

Lansoprazole 15 mg,30mg gastro-resistant capsules

What is lansoprazole and what is it used for?

The active ingredient in Lansoprazole is lansoprazole, a proton pump inhibitor. Proton pump inhibitors reduce the amount of stomach acid produced.

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

- Treatment of stomach and intestinal ulcers (ulcer).
- Treatment of inflammation in the esophagus (reflux esophagitis).
- Prevention of reflux esophagitis.
- Treatment of heartburn and acid regurgitation.
- Treatment of infections caused by the bacterium "Helicobacter pylori" when administered in combination with antibiotics.
- Treatment or prevention of stomach and intestinal ulcers (ulcer) in patients who require prolonged NSAID treatment (NSAID treatment is used for pain or inflammation).
- Treatment of Zollinger-Ellison syndrome.

Your doctor may prescribe Lansoprazole for a different indication or at a different dose than specified in this package insert. Follow your doctor's instructions on how to use this medicine. If your symptoms do not improve after 14 days or worsen, contact your doctor.

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

You are allergic (hypersensitive) to lansoprazole or any of the ingredients in this medicine. You can find the ingredients in section 6 of the package leaflet.

When should you be extra careful with this medicine?

- Lansoprazole use may cause inflammation of your kidney. Possible signs and symptoms include reduced urine or blood in your urine, and/or hypersensitivity reactions such as fever, skin rash, and stiff joints. Inform your treating doctor of any such symptoms.
- Inform your doctor if you have a severe liver condition. The doctor may need to adjust the dosage.
- Your doctor may perform additional testing in the form of an endoscopy to make a diagnosis and/or rule out malignant diseases.
- If diarrhea occurs during treatment with Lansoprazole Aurobindo, immediately contact your doctor. The use of Lansoprazole has been associated with a slight increase in infectious diarrhea.
- If your doctor has prescribed Lansoprazole in addition to other drugs intended for the treatment of a Helicobacter pylori infection (antibiotics) or together with anti-inflammatory drugs to treat your pain or rheumatism, we advise you to carefully read the package leaflets of these products as well.
- When using a proton pump inhibitor, such as Lansoprazole Aurobindo, particularly for a period longer than one year, the risk of hip, wrist, or spine fractures may slightly increase. Inform your doctor if you have osteoporosis (bone loss) or if your doctor has told you that you are at risk of developing osteoporosis (e.g. if you use steroids). If you use Lansoprazole for a prolonged period (more than 1 year), you will likely have regular contact with your doctor for monitoring. Report any new and exceptional symptoms and circumstances to your doctor whenever you speak to them.
 - Contact your doctor before using Lansoprazole Aurobindo:
- If you have low vitamin B12 in your blood or risk factors for a vitamin B12 deficiency and are being treated with lansoprazole for a long time. Like all gastric acid-reducing agents, lansoprazole can lead to reduced absorption of vitamin B12.
- If a specific blood test (chromogranin A) needs to be performed.
- If you have ever had a skin reaction after treatment with a drug similar to Lansoprazole that reduces gastric acid.
- If you get a rash on your skin, especially in areas exposed to the sun, tell your doctor as soon as possible, as it may be necessary to stop treatment with Lansoprazole Aurobindo. Don't forget to report any other flu-like symptoms, such as joint pain.

Are you using any other medicines?

Are you using any other medicines besides Lansoprazole Aurobindo, 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 that you can get without a prescription.

Inform your doctor or pharmacist in particular if you are taking medications containing one or more of the active ingredients listed below, as Lansoprazole may affect the effectiveness of these medications:

- HIV protease inhibitors, such as atazanavir and nelfinavir (used for the treatment of HIV).
 - Methotrexate (used for the treatment of autoimmune disease and cancer).
- Ketoconazole, itraconazole, rifampicin (used for the treatment of infections).
- Digoxin (used to treat heart problems).
- Theophylline (used for the treatment of asthma).
- Warfarin (used for the treatment of blood clots).
- Tacrolimus (used to prevent organ transplant rejection).
- Fluvoxamine (used for the treatment of depression and other psychiatric disorders).
- Antacids (used to treat heartburn or acid reflux).
- Sucralfate (used to heal stomach and intestinal ulcers).
- St. John's wort (Hypericum perforatum) (used for the treatment of mild depression).

What to be aware of regarding food and drink?: Take Lansoprazol at least 30 minutes before a meal with a glass of water for best results.

Pregnancy and breastfeeding: Are you pregnant, think you might be pregnant, want to become pregnant, or are you breastfeeding? Contact your doctor or pharmacist before using any medication.

Driving and using machinery: Side effects such as dizziness, fatigue, and blurred vision may occur due to the use of Lansoprazol Aurobindo. If you experience such side effects, be cautious; your reaction time may be decreased. You are responsible for assessing whether you are able to drive a vehicle or perform other tasks that require concentration. The use of medications can be a factor that complicates driving or performing other tasks due to their effects or side effects. You can find descriptions of these effects in other sections of this leaflet. Read all the information in this leaflet for more information. If you have any questions, ask your doctor or pharmacist.

Lansoprazol contains sucrose: Lansoprazol contains sucrose. If your doctor has told you that you cannot tolerate certain types of sugars, contact your doctor before taking this medication.

Lansoprazol contains sodium: This medication contains less than 1 mmol of sodium (23 mg) per capsule, which means it is essentially "sodium-free".

How to use this medication?

Always use this medicine exactly as your doctor has told you. If you are unsure about the correct use, please contact your doctor or pharmacist.

- Swallow the capsule whole with a glass of water. If you have difficulty swallowing the capsules, your doctor may advise you on other ways to take the medicine. Do not crush or chew the capsules or take the contents of an emptied capsule as this can negatively affect the effect of the medicine.
- If you take Lansoprazole once a day, try to take the medicine at around the same time every day. For best results, you should take Lansoprazole in the morning.
- If you take Lansoprazole twice a day, take the first dose in the morning and the second dose in the evening.
- For the best result of your medicine, you should take Lansoprazole at least 30 minutes before a meal.

The dosage of Lansoprazole depends on your condition. Below is the usual dosage of Lansoprazole for adults. Your doctor may prescribe a different dosage and tell you how long the treatment will last.

Treatment of heartburn and acid regurgitation: One 15 mg or 30 mg capsule every day for 4 weeks. Contact your doctor if there is no improvement within 4 weeks.

Treatment of duodenal ulcers: One 30 mg capsule daily for 2 weeks.

Treatment of gastric ulcers: One 30 mg capsule daily for 4 weeks.

Treatment of inflammation in the esophagus (reflux esophagitis): One 30 mg capsule daily for 4 weeks.

Long-term prevention of reflux esophagitis: One 15 mg capsule daily. Your doctor may adjust the dosage to one 30 mg capsule once a day.

Treatment of Helicobacter pylori infection: One 30 mg capsule daily in combination with two different antibiotics in the morning and one 30 mg capsule in combination with two different antibiotics in the evening. Treatment is usually every day for 7 days.

The recommended combinations of antibiotics are:

- 30 mg Lansoprazole with 250-500 mg clarithromycin and 1000 mg amoxicillin.
- 30 mg Lansoprazole with 250 mg clarithromycin and 400-500 mg metronidazole.

If you are being treated for an 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 success, take it at the right time and do not skip a dose.

Treatment of stomach or intestinal ulcers in patients who require prolonged NSAID treatment: Take one 30 mg capsule daily for 4 weeks.

Prevention of stomach or intestinal ulcers in patients who require prolonged NSAID treatment: Take one 15 mg capsule daily. Your doctor may adjust the dosage to one 30 mg capsule once a day.

Zollinger-Ellison syndrome: The usual dosage is two 30 mg capsules as an initial dose and then the dosage prescribed by your doctor, depending on how you respond to Lansoprazole Aurobindo.

Use in children: Lansoprazole should not be given to children.

Have you taken too much of this medicine?

If you have taken more Lansoprazole than you should, seek medical advice immediately.

Did you forget to take this medicine?

If you forget to take a dose, take it as soon as you remember, unless it is almost time for the next dose. In that case, skip the missed dose and take the next capsules as usual. Do not take a double dose to make up for a forgotten capsule.

If you stop taking this medicine: Do not stop the treatment prematurely because the symptoms have disappeared. You may not have fully recovered yet and the symptoms may return if you do not complete your treatment.

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

Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects (may affect up to 1 in 10 people): • Headache, dizziness., • Diarrhea, constipation, stomach pain, nausea, vomiting, flatulence, dry or irritated mouth or throat., • Skin rash, itching., • Changes in liver function test values., • Fatigue, benign polyps in the stomach.

Uncommon side effects (may affect up to 1 in 100 people): • Depression., • Joint or muscle pain., • Fluid retention or swelling., • Changes in blood cell values.

Rare side effects (may occur in up to 1 in 1000 people): • Fever., • Restlessness, drowsiness, confusion, hallucinations, insomnia, blurred vision., • Changes in the taste of food, loss of appetite, inflammation of the tongue (glossitis)., • Skin reactions such as a burning or tingling sensation under the skin, bruising, redness and excessive sweating., • Light sensitivity., • Hair loss., • Feeling like ants crawling on the skin, trembling., Anemia (pallor)., • Kidney problems., • Inflammation of the pancreas (pancreatitis)., • Liver inflammation (indicated by yellow skin or yellow eyes)., • Breast enlargement in men, impotence., • Candidiasis (fungal infection that can affect the skin or mucous membrane)., • Angioedema; contact your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue or throat, difficulty swallowing, hives, and breathing difficulties.

How to store this medicine?

- Keep out of sight and reach of children.
- Do not use this medicine after the expiry date stated on the blister and outer packaging after "Exp.:". The expiry date is stated as a month and a year. The last day of that month is the expiry date.
- Store below 25°C.
- Store in the original packaging to protect from moisture.
- Do not flush medicines down the sink or toilet or throw them in the trash can. Ask your pharmacist what to do with medicines that are no longer needed. They will be disposed of in a responsible manner and will not harm the environment.