

PANTAZ TABLETS

Pantoprazole sodium tablets (40 mg)

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What Pantaz is used for

Pantaz is used for treatment of:

- Bacterial infection called *Helicobacter pylori* in people with duodenal ulcers and stomach ulcers in combination with two antibiotics (Eradication therapy). The aim is to get rid of the bacteria and so reduce the likelihood of these ulcers returning
- Gastric and duodenal ulcers
- Moderate or severe reflux oesophagitis (inflammation of the oesophagus accompanied by the regurgitating of stomach acid).
- Zollinger-Ellison-Syndrome and other and other pathological hypersecretory conditions (rare condition in which one or more tumors form in your pancreas or the upper part of your small intestine)

How Pantaz works

Pantaz belongs to a medicine group known as proton pump inhibitors (PPIs). Pantaz reduces the amount of acid in your stomach.

Pantaz may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.

Before you use Pantaz

When you must not use it

Do not use Pantaz if:

- You should not take Pantaz if you are allergic to pantoprazole or any of the other ingredients of this medicine.
- You have moderate to severe liver and kidney problems
- You have mild gastrointestinal complain

Pregnancy and lactation

Do not take Pantaz if you are pregnant, trying to get pregnant or think you may be pregnant. Pantoprazole should not be used during pregnancy unless clearly necessary.

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

- Before you start to use it

Tell your doctor if you have any of the following:

- Are pregnant or plan to become pregnant. It is not known if Pantaz can harm your unborn baby.
- Are breast-feeding or planning to breast-feed. Your doctor should decide if you will take Pantaz or breast-feed. You should not do both without first talking with your doctor.
- Have reduced body stores or risk factors for reduced vitamin B12 absorption
- Doctor will plan a few tests if you have any alarm symptom (e. g. significant unintentional weight loss, recurrent vomiting, swallowing difficulty vomiting blood, low red blood cells or black, tarry stools) and when gastric ulcer is suspected or present to diagnose cancer.
- 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 about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Pantaz may affect how other medicines work, and other medicines may affect how Controlloc works. Especially tell your doctor if you take:

- Atazanavir or nelfinavir (medicines for Human Immunodeficiency Virus (HIV))
- Methotrexate (chemotherapy medication used to treat cancer

- Tacrolimus (prevent transplant rejection),
- Fluvoxamine (for depression or anxiety disorder)
- Warfarin, phenprocoumon (prevent blood clotting)

How to use Pantaz

- How much to use

Take 1 or 2 Pantaz 40mg each day for moderate to severe reflux esophagitis.

- Take 2 Pantaz 40mg + combination of any 2 antibiotics for eradication of *H. pylori* twice per day as below:
 - 1000mg amoxicillin
 - 500 clarithromycin
 - 500mg metronidazole
- Take 1 or 2 Pantaz 40mg each day for treatment of gastric and intestinal ulcer
- Take 2 Pantaz 40mg each day for long-term management of Zollinger- Ellison Syndrome. The dose may be titrated up or down

- When to use it

Pantaz is taken 1 hour before breakfast. Combination therapy for *H. pylori*, the second dose should be taken before evening meal.

- How long to use it

Continue taking Pantaz for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do 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

Pantaz should be swallowed whole with water.

- Things you must not do

Pantaz should not be chewed or crushed.

- 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, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

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.

- 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 behavioral changes).
- Sleep disorder
- Headache

- Dizziness
- Nausea
- Vomiting
- Constipation
- Dry mouth, abdominal pain and discomfort
- Liver enzymes increased

a) Subacute Cutaneous Lupus Erythematosus (SCLE)

Frequency “not known”

b) Interstitial Nephritis

Kidney problems (interstitial nephritis)

c) Hypomagnesaemia

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

d) Fracture

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

e) Clostridium Difficile Diarrhea

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

f) Fundic Gland Polyps (Benign)

Frequency “Common”: Benign polyps in the stomach

g) Vitamin B12 Deficiency

Proton pump inhibitors may cause vitamin B12 deficiency.

h) Inflammation in the large bowel

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Pantaz

- Storage

Keep out of the reach and sight of children.

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

Light yellow, circular, biconvex, enteric coated tablet having plain surface on both the sides.

- Ingredients

- Active ingredient
Pantoprazole Sodium (40 mg)

- Inactive ingredients

Yellow Iron Oxide, Polyethylene Glycol 6000 BP, Hydroxy Propyl Methyl Cellulose, Dibutyl phthalate, Crospovidone, Titanium Dioxide, Sodium Carbonate Anhydrous, Methocel, Calcium Stearate, Talcum BP, Eudragit L 100, Mannitol USP, Methylene Chloride BP, Acetone BP, Isopropyl Alcohol BP and Purified Water.

- MAL number:

MAL08061577AZ

Manufacturer

Medley Pharmaceuticals Limited
Plot 18 and 19, Zari Causeway Road,
Kachigam, Daman, 396210 India

Product Registration Holder

Unimed Sdn Bhd
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Date of revision

20/04/2021