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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. 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

This medicine contains the active substance pantoprazole. It 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 medicine 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 thinks it is possible.

Pantoprazole is used in adults for treating:
- reflux oesophagitis. This is 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 that cause too much acid to be produced in the stomach.

2. What you need to know before you are given Pantoprazole

You should not be given 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 nurse before you are given Pantoprazole:
- if you have severe liver problems. Please tell your doctor if you have ever had problems with your liver in the past. Your doctor 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 HIV protease inhibitors such as atazanavir (for the treatment of HIV infection).
- if you have osteoporosis (reduced bone density) or if you are taking corticosteroids (which can increase the risk of osteoporosis). 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.

– 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).

Tell your doctor immediately, before or after you are given this medicine, if you notice any of the following symptoms, which could be a sign of another, more serious, disease:
− an unintentional loss of weight
− vomiting, particularly if repeated
− vomiting blood; this may appear as dark coffee grounds in your vomit
− you notice blood in your stools which may be black or tarry in appearance
− difficulty in swallowing or pain when swallowing
− you look pale and feel weak (anaemia)
− chest pain
− stomach pain
− severe and/or persistent diarrhoea, because this medicine 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 persist despite your treatment, further investigations will be considered.

Tell your doctor immediately, if you get a rash on your skin, especially in areas exposed to the sun as you may need to stop your treatment with pantoprazole. Remember to also mention any other ill-effects like pain in your 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 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.

Children and adolescents
This medicine is not recommended in children and adolescents under 18 years of age as the safety and efficacy have not been established.

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

Especially, tell your doctor if you are taking:
• medicines used to treat fungal infections (such as ketoconazole, itraconazole and posaconazole)
• erlotinib (used for certain types of cancer)
• warfarin and phenprocoumon (used to thin blood)
• medicines used to treat HIV infection (such as atazanavir)
• methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer)
• fluvoxamine (used to treat depression and other psychiatric diseases)
• rifampicin (used to treat infections)
• St John's wort (*Hypericum perforatum*) (used to treat mild depression).

Pregnancy and breast-feeding
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 receiving this medicine.
There are no adequate data from the use of pantoprazole in pregnant women. Excretion of pantoprazole into human milk has been reported.
You should receive this medicine, only if your doctor considers the benefit for you greater than the potential risk for your unborn child or baby.

Driving and using machines
This medicine has no or negligible influence on the ability to drive and use machines.
If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

Pantoprazole contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. How Pantoprazole will be given

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

Adults
For gastric ulcers, duodenal ulcers and reflux oesophagitis
40 mg pantoprazole daily.

For the long-term treatment of Zollinger-Ellison syndrome and other conditions in which too much stomach acid is produced
80 mg pantoprazole daily.

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

Patients with liver problems
If you suffer from severe liver problems, the daily dose should be only 20 mg.

Children and adolescents
This medicine is not recommended in children aged under 18 years of age.

If you receive more Pantoprazole than you should
As you will receive this medicine from a doctor or nurse, you are unlikely to be given the wrong dose. There are no known symptoms of overdose.

If you have any further questions about the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Tell your doctor or nurse immediately, if you get any of the following side effects:

- **Serious allergic reactions** (may affect up to 1 in 1 000 people): swelling of the tongue and/or throat, difficulty in swallowing, hives, difficulties in breathing, allergic facial swelling (angioedema), severe dizziness with very fast heartbeat and heavy sweating.

- **Serious skin conditions** (frequency not known): you may notice one or more of the following – blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals, or skin sensitivity/rash, particularly in areas of skin exposed to light/the sun. You may also have joint pain and flu-like symptoms, a fever,

swollen glands (e.g. in the armpit) and blood tests may show changes in certain white blood cells or liver enzymes (Stevens-Johnson syndrome, Lyell syndrome, erythema multiforme, subacute cutaneous lupus erythematosus, drug reaction with eosinophilia and systemic symptoms (DRESS) and photosensitivity).

- **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, possibly leading to kidney failure).

Other side effects
Common (may affect up to 1 in 10 people)
- benign polyps in the stomach
- inflammation of the wall of the vein and blood clotting (thrombophlebitis) where the medicine is injected

Uncommon (may affect up to 1 in 100 people)
- sleep disorders
- headache, dizziness
- diarrhoea, feeling sick, vomiting, bloating and flatulence (wind), constipation, dry mouth, abdominal pain and discomfort
- skin rash, exanthema, eruption, itching
- fracture in the hip, wrist or spine
- feeling weak, exhausted or generally unwell

Rare (may affect up to 1 in 1 000 people)
- allergic reactions
- weight changes
- depression
- distortion or complete lack of the sense of taste
- disturbances in vision such as blurred vision
- pain in the joints, muscle pains
- breast enlargement in males
- raised body temperature, swelling of the extremities (peripheral oedema)

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)
- feeling of tingling, prickling or numbness, rash, possibly with pain in the joints
- 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)
- increase in liver enzymes

Rare (may affect up to 1 in 1 000 people)
- increase in bilirubin
- increased fat levels in blood
- sharp drop in granular white blood cells, associated with high fever

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
- 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

Not known (frequency cannot be estimated from the available data)
- decreased level of sodium, magnesium, calcium or potassium in blood (see section 2)

Reporting of side effects
If you get any side effects talk to you 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, 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

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 vial after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.
Keep the vials in the outer carton in order to protect from light.

Shelf life after reconstitution or reconstitution and dilution
The chemical and physical in-use stability after reconstitution, or reconstitution and dilution with sodium chloride 9 mg/ml (0.9%) solution for injection, has been demonstrated for 24 hours at 2 to 8 °C and 25 °C.
The chemical and physical in-use stability after reconstitution with sodium chloride 9 mg/ml (0.9%) solution for injection and dilution with glucose 50 mg/ml (5%) solution for injection has been demonstrated for 24 hours at 2 to 8 °C and for 12 hours at 25 °C.

From a microbiological point of view, the prepared solution should be used immediately. If not used immediately, in-use storage times and conditions prior to the use are the responsibility of the user and would not normally be longer than 24 hours at 2 to 8 °C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

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

– The other ingredients are sodium citrate, mannitol (E 421), sodium hydroxide (for pH adjustment).

What Pantoprazole looks like and contents of the pack
White or almost white uniform porous cake.

Powder is filled in 10 ml capacity clear, colourless glass type I vials. Vials are closed with bromobutyl rubber stoppers and sealed with aluminium/polypropylene flip-off seals.
The vials are placed into outer cartons.

Pack sizes: 1, 5, 10 or 50 vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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This medicine is authorised in the Member States of the European Economic Area under the following names:

Denmark	Pantoprazol Kalceks
Austria, Germany	Pantoprazol Kalceks 40 mg Pulver zur Herstellung einer Injektionslösung
Czech Republic, Norway	Pantoprazol Kalceks
Belgium	Pantoprazole Kalceks 40 mg poudre pour solution injectable
	Pantoprazole Kalceks 40 mg poeder voor oplossing voor injectie
	Pantoprazole Kalceks 40 mg Pulver zur Herstellung einer Injektionslösung
Bulgaria	Пантопразол Калцекс 40 мг прах за инжекционен разтвор
Croatia	Pantoprazol Kalceks 40 mg prašak za otopinu za injekciju
Finland	Pantoprazole Kalceks 40 mg injektiokuiva-aine, liuosta varten
France	PANTOPRAZOLE KALCEKS 40 mg, poudre pour solution injectable
Hungary	Pantoprazole Kalceks 40 mg por oldatos injekcióhoz
Ireland	Pantoprazole 40 mg powder for solution for injection
Italy	Pantoprazolo Kalceks
Latvia	Pantoprazole Kalceks 40 mg pulveris injekciju šķīduma pagatavošanai
Lithuania	Pantoprazole Kalceks 40 mg milteliai injekciniam tirpalui
Poland, Portugal, Sweden	Pantoprazole Kalceks
Romania	Pantoprazol Kalceks 40 mg pulbere pentru soluție injectabilă
Slovakia	Pantoprazol Kalceks 40 mg prášok na injekčný roztok
Slovenia	Pantoprazol Kalceks 40 mg prašek za raztopino za injiciranje
Spain	Pantoprazol Kalceks 40 mg polvo para solución inyectable EFG
The Netherlands	Pantoprazol Kalceks 40 mg poeder voor oplossing voor injectie

This leaflet was last revised in 04/2023

The following information is intended for healthcare professionals only:

Incompatibilities
This medicinal product must not be mixed with other medicinal products except those mentioned below.

Instructions on use and disposal
For single use 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 powder. The prepared solution may be administered directly or may be administered 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.

The prepared solution should be visually inspected prior to use. The appearance of the product after reconstitution is a clear yellowish solution. Only clear solutions free from particles should be used.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.