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.

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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 the stomach. It is used for treating acid-related diseases of the stomach and intestine. Pantoprazole 20mg tablets are used for:

• treating peptic ulcer disease
• treating 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 secretion condition (e.g. Zollinger–Ellison syndrome), or you have reduced body stores of vitamin B12.

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 taking or have recently taken any other medicines, including medicines obtained without a prescription.

Driving and using machines

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

4 Possible side effects

Taking any medicines

Pantoprazole tablets may influence the effectiveness of other medicines, so tell your doctor if you are taking:

• medicines such as ciclosporin, ritonavir and paclitaxel (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.
• phenprocoumon, warfarin, methotrexate, ifosfamide, ibuprofen and other medicines with an increased risk of developing stomach and intestinal complications.

5 How to store

Keep the tablets in a tight jar and out of reach of children.

6 Further information

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 ciclosporin, ritonavir and paclitaxel (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.
• phenprocoumon, warfarin, methotrexate, ifosfamide, ibuprofen and other medicines with an increased risk of developing stomach and intestinal complications.
• 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 that 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.
Unless told otherwise by your doctor, the usual dose is:

Adults and adolescents: 13 years of age and above:
To treat symptoms (e.g. heartburn, acid regurgitation, pain on swallowing) associated to gastro-esophageal 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, which can increase the possible side effects. If you can take 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.

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 sickness 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 (Steven-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, 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):

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

• The active substance is pantoprazole. Each gastro-resistant tablet contains 20mg of pantoprazole (as sodium saxulphanilate).

1. If you would like a leaflet with larger text, please contact 01271 362577.

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 sensation; a raised 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.
  • an increase in bilirubin; increased fats in the blood.

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

• 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.

How to keep:

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.

Further information:

What Pantoprazole tablets contain:

• This product contains the active substance pantoprazole. Each gastro-resistant tablet contains 20mg of pantoprazole (as sodium saxulphanilate).

• Other ingredients are:

Mannitol, Sodium carbonate anhydrous, Sodium starch glycolate, Methacrylic acid copolymer, Calcium stearate, Opadry white OY-D-7233 (Hypropolomelecol 3cP, Talc, magnesium, stearate, Polyethylene glycol 400, E1520, Sodium lauryl sulphate), Colloidal MAE 38 PD yellow (methyl cellulose) also lead to a reduction in potassium 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

Manufacturers:
Balkanpharma – Dupnita AD
3 Samokovsko Chesto Str.,
Dupnita 2600

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