Package leaflet: Information for the patient

Pantoprazol Sandoz® OTC 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 further more 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.
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Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse <after {number of} days>.

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, which blocks the ‘pump’ that produces stomach acid. Hence it reduces the amount of acid in your stomach.

[Nationally completed name] is used for the short-term treatment of reflux symptoms (for example heartburn, acid regurgitation) in adults.
Reflux is the backflow of acid from the stomach into the gullet (“foodpipe”), which may become inflamed and painful. This may cause you symptoms such as a painful burning sensation in the chest rising up to the throat (heartburn) and a sour taste in the mouth (acid regurgitation).

You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with [Nationally completed name], but this medicine is not meant to bring immediate relief. It may be necessary to take the tablets for 2-3 consecutive days to relieve the symptoms.

You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.

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 taking HIV protease inhibitors such as atazanavir, nelfinavir (for the treatment of HIV-infection). See "Other medicines and [Nationally completed name]".

Warnings and precautions
Talk to your doctor before taking [Nationally completed name] if:
- you have been treated for heartburn or indigestion continuously for 4 or more weeks
- you are over 55 years old and taking non-prescription indigestion treatment on a daily basis
- you are over 55 years old with any new or recently changed reflux symptoms
- you have previously had a gastric ulcer or stomach surgery
- you have liver problems or jaundice (yellowing of skin or eyes)
- you regularly see your doctor for serious complaints or conditions
- you are due to have an endoscopy or a breath test called a C-urea test
- you are due to have a specific blood test (Chromogranin A)
- you have ever had a skin reaction after treatment with a medicine similar to [Nationally completed name] that reduces stomach acid
- you are taking HIV protease inhibitors such as atazanavir, nelfinavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.

Do not take this medicine for longer than 4 weeks without consulting your doctor. If your reflux symptoms (heartburn or acid regurgitation) persist for longer than 2 weeks, consult your doctor who will decide about the need for long-term intake of this medicine.

If you take [Nationally completed name] for longer periods, this may cause additional risks, such as:
- reduced absorption of Vitamin B_{12}, and Vitamin B_{12} deficiency if you already have low body stores of Vitamin B_{12}. 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
- fracture of your hip, wrist or spine, especially if you already suffer from osteoporosis (reduced bone density) or if you are taking corticosteroids (which can increase the risk of osteoporosis).
- falling magnesium levels in your blood (potential symptoms: fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate). Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. You should talk to your doctor if you have been using this product for more than 4 weeks. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

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 (not related to a diet or an exercise programme)
- 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
- 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.

Your doctor may decide that you need some tests.

If you are due to have a blood test, tell your doctor that you are taking this medicine.

You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with [Nationally completed name], but this medicine is not meant to bring immediate relief. You should not take it as a preventive measure.

If you have been suffering from repetitive heartburn or indigestion symptoms for some time, remember to see your doctor regularly.

Children and adolescents
[Nationally completed name] should not be used by children and adolescents under 18 years of age due to a lack of safety information in this younger age group.

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. [Nationally completed name] may stop certain other medicines from working properly, especially medicines containing one of the following active substances:
- HIV protease inhibitors such as atazanavir, nelfinavir (for the treatment of HIV-infection). You must not use [Nationally completed name] if you are taking HIV protease inhibitors. See “Do not take [Nationally completed name]”.
- ketoconazole (used for fungal infections).
- warfarin and phenprocoumon (used to thin blood and prevent clots). You may need further blood tests.
- 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.

Do not take [Nationally completed name] with other medicines which limit the amount of acid produced in your stomach, such as another proton pump inhibitor (omeprazole, lansoprazole or rabeprazole) or an H2 antagonist (e.g. ranitidine, famotidine).

However, you may take [Nationally completed name] with antacids (e.g. magaldrate, alginic acid, sodium bicarbonate, aluminium hydroxide, magnesium carbonate, or combinations thereof), if needed.

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

Pregnancy and breast-feeding

You should not take this medicine if you are pregnant or while 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 taking this medicine.

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

[Nationally completed name] contains azo 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 [Nationally completed name] exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet a day. Do not exceed this recommended dose of 20 mg pantoprazole daily.

You should take this medicine for at least 2-3 consecutive days. Stop taking [Nationally completed name] when you are completely symptom-free. You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with [Nationally completed name], but this medicine is not meant to bring immediate relief.

If you have no symptom-relief after taking this medicine for 2 weeks continuously, consult your doctor.
Do not take [Nationally completed name] tablets for more than 4 weeks without consulting your doctor.

Take the tablet before a meal, at the same time every day. You should swallow the tablet whole with some water. Do not chew or break the tablet.

If you take more [Nationally completed name] than you should
Tell your doctor or pharmacist if you have taken more than the recommended dose. If possible take your medicine and this leaflet with you.

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, the next day, at your usual time.

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.

Tell your doctor immediately or contact the casualty department at your nearest hospital, if you get any of the following **serious side effects**. Stop taking this medicine straight away, but take this leaflet and/or the tablets with you.

- **Serious allergic reactions (frequency rare: may affect up to 1 in 1,000 people)**: Hypersensitivity reactions, so-called anaphylactic reactions, anaphylactic shock and angioedema. Typical symptoms are: swelling of the face, lips, mouth, tongue and/or throat, which may cause difficulty in swallowing or breathing, hives (nettle rash), severe dizziness with very fast heartbeat and heavy sweating.
- **Serious skin reactions (frequency not known: frequency cannot be estimated from the available data)**: You may notice one or more of the following: rash with swelling, blistering or peeling of the skin, losing skin and bleeding around eyes, nose, mouth or genitals and rapid deterioration of your general health, or rash particularly in areas of skin exposed to 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 reactions (frequency not known: frequency cannot be estimated from the available data)**: yellowing of the skin and eyes (due to severe liver damage), 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 include:

- Common side effects (may affect up to 1 in 10 people):
benign polyps in the stomach.

- Uncommon side effects (may affect up to 1 in 100 people):
headache; dizziness; diarrhoea; feeling sick, vomiting; bloating and flatulence (wind); constipation; dry mouth; bellyache and discomfort; skin rash or hives; itching; feeling weak, exhausted or generally unwell; sleep disorders; increase in liver enzymes in a blood test; fracture of the hip, wrist or spine.

- Rare side effects (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; pain in the joints; muscle pains; weight changes; raised body temperature; swelling of the

extremities; depression; increased bilirubin and fat levels in blood (seen in blood tests); breast enlargement in males; high fever and a sharp drop in circulating granular white blood cells (seen in blood tests).

- Very rare side effects (may affect up to 1 in 10,000 people):
disorientation; reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; 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 (seen in blood tests).

- Not known (frequency cannot be estimated from the available data):
hallucination, confusion (especially in patients with a history of these symptoms); decreased level of sodium in blood; decreased level of magnesium, calcium or potassium in blood (see section 2); rash, possibly with pain in the joints, feeling of tingling, prickling, pins and needles, burning sensation or numbness; inflammation in the large bowel, that causes persistent watery diarrhoea.

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 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.

This medicine does not require any special storage conditions.

For HDPE tablet containers
Do not use this medicine after the expiry date, which is stated on the container and cartonafter "EXP". The expiry date refers to the last day of that month.

For blister packs:
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.

only for HDPE tablet containers:
Shelf life after first opening of the container: 6 months

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), hydroxypropylcellulose (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 lauryl sulphate, 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

- blister packs of 7 and14 tablets,
- containers of 7 and 14 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., Veluwezoom 22, 1327 AH 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 OTC 20 mg, maagsapresistente tabletten - RVG 105876.

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

Nederland:	Pantoprazol Sandoz OTC 20 mg, maagsapresistente tabletten
Oostenrijk:	ACIDWELL 20 mg – magensaftresistente Filmtabletten
België:	ACIDWELL 20 mg maagsapresistente tabletten
Bulgarije:	ACIDWELL 20 mg
Duitsland:	Pantoprazol HEXAL akut 20 mg magensaftresistente Tabletten
Denemarken:	Pantoprazole Sandoz
Estland:	ANXEL
Griekenland:	ACIDWELL 20 mg
Spanje:	ACORLIB 20 mg comprimidos gastrorresistentes
Finland:	ACIDWELL 20 mg enterotabletti
Frankrijk:	Pantoprazole Sandoz Conseil 20 mg, comprimé gastro-résistant
Hongarije:	ACIDWELL 20 mg gyomornedv-ellenálló tabletta
Ierland:	Pantup Relief 20 mg Gastro-Resistant Tablets
Italië:	ACIDWELL 20 mg compresse gastroresistenti
Litouwen:	ANXEL 20 mg skrandyje neirios tabletes
Luxemburg:	Pantoprazol HEXAL akut 20 mg magensaftresistente Tabletten
Letland:	ANXEL
Noorwegen:	ACIDWELL 20 mg enterotabletter
Polen:	ACIDWELL
Portugal:	REDACIB
Roemenië:	Redacib 20 mg comprimate gastrorezistente
Zweden:	Pantoprazole Sandoz
Slovenië:	Acipan Control 20 mg gastrorezistentne tablete
Slowakije:	ACIDWELL 20mg gastrorezistentné tablety

Deze bijsluiter is voor het laatst goedgekeurd in januari 2024.

The following recommendations for lifestyle and dietary changes may also help to relieve heartburn or acid related symptoms.

- Avoid large meals
- Eat slowly
- Stop smoking
- Reduce alcohol and caffeine consumption
- Reduce weight (if overweight)
- Avoid tight-fitting clothing or belts
- Avoid eating less than three hours before bedtime
- Elevate bed head (if you suffer from nocturnal symptoms)
- Reduce intake of food that can cause heartburn. These might include: Chocolate, peppermint, spearmint, fatty and fried food, acidic food, spicy food, citrus fruits and fruit juices, tomatoes.