Package leaflet: Information for the patient
Protizole 40 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 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 Protizole is and what it is used for

Protizole 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.

Protizole 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 Protizole

Do not take Protizole
- 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.
- if you are taking medicines for the treatment of HIV e.g. atazanavir

Warnings and precautions
Talk to your doctor or pharmacist before using Protizole
- if you have severe liver problems. Please tell your doctor if you ever had problems with your liver in the past. 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 B_{12} and receive pantoprazole long-term treatment. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B_{12}.

- if you have ever had a skin reaction after treatment with a medicine similar to pantoprazole that reduces stomach acid.
- if you are due to have a specific blood test (Chromogranin A).

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. 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

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.

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).

Other medicines and Protizole
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines as Protizole may influence the effectiveness of these medicines.
- 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 similar medicines from working properly.
- Warfarin and phenprocoumon, which affect the thickening, or thinning of the blood. You may need further checks.
- Medicines used to treat HIV-infection, such as atazanavir (see section 2 'Do not take ').
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and cancer) because pantoprazole may increase the levels of methotrexate in the body.
- 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).

This medicine may affect the way that your body absorbs vitamin B_{12}, particularly if you need to take it for a long time. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of Vitamin B_{12}:

- Extreme tiredness or lack of energy
- Pins and needles
- Sore or red tongue, mouth ulcers
- Muscle weakness
- Disturbed vision

- Problems with memory, confusion, depression

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, or think you may be pregnant, are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
You should not use this medicine if you are pregnant or breast-feeding unless your doctor considers the benefit for you greater than the potential risk for your unborn child or baby.

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

Protizole contains lactose and sodium
Protizole contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Protizole

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

When and how should you take Protizole
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 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.

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:
- 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 Protizole than you should
Consult your doctor or pharmacist. There are no known symptoms of overdose.

If you forget to take Protizole
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 Protizole
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 these tablets and tell your doctor immediately, or contact the casualty department at your nearest hospital:

Rare (may affect up to 1 in 1,000 people)
- **Serious allergic reactions:** 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.
- a reduction in the number of white and red blood cells and/or platelets, which may be seen in blood tests. You may also notice more frequent infections, or you may bruise or bleed more than normal.

Not known (frequency cannot be estimated from the available data)

- **Serious skin conditions:** 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), rash, possibly with pain in the joints and sensitivity to light.
- **Other serious conditions:** 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 which could lead to kidney failure).

If you are on Protizole 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.

Other side effects are:

- **Common** (may affect up to 1 in 10 people)
  Benign polyps in the stomach.

- **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 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; swelling of the extremities (peripheral oedema); allergic reactions; depression; breast enlargement in males.

- **Not known** (frequency cannot be estimated from the available data)
Hallucination, confusion (especially in patients with a history of these symptoms); pins and needles; inflammation in the large bowel, that causes persistent watery diarrhoea.

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 fats in the blood.
- **Not known** (frequency cannot be estimated from the available data)
  Decreased sodium level in blood.

Reporting of side effects
If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Protizole

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.

Do not store this medicine above 30˚C in blister packs. Store in the original package.
This medicine does not require any special temperature storage conditions when packed in bottles. Store in the original package.

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 protect the environment.

6. Contents of the pack and other information

What Protizole contains

- The active substance is pantoprazole. Each gastro-resistant tablet contains 40 mg of pantoprazole (as sodium sesquihydrate).

- The other ingredients are:

  Cellulose, microcrystalline, lactose monohydrate, croscarmellose sodium, silica, colloidal anhydrous and magnesium stearate. The coating contains sodium lauryl sulphate, polysorbate 80, methacrylic acid-ethyl acrylate copolymer, triethylcitrate, polyvinyl alcohol, macrogol 3350, titanium dioxide, talc and iron oxide yellow (see section 2 'Protizole contains lactose and sodium').

What Protizole looks like and contents of the pack
The tablets are pale yellow to ochre and oblong.

Packs: plastic bottles and blister packs.

Protizole is available in the following pack sizes
Packs with 7, 14, 15, 28, 30, 50, 56, 60, 100 and 250 gastro-resistant tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer

TOWA Pharmaceutical Europe, S.L.
C/ de Sant Marti,
75-97 Martorelles,
08107 Barcelona,
Spain.

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

Austria	Pantoprazol Towa Pharmaceutical Europe 40 mg - magensaftresistente Tabletten
Ireland	Protizole 40mg gastro-resistant tablets
Italy	Pantoprazol Towa Pharmaceutical Europe 40mg
Poland	Pantoprazol Towa Pharmaceutical Europe 40mg
Portugal	Pantoprazol Lumec 40mg comprimidos gastroreresistentes

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