PACKAGE LEAFLET: INFORMATION FOR THE USER

Pantoprazole 20 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT PANTOPRAZOLE 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 is used to treat adults and adolescents 12 years of age and above for:
- 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.

Protium 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

Do not take Pantoprazole
- If you are allergic 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.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Protium
- 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 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 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. 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 Protium 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.
– 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 Protium. 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
-
- vomiting blood; this may appear as dark coffee grounds in your vomit
-
- you notice blood in your stools; which may be black or tarry in appearance
– Difficulty in swallowing or pain when swallowing
– You look pale and feel weak (anaemia)
– 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 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
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without 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 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 machines
Pantoprazole has no or negligible influence on the ability to drive or use machines.
If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

3. HOW TO TAKE PANTOPRAZOLE

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

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

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
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 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.

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

If you forget to take Pantoprazole
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
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, pharmacist or nurse.

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 (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), possible leading to kidney failure.

Other side effects are:
- 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); decreased sodium level in blood, decreased magnesium level in blood (see section 2), feeling of tingling, prickling, pins and needles, burning sensation or numbness, 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 fat levels in 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PANTOPRAZOLE
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 carton and the container after EXP. The expiry date refers to the last day of that month.
This medicine does not require any special storage conditions*.*
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 contains
- The active substance is pantoprazole. Each gastro-resistant tablet contains 20 mg of pantoprazole (as sodium sesquihydrate).

- The other ingredients are:
Core: sodium carbonate (anhydrous), mannitol, crospovidone, povidone K90, calcium stearate.
Coating: hypromellose, povidone K25, titanium dioxide (E171), yellow iron oxide (E172), propylene glycol, methacrylic acid-ethyl acrylate copolymer (1:1), polysorbate 80, sodium laurilsulfate, triethyl citrate.
Printing ink: shellac, red, black and yellow iron oxide (E172), ammonia solution, concentrated.

What Pantoprazole looks like and contents of the pack
Yellow, oval, biconvex gastro-resistant tablet imprinted with “P 20” on one side.
Blisters of 28 tablets in a cardboard carton.
Pantoprazole is available in the packs of 28 tablets.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:
PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

Parallel Product Authorisation Number:
PPA 465/403/1

Manufacturer
Takeda GmbH Production Site, Oranienburg, Lehnitzstraße 70-98, D-16515 Oranienburg, Germany

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

Name of Member State	Name of the medicine
Austria	Pantoloc 20 mg-Filmtabletten
Belgium	Pantozol
Bulgaria, Cyprus	Controloc
Czech Republic, Estonia, Greece, Hungary, Latvia, Lithuania, Romania, Slovakia, Slovenia	Controloc 20 mg
Denmark, Sweden	Pantoloc
Finland, Norway	Somac
France	Eupantol 20 mg
Germany, Netherlands	Pantozol 20 mg
Ireland	Protium 20 mg gastro-resistant tablets
Italy	Pantorc
Luxembourg	Pantozol-20
Poland	Controloc 20
Portugal	Pantoc
Spain	Pantecta 20 mg comprimidos gastrorresistentes

This leaflet was prepared by PCO Manufacturing: January 2016