Package leaflet: Information for the patient

Pantoprazol Sandoz® 20 mg, maagsapresistente tabletten

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.
- 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, 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. 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.

[Nationally completed name] is used to treat adults and adolescents 12 years of age and above for
- Symptoms (e.g. heartburn, acid regurgitation, pain on swallowing) associated to gastro-oesophageal reflux disease caused by reflux of acid from the stomach.
- Long-term management of reflux oesophagitis (inflammation of the oesophagus accompanied by the regurgitation of stomach acid) and preventing its return.

[Nationally completed name] is used to treat adults for
- Preventing duodenal and stomach ulcers caused by non-steroidal anti-inflammatory drugs (NSAIDs, for example, ibuprofen) in patients at risk who need to take NSAIDs continuously.

2. What you need to know before you take [Nationally completed name]

Do not take [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, especially when you are taking [Nationally completed name] as a long-term treatment. In the case of a rise of liver enzymes the treatment should be stopped.
- If you need to take medicines called NSAIDs continuously and receive [Nationally completed name] because you have an increased risk of developing stomach and intestinal complications. Any increased risk will be assessed according to your own personal risk factors such as your age (65 years old or more), a history of stomach or duodenal ulcers or of stomach or intestinal bleeding.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive long-term treatment with pantoprazole. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B12. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of Vitamin B12:
    - Extreme tiredness or lack of energy
    - Pins and needles
    - Sore or red tongue, mouth ulcers
    - Muscle weakness
    - Disturbed vision
    - Problems with memory, confusion, depression
- 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 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 [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.

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.
- 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.

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 [Nationally completed name] 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.

Children and adolescents
[Nationally completed name] is not recommended for use in children as it has not been proven to work in children below 12 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 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 [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 [Nationally completed name] if you are due to have a specific urine test (for THC; Tetrahydrocannabinol).

Pregnancy and 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 colouring agent and sodium
This medicine contains the azo colouring agent Ponceau 4R aluminium lake (E 124), which may cause allergic reactions.

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

3. How to take [Nationally completed name]

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

Method of administration
Take the tablets 1 hour before a meal without chewing or breaking them and swallow them whole with some water.

The recommended dose is:

Adults and adolescents 12 years of age and above

- *To treat symptoms (e.g. heartburn, acid regurgitation, pain on swallowing) associated to gastro-oesophageal reflux disease*

The usual dose is one tablet a day. This dose usually brings relief within 2 - 4 weeks – at most after another 4 weeks. Your doctor will tell you how long to continue taking the medicine. After this any recurring symptoms can be controlled by **taking one tablet daily**, when required.

- *For long-term management and for preventing the return of reflux oesophagitis*

The usual dose is one tablet a day. If the illness returns, your doctor can double the dose, in which case you can use [Nationally completed name] 40 mg tablets instead, one a day. After healing, you can reduce the dose back again to one tablet 20 mg a day.

Adults

- *To prevent duodenal and stomach ulcers in patients who need to take NSAIDs continuously*

The usual dose is one tablet a day.

Hepatic impairment
If you suffer from severe liver problems, you should not take more than one 20 mg tablet a day.

Use in children and adolescents
These tablets are not recommended for use in children below 12 years.

If you take more [Nationally completed name] than you should
Tell your doctor or pharmacist. There are no known symptoms of overdose.

If you forget to take [Nationally completed name]
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 [Nationally completed name]
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 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, 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 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, enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome) 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 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 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 blister and carton after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use [Nationally completed name] after 6 months have elapsed from opening of the HDPE-bottle.

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 [Nationally completed name] contains

- The active substance is pantoprazole. Each gastro-resistant tablet contains 20 mg of pantoprazole (as sodium sesquihydrate).

- The other ingredients are:
  Tablet core:
  calcium stearate, cellulose microcrystalline, crospovidone (type A), hyprolose (type EXF), sodium carbonate, anhydrous, silica, colloidal anhydrous

Coating:
hypromellose, iron oxide yellow (E 172), macrogol 400, methacrylic acid – ethyl acrylate copolymer (1:1), polysorbate 80, ponceau 4R aluminium lake (E 124), quinoline yellow aluminium lake (E 104), sodium laurilsulfate, titanium dioxide (E 171), triethyl citrate

What [Nationally completed name] looks like and contents of the pack

[Nationally completed name] gastro-resistant tablets are yellow, oval tablets (coated with a special layer), approx. 8.9 x 4.6 mm and available in

NL/H/0727:
blister packs of 7, 10, 14, 15, 20, 28, 30, 50, 56, 56x1, 60, 84, 90, 98, 100, 100x1, 140, 168 tablets, containers of 14, 28, 56, 98, 100, 105, 250, 500 tablets.

NL/H/0728:
blister packs of 7, 10, 14, 15, 20, 28, 30, 50, 56, 56x1, 60, 84, 90, 98, 100, 100x1, 140 tablets, containers of 7, 14, 28, 98, 100, 250, 500 tablets.

NL/H/0750:
blister packs of 7, 10, 14, 15, 20, 28, 30, 50, 56, 56x1, 60, 84, 90, 98, 100, 100x1, 140 tablets, containers of 14, 28, 98, 100, 250, 500 tablets.

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., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikanten
Salutas Pharma GmbH
Otto-von-Guericke Allee 1
D39179 Barleben
Duitsland

Lek Spolka Akcyjna
Ul. Domaniewska 50 c
02-672 Warschau
Polen

Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

Lek Pharmaceuticals d.d.
Trimlini 2 D, 9220 Lendava
Slovenië

Sandoz S.R.L.
Str. Livezeni nr. 7A
540472 Targu-Mures
Roemenië

Lek S.A.
ul.Podlipie 16
95-010 Strykow
Polen

In het register ingeschreven onder:
Pantoprazol Sandoz® 20 mg, maagsapresistente tabletten - RVG 33654

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland:	Pantoprazol Sandoz 20 mg, maagsapresistente tabletten
Oostenrijk:	Pantoprazol “1A Pharma” 20 mg – Magensaftresistente tabletten
Duitsland:	Pantoprazol – 1 A Pharma 20 mg magensaftresistente Tabletten
Spanje:	Pantoprazol Acost 20 mg comprimidos gastroresistentes EFG
Hongarije:	Pantoprazol 1 a Pharma 20 mg gyomornedv ellenalló tabletta
Portugal:	Pantoprazol 1Apharma 20 mg Comprimidos gastrorresistentes

Deze bijsluiter is voor het laatst goedgekeurd in februari 2025.