Package leaflet: Information for the user

Pantoprazole 40 mg powder for solution for injection
Pantoprazole

Read all of this leaflet carefully before you start using 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.
- 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 40 mg is and what it is used for

Pantoprazole 40 mg 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.
This preparation is injected into a vein and will only be given to you if your doctor thinks pantoprazole injections are more suitable for you at the moment than pantoprazole tablets. Tablets will replace your injections as soon as your doctor sees fit.

Pantoprazole 40 mg is used for treating:

- Reflux oesophagitis. An inflammation of your oesophagus (the tube which connects your throat to your stomach) accompanied by the regurgitation of stomach acid.

- 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 use Pantoprazole 40 mg

Do not use Pantoprazole 40 mg:
- 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 before using Pantoprazole 40 mg
- 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. In the case of a rise of liver enzymes the treatment should be stopped.
- 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 advise.
- Taking a proton pump inhibitor like Pantoprazole 40 mg, 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 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 or 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 are due to have a specific blood test (Chromogranin A)
- 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 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.

Other medicines and Pantoprazole 40 mg
Pantoprazole injections 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 40 mg 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 cancer or psoriasis). If you are taking methotrexate your doctor may temporarily stop your Pantoprazole 40 mg treatment.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 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.

Pantoprazole 40 mg contains Sodium
This medicine contains less than 1 mmol sodium (23 mg) per vial, i.e. essentially 'sodium-free'.

3. How to use Pantoprazole 40 mg

Your nurse or your doctor will administer the daily dose to you as an injection into a vein over a period of 2-15 minutes.

The usual dose is:
For gastric ulcers, duodenal ulcers and reflux oesophagitis.
One vial (40 mg pantoprazole) a day.

For the long-term treatment of Zollinger-Ellison syndrome and other conditions in which too much stomach acid is produced.
Two vials (80 mg pantoprazole) a day.

Your doctor may later adjust the dose, depending on the amount of stomach acid you produce. If you are prescribed more than two vials (80 mg) a day, the injections will be given in two equal doses. Your doctor may prescribe a temporary dose of more than four vials (160 mg) a day. If your stomach acid level needs to be controlled rapidly, a starting dose of 160 mg (four vials) should be enough to lower the amount of stomach acid sufficiently.

Use in children (under 18 years)
These injections are not recommended for use in children.

Special patient groups
If you suffer from severe liver problems, the daily injection should be only 20 mg (half a vial).

If you use more Pantoprazole 40 mg than you should
These doses are carefully checked by your nurse or your doctor so an overdose is extremely unlikely.
There are no known symptoms of overdose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The frequency of possible side effects listed below is defined using the following convention:
very common (affects more than 1 user in 10)
common (affects 1 to 10 users in 100)
uncommon (affects 1 to 10 users in 1,000)
rare (affects 1 to 10 users in 10,000)
very rare (affects less than 1 user in 10,000)
not known (frequency cannot be estimated from the available data)

If you get any of the following side effects, tell your doctor immediately, or contact the casualty department at your nearest hospital:

- **Serious allergic reactions (frequency rare):** 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):** 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), sensitivity to light, rash, possibly with pain in the joints.

- **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).

Other side effects are:
- **Common** (affects 1 to 10 users in 100)
  inflammation of the wall of the vein and blood clotting (thrombophlebitis) where the medicine is injected; benign polyps in the stomach.
- **Uncommon** (affects 1 to 10 users in 1,000)
  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.
  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).
- **Rare** (affects 1 to 10 users in 10,000)
  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** (affects less than 1 user in 10,000)
  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, feeling of tingling, prickling, pins and needles, burning sensation or numbness. Inflammation in the large bowel, that causes persistent watery diarrhoea.
  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** (affects 1 to 10 users in 1,000)
  an increase in liver enzymes.
- **Rare** (affect 1 to 10 users in 10,000)
  an increase in bilirubin; increased fats in the blood; sharp drop in circulating granular white blood cells, associated with high fever.
- **Very Rare** (affects less than 1 user in 10,000)
  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 white and red 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; Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pantoprazole 40 mg

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 label and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the vial in the outer carton in order to protect from light.

Chemical and physical in-use stability has been demonstrated for 12 hours at 25°C and 24 hours at 5±3°C.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8 ºC.

Do not use this medicine if you notice that the visual appearance has changed (e.g. if cloudiness or precipitation is observed).

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

- The other ingredients are: tetrasodium edetate, mannitol, trometamol.

The reconstituted solution should be colourless to faintly yellow and free from visible particle.

What Pantoprazole 40 mg looks like and contents of the pack
Pantoprazole 40 mg is a white to off-white powder for solution for injection. It comes in a 10 ml clear glass vial closed with a rubber stopper and sealed by an aluminium flip-off cap containing 40 mg powder for solution for injection.

Pantoprazole 40 mg is available in the following pack sizes: 1, 5 (5x1), 10 (10x1) or 20 (20x1) vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Laboratorio Reig Jofré, S.A.
Gran Capitan, 10
08970 Sant Joan Despí (Barcelona)
Spain

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

Denmark:	Pantoprazol Reig Jofre
France:	Pantoprazole REIG JOFRE 40 mg poudre pour solution injectable (IV)
Germany:	Pantoprazol Carinopharm 40 mg Pulver zur Herstellung einer Injektionslösung
Italy:	Pantoprazolo Teva Generics 40 mg polvere per soluzione iniettabile
Ireland:	Pantoprazole 40 mg powder for solution for injection
Poland:	Pantoprazole REIG JOFRE
United Kingdom:	Pantoprazole 40 mg powder for solution for injection

This leaflet was last revised in 05/2020.

The following information is intended for medical or healthcare professionals only:

A ready-to-use solution is prepared by injecting 10 ml of sodium chloride 9 mg/ml (0.9 %) solution for injection into the vial containing the dry powder. This solution may either be administered directly or after mixing it with 100 ml sodium chloride 9 mg/ml (0.9 %) solution for injection or glucose 50 mg/ml (5 %) solution for injection. Glass or plastic containers should be used for dilution.

Pantoprazole 40 mg should not be prepared or mixed with solvents other than those stated.

Chemical and physical in-use stability has been demonstrated for 12 hours at 25°C and for 24 hours at 5±3°C. From a microbiological point of view, the reconstituted/diluted solution should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8 ºC.

The medicine should be administered intravenously over 2-15 minutes.

The content of the vial is for single intravenous use only. Any product that has remained in the container or the visual appearance of which has changed (e.g. if cloudiness or precipitation is observed) must be discarded in accordance with local requirements.