

APOHEALTH Pantoprazole Heartburn Relief

Pantoprazole (as sodium sesquihydrate)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

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

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may want to read it again.

What this medicine is used for

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 a "Pharmacist Only Medicine". It 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.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- pantoprazole
- any other proton pump inhibitors
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing

- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you have severe liver disease or cirrhosis.

Do not take this medicine in combination with antibiotics or any other medicine if:

- you are allergic to any of the antibiotics or medicines your doctor may prescribe with pantoprazole
- you have moderate to severe liver or kidney disease.

Do not take this medicine in combination with atazanavir or nelfinavir (anti-viral medications).

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.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or breastfeeding, or plan to become pregnant or breast-feed.

Your doctor or pharmacist will discuss the risks and benefits involved.

Tell your doctor or pharmacist if you have:

- jaundice, liver problems or anaemia
- previously taken heartburn / indigestion medications 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
- 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)
- unintentional weight loss
- repeated vomiting
- vomited blood
- difficulty or pain when swallowing
- a feeling of weakness or you look pale
- noticed blood in your stools

Your doctor may need to perform some additional tests before you take pantoprazole.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any 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, phenprocoumon, medicines used to prevent blood clots (blood thinners)
- atazanavir and nelfinavir, medicines used to treat viral infections such as HIV

- ketoconazole, itraconazole or posaconazole, medicines used to treat fungal infection
- 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 or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking pantoprazole.

Other interactions not listed above may also occur.

How to take this medicine

The directions for use are included on the pack.

If you do not understand any written instructions, ask your doctor or pharmacist 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

The dose is one tablet per day.

How to take it

Swallow the tablet whole with a full glass of water, with or without food.

Do not crush or chew the tablets.

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

When to take it

Take your medicine at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

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

How long to take it

For effective, lasting relief, take this medicine strictly according to the directions on your pack.

This medicine 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.

This medicine 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 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 your medicine 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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much pantoprazole.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

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

Tell your doctor immediately if you become pregnant while you are taking pantoprazole.

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 you do not feel better while taking this medicine. If symptoms persist or recur within two weeks of completing use of this medicine, consult a doctor.

Further investigation may be recommended.

Things you must 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.

Things to be careful of

Be careful while driving or operating machinery until you know how this medicine affects you.

This medicine may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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 or pharmacist 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 or pharmacist 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 or pharmacist may advise you to stop smoking or at least cut down.
- Weight - your doctor or pharmacist may suggest losing some weight to help your condition.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

This medicine helps most people with heartburn and reflux, but it may have unwanted side effects in a few people. All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache or dizziness
- blurred vision
- diarrhoea, constipation, nausea or vomiting
- pain, discomfort or excessive gas in the stomach or bowel
- indigestion
- dry mouth
- metallic taste
- mild weakness, tiredness or sleep disturbances
- increased sweating or body temperature
- mild skin problems, such as itchiness and rash
- reflux after stopping the medication suddenly, especially if you have taken it for a while without consulting your doctor

The above list includes the more common side effects of pantoprazole.

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

- unusual tiredness, weakness, dizziness or fainting
- high blood pressure
- blood in the urine
- increased or decreased need to urinate
- depression, confusion or anxiety

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- chest pain, fast heartbeat, shortness of breath
- 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
- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine or bowel movements
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- 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 or jerking/shaking movements. These can be a sign of low magnesium, calcium or potassium levels in your blood
- water retention, swelling
- bleeding or bruising more easily than normal
- severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

Storage and Presentation

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

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

Disposal

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

Product description

What APOHEALTH Pantoprazole Heartburn Relief looks like

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

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

Available in blister packs of 7 or 14 tablets.

Ingredients

The active ingredient in the tablets is pantoprazole (as sodium sesquihydrate).

The tablets also contain the following as inactive ingredients:

- calcium stearate
- colloidal anhydrous silica
- crospovidone
- hypromellose
- macrogol 6000
- mannitol
- sodium carbonate
- sodium hydroxide
- sodium starch glycollate
- Eudragit L30-D55 (3700)
- Opadry AMB Aqueous Moisture Barrier Coating System 80W52172 Yellow (106688).

This medicine contains soya bean products. It may also contain a trace amount of sulfites.

This medicine is free of lactose, gluten, sucrose, tartrazine and other azo dyes.

Australian Registration Number

APOHEALTH Pantoprazole Heartburn Relief tablets (blisters): AUST R 229698.

*Not all pack sizes may be available.

Sponsor

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