PACKAGE LEAFLET: INFORMATION FOR THE USER

PANTOPRAZOLE 20 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 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 is used for:
Adults and adolescents 12 years of age and above:
- Treating symptoms (e.g. heartburn, acid regurgitation, pain on swallowing) associated with gastrooesophageal 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. 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 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 pantoprazole longterm 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

Pregnancy, breast-feeding and fertility
There are no adequate data from the use of pantoprazole in pregnant women. Excretion into human milk - 3 - 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 symptoms (e.g. heartburn, acid regurgitation, pain on swallowing) associated with gastro oesophageal reflux disease

The recommended 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 recommended 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 Pantoprazole 20 mg tablet a day.

Adults:

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

The recommended dose is one tablet a day.

Special patient groups:
Hepatic impairment:
- If you suffer from severe liver problems, you should not take more than one 20 mg tablet a day.

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 - 5 - 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 or pharmacist. 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.

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 20 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 20 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 565/64/1

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 tabletta
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