

Salpraz[®] Heartburn Relief

pantoprazole

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.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Salpraz Heartburn Relief 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 Salpraz Heartburn Relief is used for

The name of your medicine is Salpraz Heartburn Relief. It contains the active ingredient called pantoprazole.

Salpraz Heartburn Relief is used for lasting symptomatic relief of frequent heartburn and stomach acid complaints due 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 GORD.

Who should use Salpraz Heartburn Relief

Salpraz Heartburn Relief is recommended for adults 18 years of age and over, 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.

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.

There is no evidence that Salpraz Heartburn Relief is addictive.

This medicine is available only from your pharmacist or your doctor.

Before you take Salpraz Heartburn Relief

When you must not take it

Do not take Salpraz Heartburn Relief if you have an allergy to:

- any medicine containing pantoprazole or any other PPI (such as omeprazole, rabeprazole or lansoprazole)
- 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 or swallowing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take Salpraz Heartburn Relief if you:

- have severe liver disease or cirrhosis
- have recently had trouble swallowing, pain when swallowing, persistent vomiting or experienced unintended weight loss
- have recently vomited blood, had black stools or notice blood in your stools
- are taking atazanavir or nelfinavir (anti-viral medications)
- are pregnant, intend to become pregnant, are breast-feeding or wish to start breast-feeding.

Do not take Salpraz Heartburn Relief if the packaging is torn or shows signs of tampering.

Do not take Salpraz Heartburn Relief after the expiry date printed on the pack has passed.

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

If you take this medicine after the expiry date it may have no effect at all, or worse, an unexpected effect.

Salpraz Heartburn Relief should not be given to children and adolescents under 18 years of age.

Safety and effectiveness of Salpraz Heartburn Relief in children has not been established.

If you are not sure whether you should start taking Salpraz Heartburn Relief alone or in combination with any other medications, talk to your doctor or pharmacist.

Before you start to take

You must tell your doctor or pharmacist if:

1. 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

2. you are pregnant, intend to become pregnant, are breast-feeding or intend to breast-feed.

3. you have or have had any other medical conditions.

If you have not told your doctor or pharmacist about any of the above, tell them before you take Salpraz Heartburn Relief.

Talk to your doctor or pharmacist first before taking Salpraz Heartburn Relief if:

- you have taken heartburn/ indigestion medication previously for 4 or more weeks continuously to control your heartburn

- you have jaundice, liver problems or anaemia
- you have been told by your doctor that you have a gastric ulcer or gastrointestinal surgery is planned
- you have persisting heartburn symptoms despite taking Salpraz Heartburn Relief (or other similar medicines) continuously for 2 weeks
- your symptoms have recently changed including persistent vomiting or vomiting of blood, blood in stools or unexplained weight loss
- a feeling of weakness or you look pale
- you have heartburn/ indigestion symptoms for the first time and you are over 40 years of age
- you have a scheduled endoscopy (investigation of your stomach lining performed by a specialist)

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.

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 (blood thinners/ 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 take 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

The directions for use are included on the Medicine Information panel on the pack.

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

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

They may differ from the information contained in this leaflet.

How much to take

Take one Salpraz Heartburn Relief tablet per 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

For effective, lasting relief, take Salpraz Heartburn Relief strictly according to the directions on your pack.

Salpraz Heartburn Relief tablets should be taken for at least seven days, and up to 14 days.

If you purchased the pack containing 7 days' supply and you need to take it for longer than 7 days, ask your pharmacist for advice.

Do not take it for more than 14 days unless directed by a doctor.

Salpraz Heartburn Relief is not intended to provide instant relief from your heartburn/indigestion symptoms.

If you are not sure, ask your pharmacist or doctor how to take your medicine.

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

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

Use Salpraz Heartburn Relief exactly as your doctor or pharmacist has advised.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Salpraz Heartburn Relief.

If you are going to have surgery or an endoscopy, tell your doctor that you are taking Salpraz Heartburn Relief.

If you become pregnant while you are taking this medicine, tell your doctor or pharmacist immediately.

Tell your doctor or pharmacist if you do not feel better while taking Salpraz Heartburn Relief.

If symptoms persist or recur within 2 weeks of completing the course, consult your doctor.

Your doctor may recommend further investigation.

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.

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

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** - you may be advised 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** - it is advisable for you to stop smoking or at least cut down
- **Weight** - you may be advised that losing some weight will help your reflux/indigestion symptoms.

Side effects

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

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

These are the more common side effects of Salpraz Heartburn Relief.

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

- unusual tiredness, weakness, dizziness or fainting
- chest pain, fast heartbeat, shortness of breath
- 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
- bleeding or bruising more easily than normal
- skin problems such as itchiness, rash with 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
- high blood pressure
- water retention, swelling
- 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 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
- Worsening of acid related symptoms as a result of stopping your heartburn medicine

These may be serious side effects and you may need urgent medical attention. Serious side effects are rare.

Tell your doctor if you notice anything else that is making you feel unwell when you are taking, or soon after you have finished taking Salpraz Heartburn Relief.

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

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 original container until it is time to take them.

If you take the tablet out of the blister pack they may not keep well.

Keep Salpraz Heartburn Relief 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 young 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 expiry date has passed, 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 tablets are yellow oval shape, plain on both sides. The tablets are available in blister packs of 14 tablets.

Ingredients

The active ingredient in Salpraz Heartburn Relief tablets is pantoprazole.

Salpraz Heartburn Relief 20 mg tablets contain the equivalent of 20 mg pantoprazole.

Salpraz Heartburn Relief tablets also contain the following inactive ingredients: Mannitol, Sodium carbonate, Sodium starch glycollate, Crospovidone, Colloidal anhydrous silica, Calcium stearate, Hypromellose, Macrogol 6000, Purified water, Sodium hydroxide, Eudragit L30 D-55 and OpadryAMB Aqueous Moisture Barrier Coating System 80W52172 Yellow.

Salpraz Heartburn Relief does not contain sucrose, tartrazine or any other azo dyes.

Supplier

Salpraz Heartburn Relief is supplied by:

Alphapharm Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

Australian registration numbers:

Salpraz Heartburn Relief 20 mg tablets in blister packs -

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