

Pantoprazole Sandoz®

Pantoprazole (as sodium sesquihydrate) enteric coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Pantoprazole Sandoz.

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 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 the medicine.

You may need to read it again.

WHAT PANTOPRAZOLE SANDOZ IS USED FOR

This medicine contains the active ingredient pantoprazole. It belongs to a group of medicines called proton pump inhibitors (PPIs).

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

Ulcers

Pantoprazole Sandoz 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.

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

Most people who have a peptic ulcer also have bacteria called *Helicobacter pylori* in their stomach. When Pantoprazole Sandoz is taken with antibiotics the combination therapy will kill the *Helicobacter pylori* and let your ulcer heal.

This medicine 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 Sandoz 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.

This medicine is also used to prevent reflux oesophagitis from coming back.

Zollinger-Ellison syndrome

Pantoprazole Sandoz 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 not addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery.

However, do not drive a car or operate machines if you experience side effects such as dizziness or blurred vision.

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

BEFORE YOU TAKE PANTOPRAZOLE SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- the active ingredient pantoprazole or to any of the other ingredients listed at the end of this leaflet under Product Description.
- any other similar medicines.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Pantoprazole Sandoz in combination with atazanavir or nelfinavir (an anti-viral medication).

Do not take this medicine if you have cirrhosis or severe liver disease.

Do not take this medicine 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 sandoz
- you have moderate to severe liver or kidney disease.

This medicine should not be given to children under the age of 5 years.

Safety and effectiveness in children younger than 5 years has not been established.

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 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 or have had any other medical conditions.

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 Pantoprazole Sandoz.

If you have not told your doctor about any of the above, tell him/her before you start taking Pantoprazole Sandoz.

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 Sandoz may interfere with each other. These include:

- atazanavir or nelfinavir - medicines used to treat viral infections such as HIV
- warfarin or phenprocoumon - medicines used to prevent blood clots (anticoagulants)
- ketoconazole, itraconazole, posaconazole - medicines used to treat fungal infection
- tacrolimus, mycophenolate mofetil - medicines used to suppress the immune system
- methotrexate - a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer
- fluvoxamine - a medicine used to treat anxiety and depression.

These medicines may be affected by Pantoprazole Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE PANTOPRAZOLE SANDOZ

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

They may differ from the information contained in this leaflet.

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

How much to take

The usual dose is one tablet per day.

However, if your doctor also prescribes antibiotics in combination with Pantoprazole Sandoz for the treatment of duodenal ulcers, the dose of Pantoprazole Sandoz is 80 mg per day. The first 40 mg dose should be taken in the morning and the second should be taken before the evening meal for 7 days.

Your doctor may have prescribed a different dose.

The dose and frequency of Pantoprazole Sandoz that your doctor prescribes for you depends on your medical condition. Your doctor may change the dose as your condition changes.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Pantoprazole Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water with or without food.

Do not crush or chew the tablets.

The 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 Pantoprazole Sandoz

Take your medicine at about the same time each day.

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

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

How long to take Pantoprazole Sandoz

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

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

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 Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) 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 Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE TAKING PANTOPRAZOLE SANDOZ

Things you must do

Always follow your doctor's instructions carefully.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Pantoprazole Sandoz.

Tell your doctor if you become pregnant while taking Pantoprazole Sandoz.

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

If you are going to have surgery, tell the surgeon that you are taking this medicine.

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.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Pantoprazole Sandoz 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.

SIDE EFFECTS

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

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 lists 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
- nausea or vomiting
- diarrhoea, stomach pain, excessive gas in the stomach or bowel, constipation, indigestion
- 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 immediately if you notice any of the following:

- unusual tiredness or weakness
- nausea or vomiting in combination with 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, rash with swelling, blistering or peeling of the skin or rash when exposed to 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
- chest pain
- shortness of breath
- high blood pressure
- water retention, swelling
- bleeding or bruising more easily than normal
- depression, confusion or anxiety
- 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
- severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea.

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

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

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

Ask your doctor or pharmacist if you do not understand anything in this list.

AFTER TAKING PANTOPRAZOLE SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

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

Do not store Pantoprazole Sandoz 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 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 it looks like

Pantoprazole Sandoz comes in two types of tablets:

Pantoprazole Sandoz 20mg - yellow and oval shaped enteric coated tablets.

Pantoprazole Sandoz 40mg - yellow and oval shaped enteric coated tablets.

Pantoprazole Sandoz 20mg is available in blister packs of 30 enteric coated tablets.

Pantoprazole Sandoz 40mg is available in blister packs of 5 and

30 enteric coated tablets and in bottles of 30 enteric coated tablets.

Ingredients

Active ingredients:

- Pantoprazole Sandoz 20mg - 20mg pantoprazole (as sodium sesquihydrate).
- Pantoprazole Sandoz 40mg - 40mg pantoprazole (as sodium sesquihydrate).

Inactive ingredients:

- sodium carbonate anhydrous
- microcrystalline cellulose
- crospovidone
- hydroxypropylcellulose
- colloidal anhydrous silica
- calcium stearate
- Opadry complete film coating system 03B22011 Yellow
- Eudragit L30D-55
- triethyl citrate

This medicine does not contain gluten, lactose or sucrose.

Supplier

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Australian Register Numbers

Pantoprazole Sandoz 20mg enteric-coated tablets: AUST R 147362 (blisters)

Pantoprazole Sandoz 40mg enteric-coated tablets: AUST R 147367 (blisters)

Pantoprazole Sandoz 40mg enteric-coated tablets: AUST R 147368 (bottles)