

Pantoprazole Sandoz® Injection

Pantoprazole sodium sesquihydrate

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.

WHAT PANTOPRAZOLE SANDOZ IS USED FOR

This medicine is used to treat

- **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. These can be caused in part by too much acid being made in the stomach.
- **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.

Pantoprazole Sandoz 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.

This medicine contains the active ingredient pantoprazole sodium sesquihydrate. Pantoprazole sodium sesquihydrate belongs to a group of medicine 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.

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.

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

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.

BEFORE YOU ARE GIVEN PANTOPRAZOLE SANDOZ

When you must not be given it

You should not be given this medicine if you have an allergy to:

- the active ingredient pantoprazole
- 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.

Pantoprazole Sandoz should not be given in combination with atazanavir or nelfinavir (anti-viral medications).

You should not be given this medicine if you have severe liver disease or cirrhosis.

This medicine should not be given to children.

Safety and effectiveness in children has not been established.

This medicine should not be given 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 be given this medicine, talk to your doctor.

Before you given 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.

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

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

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, nelfinavir - medicines used to treat viral infections such as HIV
- warfarin, phenprocoumon - medicines used to prevent blood clots (anticoagulants)
- 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 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 being given this medicine.

HOW PANTOPRAZOLE SANDOZ IS GIVEN

Pantoprazole Sandoz will be administered by your doctor. 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 it is given

The dose and frequency of Pantoprazole Sandoz Injection will be determined by your doctor and will depend on your medical condition. Your doctor may change the dose as your condition changes.

Pantoprazole Sandoz is reconstituted with a sodium chloride solution by your doctor or pharmacist.

Your doctor will ensure that you receive the correct dose of Pantoprazole Sandoz.

Never administer this medicine to yourself.

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 it will be given for

Your doctor will determine how long you need to be treated with Pantoprazole Sandoz.

If you miss a dose

Tell your doctor as soon as possible if you realise that you have missed an appointment for receiving your dose of Pantoprazole Sandoz.

If you have problems remembering when your next dose is due, use a diary or calendar, or ask a friend to remind you.

If you are given too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 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 been given too much Pantoprazole Sandoz. Do this even if there are no signs of discomfort or poisoning.

As Pantoprazole Sandoz is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience severe side effects (This side effects are listed under the heading, 'Side effects' in this leaflet) after being given this medicine, tell your doctor or nurse immediately.

You may need urgent medical attention.

WHILE YOU ARE BEING GIVEN 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 being treated with **Pantoprazole Sandoz**.

Tell any other doctors, dentists and pharmacists who treat you that you are being given Pantoprazole Sandoz.

If you are about to have any blood tests, tell your doctor that you are being treated with this medicine. It may interfere with the results of some tests.

If you become pregnant while you are being given this medicine, tell your doctor immediately. 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.

Tell your doctor if your reflux symptoms return after you stop taking this medicine.

The symptoms of reflux may return after stopping this medicine suddenly, especially if you have taken it for a while.

Things you must not do

Do not use 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.

Do not stop using Pantoprazole Sandoz without your doctor's permission.

Your doctor may want you to gradually reduce the amount you are taking before stopping completely.

Things to be careful of

Be careful driving or operating machinery until you know how Pantoprazole Sandoz affects you.

This medicine may cause dizziness or light-headedness in some people, especially after the first dose. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given 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
- pain and swelling at the site of injection
- 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. They are usually mild and short-lived.

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
- severe skin problems such as itchiness and rash with 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
- 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 dose 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, calcium or potassium 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.

AFTER YOU ARE GIVEN PANTOPRAZOLE SANDOZ

Storage

Pantoprazole Sandoz will be stored in the original packaging in the pharmacy or on the ward.

If it is taken out of its original container it may not keep well.

Normally your doctor will provide you Pantoprazole Sandoz injection. If however, you do take your medicine injection (in the form of a dry powder) from the pharmacy to your doctor, it is important to store it in a safe place away from heat (below 25°C).

If for any reason you are given your Pantoprazole Sandoz injection to take home, the liquid product (after reconstitution) should be used as soon as possible after preparation by the pharmacist. If storage is necessary, store at 2-8°C for no longer than 12 hours.

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 stops treating you with Pantoprazole Sandoz, your

hospital pharmacist will dispose any unused medicine.

PRODUCT DESCRIPTION

What it looks like

Pantoprazole Sandoz is available as a 40mg injection. It is white to off white powder provided in a clear glass vial with a red stopper and aluminium "flip-off" cap.

Ingredients

Active ingredients:

- Pantoprazole Sandoz 40 mg - 40 mg pantoprazole as pantoprazole sodium sesquihydrate

There are no inactive ingredients in Pantoprazole Sandoz

This medicine does not contain gluten, lactose or sucrose.

Supplier

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Australian Register Number(s)

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