## SALPRAZ® HEARTBURN RELIEF

### **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

## 1. Why am I taking SALPRAZ HEARTBURN RELIEF?

SALPRAZ HEARTBURN RELIEF contains the active ingredient pantoprazole. 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).

For more information, see Section 1. Why am I taking SALPRAZ HEARTBURN RELIEF? in the full CMI.

### 2. What should I know before I take SALPRAZ HEARTBURN RELIEF?

Do not take if you have ever had an allergic reaction to SALPRAZ HEARTBURN RELIEF or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take SALPRAZ HEARTBURN RELIEF? in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with SALPRAZ HEARTBURN RELIEF and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

## 4. How do I take SALPRAZ HEARTBURN RELIEF?

- Take one tablet once a day (every 24 hours).
- Swallow your tablets whole with a little water with or without food.

More instructions can be found in Section 4. How do I take SALPRAZ HEARTBURN RELIEF? in the full CMI.

## 5. What should I know while taking SALPRAZ HEARTBURN RELIEF?

Things you should do	<ul> <li>Remind any doctor, dentist or pharmacist you visit that you are taking SALPRAZ HEARTBURN RELIEF.</li> <li>Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.</li> </ul>	
Things you should not do	<ul> <li>Do not give SALPRAZ HEARTBURN RELIEF to anyone else, even if they have the same symptoms as you.</li> <li>Do not use SALPRAZ HEARTBURN RELIEF to treat any other complaints unless your doctor tells you to.</li> </ul>	
Driving or using machines		
Looking after your medicine	Keep your tablets in a cool, dry place where the temperature stays below 30°C.	

For more information, see Section 5. What should I know while taking SALPRAZ HEARTBURN RELIEF? in the full CMI.

## 6. Are there any side effects?

Headache, dizziness, diarrhoea, nausea or vomiting, stomach pain, excessive gas in stomach or bowel, indigestion, constipation, dry mouth, metallic taste, weakness/tiredness/sleep disturbances, increased sweating/ body temperature, blurred vision, itchiness and rash, chest pain, fast heartbeat, shortness of breath, loss of appetite, feeling generally unwell, fever, 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, blistering or peeling of the skin or rash when exposed to the sun, possibly with pain in the joints and general fever, severe chills, sore throat or mouth ulcers, high blood pressure, water retention, swelling of the legs, depression, confusion or anxiety, bone fracture of the hip, wrist or spine, seizures, jerking/shaking movements, muscle cramps, severe and/or persistent diarrhoea, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

## SALPRAZ® HEARTBURN RELIEF

**Active ingredient(s):** pantoprazole (as sodium sesquihydrate)

### **Consumer Medicine Information (CMI)**

This leaflet provides important information about taking SALPRAZ HEARTBURN RELIEF. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking SALPRAZ HEARTBURN RELIEF.

#### Where to find information in this leaflet:

- 1. Why am I taking SALPRAZ HEARTBURN RELIEF?
- 2. What should I know before I take SALPRAZ HEARTBURN RELIEF?
- 3. What if I am taking other medicines?
- 4. How do I take SALPRAZ HEARTBURN RELIEF?
- 5. What should I know while taking SALPRAZ HEARTBURN RELIEF?
- 6. Are there any side effects?
- 7. Product details

## 1. Why am I taking SALPRAZ HEARTBURN RELIEF?

## SALPRAZ HEARTBURN RELIEF contains the active ingredient pantoprazole.

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. For effective, lasting relief, you should take a full course of SALPRAZ HEARTBURN RELIEF (see 'How to take SALPRAZ HEARTBURN RELIEF' below).

#### 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 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.

SALPRAZ HEARTBURN RELIEF is not addictive.

## What should I know before I take SALPRAZ HEARTBURN RELIEF?

#### Warnings

#### 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,
  - o shortness of breath or
  - o swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Always check the ingredients to make sure you can take this medicine.

- 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 breastfeeding or wish to start breastfeeding.

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.

#### Check with your doctor if you have:

- jaundice, liver problems or anaemia
- a feeling of weakness or you look pale
- previously taken heartburn/indigestion medications continuously for 4 or more weeks to control your heartburn
- persisting heartburn symptoms despite taking SALPRAZ HEARTBURN RELIEF (or other similar medicines) continuously for 2 weeks, or your symptoms have recently changed
- been told by your doctor that you have a stomach ulcer, or gastrointestinal surgery is planned
- heartburn/indigestion symptoms for the first time and you are over 40 years of age
- a scheduled endoscopy (investigation of your stomach lining performed by a specialist)
- any allergies to any other medicines, or any other substances, such as foods, preservatives or dyes
- take any medicines for any other condition
- have or have had any other medical condition

Your pharmacist or doctor can provide specific advice on whether you should take SALPRAZ HEARTBURN RELIEF.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

#### Pregnancy and breastfeeding

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Tell your doctor or pharmacist if you are breastfeeding or wish to start breastfeeding.

#### Use in children

## 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 SALPRAZ HEARTBURN RELIEF for children and adolescents under 18 years of age.

## 3. What if I am taking other medicines?

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

# Some medicines may interfere with SALPRAZ HEARTBURN RELIEF and affect how it works. 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 infections
- 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 pharmacist or doctor has more information on medicines to be careful with or to avoid while taking SALPRAZ HEARTBURN RELIEF. Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SALPRAZ HEARTBURN RELIEF.

## 4. How do I take SALPRAZ HEARTBURN RELIEF?

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

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

#### How to take

- 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 SALPRAZ HEARTBURN RELIEF

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 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 SALPRAZ HEARTBURN RELIEF

If you think that you or anyone else has taken too much SALPRAZ HEARTBURN RELIEF, urgent medical attention may be needed.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Keep telephone numbers for these places handy.

## 5. What should I know while taking SALPRAZ HEARTBURN RELIEF?

#### Things you should do

- 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 the surgeon or doctor that you are taking SALPRAZ HEARTBURN RELIEF.

- Tell your doctor or pharmacist immediately if you become pregnant while you are taking SALPRAZ HEARTBURN RELIEF.
- If symptoms persist or recur within 2 weeks of completing the course of 14 days, consult a doctor.

Your doctor may recommend further examination.

 If you are about to have any blood tests, tell your doctor that you are taking SALPRAZ HEARTBURN RELIEF.

It may interfere with the results of some tests.

 Tell your doctor if your reflux symptoms return after you stop taking SALPRAZ HEARTBURN RELIEF.

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

Take SALPRAZ HEARTBURN RELIEF exactly as directed.

#### Things you should not do

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

#### Things that may help your condition

Some self-help measures suggested below may help your condition. Talk to your pharmacist or doctor 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 pharmacist or doctor 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.

#### **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how SALPRAZ HEARTBURN RELIEF affects you.

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

#### Looking after your medicine

- 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 below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

#### Keep it 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.

#### When to discard your medicine

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 leftover.

#### Getting rid of any unwanted medicine

If you no longer need to take SALPRAZ HEARTBURN RELIEF or it is out of date, take it to any pharmacy for safe disposal.

Do not take SALPRAZ HEARTBURN RELIEF after the expiry date.

### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

#### Less serious side effects

Less serious side effects	What to do
<ul> <li>headache</li> <li>dizziness</li> <li>diarrhoea</li> <li>nausea or vomiting</li> <li>stomach pain, discomfort or excessive gas in the stomach or bowel</li> <li>indigestion</li> <li>constipation</li> <li>dry mouth</li> <li>metallic taste</li> <li>weakness or tiredness or sleep disturbances</li> </ul>	Speak to your doctor if you have any of these less serious side effects and they worry you. Some of these side effects may be due to the combination of other medicines you are taking with SALPRAZ

Less serious side effects	What to do
<ul> <li>increased sweating or body temperature</li> <li>blurred vision</li> <li>skin problems such as itchiness and rash</li> </ul>	HEARTBURN RELIEF.

Sei	ious side effects	What to do
•	unusual tiredness, weakness,	Call your
	dizziness or fainting	doctor straight
•	chest pain, fast heartbeat	away, or go
•	shortness of breath	straight to the
•	loss of appetite, feeling	Emergency
	generally unwell, fever, itching,	Department at
	yellowing of the skin and eyes,	your nearest
	and dark coloured urine or	hospital if you
	bowel movements	notice any of
•	blood in the urine	these serious
•	increased or decreased need to urinate	side effects.
•	bleeding or bruising more easily than normal	
•	skin problems such as itchiness,	
	redness, 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 fraguent infections such as	
•	frequent infections such as fever, severe chills, sore throat	
	or mouth ulcers	
•	high blood pressure	
•	water retention, swelling of the	
•	legs	
•	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 SALPRAZ	
	HEARTBURN RELIEF has been	
	associated with a small increase	
	in infectious diarrhoea	1

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell when you are taking, or soon after you have finished taking SALPRAZ **HEARTBURN RELIEF.** 

Other side effects not listed here may occur in some

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

#### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of SALPRAZ HEARTBURN RELIEF.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

### 7. Product details

This medicine is only available from your pharmacist or doctor.

#### What SALPRAZ HEARTBURN RELIEF contains

Active ingredient (main ingredient)	Pantoprazole (as sodium sesquihydrate) 20 mg	
Other ingredients (inactive ingredients)	<ul> <li>Mannitol</li> <li>Sodium carbonate</li> <li>Crospovidone</li> <li>Povidone</li> <li>Calcium stearate</li> <li>Hypromellose</li> <li>Macrogol 6000</li> <li>Methacrylic acid - ethyl acrylate copolymer (1:1)</li> <li>Triethyl citrate</li> <li>Purified talc</li> <li>Purified water</li> <li>OPADRY AMB Aqueous Moisture Barrier Coating System 80W52172 Yellow</li> <li>Carnauba Wax</li> </ul>	
Potential allergens	Trace quantities of soya bean products.	

Do not take SALPRAZ HEARTBURN RELIEF if you are allergic to any of these ingredients.

#### What SALPRAZ HEARTBURN RELIEF 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, biconvex, plain on both sides (AUST R 348230).

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

### Who distributes SALPRAZ HEARTBURN RELIEF

Alphapharm Pty Ltd trading as Viatris Level 1, 30 The Bond 30-34 Hickson Road Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in December 2025.

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