

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ISONIAZID 300 mg ADCO, 300 mg, tablets

Isoniazid

Sugar free

Read all of this leaflet carefully before you start taking ISONIAZID 300 mg ADCO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ISONIAZID 300 mg ADCO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What ISONIAZID 300 mg ADCO is and what it is used for

ISONIAZID 300 mg ADCO belongs to a group of medicines called antibacterials. ISONIAZID 300 mg ADCO works by killing bacteria that cause tuberculosis (also known as TB).

ISONIAZID 300 mg ADCO is used for the prevention and for the treatment of tuberculosis when used with other antituberculosis medicines.

2. What you need to know before you take ISONIAZID 300 mg ADCO

Do not take ISONIAZID 300 mg ADCO:

- if you are hypersensitive (allergic) to isoniazid, ethionamide, pyrazinamide, niacin, or other chemically related compounds or any of the other ingredients of ISONIAZID 300 mg ADCO (listed in section 6).

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- if you drink a lot of alcohol regularly.
- if you have liver problems (including those caused by taking any medicine).
- if you have kidney problems.
- if you have epilepsy or have ever had convulsions (fits).
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with ISONIAZID 300 mg ADCO:

- if you are elderly (over the age of 65 years of age), female, malnourished, have HIV infection as you are at high risk of experiencing liver-related side effects.
- if you have diabetes.
- if you suffer or have suffered from any mental conditions.

Your doctor will conduct regular blood tests to monitor the function of your liver.

You should have regular eyes examinations during your treatment with ISONIAZID 300 mg ADCO.

Other medicines and ISONIAZID 300 mg ADCO

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

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

- carbamazepine, phenytoin or primidone (used for the treatment of epilepsy)
- diazepam or triazolam (used for the treatment of anxiety)
- warfarin (used to prevent blood clots)
- theophylline (used for the treatment lung diseases such as asthma and bronchitis)
- rifampicin, paraminosalicylic acid, cycloserine or any other medicine used to treat tuberculosis
- disulfiram (used for the treatment of alcoholism)
- paracetamol (used for the treatment of pain and fever)
- prednisolone (used in the treatment of many conditions in order to reduce inflammation)
- aluminium containing antacids (used for the treatment of heartburn)
- levodopa (used for the treatment of Parkinson's disease)
- itraconazole or ketoconazole (used for the treatment of fungal infections)
- zalcitabine (used for the treatment of HIV infections)

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ISONIAZID 300 mg ADCO with food, drink and alcohol

ISONIAZID 300 mg ADCO should preferably be taken on an empty stomach, i.e. at least 30 minutes before a meal or 2 hours after a meal. This helps your body absorb ISONIAZID 300 mg ADCO more easily.

ISONIAZID 300 mg ADCO may be taken with meals if it causes a burning sensation or pain in the stomach, but the absorption of ISONIAZID 300 mg ADCO may be reduced.

Avoid drinking alcohol with ISONIAZID 300 mg ADCO. This may damage your liver.

ISONIAZID 300 mg ADCO 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 taking ISONIAZID 300 mg ADCO. Your doctor will be able to advise you further.

Pregnancy and breastfeeding

If you are a woman of child-bearing potential you should be advised to avoid becoming pregnant while taking ISONIAZID 300 mg ADCO.

The safe use of ISONIAZID 300 mg ADCO in pregnancy has not been established. ISONIAZID 300 mg ADCO may harm your baby if you take it while you are pregnant.

You should not breastfeed your baby if you are taking ISONIAZID 300 mg ADCO.

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 healthcare provider for advice before taking ISONIAZID 300 mg ADCO.

Driving and using machines

ISONIAZID 300 mg ADCO may influence your ability to drive and use machines. Since side effects such as convulsions have been reported in patients receiving isoniazid, as in ISONIAZID 300 mg ADCO, you should not drive, use machinery or perform any tasks that

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require concentration, until you are aware of the measure to which ISONIAZID 300 mg ADCO affects you.

3. How to take ISONIAZID 300 mg ADCO

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

Always take ISONIAZID 300 mg ADCO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and adolescents

Prophylaxis (Treatment given to prevent disease):

5 mg/kg (maximum 300 mg) once daily

It may be used in combination with rifampicin for prophylaxis against multidrug-resistant tuberculosis.

Treatment (in combination with other antituberculosis 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 are used for CNS tuberculosis and multidrug-resistant tuberculosis.

Children

Prophylaxis:

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

Treatment (in combination with other antituberculosis medicines):

10 to 20 mg per kg of body weight, up to 300 mg, once daily

Your doctor will tell you how long your treatment with ISONIAZID 300 mg ADCO will last.

If you have the impression that the effect of ISONIAZID 300 mg ADCO is too strong or too weak, tell your doctor or pharmacist.

If you take more ISONIAZID 300 mg ADCO than you should

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

If you forget to take ISONIAZID 300 mg ADCO

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

If you stop taking ISONIAZID 300 mg ADCO

If the treatment with ISONIAZID 300 mg ADCO is stopped too soon, your infection may not be completely cured. You should always consult your doctor before deciding to interrupt the course of treatment or stop taking ISONIAZID 300 mg ADCO.

4. Possible side effects

ISONIAZID 300 mg ADCO can have side effects.

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

If any of the following happens, stop taking / using ISONIAZID 300 mg ADCO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- fever,
- joint pain,
- blistering or peeling of the skin,
- swelling of lymph nodes.

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

Frequent side effects

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- loss of appetite, nausea or vomiting, unusual tiredness or weakness,

Less frequent side effects:

- blood disorders which may make you more likely to get infections, get tired very easily, or bruise very frequently,
- inflammation of the liver (hepatitis)

Side effects with an unknown frequency:

- mental disturbances including psychotic reactions such as hallucinations and delusions,
- changes in mood,
- convulsions (fits),
- pain in the eyes, temporary vision loss, blurred vision, vision disorders, blindness,
- loss of hearing,
- inflammation of the blood vessels resulting in no blood supply to organs and tissues,
- difficulty in breathing due to the scarring of the lungs,
- inflammation of the pancreas with symptoms such as stomach or back pain, nausea, vomiting, loss of appetite,
- liver failure with symptoms such as yellowing of the skin or whites of the eyes (jaundice),
- an inflammatory disease (systemic lupus erythematosus) caused when the immune system attacks its own tissues affecting the joints, skin, kidneys, blood cells, brain, heart and lungs with symptoms such as fatigue, joint pain, rash and fever,
- lupus-like syndrome is a condition that presents in the similar way as systemic lupus erythematosus, but that occurs when certain medicines are taken and resolved after discontinuation of these medicines,
- a chronic inflammatory disorder affecting many joints, including those in the hands and feet with symptoms such as pain, swelling and stiffness of the joints.

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

Tell your doctor if you notice any of the following:

Side effects with an unknown frequency:

- high or low blood sugar levels,
- a build-up of too much acid in the body with symptoms such as nausea, vomiting, fast breathing and a lack of energy,
- low levels of vitamin B3 (niacin) and nutrition problems with symptoms such as delusions or mental confusion, diarrhoea, scaly skin sores, especially in sun-exposed areas of the skin,

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- pain, pins-and-needles sensation, numbness and weakness, usually in the hands and feet due to nerve inflammation and/or damage,
- overactive or overresponsive reflexes with symptoms such as twitching, muscle spasms, change in heart rate, excessive sweating and changes in skin colour (paleness, redness, blue-grey skin colour),
- ringing in the ears,
- dizziness, feeling off-balance,
- stomach pain, nausea, vomiting, constipation, dry mouth,
- difficulty urinating and completely emptying the bladder, discomfort, pain or burning when urinating,
- breast enlargement in men,
- fever,
- increase in liver enzymes.

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. 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 mg ADCO.

5. How to store ISONIAZID 300 mg ADCO

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Protect from light and moisture.
- Do not store in a bathroom
- Do not use after the expiry date stated on the blister and 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 mg ADCO contains

The active ingredient is isoniazid 300 mg.

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The other ingredients are:

colloidal silicon dioxide, copovidone, crospovidone, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid

What ISONIAZID 300 mg ADCO looks like and contents of the pack

White to off white, circular flat faced beveled edged, uncoated tablet with score line on one side and plain on other side.

10 tablets shall be packed per blister using amber PVC/PVdC foil as a base material and hard tampered heat seal lacquer coated printed aluminium foil as a lidding material. 10 blisters packs are packed in a carton.

28 tablets shall be packed per blister using amber PVC/PVDC foil as a base material and hard tampered heat seal lacquer coated printed aluminium foil as a lidding material. 24 blisters packs are packed in a carton.

Not all packs and pack sizes may be marketed.

Holder of Certificate of Registration

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