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
- Stomach and duodenal ulcers
- Moderate or severe reflux oesophagitis (inflammation of the oesophagus accompanied by the regurgitating of stomach acid).

How Pantaz works

Pantaz is a selective "proton pump inhibitor", a medicine which reduces the amount of acid produced in your stomach. It is used for treating acid-related diseases of the stomach and intestine.

Before you use Pantaz

- When you must not use it

Do not take Pantaz if you:

- You are allergic (hypersensitive) to pantoprazole, or any of the other ingredients (listed in section Ingredients below)
- You are taking a medicine containing atazanavir for treatment of Human Immunodeficiency Virus infection (HIV)
- You have mild gastrointestinal complains such as nervous indigestion

- Before you start use it

Tell your doctor if you have any of the following:

• You have severe liver impairment

You have impaired kidney function

Prior to treatment, the possibility of cancer of gastric ulcer or esophagus should be excluded as the treatment with Pantoprazole may mask the symptoms of cancer and can thus delay diagnosis.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including those obtained without prescription.

In particular, tell your doctor if you are taking:

- Ketoconazole (used to treat fungal infections)
- Atazanavir (used to treat HIV infection)

How to use Pantaz

Always take Pantaz exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. • The tablets must not be chewed or crushed. Swallow the tablet whole with some water.

- How much to use

Adults

The usual dose is one Pantaz tablet a day.

Treatment of Erosive Esophagitis

The recommended adult oral dose is 40 mg given once daily. In individual cases the dose may be doubled particularly when there has been no response to other medicines.

In people with severe liver impairment the dose has to be reduced to 1 tablet every other day. Liver enzymes should be monitored and in the case of a rise of liver enzymes, treatment should be discontinued.

40mg daily dose of pantoprazole should not be exceeded in elderly or in people with impaired kidney function.

- When to use it

Use as directed by your doctor or pharmacist.

To be taken either during or before breakfast.

- How long to use it

Continue taking Pantaz for as long as your doctor recommends.

The treatment period for stomach ulcers is usually between 4-6 weeks. The treatment period for duodenal ulcers is usually 2-4 weeks.

- 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 a forgotten 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 is 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 and pharmacists treating you that you are taking Pantaz.

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.

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Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Pantaz to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Pregnancy and breast-feeding

There are no adequate data for the use of pantaz in pregnant women. If you are pregnant, or think you may be pregnant, or if you are breastfeeding, you should use this medicine only if your doctor considers the benefit for you to be greater than the potential risk for your unborn child. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

If you experience side effects like dizziness or disturbed vision, you should not drive or operate machinery

Side effects

Like all medicines, Pantaz can cause side effects although not everybody gets them. Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as the symptoms can be severe.

- Headache
- Diarrhoea
- Nausea
- Upper abdominal pain
- Flatulence
- Skin rash
- Itching
- Dizziness
- Swelling
- Fever
- Depression
- Disturbances of vision.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public Reporting Medicinal Problems/ Sides Effects / AEFI / Vaccine Safety).

Storage and Disposal of Pantaz

- Storage

Keep this medicine in a safe place where children cannot see or reach it. Store in a dry place at a temperature not exceeding 25°C Protect from light

- 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, Hydroxy Propyl Methyl Cellulose, Dibutyl phthalate, crospovidone, Titanium Dioxide, Sodium Carbonate Anhydrous, Methocel, Calcium Stearate, Talcum, Eudragit L 100, mannitol, Methylene Chloride, Acetone, Isopropyl Alcohol, Purified Water.

- <u>MAL number(s):</u> MAL08061577AZ

Manufacturer

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Product Registration Holder

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