

SOMAC[®] 20 mg and 40 mg

Enteric-coated tablets

Pantoprazole (as sodium sesquihydrate)



What is in this leaflet

This leaflet answers some common questions about SOMAC. 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 SOMAC against the benefits this medicine is expected to have for you.

Use SOMAC 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 is used for

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

Ulcers

SOMAC 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 SOMAC is taken with antibiotics the combination therapy will kill the *Helicobacter pylori* and let your ulcer heal.

SOMAC 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

SOMAC 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.

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

Zollinger-Ellison syndrome

SOMAC 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.

Other uses

Your doctor may have prescribed SOMAC for another reason. Ask your doctor if you have any questions about why SOMAC has been prescribed for you.

How SOMAC works

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

SOMAC works by decreasing the amount of acid the stomach makes to give relief from the symptoms and allow healing to take place.

There is no evidence that SOMAC is addictive.

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

Before you start to take SOMAC

When you must not take it

Do not take SOMAC if:

1. you have an allergy to:

- pantoprazole
- 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.

2. you have severe liver disease or cirrhosis

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

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

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

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

Do not take Somac in combination with Atazanavir (an anti-viral medication).

SOMAC should not be given to children. Safety and effectiveness of SOMAC in children have not been established.

If you are not sure whether you should start taking SOMAC alone, or SOMAC in combination with antibiotics, talk to your doctor.

Before you start to take it

You must tell your doctor 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.**

Your doctor will discuss the risks and benefits of taking SOMAC during pregnancy or while breast-feeding.

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

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

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 may be affected by SOMAC, or may affect how well it works. These may include medicines used to prevent blood clots (anticoagulants) and medicines whose activity depend on the acidity of the stomach e.g. ketoconazole.

You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

How to take SOMAC

How much to take

The usual dose is one tablet per day.

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

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

The dose and frequency of SOMAC that your doctor prescribes for you depends on your medical condition. Your doctor may change the dose as your condition changes.

How and when to take it

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

If you are taking other medicines, like antibiotics, in combination with SOMAC therapy, follow the instructions for the use of each medicine carefully.

Do not crush or chew the tablets. SOMAC tablets have a special coating to protect them from the acidic contents of your stomach. For SOMAC to work effectively, this coating must not be broken.

How long to take it

Your doctor will tell you how long to take your tablets.

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. 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

Things you must do

Use SOMAC exactly as your doctor has prescribed.

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

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

If you take SOMAC for a long period of time, e.g. over 1 year, you will need to see your doctor regularly so that he/she can monitor your condition.

Tell your doctor if you do not feel better while taking SOMAC. Your doctor may recommend further examination.

Things you must not do

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

Do not use SOMAC 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 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 as soon as possible if you have any problems while taking SOMAC, 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 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 if you notice any of the following and they worry you:

- head ache
- 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. Some of these side effects may be due to the combination of other medicines you are taking with SOMAC.

Tell 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 if you notice anything that is making you feel unwell when you are taking, or soon after you have finished taking, SOMAC.**

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

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

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

Product description

What it looks like

SOMAC 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 and oval shaped, marked with 'P20' on one side.

The 40 mg tablets are yellow and oval shaped, marked with 'P40' on one side.

SOMAC 40 mg tablets are available in blister packs of 5 and 30 tablets. SOMAC 20 mg tablets are available in blister packs of 30 tablets.

Ingredients

The active ingredient in SOMAC tablets is pantoprazole. SOMAC 40 mg tablets contain the equivalent of 40 mg pantoprazole and SOMAC 20 mg tablets contain the equivalent of 20 mg pantoprazole.

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

Manufacturer and Supplier

SOMAC is made by Nycomed GmbH, Germany and is supplied in Australia by:

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

SOMAC is supplied in New Zealand by:

Mylan New Zealand Ltd
PO Box 11-183
Ellerslie
Auckland, New Zealand

For medical enquiries, call (AUST) 1800 675 957 or (NZ) 00800 4568 9825

Australian Registration Numbers

SOMAC 40 mg - AUST R 69792

SOMAC 20 mg - AUST R 70829

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This leaflet was prepared on 2 February 2009.