Sozol 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.

1. Why am I using Sozol?

Sozol contains the active ingredient pantoprazole (as sodium sesquihydrate). Sozol is used to treat and help heal duodenal and gastric ulcers, reflux oesophagitis or reflux disease, a rare condition called Zollinger-Ellison syndrome and to prevent ulcers associated with the use of non-steroidal anti-inflammatory drugs (NSAIDs).

For more information, see Section 1. Why am I using Sozol? in the full CMI.

2. What should I know before I use Sozol?

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.

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

3. What if I am taking other medicines?

Some medicines may interfere with Sozol 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 Sozol?

- The usual dose is one tablet per day. Your doctor will prescribe the dose that is right for you.
- Swallow your tablets whole with a little water.

More instructions can be found in Section 4. How do I use Sozol? in the full CMI.

5. What should I know while using Sozol?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Sozol. • Tell your doctor immediately if you become pregnant while you are taking Sozol.
Things you should not do	• Do not stop using this medicine or change dosage unless your doctor tells you to.
Driving or using machines	• Be careful while driving or operating machinery until you know how pantoprazole affects you.
Drinking alcohol	• Your doctor may advise you to limit your alcohol intake.
Looking after your medicine	• Follow the instructions on the carton on how to take care of your medicine properly. • Store it in a cool dry place away from moisture, heat or sunlight.

For more information, see Section 5. What should I know while using Sozol? in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur.

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.

Sozol Tablets

Active ingredient(s): *Pantoprazole (as sodium sesquihydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Sozol. **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 Sozol.**

Where to find information in this leaflet:

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

1. Why am I using Sozol?

Sozol contains the active ingredient Pantoprazole (as sodium sesquihydrate). Pantoprazole belongs to a group of medicines called proton pump inhibitors (PPIs). PPIs work by decreasing the amount of acid the stomach makes, to give relief from symptoms and allow healing to take place.

Sozol is used to treat the following:

Ulcers

Pantoprazole 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.

Pantoprazole 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

Pantoprazole is 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.

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

Zollinger-Ellison syndrome

Pantoprazole 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.

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

Your doctor may have prescribed it for another reason.

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

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children.

2. What should I know before I use Sozol?

Warnings

Do not use Sozol if:

- you are allergic to pantoprazole, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. 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.
- you have severe liver disease or cirrhosis.
- the packaging is torn or shows signs of tampering.
- the expiry date printed on the pack has passed.

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

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

Do not take this medicine in combination with atazanavir or nelfinavir (anti-viral medications).

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have unintentional weight loss
- have repeated vomiting
- have vomiting blood
- have difficulty or pain when swallowing
- look pale and feel weak
- notice blood in your stools
- take any medicines for any other condition
- have or have had a 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))
- have kidney disease.
- have any other medical conditions. Your doctor may need to perform some additional tests before you take this medicine.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you 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.

Some medicines and pantoprazole may interfere with each other. These include:

- warfarin and phenprocoumon, used to prevent blood clots
- atazanavir and nelfinavir, used to treat viral infections such as HIV
- ketoconazole, itraconazole and posaconazole, used to treat fungal infections
- methotrexate, used to treat arthritis and some types of cancer
- erlotinib or related medicines, used to treat cancer
- tacrolimus and mycophenolate mofetil, used to suppress the immune system
- fluvoxamine, used to treat anxiety and depression
- pemetrexed, used to treat some types of cancer.

These medicines may be affected by pantoprazole or may affect how well it works. You may need to use different amounts of your medicine or take different medicines. Other interactions not listed above may also occur.

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

4. How do I use Sozol?

How much to take

- The usual dose is one tablet per day. Your doctor will prescribe the dose that is right for you.
- Follow the instructions provided by your doctor and use Sozol until your doctor tells you to stop.

How to take Sozol

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

It does not matter if you are taking this medicine before or after food.

When to take Sozol

Take your medicine at about the same time each day. Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

If you forget to take Sozol

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 you getting an unwanted side effect

If you use too much Sozol

If you think that you have used too much Sozol, 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 Sozol?

Things you should do

Use pantoprazole exactly as your doctor has prescribed.

Remind any doctor, dentist or pharmacist you visit that you are using Sozol. If you are going to have surgery, tell the surgeon that you are taking this medicine.

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

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, and you may need to stop pantoprazole for a period of time before the test. Do not stop pantoprazole until your doctor has discussed this with you.

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

Tell your doctor if your reflux symptoms return after you stop taking this medicine. The symptoms of reflux may return after stopping pantoprazole suddenly, especially if you have taken it for a while.

Call your doctor straight away if you:

- become pregnant while taking pantoprazole
- do not feel better or your condition worsens. Your doctor may recommend further examination.

Things you should not do

- Do not stop using this medicine or change the dosage without checking with your doctor.
- Do not take this medicine to treat any other complaint unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Sozol affects you.

Sozol may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Your doctor may ask you to limit the amount of alcohol that you drink.

Looking after your medicine

Keep your medicine in its original packaging until it is time to take it. If you take the tablets out of their original packaging, they may not keep well.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use 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 • dry mouth • metallic taste • weakness or tiredness • increased sweating or body temperature • blurred vision • skin problems, such as itchiness and rash • trouble sleeping	**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
• 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 • frequent infections such as fever, severe chills, sore throat or mouth ulcers • 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 or jerking/shaking movements. These can be a sign of low magnesium, calcium or potassium levels in your blood	**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.**

• severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea • nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine • confusion • chest pain • shortness of breath • water retention, swelling of the legs • bleeding or bruising more easily than normal • unusual tiredness or weakness • blood in the urine • increased or decreased need to urinate • high blood pressure • depression or anxiety	

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 affects 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 Sozol contains

Active ingredient (main ingredient)	pantoprazole (as sodium sesquihydrate)
Other ingredients (inactive ingredients)	mannitol sodium carbonate sodium starch glycollate crospovidone colloidal anhydrous silica calcium stearate hypromellose macrogol 6000 sodium hydroxide Eudragit L30-D55
	Opadry AMB Aqueous Moisture Barrier Coating System 80W52172 Yellow
Potential allergens	Soya bean products. May contain trace levels of sulfites.

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

What Sozol looks like

20 mg tablets

Yellow to pale yellow, oval, biconvex enteric-coated tablets, plain on both sides. AUST R 191034.

Blister pack of 5 and 30 tablets.

40 mg tablets

Yellow to pale yellow, oval, biconvex enteric-coated tablets, plain on both sides. AUST R 191035.

Blister pack of 5 and 30 tablets.

*Not all strengths and/or pack sizes may be available.

Who distributes Sozol

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel Street

CREMORNE VIC 3121

www.arrotex.com.au

This leaflet was prepared in June 2026.