

SOZOL

Pantoprazole (as sodium sesquihydrate) enteric coated tablets

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about SOZOL. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking SOZOL against the benefits they expect it will have for you. Use SOZOL as directed and follow the advice given in this leaflet.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What SOZOL is used for

The name of your medicine is SOZOL. It contains the active ingredient called pantoprazole.

Ulcers

SOZOL 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.

SOZOL 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

SOZOL 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.

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

Zollinger-Ellison syndrome

SOZOL 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.

Other uses

Your doctor may have prescribed SOZOL for another reason. Ask your doctor if you have any questions about why SOZOL has been prescribed for you.

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.

SOZOL should not be given 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.

How SOZOL works

SOZOL belongs to a group of medicines called proton pump inhibitors (PPIs). SOZOL works by decreasing the amount of acid the stomach makes, to give relief from the symptoms and allow healing to take place.

There is no evidence that SOZOL is addictive. This medicine is available only with a doctor's prescription.

Before you start to take SOZOL

When you must not take it

Do not take SOZOL if you have an allergy to:

- Any medicine containing 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 take SOZOL if you have severe liver disease or cirrhosis.

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

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

Do not take SOZOL in combination with atazanavir or nelfinavir (an anti-viral medication).

SOZOL should not be given to children.

The safety and effectiveness of SOZOL in children have not been established.

If you are not sure whether you should start taking SOZOL alone or SOZOL in combination with antibiotics, talk to your doctor.

Do not take SOZOL after the expiry date (EXP) printed on the pack, or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

You must tell your doctor if:

1. **you have any allergies to:**
 - pantoprazole
 - any of the ingredients listed at the end of this leaflet
 - any other medicines, or any other substances, such as foods, preservatives or dyes.
2. **you are pregnant, intend to become pregnant, are breastfeeding or intend to breastfeed.** Your doctor will discuss the risks and benefits of taking SOZOL during pregnancy or while breastfeeding.
3. **you have or have had any other medical conditions.**

If you have not told your doctor about any of the above, tell them before you take SOZOL.

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 SOZOL.

Taking other medicines

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

Some medicines and Sozol 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

These medicines may be affected by SOZOL, 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 SOZOL.

How to take SOZOL

How much to take

The usual dose is one tablet per day.

In children over 5 years of age, the dose of SOZOL for reflux oesophagitis or reflux disease is based on weight and may be 20 mg or 40 mg, depending on the condition being treated. Sozol should not be taken for longer than 8 weeks.

Your doctor will prescribe the dose that is right for you. The dose and frequency of SOZOL that your doctor prescribes for you depends on your medical condition. Your doctor may change the dose as your condition changes.

How and when to take it

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

Take SOZOL at about 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.

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

How long to take it

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

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre for advice (Ph: 13 11 26) or go to Accident and Emergency (Casualty) at your nearest hospital, if you think that you or anyone else may have taken too much SOZOL. Do this even if there are no signs of discomfort or poisoning.

Urgent medical attention may be needed. Keep telephone numbers for these places handy.

While you are taking SOZOL

Things you must do

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon that you are taking this medicine.

If you become pregnant while you are taking this medicine, tell your doctor or pharmacist immediately.

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.

Keep all of your doctors' 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.

Things you must not do

Do not give SOZOL to anyone else, even if they have the same symptoms as you.

Do not use SOZOL to treat any other complaints unless your doctor tells you to.

Things that may help your condition

Some self-help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- **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.

Side effects

Tell your doctor as soon as possible if you have any problems while taking SOZOL, even if you do not think the problems are connected with the medicine or they are not listed in this leaflet.

Like other medicines, SOZOL can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist any questions you may have. Tell your doctor if you notice any of the following and they worry you:

- 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

These are the more common side effects of SOZOL. Some of these side effects may be due to the combination of other medicines you are taking with SOZOL.

Tell your doctor immediately 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
- 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
- chest pain
- shortness of breath
- high blood pressure

- water retention, swelling
- swelling of the legs
- 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 or jerking/shaking movements. 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.

These may be serious side effects and you may need urgent medical attention. Serious side effects are rare. Other side effects not listed above may occur in some people.

Tell your doctor if you notice anything that is making you feel unwell when you are taking, or soon after you have finished taking SOZOL. Ask your doctor or pharmacist if you do not understand some of the information in this list.

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

After taking SOZOL

Storage

Keep your tablets in their blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep SOZOL tablets in a cool dry place where the temperature stays below 25°C.

Do not store SOZOL or any other medicines in a bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep SOZOL where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground, is a good place to store medicines.

Disposal

If your doctor tells you to stop taking SOZOL or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

SOZOL is available as 20 mg and 40 mg tablets. The tablets have an acid-resistant coating called an enteric coating.

The 20 mg tablets are yellow to pale yellow, oval shaped, and plain on both sides. The 40 mg tablets are yellow to pale yellow, oval shaped, and plain on both sides.

SOZOL 20 mg tablets are available in blister packs of 30 tablets.

SOZOL 40 mg tablets are available in blister packs of 30 tablets.

Ingredients

The active ingredient in SOZOL tablets is pantoprazole. SOZOL 20 mg tablets contain

the equivalent of 20 mg pantoprazole (as sodium sesquihydrate), and SOZOL 40 mg tablets contain the equivalent of 40 mg pantoprazole (as sodium sesquihydrate).

SOZOL tablets also contain mannitol, sodium carbonate, sodium starch glycollate, crospovidone, colloidal anhydrous silica, calcium stearate, hypromellose, macrogol 6000, sodium hydroxide, EUDRAGIT L30-D55 (Proprietary Ingredient No. 3700) and OPADRY AMB Aqueous Moisture Barrier Coating System 80W52172 Yellow (Proprietary Ingredient No. 106688).

SOZOL tablets contain soya bean products and may also contain trace levels of sulfites.

SOZOL tablets do not contain gluten, lactose, sucrose, tartrazine or other azo dyes.

Sponsor:

Arrotex Pharmaceuticals Pty Ltd
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Australian Registration Numbers

SOZOL 20 mg – AUST R 191034

SOZOL 40 mg – AUST R 191035

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