

## CONSUMER MEDICINE INFORMATION

### PANTOPRAZOLE GENERIC HEALTH

#### pantoprazole (as sodium sesquihydrate) 20 & 40 mg enteric coated tablets

### What is in this leaflet

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.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking pantoprazole against the benefits this medicine is expected to have for you.

Use pantoprazole as directed and follow the advice given in the 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 pantoprazole is used for

The name of your medicine is **PANTOPRAZOLE GENERIC HEALTH/** pantoprazole (as sodium sesquihydrate) enteric coated tablets. It contains the active ingredient called pantoprazole 20mg or 40mg.

#### Ulcers

Pantoprazole 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.

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

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

#### Zollinger-Ellison syndrome

Pantoprazole 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 pantoprazole for another reason. Ask your doctor if you have any questions about why pantoprazole has been prescribed for you.

### **How this medicine 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 and allow healing to take place.

There is no evidence that pantoprazole is addictive.

This medicine is available only with a doctor's prescription.

## **Before you start to take this medicine**

### ***When you must not take it***

#### **Do not take pantoprazole if:**

**1. You have an allergy to pantoprazole or 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 pantoprazole if the packaging is torn or shows signs of tampering.**

**Do not take pantoprazole after the expiry date (EXP) printed on the pack has passed.**

**Do not take Pantoprazole 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 pantoprazole in combination with atazanavir (an anti-viral medication).**

**Pantoprazole should not be given to children.** Safety and effectiveness of pantoprazole in children have not been established.

### ***Before you start to take it***

**You must tell your doctor if:**

**1. You have any allergies to:**

- Pantoprazole or 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 breast-feeding or intend to breast-feed.**

Your doctor will discuss the risks and benefits of taking pantoprazole during pregnancy or while breast-feeding.

**3. You have or have had weight loss, recurrent vomiting (with or without blood), difficulty in swallowing, anaemic or black stools or any other medical conditions.**

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

### ***Taking other medicines***

**Tell your doctor 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 pantoprazole, or may affect how well it works. These may include medicines used to prevent blood clots (anticoagulants), atazanavir (an anti-viral medication) 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 this medicine**

### ***How much to take***

The usual dose is one tablet per day.

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

The dose and frequency of pantoprazole 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 in combination with pantoprazole therapy, follow the instructions for the use of each medicine carefully.

**Do not crush or chew the tablets. pantoprazole tablets have a special coating to protect them from the acidic contents of your stomach. For pantoprazole 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 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 Poisons Information Centre for advice - the telephone number in Australia is 13 11 26 and in New Zealand is 0800 POISON or 0800 764 766 - or go to Accident and Emergency (Casualty) at your 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. Keep telephone numbers for these places handy.**

## **While you are taking this medicine**

### *Things you must do*

**Use pantoprazole exactly as your doctor has prescribed.**

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

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

If you take pantoprazole 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 pantoprazole.**

Your doctor may recommend further examination.

### *Things you must not do*

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

Do not use pantoprazole to treat any other complaints unless your doctor tells you to.

### *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.

## **Side effects**

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

Like other medicines, pantoprazole 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
- changes to sense of smell
- weakness or tiredness
- increased sweating
- blurred vision, conjunctivitis
- flushes, chest pain
- skin problems such as itchiness and rash
- ringing in the ears

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

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

- unusual tiredness or weakness
- nausea, vomiting, loss of appetite, feeling generally unwell, fever, hot flushes, 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, hallucination, 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 pantoprazole.**

**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 this medicine**

### *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 pantoprazole tablets in a cool dry place where the temperature stays below 25°C.

**Do not store pantoprazole or any other medicines in a bathroom or near a sink. Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep pantoprazole 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 pantoprazole 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***

PANTOPRAZOLE  
GENERIC HEALTH  
pantoprazole (as sodium sesquihydrate) 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 colored, oval shaped, biconvex enteric coated tablets plain on both sides.

The 40mg tablets are yellow colored, oval shaped, biconvex enteric

coated tablets plain on both sides.

PANTOPRAZOLE  
GENERIC HEALTH  
pantoprazole (as sodium sesquihydrate) enteric coated tablets are available in blister packs of 10, 30 and 100 tablets.

### ***Ingredients***

The active ingredient in PANTOPRAZOLE  
GENERIC HEALTH  
pantoprazole enteric coated tablets is pantoprazole as pantoprazole sodium sesquihydrate.

PANTOPRAZOLE  
GENERIC HEALTH  
pantoprazole 20mg enteric coated tablets contain the equivalent of 20 mg pantoprazole and PANTOPRAZOLE  
GENERIC HEALTH  
pantoprazole 40 mg enteric coated tablets contain the equivalent of 40 mg pantoprazole.

The core tablets also contain mannitol, crospovidone, sodium carbonate anhydrous, hydroxyl propyl cellulose, calcium stearate, while the film coating tablets contains hypromellose, titanium dioxide, iron oxide yellow, talc-purified, propylene

glycol, triethyl citrate, Eudragit L-30 D55

PANTOPRAZOLE  
GENERIC HEALTH  
pantoprazole enteric coated contain gluten, lactose, sucrose, tartrazine or other azo dyes.

## **Manufacturer and Supplier**

### **Sponsor**

Torrent Australasia Pty Ltd  
100 George St,  
Parramatta, NSW 2150  
AUSTRALIA

### **Distributor**

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

PANTOPRAZOL  
GENERIC HEALTH is a trade name of Generic Health Pty Ltd.

### ***Australian Registration Numbers***

PANTOPRAZOLE  
GENERIC HEALTH  
pantoprazole (as sodium sesquihydrate) 20 mg enteric coated tablet  
AUST R 155114.  
PANTOPRAZOLE  
GENERIC HEALTH

pantoprazole (as sodium  
sesquihydrate) 40 mg  
enteric coated tablet  
AUST R 155115.

**Date of Preparation**  
June 2010