

Logo Accord

Package leaflet: Information for the patient

Lansoprazole 15mg, 30mg Gastro-Resistant Capsules

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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Lansoprazole Capsules are and what they are used for**
- 2. What you need to know before you take Lansoprazole Capsules**
- 3. How to take Lansoprazole Capsules**
- 4. Possible side effects**
- 5. How to store Lansoprazole Capsules**
- 6. Contents of the pack and other information**

1. What Lansoprazole Capsules are and what they are used for

The active ingredient in Lansoprazole Capsules 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 Capsules for the following indications:

- 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 non-steroidal anti-inflammatory drug (NSAID) treatment (NSAID treatment is used against pain or inflammation)
- Treatment of Zollinger-Ellison syndrome.

Your doctor may have prescribed Lansoprazole Capsules for another indication or with a dose different from that which is written in this information leaflet. Please follow your doctor's instructions for taking your medicine.

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 Capsules

Do not take Lansoprazole Capsules:

- if you are allergic 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 Capsules.

Talk to your doctor or pharmacist 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 severe or persistent diarrhoea occurs during the treatment with Lansoprazole Capsules, contact your doctor immediately, as Lansoprazole has been associated with a small increase in infectious diarrhoea.

If your doctor has given you Lansoprazole Capsules 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 Capsules 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.

Taking a proton pump inhibitor like Lansoprazole, 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 you are taking corticosteroids (which can increase the risk of osteoporosis).

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.

If you take Lansoprazole Capsules 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.

Talk to your doctor before taking Lansoprazole Capsules:

- 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 Capsules that reduces stomach acid
- if you have low vitamin B12 levels or have risk factors for low vitamin B12 levels.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with lansoprazole treatment. Stop using Lansoprazole Capsules and seek medical attention immediately if you notice any of the symptoms described in section 4.

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 Capsules. Remember to also mention any other ill-effects like pain in your joints.

When taking Lansoprazole Capsules, 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.

Other medicines and Lansoprazole Capsules

Tell your doctor or pharmacist if you are taking, 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 Capsules 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 Capsules with food and drink

For the best results from your medicine you should take Lansoprazole Capsules at least 30 minutes before food.

Pregnancy and breast-feeding

If you are pregnant or 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 Capsules. 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 or pharmacist if you are unsure about anything.

Lansoprazole Capsules contain sucrose

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

Information on sodium content

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

3. How to take Lansoprazole Capsules

Always take this medicine exactly as your doctor 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 Capsules once a day, try to take them at the same time each day. You may get best results if you take Lansoprazole Capsules first thing in the morning.

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

The dose of Lansoprazole Capsules depends on your condition. The recommended doses of Lansoprazole Capsules 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 15mg or 30mg capsule every day for 4 weeks. If symptoms persist you should report to your doctor. If your symptoms are not relieved within 4 weeks, please contact your doctor.

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

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

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

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

Treatment of infection of *Helicobacter pylori*: The recommended dose is one 30mg capsule in combination with two different antibiotics in the morning and one 30mg 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:

- 30mg Lansoprazole together with 250-500 mg clarithromycin and 1000mg amoxicillin
- 30mg Lansoprazole together with 250mg clarithromycin and 400-500mg 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 30mg capsule every day for 4 weeks.

Prevention of duodenal or stomach ulcer in patients requiring continued NSAID

treatment: one 15mg capsule every day, your doctor may adjust your dose to one 30mg capsule every day.

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

Use in children

Lansoprazole Capsules should not be given to children.

If you take more Lansoprazole Capsules than you should

If you take more Lansoprazole Capsules than you have been told to, seek medical advice quickly. Contact your nearest casualty department or tell your doctor or pharmacist at once.

If you forget to take Lansoprazole Capsules

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 Capsules

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

If you get any of the following serious side effects, stop taking Lansoprazole Capsules and tell your doctor immediately, or contact the casualty department at your nearest hospital:

Rare (may affect up to 1 in 1,000 people):

- **angioedema** (symptoms may include swollen face, tongue or pharynx, difficulty to swallow, hives and difficulty breathing)
- **very severe skin reactions** with reddening, blistering, severe inflammation and skin loss (Stevens-Johnson Syndrome, toxic epidermal necrolysis, erythema multiforme)
- **inflammation of the liver** (may be seen as yellow skin or eyes)
- **pancreatitis** (symptoms include sudden intense pains in the middle of the upper abdomen, which may lead to nausea and vomiting)
- **hallucinations**, including visual hallucinations (of unknown frequency).

Very rare (may affect up to 1 in 10,000 people):

- **severe hypersensitivity reactions including anaphylactic shock** (symptoms may include fever, rash, swelling and sometimes a fall in blood pressure)

- a **reduction in the number of white blood cells** which may decrease your resistance to infection. 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).

Not known (frequency cannot be estimated from the available data):

- **severe skin reaction** drug reaction with eosinophilia and systemic systems (DRESS).

Other side effects

Common (may affect up to 1 in 10 people):

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

Uncommon (may affect up to 1 in 100 people):

- depression
- joint or muscle pain
- fluid retention or swelling
- changes in blood cell counts
- fracture of the hip, wrist or spine (see section 2 'Warnings and precautions').

Rare (may affect up to 1 in 1,000 people):

- fever
- restlessness, drowsiness, confusion, insomnia, visual disturbances, vertigo
- a change in the way things taste, loss of appetite, inflammation of your tongue (glossitis)
- skin reactions such as burning or pricking feeling under the skin, bruising, reddening and excessive sweating
- sensitivity to light
- hair loss
- 'pins and needles'/ tingling feeling on the skin (paraesthesia), trembling
- anaemia (paleness)
- kidney problems
- breast swelling in males, impotence
- candidiasis (fungal infection, may affect skin or the mucosa).

Very rare (may affect up to 1 in 10,000 people):

- inflammation of your mouth (stomatitis)
- colitis (bowel inflammation)
- increase in test values such as cholesterol and triglyceride levels
- low levels of sodium in the blood, symptoms include nausea and vomiting, headache, drowsiness and fatigue, confusion, muscle weakness or spasms, irritability, seizures, coma. Your doctor may decide to perform regular blood tests to monitor your levels of sodium.

Not known (frequency cannot be estimated from the available data):

- rash, possibly with pain in the joints

- if you are taking Lansoprazole Capsules 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
- skin-related forms of lupus or a lupus rash.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Lansoprazole Capsules

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from moisture.

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 Capsules contain

- The active substance is lansoprazole. Each capsule contains 15mg or 30mg lansoprazole.
- The other ingredients are:
 - Capsule content: Sugar spheres (sucrose and maize starch), Sodium laurilsulfate, Meglumine, Mannitol (E421), Hypromellose, Macrogol, Talc, Polysorbate 80, Titanium dioxide (E171), Methacrylic Acid-Ethyl Acrylate Copolymer (1:1), Dispersion 30%
 - Capsule shell: Gelatin, Titanium dioxide (E171)
 - Capsule shell of 15mg also contains: Quinoline yellow (E104).

What Lansoprazole Capsules look like and contents of the pack

15 mg gastro-resistant capsules, hard: opaque yellow cap and body capsules. Each capsule contains white or almost white spherical microgranules.

30 mg gastro-resistant capsules, hard: opaque white cap and body capsules. Each capsule contains white or almost white spherical microgranules.

Lansoprazole Capsules are available in blister packs containing 7, 14, 28, 56 or 98 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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