

PANTOPRAZOLE SANDOZ GASTRO-RESISTANT TABLETS

Pantoprazole 40 mg

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WHAT IS PANTOPRAZOLE SANDOZ USED FOR

Pantoprazole is used:

In adults and adolescent 12 years of age and above:

- For reflux oesophagitis (inflammation of the oesophagus accompanied by the regurgitating of stomach acid)

In adults:

- In combination with appropriate antibiotics for the eradication of *Helicobacter pylori* (bacteria) in patients with *Helicobacter pylori* associated ulcers.
- For stomach and duodenal ulcer.
- Zollinger-Ellison-Syndrome and other conditions producing too much acid in the stomach as long-term treatment.

HOW PANTOPRAZOLE SANDOZ WORKS

Pantoprazole Sandoz is a selective "proton pump inhibitor", a medicine which reduces the amount of acid produced in your stomach.

BEFORE YOU USE PANTOPRAZOLE SANDOZ

- When you must not use it

Do NOT take Pantoprazole Sandoz:

- If you are allergic (hypersensitive) to pantoprazole or any of the ingredients of Pantoprazole Sandoz.
- If you are allergic to medicines containing other proton pump inhibitors.

Pantoprazole Sandoz must not be used as combination treatment for the eradication of *H. pylori* if you have moderate to severe liver or kidney function disturbances.

- Before you start to use it

Tell your doctor if you have or have had any medical condition especially the following:

- If you have severe liver problems. Doctor will check your liver enzymes more frequently, especially when you are taking Pantoprazole Sandoz as a long-term treatment. If the liver enzyme levels increase, then treatment should be stopped.
- If you need to take medicines called NSAIDs continuously with prescribed Pantoprazole Sandoz because you have an increased risk of developing stomach and intestinal complications.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive pantoprazole as a long-term treatment. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B12.
- If you are taking any medicine for the treatment of human immunodeficiency virus (HIV)-infection at the same time as pantoprazole, ask your doctor for specific advice.

Tell your doctor before taking this medicine, if you are due to have a specific blood test (Chromogranin A).

Pregnancy and breast-feeding

Pregnancy

There are no adequate data from the use of pantoprazole in pregnant women. Women who are pregnant and intend to become pregnant should consult their doctor before taking Pantoprazole Sandoz.

Breast-feeding

There is also no information on the excretion of pantoprazole into

human breast milk. You should consult your doctor before taking Pantoprazole Sandoz if you are breast-feeding or intend to breast-feed.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicine obtained without a prescription, and herbal medicines. This is because Pantoprazole Sandoz can affect the way some other medicines work and other medicines can affect the way Pantoprazole Sandoz work.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines before you start Pantoprazole Sandoz:

- Atazanavir or nelfinavir (antiretroviral medicine for treating HIV)
- Coumarin (anticoagulants-prevent blood clot)
- Ketoconazole (an antifungal-to treat fungal infection)
- Methotrexate (chemotherapy medication used to treat cancer)
- Tacrolimus (prevent transplant rejection)
- Fluvoxamine (for depression or anxiety disorder)

HOW TO USE PANTOPRAZOLE SANDOZ

- How much to use

For treatment of reflux oesophagitis

One tablet of Pantoprazole Sandoz 40mg per day. In individual cases, the dose may be increased to two Pantoprazole Sandoz 40mg daily.

For treatment of *Helicobacter pylori* positive

Eradication of the bacteria by a combination therapy should be given:

- a) Twice daily one Pantoprazole Sandoz 40mg + twice daily 1000mg amoxicillin + twice daily 500mg clarithromycin
- b) Twice daily one Pantoprazole Sandoz 40mg + twice daily

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- 500mg metronidazole + twice daily 500mg clarithromycin
c) Twice daily one Pantoprazole Sandoz 40mg + twice daily 1000mg amoxicillin + twice daily 500mg metronidazole

For treatment of gastric and duodenal ulcer

One tablet of Pantoprazole Sandoz 40mg per day. If the ulcer does not fully heal, the dose can be increased to two Pantoprazole Sandoz 40mg daily.

For treatment of Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions

The usual dose is 80mg (one Pantoprazole Sandoz 40mg twice daily). Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine.

Children

Pantoprazole Sandoz is not recommended for use in children.

- When to use it

Take the tablet one hour before a meal, without chewing or crushing them, and swallow them whole with some water.

- How long to use it

Always take Pantoprazole Sandoz exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Do not stop treatment before talking to your doctor, as this will reduce the treatments effect.

- If you forget to use it

Do not take a double dose to make up for a forgotten dose. Take your next normal dose at the usual time.

- If you use too much (overdose)

Contact your doctor or the nearest hospital casualty department immediately. Tell your doctor or pharmacist. There are no known symptoms of overdose. Take this leaflet or some tablets with you so that people will know what you have taken.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

WHILE YOU ARE USING IT

- Things you must do

If you have any further questions on the use of this product, ask your doctor or pharmacist.

Things you must not do

- Do not take any new medicines without consulting your doctor.
- Do not give Pantoprazole Sandoz to anyone else, even if they have the same symptoms or condition as you.
- Do not stop taking the medicine unless advised by your doctor.

Things to be careful of

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

- An unintentional loss of weight
- Repeated vomiting
- Difficulty in swallowing
- Vomiting blood
- You look pale and feel weak (anaemia)
- You notice blood in your stools

Your doctor may decide that you need some tests to rule out malignant disease because pantoprazole also alleviates the symptoms of cancer and could cause delay in diagnosing it.

If your symptoms continue in spite of your treatment, further investigations will be considered. If you take Pantoprazole Sandoz on a long-term basis (longer than one year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Driving and using machines

Side effects such as dizziness and visual disturbances may occur. If affected, you should not drive or operate machinery.

SIDE EFFECTS

Like all medicines, Pantoprazole Sandoz can cause side effects, although not everybody gets them.

The most commonly reported side effects are diarrhea and headache. When you are taking this medicine, your doctor will want to monitor you (especially if you are taking it for long term). Hence, you should report any new and exceptional symptoms and circumstances whenever you see your doctor. Please tell your doctor promptly if you get any of the symptoms below:

- Rash (especially in areas exposed to the sun), possibly with pain in the joints (Subacute cutaneous lupus erythematosus, SCLE).
- Fever, extreme tiredness, pus/blood in urine.
- Involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate.
- Fracture in the hip, wrist or spine.
- Watery stool, stomach pain and fever that do not go away.
- Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems (depression, memory loss or behavioural changes).

Other side effects that may occur:

- Sleep disorder
- Headache, dizziness
- Diarrhoea
- Nausea/ vomiting
- Abdominal distension and bloating; Constipation
- Dry mouth
- Abdominal pain and discomfort
- Liver enzymes increased (transaminases, γ -GT)
- Rash / exanthema / eruption
- Pruritus
- Asthenia, fatigue and malaise

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- Subacute cutaneous lupus erythematosus (SCLE): frequency not known.
- Kidney problems (Interstitial nephritis)
- Hypomagnesaemia: Low levels of magnesium can also lead to a reduction in potassium or calcium levels in blood: frequency not known.
- Fracture. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis): frequency uncommon.
- *Clostridium difficile* diarrhoea [Severe diarrhoea which may be caused by an infection (*Clostridium difficile*) in your intestines]
- Fundic gland polyps (benign): Benign polyps in the stomach: frequency common.
- Vitamin B12 deficiency: Proton pump inhibitors may cause vitamin B12 deficiency.
- Inflammation in the large bowel, that causes persistent watery diarrhea: frequency not known.
- Severe Cutaneous Adverse Reactions (SCAR). Initial presentation include constitutional symptoms of fever, sore throat and conjunctivitis. Subsequently, following may develop: eye redness, mucositis and rash which may be itchy or painful. SCAR frequency: not known.

Stop taking Pantoprazole Sandoz and seek medical advice immediately, if you develop any of the allergic reaction signs.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my (Consumers →

Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

STORAGE AND DISPOSAL OF PANTOPRAZOLE SANDOZ

- Storage

Store below temperature 30°C.

Keep out of the reach and sight of children.

Do not use Pantoprazole Sandoz after the expiry date "EXP" which is stated on the packaging.

- Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment

PRODUCT DESCRIPTION

- What it looks like

Pantoprazole Sandoz is a yellow, oval coated tablet.

- Ingredients

Active ingredient

One Pantoprazole Sandoz contains 40mg pantoprazole as pantoprazole sodium sesquihydrate.

Inactive ingredients

Sodium carbonate anhydrous, triethyl citrate, methacrylic acid, microcrystalline cellulose, crospovidone, colloidal anhydrous silica, hydroxypropylcellulose, calcium stearate, purified water, opadry yellow.

- MAL numbers

MAL17035047AZ

MANUFACTURER

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PRODUCT REGISTRATION HOLDER

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