

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S4****ISONIAZID 100 mg PHARMA-Q tablets****Isoniazid****Sugar free**

Read all of this leaflet carefully before you take ISONIAZID 100 mg PHARMA-Q

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ISONIAZID 100 mg PHARMA-Q has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ISONIAZID 100 mg PHARMA-Q is and what it is used for
2. What you need to know before you take ISONIAZID 100 mg PHARMA-Q
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1. What ISONIAZID 100 mg PHARMA-Q is and what it is used for

ISONIAZID 100 mg PHARMA-Q contains the active substance isoniazid. Isoniazid belongs to a group of medicines called antibacterials. Isoniazid works by killing

bacteria that causes tuberculosis (TB).

ISONIAZID 100 mg PHARMA-Q is used alone for the prevention of tuberculosis (TB) or in combination with other antituberculosis medicines for the treatment of TB.

2. What you need to know before you take ISONIAZID 100 mg PHARMA-Q

Do not take ISONIAZID 100 mg PHARMA-Q:

- if you are hypersensitive (allergic) isoniazid, ethionamide, pyrazinamide, niacin or any of the other ingredients of ISONIAZID 100 mg PHARMA-Q (listed in section 6).
- if you suffer from alcoholism.
- if you have liver disease.
- if you have kidney failure.
- if you have epilepsy or have ever had convulsions (fits).
- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with ISONIAZID 100 mg PHARMA-Q:

- if you have epilepsy.
- if you have diabetes.
- if you have, or have had, problems with your kidneys.
- if you present with symptoms of hepatitis (inflammation of the liver) such as a general feeling of discomfort or illness (malaise), tiredness, anorexia and nausea.
- if you are older, female, malnourished (severely underfed).
- if you have extra-pulmonary TB (outside the lungs).
- if you have HIV infection.

- if you suffer or have suffered from psychosis (mental disturbances with hallucinations or delusions).
- if you develop any eye problems as regular eye examinations are advised while being treated with ISONIAZID 100 mg PHARMA-Q.

Other medicines and ISONIAZID 100 mg PHARMA-Q

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Please inform your doctor or pharmacist if:

- you are taking another medicine to treat tuberculosis (TB) (e.g. para-aminosalicylic acid, rifampicin, cycloserine),
- you are taking warfarin (medicine to thin the blood and prevent clotting),
- you are taking disulfiram for alcohol dependence,
- you are taking any medication for epilepsy (e.g. carbamazepine, primidone, phenytoin or ethosuximide),
- you are taking medication for HIV infection (e.g. stavudine, zalcitabine),
- you are taking paracetamol (for pain and fever), alcohol and rifampicin (medicine used to treat TB),
- you are taking a vitamin B6 or B3 supplement,
- you are taking medication for asthma or chronic obstructive pulmonary disease (e.g. theophylline),
- you are taking medication for anxiety (e.g. benzodiazepines: diazepam, triazolam, chlorzoxazone),
- you are taking medication for high blood pressure (e.g. propranolol),
- you are taking medicines containing levodopa (used in the treatment of Parkinson's disease),
- you are taking cycloserine (used to treat tuberculosis and urinary tract

infections),

- prednisolone (corticosteroid) - used to treat certain types of allergies and inflammatory conditions,
- you are taking medicines used in surgery (narcotics, e.g. alfentanil; anaesthetic e.g. enflurane),
- certain antacids,
- you are taking ketoconazole or itraconazole (used to treat fungal infections).

Laboratory tests: ISONIAZID 100 mg PHARMA-Q may interfere with the copper sulphate urine glucose tests, resulting in a false positive test. If you are going to have a blood test, it is important to tell your doctor that you are taking ISONIAZID 100 mg PHARMA-Q.

ISONIAZID 100 mg PHARMA-Q with food and drink

ISONIAZID 100 mg PHARMA-Q should be taken on an empty stomach. It may be taken with meals if gastrointestinal irritation occurs, but the absorption of ISONIAZID 100 mg PHARMA-Q may be reduced.

Avoid drinking alcohol with ISONIAZID 100 mg PHARMA-Q. This may damage your liver.

ISONIAZID 100 mg PHARMA-Q may interact with foods containing histamine or tyramine (e.g. matured cheeses, cured meat, some fish like tuna, salmon and mackerel, wine and beer), causing symptoms including headache, sweating, flushing, fast, uneven or forceful heartbeat (palpitations), dizziness, feel lightheaded or faint (due to low blood pressure). These foods should be avoided if you are taking ISONIAZID 100 mg PHARMA-Q.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ISONIAZID 100 mg PHARMA-Q.

Pregnancy

ISONIAZID 100 mg PHARMA-Q is not recommended in pregnancy.

Breastfeeding

If you are breastfeeding, you must not take ISONIAZID 100 mg PHARMA-Q, as ISONIAZID 100 mg PHARMA-Q will be transferred to your breast milk.

Driving and using machines

ISONIAZID 100 mg PHARMA-Q may cause dizziness, impaired concentration, and/or drowsiness. If you feel dizzy or drowsy while taking ISONIAZID 100 mg PHARMA-Q do not drive and do not use any tools or machines.

It is not always possible to predict to what extent ISONIAZID 100 mg PHARMA-Q may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ISONIAZID 100 mg PHARMA-Q affects them.

3. How to take ISONIAZID 100 mg PHARMA-Q

Do not share medicines prescribed for you with any other person.

Always take ISONIAZID 100 mg PHARMA-Q exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Usual dosage:

Adults: 100 mg (one tablet) 3 times daily without meals.

Recommended dose: 3-5 mg/kg body mass every 24 hours in 2 or more doses.

Children: 10 to 20 mg per kg of body mass daily.

If aluminium containing antacids are taken, they must be taken at least 1 hour after ISONIAZID 100 mg PHARMA-Q.

ISONIAZID 100 mg PHARMA-Q should not be taken with food, i.e. at least 30 minutes before or 2 hours after a meal. ISONIAZID 100 mg PHARMA-Q tablets may be taken with food if you experience irritation in the stomach.

Your doctor will tell you exactly how to take and when to take ISONIAZID 100 mg PHARMA-Q. Tuberculosis therapy must be continued for 6 months to 2 years, depending on the treatment given.

If you have the impression that the effect of ISONIAZID 100 mg PHARMA-Q is too strong or too weak, tell your doctor or pharmacist.

If you take more ISONIAZID 100 mg PHARMA-Q than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Taking too much ISONIAZID 100 mg PHARMA-Q may cause nausea (feeling sick), vomiting, dizziness, slurred speech, feeling lethargic or feeling if the room is spinning round, fits and acidosis (upset of the acid balance in the body). These effects may require emergency treatment in hospital.

If you miss a dose of ISONIAZID 100 mg PHARMA-Q

If you forget to take a dose of ISONIAZID 100 mg PHARMA-Q, take one as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the tablet or tablets at the usual time. Do not take a double dose to make up for the forgotten individual doses.

If you stop taking ISONIAZID 100 mg PHARMA-Q

Do not stop taking ISONIAZID 100 mg PHARMA-Q without first talking to your

doctor. If the full treatment prescribed by your doctor is not completed, some of the bacteria causing the TB infection may not be killed. These bacteria may continue to grow and multiply so the TB infection may not clear completely or it may return.

4. Possible side effects

ISONIAZID 100 mg PHARMA-Q can have side effects.

Not all side effects reported for ISONIAZID 100 mg PHARMA-Q are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ISONIAZID 100 mg PHARMA-Q, please consult your health care provider for advice.

If any of the following happens, stop taking ISONIAZID 100 mg PHARMA-Q and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, lips, mouth or throat which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS),
- a reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS).

These are all very serious side effects. If you have them, you may have had a serious reaction to ISONIAZID 100 mg PHARMA-Q. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis),
- severe extensive skin damage (separation of the epidermis and superficial mucous membranes) (toxic epidermal necrolysis(TEN)),
- yellowing of the skin or whites of the eyes, or urine getting darker and stools paler, fatigue, weakness, malaise, loss of appetite, nausea or vomiting caused by liver problems (hepatitis),
- peripheral neuritis or neuropathy, a result of damage to the nerves outside of the brain and spinal cord (peripheral nerves), often causes weakness, numbness and pain, usually in your hands and feet.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- nausea, vomiting, constipation, dry mouth, diarrhoea, stomach pain,
- temporary increases in liver enzymes,
- hepatitis prodromal symptoms (loss of appetite, nausea or vomiting, unusual tiredness or weakness).

Less frequent

- hypersensitivity reactions (fever, skin rashes, joint pain),
- blood disorders which may make you more likely to get infections, get tired very easily, or bruise very frequently,
- high blood sugar levels (hyperglycaemia),
- metabolic acidosis (upset of the acid balance in the body),

- low blood sugar levels,
- neurotoxicity- damage to brain or peripheral nervous system (this can alter the activity of the nervous system in ways that can disrupt or kill nerves),
- convulsions (fits),
- overactive reflexes,
- eye problems such as eye pain,
- dizziness or feeling if the room is spinning round (vertigo),
- red or itchy skin rash or peeling of the skin,
- systemic lupus erythematosus (SLE) is an autoimmune disease. In this disease, the immune system of the body mistakenly attacks healthy tissue. It can affect the skin, joints, kidneys, brain, and other organs,
- 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),
- difficulty in starting to pass urine,
- gynaecomastia (increased size of breasts in men).

Frequency unknown

- swelling of your lymph nodes,
- nicotinic acid deficiency (pellagra), a disease caused by a lack of the vitamin niacin (vitamin b3). Symptoms include inflamed skin, diarrhoea, dementia, and sores in the mouth, constipation, dry mouth,
- mental disturbances including psychotic reactions such as hallucinations and delusions, elevated mood,
- tingling or numbness in the hands or feet (pins and needles),
- loss of hearing and ringing in your ears,

- inflammation of blood vessels (vasculitis),
- a disorder which causes progressive scarring of the lung tissue, which can cause you to struggle to breathe,
- upset stomach or severe stomach pain,
- Lupus-like syndrome: Drug-induced lupus erythematosus (DIL) is a subset of lupus defined as a lupus-like syndrome that develops in temporal relation when you have taken some kind of medicine and resolves after you stop taking the medicine,
- rheumatic diseases are characterized by inflammation that affects the connecting or supporting structures of the body — most commonly the joints, but also sometimes the tendons, ligaments, bones, and muscles,
- problems with your kidneys,
- fever,
- acute liver failure, liver injury or jaundice (yellowing of the skin or whites of the eyes)
- increased liver enzymes (shows up in blood tests).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ISONIAZID 100 mg PHARMA-Q.

5. How to store ISONIAZID 100 mg PHARMA-Q

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Store in the original container.
- Keep the blister in the outer carton until required for use.
- Do not use after the expiry date stated on the label / carton / bottle

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ISONIAZID 100 mg PHARMA-Q contains

- The active substance is isoniazid. Each ISONIAZID 100 mg PHARMA-Q tablet contains 100 mg isoniazid.
- The other ingredients are: colloidal silicon dioxide, crospovidone XL 10, polyplasdone XL, magnesium stearate, maize starch, microcrystalline cellulose 101, microcrystalline cellulose 102.

What ISONIAZID 100 mg PHARMA-Q looks like and contents of the pack

ISONIAZID 100 mg PHARMA-Q tablets are white to off-white, flat, circular, bevelled edge, uncoated tablets, with break-line on one side.

ISONIAZID 100 mg PHARMA-Q tablets are packed as follows:

- PVC-PVDC/Alu blister packs of 10 or 28 tablets per blister packed in a carton.
- HDPE bottle pack containing 500 tablets or 1 000 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

29 July 2025

Registration number

57/20.2.3/0666

Access to the corresponding Professional Information

<https://www.pharmaq.co.za>