

APO-Pantoprazole Heartburn Relief

Contains the active ingredient pantoprazole (as sodium sesquihydrate)

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Pantoprazole Heartburn Relief Tablets. It contains the active ingredient pantoprazole.

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

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.

How it works

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

Pantoprazole works by decreasing the amount of acid the stomach makes, to give relief from the symptoms.

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

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children or adolescents under 18 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had cirrhosis or severe liver disease.**
- **You are taking atazanavir, an anti-viral medicine.**
- **You are hypersensitive to, or have had an allergic reaction to, pantoprazole or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, 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; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the

Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - difficulty swallowing, jaundice, liver problems, anaemia, previous gastric ulcer or gastrointestinal surgery
 - new or recently changed symptoms including persistent vomiting or vomiting of blood, blood in the stools or unexplained weight loss.
3. You have previously taken heartburn / indigestion medications continuously for 4 or more weeks to control your heartburn.
4. You are currently being treated for GORD symptoms and require pantoprazole for more than 14 days.
5. You are due to have an endoscopy (a special test ordered by your doctor).
6. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
7. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.

8. You are planning to have surgery or an anaesthetic.
9. You are currently receiving or are planning to receive dental treatment.

Taking other medicines

Tell your doctor if you are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with pantoprazole. These include:

- atazanavir, do not take this at the same time as pantoprazole
- coumarin anti-coagulants such as phenprocoumon and warfarin
- ketoconazole, itraconazole, 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.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with pantoprazole.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

The usual dose is one tablet daily

How to take it

Swallow whole with water. Do not chew or crush tablets.

When to take it

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

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor or pharmacist tells you.

It should be taken for at least 7 days and up to 14 days. It should not be taken for more than 14 days unless directed by your doctor.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Tell your doctor if you do not feel better while taking this medicine. Your doctor may recommend further examination.

Tell your doctor if symptoms persist or recur within 2 weeks of completing the course.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor or pharmacist.

Things to be careful of

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

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 - 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.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking pantoprazole or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- headache
- dizziness
- diarrhoea
- nausea or vomiting
- stomach pain

- excessive gas in the stomach or bowel
- indigestion
- constipation
- dry mouth
- metallic taste
- weakness or tiredness
- increased sweating
- blurred vision
- 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

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- unusual tiredness or weakness
- 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
- 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.

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

Allergic reactions

If you think you are having an allergic reaction to pantoprazole, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect from light and moisture.

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 this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Pantoprazole Heartburn Relief Tablets look like

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

The tablets are yellow, oval, biconvex, enteric-coated tablets engraved "APO" on one side, "20" on the other side.

Available in blister packs of 7 and 14 tablets

* Not all pack sizes may be available.

Ingredients

Each tablet contains 20 mg of pantoprazole (as sodium sesquihydrate) as the active ingredient.

It also contains the following inactive ingredients:

- lactose anhydrous
- crospovidone
- cellulose-microcrystalline
- magnesium stearate
- hypromellose
- macrogol 8000
- anhydrous sodium carbonate
- methacrylic acid copolymer
- triethyl citrate
- talc-purified
- titanium dioxide
- iron oxide yellow.

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

Australian Registration Numbers

APO-Pantoprazole Heartburn Relief 20mg tablets (blisters): AUST R 156332

Sponsor

Apotex Pty Ltd

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