

PACKAGE LEAFLET: Information for the patient

PANTOFREN

Gastro-resistant film-coated tablets – 40 mg

(Pantoprazole sodium sesquihydrate)

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further 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 symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

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1. WHAT PANTOFREN IS AND WHAT IT IS USED FOR

Pantofren contains pantoprazole, which is a drug that reduces acid production in the stomach (selective proton pump inhibitor).

Pantofren is used in adults and adolescents 12 years of age and above:

- in the treatment of moderate and severe forms of gastro-oesophageal reflux (inflammation of the gullet);

Pantofren is used in adults:

- in the treatment of gastric ulcer;
- in the treatment of duodenal ulcer;
- combined with antibiotics in the eradication of *Helicobacter pylori*;
- in the long-term treatment of conditions whereby the stomach produces hydrochloric acid in large quantities (e.g. Zollinger-Ellison syndrome).

2. BEFORE YOU TAKE PANTOFREN

Do not take Pantofren if:

- you are hypersensitive to the active substance pantoprazol or to any of the excipients of Pantofren gastro-resistant tablets;
- you are hypersensitive to medicines containing other proton pump inhibitors;
- you are taking atazanavir (for the treatment of HIV), because the concentration of the last one decreases;
- you are under 12 years old.

Take special care with Pantofren

Please contact your doctor immediately if you experience any of the following symptoms, which may be a sign of another more serious illness:

- unintentional weight loss,
- recurrent vomiting,
- pain on swallowing,
- hematemesis (vomiting blood),
- you look pale and feel weak (anaemia),
- if you have noticed blood in your stools or very dark stools;
- chest pain,
- stomach pain,
- severe and/or persistent diarrhoea because this medicine is associated with a small increase in infectious diarrhoea.

Ask your doctor before taking Pantofren if:

- you suffer from severe hepatic disorders, because dosage reduction may be necessary; monitor regularly the hepatic enzymes during treatment with Pantofren, especially during long-term treatment, because if the concentration of these enzymes increases, treatment should be stopped;
- you have ever had vitamin B12 deficiency and receive long-term treatment with pantoprazole; as with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B12;
- you are taking a HIV protease inhibitors such as atazanavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice;
- gastric ulcer is suspected to be present or if it is present, because malignancy should be excluded, as treatment with Pantofren may alleviate symptoms and delay diagnosis; your doctor may possibly perform additional diagnostics (e.g. gastroscopy = the visual inspection of the gullet, stomach and of the upper part of the intestine); please tell your doctor if your symptoms persist, despite adequate treatment with this medicine;
- 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 Pantofren 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 Pantofren. Remember to also mention any other ill-effects like pain in your joints.

If you use Pantofren 40 mg for longer than 3 months, possibly the content of magnesium in the blood decreases. Low levels of magnesium may provide: exhaustion, involuntary muscular contractions, perturbation, convulsions, dizziness and increased heart frequency. If any of these symptoms appears to you, tell your doctor immediately. Your doctor may recommend you to perform blood tests regularly to monitor magnesium levels. Low levels of magnesium may cause decrease of potassium and calcium values in the blood.

Taking proton pump inhibitors such as Pantofren, may slightly increase the risk for hip, wrist and spine fractures, especially if the drug is taken for a long time, more than a year. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (these drugs increase the risk of osteoporosis).

If you take Pantofren for a long time (more than 1 year), your doctor may keep you under regular control. You should refer any new or special symptom and circumstance whenever you see your doctor.

This medicine may affect the way that your body absorbs vitamin B12, particularly if you need to take it for a long time. 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.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Pantofren. Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Pantofren if you have been given any other medicine during treatment, especially the following:

- medicines for the treatment of fungal infections (e.g. ketoconazole, itraconazole, posaconazole) and other medicines, for which is known that their blood levels depend on acid secretion in the stomach;
- erlotinib (used to treat certain types of cancer);
- medicines for blood thinning (coumarin derivatives, like phenprocoumon or warfarin), in which case monitoring of blood clotting ability is recommended;

- atazanavir for the treatment of HIV infection; this drug should not be taken concomitantly with Pantofren;
- methotrexate (used to treat rheumatoid arthritis, psoriasis and cancer); if you are taking methotrexate your doctor may temporarily stop your treatment with Pantofren 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).

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, if you think you are pregnant or intend to become pregnant, ask your doctor or pharmacist for advice before using this medicine.

There are no adequate data on the use of Pantofren during pregnancy.

Excretion into milk has been reported.

Avoid its use during pregnancy and breast-feeding until the benefit of the treatment outweighs the risks for the foetus or baby.

Driving and using machines

Pantofren has no influence, or negligible influence on the ability to drive and use machines.

However, the appearance of some side effects like dizziness and blurred vision may affect the ability to react during driving, therefore do not drive and use machines if these effects appear.

Important information about some of the excipients of Pantofren

This drug contains maltitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains the azo colouring agent Sunset yellow FCF (E 110). It may cause allergic reactions.

3. HOW TO TAKE PANTOFREN

Always take Pantofren exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the tablets as whole (not chewed and not crushed) with a glass of water.

Treatment of gastro-oesophageal reflux

The therapy is given for adults and children over 12 years old.

The usual dose for the treatment of gastro-oesophageal reflux is 1 tablet 40 mg daily. In individual cases and especially in cases where other therapies have so far failed, the dose can increase up to 2 tablets daily.

Treatment of gastric and duodenal ulcer

The therapy is given for adults.

The usual dose for the treatment of peptic ulcer is 1 tablet 40 mg daily. In individual cases, especially in patients where other therapies have so far failed, the dose may increase to 40 mg twice daily.

*Combined treatment with antibiotics for the eradication of *Helicobacter pylori* in the treatment of gastric and duodenal ulcer*

The therapy is given for adults.

For the eradication of *Helicobacter pylori*, Pantofren should be combined with two antibacterials in a one-week triple therapy regimen. The effective regimen includes Pantofren 40 mg twice daily combined with clarithromycin 500 mg twice daily and amoxicilline 1 g twice daily, or combined with clarithromycin 250 - 500 mg twice daily and metronidazole 400 - 500 mg (or 500 mg tinidazole) twice daily; or combined with 400 - 500 mg metronidazole (or 500 mg tinidazole) and 1g amoxicillin twice daily.

Take the first Pantofren tablet 1 hour before your breakfast meal and the second tablet 1 hour before your evening meal. Follow your doctor's instructions and make sure you read the package leaflets for these antibiotics.

Zollinger-Ellison syndrome

The therapy is given for adults.

The initial recommended dose is 2 tablets 40 mg daily. Take the tablets 1 hour before the meal. Thereafter, the dose may be adjusted according to the level of gastric secretion. Higher doses than 80 mg daily, should be given in two divided doses. For a limited period and in individual cases, the daily dose may increase up to 160 mg.

Patients with severe hepatic impairment

If you suffer from severe liver problems, you should not take more than 20 mg pantoprazole daily.

If you suffer from moderate or severe liver problems, you should not take Pantoprazole for eradication of *Helicobacter pylori*.

Patients with renal impairment

In patients with renal impairment, a dosage adjustment is usually not required. The maximal dose that should be taken is 40 mg daily.

If you have kidney problems, you should not take Pantofren for eradication of *Helicobacter pylori*.

Elderly

In elderly patients, the daily dose is 40 mg. This dosage should not be exceeded.

Children under 12 years of age

There is no experience on the treatment of children under 12 years of age.

How long you should take Pantofren gastro-resistant tablets 40 mg

If you are being treated concomitantly with antibiotics, you should take 2 tablets of Pantofren 40 mg every day for 7 days; this can be extended to a maximum of 2 weeks. Then you should take 1 tablet of Pantofren 40 mg daily until the ulcer is completely healed.

Duodenal ulcers are usually healed within two weeks. If the two-week course of treatment is not sufficient, healing will be achieved in almost all cases within two other weeks of treatment.

For gastric ulcers and gastro-oesophageal reflux, a four-week course of treatment is required in most cases. If this is not sufficient, healing will be achieved in most cases within four weeks of further treatment.

In patients, where too much stomach acid is produced (Zollinger-Ellison syndrome), there are no limits on the duration of treatment, which should continue for as long as it is required.

If you do not respond to the treatment after four weeks, you should talk to your doctor who will decide whether a further prolongation of the treatment will be necessary.

If you take more Pantofren than you should

If you take more Pantofren than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

There is no information available on the effects of overdose in humans. However, if you notice signs of intoxication, please inform your doctor. Depending on the dose taken and/or symptoms that occur, your doctor will decide on the next course of action to be taken.

If you forget to take Pantofren

If you forget a dose (or more doses), take the following dose when it is time to take it usually. Do not take a double dose (or higher) to make up for a forgotten dose(s).

If you stop taking Pantofren

Always talk to your doctor, before stopping treatment with Pantofren 40 mg on your own initiative or before treatment is finished.

If you have any further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Pantofren may cause side effects, although not everybody manifests them. The frequency of the possible side effects is shown in the table below:

Very common	Occur in more than 1 in 10 users
Common	Occur in less than 1 in 10, but more than 1 in 100 users
Uncommon	Occur in less than 1 in 100, but more than 1 in 1,000 users
Rare	Occur in less than 1 in 1,000, but more than 1 in 10,000 users
Very rare	Occur in less than 1 in 10,000 users
Not known	Frequency cannot be estimated from the available data

Significant side effects

Please stop taking Pantofren immediately and tell your doctor if any of the following symptoms occurs to you:

- **serious allergic reactions (frequency rare):** swelling of the face, tongue and throat, difficulty on swallowing, rash, difficulty breathing, severe dizziness with increased pulse rate and sweating;
- **serious skin effects (frequency not known):** skin reactions with blistering or skin ulcerations and hives, rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals particularly in areas of skin exposed to light/the sun; 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 (Stevens-Johnson-Syndrome, Lyell Syndrome, Erythema multiforme, Subacute cutaneous lupus erythematosus, Drug reaction with eosinophilia and systemic symptoms (DRESS)) and sensitivity to light;
- **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 possible side effects

Common: benign polyps in the stomach.

Uncommon: headache, upper abdominal pain, diarrhoea, constipation, dry mouth, flatulence, dizziness, nausea, vomiting, fatigue, sleep disorders, allergic reactions e.g. itching and skin rash, bone fractures (in the hip, wrist or in the spine), increased liver values.

Rare: visual disturbances e.g. blurred vision, agranulocytosis, pain of the joints, hives, muscle pains, weight changes, increased body temperature, swelling of the extremities (peripheral oedema), hypersensitivity (severe allergic reactions, which are manifested as acute general symptoms such as rapid pulse, excessive sweating and substantial drop in blood pressure), gynaecomastia, taste disturbances, depression, bilirubin increased, hyperlipidemia.

Very rare: disorientation, leucopenia (which increases the risk of infections), thrombocytopenia (which increases the risk of bruises and bleeding), leucocytosis, pancytopenia.

Frequency not known: hallucinations and confusion especially in patients having a tendency to these symptoms as well as their worsening in the case they are already present, inflammation in the large bowel, that causes persistent watery diarrhoea, rash, possibly with pain in the joints, hyponatremia, decreased magnesium, calcium or potassium level in blood, feeling of tingling, prickling, pins and needles, burning sensation or numbness (paraesthesia).

By decreasing gastric acidity, Pantofren may increase the risk of gastro-intestinal infections (including *C. difficile*).

If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PANTOFREN

Keep out of the reach and sight of children.

Do not use Pantofren after the expiry date which is stated on the carton box.

Store below 25°C

Store in the original packaging.

6. FURTHER INFORMATION

What Pantofren 40 mg gastro-resistant film-coated tablets contain

The **active substance** is pantoprazole sodium sesquihydrate.

Each gastro-resistant film-coated tablet contains 45.15 mg pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole.

The **excipients**:

core of the tablet: maltitol, crospovidone, croscarmellose sodium, sodium carbonate anhydrous, calcium stearate, magnesium stearate;

film coating: polyvinyl alcohol, titanium dioxide, macrogol, talc, methacrylic acid copolymer, yellow iron oxide, triethyl citrate, sunset yellow FCF (E 110), silica, sodium bicarbonate, sodium lauryl sulfate.

Content of the pack: carton box with 14 gastro-resistant tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

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