

Pantoprazole 20mg Gastro-resistant Tablets

Read all of this leaflet carefully before you start taking this medicine.

- 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 symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- The full name of this medicine is Pantoprazole 20mg Gastro-resistant Tablets but within the leaflet it will be referred to as Pantoprazole tablets.

In this leaflet:

- 1 What Pantoprazole tablets are and what they are used for**
- 2 Before you take**
- 3 How to take**
- 4 Possible side effects**
- 5 How to store**
- 6 Further information**

1 What Pantoprazole tablets are and what they are 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 20mg tablets are used for:

Adults and adolescents 12 years of age and above:

- 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 the regurgitation of stomach acid) and preventing its return.

Adults:

- 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 Before you take

Do not take Pantoprazole tablets if you

- are **allergic** (hypersensitive) to **pantoprazole**, or any of the other ingredients of Pantoprazole tablets.
- are **allergic to** medicines containing other **proton pump inhibitors**.

Take special care with 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.
- 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.
- have an increased secretory condition (e.g. Zollinger–Ellison syndrome), or you have reduced body stores or risk factors for reduced vitamin B12 and receive pantoprazole long-term treatment. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B12.

- 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 or if you are taking corticosteroids (which can increase the risk of osteoporosis)

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.

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 a 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.

Taking other medicines

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 tablets 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.
- **Methotrexate** (used in treatment of cancer and autoimmune diseases)
- **Atazanavir** (used to treat HIV-infection).

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

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 think you may be pregnant, or if you are breast-feeding, 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.

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 machines.

3 How to take

Always take Pantoprazole tablets exactly as your doctor has told you. You should 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 symptoms (e.g. heartburn, acid regurgitation, pain on swallowing) associated to gastro-oesophageal reflux disease

The usual dose is one tablet a day. This dose usually brings relief within 2 - 4 weeks – at most after another 4 weeks. Your doctor will tell you how long to continue taking the medicine. After this any recurring symptoms can be controlled by **taking 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 40mg tablets instead, one a day. After healing, you can reduce the dose back again to one tablet 20mg 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.

Special patient groups

- If you suffer from **severe liver problems**, you should not take more than one 20mg tablet a day.
- **Children below 12 years**. These tablets are not recommended for use in children below 12 years.

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 a forgotten tablet. 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, Pantoprazole tablets 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):** 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):** 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):** 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:

Uncommon (affects 1 to 10 users in 1,000):

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 hip, wrist or spine.

Rare (affects 1 to 10 users in 10,000):

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; agranulocytosis (severe reduction in number of white blood cells, which makes infections more likely), taste disorders.

Very Rare (affects less than 1 user in 10,000):

disorientation, thrombocytopenia (reduction in blood platelets, which increases risk of bleeding or bruising), leukopenia (decrease in the number of white blood cells (leukocytes)), pancytopenia (severe reduction in blood cells which can cause weakness, bruising or make infections more likely).

Not known (frequency cannot be estimated from the available data): pins and needles / tingling, hallucination, confusion (especially in patients with a history of these symptoms); decreased sodium level, decreased calcium level, decreased potassium level in blood.

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.

Side effects identified through blood tests:

Uncommon (affects 1 to 10 users in 1,000);

an increase in liver enzymes.

Rare (affects 1 to 10 users in 10,000);

an increase in bilirubin; increased fats in the blood.

Very Rare (affects less than 1 user in 10,000);

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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 internet at 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

Keep out of the reach and sight of children.

Do not take Pantoprazole tablets after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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.

6 Further information

What Pantoprazole tablets contain

- The active substance is pantoprazole. Each gastro-resistant tablet contains 20mg of pantoprazole (as sodium sesquihydrate).
- The other ingredients are: Mannitol, Sodium carbonate anhydrous, Sodium starch glycolate, Methacrylic acid copolymer, Calcium stearate, Opadry white OY-D-7233 (hypromellose 3cP, titanium dioxide, talc, macrogol, sodium lauryl sulphate), Kollicoat MAE 30 DP yellow (methacrylic acid-ethyl acrylate copolymer dispersion 30%, propylene glycol, yellow iron oxide, titanium dioxide, talc)

What Pantoprazole tablets look like and contents of the pack

Pantoprazole 20mg Gastro-resistant Tablets are elliptical, biconvex, light yellow gastro-resistant tablets.

Pack sizes: 28

Marketing Authorisation Holder:

Actavis Group PTC ehf
Reykjavikurvegur 76-78
220 Hafnarfjordur
Iceland

Manufacturer:

Balkanpharma – Dupnitsa AD
3 Samokovsko Schosse Str.,
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This leaflet was last revised in May 2014



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