Package leaflet: Information for the patient

Pantoprazol Sandoz® injectie 40 mg, poeder voor oplossing voor injectie

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, 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 [Nationally completed name] is and what it is used for

[Nationally completed name] contains the active substance pantoprazole. [Nationally completed name] 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.

[Nationally completed name] is used for treating adults for:

– 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 [Nationally completed name]

Do not use [Nationally completed name]:

- If you are allergic to pantoprazole or to 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, pharmacist or nurse before taking [Nationally completed name].
- 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) at the same time as pantoprazole, ask your doctor for specific advice.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 (reduced bone density) or if you have been told that you are at risk of getting osteoporosis (for example, if you are taking steroids).
- If you are on [Nationally completed name] 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 have ever had a skin reaction after treatment with a medicine similar to [Nationally completed name] 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 [Nationally completed name]. Remember to also mention any other ill-effects like pain in your joints.
- Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and erythema multiforme, have been reported in association with pantoprazole treatment. Stop using pantoprazole and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- If you are due to have a specific blood test (Chromogranin A).

Tell your doctor immediately, before or after taking 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 continue in spite of your treatment, further investigations will be considered.

Children and adolescents
[Nationally completed name] is not recommended for use in children as it has not been proven to work in children below 18 years of age.

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

This is because [Nationally completed name] 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 [Nationally completed name] 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.
- Medicines used to treat HIV-infection, such as atazanavir.
- Methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) – if you are taking methotrexate your doctor may temporarily stop your [Nationally completed name] treatment because pantoprazole can increase levels of methotrexate in the blood.
- 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).

Talk to your doctor before taking pantoprazole if you are due to have a specific urine test (for THC; Tetrahydrocannabinol).

Pregnancy, breast-feeding and fertility
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 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.

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.

Driving and using machines
[Nationally completed name] 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.

[Nationally completed name] contains sodium
This medicine contains less than 1 mmol (23 mg) sodium per vial, that is to say essentially sodium free.

3. How to take [Nationally completed name]

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 recommended dose is:
Adults
- *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.

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

Use in children and adolescents
These injections are not recommended for use in children and adolescents under 18 years.

If you use more [Nationally completed name] 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 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.

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: 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 skin conditions (frequency not known: frequency cannot be estimated from the available data):** 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 or 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.
  - reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
  - widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

- **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 are:

- **Common** (may affect up to 1 in 10 people)
  inflammation of the wall of the vein and blood clotting (thrombophlebitis) where the medicine is injected; 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 in 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; high fever; 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); feeling of tingling, prickling, pins and needles, burning sensation 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)

an increase in liver enzymes.

– **Rare** (may affect up to 1 in 1,000 people)
an increase in bilirubin; increased fat levels in blood; sharp drop in circulating 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 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.

– **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 your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Nationally completed name]

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 container in outer carton in order to protect it from light.

Use the reconstituted solution within 12 hours.
Use the reconstituted and diluted solution within 12 hours.

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 be not longer than 12 hours at not more than 25°C.

Do not use [Nationally completed name] if you notice that the visual appearance has changed (e.g. if cloudiness or precipitation is observed).

The content of the vial is meant for single use; any product that has remained in the vial has to be discarded.

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 [Nationally completed name] contains

– **Active substance:** one vial [Nationally completed name] contains 45.11 mg pantoprazole sodium sesquihydrate, equivalent to 40 mg pantoprazole.

What [Nationally completed name] looks like and contents of the pack
[Nationally completed name] is a glass vial closed with a red rubber stopper and sealed by aluminium cap with plastic protective cap, containing a white to yellowish powder, i.e. the powder for solution for injection.

The vials are packed in carton boxes. Each box contains 1, 5, 10 or 20 glass vials.
Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen
Sandoz B.V., Veluwezoom 22, 1327 AH Almere, Nederland

Fabrikanten
Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

In het register ingeschreven onder:
RVG 33903

Dit geneesmiddel is goedgekeurd in de lidstaten van de Europese Economische Ruimte onder de volgende namen:

Duitsland:	Pantoprazol HEXAL 40 mg i.v. Pulver zur Herstellung einer Injektionslösung
Italië:	PANTOPRAZOLO HEXAL AG 40 mg polvere per soluzione iniettabile
Nederland:	Pantoprazol Sandoz injectie 40 mg, poeder voor oplossing voor injectie

Deze bijsluiter is voor het laatst goedgekeurd in december 2024

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 dry powder. The reconstituted solution should be colourless to faintly

yellow. This solution may be administered directly or after mixing it with 100 ml sodium chloride 9 mg/ml (0.9%) solution for injection, or glucose monohydrate 55 mg/ml (5%) solution for injection. Glass or plastic containers should be used for dilution.

[Nationally completed name] should not be prepared or mixed with solvents other than those stated.

After preparation, the solution must be used within 12 hours. 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 12 hours, at not more than 25°C.

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 whose visual appearance has changed (e.g. if cloudiness or precipitation is observed) must be discarded.