

SOMAC[®] Heartburn Relief Tablets

Pantoprazole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SOMAC 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 or pharmacist has weighed the risks of you taking SOMAC Heartburn Relief against the benefits this medicine is expected to have for you.

Use SOMAC Heartburn Relief as directed and follow the advice given in the leaflet.

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 SOMAC Heartburn Relief is used for

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

SOMAC Heartburn Relief is used for lasting symptomatic relief of frequent heartburn and stomach acid complaints due to gastro-oesophageal reflux.

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).

Who should use SOMAC Heartburn Relief

SOMAC Heartburn Relief is recommended for adults over 18 years of age suffering from heartburn at least 2 times a week.

SOMAC 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 SOMAC Heartburn Relief works

SOMAC Heartburn Relief belongs to a group of medicines called proton pump inhibitors (PPIs).

SOMAC Heartburn Relief works by decreasing the amount of acid the stomach makes to give relief from the symptoms .

SOMAC Heartburn Relief will start to suppress acid within a few hours, however it will not give instant symptom relief. You may need to take SOMAC Heartburn Relief for a few days before experiencing the full effect.

There is no evidence that SOMAC Heartburn Relief is addictive.

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

Before you start to take SOMAC Heartburn Relief

When you must not take it

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

- pantoprazole 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 SOMAC Heartburn Relief if you have severe liver disease or cirrhosis.

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

Do not take SOMAC Heartburn Relief after the expiry date (EXP) printed on the pack has passed.

Do not take SOMAC Heartburn Relief in combination with atazanavir (an anti-viral medication).

SOMAC Heartburn Relief should not be given to children and adolescents under 18 years of age. Safety and effectiveness of SOMAC Heartburn Relief in children has not been established.

If you are not sure whether you should start taking SOMAC Heartburn Relief alone or SOMAC

Heartburn Relief in combination with any other medications talk to your doctor or pharmacist.

Before you start to take it

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 SOMAC Heartburn Relief.

Talk to your doctor first before taking SOMAC Heartburn Relief if:

- you have previously taken heartburn / indigestion medications continuously for 4 or more weeks to control your heartburn
- you have jaundice, liver problems, anaemia, previous gastric ulcer or gastrointestinal surgery.
- you have new or recently changed symptoms including persistent vomiting or vomiting of blood, 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 SOMAC Heartburn Relief if you are due to have an endoscopy (a special test ordered by your doctor).

Taking other medicines

Tell your doctor or pharmacist 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 may be affected by SOMAC Heartburn Relief, or may affect how well it works. These may include medicines used to prevent blood clots (anticoagulants), atazanavir (an antiviral medication) and medicines whose activity depend on the acidity of the stomach e.g. ketoconazole.

Speak with your pharmacist or doctor if you have any concerns about taking SOMAC Heartburn Relief with other medications.

How to take SOMAC Heartburn Relief

How much to take

Take one SOMAC Heartburn Relief 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. SOMAC Heartburn Relief tablets have a special coating to protect them from the acidic contents of your stomach. For SOMAC Heartburn Relief to work effectively, this coating must not be broken.

How long to take it

Take one tablet daily for up to 14 days. You should not take it for more than 14 days unless directed by a 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 – the telephone number in Australia is 13 11 26 and in New Zealand is 0800 POISON or 0800 764 766 – or go to Accident and Emergency (Casualty) at your nearest hospital, if you think that you or anyone else may have taken too much SOMAC 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 SOMAC Heartburn Relief

Things you must do

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

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

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

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

Further examination may be recommended.

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** - you may be advised 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 condition.

Side effects

Tell your doctor or pharmacist as soon as possible if you have any problems while taking SOMAC 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, SOMAC 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 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
- blurred vision
- skin problems such as itchiness and rash

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

See your doctor immediately 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.
- skin problems such as itchiness and rash, or swelling, blistering or peeling of the skin.
- 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
- swelling of the legs
- bleeding or bruising more easily than normal
- depression, confusion or anxiety

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 or pharmacist if you notice anything that is making you feel unwell when you are taking, or soon after you have finished taking, SOMAC 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 SOMAC 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 SOMAC Heartburn Relief tablets in a cool dry place where the temperature stays below 30°C.

Do not store SOMAC 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 SOMAC 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 you stop taking SOMAC Heartburn Relief or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Germany and are supplied in Australia by:

Nycomed Pty Ltd
2-4 Lyonpark Road
North Ryde
NSW 2113
Australia

For medical enquiries, call
(AUST) 1800 675 957

Product description

What it looks like

SOMAC Heartburn Relief is available as a 20 mg tablet. The tablets have an acid-resistant coating called an enteric coating.

The tablets are yellow and oval shaped, marked with 'P20' on one side.

SOMAC Heartburn Relief tablets are available in blister packs containing 2, 7 and 14 tablets.

Ingredients

The active ingredient in SOMAC Heartburn Relief tablets is pantoprazole. Each SOMAC Heartburn Relief tablet contains the equivalent of 20 mg pantoprazole.

SOMAC Heartburn Relief tablets also contain sodium carbonate anhydrous, mannitol, crospovidone, povidone, calcium stearate, hypromellose, titanium dioxide, iron oxide yellow (CI 77492), propylene glycol, methacrylic acid copolymer, polysorbate 80, sodium lauryl sulfate, triethyl citrate and printing ink.

SOMAC Heartburn Relief tablets do not contain gluten, lactose, sucrose, tartrazine or other azo dyes.

Manufacturer and Supplier

SOMAC Heartburn Relief tablets are made by Nycomed GmbH,

Australian Registration Numbers

SOMAC Heartburn Relief
AUST R xxxxxx

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