

**PATIENT INFORMATION LEAFLET****SCHEDULING STATUS****S4****ISONIAZID PHARMA-Q 300 tablets****Isoniazid****Sugar free****Read all of this leaflet carefully before you take ISONIAZID PHARMA-Q 300**

- 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 PHARMA-Q 300 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 PHARMA-Q 300 is and what it is used for
2. What you need to know before you take ISONIAZID PHARMA-Q 300
3. How to take ISONIAZID PHARMA-Q 300
4. Possible side effects
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6. Contents of the pack and other information

**1. What ISONIAZID PHARMA-Q 300 is and what it is used for**

ISONIAZID PHARMA-Q 300 contains the active substance isoniazid. Isoniazid belongs to a group of medicines called antibacterials. Isoniazid works by killing bacteria that causes tuberculosis (also known as TB).

ISONIAZID PHARMA-Q 300 is used to treat and prevent (prophylaxis) tuberculosis. ISONIAZID PHARMA-Q 300 is used together with other antituberculosis medicines to treat TB.

## 2. What you need to know before you take ISONIAZID PHARMA-Q 300

### Do not take ISONIAZID PHARMA-Q 300:

- if you are hypersensitive (allergic) isoniazid, ethionamide, pyrazinamide, niacin or any of the other ingredients of ISONIAZID PHARMA-Q 300 (listed in section 6).
- if you suffer from alcoholism.
- if you have serious liver function problems after taking any medicine.
- if you have serious 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 PHARMA-Q 300:

- if you have epilepsy.
- if you have diabetes.
- if you drink a lot of alcohol regularly.
- if you have, or have had, problems with your liver or 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 suffer or have suffered from psychosis (mental disturbances with hallucinations or delusions).
- if you are malnourished (severely underfed).
- if you have HIV infection.
- if you develop any eye problems as regular eye examinations are advised while being



treated with ISONIAZID PHARMA-Q 300.

- if you develop signs and symptoms of conditions called Stevens-Johnson Syndrome (SJS) or Toxic Epidermal Necrolysis (TEN). This may include an increasing skin rash often with blisters or mouth ulcers.
- if you develop hypersensitivity symptoms such as fever, rash, swollen lymph nodes or liver abnormalities. This condition is called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

### **Other medicines and ISONIAZID PHARMA-Q 300**

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

It's especially important to mention:

- Stavudine or zalcitabine (used for the treatment of HIV);
- Any medicine for the treatment of epilepsy such as carbamazepine, phenytoin or primidone;
- Disulfiram (for the treatment of alcoholism);
- Rifampicin, paraminosalicylic acid or any other medicine used to treat TB;
- The benzodiazepine diazepam or triazolam (for the treatment of anxiety);
- Levodopa (for the treatment of Parkinson's disease);
- Itraconazole or ketaconazole (for the treatment of fungal infections).
- Paracetamol for pain and fever.
- Theophyllin, used for lung diseases such as asthma and bronchitis.
- Warfarin (used to prevent blood clots.
- Prednisolone (corticosteroid) – used to treat certain types of allergies and inflammatory conditions.
- Certain antacids.



**ISONIAZID PHARMA-Q 300 with food and drink**

ISONIAZID PHARMA-Q 300 should be taken on an empty stomach. It may be taken with meals if gastrointestinal irritation occurs, but the absorption of ISONIAZID PHARMA-Q 300 may be reduced.

Avoid drinking alcohol with ISONIAZID PHARMA-Q 300. This may damage your liver.

ISONIAZID PHARMA-Q 300 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 PHARMA-Q 300.

**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 PHARMA-Q 300.

***Pregnancy***

ISONIAZID PHARMA-Q 300 is not recommended in pregnancy.

Pyridoxine supplementation is recommended (see section 4.4).

***Breastfeeding***

If you are breastfeeding, you must not take ISONIAZID PHARMA-Q 300, as ISONIAZID PHARMA-Q 300 will be transferred to your breast milk.

**Driving and using machines**

ISONIAZID PHARMA-Q 300 may influence the ability to drive and use machines.

Since adverse reactions such as convulsions (fits) have been reported in patients receiving ISONIAZID PHARMA-Q 300, patients should not drive, use machinery or perform any tasks

that require concentration, until they are certain that ISONIAZID PHARMA-Q 300 does not adversely affect their ability to do so.

### 3. How to take ISONIAZID PHARMA-Q 300

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

Always take ISONIAZID PHARMA-Q 300 exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

Usual dosage:

*In adults and adolescents*

Prophylaxis: 5 mg/kg (maximum 300 mg) once daily.

Treatment: In combination with other anti-tuberculosis medicines: 5 to 15 mg/kg, once daily or in divided doses (maximum 900 mg per day), based on the type of tuberculosis and sensitivity pattern. Higher doses can be used for different types of tuberculosis.

*In children*

Prophylaxis: 10 mg per kg of body weight, up to 300 mg, once daily.

Treatment: In combination with other anti-tuberculosis medicines: 10 to 20 mg per kg of body weight, up to 300 mg, once daily. Higher doses can be used for different types of tuberculosis.

Your doctor will tell you exactly how to take and when to take ISONIAZID PHARMA-Q 300. Tuberculosis therapy must be continued for 6 months to 2 years, depending on the treatment given.

While you are taking this medicine, your doctor may ask you to have check-ups and blood tests. These are to:

- Check that your liver is working properly;

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- Make sure your medicine is working properly;
- Check the dose you are taking is right for you.

If you have the impression that the effect of ISONIAZID PHARMA-Q 300 is too strong or too weak, tell your doctor or pharmacist.

Remember: ISONIAZID PHARMA-Q 300 should not be taken with food, i.e. at least 30 minutes before or 2 hours after a meal. You should swallow ISONIAZID PHARMA-Q 300 tablets whole with a glass of water.

#### **If you take more ISONIAZID PHARMA-Q 300 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 may cause; feeling and being sick, dizziness 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 PHARMA-Q 300**

If you forget to take a dose of ISONIAZID PHARMA-Q 300, 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 PHARMA-Q 300**

Do not stop taking ISONIAZID PHARMA-Q 300 without first talking to your doctor. It is important you take the full course of this medicine, as directed by your doctor, in order to clear the infection that causes tuberculosis.

If you stop taking this medicine suddenly you may get withdrawal symptoms including a headache, difficulty in sleeping, having more dreams, feeling irritable and feeling nervous.

#### 4. Possible side effects

ISONIAZID PHARMA-Q 300 can have side effects.

Not all side effects reported for ISONIAZID PHARMA-Q 300 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ISONIAZID PHARMA-Q 300, please consult your health care provider for advice.

If any of the following happens, stop taking ISONIAZID PHARMA-Q 300 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 PHARMA-Q 300. 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)
- 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*

- 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,
- 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),

*Frequency unknown*

- mental disturbances including psychotic reactions such as hallucinations and delusions, elevated mood,
- severe stomach pain,
- inflammation of blood vessels (vasculitis),
- loss of hearing and ringing in your ears,
- tingling or numbness in the hands or feet (pins and needles),
- constipation, being sick, dry mouth, upset stomach and diarrhoea,

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- problems with your kidneys,
- fever,
- dizziness or feeling if the room is spinning round (vertigo),
- overactive reflexes,
- red or itchy skin rash or peeling of the skin,
- blood disorders (low white blood cell count, abnormal breakdown of red blood cells and an inadequate number of new blood cells),
- high blood sugar levels (hyperglycaemia),
- metabolic acidosis (upset of the acid balance in the body),
- low blood sugar levels,
- 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,
- convulsions (fits),
- eye problems such as visual disturbances and eye pain,
- a disorder which causes progressive scarring of the lung tissue, which can cause you to struggle to breathe,
- 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),
- 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,

- difficulty in starting to pass urine,
- gynaecomastia (increased size of breasts in men),

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 adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

By reporting side effects, you can help provide more information on the safety of ISONIAZID PHARMA-Q 300.

## 5. How to store ISONIAZID PHARMA-Q 300

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 PHARMA-Q 300 contains

- The active substance is isoniazid. Each ISONIAZID PHARMA-Q 300 tablet contains 300

mg isoniazid. Sugar free.

- The other ingredients are: colloidal silicon dioxide (E551), crospovidone XL 10 (E1202), polyplasdone XL, magnesium stearate (E470b), maize starch, microcrystalline cellulose 101 (E460), microcrystalline cellulose 102 (E460).

### **What ISONIAZID PHARMA-Q 300 looks like and contents of the pack**

ISONIAZID PHARMA-Q 300 tablets are white to off-white, circular, biconvex, uncoated tablets, plain on both sides.

ISONIAZID PHARMA-Q 300 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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2093

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**Access to the corresponding Professional Information**

To be confirmed.