LEAFLET: INFORMATION FOR THE PATIENT
Pantoprazole Sandoz® 20 mg, gastro-resistant tablets
pantoprazole

Read the entire 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.
- Do you have any further questions? Please ask your doctor, pharmacist, or nurse.
- Do not pass this medicine on to others. It may harm them, even if their symptoms 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.

Contents of this leaflet

1. What is Pantoprazole Sandoz 20 mg and what is it used for?

This medicine contains the active substance pantoprazole. Pantoprazole is a selective "proton pump inhibitor", a medicine that reduces the amount of acid produced in your stomach. It is used to treat acid-related stomach and intestinal diseases.

This medicine is used to treat adults and adolescents aged 12 years and older for

- Symptoms (e.g., heartburn, acid regurgitation, pain when swallowing) associated with a condition of the esophagus caused by the backflow of stomach acid from the stomach.
- Long-term treatment of reflux esophagitis (an inflammation of the esophagus, accompanied by the backflow of stomach acid) and to prevent reflux esophagitis from returning.

This medicine is used for the treatment of adults

- To prevent stomach and duodenal ulcers caused by non-steroidal anti-inflammatory drugs (NSAIDs, e.g., ibuprofen) in at-risk patients who need to use NSAIDs continuously.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to pantoprazole or any of the other ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.
- You are allergic to medicines containing other proton pump inhibitors.

When should you be extra careful with this medicine?

Contact your doctor, pharmacist, or nurse before using this medicine:

• if you have severe liver problems. If you have ever had liver problems, you must tell your doctor. Your doctor will check your liver enzymes more frequently, especially when you use this medicine as a long-term treatment; the treatment may be discontinued if necessary. In case of an increase in liver enzymes, the treatment should be stopped.
• if you need to use medicines continuously that are called NSAIDs and you are given this medicine because you have an increased risk of stomach and intestinal complications. Whether you have an increased risk will be assessed based on your personal risk factors, such as your age (65 years or older), a history of stomach or duodenal ulcers, or stomach or intestinal bleeding.
• if you have reduced body reserves of or risk factors for a reduced amount of vitamin B12 and you are treated long-term with this pantoprazole. Like all acid-reducing medicines, pantoprazole can lead to reduced absorption of vitamin B12. Contact your doctor if you notice any of the following complaints, as they may indicate a vitamin B12 deficiency:
o extreme fatigue or lack of energy
o feeling of pins and needles
o sore or red tongue, mouth ulcers
o muscle weakness
o disturbed vision
o memory problems, confusion, depression
• if you are using HIV protease inhibitors such as atazanavir (for the treatment of an HIV infection) at the same time as this medicine. Consult your doctor for specific advice.
• taking proton pump inhibiting medicines like pantoprazole, especially for a period longer than a year, may slightly increase your risk of breaking your hip, wrist, or spine. Tell your doctor if you have osteoporosis (bone thinning) or if your doctor has told you that you are at risk of osteoporosis (for example, because you use steroids).
• if you use this medicine for more than three months, it is possible that the magnesium level in your blood may decrease. A low magnesium level can manifest as fatigue, involuntary muscle contractions, disorientation, seizures, dizziness, and increased heart rate. If you experience any of these symptoms, inform your doctor immediately. Low magnesium levels can also lead to a decrease in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels.
• if you need to undergo a specific blood test (chromogranin A).
• if you have ever had a skin reaction after treatment with a medicine similar to this one that inhibits stomach acid production.

Inform your doctor as soon as possible if you develop a rash, especially on areas exposed to sunlight, as you may need to stop treatment with this medicine. Also, remember to report other side effects such as joint pain.

Consult your doctor immediately, before or after taking this medicine, if you notice any of the following symptoms, which may be a sign of another, more serious condition:

• unintended weight loss

• vomiting, especially if recurrent
• vomiting blood; this may appear as dark coffee grounds in your vomit
• you notice blood in your stool; it may be black or tarry in appearance
• difficulty swallowing or pain when swallowing
• you look pale and feel weak (anemia)
• chest pain
• stomach pain
• severe and/or persistent diarrhea, as this medicine has been associated with a slight increase in diarrhea caused by an infection
• there have been reports of severe skin reactions with the treatment of pantoprazole, including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), and erythema multiforme. Stop using pantoprazole and seek immediate medical attention if you notice symptoms associated with these severe skin reactions described in section 4.

Your doctor may decide that you need to undergo several tests to rule out a malignant disease, as this medicine also relieves the symptoms of cancer; this could delay the diagnosis. If your symptoms persist despite treatment, further investigations will be considered.

If you use this medicine long-term (more than 1 year), your doctor will likely keep you under regular supervision. Each time you visit your doctor, you should report any new and exceptional symptoms and details.

Children and adolescents

This medicine is not recommended for use in children, as efficacy has not been proven in children under 12 years of age.

Are you taking any other medicines?

Are you using any other medicines besides Pantoprazole Sandoz 20 mg, have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. This also applies to medicines for which you do not need a prescription.

This is because pantoprazole can affect the action of other medicines. Therefore, tell your doctor if you are using any of the following medicines:

• medicines such as ketoconazole, itraconazole, and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer), because Pantoprazole Sandoz 20 mg can cause these and other medicines not to work properly.
• warfarin and phenprocoumon, which affect the clotting or thinning of the blood. Additional monitoring tests may be required.
• medicines used to treat HIV infection (such as atazanavir).
• methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer); if you are using methotrexate, your doctor may temporarily stop treatment with Pantoprazole Sandoz 20 mg, as pantoprazole can increase the amount of methotrexate in your blood.

• fluvoxamine (used to treat depression or other psychiatric disorders). If you are using fluvoxamine, your doctor may reduce the dosage.
• rifampicin (used to treat infections).
• St. John's wort (Hypericum perforatum) (used to treat mild depression).

If you need to undergo a specific urine test (for THC, tetrahydrocannabinol), discuss this with your doctor before taking Pantoprazole Sandoz.

Pregnancy, breastfeeding, and fertility

There is insufficient data on the use of this medicine in pregnant women. Excretion in breast milk has been reported.

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

You should only use this medicine if your doctor believes that the benefit to you outweighs the potential risk to 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 such as dizziness and impaired vision, you should not drive vehicles or operate machines.

Pantoprazole Sandoz contains dye and sodium.

Pantoprazole Sandoz 20 mg contains the azo dye Ponceau 4R aluminium carmine (E124), which may cause allergic reactions.

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

3. How do you use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

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 dosage is:

Adults and adolescents from 12 years:

For the treatment of symptoms (e.g., heartburn, acid regurgitation, pain when swallowing) associated with esophageal disease:

The usual dose is one tablet per day. This dose generally provides relief of symptoms within 2-4 weeks, and at the latest after another 4 weeks. Your doctor will tell you how long to continue using the medicine. If symptoms recur, they can be controlled by taking one tablet per day, if necessary.

For the long-term treatment of reflux esophagitis and to prevent reflux esophagitis from returning:

The usual dose is one tablet per day. If the disease recurs, your doctor may double the dose. In this case, you can alternatively use Pantoprazole Sandoz 40 mg tablets, one per day. After healing, you can reduce the dose back to one 20 mg tablet per day.

Adults:

To prevent duodenal ulcers in patients who need to continuously take NSAIDs:

The usual dose is one tablet per day.

Patients with liver problems

If you have severe liver problems, you should not take more than one 20 mg tablet per day.

Use in children and adolescents

These tablets are not recommended for children under 12 years.

Have you used too much of this medicine?

Tell your doctor or pharmacist. No symptoms of overdose are known.

Have you forgotten to use this medicine?

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 using this medicine

Do not stop taking these tablets without first consulting your doctor or pharmacist.

Do you have any other questions about the use of this medicine? Then contact your doctor, pharmacist, or nurse.

4. Possible side effects

Like any medicine, this medicine can cause side effects. Not everyone experiences them.

If you experience any of the following side effects, you should stop taking these tablets and immediately inform your doctor or contact the Emergency Department of the nearest hospital:

• Severe allergic reactions (frequency rare: occur in less than 1 in 1000 users): swelling of the tongue and/or throat, difficulty swallowing, hives (urticaria), breathing difficulties, allergic swelling of the face (Quincke's edema/angioedema), severe dizziness with a very fast heartbeat and heavy sweating
• Severe skin conditions (frequency unknown: cannot be estimated from the available data): You may experience one or more of the following symptoms:
o blistering of the skin and rapid deterioration of your general health, superficial damage (including slight bleeding) of the eyes, nose, mouth/lips or genitals, or sensitivity of the skin/rash especially on skin exposed to light/sun. You may also experience joint pain or flu-like symptoms, fever, swollen lymph nodes (e.g., in the armpit), and blood tests may show changes in some white blood cells or liver enzymes.
o reddish, flat, ring-shaped or round spots on the trunk, often with a blister in the center, peeling skin, sores in the mouth, throat, nose, and on the genitals and eyes. This severe skin rash may be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
o widespread rash, high body temperature, and enlarged lymph nodes (DRESS syndrome or drug-induced hypersensitivity syndrome) and sensitivity to light.
• Other serious conditions (frequency unknown): yellowing of the skin or whites of the eyes (severe liver cell damage, jaundice) or fever, rash, and enlarged kidneys, sometimes with pain when urinating and lower back pain (severe kidney inflammation), possibly leading to kidney failure

Other possible side effects include:

• Common (may affect 1 in 10 users) benign stomach polyps
• Uncommon (may affect less than 1 in 100 users) headache; dizziness; diarrhea; feeling sick, vomiting; bloated stomach and flatulence; constipation; dry mouth; pain and discomfort in the upper abdomen; outbreak of itchy skin rash (rash/exanthema/eruptions); itching; feeling weak, exhausted or unwell; sleep problems; fractures of the hip, wrist, or spine
• Rare (may affect less than 1 in 1000 users) distortion of or total lack of sense of taste; impaired vision, such as blurred vision; hives (urticaria); joint pain; muscle pain; changes in weight; increased body temperature; high fever; swollen arms and/or legs (peripheral edema); allergic reactions; depression; breast enlargement in men
• Very rare (may affect less than 1 in 10,000 users) disorientation
• Unknown (frequency cannot be estimated from the available data) hallucinations, confusion (especially in patients with a history of these symptoms), tingling, prickling sensation, numbness, burning sensation or numbness, rash, possibly with joint pain; inflammation of the colon, causing persistent watery diarrhea

Side effects identified by blood tests:

• Sometimes (may occur in less than 1 in 100 users) an increase in liver enzymes
• Rarely (may occur in less than 1 in 1,000 users) an increase in bilirubin levels; increased fat levels in the blood; severe decrease in circulating white blood cells (granulocytes), accompanied by high fever
• Very rarely (may occur in less than 1 in 10,000 users) a decrease in the number of platelets, which may lead to more bleeding than normal or more frequent bruising; a decrease in the number of white blood cells, which may lead to more frequent infections; simultaneous abnormal decrease in the number of white and red blood cells and platelets
• Not known (frequency cannot be determined from the available data) lower sodium, magnesium, calcium, or potassium in the blood (see section 2).

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the box after "EXP.:". It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine.

Do not use this medicine if 6 months have passed since first opening the jar.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

• The active substance in this medicine is pantoprazole. Each gastro-resistant tablet contains 20 mg pantoprazole (as sodium sesquihydrate).
• The other substances in this medicine are:
Tablet core: calcium stearate, microcrystalline cellulose, crospovidone (type A), hydroxypropylcellulose (type EXF), anhydrous sodium carbonate, anhydrous colloidal silica.
Coating: hypromellose, iron oxide yellow (E172), macrogol 400, methacrylic acid-ethyl acrylate copolymer (1:1), polysorbate 80, Ponceau 4R aluminium lake (E124), quinoline yellow aluminium lake (E104), sodium lauryl sulfate, titanium dioxide (E171), triethyl citrate.

What does Pantoprazol Sandoz 20 mg look like and what is in a package?

Gastro-resistant tablets

Pantoprazole Sandoz 20 mg, gastro-resistant tablets are yellow, oval tablets (coated with a special layer), approximately 8.9 x 4.6 mm and available in:

blister packs with 7, 10, 14, 15, 20, 28, 30, 50, 56, 56x1, 60, 84, 90, 98, 100, 100x1, 140, 168 tablets

containers with 14, 28, 56, 98, 100, 105, 250 or 500 tablets.

Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder:
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Netherlands

Manufacturers:
Salutas Pharma GmbH
Otto-von-Guericke Allee 1
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Registered under

Pantoprazole Sandoz 20 mg, gastro-resistant tablets is registered under RVG 33657.

This medicine is registered in member states of the European Economic Area under the following names

Netherlands: Pantoprazole Sandoz 20 mg, gastro-resistant tablets
Austria: Pantoprazole Sandoz 20 mg Magensaftresistente tabletten
Belgium: Pantoprazole 20 mg gastro-resistant tablets
Germany: Pantoprazole Sandoz 20 mg magensaftresistente Tabletten
Denmark: Pantoprazole Sandoz
Greece: Ozepran
Spain: PANTOPRAZOL SANDOZ 20 mg gastro-resistant tablets EFG
Finland: Pantoprazole Sandoz 20 mg enteric-coated tablets
France: Pantoprazole Sandoz 20 mg, gastro-resistant tablet
Italy: PANTOPRAZOLO SANDOZ 20 mg gastro-resistant tablets
Norway: Pantoprazole Sandoz 20 mg enteric-coated tablets
Poland: IPP 20
Portugal: PANTOPRAZOL SANDOZ, GASTRO-RESISTANT TABLETS 20 mg
Sweden: Pantoprazole Sandoz 20 mg enteric-coated tablets
Slovenia: ACIPAN 20 mg gastro-resistant tablets
Slovakia: Pantoprazole Sandoz 20 mg, gastro-resistant tablets
United Kingdom: Pantoprazole 20 mg Gastro-resistant Tablets

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