

PACKAGE LEAFLET: INFORMATION FOR THE USER

PANTOPRAZOLE 40 MG GASTRO-RESISTANT TABLETS Pantoprazole (as pantoprazole 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 of the 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 is and what it is used for
2. What you need to know before you take Pantoprazole
3. How to take Pantoprazole
4. Possible side effects
5. How to store Pantoprazole
6. Contents of the pack and other information

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 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 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

Do not take Pantoprazole:

- if you are allergic to pantoprazole or 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 or pharmacist before taking Pantoprazole

- 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 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.
- If you are taking a medicine called atazanavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.
- If you have ever had a skin reaction after treatment with a medicine similar to Pantoprazole Tablets 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 Tablets. Remember to also mention any other ill-effects like pain in your joints.

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.

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).

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.

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 a prescription.

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.
- Atazanavir (used to treat HIV-infection).
- methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer). If you are taking methotrexate your doctor may temporarily stop your pantoprazole treatment

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

Pregnancy, breast-feeding and fertility

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.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

If you experience side effects such as 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 have told you. Check with your doctor or pharmacist if you are not sure.

When and how should you take Pantoprazole?

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 recommended dose is:

Adults and adolescents 12 years of age and above:

To treat reflux oesophagitis

The recommended 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, two times a day plus two antibiotic tablets of either amoxicillin, clarithromycin and metronidazole (or 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 the treatment of stomach and duodenal ulcers

The recommended 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.

Special patient groups:

Renal and hepatic impairment:

- If you have kidney problems, moderate or severe liver problems, you should not take Pantoprazole for eradication of *Helicobacter pylori*.
- If you suffer from severe liver problems, you should not take more than one Pantoprazole 20 mg tablet a day (for this purpose tablets containing 20 mg pantoprazole are available).

Paediatric population:

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

If you take more Pantoprazole than you should

Consult 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 a 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 on 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 this medicine 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 1000 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:** 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:

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 of the hip, wrist or spine.

Rare (may affect up to 1 in 1000 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 the available data)

- hallucination, confusion (especially in patients with a history of these symptoms)
- decreased sodium in the blood
- cramps in the muscles

- unusual skin sensations such as numbness, tingling, pricking, burning or creeping on skin (paraesthesia).
- rash, possibly with pain in the joints.

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 (may affect up to 1 in 100 people)

- an increase in liver enzymes.

Rare (may affect up to 1 in 1000 people)

- an increase in bilirubin; increased fats in the blood; sharp drop in circulating granular white blood cells.

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 HPRC 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.

Store below 30°C.

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

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Pantoprazole tablets contain

- The active substance is pantoprazole, each gastro-resistant tablet contains 40 mg pantoprazole (as pantoprazole sodium sesquihydrate)
- The other ingredients are:

Tablet core: Disodium Phosphate Anhydrous, Mannitol (E421), Cellulose Microcrystalline, Croscarmellose Sodium, Magnesium Stearate (vegetable)

Tablet coat: Hypromellose, Triethyl Citrate, Sodium Starch Gylcollate (Type A), Methacrylic acid-Ethyl acrylate copolymer, Yellow Iron Oxide (E172).

What Pantoprazole look like and contents of the pack

Pantoprazole 40 mg Gastro-resistant Tablets are oval, yellow tablets and are available in aluminium blister packs of 28 tablets.

Product procured from within the EU, repackaged and distributed by:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

Parallel Product Authorisation Holder;

WPR Healthcare Limited, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

PPA no: PPA 565/64/2

Manufacturer:

Teva Pharma S.L.U., Poligono Industrial Malpica, calle C, 50016 Zaragoza, Spain.

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This medicinal product is authorized in the Member States of the EEA under the following names:

Ireland Pantoprazole Teva Pharma 20 mg Gastro-resistant Tablets
Belgium Pantoprazole Teva 20 mg maagsapresistente tabletten
Bulgaria PRAZOLPAN 20 mg gastro-resistant tablets
(ПРАЗОЛПАН 20 mg стомашно-устойчиви таблетки)
Denmark Pantoprazole Teva
Greece Pantoprazole Teva Pharma 20 mg
Γαστροανθεκτικά Δισκία
Finland Pantoprazole ratiopharm 20 mg enterotablettia
Hungary Pantoprazole-Teva 20 mg gyomornedv-ellenálló tableta
Italy Pantoprazolo Teva Italia
Netherlands Pantoprazol Teva 20 mg, maagsapresistente tabletten
Romania Pantoprazole Teva 20 mg comprimate gastrorezistente
Sweden Ulzate 20 mg enterotabletter Slovenia Pantoprazol Teva 20 mg gastrorezistentne tablete