

Package leaflet: Information for the user

Isoniazid 100mg Tablets

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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Isoniazid tablets are and what they are used for

Isoniazid is an antibiotic (antibacterial medicine) for treating infections. It belongs to a group of antibiotics called antituberculosis drugs and is used to treat and prevent tuberculosis (TB), an infectious disease mainly affecting the lungs.

2. What you need to know before you take Isoniazid tablets

Do not take Isoniazid tablets:

- if you are allergic to isoniazid or any of the other ingredients of this medicine (listed in section 6),
- if you have ever suffered from liver damage caused by a medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Isoniazid tablets:

- if you have or have had problems with your liver or kidneys,
- if you drink a lot of alcohol. It is also best to avoid drinking alcohol whilst you are taking this medicine,
- if you are diabetic,
- if you have extra-pulmonary TB (outside the lungs),
- if you have the HIV infection,
- if you have suffered mental disturbances (psychosis),
- if you have malnutrition,
- if you have epilepsy or have ever had convulsions (fits),
- if you are presently taking itraconazole (to treat fungal infections). It is not recommended to combine isoniazid and itraconazole.

Other medicines and Isoniazid tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription or herbal medicines. Isoniazid may interact with other 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 disulfiram for alcohol dependence,
- you are taking any medication for epilepsy (e.g. carbamazepine, primidone, phenytoin),
- you are taking medication for HIV infection (e.g. stavudine, zalcitabine),
- 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 drugs containing levodopa (used in the treatment of Parkinson's disease),

- you are taking cycloserine (used to treat tuberculosis and urinary tract infections),
- you are taking ketoconazole or itraconazole (used to treat fungal infections).

Isoniazid tablets with food and drink

Isoniazid tablets should be taken preferably on an empty stomach, i.e. at least 30 minutes before a meal or 2 hours after a meal. Tablets must be swallowed whole and not chewed.

Isoniazid 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 receiving isoniazid. Your doctor will be able to advise further.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You may be given additional vitamin supplementation if you are taking this medicine whilst pregnant.

You and your baby may be given additional vitamin supplementation if you take this medicine whilst you are breast-feeding. Your baby should be checked by your doctor at regular intervals.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. However, you may experience side-effects such as dizziness and confusion during treatment with isoniazid. Therefore, do not drive a car or operate machinery until you know how isoniazid affects you.

3. How to take Isoniazid tablets

Always take Isoniazid tablets exactly as your doctor has told you.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Remember: Isoniazid tablets should **not be taken with food**. You should swallow Isoniazid tablets whole with a glass of water.

Adults

The usual dose of Isoniazid tablets is 4 to 5 mg per kilogram (kg) of your bodyweight per day, up to a maximum of 300 mg daily. This may be taken as a single dose or as divided doses throughout the day. Your doctor will tell you exactly how much medicine to take and when to take it. Higher doses (up to 10 mg per kg per day) may be used to treat tuberculous meningitis (tuberculosis causing inflammation of the brain's membranes).

Elderly

If you are elderly, your doctor may tell you to take a slightly lower dose because your liver and kidneys are not working as well as they should.

Use in children

The usual dose of children above the age of three months is 10 to 15 mg per kg of body weight per day. This may be taken by your child as a single dose or as divided doses throughout the day. Your doctor will tell you exactly how much medicine your child should take and when to take it.

Children under three months should not take Isoniazid tablets.

Medical check-ups

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.

If you take more Isoniazid tablets than you should

If you (or someone else) take too many tablets, or you think a child may have swallowed any tablets, contact your nearest hospital casualty department or tell your doctor immediately. Take this leaflet, and any tablets that you still have to show the doctor.

You may experience some of these side effects; slurred speech, high blood sugar, slow breathing, hallucinations, dizziness, fits, or coma.

If you forget to take Isoniazid tablets

If you miss a dose, just carry on with the next one as normal. **Do not take a double dose to make up for a forgotten dose.**

If you have forgotten several doses tell your doctor when you have your next check-up or blood test. Occasionally people get headache, sleeplessness, excessive dreaming, irritability or nervousness if several doses are missed, or when the treatment is stopped.

If you stop taking Isoniazid tablets

Do not stop taking Isoniazid tablets 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.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects contact your doctor as soon as possible:

- Inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis, frequency not known).
- Severe extensive skin damage (separation of the epidermis and superficial mucous membranes) (toxic epidermal necrolysis (TEN), may affect up to 1 in 1,000 people).
- A drug reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS syndrome, may affect up to 1 in 1,000 people).
- 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, may affect up to 1 in 100 people).

Other side effects:

- Convulsions (fits).
- Severe stomach pain.
- 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).
- Mental disturbances including psychotic reactions such as hallucinations and delusions.
- Blood disorders which may make you more likely to get infections.
- High blood sugar levels, although you may not notice any symptoms.

- Inflammation of blood vessels (vasculitis) - frequency not known.
- Acidosis (upset of the acid balance in the body) which may make you feel or be sick, be drowsy or have breath that smells of "pear drops".
- Gynaecomastia (increased size of breasts in men).
- Low levels of vitamin B6 and nutrition problems. This can make you feel irritable, have difficulty sleeping, weak muscles, and cracks at the corner of the mouth or lose weight.
- Eye problems such as visual disturbances and eye pain.
- If you have severe problems with your kidneys, you may get loss of hearing and ringing in your ears.
- Tingling or numbness in the hands or feet (pins and needles).
- Constipation.
- Difficulty in starting to pass urine.
- Upset stomach and diarrhoea.
- Fever.
- Feeling and being sick.
- Loss of appetite and chills.
- Dry mouth.
- Overactive reflexes.
- Dizziness or feeling if the room is spinning round (vertigo).
- Red or itchy skin rash or peeling of the skin.

Side effects with this medicine are more common in people aged over 35 and in people who break down isoniazid more slowly. The risk of having side effects increases with high doses of Isoniazid tablets.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Isoniazid tablets

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist 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 Isoniazid tablets contain

- The active substance is isoniazid. Each tablet contains 100mg of isoniazid.
- The other ingredients are: calcium hydrogen phosphate, maize starch (dried), purified talc, colloidal anhydrous silica and magnesium stearate.

What Isoniazid tablets look like and contents of the pack

Isoniazid tablets are white, circular, biconvex uncoated tablets having plain surface on both the sides.

Isoniazid tablets are available in blister packs of 7, 10, 14, 20, 28, 30, 56, 60, 84, 90, 100 or 112. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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