s ability to take up this medicine.

The active substances in [TB302 trade name] may also interfere with a great number of other medicines, including for instance:

- other medicines to treat HIV infection (e.g. dolutegravir, maraviroc, raltegravir,)
- other medicines to treat fungal infections (e.g. ketoconazole, fluconazole, itraconazole)
- antibiotics (e.g. clarithromycin, chloramphenicol, doxycycline, trimethoprim)
- ethionamide (another TB medicine)
- medicines to treat malaria (e.g. amodiaquine, artemether, artesunate, dihydroartemisinin, lumefantrine, quinine)

- immunosuppressant drugs (e.g. ciclosporin, tacrolimus)
- medicines to treat heart conditions (e.g. verapamil, digoxin, clopidogrel)
- medicines to treat blood lipids (e.g. atorvastatin, simvastatin)
- some medicines to treat diabetes (e.g. glibenclamide, glimepiride, repaglinide)
- oral contraceptive pills
- mifepristone (a medicine for abortions)
- medicines to treat epileptic seizures (e.g. phenytoin, carbamazepine, valproate)
- medicines used to help you sleep (benzodiazepines, e.g. diazepam, flurazepam, nitrazepam, triazolam, midazolam; also zolpidem or zopiclone)
- medicines for the treatment of certain psychiatric conditions (neuroleptics, e.g. chlorpromazine, haloperidol; antidepressants such as amitriptyline or nortriptyline)
- medicines for prevention of blood clots (warfarin)
- medicines used in surgery (narcotics or anaesthetics, e.g. alfentanil, enflurane)
- corticosteroids (e.g. prednisolone, medicines for the treatment of inflammations and other diseases, such as asthma or rheumatoid arthritis)
- levothyroxine for thyroid problems
- medicines to treat pain (e.g. morphine, paracetamol)
- codeine (medicine to treat cough)
- methadone (medicine for drug addiction)
- disulfiram (medicine used for the treatment of chronic alcoholism)
- praziquantel for worm infections.

Taking any of these medicines together with [TB302 trade name] may be unsuitable or your health care provider may need to alter your dose.

[TB302 trade name] with food and drink

[TB302 trade name] should be taken on an empty stomach (at least 1 hour before or 2 hours after a meal).

You should not drink alcohol while taking [TB302 trade name] as it increases the risk of liver damage.

When taken with cheese or fish (histamine- or tyramine-rich food) [TB302 trade name] may cause redness/itching of the skin, hot feeling, rapid or pounding heartbeat, sweating, chills or clammy feeling, headache, and/or light-headedness. If you get these side effects, you should avoid eating cheese and fish while taking this medicine.

Pregnancy, breast-feeding and contraception

This medicine can be used during pregnancy. However, you may need to be carefully monitored for side effects. If you become pregnant, think you might be, or are planning a pregnancy, tell your health care provider right away, so you can discuss your treatment.

You can breast-feed while taking this medicine. Isoniazid and rifampicin pass into breast milk but only in very small amounts. No negative effects have been reported in breast-fed-infants whose mothers were receiving this medicine. However, amounts in breast milk are so low that you cannot rely upon breast-feeding to prevent or treat tuberculosis in your child.

As a precaution, your health care provider may recommend that you take vitamin B6 (pyridoxine) while you are pregnant and breast-feeding; your baby may also be given vitamin B6. Because rifampicin can interfere with vitamin K, which affects blood clotting, your health care provider may also give you or your baby extra vitamin K around the time the baby is born.

[TB302 trade name] may reduce the effects of **contraceptive** pills, implants or injections. As a precaution, if you need contraception you should use a different or additional method (condoms, intra-uterine device, pessary) during treatment with [TB302 trade name].

Driving and using machines

[TB302 trade name] is not likely to affect your ability to drive or operate machinery.

However, make sure you feel well enough to take on any skilled tasks.

Other ingredients of [TB302 trade name]

This medicine contains aspartame. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take [TB302 trade name]

Your health care provider will decide on the right doses and combination of medicines for your TB, based on your age, weight and condition.

Always take [TB302 trade name] exactly as your health care provider has told you. Check with your health care provider if you are not sure.

Do not change the dose unless your health care provider tells you to. Your treatment will need to go on for several months, but it is important to take the full course of treatment recommended by your health care provider, even if you feel better.

Make a mixture with the tablets in drinking water before taking the dose. See “**Instructions for taking [TB302 trade name] tablets**”, below.

For information on how to take any other medicines you need for your TB treatment, discuss with your health care provider and see the leaflets that come with those medicines as well.

Treatment of tuberculosis

To treat TB, you will need to take a combination of medicines for the first 2 months of treatment. After that, you will take [TB302 trade name] on its own for another 2 or 4 months. Your health care provider will explain how long you need to take the medicine for, and what other medicines you need.

The dose of [TB302 trade name] needed to treat TB depends on weight, as follows:

Patient's weight	Dose of [TB302 trade name] tablets
4 to less than 8 kg	1 tablet once daily
8 to less than 12 kg	2 tablets once daily
12 to less than 16 kg	3 tablets once daily
16 to less than 25 kg	4 tablets once daily

Children weighing 25 kg or more will be switched to another medicine, to ensure they get the right dose of the active substances isoniazid and rifampicin.

Prevention of tuberculosis

To prevent TB, [TB302 trade name] is taken once a day on its own, for 3 months. The dose is the same as for treatment, above.

Instructions for taking [TB302 trade name] tablets

Take the tablets on an empty stomach (at least 1 hour before or 2 hours after a meal). Try to take [TB302 trade name] at the same time each day.

Add each tablet to 10 mL of drinking water (about 2 teaspoonfuls); the maximum volume of water for preparing a dose is 50 mL. Your health care provider will explain how many tablets to use for each dose. The usual number of tablets per dose for children of different weights are given in the tables above, but always use the number of tablets your health care provider recommends.

1. Place the required amount of drinking water in a small, clean cup or bowl and add the required number of tablets.
2. Stir gently until the tablets break up completely and are fully mixed with the water.

3. Drink all the mixture immediately.
4. Rinse the cup with a little more drinking water (about 10 mL) and drink this to make sure you have taken the full dose.

If you take more [TB302 trade name] than you should

If you accidentally take too many [TB302 trade name], contact your health care provider or nearest emergency department for advice. Take your medicine with you so that you can easily describe what you have taken.

If you forget to take [TB302 trade name]

It is important not to miss a dose of [TB302 trade name]. If you miss or forget to take a dose, the missed dose should be taken as soon as possible, unless it is less than 6 hours till your next dose, in which case skip the missed dose and just take the next regular dose.

If you vomit less than 1 hour after taking [TB302 trade name], take another tablet. You do not need to take another tablet if you vomited more than 1 hour after taking this medicine.

If you stop taking [TB302 trade name]

Don't stop taking [TB302 trade name] without checking with your health care provider. Talk to your health care provider before you stop taking [TB302 trade name] for any reason, particularly if you get any side effects or have another illness.

If you have stopped your treatment with [TB302 trade name] for any reason, speak to your health care provider before you start taking [TB302 trade name] again.

If you have any questions on the use of this medicine, ask your health care provider.

4. Possible side effects

Like all medicines, [TB302 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 [TB302 trade name] and 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.

The most important adverse effects of isoniazid and rifampicin are nerve injuries (peripheral neuropathy, see below) and inflammation of the liver (hepatitis) which can sometimes be severe or even fatal. **Tell your health care provider right away** if you get signs of *liver problems* (see Warnings and Precautions, in section 2, above). Other important side effects you need to tell your health care provider about right away are *severe skin reactions* and *new or worsening breathlessness*.

The following side effects have been reported in patients treated with [TB302 trade name]:

Very common side effects

(may affect more than 1 in 10 people):

- fever and chills

Common side effects

(may affect up to 1 in 10 people):

- low levels of blood platelets (needed for blood to clot normally), sometimes with small purplish spots on the skin
- headache, dizziness
- feeling sick (nausea)
- vomiting
- worsening of TB symptoms that had previously been getting better
- increased liver enzymes or bilirubin as measured in blood tests. Usually, liver enzyme increases occur during the first 1-3 months of therapy and return to normal despite continued treatment.

When the values rise above a certain level, your health care provider may decide to stop treatment with [TB302 trade name].

Uncommon side effects

(may affect up to 1 in 100 people)

- low levels of white blood cells in blood tests (leukopenia)
- convulsions (fits)
- brain problems leading to confusion or reduced consciousness (toxic encephalopathy)
- inflammation or damage to the optic nerve
- memory problems
- psychosis (abnormal thinking, sometimes with delusions or hallucinations)
- dizziness
- increased seizures (fits) in people with epilepsy
- bleeding in the brain (cerebral haemorrhage)
- diarrhoea
- inflammation of the liver (hepatitis), which can be severe.

Side effects of which it is not known how often they may occur

- infection of the bowel leading to pain and severe diarrhoea (pseudomembranous colitis)
- flu
- formation of tiny clots in the blood vessels, which can affect circulation and lead to damage to the kidneys (thrombotic microangiopathy, thrombocytopenic purpura, haemolytic-uraemic syndrome)
- changes in the white blood cell counts (eosinophilia, agranulocytosis), possibly resulting in an increased risk of infection
- anaemias (low red blood cell counts), sometimes with breakdown of red blood cells (haemolytic anaemia) or problems with bone marrow (aplastic anaemia)
- problems with blood clotting
- swollen lymph glands (lymphadenopathy)
- life-threatening allergic (anaphylactic) reactions with breathing difficulties and low blood pressure
- problems with adrenal glands
- breast enlargement in men (gynaecomastia)
- decreased appetite
- high blood sugar (hyperglycaemia)
- a vitamin deficiency syndrome called pellagra (with e.g. dementia, loose stools and skin inflammation)
- sensations of tingling, pricking, or numbness of the skin, especially in the feet and hands (peripheral neuropathy). Your health care provider may recommend you take vitamin B6 (pyridoxine) to reduce the risk (see above, "Warnings and Precautions").
- problems with walking and balance (possible signs of a brain problem called cerebellar syndrome); this is more likely if you already have kidney disease
- shock (loss of blood flow to your organs)
- flushing
- inflammation of blood vessels (vasculitis)
- unexpected bleeding
- shortness of breath, wheezing
- reddish discoloration of body fluids such as urine, phlegm, tears, saliva and sweat, staining of soft contact lenses, dentures or teeth
- inflammation of the lungs (pneumonitis)
- belly pain or discomfort
- constipation
- dry mouth

- inflammation of the pancreas (usually with severe pain in the back or stomach)
- severe skin reactions with fever and flu-like symptoms, blisters or pustules, or involvement of the mucous membranes of mouth or genitals
- itching or itchy rashes, nettle rash (urticaria)
- acne
- hair loss
- muscle weakness or soreness
- bone pain
- rheumatic condition with rashes, kidney problems (lupus-like syndrome)
- kidney damage
- excess bleeding after delivery of a baby
- menstrual disturbances
- porphyria (a condition where the body cannot break down certain chemicals called porphyrins)
- swelling of the feet or ankles (oedema)
- low blood pressure.

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 [TB302 trade name]

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

Bottle pack

Do not store above 25°C. Store in dry place. Protect from light. Once opened, use within 120 days.

Strip pack

Do not store above 30°C. Store in dry place. Protect from light.

Do not use this medicine after the expiry date stated on the label, carton or 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 [TB302 trade name] contains

- The active ingredients are 50 mg isoniazid and 75 mg rifampicin
- The other ingredients of [TB302 trade name] are microcrystalline cellulose, crospovidone, povidone, bleached shellac, croscarmellose sodium, aspartame, trusil raspberry flavour and magnesium.

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

What [TB302 trade name] looks like and contents of the pack

Mottled brick-red, round, uncoated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have a score line on one side and are plain on the other side.

The score line can be used to break the tablet for ease of swallowing but not to divide it into equal doses.

Bottle pack

[TB302 trade name] are packed in an LDPE bag put in a triple laminated sachet, kept in an HPDE bottle (round, milky white container with screw thread cap), finally sealed with a tagger seal along with the pack insert. Pack size: 100 tablets

Strip pack

Alu/alu strip packs, each containing 10 or 28 tablets. Available in cartons of 10 x 10 tablets or 3 x 28 tablets.

Supplier and Manufacturer

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For any information about this medicine, contact the local representative of the supplier.

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