

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

[TB308 trade name][†]
Isoniazid

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 [TB308 trade name] is and what it is used for
2. What you need to know before you take [TB308 trade name]
3. How to take [TB308 trade name]
4. Possible side effects
5. How to store [TB308 trade name]
6. Contents of the pack and other information

1. What [TB308 trade name] is and what it is used for

[TB308 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 health care provider has chosen the combination that is right for your condition.

[TB308 trade name] is also used on its own or with other medicines to *prevent* TB if there is a high chance you could catch it.

[TB308 trade name] contains the active substance isoniazid, which is an antibiotic that kills the bacteria responsible for TB by preventing them from making their protective cell wall.

2. What you need to know before you take [TB308 trade name]

Do not take [TB308 trade name]:

- if you are allergic (hypersensitive) to isoniazid or any of the other ingredients of [TB308 trade name] listed at the end of this leaflet
- if you have any sort of liver disease
- if you have ever had liver problems after taking isoniazid or any other medicine
- if you have ever had severe side effects with isoniazid, including fever, chills or inflammation of the joints.

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

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

Warnings and precautions

Talk to your health care provider before taking [TB308 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
- 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 [TB308 trade name].

It is also important to tell your health care provider if you are pregnant or have just given birth, or if you drink alcohol regularly or use injection drugs like heroin.

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 [TB308 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 [TB308 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 [TB308 trade name].

Peripheral neuropathy (tingling, pricking or numbness, especially of hands and feet) is the most common side effect of isoniazid (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 or if you are taking a high dose of isoniazid.

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

Resistance

When it is used to treat TB, this medicine must always be taken with other TB medicines as your health care provider recommends. Using the medicine alone or not taking the recommended doses can make the disease resistant to the medicine, so your treatment may no longer work to cure your TB.

Other medicines and [TB308 trade name]

Tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Make sure you mention herbal medicines you might have been taking. These may affect the action of [TB308 trade name], or [TB308 trade name] may affect their action. Side effects of either medicine may become worse or the medicines may become less effective.

Where possible, [TB308 trade name] should not be used with other medicines that can damage the liver or the nerves, since their side effects may add up and increase the risks. Your health care provider will be able to tell you if changes are needed to your treatment.

You should not be take antacids (medicines for indigestion) with [TB308 trade name], especially antacids that contain aluminium hydroxide, as they lower the dose of isoniazid that your body absorbs.

It is not known whether isoniazid interacts with medicines to treat hepatitis C infection (such as daclatasvir, dasabuvir, elbasvir, glecaprevir, grazoprevir, ledipasvir, ombitasvir, paritaprevir, pibrentasvir, simeprevir, sofosbuvir, velpatasvir or voxilaprevir). However, since hepatitis C causes chronic liver disease, you will need to be carefully monitored during treatment with isoniazid if you are also being treated with these medicines.

Taking [TB308 trade name] with other medicines

The active substance in [TB308 trade name] may also interact with the following medicines:

- medicines to treat epileptic seizures (e.g. phenytoin, carbamazepine, primidone)
- warfarin (to prevent blood clots)
- benzodiazepine medicines used to treat anxiety or help you sleep (e.g. chlorzoxazone, diazepam, flurazepam, midazolam, triazolam)
- medicines for fungal infections (itraconazole, ketoconazole)
- medicines used in surgery (strong painkillers, e.g. alfentanil; anaesthetics e.g. enflurane)
- levodopa (medicine for the treatment of Parkinson's disease)
- theophylline (medicine for the treatment of asthma)
- procainamide (medicine for the treatment of cardiac arrhythmias)
- corticosteroids (e.g. prednisolone, medicines for the treatment of inflammation and other diseases, such as asthma or rheumatoid arthritis)
- disulfiram (medicine to treat dependence on alcohol).

Taking [TB308 trade name] with food and drink

Take [TB308 trade name] on an empty stomach (at least one hour before or two hours after a meal). This helps your body absorb isoniazid better.

Taking isoniazid with foods and drinks such as matured cheeses, cured meat, some oily fish like tuna, salmon or mackerel, wine and beer (all of which contain histamine or tyramine) may cause effects such as headache, sweating, flushing, heartbeat becoming fast, uneven or forceful (palpitations), dizziness, feeling lightheaded or faint (due to low blood pressure). Avoid these foods if you are receiving isoniazid.

Do not drink alcohol regularly or excessively while taking [TB308 trade name]. This increases your risk of liver damage.

Pregnancy and breast-feeding

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.

Isoniazid passes into breast milk in small amounts, but no harmful effects have been reported in breast-fed infants whose mothers were receiving isoniazid. However, your health care provider may recommend that you and your baby take vitamin B6 (pyridoxine) to reduce any risks. Not enough isoniazid passes into the milk to protect your baby from TB or to treat any TB infection your baby may get.

Driving and using machines

[TB308 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.

Important information about some of the other ingredients of [TB308 trade name]

This medicine contains mannitol, which may have a mild laxative effect.

3. How to take [TB308 trade name]

Your health care provider will decide on the right doses and combination of medicines to treat your TB, based on your age, weight and condition, including whether your TB is resistant to standard treatments.

For the treatment of TB, [TB308 trade name] must be used with other medicines.

Always take [TB308 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 may need to go on for many months, but it is important to take the full course of treatment recommended by your health care provider, even if you feel better.

Swallow [TB308 trade name] whole with water or another drink. For small children who cannot swallow tablets whole, they may be crushed in a small clean bowl or cup and a small amount of soft food or liquid can be added. The whole mixture should be given to the child right away.

Take the tablets on an empty stomach (at least 1 hour before or 2 hours after a meal).

For information on how to take the 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

The dose of [TB308 trade name] needed to treat TB depends on your weight, and whether your TB responds to standard medicines or is resistant to standard medicines.

For **TB that responds to standard medicines** (drug-susceptible TB), the usual doses are given in the table below but always take the medicine as recommended by your health care provider

Patient's weight	Dose of [TB308 trade name] tablets
4 to less than 8 kg	½ tablet once daily
8 to less than 12 kg	1 tablet once daily
12 to less than 16 kg	1½ tablet once daily
16 to less than 25 kg	2 tablets once daily

In adults and patients weighing more than 25 kg, the amount of isoniazid you need changes, and the following doses are usually recommended:

Patient's weight	Number of tablets of [TB308 trade name]
25 to less than 30 kg	1½ tablets once daily
30 kg to less than 65 kg	3 tablets once daily*

*Your health care provider may switch you to another tablet containing more isoniazid, to reduce the number of tablets you have to take

If you gain weight to more than 65 kg, your health care provider may adjust your medicines to make sure you are getting enough isoniazid.

Treatment of drug-resistant TB

If [TB308 trade name] is added to other TB medicines to manage **TB resistant to standard medicines**, the usual recommended dose of the medicine based on weight is as follows:

Patient's weight	Number of [TB308 trade name] tablets
3 to less than 5 kg	½ tablet daily
5 to less than 7 kg	1 tablet daily
7 to less than 10 kg	1½ tablets daily
10 to less than 16 kg	2 tablets daily
16 to less than 24 kg	3 [†] tablets daily
24 to less than 36 kg	4 tablets daily
36 to less than 46 kg	4½ [†] tablets daily

[†]Your health care provider may switch you to a medicine containing a higher dose of isoniazid, to reduce the number of tablets taken

For patients weighing 46 kg or more, your health care provider may choose another medicine containing more isoniazid, to reduce the number of tablets you need to take.

Prevention of tuberculosis

When isoniazid is used to prevent tuberculosis, it can be used alone or with another TB medicine (usually rifampicin or rifapentine). The dose of [TB308 trade name] depends on whether you take it alone or with another medicine, and on your weight. Your health care provider will choose suitable medicines and tell you the right doses to take.

For adults and older children, another medicine that contains a higher amount of isoniazid is usually preferred.

If you are given [TB308 trade name] on its own

If [TB308 trade name] is used **on its own**, then the following daily doses, taken for 6 or 9 months, have been recommended in those weighing less than 25 kg:

Person's weight	Dose of [TB308 trade name] tablets
4 to less than 8 kg	½ tablet once daily
8 to less than 12 kg	1 tablet once daily
12 to less than 16 kg	1½ tablets once daily
16 to less than 25 kg	2 tablets once daily
25 kg or more	Your health care provider may choose another medicine that contains more isoniazid

If [TB308 trade name] is **used with another medicine**, the dose depends on which combination you get:

If you are given [TB308 trade name] with the medicine rifampicin

When you take [TB308 trade name] with rifampicin, you should take it **once a day for 3 months**. The dose of [TB308 trade name] is the same as if you take it alone (see above). For the dose of rifampicin, see the patient information leaflet that comes with the rifampicin medicine.

If you are given [TB308 trade name] with the medicine rifapentine

You will only have to take the medicine **once a week for 3 months**. The usual dose depends on age and weight as follows:

Person's weight		Dose of [TB308 trade name] tablets
6 to less than 10 kg	<i>Under 6 months of age</i>	1 tablet once a week
	<i>6 months or older</i>	1½ tablet once a week
10 to less than 15 kg		2½ tablet once a week
15 to less than 20 kg		3 tablets once a week
20 to less than 30 kg		4½ tablets once a week
30 to less than 40 kg		6 tablets once a week
40 to less than 50 kg		7½ tablets once a week
50 kg or more		9 tablets once a week

Adults and some teenagers may be given a different course of the medicine (**3 tablets once a day for 4 weeks**, together with rifapentine), but your health care provider will explain if this is the case.

Taking pyridoxine with [TB308 trade name]

Your health care provider may recommend that you also take pyridoxine (vitamin B6). Pyridoxine can help reduce the chance of getting peripheral neuropathy, a side effect of [TB308 trade name] that can affect nerves and cause tingling, pricking or numbness, especially of your hands and feet.

This vitamin is especially important if you are pregnant or breastfeeding, have HIV infection, malnutrition, alcohol dependence, kidney problems or diabetes. It is also recommended if you are taking high doses of isoniazid.

Your health care provider will tell you how much pyridoxine to take – you should also read the patient information leaflet supplied with any pyridoxine tablets you are given.

If you take more [TB308 trade name] than you should

If you accidentally take too many [TB308 trade name], contact your health care provider or nearest emergency department for advice. Take the medicine with you so that you can easily describe what you have taken.

If you forget to take [TB308 trade name]

It is important not to miss a dose of [TB308 trade name]. If you have missed a dose of this medicine, contact your health care provider to ask what to do, as your treatment may need to be adjusted.

If you vomit less than 1 hour after taking [TB308 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 [TB308 trade name]

Don't stop taking [TB308 trade name] without checking with your health care provider. Talk to your health care provider before you stop taking [TB308 trade name] for any reason, particularly if you get any side effects or have another illness.

If you have stopped your treatment with [TB308 trade name] for any reason, speak to your health care provider before you start taking [TB308 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, this medicine can cause side effects, although not everybody gets them. When treating tuberculosis, it is not always possible to distinguish between unwanted effects of [TB308 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 tell your health care provider of any change in your health.

If you get any of the following side effects, contact your health care giver as soon as possible:

- signs of liver damage (see Warnings and Precautions, above)
- signs of nerve damage (peripheral neuropathy, see Warnings and Precautions above)
- severe pain in the belly and back which can be signs of inflammation of the pancreas
- severe extensive skin damage and blistering, often with flu-like symptoms (toxic epidermal necrolysis or TEN)
- a drug reaction that causes rash, fever, inflammation of internal organs, blood abnormalities and general illness (DRESS syndrome).

The following side effects have been reported in patients treated with isoniazid.

Very common side effects (*may affect more than 1 in 10 people*)

- sensations of tingling, pricking, or numbness of the skin, especially in the feet and hands (peripheral neuropathy).
- increases of liver enzymes measured in blood samples. Usually, these enzyme increases return to normal within 3 months despite continued treatment. When the values rise above a certain level your health care provider may decide to stop treatment with [TB308 trade name].

Uncommon side effects (*may affect up to 1 in 100 people*)

- inflammation of the liver (hepatitis), which can cause yellowing of the skin or whites of the eyes, or urine getting darker and stools paler, fatigue, weakness
- epileptic fits (seizures)
- inflammation of the brain (encephalopathy)
- mental disturbances including psychotic reactions such as hallucinations and delusions
- memory problems.
- eye problems such as visual disturbances and eye pain

Rare side effects (*may affect up to 1 in 1 000 people*)

- A drug reaction that causes rash, fever, inflammation of internal organs, blood abnormalities and illness affecting the whole body (DRESS syndrome)
- Severe extensive skin damage (blistering on the skin and in body openings such as the mouth and nose): toxic epidermal necrolysis (life-threatening reaction with flu-like effects and blistering in the skin, mouth, eyes and genitals)

The frequency of the following side effects is **not known**.

- allergic reactions, including:
 - skin reactions, such as rash (exanthema, erythema) and itching (pruritus), but also severe forms with fever, blisters and involvement of the mucous membranes (e.g. erythema multiforme, Stevens-Johnson syndrome)
 - inflammation of blood vessels (vasculitis)
 - swollen or painful lymph nodes (lymphadenopathy)
 - painful disorder affecting joints, muscles, tendons (rheumatic syndrome)
 - connective tissue disorders such as lupus syndrome which can affect the skin and kidneys (symptoms may include a butterfly-shaped rash over the cheeks and nose, tiredness, a high temperature, feeling or being sick, joint pain and weight loss)
 - fever
- vertigo (spinning sensation and loss of balance)
- elevated mood, personality changes
- inflammation of the lungs (pneumonitis), scarring of the lungs (interstitial lung disease)

- build-up of acid in the body (metabolic acidosis); increased blood levels of glucose; a vitamin B3 deficiency syndrome called pellagra (with symptoms such as dementia, loose stools and skin inflammation); vitamin B6 deficiency (irritability, difficulty sleeping, weak muscles, cracks at the corner of the mouth and weight loss)
- nausea, vomiting, loss of appetite, dry mouth, constipation, belly pain
- difficulty in passing urine
- changes in the white blood cell counts (leucopenia, neutropenia, eosinophilia, agranulocytosis), possibly resulting in an increased risk of infection
- decreased red blood cell counts (anaemia), possibly leading to tiredness, weakness and shortness of breath
- decreased platelet count, possibly resulting in an increased risk of bruising and bleeding
- inflammation of the joints (arthritis)
- muscle weakness, overactive reflexes
- increased size of breasts in men (gynaecomastia)
- loss of hearing and ringing in your ears may occur if you have severe problems with your kidneys
- inflammation of the pancreas, which causes severe pain in the abdomen and back
- a positive test result for antibodies against your body's tissues
- withdrawal symptoms, which may occur after you stop taking [TB308 trade name], include headache, insomnia, excessive dreaming, irritability and nervousness.

Side effects with this medicine are more common in people aged over 35 years and in people who break down isoniazid more slowly. The risk of side effects increases with high doses of [TB308 trade name].

If you notice any of the side effects listed above or if any of the side effects get serious, talk to your health care provider.

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 [TB308 trade name]

Do not store above 30°C. Store in the original package. 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, 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 or 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 [TB308 trade name] contains

- The active ingredient is isoniazid
- The other ingredients of [TB308 trade name] are colloidal anhydrous silica, croscarmellose sodium, mannitol, microcrystalline cellulose, povidone, pregelatinized starch and stearic acid.

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

What [TB308 trade name] looks like and contents of the pack

White to off-white, capsule-shaped, uncoated tablets. They are biconvex (rounded on top and bottom) with bevelled edges. The tablets have 'M' debossed (stamped into) one side and 'IS' debossed to the left and '7' debossed to the right of a break line on the other side.

The break line can be used to divide [TB308 trade name] into equal doses.

The medicine is available in the following packs:

HDPE bottle

Round, opaque white plastic (HDPE) bottle containing 100 tablets. It also contains cotton fibre to keep the tablets in place. The bottle has an aluminium foil seal and an opaque white plastic (polypropylene) screw cap.

Blister pack

Opaque white plastic (PVC/PVDC) on aluminium foil blister cards, each containing 10 tablets. Available in cartons of 10×10 tablets.

Supplier and Manufacturer

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>