

SALPRAZ HEARTBURN RELIEF

Pantoprazole (as sodium sesquihydrate) enteric coated tablets (Reformulation 2)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SALPRAZ HEARTBURN RELIEF.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

Use SALPRAZ HEARTBURN RELIEF as directed and follow the advice given in this leaflet.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking SALPRAZ HEARTBURN RELIEF against the benefits of this medicine is expected to 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 SALPRAZ HEARTBURN RELIEF is used for

The name of your medicine is SALPRAZ HEARTBURN RELIEF. It contains the active ingredient called pantoprazole.

Heartburn and Gastro-Oesophageal Reflux disease

SALPRAZ HEARTBURN RELIEF is used for the relief of symptoms of frequent heartburn, acid regurgitation and stomach acid complaints due to gastro-oesophageal reflux disease

(GORD). 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.

Frequent heartburn is when you have heartburn for two or more days a week. Heartburn that occurs frequently is a typical symptom of gastro-oesophageal reflux disease (GORD). SALPRAZ HEARTBURN RELIEF is recommended for adults over 18 years of age suffering from heartburn at least 2 times a week. SALPRAZ HEARTBURN RELIEF is not the right medicine for you if you suffer heartburn only occasionally (one episode of heartburn a week or less), or if you want immediate relief of heartburn.

How SALPRAZ HEARTBURN RELIEF works

SALPRAZ HEARTBURN RELIEF belongs to a group of medicines called proton pump inhibitors (PPIs). SALPRAZ HEARTBURN RELIEF works by decreasing the amount of acid the stomach makes to give relief from the symptoms and allow healing to take place.

SALPRAZ HEARTBURN RELIEF will start to suppress acid within a few hours, however it will not give instant symptom relief. You may need to take SALPRAZ HEARTBURN RELIEF for a few

days before experiencing the full effect.

This medicine is not addictive. This medicine is available only from your pharmacist or doctor. This medicine is not expected to affect your ability to drive a car or operate machinery. SALPRAZ HEARTBURN RELIEF should not be given to children and adolescents under 18 years of age. There is not enough information to recommend the use of this medicine for children and adolescents under 18 years of age.

Before you start to take SALPRAZ HEARTBURN RELIEF

When you must not take it

Do not take SALPRAZ HEARTBURN RELIEF if:

- You have an allergy to pantoprazole, any other PPI (such as omeprazole, rabeprazole or lansoprazole) or any of the ingredients listed at the end of this leaflet.
- Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.
- Do not take this medicine if you have severe liver disease or cirrhosis.
- Have recently had trouble swallowing, pain when

swallowing, persistent vomiting or experienced unintended weight loss.

- Do not take SALPRAZ HEARTBURN RELIEF in combination with atazanavir or nelfinavir (antiviral medications).
- Do not take after the expiry date (EXP) printed on the pack or if the packaging is damaged or shows signs of tampering. If it has expired or is damaged return it to your pharmacist for disposal.
- SALPRAZ HEARTBURN RELIEF should not be given to children and adolescents < 18 years. Safety and effectiveness of SALPRAZ HEARTBURN RELIEF in children has not been established.
- If you are taking antibiotics, please check with your doctor or pharmacist before taking SALPRAZ HEARTBURN RELIEF.

Before you start to take it

Tell your doctor first before taking SALPRAZ HEARTBURN RELIEF if:

- A feeling of weakness or you look pale.
- You have previously taken heartburn/indigestion medication continuously for 4 or more weeks to control your heartburn. You have jaundice, liver problems, anaemia, difficulty swallowing, previous gastric ulcer or gastrointestinal surgery.
- You have new or recently changed symptoms including persistent vomiting or vomiting of blood, black stools or blood in the stools or unexplained weight loss.
- If you have experienced any of the above, you should see your doctor immediately. If you have suffered from frequent heartburn/indigestion symptoms for some time you should see your doctor.
- You should also speak to your doctor before taking SALPRAZ

HEARTBURN RELIEF if you are due to have an endoscopy (a special test ordered by your doctor).

- You have any allergies to:
 - Pantoprazole
 - Any of the ingredients listed at the end of this leaflet
 - Any other medicines, or any other substances, such as foods, preservatives or dyes.
- You are pregnant, intend to become pregnant, are breastfeeding or intend to breastfeed.
 - Your doctor will discuss the risks and benefits of taking SALPRAZ HEARTBURN RELIEF during pregnancy or while breast-feeding.
- You have or have had any other medical conditions.
 - If you have not told your doctor about any of the above, tell them before you take SALPRAZ HEARTBURN RELIEF.

Taking other medicines

Tell your doctor 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 and SALPRAZ HEARTBURN RELIEF may interfere with each other. These include:

- Warfarin, phenprocoumon - medicines used to prevent blood clots (anticoagulants).
- Atazanavir, nelfinavir - 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 SALPRAZ HEARTBURN RELIEF, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking SALPRAZ HEARTBURN RELIEF.

How to take SALPRAZ HEARTBURN RELIEF

How much to take

Take one tablet once a day (every 24 hours).

How and when to take it

Swallow your tablets whole with a little water with or without food.

Do not crush or chew the tablets. SALPRAZ HEARTBURN RELIEF tablets have a special coating to protect them from the acidic contents of your stomach. For SALPRAZ HEARTBURN RELIEF to work effectively, this coating must not be broken.

How long to take it

SALPRAZ HEARTBURN RELIEF tablets should be taken for at least seven days, and up to 14 days. You should not take it for more than 14 days unless directed by the doctor.

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 it 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 Poisons Information Centre for advice (Ph: 13 11 26) or go to Accident and Emergency (Casualty) at your nearest hospital, if you think that you or anyone else may have taken too much SALPRAZ HEARTBURN RELIEF. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places handy.

While you are taking SALPRAZ HEARTBURN RELIEF

Things you must do

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

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.

If symptoms persist or recur within 2 weeks of completing the course, consult a doctor. Your doctor may recommend further examination.

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.

Use SALPRAZ HEARTBURN RELIEF exactly as directed.

Tell your doctor immediately if you become pregnant while you are taking SALPRAZ HEARTBURN RELIEF.

Tell all doctors, dentists and pharmacists who are treating you that you are taking SALPRAZ HEARTBURN RELIEF.

Things you must not do

Do not give SALPRAZ HEARTBURN RELIEF to anyone else, even if they have the same symptoms as you. Do not use SALPRAZ HEARTBURN RELIEF to treat any other complaints unless your doctor tells you to.

SALPRAZ HEARTBURN RELIEF may cause dizziness and visual disturbances. If affected, do not drive or operate machinery.

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.**

Side effects

Tell your doctor as soon as possible if you have any problems while taking SALPRAZ HEARTBURN RELIEF, even if you do not think the problems are connected with the medicine or they are not listed in this leaflet.

Like other medicines, SALPRAZ HEARTBURN RELIEF 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.

Ask your doctor or pharmacist any questions you may have. Tell your doctor if you notice any of the following and they worry you:

- headache
- dizziness
- diarrhoea
- nausea or vomiting
- stomach pain, discomfort
- excessive gas in the stomach or bowel
- indigestion
- constipation
- dry mouth
- metallic taste
- weakness or tiredness or sleep disturbances
- increased sweating or body temperature
- blurred vision
- skin problems such as itchiness and rash

These are the more common side effects of SALPRAZ HEARTBURN RELIEF. Some of these side effects may be due to the combination of

other medicines you are taking with SALPRAZ HEARTBURN RELIEF.

Tell your doctor immediately if you notice any of the following:

- unusual tiredness, weakness, dizziness or fainting
- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine or bowel movements
- 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 or rash when exposed to the sun, possibly with pain in the joints and general fever
- 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, fast heartbeat
- shortness of breath
- high blood pressure
- water retention, swelling of the legs
- 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, jerking/shaking movements or muscle cramps. 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

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

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

After taking SALPRAZ HEARTBURN RELIEF

Storage

Keep your tablets in their blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.

Keep SALPRAZ HEARTBURN RELIEF tablets in a cool dry place where the temperature stays below 30°C.

Do not store SALPRAZ HEARTBURN RELIEF or any other medicines in a bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep SALPRAZ HEARTBURN RELIEF 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 SALPRAZ HEARTBURN RELIEF or the tablets have passed their expiry date, ask your

pharmacist what to do with any tablets that are left over.

Product description

What it looks like

SALPRAZ HEARTBURN RELIEF is available as 20 mg tablets. The tablets have an acid-resistant coating called an enteric coating.

The 20 mg tablets are yellow and oval shaped, plain on both sides.

SALPRAZ HEARTBURN RELIEF 20 mg tablets are available in blister packs of 7 & 14 tablets. Not all pack sizes may be marketed.

Ingredients

The active ingredient in SALPRAZ HEARTBURN RELIEF tablets is pantoprazole. SALPRAZ HEARTBURN RELIEF 20 mg tablets contain the equivalent of 20 mg pantoprazole (as sodium sesquihydrate).

SALPRAZ HEARTBURN RELIEF tablets also contain Mannitol, Sodium Carbonate, Crospovidone, Povidone (Povidone K-30), Calcium Stearate, Hypromellose, Macrogol 6000, Methacrylic Acid-ethyl acrylate Copolymer Dispersion, Triethyl Citrate, Purified Talc, Purified water, Opadry AMB 80W52172 (Yellow) and Carnauba Wax.

SALPRAZ HEARTBURN RELIEF tablets do not contain gluten, lactose, sucrose, tartrazine or other azo dyes.

SALPRAZ HEARTBURN RELIEF tablets contain traces of soya bean products.

Sponsor

Alphapharm Pty Ltd
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www.mylan.com.au

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20 mg – AUST R 348230

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