

HEARTBURN RELIEF

Pantoprazole

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you take Heartburn Relief.

This leaflet answers some common questions about Heartburn Relief. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Sometimes new risks are found even when a medicine has been used for many years. Your doctor or pharmacist has weighed the expected benefits of you taking Heartburn Relief against the risks this medicine could have for you.

Use Heartburn Relief as directed and follow the advice given in this leaflet.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

What Heartburn Relief is used for?

Heartburn Relief contains the active ingredient pantoprazole.

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

Frequent heartburn is when you have heartburn for two or more days a week. Heartburn that occurs frequently is a typical symptom of gastro-oesophageal reflux disease (GORD).

Who should use Heartburn Relief

Heartburn Relief is recommended for adults over 18 years of age suffering from heartburn at least 2 times a week.

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

How Heartburn Relief works

Heartburn Relief belongs to a group of medicines called proton pump inhibitors (PPIs).

Heartburn Relief works by decreasing the amount of acid the stomach makes to give relief from symptoms.

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

There is no evidence that Heartburn Relief is addictive.

This medicine is only available from your pharmacist or your doctor.

Before you take Heartburn Relief

Do not take if:

You must not take Heartburn Relief if:

- you have ever had an allergic reaction to pantoprazole (see "Side Effects") or any of the ingredients listed toward the end of this leaflet (see "Ingredients");
- the expiry date (EXP) printed on the pack has passed; or
- the packaging is torn or shows signs of tampering.

Do not take Heartburn Relief if you have severe liver disease of cirrhosis.

Do not take Heartburn Relief in combination with atazanavir (an anti-viral medication).

Heartburn Relief should not be given to children or adolescents under 18 years of age. The safety and effectiveness of Heartburn Relief in children has not been established.

If you are not sure whether you should start taking Heartburn Relief alone or in combination with any other medications, talk to your doctor or pharmacist.

You must tell your doctor or pharmacist if:

1. you have any allergies to:
 - pantoprazole;
 - any of the ingredients listed at the end of this leaflet; or
 - any foods, dyes, preservatives or any other medicines.
2. you are pregnant, intend to become pregnant, are breast-feeding or intend to breast-feed.
3. you have or have had any other medical conditions.

If you have not told your doctor or pharmacist about any of the above, tell them before you take Heartburn Relief.

Talk to your doctor or pharmacist first before taking Heartburn Relief if:

- you have previously taken heartburn/indigestion medications continuously for four or more weeks to control your heartburn.
- you have jaundice, liver problems, anaemia, previous gastric ulcer or gastrointestinal surgery.
- you are have new or recently changed symptoms including persistent vomiting, vomiting of blood, blood in the stools or unexplained weight loss.

If you have experienced any of the above you should see your doctor immediately.

You should speak to your doctor if you have suffered from frequent heartburn/indigestion symptoms for some time.

You should also speak to your doctor before taking Heartburn Relief if you are due to have an endoscopy (a special test ordered by your doctor).

Taking other medicines

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

Some medicines may be affected by Heartburn Relief, or may affect how well it works. These may include medicines used to prevent blood clots (anti-coagulants), atazanavir (an antiviral medication) and medicines whose activity depend on the acidity of the stomach, eg. ketoconazole.

Speak with your pharmacist or doctor if you have any concerns about taking Heartburn Relief with other medications.

How to take Heartburn Relief

How much to take

Take one (1) Heartburn Relief tablet once a day (every 24 hours).

How and when to take it

Heartburn Relief should be swallowed whole with a little water. It can be taken with or without food.

How long to take it for

Take one (1) tablet daily for at least 7 days, and up to 14 days. You should not take it for more than 14 days unless directed by a doctor.

Use in children

Heartburn Relief should not be given to children or adolescents under 18 years of age.

What if I forget to take it?

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

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre for advice, or go to the Accident and Emergency department at your nearest hospital, if you think you or anyone else may have taken too much Heartburn Relief, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Telephone numbers for Poisons Information Centres are – in Australia call 13 11 26; in New Zealand call 0800 764 766. Keep these telephone numbers for these places handy.

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

While you are taking Heartburn Relief

Your doctor or pharmacist will be able to tell you whether there are any special instructions while you are taking Heartburn Relief.

Things you must do

Use Heartburn Relief exactly as your doctor or pharmacist has advised.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Heartburn Relief.

Tell your doctor or pharmacist if you do not feel better while taking Heartburn Relief.

If symptoms persist or recur within 2 weeks of completing the course, consult a doctor. Further examination may be recommended.

Things that may help your condition

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- **Alcohol** – you may be advised 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** – you may be advised 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** – it is advisable for you to stop smoking or at least cut down.
- **Weight** – you may be advised that losing some weight will help your condition.

What are the side effects?

Check with your doctor as soon as possible if you have any problems, or think you are experiencing any side effects or allergic reactions due to taking Heartburn Relief, even if you do not think the problems are connected with the medicine or they are not listed in this leaflet.

Like other medicines, Heartburn Relief can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist any questions you may have.

The most commonly reported side effects are as follows. Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dizziness
- headache
- diarrhoea
- feeling sick, also called nausea
- vomiting
- stomach pain
- excessive gas in the stomach or bowel
- feeling weak or tired
- indigestion
- constipation
- blurred vision
- dry mouth
- metallic taste

- increased sweating
- skin problems such as itchiness and/or rash

Tell your doctor immediately if you notice any of the following:

- unusual tiredness or weakness.
- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.
- skin problems such as itchiness and rash, or swelling, blistering or peeling of the skin.
- 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.
- swelling of the legs.
- bleeding or bruising more easily than normal.
- depression, confusion or anxiety.

These may be serious side effects and you may need urgent medical attention. Serious side effects are rare.

If you think you are having an allergic reaction to Heartburn Relief, TELL YOUR DOCTOR IMMEDIATELY or go to the Accident and Emergency department at your nearest hospital.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell when you are taking, or soon after you have finished taking, Heartburn Relief.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

How do I store Heartburn Relief?

Keep Heartburn Relief where children cannot reach them. A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Keep Heartburn Relief in the container that they were supplied in until it is time to take them.

If you take the tablets out of the blister pack, they may not keep well.

Store Heartburn Relief in a cool dry place where the temperature stays below 25°C.

Do not store Heartburn Relief, or any other medicines, in a bathroom, near a sink or on a window sill. Heat and dampness can destroy some medicines.

Return any unused or expired medicine to your pharmacist.

Product description

What Heartburn Relief looks like

Heartburn Relief is available as a 20mg tablet. The tablets have an acid-resistant coating called an enteric coating.

Heartburn Relief are yellow coloured, oval shape, biconvex, enteric coated tablets, plain on both sides.

Heartburn Relief is available in blister packs containing 7 and 14 tablets.

Ingredients

The active ingredient in Heartburn Relief is pantoprazole.

Each Heartburn Relief tablet contains the equivalent of 20mg pantoprazole.

Each Heartburn Relief tablet also contains:

- sodium carbonate anhydrous
- hydroxypropylcellulose
- mannitol
- crospovidone
- calcium stearate
- hypromellose
- titanium dioxide
- iron oxide yellow
- propylene glycol
- EUDRAGIT L30D-55
- triethyl citrate
- talc-purified
- purified water

Heartburn Relief does not contain gluten, lactose, sucrose, tartrazine or other azo dyes.

Supplier

Heartburn Relief is supplied by:

Generic Health Pty Ltd
Suite 1, Level 1
1175 Toorak Road
Camberwell VIC 3124

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

You may also be able to find general information about your condition and its treatment from patient information groups.

The information provided applies only to Heartburn Relief.

Australian Registration Numbers:

Heartburn Relief 20 mg: AUST R 183533

This leaflet was prepared in November 2010.