

Somac[®] Injection

pantoprazole sodium

Consumer Medicine Information (CMI)

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.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on this medicine.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about using 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

- **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.

- **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.

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

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

Ask your doctor if you have any questions about why it has been prescribed for you.

Your doctor may have prescribed it for another purpose.

This medicine is not addictive.

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

This medicine is not expected to affect your ability to drive a car or operate machinery.

However, do not drive a car or operate machines if you experience side effects such as dizziness or blurred vision.

Before you use Somac

When you must not use it

Do not use Somac if 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.

Do not use Somac if you have severe liver disease or cirrhosis.

Do not use Somac in combination with atazanavir or nelfinavir (antiviral medications). Do not give Somac injection to children.

Safety and effectiveness in children have not been established.

Do not use it 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.

Before you start to use it

Tell your doctor if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any other medical conditions.

Tell your doctor if you are pregnant, intend to become pregnant, or are breastfeeding.

Your doctor can discuss the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you use Somac Injection.

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.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Somac Injection may interfere with each other. These include

- warfarin, phenprocoumon - medicines used to prevent blood clots (anticoagulants)
- ketoconazole, itraconazole, posaconazole - medicines used to treat fungal infection
- atazanavir, nelfinavir – medicines used to treat viral infections such as HIV
- 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

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 has more information on medicines to be careful with or to avoid while taking Somac Injection.

How to 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 on the box, ask your doctor or pharmacist for help.

How much to use and when to use it

The dose and frequency of your Somac Injection will be determined by your doctor and will depend on your medical condition. Your doctor may change the dose as your condition changes.

How to use it

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

How long to use it

Continue using your medicine for as long as your doctor tells you.

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

If a dose is missed

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

If too much is given (overdose)

Your doctor will ensure that you receive the correct dose of Somac Injection.

Never administer this medicine to yourself.

Overdose is unlikely with Somac. However it may cause an increase in side effects. (The side effects are listed under the heading, 'Side effects' in this leaflet.)

While you are using Somac Injection

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with Somac Injection.

Tell any other doctors, dentists and pharmacists who treat you that you are being given Somac Injection.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

If you become pregnant while you are being given this medicine, tell your doctor immediately.

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 reflex 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.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are given Somac Injection. All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. You may need medical attention if you get some of the side-effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- headache
- diarrhoea
- nausea or vomiting
- stomach pain
- excessive gas in the stomach or bowel
- indigestion
- constipation
- increased sweating or body temperature
- dry mouth
- pain and swelling at the site of injection
- dizziness
- weakness or tiredness
- metallic taste
- blurred vision
- skin problems such as itchiness and rash
- trouble sleeping

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible 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

- blood in the urine
- increased or decreased need to urinate
- skin problems such as itchiness, 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
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- chest pain
- shortness of breath
- high blood pressure
- 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

The above list includes serious side effects that may require medical attention. Serious side effects are rare. Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some people. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

After using Somac

Storage

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 store it in a safe place away from heat (below 25°C) and away from light. Do not leave your Somac Injection in a car.

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 taking Somac Injection at home, always ensure that it is stored in a place where children cannot reach it i.e. a locked cupboard at least one-and-a-half meters (5 feet) above the ground is a good place to store medicine.

Disposal

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

Product description

What it looks like

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

Ingredients

The active ingredient in Somac Injection is pantoprazole sodium.

The inactive ingredients are:

- disodium edetate
- sodium hydroxide

Supplier

Somac Injection is supplied in Australia by:

Takeda Pharmaceuticals Australia Pty Ltd

Level 39
225 George Street
Sydney NSW 2000
Australia
Telephone: 1800 012 612
www.takeda.com/en-au

Australian Registration Number
AUST R 121427

SOMAC® is a registered trademark
of Takeda GmbH

This leaflet was prepared in
November 2020