

**Patient Information Leaflet:
Isoniazid 50 mg & 100mg Tablets BP Isoniazid**

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- In this leaflet, Isoniazid 50 mg & 100 mg Tablets BP are called Isoniazid.

In this leaflet:

1. What Isoniazid is for
2. Before you take Isoniazid
3. How to take Isoniazid
4. Possible side effects
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6. Further information.

1. What Isoniazid is for

Isoniazid belongs to a group of medicines called antibacterials. Isoniazid works by killing bacteria that cause tuberculosis (also known as TB)

Isoniazid is used to treat tuberculosis inside the lungs (pulmonary TB) and outside the lungs (extrapulmonary TB).

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.

2. Before you take Isoniazid

Do not take Isoniazid if:

- You are allergic to Isoniazid or any of the other ingredients of Isoniazid (see Section 6)
- You have ever had serious liver problems after taking any medicine.

If any of the above applies to you, talk to your doctor or pharmacist.

Check with your doctor before taking Isoniazid if:

- You have epilepsy or have ever had convulsions (fits)
- You have diabetes
- You drink a lot of alcohol regularly
- You have, or have had, problems with your liver or kidneys
- You suffer or have suffered from psychosis (mental disturbances with hallucinations or delusions)
- You are malnourished (severely underfed)
- You have HIV infection
- You have extra-pulmonary TB (outside the lungs).

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

- Stavudine (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 drug used to treat TB
- The benzodiazepine diazepam (for the treatment of anxiety)
- Levodopa (for the treatment of Parkinson's disease)
- Itraconazole or ketoconazole (for the treatment of fungal infections)
- Any other medicine, including medicines obtained without a prescription

These medicines can interfere with how well your treatment works.

Taking Isoniazid with food and drink:

Isoniazid should be taken on an empty stomach, so take it at least 30 minutes before a meal or two hours after a meal. This helps your body absorb Isoniazid more easily. Avoid drinking alcohol with Isoniazid. This may damage your liver. 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 and breast-feeding:

If you are pregnant, trying to become pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking Isoniazid.

This medicine contains Lactose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Isoniazid

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

Adults:

The usual dose of Isoniazid 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.

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 than you should:

Do not take more Isoniazid than you should. If you accidentally take too much, immediately contact the nearest hospital casualty department or your doctor.

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 forget to take Isoniazid:

Do not take a double dose to make up for a missed dose. Simply take the next dose as planned.

If you stop taking Isoniazid:

Do not stop taking Isoniazid 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 about the use of this medicine, ask your doctor or pharmacist.

4. Possible side-effects

Like all medicines Isoniazid 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, 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.

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 Yellow Card Scheme on the MHRA website (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

Keep out of the sight and reach of children.

Do not use Isoniazid after the expiry date on the pack. The expiry date refers to the last day of that month. Store below 25°C.

Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

6. Further information

What Isoniazid contains:

- The active substance in Isoniazid Tablets BP is isoniazid
- Isoniazid tablets come in two strengths: 50 mg and 100 mg. Each 50 mg tablet contains 50 mg isoniazid. Each 100 mg tablet contains 100 mg isoniazid.

The other ingredients in Isoniazid are lactose 170 mesh, maize starch, microcrystalline cellulose, alginate acid (E400), magnesium stearate and purified water.

What Isoniazid looks like and contents of the pack:

Isoniazid tablets are round, white to off white biconvex, uncoated tablets.

The 50 mg tablets are embossed with “50 151” on one side and “EVANS” on the other.

The 100 mg tablets are embossed with "100 152" on one side and "EVANS" on the other.
Isoniazid 50 mg and 100 mg tablets come in a polyethylene bottle with child resistant closure. Containers may contain 7, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120 or 250 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

RPH Pharmaceuticals AB, Box 603, 101 32 Stockholm, Sweden.

Manufacturer:

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If this leaflet is difficult to see or read, or you would like it in a different format, please contact
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