

Package leaflet: Information for the user**Isoniazid 50 mg/2 ml Solution for Injection**

Isoniazid

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- 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

1. What Isoniazid is and what it is used for
2. What you need to know before you use Isoniazid
3. How to use Isoniazid
4. Possible side effects
5. How to store Isoniazid
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1. What Isoniazid is and what it is used for

Isoniazid 50 mg/2 ml Solution for Injection contains Isoniazid. Isoniazid belongs to a group of medicines called antibacterials, which work by killing the bacteria that cause tuberculosis (also known as TB).

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

You will receive your doses of Isoniazid by injections given to you by a doctor or nurse.

Tuberculosis is a serious disease. It is important that you receive effective treatment for this condition as it can be passed on to other people and, if left untreated, it can be fatal.

2. What you need to know before you use Isoniazid**Do not use Isoniazid if you**

- are allergic to Isoniazid, or any of the other ingredients of this medicine (listed in Section 6).

Warnings and Precautions

Talk to your doctor or pharmacist before using this medicine if you:

- have kidney problems or have been told by your doctor that you have a slow acetylator status. Your doctor may wish to change your dose.
- have liver problems including hepatitis.
- are alcohol dependent or drink excessively. You may be more likely to suffer from fits or mental disturbances if you regularly drink alcohol whilst taking this medicine.
- have previously had “fits” or suffer from epilepsy. This medicine can increase the likelihood of fits.

- have a mental illness (psychosis). This medicine can increase the likelihood of experiencing mental disturbances.
- suffer from porphyria (a rare illness which affects the metabolism).
- have suffered from pancreatitis caused by taking Isoniazid in the past.

Children and adolescents

This medicine can be used in children and adolescents of all ages.

Other medicines and Isoniazid

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking:

- phenytoin, primidone, carbamazepine or ethosuximide (used to treat epilepsy)
- rifampicin and cycloserine (antibiotics used to treat infections, including tuberculosis)
- diazepam (used to treat conditions including anxiety and sleep problems)
- triazolam (usually used as a sedative to treat severe sleep problems)
- chlorzoxazone (used for treating discomfort caused by muscle spasms)
- theophylline (used in asthma, chronic obstructive pulmonary disease, bronchitis and heart failure)
- disulfiram (used in alcohol dependence)
- prednisolone (used in a wide range of inflammatory and auto-immune conditions)
- levodopa (used in the treatment of conditions, such as Parkinson's disease).

Your doctor may wish to monitor you closely if you are using Isoniazid with these medications.

Isoniazid with food and alcohol

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, think you may be pregnant or are planning to have a baby, talk to your doctor or pharmacist before using this medicine. Isoniazid is generally regarded as safe during pregnancy, but during early pregnancy there may be an increased risk of deformation of the foetus.

If you are breast-feeding, tell your doctor before using this medicine. Isoniazid is excreted in the breast milk, which can be passed on to your child. If you are breast-feeding, you and your child may also be given another medicine called pyridoxine to help minimise side effects.

Driving and using machines

Isoniazid can cause fits, mental health problems and optic neuritis (inflammation of the optic nerve that may cause loss of vision.) If affected you should not drive or use machinery.

3. How to use Isoniazid

You will receive your doses of Isoniazid by injections given to you by a doctor or nurse. Isoniazid can be injected into the muscles, veins, spine or chest.

Use in Adults and Children

The recommended dose for adults, when injected into a vein or the muscles, is 200 to 300 mg (four to six ampoules) as a single daily dose.

The recommended dose for children, when injected into a vein or the muscles, is 100 to 300 mg (two to six ampoules) as a single daily dose.

Doses much larger than these can sometimes be given. In particular, a higher dose may be used for the treatment of meningitis caused by an infection of tuberculosis.

If you receive your injection in the chest, a lower dose of 50 to 250 mg (one to five ampoules) is recommended.

If you receive your injection in the spine, a much lower dose of 25 to 50 mg for adults and 10 to 20 mg for children is recommended. You may also be given another medicine called pyridoxine to help reduce the chance of side effects.

Newborn babies (less than 4 weeks old)

The recommended dose, when injected into a vein or the muscles, for newborn babies is 3 – 5 mg per kg of body weight, up to a maximum of 10 mg per kg daily.

Elderly

No dosage adjustments are necessary in the elderly.

Patients with kidney problems

Your doctor may wish to change your dose. If you are receiving dialysis, Isoniazid should be given to you after your dialysis treatments.

Patients with liver problems

Your doctor may wish to monitor your liver enzymes closely.

Regular tests

Your doctor may want you to have a monthly blood test to make sure your liver function is not being affected by this medicine.

If you use more Isoniazid than you should

If you think you have been given too much of this medicine tell your doctor or nurse straight away. The common signs of overdose are the side effects as listed in Section 4 of this leaflet together with the following:

- Difficulty walking, tremor and altered coordination
- Deep, rapid breathing
- Feeling or being sick
- Faster heart beat
- Dizziness

- Hallucinations
- Slurred speech
- Increased visual sensitivity
- Overactive reflexes (e.g. twitching).

In severe cases of overdose, fits may occur. If this happens tell your doctor or nurse immediately.

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.

Serious side effects

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

- Difficulty breathing, swelling of the mouth, throat, face or lips. You could be experiencing a severe allergic reaction.
- 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, haematological 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).
- Fits (for further information on when fits may be more likely to occur see section 2 'Warnings and Precautions').
- Vision problems such as loss of sight, blurred vision and reduced vision.
- Blood disorders which may cause tiredness and flu-like symptoms.
- Reduction in blood platelets, which increases risk of bleeding or bruising.
- High blood sugar levels, signs of which include increased hunger, increased thirst and going to the toilet more often.
- Mental health problems, signs of which may include hallucinations, delusions, confusion, disturbed thoughts and a lack of self-awareness.

Other side effects (frequency not known)

- Inflammation of the blood vessels
- Fever
- Nerve problems which can cause movement problems, tingling and numbness (this can be prevented with the use of pyridoxine)
- Hair loss
- Skin conditions (including lumpy red rash, red/purple skin discolouration, skin scaling)
- Immune system problems with symptoms that include tiredness, joint pain and skin rashes
- Vitamin B3 deficiency (Pellagra), symptoms of which include memory problems, diarrhoea, scaly skin rash

- Breast growth in males.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the internet at www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Isoniazid

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

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

Do not store above 25°C. Keep away from light sources.

Do not throw away any medicine 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 contains**

The active substance is Isoniazid. Each ampoule contains 50 mg of Isoniazid in 2 ml of solution.

The other ingredients are Hydrochloric Acid and Water for Injections.

What Isoniazid looks like and contents of the pack

Isoniazid ampoules are colourless glass ampoules with dark red and orange colour rings.

Isoniazid is available in packs containing 10 ampoules. Each ampoule contains 2 ml of solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Alliance Pharmaceuticals Limited, Avonbridge House, Bath Road, Chippenham, Wiltshire, SN15 2BB, UK

Manufacturer: Boots Contract Manufacturing, 1 Thane Road, Nottingham, Nottinghamshire, NG2 3AA, United Kingdom

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