

# APO-Pantoprazole

Contains the active ingredient, pantoprazole (as sodium sesquihydrate)

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## Consumer Medicine Information

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

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### What is in this leaflet

**Read this leaflet carefully before taking your medicine Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.**

This leaflet answers some common questions about your medicine.

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. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Keep this leaflet with your medicine.

You may want to read it again.

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### What pantoprazole is used for

The name of your medicine is APO-Pantoprazole. It contains the active ingredient, pantoprazole (as sodium sesquihydrate).

It 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).

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.

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.

Your doctor may have prescribed it for another reason.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

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

There is no evidence that this medicine is addictive.

### Use in children

There is not enough information to recommend the use of this medicine in children.

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### Before you take pantoprazole

#### When you must not take it

Do not take APO-Pantoprazole if you are lactose-intolerant. The tablets contain lactose.

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

Some of the symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain; or rash, itching or hives on the skin.

**Do not take pantoprazole if you have severe liver disease or cirrhosis**

**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).**

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

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

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

**Tell your doctor if:**

**1. You have allergies to:**

- pantoprazole
  - any other ingredients listed at the end of this leaflet
  - any other substances, such as foods, preservatives or dyes.
- 2. You have or have had any medical conditions**
- 3. You plan to become pregnant or breast-feed.**

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

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

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

**Tell your doctor or pharmacist if you are taking any other medicines, including any 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) and medicines whose activity depend on the acidity of the stomach e.g. ketoconazole.

Your doctor and pharmacist can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking pantoprazole.

Other interactions not listed above may also occur.

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## **How to take this medicine**

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

### ***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 to take it***

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

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

### ***When to take it***

**Take it at about the same time each day.**

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

### ***How long to take it***

**Continue taking your medicine for as long as your doctor tells you.**

**Make sure you have enough to last over weekends and holidays.**

### ***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 your medicine 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 the Poisons Information Centre (Tel: 13 11 26 for Australia) for advice, or go to the Accident and Emergency Department at the 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.

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## **While you are taking pantoprazole**

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### ***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 this medicine to anyone else, even if their symptoms seem similar to yours.**

**Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.**

**Do not stop taking your medicine, or change the dosage, without checking with your doctor.**

### ***Things to be careful of***

**Be careful while driving or operating machinery until you know how pantoprazole 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.

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## **Side effects of pantoprazole**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are 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. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

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

**Tell your doctor or pharmacist 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. Some of these side effects may be due to the combination of other medicines you are taking with pantoprazole.

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

- 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 pantoprazole.

**Ask your doctor or pharmacist if you do not understand some of the information in this list.**

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## After taking this medicine

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### Storage

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

If you take the tablets out of their original packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

**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 it 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, ask your pharmacist what to do with any medicine that is left over.**

### Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

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## Product description

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### What APO-Pantoprazole looks like

The tablets are available as 20 mg and 40 mg strengths. The tablets have an acid-resistant coating called an enteric coating.

#### 20 mg tablets

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

Available in blister packs of 30 tablets and bottles of 30, 100 and 500 tablets.

#### 40 mg tablets

The 40 mg tablets are yellow, oval, biconvex, enteric-coated tablets engraved "APO" on one side, "40" on the other side

Available in blister packs of 5 and 30 tablets and bottles of 30, 100 and 500 tablets.

### Ingredients

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

The tablets also contain the following as inactive ingredients: lactose anhydrous, crospovidone, cellulose-microcrystalline, magnesium stearate, hypromellose, macrogol 8000, anhydrous sodium carbonate, methacrylic acid copolymer, triethyl citrate, talc-purified, titanium dioxide and iron oxide yellow.

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

### Australian Registration Numbers

APO-Pantoprazole 20 mg tablets (blisters): AUST R 156338.

APO-Pantoprazole 40 mg tablets (blisters): AUST R 156334.

APO-Pantoprazole 20 mg tablets (bottles): AUST R 156339.

APO-Pantoprazole 40 mg tablets (bottles): AUST R 156341.

\*Not all strengths, pack types and/or pack sizes may be available.

### Sponsor

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Australia

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