Package leaflet: Information for the user

Pantoprazole 40mg 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. 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 Tablet are and what they are used for

Pantoprazole Tablets are selective “proton pump inhibitors”, which are medicines that reduce the amount of acid produced in your stomach. They are used for treating acid-related diseases of the stomach and intestine.

Pantoprazole Tablets are 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 Tablets

Do not take Pantoprazole Tablets:
• If you are allergic to pantoprazole or to any of the other ingredients in Pantoprazole Tablets (see 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 Tablets:

- 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 Tablets 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 Pantoprazole Tablets as a long-term treatment. 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 or 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 if you notice any of the following symptoms:
• an unintentional loss of weight
• repeated vomiting
• difficulty in swallowing or pain when swallowing
• vomiting blood; this may appear as dark coffee grounds in your vomit
• you look pale and feel weak (anaemia)
• you notice blood in your stools; which may appear be black or tarry in appearance
• chest pain
• stomach pain
• severe and/or persistent diarrhoea, as Pantoprazole Tablets have 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 Tablets 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.

Children and adolescents
Pantoprazole is not recommended for use in children as it has not been proven to work in children below 12 years of age.

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

Pantoprazole Tablets 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.
- 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).

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 machinery
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.

3. How to take Pantoprazole Tablets

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

When and how should you take Pantoprazole Tablets?
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 usual dose is:

Adults and adolescents 12 years of age and above:
To treat reflux oesophagitis
The usual 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 twice a day plus two antibiotic tablets of either amoxicillin, clarithromycin and metronidazole (tinidazole), each to be taken twice 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 treatment of stomach and duodenal ulcers.
The usual 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.

Patients with kidney problems
• If you have kidney problems, moderate or severe liver problems, you should not take Pantoprazole Tablets 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.

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

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

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

If you have any further questions about the use of this product, 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:

• **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 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).

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; fractures of 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; 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.
• **Not known**(frequency cannot be estimated from available data): hallucination, confusion (especially in patients with a history of these symptoms); decreased sodium level in blood; 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 fats in the 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.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting systems listed below:

United Kingdom:
Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland:
HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie

Malta:
ADR Reporting,Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pantoprazole Tablets

Keep this medicine out the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the label and blister. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original container to protect from moisture.

Do not throw away 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 Tablets contain
• The active ingredient is pantoprazole. Each gastro-resistant tablet contains 40mg of pantoprazole (as sodium sesquihydrate).
• The other ingredients are:
Core: mannitol (E421), partially pre-gelatinised maize starch, colloidial anhydrous silica, sodium carbonate (E500) (i), calcium stearate, talc (E553b), sodium starch glycolate (type A).
Coating: methacrylic acid – ethyl acrylate copolymer, sodium hydroxide (E524), triethyl citrate (E1505), talc (E553b), hypromellose (E464), titanium dioxide (E171), macrogol 4000, iron oxide yellow (E172), and blue indigo carmine aluminium lake (E132).

What Pantoprazole Tablets look like and contents of the pack
A yellow, oval, biconvex gastro-resistant tablet; plain on both sides.

Packs: blister pack and outer cardboard carton.

Pantoprazole Tablets are available in a pack size of 28 tablets.

Marketing Authorisation Holder:
Wockhardt UK Ltd, Ash Road North, Wrexham, LL13, 9UF, UK.

Manufacturer:
CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)
Please be ready to give the following information:

Product name	Reference number
Pantoprazole 40mg gastro-resistant tablets	29831/0373

This is a service provided by the Royal National Institute of Blind People.
For the Republic of Ireland please call +44 1978 661 261

This medicinal product is authorised in the following Member States in the EEA, under the following names:
Cyprus - Pantoprazole Wockhardt 40mg Gastro-resistant Tablets
Malta - Pantoprazole 40mg Gastro-resistant Tablets
Republic of Ireland - Pantoprazole 40mg Gastro-resistant Tablets
United Kingdom - Pantoprazole 40mg Gastro-resistant Tablets

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