

LABELLING 40mg TEXT TO APPEAR ON THE PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET PANTOPRAZOLE 40 mg GASTRO-RESISTANT TABLETS

pantoprazole (as sodium sesquihydrate)

The name of this medicine is Pantoprazole 40 mg Gastro-Resistant Tablets, which will be referred to as Pantoprazole Tablets throughout this leaflet.

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 further questions, ask your doctor or your 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. (see Section 4)

What is in this leaflet:

1. What Pantoprazole Tablets are and what they are used for
2. What you need to know before you take Pantoprazole Tablets
3. How to take Pantoprazole Tablets
4. Possible side effects
5. How to store Pantoprazole Tablets
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 is 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 the 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 TABLETS

Do not take Pantoprazole tablets

- . • If you are allergic to pantoprazole, or to any of the other ingredients in 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 tablets

. • If you have severe liver problems. Please tell your doctor if you have ever had problems with your liver in the past. 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.

• 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 containing atazanavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.

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 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**.

Pantoprazole if used in high doses and over long durations (>1 year), may modestly increase the risk of hip, wrist and spine fracture, predominantly in the elderly or in presence of other recognised risk factors

If you are on Pantoprazole Tablets 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.(See section 4: Possible side effects)

Talk to your doctor before taking Pantoprazole Tablets:

- 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.

Taking other medicines

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).

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

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.

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 PANTOPRAZOLE TABLETS

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.

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 two times 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.

Use in children and adolescents

Unless told otherwise by your doctor, the usual dose is:

Adults and adolescents 12 years of age and above:

To treat reflux oesophagitis

The usual 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.

For the treatment of stomach and duodenal ulcers. The usual 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:

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 tablet 20 mg pantoprazole a day (for this purpose tablets containing 20 mg pantoprazole are available).

- 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 the forgotten dose. 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 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 reduction in white blood cells (Agranulocytosis) (frequency : Rare (may affect up to 1 in 1,000 people)

-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: 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). Rash possibly with pain in joints (**frequency: Not known: frequency cannot be estimated from the available**

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; Fracture of the hip, wrist or spine skin rash, exanthema, eruption; itching; feeling weak, exhausted or generally unwell; sleep disorders.

-Rare (may affect up to 1 in 1,000 people) disturbances in vision such as blurred vision; hives; pain in the joints; muscle pains; weight changes; raised body temperature; Taste disorders
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);, tingling feeling such as pins and needles as well as muscle cramps.

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.

-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 and low levels of all types of blood cells (Pancytopenia).

Not known (frequency cannot be estimated from the available data) decreased sodium level in blood, decreased magnesium levels in the blood, decreased potassium levels in the blood

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 TABLETS

Keep out of the sight and reach of children.

Do not use Pantoprazole Tablets 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.

Store in the original package to protect from moisture. This medicinal product does not require any special temperature storage conditions. Do not use if you notice your tablets are broken or chipped, return them to your pharmacist. Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What Pantoprazole 40 mg Tablets contain:

The active ingredient is pantoprazole. One tablet contains 40 mg of pantoprazole (as sodium sesquihydrate). The other ingredients are: Tablet core: Sodium carbonate anhydrous, mannitol (E421), crospovidone, calcium stearate, hydroxypropyl cellulose (E463). Seal coating: Hypromellose (E464), titanium dioxide (E171), yellow iron oxide (E172), propylene glycol (E1520) Enteric coating: Methacrylic acid-ethyl acrylate copolymer (1:1) 30% dispersion, triethyl citrate (E1505).

What Pantoprazole 40 mg tablets look like and contents of the pack

Pantoprazole Tablets are yellow coloured, capsule-shaped, biconvex tablets plain on both sides.

Tablet dimensions: length 10 mm; width 5 mm. Your medicine is available in blisters containing 28 tablets.

Marketing Authorisation Holder:

Fannin (UK) Limited, 42-46 Booth Drive, Park Farm South,
Wellingborough, Northamptonshire NN8 6GT, UK.

Manufacturer responsible for batch release:

Fannin (UK) Limited, 57 High Street, Odiham, Hampshire, RG29 1LF, UK.

This information is available in alternative formats upon request.

This leaflet was last revised in January 2016