Somac® Heartburn Relief Tablets

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.

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1. Why am I using SOMAC Heartburn Relief?

SOMAC Heartburn Relief contains the active ingredient pantoprazole sodium sesquihydrate. SOMAC Heartburn Relief is used for the lasting symptomatic relief of frequent heartburn and stomach acid complaints due to gastro-oesophageal reflux disease (GORD). For more information, see Section 1. Why am I using SOMAC Heartburn Relief? in the full CMI.

2. What should I know before I use SOMAC Heartburn Relief?

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 pharmacist or 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 pharmacist or doctor if you have severe liver disease or cirrhosis.**

For more information, see Section 2. What should I know before I use SOMAC Heartburn Relief? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SOMAC Heartburn Relief 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 Heartburn Relief?

Take one SOMAC Heartburn Relief tablet every day (once every 24 hours) for at least seven days, and up to 14 days. Swallow SOMAC Heartburn Relief 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 use SOMAC Heartburn Relief? in the full CMI.

5. What should I know while using SOMAC Heartburn Relief?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using SOMAC Heartburn Relief.

	• Tell your pharmacist or doctor if you are pregnant, or plan to become pregnant or are breastfeeding.
Things you should not do	• Do not stop using SOMAC Heartburn Relief without talking to your pharmacist or doctor first. • Do not use SOMAC Heartburn Relief to treat any other complaints unless your pharmacist or doctor tells you to. • Do not give SOMAC to anyone else, even if they have the same symptoms as you.
Driving or using machines	• Do not drive or operate machinery if SOMAC Heartburn Relief affects your ability to concentrate and react.
Drinking alcohol	• Your pharmacist or doctor may advise you to limit your alcohol intake to help your condition.

Looking after your medicine	• Keep SOMAC Heartburn Relief in a cool, dry place where the temperature stays below 30°C.

For more information, see Section 5. What should I know while using SOMAC Heartburn Relief? 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® Heartburn Relief Tablets

Active ingredient(s): *pantoprazole sodium sesquihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SOMAC Heartburn Relief. 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 Heartburn Relief.**

Where to find information in this leaflet:

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

1. Why am I using SOMAC Heartburn Relief?

SOMAC Heartburn Relief contains the active ingredient pantoprazole sodium sesquihydrate.
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.

Reflux disease

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

These symptoms 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 GORD.

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.

SOMAC Heartburn Relief will start to suppress acid within a few hours, however it is not intended to provide instant symptom relief. For effective, lasting relief, you

should take a full course of SOMAC Heartburn Relief (see ‘How do I use SOMAC Heartburn Relief?' below).

2. What should I know before I use SOMAC Heartburn Relief?

Warnings

Do not take SOMAC Heartburn Relief 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 Heartburn Relief in combination with atazanavir or nelfinavir (anti-viral medications).

Do not give SOMAC Heartburn Relief to children or adolescents under 18 years of age. There is not enough information to recommend the use of this

medicine for children and adolescents under the age of 18 years.

Check with your doctor if you:

- you have any allergies to any other medicines, foods, preservatives or dyes
- have jaundice, liver problems or anaemia
- a feeling of weakness or you look pale
- previously taken heartburn / indigestion medications continuously for 4 or more weeks
- persisting heartburn symptoms despite taking SOMAC Heartburn Relief (or other similar medicines) continuously for 2 weeks, or your symptoms have recently changed
- been told by your doctor that you have a stomach ulcer, or gastrointestinal surgery is planned
- heartburn/ indigestion symptoms for the first time and you are over 40 years of age
- a scheduled endoscopy (investigation of your stomach lining performed by a specialist)
- have reduced body stores or risk factors for reduced vitamin B12, (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 Heartburn Relief.

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

Some medicines and SOMAC Heartburn Relief 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 Heartburn Relief 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 Heartburn Relief.

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 Heartburn Relief.

4. How do I use SOMAC Heartburn Relief?

The directions for use are included on the Medicine Information panel on the pack.

If you do not understand the instructions, ask your doctor or pharmacist for help.

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

How much to take

Take one SOMAC Heartburn Relief tablet every day (once every 24 hours).

When to take SOMAC Heartburn Relief

Take SOMAC Heartburn Relief 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.

How to take SOMAC Heartburn Relief

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 SOMAC Heartburn Relief

For effective, lasting relief, take SOMAC Heartburn Relief strictly according to the directions on your pack.

SOMAC Heartburn Relief tablets should be taken for at least seven days, and up to 14 days.

If you purchased the pack containing 7 days' supply and you need to take it for longer than 7 days, ask your pharmacist for advice.

Do not take beyond 14 days without consulting your doctor.

SOMAC Heartburn Relief is not intended to provide instant relief from your heartburn/ indigestion symptoms.

If you are not sure, ask your pharmacist or doctor how to take your medicine.

If you forget to take SOMAC Heartburn Relief

SOMAC Heartburn Relief 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 take too much SOMAC Heartburn Relief

If you think that you have taken too much SOMAC Heartburn Relief, 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 Heartburn Relief?

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 Heartburn Relief.**
- **Tell any other doctors, dentists and pharmacists who treat you that you are taking SOMAC Heartburn Relief.**
- **If you are going to have surgery, tell the surgeon that you are taking SOMAC Heartburn Relief.**
- **If you become pregnant while you are taking SOMAC Heartburn Relief, tell your doctor or pharmacist immediately.**
- **If you are about to have any blood tests, tell your doctor or pharmacist that you are taking SOMAC Heartburn Relief.** 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 or pharmacist if you do not feel better while taking SOMAC Heartburn Relief. If your symptoms recur within 2 weeks of completing your course, consult your doctor.** Further investigation may be recommended.
- **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 Heartburn Relief to treat any other complaints unless your doctor tells you to.
- Do not give SOMAC Heartburn Relief 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 Heartburn Relief affects you. A small number of patients have felt dizzy or had problems with their vision after taking SOMAC Heartburn Relief.

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 until it is time to take them.
- Follow the instructions on the carton on how to take care of your medicine properly.
- Keep SOMAC Heartburn Relief in a cool, dry place where the temperature stays below 30°C.
- 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 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
• 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	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• 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))	**Speak to your doctor immediately if you have any of these side effects.** **These side effects may require medical attention.**

Serious side effects	What to do
• 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	
• 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	**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.**

Serious side effects	What to do
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	

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 available over-the-counter without a doctor's prescription.

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

What SOMAC Heartburn Relief contains

Active ingredient **(main ingredient)**	pantoprazole sodium sesquihydrate
Other ingredients **(inactive ingredients)**	• 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

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

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

What SOMAC Heartburn Relief looks like

SOMAC Heartburn Relief 20 mg tablets - yellow and oval shaped, marked with 'P20' on one side. SOMAC Heartburn Relief 20 mg tablets are available in blister packs of 7 and 14 tablets.

Pharmacy Medicine (7 tablets) – AUST R 234279

Pharmacist Only Medicine (14 tablets) AUST R 154252

Who distributes SOMAC Heartburn Relief

Takeda Pharmaceuticals Australia Pty Ltd

Level 39

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Sydney NSW 2000

Australia

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www.takeda.com/en-au

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