

1.3.2.1 Patient Information Leaflet

SCHEDULING STATUS

S3

ISONIAZID MYLAN 300 mg, tablets

Isoniazid

Contains sugar: Mannitol 207 mg

Read all of this leaflet carefully before you start taking ISONIAZID MYLAN 300 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ISONIAZID MYLAN 300 mg 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 MYLAN 300 mg is and what it is used for.
2. What you need to know before you take ISONIAZID MYLAN 300 mg.
3. How to take ISONIAZID MYLAN 300 mg.
4. Possible side effects.

1.3.2.1 Patient Information Leaflet

5. How to store ISONIAZID MYLAN 300 mg.
6. Contents of the pack and other information.

1. What ISONIAZID MYLAN 300 mg is and what it is used for

ISONIAZID MYLAN 300 mg contains isoniazid that belongs to a group of medicines called antituberculosis medicines.

This means that it stops the bacteria that cause tuberculosis from growing and multiplying. ISONIAZID MYLAN 300 mg is also used with other antituberculosis medicine for the treatment of tuberculosis (also known as TB).

2. What you need to know before you take ISONIAZID MYLAN 300 mg

Do not take ISONIAZID MYLAN 300 mg

- if you are hypersensitive (allergic) to isoniazid or any of the other ingredients of ISONIAZID MYLAN 300 mg (listed in section 6);
- if you are hypersensitive to other chemically related medicines such as ethionamide, pyrazinamide and niacin;
- if you have impairment of your liver function;
- if you have an active liver disease irrespective of the cause;
- if you have suffered liver problems with previous use of isoniazid;
- if you suffered severe side effects when previously exposed to isoniazid;



1.3.2.1 Patient Information Leaflet

- if you suffer from severe kidney dysfunction;
- if you have epilepsy or have ever had convulsions (fits);
- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with ISONIAZID MYLAN 300 mg:

- if you drink a lot of alcohol regularly;
- if you have, or have had, problems with your liver or kidneys;
- if you suffer or have suffered from psychosis (mental disturbances with hallucinations or delusions);
- if you have diabetes mellitus (high blood sugar levels);
- if you are an elderly person;
- if you have HIV infection (AIDS);
- if you are malnourished (severely underfed);
- if you have extra-pulmonary TB (outside the lungs);
- if you are on treatment with Warfarin, a medicine used to prevent blood clotting, as it increases the Warfarin concentration in your blood and may increase the risk of bleeding;
- if you are treated with antiepileptic medicines such as carbamazepine, primidone, phenytoin or valproate as it may increase the blood concentrations of these medicines;



1.3.2.1 Patient Information Leaflet

- if you are taking a medicine called disulfiram as ISONIAZID MYLAN 300 mg may increase the concentrations of disulfiram;
- if you are a user of injection drugs (e.g. heroin);
- if you use any chronically administered medication concurrently (see 'Taking other medicines');
- if you suffer from tingling in the hands and feet (peripheral neuropathy) (see below).

You should promptly report signs or symptoms consistent with liver damage. These include any of the following: unexplained lack of appetite, nausea, vomiting, dark urine, yellowing of the skin and the eyes (jaundice), rash, tingling in the hands and feet, persistent tiredness, weakness lasting longer than 3 days and/or abdominal tenderness, especially in the right upper region of your belly. Your healthcare provider will test your blood regularly to check for any problems with your liver.

Peripheral neuropathy (tingling in the hands and feet) is the most common side effect of ISONIAZID MYLAN 300 mg (see section 4 'Possible side effects'). If you have kidney problems, you may be at increased risk of experiencing ISONIAZID MYLAN 300 mg side effects including peripheral neuropathy. A certain vitamin, called pyridoxine, should be taken routinely at doses of 10 mg per day during treatment with ISONIAZID MYLAN 300 mg, since it largely reduces the risk of developing peripheral neuropathy.



1.3.2.1 Patient Information Leaflet

Children

ISONIAZID MYLAN 300 mg tablet formulation is not suitable for use in children.

Other medicines and ISONIAZID MYLAN 300 mg

Always tell your healthcare provider if you are taking any other medicine. This includes all complementary or traditional medicines.

Tell your doctor if you are taking any of the following medicines:

- Any medicine for the treatment of epilepsy such as carbamazepine, phenytoin, primidone or valproate.
- Disulfiram (for the treatment of alcoholism).
- Rifampicin, para-aminosalicylic acid or any other medicine used to treat TB.
- Diazepam, flurazepam, triazolam, midazolam (for the treatment of anxiety).
- Levodopa (for the treatment of Parkinson's disease).
- Itraconazole or ketoconazole (for the treatment of fungal infections).
- Stavudine (used for the treatment of HIV).
- Aluminium hydroxide (medicine used to treat indigestion).
- Medicines for the treatment of certain psychiatric conditions (neuroleptics, e.g. chlorpromazine, haloperidol).
- Medicines for prevention of blood clots (coumarin- or indandione-derivates, e.g. warfarin,



1.3.2.1 Patient Information Leaflet

phenindione).

- Medicines used in surgery (narcotics, e.g. alfentanil; anaesthetic e.g. enflurane),
- Theophylline (medicine for the treatment of asthma).
- Procainamide (medicine for the treatment of cardiac dysrhythmias).
- Corticosteroids (e.g. prednisolone, medicines for the treatment of inflammation and other diseases, such as asthma or rheumatoid arthritis).
- Paracetamol (a pain killer).
- Medicines toxic to the liver.
- Medicines toxic to the nervous system.

ISONIAZID MYLAN 300 mg with food and drink:

ISONIAZID MYLAN 300 mg tablets should be taken preferably on an empty stomach, i.e. at least 30 minutes before a meal or 2 hours after a meal.

Do not drink alcohol while taking ISONIAZID MYLAN 300 mg. This increases your risk for liver damage.

Pregnancy, breastfeeding and fertility

Pregnancy:

You should not be treated with ISONIAZID MYLAN 300 mg if you are pregnant.

Breastfeeding:



1.3.2.1 Patient Information Leaflet

ISONIAZID MYLAN 300 mg crosses into your breastmilk. You should not breastfeed your baby if you are on treatment with ISONIAZID MYLAN 300 mg.

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 healthcare provider for advice before taking ISONIAZID MYLAN 300 mg.

Driving and using machines

ISONIAZID MYLAN 300 mg may affect your ability to drive and use machines. You should not drive or use machines before you know how ISONIAZID MYLAN 300 mg may affect you.

Important information about some of the ingredients of ISONIAZID MYLAN 300 mg tablets:

ISONIAZID MYLAN 300 mg tablets contain mannitol which may cause loose bowels.

3. How to take ISONIAZID MYLAN 300 mg

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

Always take ISONIAZID MYLAN 300 mg exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.



1.3.2.1 Patient Information Leaflet

If you take aluminium-containing antacids, they must be taken at least one hour after ISONIAZID MYLAN 300 mg.

The usual dose is:

Adults and Adolescents (weight > 45 kg):

One ISONIAZID MYLAN 300 mg tablet daily.

Do not take more than the recommended dose.

Children:

ISONIAZID MYLAN 300 mg is not suitable for children.

Your doctor will tell you how long your treatment with ISONIAZID MYLAN 300 mg will last.

Do not stop treatment early because your infection that causes tuberculosis may not be cleared.

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

If you take more ISONIAZID MYLAN 300 mg than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

1.3.2.1 Patient Information Leaflet

If you forget to take ISONIAZID MYLAN 300 mg:

Do not take a double dose to make up for forgotten individual doses.

If you stop taking ISONIAZID MYLAN 300 mg:

Do not stop treatment early because your infection that causes tuberculosis may not be cleared.

4. Possible side effects

ISONIAZID MYLAN 300 mg can have side effects.

Not all side effects reported for ISONIAZID MYLAN 300 mg are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking ISONIAZID MYLAN 300 mg, please consult your healthcare provider for advice.

If any of the following happens, stop taking ISONIAZID MYLAN 300 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing,



1.3.2.1 Patient Information Leaflet

- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ISONIAZID MYLAN 300 mg. 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 known as toxic epidermal necrolysis),
- serious skin rashes including Stevens-Johnson syndrome (flu-like symptoms appear first. A painful rash that spreads and blisters follows),
- 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).

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

Tell your doctor if you notice any of the following:



1.3.2.1 Patient Information Leaflet

Frequent side effects:

- sensations of tingling, pricking, or numbness of the skin, especially in the feet and hands (peripheral neuropathy),
- increases of liver enzymes as measured in blood samples. Usually, these enzyme increases return to normal within three months despite continued treatment. When the values rise above a certain level.

Less frequent side effects:

- epileptic seizures,
- inflammation of the brain,
- personality changes,
- memory impairment.

Frequency not known:

- blood disorders which may make you more likely to get infections,
- high blood sugar levels,
- acidosis (upset of the acid balance in the body),
- low levels of vitamin B6 and nutrition problems,
- mental disturbances including psychotic reactions such as hallucinations and delusions,



1.3.2.1 Patient Information Leaflet

- eye problems such as visual disturbances and eye pain,
- dizziness or feeling if the room is spinning around (vertigo),
- ringing in the ears (tinnitus),
- loss of hearing,
- inflammation of blood vessels (vasculitis),
- severe stomach pain,
- constipation,
- upset stomach and diarrhoea,
- feeling and being sick,
- dry mouth,
- red or itchy skin rash or peeling of the skin,
- connective tissue disorders such as Lupus syndrome,
- difficulty in starting to pass urine,
- gynaecomastia (increased size of breasts in men),
- fever,
- visual changes due to inflammation of the optic nerve (optic atrophy or neuritis),
- inflammation of the joints (arthritis),
- inflammation of the lungs (pneumonitis),
- changes in the white blood cell counts (leucopenia, neutropenia, eosinophilia,



1.3.2.1 Patient Information Leaflet

agranulocytosis), possibly resulting in an increased risk of infection,

- decreased red blood cell counts (anaemia), possibly leading to fatigue, weakness and shortness of breath,
- decreased platelet count, possibly resulting in an increased risk of bruising and bleeding.

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 “6.04 Adverse Drug Reaction 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 MYLAN 300 mg.

5. How to store ISONIAZID MYLAN 300 mg

Store all medicines out of reach of children.

Store at or below 30 °C.



1.3.2.1 Patient Information Leaflet

Protect from light.

Keep the tablets in the original container until required for use.

Do not use after the expiry date stated on the label.

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 MYLAN 300 mg contains

The active substance is isoniazid. ISONIAZID MYLAN 300 mg contains 300 mg of isoniazid per tablet.

The other ingredients are:

Colloidal anhydrous silica, croscarmellose sodium, microcrystalline cellulose, povidone, pregelatinised starch and stearic acid.

What ISONIAZID MYLAN 300 mg looks like and contents of the pack

HDPE bottle pack comprising a round wide-mouth, white, high-density polyethylene bottle with a white opaque polypropylene screw cap, an aluminium induction sealing liner wad, an absorbent cotton and a desiccant.

The bottle pack may be placed in an outer carton based on commercial requirement.

Pack sizes of 30's and 1000's.

1.3.2.1 Patient Information Leaflet

Holder of Certificate of Registration

VIATRIS HEALTHCARE (PTY) LTD

4 Brewery Street

Isando, 1601

Gauteng

Republic of South Africa

This leaflet was last revised in

Date of registration: 19 May 2020

Date of revision: 18 October 2024

Registration number

52/20.2.3/0986