

# ISONIAZID tablets

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using ISONIAZID?

Isoniazid contains the active ingredient Isoniazid. Isoniazid is used to treat tuberculosis in combination with other anti-tubercular agents.

For more information, see Section [1. Why am I using ISONIAZID?](#) in the full CMI.

### 2. What should I know before I use ISONIAZID?

Do not use if you have ever had an allergic reaction to Isoniazid or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Isoniazid?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Isoniazid and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use ISONIAZID?

- The tablet should be swallowed whole with a glass of water.
- The recommended doses of ISONIAZID tablets are Adults: 4 to 5 mg per kg of body weight in divided doses up to a maximum of 300 mg daily. In tuberculous meningitis up to 10mg per kg of bodyweight may be given daily for the first 1 to 2 weeks of treatment.
- Children: 5 to 20 mg per kg of body weight daily. Your doctor will advise you of the correct dose, depending on your weight or the weight of your child.

More instructions can be found in Section [4. How do I use ISONIAZID?](#) in the full CMI.

### 5. What should I know while using ISONIAZID?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Isoniazid.</li><li>• Use Isoniazid tablets exactly as directed or as your doctor has prescribed.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take any other medicines while you are taking ISONIAZID tablets without first telling your doctor.</li><li>• Do not give this medicine to anyone else, even if his or her symptoms seem like you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how ISONIAZID affects you.</li><li>• ISONIAZID may cause dizziness in some people and therefore may affect alertness.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• If you drink alcohol, it could make some of the unwanted side effects of ISONIAZID worse.</li><li>• Your doctor may suggest that you avoid alcohol completely or reduce the amount of alcohol you drink while you are taking ISONIAZID tablets.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep ISONIAZID tablets in a cool dry place where the temperature stays below 25°C and protect from light.</li></ul>

For more information, see Section [5. What should I know while using ISONIAZID?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include jaundice, nausea, vomiting, dizziness, drowsiness, skin rashes, tiredness, fever, pain in arms or legs and enlarged breast tissue in men. Side effects such as liver inflammation or allergic reactions can occur.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ISONIAZID tablets

Active ingredient(s): *Isoniazid*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Isoniazid. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Isoniazid.**

Where to find information in this leaflet:

- [1. Why am I using Isoniazid?](#)
- [2. What should I know before I use Isoniazid?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Isoniazid?](#)
- [5. What should I know while using Isoniazid ?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using ISONIAZID?

**Isoniazid contains the active ingredient Isoniazid.** Isoniazid belongs to a group of medicines called tuberculostatic agents.

**Isoniazid is used to treat tuberculosis in combination with other anti-tubercular agents.**

## 2. What should I know before I use ISONIAZID?

### Warnings

**Do not use ISONIAZID if:**

- You are allergic to Isoniazid or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic reaction to ISONIAZID may include red itchy skin rashes, difficulty breathing, hay fever symptoms, swelling of the face or throat or faintness.
- You have had severe reactions to ISONIAZID, for example fever, chills, or arthritis.
- You have previously experienced liver problems after taking ISONIAZID tablets or any other medicines.
- You have acute liver problems from any cause.

**Check with your doctor if you:**

- have any other medical conditions
- take any medicine for any other condition
- have impaired kidney or liver function
- have a history of psychosis (mental disturbances with hallucinations or delusions)
- drink alcohol

Elderly patients and patients over 50 years old are more likely to develop hepatitis, a possible side effect of using ISONIAZID. Older patients should be closely monitored by their doctors whilst using this medication.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ISONIAZID tablets:

These include:

- Phenytoin, carbamazepine or primidone (medicines used to treat epilepsy)
- Rifampicin (a medicine used to treat tuberculosis)
- Paracetamol (a medicine used to treat pain relief)
- Aluminum hydroxide gel, an antacid used to treat heart burn.
- Disulfiram used to treat alcoholism.
- Ketoconazole or itraconazole, medicines used to treat fungal infections.
- Stavudine (used for the treatment of HIV)
- Corticosteroids used to treat inflammation.
- Diazepam used to treat anxiety and other mental health problems.
- Blood thinners used to prevent clots.
- Theophylline's used to treat breathing problems.
- Levodopa (used in the management of Parkinson's disease)

The above medicines may either reduce the effectiveness of ISONIAZID tablets, reduce their own effectiveness and/or react with it resulting in untoward or sometimes dangerous side effects.

This list is not exhaustive. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ISONIAZID tablets.

To ensure that the treatment of your condition is effective your doctor will prescribe other medication to be taken over the same time as ISONIAZID.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ISONIAZID.**

Foods rich in tyramine and/or histamine such as cured meat, some cheeses (e.g. matured cheeses), wine, beer and some fish (e.g. tuna, mackerel, salmon). are best avoided during treatment with ISONIAZID, as symptoms such as headache, sweating, palpitations, flushing, and low blood pressure can occur.

## 4. How do I use ISONIAZID?

### How much to take / use

- The recommended doses of ISONIAZID tablets are:

*Adults:* 4 to 5 mg per kg of body weight in divided doses up to a maximum of 300 mg daily. In tuberculous meningitis up to 10mg per kg of bodyweight may be given daily for the first 1 to 2 weeks of treatment.

*Children:* 5 to 20 mg per kg of body weight daily. Your doctor will advise you of the correct dose, depending on your weight or the weight of your child.

- The tablet should be swallowed whole with a glass of water.

### If you forget to use ISONIAZID

ISONIAZID should be used regularly at the same time each day. If you miss your dose at the usual time, take your dose as soon as you remember, and then go back to taking it as you would normally.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

**If you are unsure about whether to take your next dose, speak to your doctor or pharmacists.**

**Do not try to make up for missed doses by taking more than one dose at a time.**

This may increase the chance of getting an unwanted side effect.

**If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.**

### If you use too much ISONIAZID

If you think that you have used too much ISONIAZID, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre

(by calling 13 11 26), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using ISONIAZID?

### Things you should do

- Use ISONIAZID tablets exactly as directed or as your doctor has prescribed.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using ISONIAZID.
- Tell your doctor or pharmacist immediately if you feel sick (nauseous), fatigue tired or generally unwell or have a loss of appetite while taking ISONIAZID.
- Tell your doctor if you notice any problems with your eyes while taking ISONIAZID or if you feel that ISONIAZID is not helping your condition.
- Make sure to keep all of your doctor's appointments and have any tests done that are ordered by your doctor.
- If you have to have any urine tests tell your doctor that you are using this medicine as Isoniazid may affect the results if some laboratory tests.

See your doctor regularly. Your doctor needs to check your progress and see whether you need to keep taking ISONIAZID tablets.

**Always discuss with your doctor any problems or difficulties during or after taking ISONIAZID tablets.**

Remind any doctor, dentist, or pharmacist you visit that you are using ISONIAZID.

### Things you should not do

- Do not take any other medicines while you are taking ISONIAZID tablets without first telling your doctor.
- Do not give this medicine to anyone else, even if his or her symptoms seem like you.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how ISONIAZID affects you.**

ISONIAZID may cause dizziness in some people and therefore may affect alertness.

Some people may experience side effects such as nausea, vomiting, constipation, drowsiness, dizziness, which may further affect the risk when driving or using machinery.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

If you drink alcohol, it could make some of the unwanted side effects of ISONIAZID worse.

Your doctor may suggest that you avoid alcohol completely or reduce the amount of alcohol you drink while you are taking ISONIAZID tablets.

### Looking after your medicine

- Follow the instructions in the carton on how to take care of your medicine properly.
- Do not take ISONIAZID if the tablets do not look quite right.
- Keep ISONIAZID tablets in a cool dry place where the temperature stays below 25°C and protect from light.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.
- Heat and dampness can destroy medicines.

**Keep it where young children cannot reach it.**

**A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.**

Keep your tablets in the bottle they were provided in until it is time to take them.

### When to discard your medicine (as relevant)

If your doctor tells you to stop taking this medication or it has passed the expiry date, ask your pharmacist what to do with any tablets that are left over.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• Nausea (feeling sick)</li> <li>• Vomiting</li> <li>• Dizziness</li> <li>• Drowsiness</li> <li>• Skin rashes (mild)</li> <li>• Tiredness</li> <li>• Enlarged breast tissue in men</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Signs of an allergic reaction such as red itchy skin rashes, difficulty breathing, hay fever symptoms, swelling of the face or throat or faintness</li> <li>• Fever, rash, facial swelling, enlarged lymph nodes</li> <li>• Lupus-like syndrome, causing symptoms such as swollen joints, tiredness and rashes</li> <li>• Jaundice (yellowing of skin), fatigue, abdominal pain, loss of appetite, dark urine, pale stools</li> <li>• Severe pain in the abdomen and back</li> <li>• Numbness, tingling, burning pain, and muscle weakness, often starting in the hands and feet</li> <li>• Muscle loss or weakness</li> <li>• Poor coordination and/or balance, tremor, change in speech, involuntary eye movements</li> <li>• Fits/convulsions</li> <li>• Changes in consciousness or behavior, confusion, memory loss, agitation</li> <li>• Eye pain, changes in vision</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

Check with your doctor as soon as possible if you have any problems while taking ISONIAZID tablets even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

## What ISONIAZID contains

<b>Active ingredient (main ingredient)</b>	Isoniazid
<b>Other ingredients (inactive ingredients)</b>	Cellulose microcrystalline Silica colloidal anhydrous Sodium starch glycollate Calcium stearate Gelatin Propyl hydroxybenzoate Lactose Starch maize Sodium benzoate Starch-wheat dextrin
<b>Potential allergens</b>	N/A

Contains hydroxybenzoate, benzoate, sugars as lactose and gluten.

**Do not take this medicine if you are allergic to any of these ingredients.**

## What ISONIAZID looks like

Isoniazid tablets are white scored tablets and are available in bottles of 100 tablets. (Aust R 13455).

## Who distributes ISONIAZID

Arrotex Pharmaceuticals Pty Ltd  
15-17 Chapel Street  
Cremorne Victoria 3121

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