

Pantoprazole SUN

Pantoprazole (as Sodium)

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about PANTOPRAZOLE SUN. 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 PANTOPRAZOLE SUN against the benefits this medicine is expected to have for you.

Use PANTOPRAZOLE SUN as directed and follow the advice given in the leaflet.

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 SUN is used for

Ulcers

PANTOPRAZOLE SUN 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 SUN 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 SUN is also used to prevent reflux oesophagitis from coming back.

Zollinger-Ellison syndrome

PANTOPRAZOLE SUN 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.

PANTOPRAZOLE SUN belongs to a group of medicines called proton pump inhibitors (PPIs).

PANTOPRAZOLE SUN 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 PANTOPRAZOLE SUN has been prescribed for you

Your doctor may have prescribed PANTOPRAZOLE SUN for another reason.

There is no evidence that PANTOPRAZOLE SUN is addictive.

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

Before you use PANTOPRAZOLE SUN

When you must not use it

Do not use PANTOPRAZOLE SUN if you have an allergy to:

- **Pantoprazole sodium, the active ingredient of PANTOPRAZOLE SUN**
- **Any of the ingredients listed at the end of this leaflet.**

Some 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 use PANTOPRAZOLE SUN if you have or have had cirrhosis or moderate to severe liver or kidney disease.

Do not use PANTOPRAZOLE SUN in combination with atazanavir (an anti-viral medication).

Do not use PANTOPRAZOLE SUN if the packaging is torn or shows signs of tampering.

Do not use PANTOPRAZOLE SUN after the expiry date (EXP) printed on the pack has passed.

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

PANTOPRAZOLE SUN should not be given to children.

Safety and effectiveness of PANTOPRAZOLE SUN in children have not been established.

If you are not sure whether you should start being treated with

PANTOPRAZOLE SUN, talk to your doctor.

Before you start to use it

You must tell your doctor if you have any allergies to:

- PANTOPRAZOLE SUN (pantoprazole sodium)
- any other medicines, or any other substances, such as foods, preservatives or dyes.

You must tell your doctor if you are pregnant, intend to become pregnant, are breast-feeding or intend to breast-feed.

Your doctor will discuss the risks and benefits of being given PANTOPRAZOLE SUN during pregnancy or while breast-feeding.

If you have not told your doctor about any of the above, tell them before you take PANTOPRAZOLE SUN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by PANTOPRAZOLE SUN, or may affect how well it works. These may include atazanavir (an anti-viral medication), medicines used to prevent blood clots (anticoagulants) and medicines whose activity depend on the acidity of the stomach e.g. ketoconazole.

You may need different amounts of your medicine, 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 medicines.

How to use PANTOPRAZOLE SUN

Pantoprazole SUN powder for injection 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 instruction, ask your doctor or pharmacist for help.

How much to use and when to use it

The dose and frequency of your injection PANTOPRAZOLE SUN powder for injection will be determined by your doctor and will depend on your medical condition. Your doctor may change the dose as your condition changes.

How to use it

PANTOPRAZOLE SUN is reconstituted with a sodium chloride solution by your doctor or pharmacist.

Your doctor will ensure that you receive the correct dose of PANTOPRAZOLE SUN.

Never administer this medicine to yourself.

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

How long to use it

Your doctor will determine how long you need to be treated with PANTOPRAZOLE SUN.

If a dose is missed

Tell your doctor as soon as possible if you realize that you missed an appointment for receiving your dose of PANTOPRAZOLE SUN, you

doctor will determine when your next dose is due.

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

If too much is given (overdose)

Immediately telephone your doctor or the Poison 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 been given too much PANTOPRAZOLE SUN. Do this even if there are no signs of discomfort or poisoning.

As PANTOPRAZOLE SUN 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 (The side effects are listed under the heading, 'Side effects' in this leaflet.) after being given this medicines, tell your doctor or nurse immediately.

You may need urgent medical attention.

While you are using PANTOPRAZOLE SUN

Things you must do

Always follow your doctor's instructions carefully.

Tell your doctor immediately if you become pregnant while you are being given PANTOPRAZOLE SUN.

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.

If you are about to start taking a new medicines, tell your doctors,

dentists and pharmacists that you are being given PANTOPRAZOLE SUN.

Things you must not do

Do not use PANTOPRAZOLE SUN to treat any other complains unless your doctor tells you to.

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

Do not stop using PANTOPRAZOLE SUN 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 SUN 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 chair, 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 have any problems while being treated with PANTOPRAZOLE SUN, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, PANTOPRAZOLE SUN can cause some side effects. If they occur, most are likely to be minor and

temporary. However, some may be serious and you may need medical attention.

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

Ask your doctor or pharmacist any questions you may have.

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

- headache
- diarrhoea
- nausea or vomiting
- stomach pain
- excessive gas in the stomach or bowel
- indigestion
- constipation
- increased sweating
- dry mouth
- pain and swelling at the site of injection
- dizziness
- weakness or tiredness
- metallic taste
- blurred vision
- skin problems such as itchiness and rash

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor immediately 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.
- 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 being treated with PANTOPRAZOLE SUN.

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

After using PANTOPRAZOLE SUN

Storage

Normally your doctor will provide your injection PANTOPRAZOLE SUN powder for injection. If however, you do take your injection PANTOPRAZOLE SUN powder for injection from the pharmacy to your doctor, it is important to store it in a safe place away from heat (below 25°C) and away from light. Do not leave your PANTOPRAZOLE SUN in a car.

If for any reason you take your injection PANTOPRAZOLE SUN powder for injection home, use as soon as possible after preparation. If storage is necessary, store at 2-8°C for no longer than 12 hours.

When taking injection PANTOPRAZOLE SUN powder for injection at home, always ensure that it is stored in a place where children cannot reach it i.e. 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 SUN, your hospital pharmacist will dispose of any unused medicine.

Product Description

What it looks like

PANTOPRAZOLE SUN is available as an injection powder for injection, containing pantoprazole sodium equivalent to 40 mg pantoprazole. PANTOPRAZOLE SUN is a white to off white powder provided in a colourless glass vial sealed with a grey rubber stopper and fitted with red flip off aluminium cap.

PANTOPRAZOLE SUN is available in 1 and 10 vials.

Ingredients

The active ingredient in injection PANTOPRAZOLE SUN powder for injection is pantoprazole (as sodium). There are no inactive ingredients in PANTOPRAZOLE SUN.

Sponsor

Pantoprazole SUN is supplied in Australia by:

Sun Pharma ANZ Pty Ltd
Macquarie Park NSW 2113

Email:

customerservice.aus@sunpharma.com

Tel: 1800 726 229

Pantoprazole SUN 40mg powder
for injection: AUST R 172172

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