LEAFLET: INFORMATION FOR THE PATIENT
Pantoprazole Sandoz® 40 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 questions? Please contact your doctor, pharmacist, or nurse.
- Do not pass this medicine on to others, as it is prescribed only for you. It may harm others, even if their symptoms are the same as yours.
- If you experience any side effects listed in section 4, or if you notice any side effects not listed in this leaflet, please contact your doctor, pharmacist, or nurse.

Contents of this leaflet

1. What is Pantoprazole Sandoz 40 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:

- Reflux esophagitis: an inflammation of your esophagus (the connection between your throat and your stomach), accompanied by the backflow of stomach acid.

This medicine is used to treat adults for:

- An infection with a bacterium called Helicobacter pylori in patients with duodenal and stomach ulcers, in combination with two antibiotics (eradication treatment). The goal is to eliminate the bacteria and thereby reduce the chance of these ulcers returning.
- Stomach ulcers and duodenal ulcers.
- Zollinger-Ellison syndrome and other conditions where too much acid is produced in the stomach.

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.

• You are allergic to medicines that contain 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. In case of an increase in liver enzymes, the treatment should be stopped.
• if you have reduced body reserves or risk factors for reduced vitamin B12 levels and you are treated with pantoprazole for a long time. 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 HIV infection). 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 are using 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, tell 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 medicine that inhibits the production of stomach acid.

Tell 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 repeated
• vomiting blood; this may appear as dark coffee grounds in your vomit
• you notice blood in your stool; which 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 some 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 (longer than 1 year), your doctor will likely keep you under regular surveillance. 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 taking any other medicines besides Pantoprazole Sandoz 40 mg, have you recently done so, or is there a possibility that you will take 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 Sandoz 40 mg can affect the action of other medications. Therefore, tell your doctor if you are using any of the following medications:

• medications such as ketoconazole, itraconazole, and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer), because Pantoprazole Sandoz 40 mg can cause these and other medications to not work properly.
• warfarin and phenprocoumon, which affect the clotting or thinning of the blood. Additional monitoring tests may be necessary.
• medications 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 40 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 medication 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 medication.

You should only use this medication if your doctor believes that the benefit to you outweighs the potential risk to your unborn child or baby.

Driving and using machines

This medication has no or negligible influence on the ability to drive and use machines.

If you experience side effects such as dizziness and disturbed vision, you should not drive vehicles or operate machines.

Pantoprazole Sandoz contains dye and sodium.

Pantoprazole Sandoz 40 mg contains the azo dye Ponceau 4R aluminium carmine (E124), which can cause allergic reactions.

This medication contains less than 1 mmol sodium (23 mg) per gastro-resistant tablet, which means it is essentially “sodium-free”.

3. How do you use this medication?

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 reflux esophagitis:

The usual dose is one tablet per day. Your doctor may tell you to switch to 2 tablets per day. The treatment duration for reflux esophagitis is usually between 4 and 8 weeks. Your doctor will tell you how long you need to take your medicine.

Adults:

For the treatment of an infection with a bacterium called Helicobacter pylori in patients with duodenal ulcers and stomach ulcers, in combination with two antibiotics (eradication treatment):

One tablet twice a day, plus two antibiotic tablets: either amoxicillin or clarithromycin or metronidazole (or tinidazole), which you should take twice a day each along with your pantoprazole tablet. Take the first pantoprazole tablet 1 hour before breakfast and the second pantoprazole tablet 1 hour before your evening meal. Follow your doctor's instructions and make sure to read the leaflets of these antibiotics. The usual treatment duration is 1-2 weeks.

For the treatment of stomach ulcers and duodenal ulcers:

The usual dose is one tablet per day. After consulting your doctor, the dose may be doubled. Your doctor will tell you how long to continue using the medicine. The treatment duration for stomach ulcers is usually between 4 and 8 weeks. The treatment duration for duodenal ulcers is usually between 2 and 4 weeks.

For the long-term treatment of Zollinger-Ellison syndrome and other conditions where too much stomach acid is produced:

The recommended starting dose is usually two tablets per day. Take the two tablets 1 hour before a meal. Your doctor may adjust the dose later, depending on the amount of stomach acid you produce. If more than two tablets per day are prescribed, take the tablets divided over two intakes.

If your doctor prescribes a dose of more than four tablets per day, he or she will tell you exactly when to stop using the medicine.

Patients with kidney problems

If you have kidney problems, or moderate or severe liver problems, you should not take this medicine for the eradication of Helicobacter pylori.

Patients with liver problems

If you have severe liver problems, you should not take more than 20 mg pantoprazole per day (for this purpose, tablets with 20 mg pantoprazole are available). If you have moderate or severe liver problems, you should not take this medicine for the eradication of Helicobacter pylori.

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.

Did you forget 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 using these tablets without first consulting your doctor, pharmacist, or nurse.

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 not known: 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 not known): 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 side effects are:

• Common (may affect 1 in 10 users) benign stomach polyps
• Uncommon (may affect less than 1 in 100 users) headache; dizziness; diarrhea; feeling nauseous, 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 vertebrae
• Rare (may affect less than 1 in 1,000 users) distortion or total lack 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
• Not known (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 through blood tests:

• Sometimes (may affect less than 1 in 100 users) an increase in liver enzymes.
• Rare (may affect 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 rare (may affect 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 red and white blood cells and platelets
• Not known (frequency cannot be estimated from the available data) low sodium, magnesium, calcium, or potassium in the blood (see section 2).

Reporting of side effects

If you experience side effects, contact your doctor, pharmacist, or nurse. 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 this 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 package and other information

What substances are in this medicine?

• The active substance in this medicine is: pantoprazole. Each gastro-resistant tablet contains 40 mg pantoprazole (as sodium sesquihydrate).
• The other substances in this medicine are:
Tablet core: calcium stearate, microcrystalline cellulose, crospovidone (type A), hydroxypropyl cellulose (type EXF), anhydrous sodium carbonate, anhydrous colloidal silicon.
Coating: hypromellose, iron oxide yellow (E172), macrogol 400, methacrylic acid-ethyl acrylate copolymer (1:1), polysorbate 80, Ponceau 4R aluminium carmine (E124), quinoline yellow aluminium carmine (E104), sodium lauryl sulfate, titanium dioxide (E171), triethyl citrate.

What does Pantoprazole Sandoz 40 mg look like and what is in a package?

Gastro-resistant tablets

Pantoprazole Sandoz 40 mg, gastro-resistant tablets are yellow, oval tablets (coated with a special layer), approximately 11.7 x 6.0 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 40 mg, gastro-resistant tablets - RVG 33658.

This medicine is registered in member states of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names

Netherlands: Pantoprazole Sandoz 40 mg, gastro-resistant tablets
Austria: Pantoprazole Sandoz 40 mg gastro-resistant tablets
Belgium: Pantoprazole 40 mg gastro-resistant tablets
Germany: Pantoprazole Sandoz 40 mg gastro-resistant tablets
Denmark: Pantoprazole Sandoz
Greece: Ozepran
Spain: Pantoprazole Sandoz 40 mg gastro-resistant tablets EFG
Finland: Pantoprazole Sandoz 40 mg enteric-coated tablets
France: Pantoprazole Sandoz 40 mg, gastro-resistant tablet
Italy: PANTOPRAZOLE SANDOZ 40 mg gastro-resistant tablets
Norway: Pantoprazole Sandoz 40 mg enteric-coated tablets
Poland: IPP 40
Portugal: Pantoprazole Sandoz, 40 mg gastro-resistant tablets
Sweden: Pantoprazole Sandoz 40 mg enteric-coated tablets
Slovenia: ACIPAN 40 mg gastro-resistant tablets
Slovakia: Pantoprazole Sandoz 40 mg, gastro-resistant tablets
United Kingdom (Northern Ireland): Pantoprazole 40 mg Gastro-resistant Tablets

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