

Pantoprazole-AFT

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 Pantoprazole-AFT?

Pantoprazole-AFT contains the active ingredient pantoprazole. Pantoprazole-AFT works by decreasing the amount of acid the stomach makes to give relief from the symptoms and allow healing to take place.

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

2. What should I know before I use Pantoprazole-AFT?

Do not use if you have ever had an allergic reaction to pantoprazole 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 Pantoprazole-AFT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Pantoprazole-AFT 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 Pantoprazole-AFT?

- Follow all directions given to you by your doctor or pharmacist carefully.
- The dose and frequency of your injection will be determined by your doctor and will depend on your medical condition.

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

5. What should I know while using Pantoprazole-AFT?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Pantoprazole-AFT.• Tell your doctor if you become pregnant while you are being given this medicine.
Driving or using machines	Do not drive a car or operate machines if you experience side effects such as dizziness or blurred vision.
Looking after your medicine	<ul style="list-style-type: none">• Normally your doctor will provide your Pantoprazole-AFT injection.• If however, you do take your Pantoprazole-AFT injection from the pharmacy to your doctor, it is important to store it in a safe place away from heat (below 25 °C) and away from light.

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

6. Are there any side effects?

Like all medicines, Pantoprazole-AFT can cause side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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.

Pantoprazole-AFT

Active ingredient(s): *pantoprazole (as sodium sesquihydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Pantoprazole-AFT. **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 Pantoprazole-AFT.**

Where to find information in this leaflet:

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

1. Why am I using Pantoprazole-AFT?

Pantoprazole-AFT contains the active ingredient pantoprazole. Pantoprazole-AFT belongs to a group of medicines called proton pump inhibitors (PPIs). This medicine works by decreasing the amount of acid the stomach makes to give relief from the symptoms and allow healing to take place.

Ulcers

Pantoprazole-AFT is used to treat and help heal duodenal and gastric ulcers. Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out of the stomach. These can be caused in part by too much acid being made in the stomach.

Reflux disease

Pantoprazole-AFT is also used to treat reflux oesophagitis or reflux disease. This can be caused by “washing back” (reflux) of food and acid from the stomach into the food pipe, also known as the oesophagus.

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

Pantoprazole-AFT is also used to prevent reflux oesophagitis from coming back.

Zollinger-Ellison syndrome

Pantoprazole-AFT is used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces very large amounts of acid, much more than in ulcers and reflux disease.

Ask your doctor if you have any questions about why it has been prescribed for you.

Your doctor may have prescribed it for another purpose.

This medicine is not addictive.

2. What should I know before I use Pantoprazole-AFT?

Warnings

Do not use Pantoprazole-AFT:

- If you are allergic to pantoprazole, 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 symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.
- if you have severe liver disease or cirrhosis.
- in combination with atazanavir or nelfinavir (antiviral medications).
- In children. Safety and effectiveness in children have not been established.
- After the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering. If it has expired or is damaged return it to your pharmacist for disposal.

Check with your doctor if you:

- have any allergies to any other medicines, foods, preservatives or dyes.
- have or have had any other medical conditions.
- have any of the following symptoms:
 - unintentional weight loss
 - repeated vomiting
 - vomiting blood
 - difficulty or pain when swallowing
 - you look pale and feel weak
 - you notice blood in your stools

If you have not told your doctor about any of the above, tell them before you use Pantoprazole-AFT injection. Your doctor may need to perform some additional tests before you take Pantoprazole-AFT injection.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for 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.

Your doctor can discuss the risks and benefits involved.

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 and Pantoprazole-AFT injection may interfere with each other. These include:

- warfarin, phenprocoumon – medicines used to prevent blood clots (anticoagulants)
- ketoconazole, itraconazole, posaconazole – medicines used to treat fungal infection
- atazanavir, nelfinavir – medicines used to treat viral infections such as HIV
- methotrexate – a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer
- tacrolimus, mycophenolate mofetil – medicines used to suppress the immune system
- fluvoxamine – a medicine used to treat anxiety and depression

These medicines may be affected by Pantoprazole-AFT injection or may affect how well it works. You may need to use different amounts of your medicine or take different medicines. Your doctor has more information on medicines to be careful with or to avoid while taking Pantoprazole-AFT injection.

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

4. How do I use Pantoprazole-AFT?

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to use & when to use

The dose and frequency of your injection will be determined by your doctor and will depend on your medical condition. Your doctor may change the dose as your condition changes.

How to use Pantoprazole-AFT

Pantoprazole-AFT injection is reconstituted by your doctor or pharmacist.

How long to use to Pantoprazole-AFT

Continue using your medicine for as long as your doctor tells you. Your doctor will determine how long you need to be treated with Pantoprazole-AFT injection.

If you forget to use Pantoprazole-AFT

If a dose of Pantoprazole-AFT injection is missed, your doctor will determine when your next dose is due.

If you use too much Pantoprazole-AFT

Your doctor will ensure that you receive the correct dose of Pantoprazole-AFT injection. Never administer this medicine to yourself.

Overdose is unlikely with Pantoprazole-AFT. However, it may cause an increase in side effects. (The side effects are listed under the heading, 'Side effects' in this leaflet.)

If you think that you have used too much Pantoprazole-AFT, 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 Pantoprazole-AFT?

Things you should do

Call your doctor straight away if:

- You become pregnant while you are being given this medicine
- Your reflux symptoms return after you stop taking this medicine. The symptoms of reflux may return after stopping this medicine suddenly, especially if you have taken it for a while.

Remind any doctor, dentist or pharmacist you visit that you are using Pantoprazole-AFT.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Pantoprazole-AFT affects you.

This medicine is not expected to affect your ability to drive a car or operate machinery.

However, do not drive a car or operate machines if you experience side effects such as dizziness or blurred vision.

Looking after your medicine

Storage

Normally your doctor will provide your Pantoprazole-AFT injection. If however, you do take your Pantoprazole-AFT injection from the pharmacy to your doctor, it is important

to store it in a safe place away from heat (below 25°C) and away from light. Do not leave your Pantoprazole-AFT injection in a car.

If for any reason you take your Pantoprazole-AFT injection home, use it as soon as possible after preparation. If storage is necessary, store at 2-8 °C for no longer than 12 hours.

Follow the instructions in the carton on how to take care of your medicine properly.

When taking Pantoprazole-AFT injection at home, always ensure that it is stored in a place where children cannot reach it i.e. a locked cupboard at least one-and-a-half meters (5 feet) above the ground is a good place to store medicine.

Getting rid of any unwanted medicine

If your doctor stops treating you with Pantoprazole-AFT injection, your hospital pharmacist will dispose of any unused 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.

Tell your doctor as soon as possible if you do not feel well while you are given Pantoprazole injection.

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
<p>Gastrointestinal/ digestion related:</p> <ul style="list-style-type: none"> • Diarrhoea • Nausea or vomiting • Stomach pain • Excessive gas in the stomach or bowel • Indigestion • Constipation <p>Local/ skin related:</p> <ul style="list-style-type: none"> • Pain and swelling at the site of injection • Skin problems such as itchiness and rash <p>Body as whole:</p> <ul style="list-style-type: none"> • Headache • Increased sweating or body temperature • Dry mouth 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>These are more common side effects of your medicine. They are usually mild and short-lived.</p>

<ul style="list-style-type: none"> • Dizziness • Weakness or tiredness • Metallic taste • Blurred vision • Trouble sleeping 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • unusual tiredness or weakness • nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine • blood in the urine • increased or decreased need to urinate • severe skin problems such as itchiness, redness, rash with swelling, blistering or peeling of the skin or rash when exposed to the sun, possibly with pain in the joints and general fever • swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing • frequent infections such as fever, severe chills, sore throat or mouth ulcers • chest pain • shortness of breath • high blood pressure • water retention, swelling • bleeding or bruising more easily than normal • depression, confusion or anxiety • bone fracture of the hip, wrist or spine (mainly a risk in people who take high doses of PPIs or use them long term (a year or longer)) • symptoms such as seizures, abnormal or fast heartbeat, jerking/shaking movements or muscle cramps. These can be a sign of low magnesium, calcium or potassium levels in your blood • severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea 	<p>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.</p> <p>These side effects are rare.</p>

Other side effects not listed above may occur in some people. Some of the side effects can only be found when your doctor does tests from time to time to check your progress.

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

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. 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 Pantoprazole-AFT contains

Active ingredient (main ingredient)	Pantoprazole (as sodium sesquihydrate)
Other ingredients (inactive ingredients)	Mannitol Tribasic sodium phosphate dodecahydrate

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

What Pantoprazole-AFT looks like

Pantoprazole-AFT Injection is a white to off-white powder provided in a glass vial. (Aust R 288085).

Who distributes Pantoprazole-AFT

AFT Pharmaceuticals Pty Ltd.
113 Wicks Road
North Ryde, NSW 2113

This leaflet was prepared in August 2024.