

NEW ZEALAND CONSUMER MEDICINE INFORMATION

PANZOP RELIEF

Pantoprazole Enteric-coated Tablets 20 mg & 40 mg



What is in this leaflet

This leaflet answers some common questions about PANZOP RELIEF.

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 PANZOP RELIEF against the benefits they expect it will have for you.

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 PANZOP RELIEF is used for

PANZOP RELIEF contains the active ingredient pantoprazole. It belongs to a group of medicines called Proton Pump Inhibitors or PPIs.

Ulcers

PANZOP RELIEF is used to treat or help heal peptic ulcers of the stomach and duodenum. These can be caused in part by too much acid being made in the stomach. PANZOP RELIEF is also used to help stop duodenal ulcers re-occurring.

Reflux Oesophagitis

PANZOP RELIEF is used to treat reflux oesophagitis or reflux disease. This is 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.

Helicobacter pylori

PANZOP RELIEF can also be used in combination with certain antibiotics to help eliminate *H. pylori* infections in certain people with ulcers or chronic gastritis. *H. pylori* is a bacteria which is associated with the development of ulcers.

Zollinger-Ellison Syndrome

PANZOP RELIEF is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

PANZOP RELIEF 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 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 expected to affect your ability to drive a car or operate machinery.

There is insufficient information to recommend the use of this medicine in children.

Before you take PANZOP RELIEF

When you must not take it

Do not take PANZOP RELIEF if you have an allergy to:

- any medicine containing pantoprazole
- any of the ingredients listed at the end of this leaflet.

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 give this medicine to a child under the age of 12 years. Safety and effectiveness in children younger than 12 years have not been established.

Patients with severe liver or kidney problems should not take this medicine.

Patients who are taking HIV protease inhibitors such as atazanavir or nelfinavir should not take this medicine.

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.

Before you start to take it

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

Tell your doctor if you have or have had any of the following medical conditions:

- impaired kidney function
- impaired liver function.

Tell your doctor if you are pregnant or plan to become

pregnant or are breast-feeding.
Your doctor can discuss with you the risks and benefits involved.

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 PANZOP RELIEF.

If you have not told your doctor about any of the above, tell him/her before you start taking PANZOP RELIEF.

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 PANZOP RELIEF may interfere with each other. These include:

- warfarin, phenprocoumon – medicines used to prevent blood clots (anticoagulants)
- atazanavir, nelfinavir - antiretroviral medicines used to treat HIV
- medicines used to treat fungal infections, such as ketoconazole, itraconazole or posaconazole
- 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 PANZOP RELIEF or may affect how well it works. You may need different amounts of your

medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take PANZOP RELIEF

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 take

Take PANZOP RELIEF tablets as instructed by your doctor.

Adults

The usual dose of PANZOP RELIEF can vary from 20 mg to 40 mg daily, but can be higher. The dose is dependent on the condition being treated and how severe it is.

How to take it

Swallow the tablets whole with a full glass of water. Do not halve, crush or chew.

When to take it

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.

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

How long to take it

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

This medicine helps to treat your condition and where it does not cure it, it helps to control it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking your medicine 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 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 the National Poisons Information Centre (0800 POISON or 0800 764 766) 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 PANZOP RELIEF. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking PANZOP RELIEF

Things you must do

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

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 or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor 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 doctor's appointments so that your progress can be checked.

Your doctor may do some tests (such as liver function 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 take PANZOP RELIEF 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.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PANZOP RELIEF.

This medicine helps most people with stomach or duodenal ulcers, reflux disease or Zollinger-Ellison syndrome, but it may have unwanted side effects in a few people. 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:

- diarrhoea, constipation or wind (flatulence)
- nausea and/or vomiting
- dry mouth
- headache and/or dizziness
- blurred vision
- stomach pain
- excessive gas in the stomach or bowel
- indigestion
- constipation
- metallic taste
- weakness or tiredness
- increased temperature or body temperature
- skin problems such as itchiness and rash
- trouble sleeping.

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

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
- increased or decreased need to urinate
- 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 or changes in mood
- bone fracture of the hip, wrist or spine (mainly a risk in people who take high doses of PPIs or use them long term)
- symptoms such as seizures, abnormal or fast heartbeat or jerking/shaking movements.
- severe and/or persistent diarrhoea
- skin rash and/or itching (hives)
- painful or swollen joints
- aching, tender or weak muscles
- hallucinations, confusion and/or disorientation
- increased sensitivity of the skin to sun

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- severe skin reaction which may include redness, blistering and peeling of the skin, accompanied by fever and chills, aching muscles and generally feeling unwell
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing

- ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals
- swelling of the hands, ankles or feet
- blood in your urine.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

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

Some of these side effects (for example, changes in liver and kidney function) can only be found when your doctor does tests from time to time to check your progress.

After taking PANZOP RELIEF

Storage

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

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

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

Do not store PANZOP RELIEF 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 your doctor tells you to 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

20 mg: dark yellow, oval, biconvex, enteric coated tablets, plain on both sides and approximately 4.3 mm x 8.4 mm. 40 mg: dark yellow, oval, biconvex, enteric coated tablets, plain on both sides and approximately 5.7 mm x 11.6 mm.

Ingredients

Each PANZOP RELIEF tablet contains 20 mg or 40 mg of pantoprazole as the active ingredient.

It also contains:

- sodium carbonate
- mannitol
- crospovidone
- povidone
- calcium stearate
- eudragit
- triethyl citrate
- hypromellose
- titanium dioxide
- macrogol
- iron oxide yellow.

This medicine does not contain lactose or gluten.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Eilerslie,
Auckland.
Telephone: (09) 579 2792

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