

SALPRAZ

pantoprazole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SALPRAZ. 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 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 is used for

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

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 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 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 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.

This medicine belongs to a group of medicines called proton pump inhibitors (PPIs).

This medicine 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 this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

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.

Salpraz should not be given 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.

Before you take SALPRAZ

When you must not take it

Do not take SALPRAZ if you have an allergy to:

- any medicine containing pantoprazole
- 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 if you have severe liver disease or cirrhosis.

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).

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any other medical conditions.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss the risks and benefits involved.

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

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.

Taking other medicines

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

Some medicines and SALPRAZ 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 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 or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or to avoid while taking this medicine.

How to 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 on the pack, ask your doctor or pharmacist for help.

How much to take

The usual dose is 40 mg per day.

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 depending on the condition being treated.

SALPRAZ should not be taken for longer than 8 weeks.

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.

How to take it

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

Do not crush or chew your 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 before you take this medicine.

When to take it

Take your medicine at about 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 long to take it

Continue taking your medicine for as long as your doctor tells you.

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 doctor or pharmacist.

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. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking SALPRAZ

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.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

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

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.

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 must not do

Do not take SALPRAZ to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same symptoms as you.

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 or pharmacist as soon as possible if you do not feel well while you are taking SALPRAZ.

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.

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

These are the more common side effects of SALPRAZ.

Tell your doctor as soon as possible 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
- blood in the urine
- increased or decreased need to urinate
- 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
- chest pain
- shortness of breath
- high blood pressure
- water retention, swelling
- 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 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

The above list includes serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

After taking SALPRAZ

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

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

Do not store SALPRAZ 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 it where children cannot reach it.

A locked cupboard at least one-and-a-half metres (5 feet) above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine 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 is available as 20 mg and 40 mg tablets.

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

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

The 40 mg tablets are yellow, oval shaped, plain on both sides.

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

Ingredients

The active ingredient in SALPRAZ tablets is pantoprazole.

SALPRAZ 40 mg tablets contain the equivalent of 40 mg pantoprazole and;

SALPRAZ 20 mg tablets contain the equivalent of 20 mg pantoprazole.

SALPRAZ tablets also contain:

- Sodium Carbonate
- Calcium stearate
- Mannitol
- Povidone K-30
- Crospovidone
- Hypromellose
- Macrogol 6000
- Methacrylic acid- ethyl acrylate copolymer (1:1)
- Triethyl citrate
- Purified Talc
- Opadry AMB 80W52172 Yellow

- Carnauba Wax (Powder)
- Purified water

SALPRAZ also contains traces of soya bean products.

SALPRAZ tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

SALPRAZ is supplied by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

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Australian registration numbers:

20 mg tablets - AUST R 330563

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