

## **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.*

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\* [https://extranet.who.int/prequal/sites/default/files/document\\_files/75%20SRA%20clarification\\_Feb2017\\_newtempl.pdf](https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf)

## Information for the patient

[TB405 trade name]<sup>†</sup>

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 [TB405 trade name] is and what it is used for
2. What you need to know before you take [TB405 trade name]
3. How to take [TB405 trade name]
4. Possible side effects
5. How to store [TB405 trade name]
6. Contents of the pack and other information

#### 1. What [TB405 trade name] is and what it is used for

[TB405 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.

[TB405 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.

[TB405 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 [TB405 trade name]

##### **Do not take [TB405 trade name]:**

- if you are allergic (hypersensitive) to isoniazid or any of the other ingredients of [TB405 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.

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<sup>†</sup> 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 [TB405 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 [TB405 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 [TB405 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 [TB405 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 [TB405 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 [TB405 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 [TB405 trade name], or [TB405 trade name] may affect their action. Side effects of either medicine may become worse or the medicines may become less effective.

Where possible, [TB405 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 [TB405 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 [TB405 trade name] with other medicines**

The active substance in [TB405 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 [TB405 trade name] with food and drink**

Take [TB405 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 [TB405 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

[TB405 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 [TB405 trade name]

This medicine contains aspartame in each tablet. 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 [TB405 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, [TB405 trade name] must be used with other medicines.

Always take [TB405 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.

Make a mixture with the tablets in drinking water before taking the dose. See “**Instructions for taking [TB405 trade name] tablets**”, below.

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 [TB405 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 [TB405 trade name] tablets
4 to less than 8 kg	½ tablet <sup>†</sup> 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
<sup>†</sup> May be given as 5 mL of a mixture produced by mixing 1 tablet in 10 mL of water, see “ <b>Instructions for taking [TB405 trade name] tablets</b> ”, below	

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 [TB405 trade name]
25 to less than 30 kg	1½ tablets per day
30 kg to less than 65 kg	3 tablets per day*

\*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 ensure you are getting enough isoniazid.

#### *Treatment of drug-resistant TB*

If [TB405 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 tablets of [TB405 trade name] daily
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

\*May be given as 5 mL of a mixture produced by mixing 1 tablet in 10 mL of water, see **Instructions for taking [TB405 trade name] tablets**, below

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

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 [TB405 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 [TB405 trade name] on its own*

If [TB405 trade name] is used **on its own**, then the following daily doses, given for 6 or 9 months, have been recommended in those weighing less than 25 kg:

Person's weight	Dose of [TB405 trade name] tablets
4 to less than 8 kg	½ tablet once daily  May be given as 5 mL of a mixture produced by mixing 1 tablet in 10 mL of water, see 'Instructions for taking [TB405 trade name] tablets', below
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 [TB405 trade name] is **used with another medicine**, the dose depends on which combination you get.

*If you are given [TB405 trade name] with the medicine rifampicin*

When you take [TB405 trade name] with rifampicin, you should take it **once a day for 3 months**. The dose of [TB405 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 [TB405 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 [TB405 trade name] tablets
3 to less than 6 kg	<i>Under 3 months of age</i>	Mix 1 tablet in exactly 10 mL of water (see 'Instructions for taking [TB405 trade name] tablets', below). Give <b>6 mL</b> of this mixture once a week
	<i>3 months or older</i>	Mix 1 tablet in exactly 10 mL of water (see 'Instructions for taking [TB405 trade name] tablets', below). Give <b>7 mL</b> of this mixture once a week
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 tablets once a week
10 to less than 15 kg		2½ tablets 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 [TB405 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 [TB405 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 [TB405 trade name] than you should**

If you accidentally take too many [TB405 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 [TB405 trade name]**

It is important not to miss a dose of [TB405 trade name]. If you have missed doses 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 [TB405 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 [TB405 trade name]**

Don't stop taking [TB405 trade name] without checking with your health care provider. Talk to your health care provider before you stop taking [TB405 trade name] for any reason, particularly if you get any side effects or have another illness.

If you have stopped your treatment with [TB405 trade name] for any reason, speak to your health care provider before you start taking [TB405 trade name] again.

**Instructions for taking [TB405 trade name] tablets.**

***If the dose is at least 1 tablet***

Mix the tablets in drinking water and take this mixture. Use 10 mL of water for each tablet, but no more than 50 mL in total.

1. Place the required amount of drinking water into a small, clean cup or bowl and add the required number of tablets. If your dose includes a half tablet, break the tablet carefully along the break line.
2. Swirl the cup or bowl gently until tablets break down and are fully mixed with the water
3. Drink all the mixture immediately.
4. Rinse the cup a little more drinking water (about 10 mL) and drink this to make sure you have taken the full dose.

***If the dose is less than 1 tablet***

You will need:

- 1 tablet of [TB405 trade name]
  - drinking water
  - a 10-mL oral syringe
  - a container such as a small bowl or a cup
1. Use the oral syringe to measure 10 mL drinking water into the bowl or cup.
  2. Add 1 tablet of [TB405 trade name] and swirl the bowl or cup gently until the tablet breaks down and is fully mixed with the water.
  3. Use the oral syringe to draw up the right amount of the mixture and give it straight away.
  4. Throw away any mixture left in the cup.

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 [TB405 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 [TB405 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 [TB405 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 [TB405 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 [TB405 trade name]**

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

Do not store above 30°C.

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.

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 [TB405 trade name] contains**

- The active ingredient is isoniazid 100 mg.
- The other ingredients of [TB405 trade name] are microcrystalline cellulose, crospovidone, colloidal anhydrous silica, aspartame, orange flavour and magnesium stearate.

#### **What [TB405 trade name] looks like and contents of the pack**

White to off white, round, uncoated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have a break line on one side and are plain on the other side.

The break line is intended for dividing the tablet into equal doses when half a tablet dose is to be administered.

Aluminium foil strip packs, each containing 10 tablets. Available in cartons of 10 x 10 tablets.

#### **Supplier and Manufacturer**

##### ***Supplier***

S Kant Healthcare Limited  
3-A, Shiv Sagar Estate  
North Wing  
Dr. Annie Besant Road  
Worli, Mumbai 400 018  
India  
Tel: + 91 22 6622 7575  
Fax: + 91 22 6622 7500/6622 7600

##### ***Manufacturer***

S Kant Healthcare Limited  
Plot No. 1802-1805  
G.I.D.C. Phase III  
Vapi 396 195  
Gujarat  
India  
Tel: + 91 260 6539518  
Fax: + 91 260 2430527  
Email: regulatory@skant.com

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

**This leaflet was last revised in May 2025**

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