

# Pantoprazole AN tablets

*Pantoprazole (as sodium sesquihydrate) enteric coated tablets*

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about PANTOPRAZOLE AN.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking PANTOPRAZOLE AN against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

Keep this leaflet with your medicine.

You may need to read it again.

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### What PANTOPRAZOLE AN is used for

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The name of your medicine is PANTOPRAZOLE AN. It contains the active ingredient called pantoprazole. It belongs to a group of medicines called proton pump inhibitors (PPIs).

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

#### Ulcers

PANTOPRAZOLE AN 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.

PANTOPRAZOLE AN 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 AN 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 AN is also used to prevent reflux oesophagitis from coming back.

#### Zollinger-Ellison disease

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

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

There is no evidence that PANTOPRAZOLE AN is addictive.

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### Before You Take PANTOPRAZOLE AN

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*When you must not take PANTOPRAZOLE AN*

**Do not take PANTOPRAZOLE AN if you are allergic to medicines containing pantoprazole or any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

**Do not take PANTOPRAZOLE AN if you have severe liver disease or cirrhosis.**

**Do not take PANTOPRAZOLE AN in combination with antibiotics or any other medicine if:**

- you are allergic to any of the antibiotics or medicines your doctor may have prescribed with PANTOPRAZOLE AN
- you have moderate to severe liver or kidney disease

**Do not take PANTOPRAZOLE AN in combination with atazanavir (an anti-viral medication)**

**PANTOPRAZOLE AN should not be given to children.**

Safety and effectiveness of PANTOPRAZOLE AN in children have not been established.

If you are not sure whether you should start taking PANTOPRAZOLE AN alone, or in

combination with antibiotics, talk to your doctor.

**Do not take this medicine after the expiry date (EXP) 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.

### *Before you start to take PANTOPRAZOLE AN*

**Tell your doctor if you are allergic to pantoprazole, any other medicines, foods, dyes or preservatives.**

**Tell your doctor if you are pregnant or plan to become pregnant.**

Your doctor will discuss the risks and benefits of taking PANTOPRAZOLE AN during pregnancy.

**Tell your doctor if you are breastfeeding or wish to breastfeed.**

Your doctor will discuss the risks and benefits of taking PANTOPRAZOLE AN when breastfeeding.

Tell your doctor if you have or have or have had any other medical conditions.

If you have not told your doctor about any of the above, tell them before you start taking PANTOPRAZOLE AN.

### *Taking other medicines*

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by PANTOPRAZOLE AN, 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.

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## How to take PANTOPRAZOLE AN

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### *How much to take*

The usual dose is one tablet per day.

However, if your doctor also prescribes antibiotics in combination with PANTOPRAZOLE AN for the treatment of duodenal ulcers, the dose of PANTOPRAZOLE AN 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 PANTOPRAZOLE AN 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 PANTOPRAZOLE AN*

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

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

**Do not crush or chew the tablets. PANTOPRAZOLE AN tablets have a special coating to protect them from the acidic contents of your stomach. For PANTOPRAZOLE AN 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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.**

**Do not take a double dose to make up for the dose you missed.**

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

### *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 you or anyone else may have taken too much PANTOPRAZOLE AN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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## While you are taking PANTOPRAZOLE AN

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### *Things you must do*

**Use PANTOPRAZOLE AN exactly as your doctor has prescribed.**

**Tell your doctor immediately if you become pregnant while taking PANTOPRAZOLE AN.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking PANTOPRAZOLE AN.**

**If you take PANTOPRAZOLE AN 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 AN.**

Your doctor may recommend further examination.

**Visit your doctor regularly so they can check on your progress.**

**Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.**

Your doctor may think it is not working effectively and change your treatment unnecessarily.

*Things you must not do*

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

**Do not use PANTOPRAZOLE AN 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.

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## Side Effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PANTOPRAZOLE AN, 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 AN 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 PANTOPRAZOLE AN. Some of these side effects may be due to the combination of other medicines you are taking with PANTOPRAZOLE AN.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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

**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

The above list includes serious side effects that may require urgent medical attention or hospitalisation.

**Tell your doctor if you notice anything that is making you feel unwell. Ask your doctor or pharmacist if you do not understand some of the information in this list.**

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## After taking PANTOPRAZOLE AN

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*Storage*

**Keep your tablets in the 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 your tablets in a cool dry place where the temperature stays below 30 degrees Celsius.

**Do not store PANTOPRAZOLE AN or any other medicine in the bathroom or near a sink.**

**Do not leave PANTOPRAZOLE AN in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep PANTOPRAZOLE AN 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.

### *Disposal*

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

tablets contain the equivalent of 20 mg pantoprazole

PANTOPRAZOLE AN tablets also contain Mannitol, Sodium carbonate anhydrous, Sodium starch glycollate, Crospovidone, colloidal anhydrous silica, Calcium stearate, Hypromellose, Macrogol 6000, Purified water, Sodium hydroxide, Eudragit L30-D55 and Opadry AMB Aqueous Moisture Barrier Coating System 80W52172 Yellow.

PANTOPRAZOLE AN tablets do not contain gluten, lactose, sucrose, tartrazine or other azo dyes.

### **Name and Address of the Sponsor**

Amneal Pharma Australia Pty Ltd  
12 River Street  
South Yarra 3141  
Australia

### **Date of Preparation**

November 14, 2014

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## Product description

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### *What it looks like*

PANTOPRAZOLE AN 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.

PANTOPRAZOLE AN 20 mg tablets are available in blister packs of 30 tablets (AUST R 158197)

PANTOPRAZOLE AN 40 mg tablets are available in blister packs of 5 and 30 tablets (AUST R 158196).

### *Ingredients*

The active ingredient in PANTOPRAZOLE AN tablets is pantoprazole. PANTOPRAZOLE AN 40 mg tablets contain the equivalent of 40 mg pantoprazole and PANTOPRAZOLE AN 20 mg