

PANTOR TABLET

Pantoprazole sodium sesquihydrate (20 mg, 40 mg)

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What Pantor is used for

Pantor 40 is indicated for the short term treatment of duodenal ulcer, gastric ulcers and reflux esophagitis (inflammation of the oesophagus (a tube that runs from the throat to the stomach) accompanied by the regurgitation of stomach acid). If the duodenal ulcer has been demonstrated to be associated with *Helicobacter pylori* (bacteria) infection, Pantor 40 used in combination with appropriate antibiotics may be useful.

Pantor 20 is indicated for symptomatic treatment improvement (e.g. heartburn, acid regurgitation, pain on swallowing) and healing of mild gastro- esophageal reflux disease (GERD) caused by reflux of acid from the stomach.

Pantor 20 is indicated for long term management and prevention of relapse in Gastro Esophageal Reflux Disease (GERD).

How Pantor works

Pantoprazole is a selective “proton pump inhibitor”. Pantoprazole belongs to a group known as substituted benzimidazole which stop the secretion of gastric acid in the stomach by specific blockade of the proton pumps of the parietal cells.

Before you use Pantor

- When you must not use it

Do not take Pantor:

- If you are allergic (hypersensitive) to pantoprazole or to any of the other ingredient of Pantor.
- If you have severe liver disease. Your doctor will check your liver enzymes more frequently, especially when you are taking

Pantor as a long term treatment. Prior to treatment, the possibility of a life-threatening gastric ulcer or a life-threatening oesophagus disease should be excluded. Diagnosis of reflux oesophagitis will be confirmed by endoscopy (used for examination of digestive tract).

- Safety and efficacy in children have not been established.
- Pantor is not indicated for mild gastro-intestinal symptoms such as nervous indigestion.

Pregnancy and lactation

Do not take Pantor if you are pregnant or plan to become pregnant or think you might be pregnant.

Do not take Pantor if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Take special care with Pantor.

- Tell your doctor if you have or have had any other medical conditions.
- Tell your doctor before taking this medicine, if you are due to have a specific blood test (Chromogranin A).

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop especially medicine such as ketoconazole (used to treat fungal infections) because Pantor may affect this and other medicines from working properly.

How to use Pantor

- How much to use

The recommended dosage is once daily of Pantor.

Duodenal Ulcer:

The recommended oral dosage is 40 mg Pantor once daily in the morning for 2 to 4 weeks.

Gastric Ulcer and Reflux Oesophagitis:

The recommended oral dosage is 40 mg Pantor once daily in the morning for 4 to 8 weeks.

Mild Gastro-Esophageal Reflux Disease (GERD):

The recommended oral dosage is 20 mg Pantor per day for 4 to 8 weeks.

Long Term Management and Prevention of Relapse in GERD:

For long term management a maintenance dose of one Pantor 20 mg tablet per day is recommended, increasing to 40 mg Pantor per day if relapse occurs.

- When to use it

Swallow your tablets whole with a little water with or without food and should be taken in the morning.

- How long to use it

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

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Pantor.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

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

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- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, do not drive or use machines and contact your doctor immediately.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine:

- Gastrointestinal complaint such as upper abdominal pain, diarrhea, constipation or wind (flatulence).
- Headache.
- Allergic reaction such as skin rash, pruritus (itchy skin), urticaria (chronic hives) angioedema (swelling that affects deeper layers in your skin) or anaphylactic shock (life-threatening allergic reaction).
- Less frequent report are nausea, dizziness, disturbance in vision (blurred vision), peripheral edema (swelling from fluid accumulation that commonly occurs in the feet and legs) depression, fever and myalgia (muscle pain).

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 contraction, 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 behavioral changes).

Frequency ‘not known’: Inflammation in the large bowel, that cause persistent watery diarrhea.

Subacute Cutaneous Lupus Erythematosus (SCLE).

Frequency “not known”.

Interstitial Nephritis.

Kidney problems (interstitial nephritis).

Hypomagnesaemia.

Frequency “not known”: Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood.

Fracture.

Frequency “uncommon”. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Clostridium Difficile Diarrhea.

Severe diarrhea which may be caused by an infection (Clostridium difficile) in your intestines.

Fundic Gland Polyps (Benign).

Frequency “Common”. Benign polyps in the stomach.

Vitamin B12 Deficiency.

Proton pump inhibitors may cause vitamin B12 deficiency.

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 npra.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Pantor

- Storage

- Store below 30°C.

- 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

Pantor Tablets 20 mg:

Yellow colored, oval shape, biconvex, enteric coated tablets, plain on both sides with a length of 8.9 mm.

Pantor Tablets 40 mg:

Yellow colored, oval shape, biconvex, enteric coated tablets, plain on both sides with a length of 11.7 mm.

Ingredients

Active ingredient

- Pantoprazole sodium sesquihydrate.

Inactive ingredients

- Mannitol.
- Crospovidone.
- Sodium carbonate, anhydrous.
- Hydroxy propyl cellulose.
- Calcium stearate.
- Hypromellose.
- Titanium dioxide.
- Ferric oxide yellow.
- Propylene glycol.
- Methacrylic acid-Ethylacrylate copolymer (1:1) dispersion 30%.
- Triethyl citrate.
- Talc.
- Purified water.

- MAL number(s):

PANTOR TABLETS 20 MG:
MAL10021801AZ

PANTOR TABLETS 40 MG:
MAL10021802AZ

Manufacturer

Torrent Pharmaceuticals LTD.
Indrad 382 721, District: Mehsana,
India.

Product Registration Holder

Laboratories Torrent (Malaysia) Sdn.
Bhd.

Suite E-08-08 Plaza Mont Kiara,
No. 2 Jalan Kiara Mont Kiara,
50480 Kuala Lumpur,
Malaysia.

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