

# Chemists' Own Heartburn Relief Pantoprazole Tablets

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

## Consumer Medicine Information (CMI)

This leaflet provides important information about using this medicine. **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 this medicine.**

**Where to find information in this leaflet:**

- [1. Why am I using this medicine?](#)
- [2. What should I know before I use this medicine?](#)
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- [4. How do I use this medicine?](#)
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## 1. Why am I using this medicine?

**Chemists' Own Heartburn Relief Pantoprazole Tablets contain the active ingredient Pantoprazole (as sodium sesquihydrate).**

Pantoprazole is used for symptomatic relief of frequent heartburn and stomach acid complaints due to gastro-oesophageal reflux (GORD).

Reflux 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.

### How it works

Pantoprazole belongs to a group of medicines called proton pump inhibitors (PPIs). It works by decreasing the amount of acid the stomach makes to give relief from the symptoms of reflux and heartburn.

This medicine will start to suppress acid within a few hours; however, it will not give instant symptom relief. You may need to take it for a few days before experiencing the full effect.

This medicine is recommended for adults suffering from heartburn at least two times a week. It 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.

**Ask your doctor or pharmacist if you have any questions about why this medicine has been recommended for you.**

This medicine is available without a doctor's prescription, but your pharmacist's advice is required.

This medicine is not addictive.

**Do not give this medicine to children or adolescents under 18 years of age.**

There is not enough information to recommend the use of this medicine in children under 18 years of age.

## 2. What should I know before I use this medicine?

### Warnings

**Do not use this medicine 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. 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.
- you have severe liver disease or cirrhosis.
- have recently had trouble swallowing, pain when swallowing, persistent vomiting or experienced unintended weight loss
- have recently vomited blood, had black stools or notice blood in your stools
- are taking atazanavir or nelfinavir (anti-viral medications)
- the packaging is torn or shows signs of tampering.
- the expiry date printed on the pack has passed.

### Before you start to take it

**Check with your doctor or pharmacist if you have:**

- jaundice, liver problems or anaemia
- a feeling of weakness or you look pale
- previously taken heartburn or indigestion medications continuously for 4 or more weeks
- persisting heartburn symptoms despite taking this medication (or similar medication) continuously for 2 weeks, or your symptoms have recently changed

- been told by your doctor that you have a stomach ulcer, or gastrointestinal surgery is planned.
- heartburn or indigestion symptoms for the first time and you are over 40 years of age
- a scheduled endoscopy (investigation of your stomach lining performed by a specialist)
- any allergies to any medicines or other substances, such as foods, preservatives or dyes.

Your doctor or pharmacist can provide specific advice on whether you should take this medication. Tell your doctor or pharmacist if you have any other medical conditions.

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 with you 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 may interfere with each other. These include:**

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

These medicines may be affected by pantoprazole or may affect how well it works. You may need to use different amounts of your medicine or take different medicines. Other interactions not listed above may also occur.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Chemists' Own Heartburn Relief Pantoprazole Tablets.**

## **4. How do I use this medicine?**

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 pharmacist or doctor. They may differ from the information in this leaflet.

### **How much to take**

- The usual dose is one tablet every day (once every 24 hours).

### **How to take this medicine**

- Swallow tablets whole with water.
- Do not crush or chew the tablets. this medicine 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.

It does not matter if you are taking this medicine before or after food.

### **How long to take this medicine**

For effective, long-lasting relief, take this medicine strictly according to the directions on your pack. This medication should be taken for at least seven (7) days, or up to fourteen (14) days.

If you purchased a 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.** This medication is not intended to provide instant relief from your heartburn or indigestion symptoms.

### **If you forget to take this medicine**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.** Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

**Do not take a double dose to make up for the dose that you missed.** This may increase the chance of you getting an unwanted side effect.

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

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

### **If you use too much this medicine**

If you think that you have used too much this medicine, 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.** Urgent medical attention may be needed.

## 5. What should I know while using this medicine?

### Things you should do

Tell any doctor, dentist or pharmacist you visit that you are using this medicine.

If you are going to have surgery or an endoscopy, tell your doctor that you are taking this medicine.

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 or pharmacist if you do not feel better while taking this medicine.

If your symptoms recur within two (2) weeks of completing your course, consult your doctor.

Tell your doctor if your reflux symptoms return after you stop taking this medicine. The symptoms of reflux may return after stopping pantoprazole suddenly, especially if you have taken it for a while.

### Call your doctor straight away if you:

- become pregnant while taking this medicine.

### Things you should not do

- Do not take this medicine to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.

### Driving or using machines

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

This medicine may cause dizziness and visual disturbances in some people.

### Drinking alcohol

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

Alcohol may contribute to your condition.

### 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 meal 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 its original packaging until it is time to take it. If you take the tablets out of their original packaging, they may not keep well.

Follow the instructions on 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 windowsills.

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

### 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>• headache</li> <li>• dizziness</li> <li>• diarrhoea</li> <li>• constipation</li> <li>• nausea or vomiting</li> <li>• stomach pain</li> <li>• pain, discomfort or excessive gas in the stomach or bowel</li> <li>• indigestion</li> <li>• dry mouth</li> <li>• metallic taste</li> <li>• mild weakness or tiredness</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<ul style="list-style-type: none"> <li>increased sweating or body temperature</li> <li>blurred vision</li> <li>skin problems, such as itchiness and rash</li> <li>trouble sleeping</li> </ul>	
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## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>unusual tiredness, weakness, dizziness or fainting</li> <li>chest pain, fast heartbeat, shortness of breath</li> <li>loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine or bowel movements</li> <li>blood in the urine</li> <li>increased or decreased need to urinate</li> <li>bleeding or bruising more easily than normal</li> <li>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</li> <li>swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing</li> <li>frequent symptoms of infections such as fever, severe chills, sore throat or mouth ulcers</li> <li>high blood pressure</li> <li>water retention, swelling</li> <li>depression, confusion or anxiety</li> <li>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))</li> <li>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</li> <li>severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea</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.

## 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 this medicine contains

<b>Active ingredient (main ingredient)</b>	pantoprazole (as sodium sesquihydrate)
<b>Other ingredients (inactive ingredients)</b>	mannitol sodium carbonate sodium starch glycolate crospovidone colloidal anhydrous silica calcium stearate hypromellose macrogol 6000 sodium hydroxide Eudragit L30-D55 Opadry AMB Aqueous Moisture Barrier Coating System 80W52172 Yellow
<b>Potential allergens</b>	Soya bean products. May contain trace levels of sulfites.

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

## What Chemists' Own Heartburn Relief Pantoprazole Tablets looks like

The tablets are available in a 20 mg strength and have an acid-resistant coating called an enteric coating.

The tablets are yellow to pale yellow, oval, biconvex enteric-coated tablets, plain on both sides.

Available in blister packs of 7 or 14 tablets (AUST R 259838).

\*Not all pack sizes may be available.

## **Who distributes Chemists' Own Heartburn Relief Pantoprazole Tablets**

Arrotex Pharmaceuticals Pty Ltd  
15 – 17 Chapel Street  
CREMORNE VIC 3121

[www.arrotex.com.au](http://www.arrotex.com.au)

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