

Package leaflet: Information for the patient

Lansoprazole Krka 15 mg gastro-resistant capsules, hard Lansoprazole Krka 30 mg gastro-resistant capsules, hard lansoprazole

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 or 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lansoprazole Krka is and what it is used for
2. What you need to know before you take use Lansoprazole Krka
3. How to take Lansoprazole Krka
4. Possible side effects
5. How to store Lansoprazole Krka
6. Contents of the pack and other information

1. What Lansoprazole Krka is and what it is used for

The active ingredient in Lansoprazole Krka is lansoprazole, which is a proton pump inhibitor. Proton pump inhibitors reduce the amount of acid that your stomach makes.

Your doctor may prescribe Lansoprazole Krka for the following indications in adults:

- Treatment of duodenal and stomach ulcer
- Treatment of inflammation in your oesophagus (reflux oesophagitis)
- Prevention of reflux oesophagitis
- Treatment of heartburn and acid regurgitation
- Treatment of infections caused by the bacteria *Helicobacter pylori* when given in combination with antibiotic therapy
- Treatment or prevention of duodenal or stomach ulcer in patients requiring continued NSAID (nonsteroidal anti-inflammatory drugs) treatment (NSAID treatment is used against pain or inflammation)
- Treatment of Zollinger-Ellison syndrome.

Your doctor may have prescribed Lansoprazole Krka for another indication or with a dose different from that which is written in this information leaflet. Please take your medicine in consultation with your doctor.

You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

2. What you need to know before you take Lansoprazole Krka

Do not take Lansoprazole Krka

- if you are allergic (hypersensitive) to lansoprazole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Lansoprazole Krka.

Please tell your doctor if you have serious liver disease. The doctor may have to adjust your dosage.

Your doctor may perform or have performed an additional investigation called an endoscopy in order to diagnose your condition and/or exclude malignant disease.

If diarrhoea occurs during the treatment with Lansoprazole Krka contact your doctor immediately, as Lansoprazole Krka has been associated with a small increase in infectious diarrhoea.

If your doctor has given you Lansoprazole Krka in addition to other medicines intended for the treatment of *Helicobacter pylori* infection (antibiotics) or together with anti-inflammatory medicines to treat your pain or rheumatic disease: please also read the package leaflets of these medicines carefully.

If you take Lansoprazole Krka 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.

Taking a proton pump inhibitor like Lansoprazole Krka, 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 your doctor has told you that you are at risk of getting osteoporosis (for example, if you are taking steroids).

When taking lansoprazole, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

Talk to your doctor before taking lansoprazole:

- if you have low vitamin B₁₂ levels or have risk factors for low vitamin B₁₂ levels and receive long-term treatment with lansoprazole. As with all acid reducing agents, lansoprazole may lead to a reduced absorption of vitamin B₁₂.
- 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 Lansoprazole Krka that reduces stomach acid talk to your doctor before taking Lansoprazole Krka. 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 Lansoprazole Krka. Remember to also mention any other ill-effects like pain in your joints.
- Serious skin reactions [Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS)] have been reported in association with Lansoprazole Krka treatment. Stop using Lansoprazole Krka and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4

Other medicines and Lansoprazole Krka

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

In particular tell your doctor or pharmacist if you are taking medicines containing any of the following active substances as Lansoprazole Krka, may affect the way these medicines work:

- HIV protease inhibitors such as atazanavir and nelfinavir (used to treat HIV)
- methotrexate (used to treat autoimmune disease and cancer)

- ketoconazole, itraconazole, rifampicin (used to treat infections)
- digoxin (used to treat heart problems)
- warfarin (used to treat blood clots)
- theophylline (used to treat asthma)
- tacrolimus (used to prevent transplant rejection)
- fluvoxamine (used to treat depression and other psychiatric diseases)
- antacids (used to treat heartburn or acid regurgitation)
- sucralfate (used for healing ulcers)
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)

Lansoprazole Krka with food and drink and alcohol

For the best results from your medicines you should take Lansoprazole Krka at least 30 minutes before food with a glass of water.

Pregnancy and breast-feeding and fertility

If you are pregnant, 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

Side effects such as dizziness, vertigo, tiredness and visual disturbances sometimes occur in patients taking Lansoprazole Krka . If you experience side effects like these you should take caution as your ability to react may be decreased.

You alone are responsible to decide if you are in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration. Because of their effects or undesirable effects, one of the factors that can reduce your ability to do these things safely is your use of medicines.

Descriptions of these effects can be found in other sections.

Read all the information in this leaflet for guidance.

Discuss with your doctor, nurse or pharmacist if you are unsure about anything.

Lansoprazole Krka contains sucrose and sodium.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

3. How to take Lansoprazole Krka

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

Swallow the capsule whole with a glass of water. If you find the capsules difficult to swallow your doctor may advise on alternative ways to take your medicine. Do not crush or chew these capsules or the content of an emptied capsule because this will stop them from working properly.

If you are taking Lansoprazole Krka once a day, try to take it at the same time each day. You may get best results if you take Lansoprazole Krka first thing in the morning.

If you are taking Lansoprazole Krka twice a day, you should have the first dose in the morning and the second dose in the evening.

The dose of Lansoprazole Krka depends on your condition. The usual doses of Lansoprazole Krka for adults are given below. Your doctor will sometimes prescribe you a different dose and will tell you how long your treatment will last.

Treatment of heartburn and acid regurgitation: one 15 mg or 30 mg capsule for 4 weeks. If your symptoms are not relieved within 4 weeks, please contact your doctor.

Treatment of duodenal ulcer: one 30 mg capsule every day for 2 weeks

Treatment of stomach ulcer: one 30 mg capsule every day for 4 weeks

Treatment of inflammation in your oesophagus (reflux oesophagitis): one 30 mg capsule every day for 4 weeks

Long-term prevention of reflux oesophagitis: one 15 mg capsule every day, your doctor may adjust your dose to one 30 mg capsule every day

Treatment of infection of *Helicobacter pylori*: The usual dose is one 30 mg capsule in combination with two different antibiotics in the morning and one 30 mg capsule in combination with two different antibiotics in the evening. Treatment will usually be every day for 7 days.

The recommended combinations of antibiotics are:

- 30 mg Lansoprazole Krka together with 250–500 mg clarithromycin and 1000 mg amoxicillin
- 30 mg Lansoprazole Krka together with 250 mg clarithromycin and 400–500 mg metronidazole

If you are being treated for infection because you have an ulcer, it is unlikely that your ulcer will return if the infection is successfully treated. To give your medicine the best chance of working, take it at the right time and **do not miss a dose**.

Treatment of duodenal or stomach ulcer in patients requiring continued NSAID treatment: one 30 mg capsule every day for 4 weeks.

Prevention of duodenal or stomach ulcer in patients requiring continued NSAID treatment: one 15 mg capsule every day, your doctor may adjust your dose to one 30 mg capsule every day.

Zollinger-Ellison syndrome: The usual dose is two 30 mg capsules every day to start with, then depending on how you respond to Lansoprazole Krka the dose that your doctor decides is best for you.

Use in children

Lansoprazole Krka should not be given to children.

If you take more Lansoprazole Krka than you should

If you take more Lansoprazole Krka than you have been told to, seek medical advice quickly.

If you forget to take Lansoprazole Krka

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. If this happens skip the missed dose and take the remaining capsules as normal. Do not take a double dose to make up for a forgotten capsule.

If you stop taking Lansoprazole Krka

Do not stop treatment early because your symptoms have got better. Your condition may not have been fully healed and may reoccur if you do not finish your course of treatment.

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

4. Possible side effects

Like all medicines, Lansoprazole Krka can cause side effects, although not everybody gets them.

Stop using Lansoprazole Krka and seek medical attention immediately if you notice any of the following symptoms:

- 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).

The following side effects are common (occur in more than 1 in 100 patients):

- headache, dizziness
- feeling or being sick, diarrhoea, stomach pains, constipation, wind, dry or sore mouth or throat, benign polyps in the stomach
- changes in liver function test values
- skin rash, itching
- tiredness.

The following side effects are uncommon (occur in less than 1 in 100 patients):

- changes in blood cell counts
- depression
- joint or muscle pain, fracture of the hip, wrist or spine
- fluid retention or swelling

The following side effects are rare (occur in less than 1 in 1000 patients):

- anaemia (paleness)
- insomnia, hallucinations, confusion
- restlessness, vertigo, feelings of ants creeping over the skin (paraesthesia), drowsiness, trembling
- visual disturbances
- inflammation of your tongue (glossitis), candidiasis (fungal infection, may affect skin or the mucosa), pancreatitis, a change in the way things taste
- inflammation of the liver (may be seen as yellow skin or eyes)
- skin reactions such as burning or pricking feeling under the skin, bruising, reddening, hair loss
- sensitivity to light
- kidney problems
- breast swelling in males
- fever, excessive sweating, angioedema, loss of appetite, impotence; You should see your doctor immediately if you experience symptoms of angioedema, such as swollen face, tongue or pharynx, difficulty to swallow, hives and difficulties to breath.

The following side effects are very rare (occur in less than 1 in 10000 patients):

- very rarely Lansoprazole Krka may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis)
- Low levels of sodium in the blood. Common symptoms include nausea and vomiting, headache, drowsiness and fatigue, confusion, muscle weakness or spasms, irritability, seizures, coma

- bowel inflammation (colitis), inflammation of your mouth (stomatitis)
- very severe skin reactions with reddening, blistering, severe inflammation and skin loss
- severe hypersensitivity reactions including shock. Symptoms of a hypersensitivity reaction may include fever, rash, swelling and sometimes a fall in blood pressure
- changes in test values such as cholesterol and triglyceride levels

The occurrence of following side effects is not known (cannot be estimated from the available data):

- If you are on lansoprazole 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, 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.
- Visual hallucinations.
- Rash, possibly with pain in the joints.

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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lansoprazole Krka

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 packaging after EXP. The expiry date refers to the last day of that month.

Blisters:

Do not store above 25 °C. Store in the original package in order to protect from moisture.

Containers:

Do not store above 25 °C. Store in the original package. Keep the container (bottle) tightly closed, in order to protect from moisture.

Use the contents within 4 months of opening the container.

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 Lansoprazole Krka contains

- The active substance is lansoprazole.
Each gastro-resistant capsules, hard contains 15 mg or 30 mg of lansoprazole.
- The gastro-resistant capsules, hard also contain sugar granules (sucrose, maize starch), povidone, disodium hydrogen phosphate dihydrate, sodium laurilsulfate, methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 per cent, talc, macrogol, titanium dioxide (E 171), polysorbate 80.
Capsule shell: gelatine, titanium dioxide (E171). The 15 mg capsule also contains red iron oxide (E172). See section 2: »Lansoprazole Krka contains sucrose and sodium«.

What Lansoprazole Krka looks like and contents of the pack

Gastro-resistant capsules, hard 15 mg: white/red-brownish gelatine capsule containing white or light brown or lightly pink enteric-coated pellets.

Gastro-resistant capsules, hard 30 mg: white gelatine capsule containing white, light brown or lightly pink enteric-coated pellets.

Pack sizes:

A plastic container of 14, 28, 56 and 98 capsules. The 98 capsule container contains one silica gel desiccant capsule.

Boxes of 7 (*30 mg*), 14, 28, 49, 56 and 98 capsules in blister packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

This medicine is authorised in the Member States of the European Economic Area under the following names:

Name of the Member State	Name of the medicine
Belgium	Lansoprazol Krka
Ireland	Lansoprazole Krka

This leaflet was last revised in