

# Pantoprazole Generichealth

## Consumer Medicine Information (CMI) Summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Pantoprazole Generichealth?

Pantoprazole Generichealth contains the active ingredient pantoprazole sodium sesquihydrate. Pantoprazole Generichealth is used to treat duodenal and gastric ulcers, reflux oesophagitis or reflux disease, and rare condition called Zollinger-Ellison syndrome.

For more information, see Section [1. Why am I using Pantoprazole Generichealth?](#) in the full CMI.

### 2. What should I know before I use Pantoprazole Generichealth?

Do not take if you have ever had an allergic reaction to pantoprazole or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Pantoprazole Generichealth?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Pantoprazole Generichealth and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Pantoprazole Generichealth?

- Follow all directions given to you by your doctor or pharmacist carefully.
- They may differ from the information contained in this leaflet.
- If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

More instructions can be found in Section [4. How do I use Pantoprazole Generichealth?](#) in the full CMI.

### 5. What should I know while using Pantoprazole Generichealth?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind the doctor, dentist or pharmacist you visit that you are using Pantoprazole Generichealth.</li><li>• If you are going to have surgery, tell the surgeon that you are taking this medicine.</li><li>• If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking Pantoprazole Generichealth.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li><li>• Do not use this medicine to treat any other complaints unless your doctor tells you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• This medicine is not expected to affect your ability to drive a car or operate machinery.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Your doctor may advise you to limit your alcohol intake.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in their blister pack until it is time to take them.</li><li>• Keep Pantoprazole Generichealth tablets in a cool dry place where the temperature stays below 25°C.</li><li>• Do not store Pantoprazole Generichealth or any other medicines in a bathroom or near a sink.</li></ul>

For more information, see Section [5. What should I know while using Pantoprazole Generichealth?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects of Pantoprazole Generichealth include headache, dizziness, diarrhoea, nausea or vomiting, stomach pain, excessive gas in the stomach or bowel, etc.

Serious side effects include unusual tiredness or weakness, nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine, blood in the urine, chest pain, shortness of breath, severe or persistent diarrhea, etc.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Pantoprazole Generichealth

Active ingredient(s): (*pantoprazole sodium sesquihydrate*) enteric-coated tablets

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Pantoprazole Generichealth. **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 Pantoprazole Generichealth.**

Where to find information in this leaflet:

- [1. Why am I using Pantoprazole Generichealth?](#)
- [2. What should I know before I use Pantoprazole Generichealth?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Pantoprazole Generichealth?](#)
- [5. What should I know while using Pantoprazole Generichealth?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Pantoprazole Generichealth?

Pantoprazole Generichealth contains the active ingredient **pantoprazole sodium sesquihydrate**. Pantoprazole Generichealth belongs to a group of medicines called proton pump inhibitors (PPIs).

Pantoprazole Generichealth works by decreasing the amount of acid the stomach makes, to give relief from the symptoms and allow healing to take place.

### Ulcers

Pantoprazole Generichealth 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.

This can be caused by too much acid being made in the stomach.

Most people who have a peptic ulcer also have bacteria called *Helicobacter pylori* in their stomach. When Pantoprazole Generichealth is taken with antibiotics the combination therapy will kill the *Helicobacter pylori* and let your ulcer heal.

Pantoprazole Generichealth 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

Pantoprazole Generichealth 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.

Pantoprazole Generichealth is also used to prevent reflux oesophagitis from coming back.

### Zollinger-Ellison Syndrome

Pantoprazole Generichealth 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.

**Ask your doctor if you have any questions about why it has been prescribed for you.** Your doctor may have prescribed it for another purpose.

This medicine is not addictive. This medicine is available only with a doctor's prescription.

Pantoprazole Generichealth should not be given to children under 5 years of age. There is not enough information to recommend the use of this medicine for children under the age of 5 years.

## 2. What should I know before I use Pantoprazole Generichealth?

### Warnings

**Do not use Pantoprazole Generichealth if:**

- you are allergic to pantoprazole, 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.

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

**Do not take Pantoprazole Generichealth 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 Generichealth;
- you have moderate to severe liver or kidney disease.

**Do not take Pantoprazole Generichealth in combination with atazanavir or nelfinavir (anti-viral medications).**

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor 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 the risks and benefits involved.

## Tell your doctor if you have any of the following symptoms:

- unintentional weight loss;
- repeated vomiting;
- vomiting blood;
- difficulty or pain when swallowing;
- you look pale and feel weak;
- you notice blood in your stools.

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

## 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 Generichealth may interfere with each other. These include:

- warfarin, phenprocoumon – medicines used to prevent blood clots (anticoagulants);
- atazanavir, nelfinavir – medicines used to treat viral infections such as HIV;
- 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;
- 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 Generichealth or may affect how well it works. You may need to use different amounts of your medicine or take different medicines.**

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Pantoprazole Generichealth.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Pantoprazole Generichealth.**

## 4. How do I take Pantoprazole Generichealth?

### How much to take

The usual dose is 40 mg tablet per day.

However, if your doctor also prescribes antibiotics in combination with Pantoprazole Generichealth for the treatment of duodenal ulcers, the dose of Pantoprazole Generichealth is 80 mg tablets per day. The first 40 mg tablet should be taken in the morning, and the second should be taken before the evening meal for 7 days.

Your doctor will prescribe the dose that is right for you.

In children over 5 years of age, the dose of pantoprazole for reflux oesophagitis or reflux disease is based on weight and may be 20 mg or 40 mg, depending on the condition being treated. Pantoprazole Generichealth should not be taken for longer than 8 weeks.

The dose and frequency of Pantoprazole Generichealth that your doctor prescribes for you depends on your medical condition. Your doctor may change the dose as your condition changes.

### When to take Pantoprazole Generichealth

Take Pantoprazole Generichealth at about the same time each day.

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

If you are taking other medicines, like antibiotics, in combination with Pantoprazole Generichealth therapy, follow the instructions for the use of each medicine carefully.

### How to take Pantoprazole Generichealth

Swallow your tablets whole with a little water with or without food.

Pantoprazole granules (available from other brands) may be used in children or adult patients unable to swallow tablets.

### If you forget to take Pantoprazole Generichealth

**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 you missed.**

This may increase the chance of getting an unwanted side effect.

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

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

## **If you take too much Pantoprazole Generichealth**

Immediately telephone your doctor or Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 764 766) or go to Accident and Emergency at your nearest hospital, if you or anyone else may have taken too much Pantoprazole Generichealth.

Urgent medical attention may be needed.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while taking Pantoprazole Generichealth?**

### **Things you should do**

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

If you become pregnant while you are taking this medicine, tell your doctor or pharmacist immediately.

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.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

### **Things you should not do**

Do not stop using this medicine suddenly.

**Do not give this medicine to anyone else, even if they have the same symptoms as you.**

Do not take Pantoprazole Generichealth if the packaging is damaged or shows signs of tampering.

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

### **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.

#### **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 mealtimes.

#### **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.

### **Driving or using machines**

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

This medicine is not expected to affect your ability to drive a car or operate machinery.

However, do not drive a car or operate machines if you experience side effects such as dizziness or blurred vision.

### **Drinking alcohol**

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

### **Looking after your medicine**

Store it in a cool dry place away from moisture, heat or sunlight. For example:

- do not leave it in the car or on windowsills. Heat and dampness can destroy some medicines.

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

Follow the instructions on the carton on how to take care of your medicine properly.

### **When to discard your medicine**

If your doctor tells you to stop taking Pantoprazole Generichealth or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

### **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.

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Pantoprazole Generichealth.**

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
<p><b>Digestion related:</b></p> <ul style="list-style-type: none"> <li>• Indigestion</li> <li>• Constipation</li> <li>• Diarrhoea</li> <li>• Nausea or vomiting</li> <li>• Stomach pain</li> <li>• Excessive gas in the stomach or bowel</li> </ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>• Skin problems such as itchiness and rash</li> </ul> <p><b>Miscellaneous:</b></p> <ul style="list-style-type: none"> <li>• Dry mouth</li> <li>• Metallic taste</li> <li>• Weakness or tiredness</li> <li>• Increased sweating or body temperature</li> <li>• Blurred vision</li> <li>• Trouble sleeping</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

These are the more common side effects of Pantoprazole Generichealth.

### Serious side effects

Serious side effects	What to do
<p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>• Skin problems such as itchiness, rash with swelling, blistering or peeling of the skin or rash when exposed to the sun, possibly with pain in the joints</li> <li>• Yellowing of skin</li> </ul> <p><b>Infection related:</b></p> <ul style="list-style-type: none"> <li>• Fever, severe chills, sore throat or mouth ulcer</li> </ul> <p><b>Miscellaneous:</b></p> <ul style="list-style-type: none"> <li>• Increased or decreased need to urinate</li> <li>• Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing</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>

- Chest pain
- Shortness of breath
- High blood pressure
- Water retention, swelling
- Bleeding or bruising more easily than normal
- Depression, confusion or anxiety
- 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.
- Severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea.

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

**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.

**Ask your doctor or pharmacist if you do not understand anything in this list.**

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

### 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 Pantoprazole Generichealth contains

<b>Active ingredient (main ingredient)</b>	Pantoprazole (as sodium sesquihydrate)
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• Mannitol;</li> <li>• Sodium carbonate;</li> </ul>

	<ul style="list-style-type: none"> <li>• Sodium starch glycollate;</li> <li>• Crospovidone;</li> <li>• Colloidal anhydrous silica;</li> <li>• Calcium stearate;</li> <li>• Hypromellose;</li> <li>• Macrogol 6000;</li> <li>• Sodium hydroxide;</li> <li>• Eudragit L30-D55;</li> <li>• Opadry AMB Aqueous Moisture Barrier Coating System 80W52172 Yellow.</li> </ul>
<b>Potential allergens</b>	Pantoprazole Generichealth tablets do not contain gluten, lactose, sucrose, tartrazine or other azo dyes.

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

### **What Pantoprazole Generichealth looks like**

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

Pantoprazole generichealth 20 mg tablets are yellow to pale yellow, oval shaped, biconvex enteric-coated tablets plain on both sides ARTG No 191032.

Pantoprazole generichealth 40 mg tablets are yellow to pale yellow, oval shaped, biconvex enteric-coated tablets plain on both sides ARTG No 191033.

Pantoprazole Generichealth tablets are available in blister packs 30 tablets.

### **Sponsor**

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This leaflet was prepared in July 2025.