

Pantoleze™ Heartburn Relief

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using Pantoleze Heartburn Relief. **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 Pantoleze Heartburn Relief.**

Where to find information in this leaflet:

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

1. Why am I using Pantoleze Heartburn Relief?

Pantoleze Heartburn Relief contains the active ingredient pantoprazole (as sodium sesquihydrate). Pantoleze Heartburn Relief 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.

Pantoleze Heartburn Relief is used for lasting symptomatic relief of frequent heartburn and stomach acid complaints due to gastro-oesophageal reflux disease (GORD).

These symptoms 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.

Frequent heartburn is when you have heartburn for two or more days a week. Heartburn that occurs frequently is a typical symptom of GORD.

Pantoleze Heartburn Relief is not the right medicine for you if you suffer heartburn only occasionally (one episode of heartburn a week or less), or if you want immediate relief of heartburn.

Pantoleze Heartburn Relief will start to suppress acid within a few hours, however it is not intended to provide instant symptom relief. For effective, lasting relief, you should take a full course of Pantoleze Heartburn Relief (see Section [4. How do I use Pantoleze Heartburn Relief?](#) below).

Pantoleze Heartburn Relief is not addictive.

Pantoleze Heartburn Relief is for use by adults over 18 years of age.

Do not give Pantoleze Heartburn Relief to children or adolescents under 18 years of age.

2. What should I know before I use Pantoleze Heartburn Relief?

Warnings

Do not use Pantoleze Heartburn Relief if:

- you are allergic to pantoprazole, any other PPI (such as omeprazole, rabeprazole or lansoprazole), or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have severe liver disease or cirrhosis
- you have recently had trouble swallowing, pain when swallowing, persistent vomiting or experienced unintended weight loss
- you have recently vomited blood, had black stools or notice blood in your stools
- you are taking atazanavir or nelfinavir (anti-viral medications)
- you are pregnant, intend to become pregnant, are breast-feeding or wish to start breast-feeding.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor or pharmacist if you:

- have any other medical conditions, including jaundice, liver problems or anaemia
- have a feeling of weakness or you look pale
- have previously taken heartburn / indigestion medications continuously for 4 or more weeks
- have persisting heartburn symptoms despite taking Pantoleze Heartburn Relief (or other similar medicines) continuously for 2 weeks, or your symptoms have recently changed
- have been told by your doctor that you have a stomach ulcer, or gastrointestinal surgery is planned
- have heartburn/ indigestion symptoms for the first time and you are over 40 years of age
- have a scheduled endoscopy (investigation of your stomach lining performed by a specialist)
- have any allergies to any medicines or other substances, such as foods, preservatives or dyes
- take any medicines for any other condition.

Your pharmacist or doctor can provide specific advice on whether you should take Pantoleze Heartburn Relief.

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 or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist 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 and Pantoleze Heartburn Relief may interfere with each other. These include:

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

These medicines may be affected by Pantoleze Heartburn Relief or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

4. How do I use Pantoleze Heartburn Relief?

The directions for use are included on the Medicine Information panel on the pack.

If you do not understand the instructions on the pack, ask your pharmacist or doctor for help.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

- Take one Pantoleze Heartburn Relief tablet every day (once every 24 hours).
- Swallow the tablet whole with a little water, with or without food.
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

Do not crush or chew the tablets.

Pantoleze Heartburn Relief tablets have a special coating to protect them from the acidic contents of your stomach. For the tablets to work effectively, this coating must not be broken.

When to take Pantoleze Heartburn Relief

- Pantoleze Heartburn Relief should be used for lasting symptomatic relief of frequent heartburn and stomach acid complaints due to gastro-oesophageal reflux disease (GORD).

How long to take Pantoleze Heartburn Relief

- For effective, lasting relief, take Pantoleze Heartburn Relief strictly according to the directions on your pack.
- Pantoleze Heartburn Relief tablets should be taken for at least seven days, and up to 14 days.
- If you purchased the pack containing 7 days' supply and you need to take it for longer than 7 days, ask your pharmacist for advice.
- Do not take beyond 14 days without consulting your doctor.
- Pantoleze Heartburn Relief is not intended to provide instant relief from your heartburn/ indigestion symptoms.
- If you are not sure, ask your pharmacist or doctor how to take your medicine.

If you forget to take Pantoleze Heartburn Relief

Pantoleze Heartburn Relief 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 continue to take 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. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you use too much Pantoleze Heartburn Relief

If you think that you have used too much Pantoleze Heartburn Relief, 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 Pantoleze Heartburn Relief?

Things you should do

- Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.
- If you are going to have surgery or an endoscopy, tell your doctor that you are taking Pantoleze Heartburn Relief.
- If you become pregnant while you are taking this medicine, tell your doctor or pharmacist immediately.
- Tell your doctor or pharmacist if you do not feel better while taking Pantoleze Heartburn Relief. If your symptoms recur within 2 weeks of completing your course, consult your doctor. Further investigation may be recommended.
- 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.
- Tell your doctor if 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 Pantoleze Heartburn Relief.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Pantoleze Heartburn Relief affects you.

Pantoleze Heartburn Relief may cause dizziness and visual disturbances in some people. If affected, do not drive or operate machinery.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Things that may help your condition

Some self-help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

- **Alcohol** – your doctor may advise you to limit your alcohol intake.
- **Aspirin and many other medicines used to treat arthritis, period pain, headaches** – these medicines may irritate the stomach and may make your condition worse. Your doctor or pharmacist may suggest other medicines you can take.
- **Caffeine** –

your doctor may advise you to limit the number of drinks which contain caffeine, such as coffee, tea, cocoa and cola drinks, because they contain ingredients that may irritate your stomach.

- **Eating habits** – eat smaller, more frequent meals. Eat slowly and chew your food carefully. Try not to rush at meals times.
- **Smoking** – your doctor may advise you to stop smoking or at least cut down.
- **Weight** – your doctor may suggest losing some weight to help your condition.

Looking after your medicine

- Keep your medicine in the original container. If you take it out of its original container it may not keep well.
- Keep your medicine in a cool dry place where the temperature stays below 25°C.

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

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 window sills.

Keep it where young children cannot reach it.

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

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.

Less serious side effects

Less serious side effects	What to do
Eye-related: <ul style="list-style-type: none"> • blurred vision Gut-related: <ul style="list-style-type: none"> • diarrhoea, constipation, nausea or vomiting • indigestion • dry mouth • pain, discomfort or excessive gas in the stomach or bowel 	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

<p>Mood and brain-related:</p> <ul style="list-style-type: none"> • headache or dizziness • metallic taste <p>Skin-related:</p> <ul style="list-style-type: none"> • mild skin reactions such as itchiness and rash <p>General disorders:</p> <ul style="list-style-type: none"> • mild weakness, tiredness or sleep disturbances • increased sweating or body temperature 	
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<ul style="list-style-type: none"> • increased or decreased need to urinate <p>Liver-related:</p> <ul style="list-style-type: none"> • loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine or bowel movements <p>Mood and brain-related:</p> <ul style="list-style-type: none"> • depression, confusion or anxiety <p>Muscle-Joint-related:</p> <ul style="list-style-type: none"> • 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)) <p>Skin-related:</p> <ul style="list-style-type: none"> • 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 	
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Serious side effects

Serious side effects	What to do
<p>Allergy-related:</p> <ul style="list-style-type: none"> • unusual tiredness, weakness, dizziness or fainting • chest pain, fast heartbeat, shortness of breath • swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing <p>Bleeding-related:</p> <ul style="list-style-type: none"> • blood in the urine • bleeding or bruising more easily than normal <p>Electrolytes-related:</p> <ul style="list-style-type: none"> • 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 <p>Gut-related:</p> <ul style="list-style-type: none"> • severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea <p>Heart-related:</p> <ul style="list-style-type: none"> • high blood pressure • water retention, swelling <p>Infection-related:</p> <ul style="list-style-type: none"> • frequent symptoms of infections such as fever, severe chills, sore throat or mouth ulcers <p>Kidney-related:</p>	<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>

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.

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.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Pantoleze Heartburn Relief contains

Active ingredient (main ingredient)	pantoprazole (as sodium sesquihydrate)
Other ingredients (inactive ingredients)	sodium carbonate anhydrous microcrystalline cellulose crospovidone hydroxypropylcellulose colloidal anhydrous silica calcium stearate Opadry complete film coating system 03B22011 Yellow Eudragit L30D-55 triethyl citrate

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

What Pantoleze Heartburn Relief looks like

Pantoleze Heartburn Relief – yellow and oval shaped enteric coated tablets. The tablets have an acid-resistant coating called an enteric coating. Pack size of 7 and 14 enteric coated tablets (Aust R 483225).

Who distributes Pantoleze Heartburn Relief

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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