

APO-Pantoprazole Tablets

Contains the active ingredient, pantoprazole (as sodium sesquihydrate)

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine.

You may want to read it again.

What this medicine is used for

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

This medicine belongs to a group of medicines called proton pump inhibitors (PPIs). PPIs work by decreasing the amount of acid the stomach makes, to give relief from the symptoms and allow healing to take place.

Ulcers

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).

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.

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

Your doctor may have prescribed it for another reason.

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.

Before you take this medicine

When you must not take it

Do not take APO-Pantoprazole 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 (anti-viral medications).

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 especially the following:

- a 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))
- kidney disease.

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.

4. 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 this medicine.

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 and pantoprazole may interfere with each other. These include:

- warfarin and phenprocoumon - medicines used to prevent blood clots (anticoagulants)
- atazanavir, - 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, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines.

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.

How to take this medicine

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 the tablets 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.

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 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.

Possible side effects

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

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 or body temperature
- 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:

- 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
- increased or decreased need to urinate
- 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.

Storage and disposal

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.

New Formulation

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Old Formulation

Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect from light and moisture.

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.

Product description

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.

New Formulation

20 mg tablets

Yellow, oval, biconvex enteric-coated tablets, plain on both sides.

Blister pack of 5 and 30 tablets.

40 mg tablets

Yellow, oval, biconvex enteric-coated tablets, plain on both sides.

Blister pack of 5 and 30 tablets.

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

Old Formulation

20 mg tablets

Yellow, oval, biconvex, enteric-coated tablets engraved "APO" on one side, "20" on the other side.

Blister pack of 30 tablets.

Bottle of 30, 100 and 500 tablets.

40 mg tablets

Yellow, oval, biconvex, enteric-coated tablets engraved "APO" on one side, "40" on the other side.

Blister pack of 5 and 30 tablets.

Bottle of 30, 100 and 500 tablets.

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

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

Ingredients

New Formulation

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

The tablets also contain the following as inactive ingredients:

- mannitol
- anhydrous sodium carbonate
- sodium starch glycolate
- crospovidone
- anhydrous colloidal silica
- calcium stearate
- hypromellose
- macrogol 6000
- sodium hydroxide
- Eudragit L30-D55
- Opadry AMB Aqueous Moisture Barrier Coating System 80W52172 Yellow.

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

Old Formulation

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

The tablets also contain the following as inactive ingredients:

- anhydrous lactose
- crospovidone
- microcrystalline cellulose
- magnesium stearate
- hypromellose
- macrogol 8000
- anhydrous sodium carbonate
- methacrylic acid copolymer
- triethyl citrate
- purified talc
- titanium dioxide
- iron oxide yellow.

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

Australian Registration Numbers

New Formulation

APO-Pantoprazole 20 mg tablets (blister): AUST R 213715.

APO-Pantoprazole 40 mg tablets (blister): AUST R 213716.

Old Formulation

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

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

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

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

Sponsor

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