

BROWN & BURK UK LTD
MODULE 1 ADMINISTRATIVE AND PRESCRIBING INFORMATION
MODULE 1.3 PRODUCT INFORMATION
PANTOPRAZOLE GASTRO-RESISTANT TABLETS, 20 mg

PACKAGE LEAFLET

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Package leaflet: Information for the user
Pantoprazole 20mg Gastro-resistant Tablets
pantoprazole (as sodium sesquihydrate)

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 Tablets is and what it is used for
2. What you need to know before you take Pantoprazole Tablets
3. How to take Pantoprazole Tablets
4. Possible side effects
5. How to store Pantoprazole Tablets
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1. What Pantoprazole Tablets is and what it is used for

Pantoprazole Tablets contains the active substance Pantoprazole (as Pantoprazole sodium sesquihydrate). Pantoprazole Tablets are selective “proton pump inhibitor”, which are medicine that reduce the amount of acid produced in your stomach. It is used for treating acid-related diseases of the stomach and intestine.

Pantoprazole Tablets are used for:

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

- Treating symptoms (e.g. heartburn, acid regurgitation, pain on swallowing) associated to gastro-oesophageal reflux disease caused by reflux of acid from the stomach.
- Long-term management of reflux oesophagitis (inflammation of the oesophagus accompanied by regurgitation of stomach acid) and preventing its return.

Pantoprazole is used to treat adults for:

Preventing duodenal and stomach ulcers caused by non-steroidal anti-inflammatory drugs (NSAIDs, for example ibuprofen) in patients at risk who need to take NSAIDs continuously.

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

Do not take Pantoprazole Tablets

- If you are allergic (hypersensitive) to pantoprazole, or to any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to medicines containing other proton pump inhibitors.

Warning and precautions

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Talk to your doctor or pharmacist before taking Pantoprazole Tablets

- If you have severe liver problems. Please tell your doctor if you have ever had problems with your liver. 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 need to take medicines called NSAIDs continuously and receive Pantoprazole Tablets because you have an increased risk of developing stomach and intestinal complications. Any increased risk will be assessed according to your own personal risk factors such as your age (65 years old or more), a history of stomach or duodenal ulcers or of stomach or intestinal bleeding.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive long-term treatment with Pantoprazole Tablets. 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 are due to have a specific blood test (Chromogranin A).
- 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.

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
- difficulty in swallowing or pain when swallowing
- vomiting blood; this may appear as black coffee grounds in your vomit
- you look pale and feel weak (anaemia)
- you notice blood in your stools; which may be black and tarry in appearance
- 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 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.

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Children and adolescents

Pantoprazole Tablets 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.

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.
- 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 level of methotrexate in 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 the 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.

3. How to take Pantoprazole Tablets

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

The recommended dose is:

Adults and adolescents 12 years of age and above:

To treat symptoms (e.g. heartburn, acid regurgitation,, pain on swallowing) associated to gastro-oesophageal reflux disease

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The usual dose is one tablet a day. This dose usually brings relief within 2 to 4 weeks-at most after another four weeks. Your doctor will tell you how long to continue taking the medicine. After this any reoccurring symptoms can be controlled by **talking one tablet daily** when required.

For long-term management and for preventing the return of reflux oesophagitis

The usual dose is one tablet a day. If the illness returns, your doctor can double the dose, in which case you can use Pantoprazole 40 mg Tablets instead, one a day. After healing, you can reduce the dose back again to one tablet 20 mg a day.

Adults:

To prevent duodenal and stomach ulcers in patients who need to take NSAIDs continuously

The usual dose is one tablet a day.

Patients with liver problems

If you suffer from severe liver problems, you should not take more than one 20 mg tablet a day.

Use in children and adolescents

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

Method of administration

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

If you take more Pantoprazole Tablets than you should

Tell 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 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:

- **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, or skin sensitivity/rash, particularly in areas of skin exposed to light/the sun. You may also have joint pain or flu-like

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symptoms, a fever, swollen glands (e.g. in the armpit) and blood tests may show changes in certain white blood cells or liver enzymes (Stevens-Johnson-Syndrome, Lyell-Syndrome, Erythema multiforme, Subacute cutaneous lupus erythematosus, Drug reaction with eosinophilia and systemic symptoms (DRESS), Photosensitivity).

- **Other serious conditions (frequency not known):** 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)
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 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.
- **Not known** (frequency cannot be estimated from the available data)
Hallucination, confusion (especially in patients with a history of these symptoms); rash, possibly with pain in the joints, 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 levels 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.
- **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

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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 Yellow Card Scheme, website www.mhra.gov.uk/yellowcard. 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 of the sight and reach of children.

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

Store in the original package in order to protect from light and 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 to protect the environment.

6. Contents of the pack and other information

What Pantoprazole Tablets contain

- The active substance is pantoprazole. Each tablet contains 20 mg of pantoprazole (as sodium sesquihydrate).
- The other ingredients are mannitol, crospovidone, anhydrous sodium carbonate, hydroxypropylcellulose, calcium stearate, hypromellose, yellow iron oxide (E172), Ferric oxide red, methacrylic acid-ethylacrylate -copolymer (1:1) and triethyl citrate.

What Pantoprazole Tablets looks like and contents of the pack

Orange coloured, enteric coated oval biconvex tablets plain on both the sides.

Packs: Cartons containing aluminium blisters and HDPE container with polypropylene cap.

Pantoprazole 20 mg tablets are available in the following pack sizes:

Cartons of 7, 14, 15, 28, 30, 56, 60, 84, 90, 98, 100, 112, 140, 280, 500 & 700 tablets.

HDPE container of 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Brown & Burk UK Ltd
5 Marryat Close
Hounslow West
Middlesex
TW4 5DQ
UK.

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