

# SALPRAZ®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) 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?

SALPRAZ contains the active ingredient pantoprazole (as sodium sesquihydrate). SALPRAZ is used to treat and help heal duodenal and gastric ulcers. SALPRAZ may also be used to prevent ulcers associated with the use of non-steroidal anti-inflammatory drugs (NSAIDs). SALPRAZ is also used to treat reflux oesophagitis or reflux disease and can be used to prevent reflux oesophagitis from coming back. SALPRAZ is also used to treat a rare condition called Zollinger-Ellison syndrome.

For more information, see Section [1. Why am I taking SALPRAZ?](#) in the full CMI.

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

Do not take if you have ever had an allergic reaction to pantoprazole 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. Tell your doctor if you have severe liver disease or cirrhosis.**

For more information, see Section [2. What should I know before I take SALPRAZ?](#) in the full CMI.

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

Some medicines may interfere with SALPRAZ 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?**

Swallow SALPRAZ tablets whole with a little water with or without food. Do not crush or chew the tablets.

More instructions can be found in Section [4. How do I take SALPRAZ?](#) in the full CMI.

### **5. What should I know while taking SALPRAZ?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking SALPRAZ.</li></ul>
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	<ul style="list-style-type: none"> <li>• Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop taking SALPRAZ without talking to your doctor first.</li> <li>• Do not take SALPRAZ to treat any other complaints unless your doctor tells you to.</li> <li>• Do not give SALPRAZ to anyone else, even if they have the same symptoms as you.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Do not drive or operate machinery if SALPRAZ affects your ability to concentrate and react.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Your doctor may advise you to limit your alcohol intake to help your condition.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep SALPRAZ in a cool, dry place where the temperature stays below 30°C.</li> </ul>

For more information, see Section [5. What should I know while taking SALPRAZ?](#) 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, sore breasts, dry mouth, taste disturbances, metallic taste, weakness/ tiredness, trouble sleeping. Increased sweating/body temperature, blurred vision, skin problems, unusual tiredness or weakness, tingling or numbness, blood in urine, increased or decreased need to urinate, frequent infections, chest pain, high blood pressure, irregular heartbeat, water retention, swelling, bleeding/bruising more easily than normal, depression, confusion or anxiety, bone fracture of hip, wrist or spine, seizures, abnormal or fast heartbeat, jerking/shaking movements or muscle cramps, severe and/or persistent diarrhoea. Signs of liver inflammation including yellowing of skin/ eyes, nausea, vomiting, loss of appetite, feeling unwell, fever, itching and dark coloured urine; severe skin problems such as itchiness, redness, rash with swelling, blistering or peeling of skin or rash when exposed to sun, possibly with pain in joints and general fever; swelling of face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing; shortness of breath, wheezing or difficulty breathing; black stools; vomiting blood.

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®

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

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## Consumer Medicine Information (CMI)

This leaflet provides important information about taking SALPRAZ. **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.**

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

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

## 1. Why am I taking SALPRAZ?

**SALPRAZ contains the active ingredient pantoprazole (as sodium sesquihydrate).** SALPRAZ belongs to a group of medicines called proton pump inhibitors (PPIs). SALPRAZ works by decreasing the

amount of acid the stomach makes, to give relief from the symptoms and allow healing to take place.

## **Ulcers**

SALPRAZ 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.

Most people who have a peptic ulcer also have bacteria called *Helicobacter pylori* in their stomach. When SALPRAZ is taken with antibiotics the combination therapy will kill the *Helicobacter pylori* and let your ulcer heal.

SALPRAZ may also be used to prevent ulcers associated with the use of non-steroidal anti-inflammatory drugs (NSAIDs). These are medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis (inflammation of the joints).

## **Reflux disease**

SALPRAZ 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.

SALPRAZ is also used to prevent reflux oesophagitis from coming back.

### **Zollinger-Ellison syndrome**

SALPRAZ is also 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.

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.

SALPRAZ is not addictive.

## **2. What should I know before I take SALPRAZ?**

### **Warnings**

#### **Do not take SALPRAZ if:**

- you have an allergy to:
  - any medicine containing pantoprazole sodium sesquihydrate, or any of the ingredients listed at the end of this leaflet.
  - any medicines containing proton pump inhibitors.

Some 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

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

- **you have severe liver disease or cirrhosis.**
- after the expiry date 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.

**Do not take SALPRAZ in combination with antibiotics or any other medicine if:**

- you are allergic to any of the antibiotics or medicines your doctor may prescribe with SALPRAZ
- you have moderate to severe liver or kidney disease

**Do not take SALPRAZ in combination with atazanavir or nelfinavir (anti-viral medications).**

**Check with your doctor if you:**

- you have any allergies to any other medicines, foods, preservatives or dyes
- have reduced body stores or risk factors for reduced vitamin B12, as pantoprazole may lead to a reduced
- absorption of vitamin B12
- have or have had any other medical conditions
- take any medicines for any other condition

## **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 SALPRAZ.

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

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 if you are pregnant or plan to become pregnant.** It is not known if it is safe for you to take SALPRAZ while you are pregnant. It may affect your baby.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.** It is not known if your baby can take in SALPRAZ from breast milk if you are breastfeeding.

Your doctor can discuss the risks and benefits involved.

## Children

**Do not give SALPRAZ to children under 5 years of age.**

There is not enough information to recommend the use of this medicine for children under the age of 5 years.

### **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.

**Do not take SALPRAZ in combination with atazanavir or nelfinavir (anti-viral medications).**

**Some medicines may interfere with SALPRAZ 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 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
- pemetrexed - a medicine used to treat some types of cancer

These medicines may be affected by SALPRAZ 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

**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.**

## **4. How do I take SALPRAZ?**

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**

- The dose and frequency of SALPRAZ that your doctor prescribes for you depends on your medical condition. Your doctor may change the dose as your condition changes.
- The usual dose is 40 mg per day.

- However, if your doctor also prescribes antibiotics in combination with SALPRAZ for the treatment of duodenal ulcers, the dose of SALPRAZ is 80 mg per day. The first 40 mg dose should be taken in the morning and the second 40 mg dose should be taken before the evening meal for 7 days.

Your doctor will prescribe the dose that is right for you.

- In children over 5 years of age, the dose of SALPRAZ for reflux oesophagitis or reflux disease is based on weight and may be 20 mg or 40 mg per day, depending on the condition being treated.

SALPRAZ should not be taken for longer than 8 weeks.

## **When to take SALPRAZ**

- **SALPRAZ should be taken around the same time each day.**
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- If you are taking other medicines, like antibiotics, in combination with SALPRAZ therapy, follow the instructions for the use of each medicine carefully.

## **How to take SALPRAZ**

- Swallow your tablets whole with a little water with or without food.
- **Do not crush or chew the tablets.**  
SALPRAZ tablets have a special coating to protect them from the acidic contents of your stomach.

For SALPRAZ to work effectively, this coating must not be broken.

## **How long to take SALPRAZ**

- Continue taking your medicine for as long as your doctor or pharmacist tells you.

## **If you forget to take SALPRAZ**

**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 getting an unwanted side effect.

**If you have trouble remembering when to take your medicine, ask your pharmacist for hints.**

## **If you take too much SALPRAZ**

If you think that you or anyone else has taken too much SALPRAZ, urgent medical attention maybe 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.**

## **5. What should I know while taking SALPRAZ?**

### **Things you should do**

- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking SALPRAZ.**
- **Tell any other doctors, dentists and pharmacists who treat you that you are taking SALPRAZ.**
- **If you are going to have surgery, tell the surgeon or anaesthetist that you are taking SALPRAZ.**
- **If you become pregnant while you are taking SALPRAZ, tell your doctor or pharmacist immediately.**
- **If you are about to have any blood tests, tell your doctor that you are taking SALPRAZ.** It may interfere with the results of some tests.
- **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 should not do

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

## Driving or using machines

**Be careful before you drive or use any machines or tools until you know how SALPRAZ affects you.** This medicine is not expected to affect your ability to drive a car or operate machinery.

However, do not drive a car or operate machinery if you experience side effects such as dizziness or blurred vision.

## Things that may help your condition

Some self-help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

- **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.

## **Looking after your medicine**

- Keep your tablets in their blister pack until it is time to take them.
- Keep SALPRAZ where the temperature stays below 30°C.

Follow the instructions on 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 this medicine or if the medicines have passed their expiry date, ask your pharmacist what to do with any tablets or granules that are left over.

## **Getting rid of any unwanted medicine**

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

Do not take this medicine 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.

This medicine helps most people with peptic ulcers or reflux disease, but it may have unwanted side effects in a few people.

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 list of side effects. You may not experience any of them.

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

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>● headache</li><li>● dizziness</li><li>● diarrhoea</li><li>● nausea or vomiting</li><li>● stomach pain</li><li>● excessive gas in the stomach or bowel</li><li>● indigestion</li><li>● constipation</li><li>● sore breasts</li><li>● dry mouth</li><li>● metallic taste</li><li>● taste disturbances</li><li>● weakness or tiredness</li><li>● trouble sleeping</li><li>● increased sweating or body temperature</li><li>● blurred vision</li><li>● skin problems such as itchiness and rash</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>● unusual tiredness or weakness</li><li>● tingling or numbness (“pins and needles”)</li><li>● blood in the urine</li><li>● increased or decreased need to urinate</li><li>● frequent infections such as fever, severe chills, sore throat or mouth ulcers</li><li>● chest pain</li><li>● high blood pressure</li><li>● irregular (fast or slow) heartbeat</li><li>● water retention, swelling</li><li>● bleeding or bruising more easily than normal</li><li>● depression, confusion or anxiety</li><li>● 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))</li></ul>	<p><b>Speak to your doctor immediately if you have any of these side effects.</b></p> <p><b>These side effects may require medical attention.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● 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</li> <li>● severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea</li> </ul>	
<ul style="list-style-type: none"> <li>● signs of liver inflammation including yellowing of the skin or eyes, nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching and dark coloured urine</li> <li>● severe skin problems such as itchiness, redness, rash with swelling, blistering or peeling of the skin or rash when exposed to the sun, possibly with</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>pain in the joints and general fever</p> <ul style="list-style-type: none"> <li>● swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing</li> <li>● shortness of breath, wheezing or difficulty breathing</li> <li>● black (blood stained) stools</li> <li>● vomiting blood</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **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](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**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 with a doctor's prescription.

### **What SALPRAZ contains**

<b>Active ingredient (main ingredient)</b>	Pantoprazole (as sodium sesquihydrate) 20 mg and 40 mg
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• Sodium carbonate</li><li>• Calcium stearate</li><li>• Mannitol</li><li>• Povidone</li><li>• Crospovidone</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>• OPADRY AMB Aqueous Moisture Barrier Coating System 80W52172 Yellow (ID 106688)</li></ul>

	<ul style="list-style-type: none"> <li>• Carnauba wax</li> <li>• Purified water</li> </ul>
<b>Potential allergens</b>	contains traces of soya bean products

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What SALPRAZ looks like**

SALPRAZ is available as 20 mg and 40 mg tablets.

The tablets have an acid-resistant coating called an enteric coating.

The 20 mg and 40 mg tablets are yellow coloured, oval, biconvex enteric coated tablets plain on both sides.

The 20 mg and 40 mg tablets are available in packs of 30 tablets.

**SALPRAZ 20 mg tablets - AUST R 330563**

**SALPRAZ 40 mg tablets - AUST R 330562**

## **Who distributes SALPRAZ**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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SALPRAZ® is a Viatris company trade mark

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