

PHARMANIAGA ISONIAZID TABLET

Isoniazid (100mg, 400mg)

What is in this leaflet

1. What Pharmaniaga Isoniazid Tablet is used for
2. How Pharmaniaga Isoniazid Tablet works
3. Before you use Pharmaniaga Isoniazid Tablet
4. How to use Pharmaniaga Isoniazid Tablet
5. While you are using it
6. Side effects
7. Storage and Disposal of Pharmaniaga Isoniazid Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What Pharmaniaga Isoniazid Tablet is used for

Isoniazid is used to treat tuberculosis in combination with other antitubercular medicines.

How Pharmaniaga Isoniazid Tablet works

Pharmaniaga Isoniazid Tablet contain the active ingredient isoniazid.

Isoniazid belongs to a group of medicines called tuberculostatic agents. It acts by stopping the growth of the bacteria responsible for causing tuberculosis.

Before you use Pharmaniaga Isoniazid Tablet

- When you must not use it

Do not take Pharmaniaga Isoniazid Tablet if:

- You are allergic to isoniazid, ethionamide, pyrazinamide, niacin (nicotinic acid), or other chemically related medications.
- You have had drug-induced hepatitis, previous isoniazid-associated hepatic injury, severe reactions to isoniazid for example fever, chills, arthritis and acute liver disease of any aetiology.
- You are epileptics and patients with chronic alcoholism or impaired liver or kidney function.
- You are taking potentially hepatotoxic agents.

You must tell your doctor or pharmacist if you have had any of the above conditions.

Do not take Pharmaniaga Isoniazid Tablet after the expiry date (EXP) printed on the pack. If you take it after the expiry date has passed, it may not work as well.

Do not take Pharmaniaga Isoniazid Tablet if the packaging is torn or shows signs of tampering.

- Before you start to use it

You must tell your doctor if

- you are allergic to any other medicines, foods, dyes or preservatives
- you have epilepsy or ever had convulsions (fits)
- you have diabetes
- you have other medical problems such as kidney or liver disease
- you drink a lot of alcohol regularly

If you are pregnant, intend to become pregnant, are breast-feeding or plan to breastfeed, your doctor or pharmacist will discuss the possible risks and benefits of using isoniazid during pregnancy and breast-feeding.

If you have not told your doctor or pharmacist about any of the above, tell them before you take any Pharmaniaga Isoniazid Tablet.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicine, including any that you buy without a prescription from a pharmacy, medical hall or any other source.

Tell your doctor or pharmacist if you are taking the following: -

- Alcohol
- Alfentanil (anaesthesia)
- Carbamazepine (anticonvulsant)
- Disulfiram (alcohol deterrent)
- Hepatotoxic medications (Medicines that may cause liver toxic)
- Ketoconazole or miconazole, injection of Rifampin (antifungal and antibiotic)
- Phenytoin (anti-seizure)

How to use Pharmaniaga Isoniazid Tablet

- How much to use

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

The normal recommended dose of Pharmaniaga Isoniazid Tablet is:

Adults:

For preventive treatment of Tuberculosis: Commonly 4 to 5 mg per kilogram body-weight daily (maximum 300mg daily).

For treatment of Tuberculous meningitis: Up to 10 mg per kilogram body-weight daily (during first to second week of treatment).

For Intermittent treatment regimens:

15 mg per kg (maximum 900 mg daily) has been given two or three times weekly in treatment.

Children:

Children in 3 months and above: 10 to 15 mg per kg body-weight daily.

- When to use it

Use as directed by your doctor or pharmacist.

Pharmaniaga Isoniazid Tablet should not be taken with food. Swallow the tablet with a glass of water.

Try to take it the same time everyday so that you do not forget to take your medicine.

- How long to use it

Continue taking Pharmaniaga Isoniazid Tablet for as long as your doctor recommends. Treatment for TB is usually six months.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

PHARMANIAGA ISONIAZID TABLET

Isoniazid (100mg, 400mg)

- If you use too much (overdose)

Go to the Emergency Department of your nearest hospital if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor or pharmacist has told you.

If you need other medical treatment, inform all the doctors, dentists and pharmacists that you are taking Pharmaniaga Isoniazid Tablet.

Tell your doctor immediately if you became pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor.

Do not give Pharmaniaga Isoniazid Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine unlikely to effect the ability to drive or use machinery.

Side effects

Like all medicines, Pharmaniaga Isoniazid Tablet can cause side effects, although not everybody gets them.

Inform your doctor or pharmacist immediately if you experience any of the following side effects after taking this medicine.

- Peripheral neuropathy (damaged nerve between brain and spinal cord to the rest of body)
- Convulsion, memory impairment, mental depression, psychosis
- Blurred vision or loss of vision, with or without eye pain.

- Dry mouth, constipation, hyperreflexia
- Yellowing of skin or eyes, urine getting darker, fatigue, weakness, loss of appetite, nausea and vomiting (signs of jaundice and liver problems)
- Inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis)
- Burning or pain in hand and feet.
- Skin rashes and joint pain.
- Fever and sore throat.
- Unusual bleeding and bruising
- Unusual tiredness or weak

Some people may get other side effects of Pharmaniaga Isoniazid Tablet. The risk of side effects increases with high doses of isoniazid.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Pharmaniaga Isoniazid Tablet

- Storage

Keep all medicines out of sight and reach of children.

Do not take this medicine after the expiry date stamped on the pack.

Store below 30°C. Protect from light. Keep container tightly closed.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Pharmaniaga Isoniazid Tablet 100mg:

Yellow, round flat bevelled edge tablet with KK marking on one side and breakline on the other.

Pharmaniaga Isoniazid Tablet 400mg:
Yellow, round, flat bevelled edge tablet with KK marking on one side and quadrisect on the other.

- Ingredients

- Active ingredient(s)

Pharmaniaga Isoniazid Tablet 100mg:

- Active ingredient:

Isoniazid 100mg

- Inactive ingredients:

Lactose Monohydrate, Maize Starch, Acacia, Ariavit Quinoline Yellow, Sodium Starch Glycolate, Magnesium Stearate

Pharmaniaga Isoniazid Tablet 400mg:

- Active ingredient:

Isoniazid 400mg

- Inactive ingredients:

Lactose Monohydrate, Maize Starch, Acacia, Ariavit Quinoline Yellow, Sodium Starch Glycolate, Magnesium Stearate

- MAL number:

Pharmaniaga Isoniazid Tablet 100mg:
MAL19961323AZ

Pharmaniaga Isoniazid Tablet 400mg:
MAL19961322AZ

Manufacturer and Product Registration Holder

Pharmaniaga Manufacturing Berhad (198001006232),
No. 11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650, Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

Date of revision

23/7/2024

Serial Number

NPRA (R2/1)200429/429