

Gastenz®

Pantoprazole (as sodium sesquihydrate) enteric coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Gastenz.

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 or pharmacist has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

Take this medicine 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 Gastenz is used for

Gastenz contains the active ingredient pantoprazole.

It is used for lasting symptomatic relief of frequent heartburn and stomach acid complaints due to gastro-oesophageal reflux.

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.

Frequent heartburn is when you have heartburn for two or more days a week. Heartburn that occurs

frequently is a typical symptom of gastro-oesophageal reflux disease (GORD).

Gastenz is recommended for adults 18 years of age and over, suffering from heartburn at least 2 times a week.

It is not the right medicine for you if you suffer from heartburn only occasionally (one episode of heartburn a week or less), or if you want immediate relief of heartburn.

How Gastenz works

Pantoprazole belongs to a group of medicines called proton pump inhibitors (PPIs). It works by decreasing the amount of acid the stomach makes, to give relief from the symptoms.

It will start to suppress acid within a few hours, however it will not give instant symptom relief. You may need to take this medicine for a few days before experiencing the full effect.

This medicine is not addictive.

Before you take Gastenz

When you must not take it

Do not take this medicine if you have an allergy to:

- the active ingredient pantoprazole or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines.

Some of the 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.

Do not take Gastenz in combination with atazanavir (an anti-viral medication).

Do not take this medicine if you have cirrhosis or severe liver disease.

Do not take this medicine if you have recently had trouble swallowing, pain when swallowing, persistent vomiting or experienced unintended weight loss.

Do not take this medicine if you have recently vomited blood, had black stools or notice blood in your stools.

Do not take this medicine if you are pregnant, intend to become pregnant, are breast-feeding or wish to start breast-feeding.

This medicine should not be given to children and adolescents under the age of 18 years.

Safety and effectiveness in children and adolescents has not been established.

Do not take this medicine after the expiry date 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.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other

medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breastfeeding.

They can discuss with you the risks and benefits involved.

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

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Gastenz.

Talk to your pharmacist or doctor first before taking this medicine if:

- you have previously taken heartburn / indigestion medications continuously for 4 or more weeks to control your heartburn
- you have jaundice, liver problems, anaemia, a feeling of weakness or you look pale, previous gastric ulcer or gastrointestinal surgery
- you have persisting heartburn symptoms despite taking Gastenz (or other similar medicines) continuously for 2 weeks, or your symptoms have recently changed
- you have heartburn/ indigestion symptoms for the first time and you are over 40 years of age
- you have new or recently changed symptoms including persistent vomiting or vomiting of blood, blood in the stools or unexplained weight loss
- you ever had a skin reaction after treatment with a medicine similar to Gastenz that reduces stomach acid.

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Gastenz. Remember to also mention any other ill-effects like pain in your joints.

If you have experienced any of the above you should see your doctor immediately.

If you have suffered from frequent heartburn / indigestion symptoms for some time you should see your doctor.

You should also speak to your doctor before taking this medicine if you are due to have an endoscopy (a special test ordered by your doctor).

Taking other medicines

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

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

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

These medicines may be affected by Gastenz or may affect how well it works.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine. Speak with your doctor or pharmacist if you have any concerns about taking Gastenz with other medications.

How to take Gastenz

Follow the instructions given in this leaflet. If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Take one tablet once a day (every 24 hours).

How to take it

Swallow the tablets whole with a full glass of water with or without food.

Do not crush or chew the tablets.

The 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.

When to take Gastenz

Take your medicine 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.

How long to take Gastenz

Take one tablet daily for at least seven days, and up to 14 days. If the pack has 7 days' supply and if you need to use longer than 7 days, ask your pharmacist for advice. You should not take it for more than 14 days unless directed by a doctor.

If you forget to take it

Take your dose as soon as you remember, and continue to take 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 that you missed.

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

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

You may need urgent medical attention.

While you are taking Gastenz

Things you must do

Take this medicine exactly as your doctor or pharmacist has advised.

Tell your doctor if you become pregnant while taking Gastenz.

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

Tell your doctor or pharmacist if you do not feel better while taking this medicine.

If symptoms persist or recur within 2 weeks of completing the course, consult a doctor.

Further examination may be recommended.

Things you must not do

Do not take Gastenz to treat any other complaints 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. 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 or pharmacist as soon as possible if you do not feel well while you are taking Gastenz.

All medicines can have side effects. Sometimes they are serious, 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 the following lists of side effects. You may not experience any of them.

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

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

- headache, dizziness
- nausea or vomiting
- diarrhoea, stomach pain, discomfort, excessive gas in the stomach or bowel, constipation, indigestion
- dry mouth
- metallic taste
- mild weakness or tiredness or sleep disturbances
- increased sweating or body temperature
- blurred vision
- skin problems such as itchiness and rash.

The above list includes the more common side effects of your medicine.

Tell your doctor immediately if you notice any of the following:

- unusual tiredness, weakness, dizziness or fainting
- chest pain, fast heartbeat, shortness of breath
- nausea or vomiting in combination with loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine or bowel movements
- blood in the urine
- increased or decreased need to urinate
- skin problems such as itchiness and rash, or swelling, blistering or peeling of the skin
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- frequent symptoms of infections such as fever, severe chills, sore throat or mouth ulcers
- 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 or jerking/shaking movements. These can be a sign of low magnesium 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 urgent medical attention. Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking Gastenz

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Gastenz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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 you stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Gastenz 20mg - yellow and oval shaped enteric-coated tablets.

Available in blister packs of 7 and 14 enteric-coated tablets.

Ingredients

Active ingredients:

- 20mg pantoprazole (as sodium sesquihydrate)

Inactive ingredients:

- sodium carbonate
- microcrystalline cellulose
- crospovidone
- hypromellose
- colloidal anhydrous silica
- calcium stearate
- Opadry complete film coating system 03B22011 Yellow
- Eudragit L30D-55
- triethyl citrate

This medicine does not contain gluten, lactose or sucrose.

Supplier

Gastenz is supplied in Australia by:

Sandoz Pty Ltd
 ABN 60 075 449 553
 54 Waterloo Road
 Macquarie Park, NSW 2113
 Australia
 Tel: 1800 726 369

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