

Pantoprazole APOTEX Tablets

Pantoprazole (as sodium sesquihydrate)

Consumer Medicine Information

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

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 using this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may want to read it again.

What this medicine is used for

Pantoprazole 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 symptoms and allow healing to take place.

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 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.

This medicine is not addictive.

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 pantoprazole if you have an allergy to:

- pantoprazole
- other proton pump inhibitors
- 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
- 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 or nelfinavir (anti-viral medications).

Do not take this medicine after the expiry date 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.

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 you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- 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.

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

Your doctor can discuss with you 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 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 get 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

- atazanavir and nelfinavir, medicines used to treat viral infections such as HIV
- ketoconazole, itraconazole and posaconazole, medicines used to treat fungal infections
- methotrexate, a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer
- tacrolimus and 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 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 differ to the information contained 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.

How to take it

Swallow your tablets whole with water.

Do not crush or chew the tablets. Pantoprazole APOTEX 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 your medicine 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.

It does not matter if you are taking this medicine before or after food.

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 (telephone 13 11 26) for advice, or go to Accident and Emergency 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

If you are about to be started on any new medicine, remind your

doctor and pharmacist that you are taking pantoprazole.

Tell any other doctors, dentists and pharmacists who treat you that you are taking pantoprazole.

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

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.

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 they 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 take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

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.

This medicine may cause dizziness, in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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 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.
- 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
- trouble sleeping

The above list includes the more common side effects of your medicine.

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

- unusual tiredness or weakness
- blood in the urine
- increased or decreased need to urinate
- high blood pressure
- depression or anxiety

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

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- skin problems such as itchiness and rash, or swelling, blistering or peeling of the skin or rash when exposed to the sun, possibly with pain in the joints
- 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
- 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 levels in your blood

Side effects

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

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- dizziness
- diarrhoea
- nausea or vomiting

- severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea
- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine
- confusion
- chest pain
- shortness of breath
- swelling of the legs
- bleeding or bruising more easily than normal

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people.

Storage and disposal

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

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

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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What Pantoprazole APOTEX 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

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

Blister pack of 5 and 30 tablets.

40 mg tablets

Yellow to pale 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.

Ingredients

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

The tablets also contain the following:

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

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

Australian Registration Numbers

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

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

Sponsor

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