

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ISONIAZID 300 UNIMED (300 mg tablets)

Isoniazid

Sugar free

Please read this leaflet carefully before you start taking ISONIAZID 300 UNIMED

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ISONIAZID 300 UNIMED has been prescribed for you personally and you should not share your medicine with other people.

What is in this leaflet

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

1. What ISONIAZID 300 UNIMED is and what it is used for

Isoniazid is the active ingredient in ISONIAZID 300 UNIMED. It belongs to a group of medicines called

antibacterials. Isoniazid works by killing bacteria that cause tuberculosis (also known as TB), both in the lungs and outside of the lungs.

2. What you need to know before you take ISONIAZID 300 UNIMED

Do not take ISONIAZID 300 UNIMED:

- If you are hypersensitive (allergic) to isoniazid or any of the other ingredients of ISONIAZID 300 UNIMED (listed in section 6);
- if you have liver disease;
- if you have drug or alcohol-induced liver disease;
- if you have experienced liver damage before when taking isoniazid;
- If you have severe kidney disease;
- If you experience fits;
- If you suffer from alcoholism;
- If you are pregnant.

Warnings and precautions

Tell your doctor or healthcare provider before using ISONIAZID 300 UNIMED:

- If you have epilepsy or have ever had convulsions (fits);
- if you have diabetes;
- 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 had tuberculosis outside of the lungs before;
- if you have HIV infection;
- if you are taking any other medication;
- if you are pregnant;
- if you are a slow acetylator of isoniazid (i.e your body takes longer to clear medicines from your liver);
- if you are elderly.

Special care should be taken with ISONIAZID 300 UNIMED

- If you develop an unexplained lack of appetite, nausea, vomiting, dark urine, yellowing of the skin and the eye white (jaundice), tingling in the hands and feet, persistent tiredness, weakness or fever lasting longer than 3 days, or abdominal tenderness, stop taking ISONIAZID 300 UNIMED and go to your doctor or healthcare provider;
- if you are malnourished (severely underfed);
- if you drink a lot of alcohol regularly;
- if you are a user of injection drugs;
- if you develop any eye problems as regular eye examinations are advised while on treatment with ISONIAZID 300 UNIMED;

- 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).

Medical check-ups

Before you start this medicine, and 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;
- Make sure your medicine is working properly;
- Check the dose you are taking is right for you.

Other medicines and ISONIAZID 300 UNIMED

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

The active agent in ISONIAZID 300 UNIMED may interact with the following medicines, by either:

Intensifying or prolonging their effects:

- medicines used for the treatment of tuberculosis (paraminosalicylic acid, rifampicin, cycloserine);

- medicines to treat epileptic seizures (e.g. phenytoin, carbamazepine, primidone, ethosuximide);
- medicines used to help you sleep (benzodiazepines, e.g. diazepam, triazolam);
- medicines for prevention of blood clots (coumarin- or indandione-derivates, e.g. warfarin),
- theophylline (medicine for the treatment of asthma),
- prednisolone (corticosteroid) - used to treat certain types of allergies and inflammatory conditions.
- Certain antacids.

Increasing the risk of organ damage:

- medicines toxic to the liver, such as paracetamol (pain killer), acetaminophen (pain killer), chlorzoxazone or rifampicin (used for tuberculosis)
- medicines toxic to the nervous system, such as stavudine

Weakening or shortening their effects, as follows:

- medication for Parkinson's disease, levodopa;
- medicines used for fungal infections (itraconazole, ketoconazole)

The HIV medicine, zalcitabine, decreases the effects of ISONIAZID 300 UNIMED.

ISONIAZID 300 UNIMED with food and alcohol

If you take these tablets concurrently with cheese or fish, cured meat, wine or beer, you may experience redness or itching of the skin, hot feeling, rapid or pounding heartbeat, sweating, chills or clammy feeling, headache, or light headedness.

Do not drink alcohol while using this medicine. This increases your risk for liver damage.

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 300 UNIMED.

ISONIAZID 300 UNIMED is not recommended in pregnancy.

This medicine may be found in your breast milk. If you are breastfeeding, you must not take ISONIAZID 300 UNIMED.

Your doctor may give you a supplement called pyridoxine, if you are pregnant or breastfeeding.

Driving and using machines

ISONIAZID 300 UNIMED may cause effects such as dizziness and fits. You should not drive or operate machinery whilst on treatment.

It is not always possible to predict to what extent ISONIAZID 300 UNIMED may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ISONIAZID 300 UNIMED affects you.

3. How to take ISONIAZID 300 UNIMED

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

Always take ISONIAZID 300 UNIMED exactly as your doctor or pharmacist has told you.

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

Your doctor will choose the dose that is right for you, or your child, based on body weight.

Also, the dosing intervals most suitable for you, or your child, will be selected by your doctor

or health care provider. Your doctor may also recommend other tuberculosis medicines to be taken with ISONIAZID 300 UNIMED.

Adults

The usual dose for prevention of tuberculosis is:

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

The usual dose for treatment of tuberculosis is:

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.

Children

The usual dose for prevention of tuberculosis is:

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

The usual dose for treatment of tuberculosis is:

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.

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;

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

How and when should you take ISONIAZID 300 UNIMED

ISONIAZID 300 UNIMED tablets must be swallowed with water.

These tablets should be taken on an empty stomach (at least 30 minutes before or two hours after a meal). This helps your body absorb isoniazid more easily.

Certain foods, such as cheese, fish, cured meats, wine and beer should be avoided while using this medicine.

How long should you take ISONIAZID 300 UNIMED

Your doctor will tell you how long your treatment with ISONIAZID 300 UNIMED will last. Do not stop treatment early because tuberculosis is a serious infectious disease that can be passed on to other people. If left untreated it can spread through your body and may be fatal. It is important that you receive effective treatment for this condition. If you have the impression that the effect of ISONIAZID 300 UNIMED is too strong or weak, tell your doctor or pharmacist.

If you take more ISONIAZID 300 UNIMED than you should

You may feel nauseous, dizzy or a feeling of the room spinning round, have hallucinations or slurred speech. You may also have fits, breathing problems and even fall into a coma. These effects may require emergency treatment in hospital.

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

If you forget to take ISONIAZID 300 UNIMED

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

Simply take the next dose as planned.

If you stop taking ISONIAZID 300 UNIMED

Keep taking the medicine for as long as your doctor has told you, even if you are feeling better. If you stop the medicine too soon, your infection may not be completely cured.

You should not stop treatment unless your doctor or health care provider tells you to.

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.

If you have any further questions on the use of this medicine, ask your doctor or health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

ISONIAZID 300 UNIMED can have side effects.

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

If any of the following happens, stop taking ISONIAZID 300 UNIMED 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;

- unexplained loss of appetite, nausea, vomiting, fatigue, restlessness and weakness, or yellowing of the skin, eyes and urine. These are signs that the liver may be adversely affected;
- severe skin reactions, with fever, peeling, blisters and involvement of the mucous membranes.

These are all very serious side effects. If you have them, you may have had a serious reaction to ISONIAZID 300 UNIMED. 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 or experience any of the following:

- convulsions;
- vision loss or pain with eye movement;
- memory problems;
- irritability, personality changes, concentration difficulties or confusion, which are signs that your brain has been affected;
- delusions, hallucinations, suspiciousness;
- sudden unexplained movements;
- weakness, numbness and pain from nerve damage of the hands and feet;
- muscle and joint pain with fever, sores, a butterfly-shaped rash on the face, which may indicate lupus.

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- fever, an often itchy rash which may be measles-like or consist mainly of skin discolouration or patches of rough, red skin and silvery white scales, facial swelling, enlarged and sometimes painful glands in the neck, armpit, groin or other areas.

Frequency unknown:

- fatigue, shortness of breath, bruising more than usual, red or purple colouring beneath the skin, gum or nose-bleeds; red or pink urine, rash, itching, diarrhoea; tightness of the chest, runny nose. These are signs of blood disorders.
- Inflammation of blood vessels (vasculitis);
- skin rash with or without itching;
- loss of hearing and ringing in your ears;
- a disorder which causes progressive scarring of the lung tissue, which can cause you to struggle to breathe;
- tingling or numbness in the hands or feet (pins and needles);
- difficulty in starting to pass urine;
- upset stomach, constipation;
- stomach pain;
- inflammation of an organ called the pancreas;
- fever;

- 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;
- dizziness or feeling if the room is spinning round (vertigo);
- gynaecomastia (increased size of breasts in men);
- low levels of vitamin B6 and nutrition problems, which can make you feel irritable, have difficulty sleeping, weak muscles, cracks at the corner of the mouth or lose weight;

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 or 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 300 UNIMED.

5. How to store ISONIAZID 300 UNIMED

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original container.

Keep the container tightly closed.

Keep the blisters in the outer carton, until required for use.

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

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 300 UNIMED contains

The active ingredient is isoniazid 300 mg per tablet.

The other ingredients are:

Intragranular ingredients: Microcrystalline cellulose 101, maize starch, crospovidone XL, purified water.

Extragranular ingredients: Polyplasdone XL, colloidal silicon dioxide, microcrystalline cellulose 102, magnesium stearate (vegetable grade).

What ISONIAZID 300 UNIMED looks like and contents of the pack

White to off-white, circular, biconvex, uncoated tablets, plain on both sides.

Pack size: Multiple blisters may be packed in a vanished, printed cardboard carton (PVC/PVdC aluminium foil blister packs of 10 or 28 tablets each).

Opaque, white, HDPE bottles with caps containing 500 or 1000 tablets. These tablets are packed within a triple laminate pouch (Polyester/Aluminum/Polyethylene). Each pouch contains 500 or 1000 tablets and is heat sealed.

Not all pack sizes may be marketed.

Holder of the Certificate of Registration

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Access to the corresponding Professional Information

The Professional Information is contained in the packaging of ISONIAZID 300 UNIMED.