Package leaflet: Information for the patient

Pantoprazole Mylan 40 mg
Gastro-resistant Tablets
pantoprazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Pantoprazole Mylan is and what it is used for

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.

Pantoprazole Mylan is used for treating:

Adults and adolescents 12 years of age and above:
- Reflux oesophagitis. An inflammation of your oesophagus (the tube which connects your throat to your stomach) accompanied by the regurgitation of stomach acid.

Adults:
- 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.

2. What you need to know before you take Pantoprazole Mylan

Do not take Pantoprazole Mylan:
- if you are allergic to pantoprazole or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to medicines containing other proton pump inhibitors.

Warnings and precautions
Talk to your doctor or pharmacist before taking Pantoprazole Mylan:
- if you have severe liver problems. Please tell your doctor if you have ever had problems with your liver in the past. Your doctor 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 B_{12} and receive pantoprazole long-term treatment. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B_{12}. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of Vitamin B_{12}:
    - extreme tiredness or lack of energy
    - pins and needles
    - sore or red tongue, mouth ulcers
    - muscle weakness
    - disturbed vision
    - problems with memory, confusion, depression
- if you are taking a medicine containing 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 (reduced bone density) or if you have been told that you are at risk of getting osteoporosis (for example, if you are taking steroids).
- 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.
- serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and erythema multiforme, have been reported in association with pantoprazole treatment. Stop using pantoprazole and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- if you are due to have a specific blood test (Chromogranin A).

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
- severe and/or persistent diarrhoea, as pantoprazole has been associated with a small increase in infectious diarrhoea.

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.

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.

Other medicines and Pantoprazole Mylan
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines as Pantoprazole Mylan may influence the effectiveness of these medicines.

- 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 similar medicines from working properly.
- Warfarin and phenprocoumon, which affect the thickening, or thinning of the blood. You may need further checks.
- Atazanavir (used to treat HIV-infection) (see section 2 'Warnings and Precautions').
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and cancer) because pantoprazole may increase the levels of methotrexate in the body.
- 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).

Talk to your doctor before taking pantoprazole if you are due to have a specific urine test (for THC; Tetrahydrocannabinol).

Pregnancy, breast-feeding and fertility
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
If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

Pantoprazole Mylan contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Pantoprazole Mylan

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

When and how should you take Pantoprazole Mylan
Take the tablets 1 hour before a meal without chewing or breaking them and swallow them whole with some water.

Unless told otherwise by your doctor, the recommended dose is:

Adults and adolescents 12 years of age and above:
To treat reflux oesophagitis
The recommended dose is one tablet a day. Your doctor may tell you to increase to 2 tablets daily. The treatment period for reflux oesophagitis 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, two times a day plus two antibiotic tablets of either amoxicillin, clarithromycin and metronidazole (or tinidazole), 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 ulcers
The recommended dose is one tablet 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 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.
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.

Special patient groups:
- If you have kidney problems, moderate or severe liver problems, you should not take pantoprazole for eradication of *Helicobacter pylori*.
- 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).
- Children below 12 years. These tablets are not recommended for use in children below 12 years.

If you take more Pantoprazole Mylan than you should
Consult your doctor or pharmacist. There are no known symptoms of overdose.

If you forget to take Pantoprazole Mylan
Do not take a double dose to make up for a forgotten dose. Take your next, normal dose at the usual time.

If you stop taking Pantoprazole Mylan
Do not stop taking these tablets without first talking to your doctor or pharmacist.

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

4. Possible 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 contact the casualty department at your nearest hospital:**

Rare (may affect up to 1 in 1,000 people)
- **Serious allergic reactions:** 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.
- a reduction in the number of white and red blood cells and/or platelets, which may be seen in blood tests. You may notice more frequent infections, or you may bruise or bleed more than normal.

Not known (frequency cannot be estimated from the available data)
- **Serious skin conditions:** you may notice one or more of the following - blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals, or skin sensitivity/rash, particularly in areas of skin exposed to light/the sun. You may also have joint pain or flu-like symptoms, a fever, swollen glands (e.g. in the armpit) and blood tests may show changes in certain white blood cells or liver enzymes.
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).

- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- **Other serious conditions:** 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 which could lead to kidney failure).

Other side effects are:
- **Common** (may affect up to 1 in 10 people)
  benign polyps in the stomach.
- **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 of the wrist, hip or spine.
- **Rare** (may affect up to 1 in 1,000 people)
  Changes to 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; swelling of the extremities (peripheral oedema); depression; breast enlargement in males.
- **Not known** (frequency cannot be estimated from the available data)
  Hallucination, confusion (especially in patients with a history of these symptoms); feeling of tingling, prickling, pins and needles, burning sensation or numbness, inflammation in the large bowel, that causes persistent watery diarrhoea.

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 fats in the blood.
- **Not known** (frequency cannot be estimated from the available data)
  decreased level of sodium, magnesium, calcium or potassium in blood (see section 2).

Reporting of side effects
If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pantoprazole Mylan

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date, which is stated on the packaging after 'EXP'. The expiry date refers to the last day of that month.

For blister pack: This medicine does not require any special storage conditions.
For PVC/PE/PVdC Blister Pack: Do not store above 25°C.
For HDPE bottles: Once opened use within 100 days. Keep the container tightly closed in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Pantoprazole Mylan contains
The active substance is pantoprazole sodium sesquihydrate equivalent to 40 mg of pantoprazole.

The other ingredients are sodium carbonate, mannitol, crospovidone, povidone and calcium stearate. The coating contains methacrylic acid-ethyl acrylate copolymer (1:1), sodium laurilsulfate, polysorbate 80, triethyl citrate, hypromellose, titanium dioxide, macrogol 400 and iron oxide yellow.

What Pantoprazole Mylan looks like and contents of the pack
Pantoprazole tablets are banana yellow film coated, oval, approximately 5.7 mm x 11.6 mm, biconvex tablets that are blank on both sides. They are available in plastic bottles and blisters.

Bottle pack comprising of white HDPE bottle with screw cap containing 14, 28, 30, 50, 56, 60, 90, 98, 100 or 250 tablets. The bottle contains also a small plastic canister with silica gel, or a sachet containing silica gel and activated carbon, which protects the tablets from moisture. The canister or sachet cannot be eaten and shouldn't be removed from the bottle.

Blister pack comprising of Aluminium blisters with or without a desiccant layer packed in cardboard cartons containing 7, 7 x 1, 14, 14 x 1, 28, 28 x 1, 30, 56, 56 x 1, 70, 70 x 1, 96, 98 tablets.

PVC/PE/PVdC blister pack with Aluminium lidding foil packed in cardboard cartons containing 7, 7 x 1, 14, 14 x 1, 28, 28 x 1, 30, 56, 70, 70 x 1, 96, 98 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
McDermott Laboratories Limited trading as Gerard Laboratories, 35/36, Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

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This medicinal product is authorised in the Member States of the EEA under the following names:

Country	**Invented Name**
Malta (RMS)	Pantoprazole Mylan 40 mg Gastro-resistant tablets
Belgium	Pantoprazole Viatris 40 mg maagsapresistente tabletten
Czech Republic	Pantomyl 40 mg
Denmark	Pantoprazol Viatris enterotabletter 40 mg
Finland	Pantoprazol Viatris 40 mg
France	PANTOPRAZOLE VIATRIS 40 mg comprimé gastro-resistant
Germany	Pantoprazol dura 40 mg magensaftresistente Tabletten
Greece	Pantoprazole/ Mylan Generics gastro-resistant tablets 40 mg/TAB
Ireland	Pantoprazole Mylan 40 mg Gastro-resistant tablets
Luxembourg	Pantoprazole Viatris 40 mg comprimé gastro-résistant

Poland	Pamyl 40 mg tabletki dojelitowe
Portugal	Pantoprazol Mylan 40 mg Comprimido gastrorresistente
Slovakia	Pantomyl 40 mg
Spain	Pantoprazol Viatris 40 mg comprimidos gastrorresistentes EFG
Sweden	Pantoprazol Viatris 40 mg enterotabletter
The Netherlands	Pantoprazol Viatris 40 mg maagsapresistente tabletten

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