

Panthron™

pantoprazole (as sodium sesquihydrate) delayed release 20 mg and 40 mg tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Panthron™. 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 taking Panthron™ against the benefits this medicine is expected to have for you.

Use Panthron™ 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 is Panthron™ used for

The name of your medicine is Panthron™. It contains the active ingredient called pantoprazole (as sodium sesquihydrate).

Ulcers

Panthron™ is used to treat and help heal duodenal and gastric ulcers. Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out of the stomach. Panthron™ may also be used to prevent ulcers associated with the use of non-steroidal anti-inflammatory drugs (NSAIDs). These are medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis (inflammation of the joints).

Reflux disease

Panthron™ is also used to treat reflux oesophagitis or reflux disease. 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. Panthron™ is also used to prevent reflux oesophagitis from coming back.

Zollinger-Ellison syndrome

Panthron™ is used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces very large amounts of acid, much more than in ulcers and reflux disease.

Other uses

Your doctor may have prescribed Panthron™ for another reason. Ask your doctor if you have any questions about why Panthron™ has been prescribed for you.

How Panthron™ works

Panthron™ belongs to a group of medicines called proton pump inhibitors (PPIs). Panthron™ works by decreasing the amount of acid the stomach makes to give relief from the symptoms and allow healing to take place. There is no evidence that Panthron™ is addictive. This medicine is available only with a doctor's prescription.

Before you start to take Panthron™

When you must not take it

Do not take Panthron™ if:

- you have an allergy to:**
 - pantoprazole
 - any of the ingredients listed at the end of this leaflet.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.

2. **you have severe liver disease or cirrhosis.**

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

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

Do not take Panthron™ in combination with atazanavir (an anti-viral medication).

Panthron™ should not be given to children.

Safety and effectiveness of Panthron™ in children have not been established.

If you are not sure whether you should start taking Panthron™ alone, or Panthron™ in combination with antibiotics, talk to your doctor.

Do not take Panthron™ if the packaging is torn or shows signs of tampering. Do not take Panthron™ after the expiry date (EXP) printed on the pack has passed.

Before you start to take it

You must tell your doctor if:

1. **you have any allergies to:**
 - pantoprazole
 - any of the ingredients listed at the end of this leaflet
 - any other medicines, or any other substances, such as foods, preservatives or dyes.
2. **you are pregnant, intend to become pregnant, are breastfeeding or intend to breastfeed.**

Your doctor will discuss the risks and benefits of taking Panthron™ during pregnancy or while breastfeeding.
3. **you have or have had any other medical conditions.**

If you have not told your doctor about any of the above, tell them before you take Panthron™.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, super-market or health food shop. Some medicines may be affected by Panthron™, or may affect how well it works. These may include medicines used to prevent blood clots (anticoagulants) and medicines whose activity depend on the acidity of the stomach e.g. ketoconazole. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

How to take Panthron™

How much to take

The usual dose is one tablet per day. However, if your doctor also prescribes antibiotics in combination with Panthron™ for the treatment of duodenal ulcers, the dose of Panthron™ is two 40 mg tablets per day. The first tablet should be taken in the morning and the second tablet should be taken before the evening meal for 7 days. Your doctor will prescribe the dose that is right for you. The dose and frequency of Panthron™ that your doctor prescribes for you depends on your medical condition. Your doctor may change the dose as your condition changes.

How and when to take it

Swallow your tablets whole with a little water with or without food. If you are taking other medicines, like antibiotics, in combination with Panthron™ therapy, follow the instructions for the use of each medicine carefully.

Do not crush or chew the tablets. Panthron™ tablets have a special coating to protect them from the acidic contents of your stomach. For Panthron™ to work effectively, this coating must not be broken.

How long to take it

Your doctor will tell you how long to take your tablets.

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 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 getting an unwanted side effect. If you trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

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

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

You may need urgent medical attention.

Keep telephone numbers for these places handy.

While you are taking Panthron™

Thing you must do

Use Panthron™ exactly as your doctor has prescribed.

Tell your doctor immediately if you became pregnant while you are taking Panthron™.

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

If you take Panthron™ for a long period of time, e.g. over 1 year, you will need to see your doctor regularly so that he/she can monitor your condition.

Tell your doctor if you do not feel better while taking Panthron™.

Your doctor may recommend further examination.

Thing you must not do

Do not Panthron™ to anyone else, even if they have the same symptoms as you. Do not use Panthron™ to treat any other complaints unless your doctor tells you to.

Thing 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.

Side effects

Tell your doctor as soon as possible if you have any problems while taking Panthron™, even if you do not think the problems are connected with the medicine or they are not listed in this leaflet.

Like other medicines, Panthron™ can cause some side effects. If they occur, most are 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. Tell your doctor if you notice any of the following and they worry you:**

- 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

These are the more common side effects of Panthron™. Some of these side effects may be due to the combination of other medicines you are taking with Panthron™.

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

Tell your doctor if you notice anything that is making you feel unwell when you are taking, or soon after you have finished taking Panthron™. Ask your doctor or pharmacist if you do not understand some of the information in this list.

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

After taking Panthron™

Storage

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

If you take the tablets out of the blister pack they may not keep well. Keep Panthron™ tablets in a cool dry place where the temperature stays below 30°C.

Do not store Panthron™ or any other medicines in a bathroom or near sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Panthron™ 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 tells you to stop taking Panthron™ or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

Panthron™ is available as 20 mg and 40 mg tablets. The tablets have an acid-resistant coating called an enteric coating.

The 20 mg tablets are yellow and oval shaped, plain on both sides. The 40 mg tablets are yellow and oval shaped, plain on both sides.

Panthron™ 40 mg tablets are available in blister pack of 5, 14, 15, 28, 30, 50, 56, 60, 100 and 140 tablets. Panthron™ 20 mg tablets are available in blister pack of 5, 14, 15, 28, 30, 50, 56, 60, 100 and 140 tablets (Not all may be marketed).

Ingredients

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

- Panthron™ 40 mg tablets contain equivalent of 40 mg pantoprazole (as sodium sesquihydrate) and
- Panthron™ 20 mg tablets contain equivalent of 20 mg pantoprazole (as sodium sesquihydrate).

Panthron™ tablets also contain

- mannitol,
- sodium carbonate anhydrous,
- sodium starch glycollate,
- crospovidone,
- silica colloidal anhydrous,
- calcium stearate,
- hypromellose,
- Macrogol 6000,
- purified water,
- sodium hydroxide,
- Eudragit L30-D55 and
- Opadry AMB Aqueous Moisture Barrier Coating System 80W52172 Yellow.

Panthron™ tablets do not contain gluten, lactose, sucrose, tartrazine or other azo dyes.

Sponsor/Marketing Authorisation Holder

Eris Pharmaceuticals (Australia) Pty Ltd

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Australian Registration Number:

Panthron™ 20 mg AUST R 158192

Panthron™ 40 mg AUST R 158195

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