

SOMAC[®] Tablets and Granules

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using SOMAC?

SOMAC contains the active ingredient pantoprazole sodium sesquihydrate. SOMAC is used to treat and help heal duodenal and gastric ulcers. SOMAC may also be used to prevent ulcers associated with the use of non-steroidal anti-inflammatory drugs (NSAIDs). SOMAC is also used to treat reflux oesophagitis or reflux disease and can be used to prevent reflux oesophagitis from coming back. SOMAC is also used to treat a rare condition called Zollinger-Ellison syndrome. For more information, see Section [1. Why am I using SOMAC?](#) in the full CMI.

2. What should I know before I use SOMAC?

Do not use 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 use SOMAC?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SOMAC 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 use SOMAC?

The dose of SOMAC that your doctor prescribes for you depends on your medical condition. Take Somac for as long as your doctor instructs you to. Swallow SOMAC tablets whole with a little water with or without food. Do not crush or chew the tablets.

Take SOMAC granules half an hour before a meal without chewing or crushing the granules. Take the granules in apple juice, orange juice or water. More instructions can be found in Section [4. How do I use SOMAC?](#) in the full CMI.

5. What should I know while using SOMAC?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using SOMAC.Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.
Things you should not do	<ul style="list-style-type: none">Do not stop using SOMAC without talking to your doctor first.Do not use SOMAC to treat any other complaints unless your doctor tells you to.Do not give SOMAC to anyone else, even if they have the same symptoms as you.
Driving or using machines	<ul style="list-style-type: none">Do not drive or operate machinery if SOMAC affects your ability to concentrate and react.
Drinking alcohol	<ul style="list-style-type: none">Your doctor may advise you to limit your alcohol intake to help your condition.
Looking after your medicine	<ul style="list-style-type: none">Keep SOMAC in a cool, dry place where the temperature stays below 25°C (granules) or 30°C (tablets).

For more information, see Section [5. What should I know while using SOMAC?](#) 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.

Somac[®] Tablets and Granules

Active ingredient(s): *pantoprazole sodium sesquihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SOMAC. It does not take the place of talking to your doctor or pharmacist. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SOMAC.**

Where to find information in this leaflet:

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

1. Why am I using SOMAC?

SOMAC contains the active ingredient pantoprazole sodium sesquihydrate. 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.

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 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.

2. What should I know before I use SOMAC?

Warnings

Do not use SOMAC if:

- you are allergic to pantoprazole sodium sesquihydrate, or any of the ingredients listed at the end of this leaflet.
- you are allergic to any medicines containing proton pump inhibitors.
- always check the ingredients to make sure you can use this medicine.
- symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.
- 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 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 or nelfinavir (anti-viral medications).

Do not give SOMAC 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.

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 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 SOMAC.

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

Check with your doctor if you are pregnant or intend to become pregnant. It is not known if it is safe for you to take SOMAC 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 SOMAC from breast milk if you are breastfeeding.

Ask your doctor about the risks and benefits involved.

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 SOMAC in combination with atazanavir or nelfinavir (anti-viral medications).

Some medicines and SOMAC 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 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 SOMAC or may affect how well it works. You may need to use 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 SOMAC.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SOMAC.

4. How do I use SOMAC?

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 SOMAC 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 20 or 40 mg per day.

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

Take Somac for as long as your doctor instructs you to.

When to take SOMAC

SOMAC 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 SOMAC therapy, follow the instructions for the use of each medicine carefully.

How to take SOMAC

Tablets:

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

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.

Granules:

If you are using SOMAC granules, take it half an hour before a meal without chewing or crushing the granules.

Take the granules in apple juice, orange juice or water as follows:

1. open sachet

2. sprinkle intact granules into a small volume of apple juice, pulp-free orange juice, or water (at least 15 mL). Alternatively, a tablespoon may be used
3. mix briefly just before drinking
4. drink straight away
5. to ensure that you have taken all the medicine, rinse the container thoroughly once or twice with apple juice, orange juice or water to remove any remaining granules and drink immediately

You can also take the granules in apple sauce as follows:

1. open sachet
2. sprinkle intact granules on a teaspoon of apple sauce
3. swallow within 10 minutes of preparation

Do not crush or chew the granules. SOMAC granules 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.

SOMAC granules are intended for people who have difficulty swallowing tablets including those who require a nasogastric tube.

If you forget to take SOMAC

SOMAC should be used regularly at the same time each day.

If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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 use too much SOMAC

If you think that you have used too much SOMAC, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 using SOMAC?

Things you should do

- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking SOMAC.**

- **Tell any other doctors, dentists and pharmacists who treat you that you are taking SOMAC.**
- **If you are going to have surgery, tell the surgeon that you are taking SOMAC.**
- **If you become pregnant while you are taking SOMAC, tell your doctor or pharmacist immediately.**
- **If you are about to have any blood tests, tell your doctor that you are taking SOMAC.** 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 use SOMAC to treat any other complaints unless your doctor tells you to.
- Do not give SOMAC 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 SOMAC affects you. A small number of patients have felt dizzy or had problems with their vision after taking SOMAC.

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, and granules in their sachet pack until it is time to take them.

- Follow the instructions on the carton on how to take care of your medicine properly.
- Keep SOMAC in a cool, dry place where the temperature stays below 25°C (granules) or 30°C (tablets).
- Do not store it or any other medicines in the bathroom, near a sink or windowsill. Do not leave it in the car. 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 use 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.

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"> • headache • dizziness • diarrhoea • nausea or vomiting • stomach pain • excessive gas in the stomach or bowel • indigestion • constipation • sore breasts • dry mouth • metallic taste • taste disturbances • weakness or tiredness • trouble sleeping • increased sweating or body temperature • blurred vision • skin problems such as itchiness and rash 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • unusual tiredness or weakness • tingling or numbness (“pins and needles”) • blood in the urine • increased or decreased need to urinate • frequent infections such as fever, severe chills, sore throat or mouth ulcers • chest pain • high blood pressure • irregular (fast or slow) heartbeat • 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, 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 	<p>Speak to your doctor immediately if you have any of these side effects.</p> <p>These side effects may require medical attention.</p>
<ul style="list-style-type: none"> • 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 • 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 pain in the joints and general fever • swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing • shortness of breath, wheezing or difficulty breathing • black (blood stained) stools • vomiting blood 	<p>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.</p>

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. 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 SOMAC contains

Active ingredient (main ingredient)	pantoprazole sodium sesquihydrate
Other ingredients (inactive ingredients)	Tablets: <ul style="list-style-type: none">• sodium carbonate• mannitol• crospovidone• povidone• calcium stearate• hypromellose• titanium dioxide• iron oxide yellow• propylene glycol• methacrylic acid copolymer• polysorbate 80• sodium lauryl sulfate• triethyl citrate• opacode brown S-1-16530 printing ink Granules: <ul style="list-style-type: none">• microcrystalline cellulose• sodium carbonate• crospovidone• hypromellose• polysorbate 80• povidone• titanium dioxide• iron oxide yellow• EUDRAGIT L30D-55• triethyl citrate• purified talc

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

Somac tablets and granules do not contain gluten, lactose, sucrose, tartrazine or other azo dyes.

What SOMAC looks like

Tablets:

SOMAC 20 mg tablets - yellow and oval shaped, marked with 'P20' on one side. SOMAC 20 mg tablets are available in blister packs of 30 tablets. (AUST R 70829)

SOMAC 40 mg tablets - yellow and oval shaped, marked with 'P40' on one side. SOMAC 40 mg tablets are available in blister packs of 30 tablets. (AUST R 69792)

Granules:

SOMAC 40 mg granules – pale yellowish to dark brownish in colour. SOMAC 40 mg granules are available in single aluminium foil sachets in packs of 30 sachets. (AUST R 148005)

Who distributes SOMAC

Takeda Pharmaceuticals Australia Pty Ltd

Level 39

225 George Street

Sydney NSW 2000

Australia

Telephone: 1800 012 612

www.takeda.com/en-au

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