

# PANTOMAC

Pantoprazole Gastro-Resistant Tablets 40mg

Consumer Medication Information Leaflet (RiMUP)

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## What is Pantomac used for

Pantoprazole is used to treat adults and adolescents 12 years of age and above for

- Reflux esophagitis. An inflammation of your oesophagus (the tube which connects your throat to your stomach) accompanied by the regurgitation of stomach acid.

Pantoprazole is used to treat adults for

- An infection with a bacterium called *Helicobacter pylori* in patients 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.
- Zollinger-Ellison-Syndrome and other conditions producing too much acid in the stomach.

## How Pantomac works

Pantomac contains the active substance Pantoprazole. Pantoprazole 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 Pantomac

### -When you must not use it

- If you are allergic to pantoprazole or to any of the other ingredients of this medicine.
- If you are allergic to medicines containing other proton pump inhibitors.

### -Before you start to use it

Talk to your doctor, pharmacist or nurse before taking Pantoprazole

- If you have severe liver problems. Please tell your doctor if you ever had problems with your liver in the past. He will check your liver enzymes more frequently, especially when you are taking Pantoprazole as a long-term treatment. In the case of a rise of liver enzymes the treatment should be stopped.

- If you have reduced body stores or risk factors for reduced vitamin B12 and receive long-term treatment with pantoprazole. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B12.

- If you are taking HIV protease inhibitors such as atazanavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.

- Taking a proton pump inhibitor like pantoprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

- If you are on Pantoprazole for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

- If you have ever had a skin reaction after treatment with a medicine similar to Pantoprazole that reduces stomach acid.

- If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Pantoprazole. Remember to also mention any other ill-effects like pain in your joints.

- If you are due to have a specific blood test (Chromogranin A)

Tell your doctor immediately, before or after taking this medicine, if you

notice any of the following symptoms, which could be a sign of another, more serious, disease:

- An unintentional loss of weight
- Vomiting, particularly if repeated
- Vomiting blood; this may appear as dark coffee grounds in your vomit
- You notice blood in your stools; which may be black or tarry in appearance
- Difficulty in swallowing or pain when swallowing
- You look pale and feel weak (anaemia)
- Chest pain
- Stomach pain
- Severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea.

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 on a long-term basis (longer than 1 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.

### -Taking other medications

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

- This is because Pantoprazole may influence the effectiveness of other medicines, so tell your doctor if you are taking:

- Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer) because Pantoprazole may stop these and other medicines from working properly.

- Warfarin and phenprocoumon, which affect the thickening, or thinning of the blood. You may need further checks.

- Medicines used to treat HIV-infection, such as atazanavir.

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- Methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) – if you are taking methotrexate your doctor may temporarily stop your Pantoprazole treatment because pantoprazole can increase levels of methotrexate in the blood. Fluvoxamine (used to treat depression and other psychiatric diseases – if you are taking fluvoxamine your doctor may reduce the dose).  
- Rifampicin (used to treat infections).  
- St John's wort (Hypericum perforatum) (used to treat mild depression).

## How to use Pantomac

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### -How much to use

Adults and adolescents 12 years of age and above

#### *To treat reflux esophagitis*

The usual dose is one tablet of Pantoprazole 40 mg a day. Your doctor may tell you to increase to 2 tablets of Pantoprazole 40 mg daily. The treatment period for reflux esophagitis is usually between 4 and 8 weeks. Your doctor will tell you how long to take your medicine.

#### Adults

For the treatment of an infection with a bacterium called *Helicobacter pylori* in patients with duodenal ulcers and stomach ulcers in combination with two antibiotics (Eradication therapy).

- One tablet of Pantoprazole 40 mg, two times a day plus two antibiotic tablets of either amoxicillin (1000 mg), clarithromycin (500 mg) and metronidazole (500 mg), each to be taken two times a day with your pantoprazole tablet. Take the first pantoprazole tablet 1 hour before breakfast and the second pantoprazole tablet 1 hour before your evening meal. Follow your doctor's instructions and make sure you read the package leaflets for these antibiotics. The usual treatment period is one to two weeks.

For the treatment of stomach and duodenal ulcer

- The usual dose is one tablet of Pantoprazole 40 mg a day.

After consultation with your doctor, the dose may be doubled.

- Your doctor will tell you how long to take your medicine. The treatment period for stomach ulcers is usually between 4 and 8 weeks. The treatment period for duodenal ulcers is usually between 2 and 4 weeks.

For the long-term treatment of Zollinger-Ellison-Syndrome and of other conditions in which too much stomach acid is produced

- The recommended starting dose is usually two tablets of Pantoprazole 40 mg a day.

- Take the two tablets 1 hour before a meal. Your doctor may later adjust the dose, depending on the amount of stomach acid you produce. If prescribed more than two tablets a day, the tablets should be taken twice daily.

## Patients with kidney problems

If you have kidney problems, you should not take Pantoprazole for eradication of *Helicobacter pylori*.

## Patients with liver problems

If you suffer from severe liver problems, you should not take more than one tablet 20 mg pantoprazole a day (for this purpose tablets containing 20 mg pantoprazole are available).

If you suffer from moderate or severe liver problems, you should not take Pantoprazole for eradication of *Helicobacter pylori*.

## Use in children and adolescents

These tablets are not recommended for use in children below 12 years.

### -When to use it

Take the tablets 1 hour before a meal without chewing or breaking them and swallow them whole with some water.

### -How long to use it

If your doctor prescribes a daily dose of more than four tablets a day, you

will be told exactly when to stop taking the medicine.

### -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)

Consult your doctor or pharmacist. There are no known symptoms of overdose.

## While you are using it

### -Things you must do

Keep taking Pantoprazole until the treatment is finished, even if you feel better. You need every dose to help fight the infection. If you have any further questions on the use of this product, ask your doctor or pharmacist.

### -Things you must not do

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

### -Things to be careful of

#### *Pregnancy and breast-feeding*

- There are no adequate data from the use of pantoprazole in pregnant women. Excretion into human milk has been reported.

- If you are pregnant or breast feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- You should use this medicine, only if your doctor considers the benefit for you greater than the potential risk for your unborn child or baby.

#### *Driving and using machines*

- Pantoprazole has no or negligible influence on the ability to drive and use machines.

- If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

## Side effects

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

If you get any of the following side effects, stop taking these tablets and tell your doctor immediately, or

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contact the casualty department at your nearest hospital:

- Serious allergic reactions (frequency rare: may affect up to 1 in 1,000 people): swelling of the tongue and/or throat, difficulty in swallowing, hives (nettle rash), difficulties in breathing, allergic facial swelling (Quincke's oedema / angioedema), severe dizziness with very fast heartbeat and heavy sweating.

- Serious skin conditions (frequency not known: frequency cannot be estimated from the available data): blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals (Stevens-Johnson-Syndrome, Lyell-Syndrome, Erythema multiforme), and sensitivity to light.

- Other serious conditions (frequency not known: frequency cannot be estimated from the available data): yellowing of the skin or whites of the eyes (severe damage to liver cells, jaundice) or fever, rash, and enlarged kidneys sometimes with painful urination, and lower back pain (serious inflammation of the kidneys), possibly leading to kidney failure.

## Other side effects are:

- Common (may affect up to 1 in 10 people)

Fundic gland polyps (benign)

- Uncommon (may affect up to 1 in 100 people)

Headache; dizziness; diarrhoea; feeling sick, vomiting; bloating and flatulence (wind); constipation; dry mouth; abdominal pain and discomfort; skin rash, exanthema, eruption; itching; feeling weak, exhausted or generally unwell; sleep disorders; fracture in the hip, wrist or spine.

- Rare (may affect up to 1 in 1,000 people)

Distortion or complete lack of the sense of taste; disturbances in vision such as blurred vision; hives; pain in the joints; muscle pains; weight changes; raised body temperature; high fever; swelling of the extremities (peripheral oedema); allergic reactions; depression; breast enlargement in males.

- Very Rare (may affect up to 1 in

10,000 people) Disorientation, inflammation in the large bowel

- Not known (frequency cannot be estimated from the available data) Hallucination, confusion (especially in patients with a history of these symptoms); decreased sodium level in blood, decreased magnesium level in blood (see section 2), feeling of tingling, prickling, pins and needles, burning sensation or numbness, rash, possibly with pain in the joints.

## Side effects identified through blood tests:

- Uncommon (may affect up to 1 in 100 people) an increase in liver enzymes.

- Rare (may affect up to 1 in 1,000 people) an increase in bilirubin; increased fat levels in blood; sharp drop in circulating granular white blood cells, associated with high fever.

- Very Rare (may affect up to 1 in 10,000 people) a reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; a reduction in the number of white blood cells, which may lead to more frequent infections; coexisting abnormal reduction in the number of red and white blood cells, as well as platelets.

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).

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) 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 visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Storage and Disposal of Pantomac

### -Storage

- Keep this medicine out of the sight and reach of children.

- Store below 30 °C.

- Do not use this medicine after the expiry date which is stated on the carton and the container after EXP. The expiry date refers to the last day of that month.

- This medicine does not require any special storage conditions.

### -Disposal

Do not throw away any medicines via wastewater or household waste. Ask

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your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **Product Description**

### -What it looks like

Yellow colored, enteric coated, oval biconvex tablets plain on both the side.

### -Ingredients

Active ingredient(s)

Each gastro-resistant tablet contains:  
Pantoprazole                      Sodium  
Sesquihydrate                      equivalent                      to  
Pantoprazole .....40mg

Inactive ingredient(s)

Crospovidone (Type B), Sodium Carbonate Anhydrous, Hydroxy Propyl Cellulose, Sodium Carbonate Anhydrous, Calcium Stearate, Hypromellose, Ferric Oxide yellow, Methacrylic Acid Ethyl Acrylate Copolymer (1:1) Dispersion 30% (Edugragit L-30 D-55), Triethyl Citrate

### -MAL number

MAL20046099AZ

## **Manufacturer**

Micro Labs Limited  
Plot No. S-155 to S-159 & N1,  
Phase III & IV, Verna Industrial Estate, Verna Salcette, GOA - 403 722, INDIA

## **Product Registration Holder**

Healol Pharmaceuticals Sdn Bhd  
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23/12/2020

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