

# Somac® Injection

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## 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 Injection?

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

### 2. What should I know before I use SOMAC Injection?

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 Injection?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with SOMAC Injection 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 Injection?**

The dose and frequency of SOMAC Injection that your doctor prescribes for you depends on your medical condition. Your doctor may change the dose as your condition changes. Somac Injection is reconstituted with sodium chloride solution by your doctor or pharmacist. More instructions can be found in Section [4. How do I use SOMAC Injection?](#) in the full CMI.

### **5. What should I know while using SOMAC Injection?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>● Remind any doctor, dentist or pharmacist you visit that you are using</li></ul>
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	<p>SOMAC Injection.</p> <ul style="list-style-type: none"> <li>• Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>• Do not stop using SOMAC Injection without talking to your doctor first.</li> <li>• Do not use SOMAC Injection to treat any other complaints unless your doctor tells you to.</li> <li>• Do not give SOMAC Injection to anyone</li> </ul>

	<p>else, even if they have the same symptoms as you.</p>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>• Do not drive or operate machinery if SOMAC Injection affects your ability to concentrate and react.</li> </ul>
<p><b>Drinking alcohol</b></p>	<ul style="list-style-type: none"> <li>• Your doctor may advise you to limit your alcohol intake to help your condition.</li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>• Keep SOMAC Injection in a cool place where the temperature stays below 25°C. Keep the vial in the outer</li> </ul>

	carton to protect from light.
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For more information, see Section [5. What should I know while using SOMAC Injection?](#) 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, pain and swelling at the site of injection, 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® Injection

Active ingredient(s): *pantoprazole sodium*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using SOMAC Injection. 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 Injection.**

**Where to find information in this leaflet:**

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

## 1. Why am I using SOMAC Injection?

**SOMAC Injection contains the active ingredient pantoprazole sodium.** SOMAC Injection belongs to a group of medicines called proton pump inhibitors (PPIs). SOMAC Injection works by decreasing the

amount of acid the stomach makes, to give relief from the symptoms and allow healing to take place.

## **Ulcers**

SOMAC Injection 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.

## **Reflux disease**

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

## **Zollinger-Ellison syndrome**

SOMAC Injection 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 Injection?**

### **Warnings**

#### **Do not take SOMAC Injection if:**

- you are allergic to pantoprazole sodium, 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 Injection in combination with atazanavir or nelfinavir (anti-viral medications).**

**Do not give SOMAC Injection 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 Injection.

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

**Some medicines and SOMAC Injection 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 Injection 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 Injection.

**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 Injection.**

## **4. How do I use SOMAC Injection?**

**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 Injection that your doctor prescribes for you depends on your medical condition.

Your doctor may change the dose as your condition changes.

## **When to take SOMAC Injection**

Your doctor will determine when you are to be given Somac Injection.

## **How to take SOMAC Injection**

Somac Injection is reconstituted with sodium chloride solution by your doctor or pharmacist.

Your doctor will determine how long you need to be treated with Somac Injection.

SOMAC Injection is intended for people who are unable to take tablets or granules.

## **If you forget to take SOMAC Injection**

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

If a dose of Somac Injection is missed, your doctor will determine when your next dose is due.

## **If you take too much SOMAC Injection**

If you think that you have been given too much SOMAC Injection, 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 Injection?**

**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 Injection.**
- **Tell any other doctors, dentists and pharmacists who treat you that you are taking SOMAC Injection.**
- **If you are going to have surgery, tell the surgeon that you are taking SOMAC Injection.**
- **If you become pregnant while you are taking SOMAC Injection, tell your doctor or pharmacist immediately.**

- **If you are about to have any blood tests, tell your doctor that you are taking SOMAC Injection.** 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 Injection to treat any other complaints unless your doctor tells you to.
- Do not give SOMAC Injection 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 Injection 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**

- Normally your doctor will provide your Somac Injection. If however, you do take your Somac Injection from the pharmacy to your doctor, it is important to keep SOMAC Injection in a cool place where the temperature stays below 25°C. Keep the vial in the outer carton to protect from light.
- 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.

If for any reason you take your Somac Injection home, use as soon as possible after preparation. If storage is necessary, store at 2-8°C for no longer than 12 hours.

## **When to discard your medicine**

If your doctor stops treating you with Somac Injection, your hospital pharmacist will dispose of any unused medicine.

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

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>● unusual tiredness or weakness</li><li>● tingling or numbness (“pins and needles”)</li><li>● blood in the urine</li><li>● increased or decreased need to urinate</li><li>● frequent infections such as fever, severe chills, sore throat or mouth ulcers</li><li>● chest pain</li><li>● high blood pressure</li><li>● irregular (fast or slow) heartbeat</li><li>● water retention, swelling</li><li>● bleeding or bruising more easily than normal</li><li>● depression, confusion or anxiety</li><li>● 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))</li></ul>	<p><b>Speak to your doctor immediately if you have any of these side effects.</b></p> <p><b>These side effects may require medical attention.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● 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</li> <li>● severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea</li> </ul>	
<ul style="list-style-type: none"> <li>● 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</li> <li>● 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</li> </ul>	<p><b>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.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>pain in the joints and general fever</p> <ul style="list-style-type: none"> <li>● swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing</li> <li>● shortness of breath, wheezing or difficulty breathing</li> <li>● black (blood stained) stools</li> <li>● vomiting blood</li> </ul>	

**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](http://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 Injection contains**

<b>Active ingredient (main ingredient)</b>	pantoprazole sodium
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• disodium edetate</li><li>• sodium hydroxide</li></ul>

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

Somac Injection does not contain gluten, lactose, sucrose, tartrazine or other azo dyes.

### **What SOMAC Injection looks like**

Somac Injection is available as 40 mg injection. Somac Injection is a white to off-white powder provided in a glass vial.

Australian Registration Number

AUST R 121427

## **Who distributes SOMAC Injection**

Takeda Pharmaceuticals Australia Pty Ltd

Level 39

225 George Street

Sydney NSW 2000

Australia

Telephone: 1800 012 612

[www.takeda.com/en-au](http://www.takeda.com/en-au)

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