

PACKAGE LEAFLET

Package leaflet: Information for the user
Lansoprazole 15 mg and 30 mg Gastro-resistant Capsules
(lansoprazole)

Read all of 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. 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.

In this leaflet:

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

1. What Lansoprazole is and what it is used for

The active ingredient in Lansoprazole Gastro-resistant 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 for the following conditions:

- 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 treatment (NSAID treatment is used against pain or inflammation)
- treatment of Zollinger-Ellison Syndrome.

Your doctor may have prescribed Lansoprazole 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.

2. What you need to know before you take Lansoprazole

Do not take Lansoprazole:

- if you are allergic (hypersensitive) to lansoprazole or any of the other ingredients of Lansoprazole
- if you are taking a medicine containing the active substance atazanavir (used in the treatment of HIV)
- if you have ever had a skin reaction after treatment with a medicine similar to Lansoprazole that reduces stomach acid.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lansoprazole, if:

- you have serious liver disease. The doctor may have to adjust your dosage
- you are due to have a specific blood test (Chromogranin A).

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 contact your doctor immediately, as Lansoprazole has been associated with a small increase in infectious diarrhoea.

If your doctor has given you Lansoprazole 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 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.

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

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 or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

- ketoconazole, itraconazole, rifampicin (used to treat infection)
- digoxin (used to treat heart problems)
- 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).

Taking Lansoprazole with food and drink

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

Pregnancy and breast-feeding

If you are pregnant, breast-feeding or if there is a chance you might be pregnant 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. If you experience side effects like these you should take care 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.

Important information about some of the ingredients of Lansoprazole

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

3. How to take Lansoprazole

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

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

The dose of Lansoprazole depends on your condition. The usual doses of Lansoprazole 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 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 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 together with 250-500 mg clarithromycin and 1000 mg amoxicillin.

30 mg Lansoprazole 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 the dose that your doctor decides is best for you.

Lansoprazole should not be given to children.

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

If you take more Lansoprazole than you should

If you take more Lansoprazole than you have been told to, seek medical advice quickly or consult the Toxicological Information Service.

If you forget to take Lansoprazole

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

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 product, ask your doctor or pharmacist.

4. Possible side effects

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

Tell your doctor **immediately** if you notice any of the following serious side effects – you may need urgent medical treatment:

- skin reactions such as burning or pricking feeling under the skin, bruising, reddening and excessive sweating
- angioedema; you should see your doctor immediately if you experience symptoms of angioedema, such as swollen face, tongue or pharynx, difficulty swallowing, hives and difficulty breathing
- severe hypersensitivity reactions including shock. Symptoms of a hypersensitivity reaction may include fever, rash, swelling and sometimes a fall in blood pressure
- very severe skin reactions with reddening, blistering, severe inflammation and skin loss
- very rarely Lansoprazole 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 done to check possible reduction of white blood cells (agranulocytosis)

- 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.

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

- benign polyps in the stomach
- 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.

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

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

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

- fever
- restlessness, drowsiness, confusion, hallucinations, insomnia, visual disturbances, vertigo
- a change in the way things taste, loss of appetite, inflammation of your tongue (glossitis)
- sensitivity to light
- hair loss
- pins and needles (paraesthesia), trembling
- anaemia (paleness)
- kidney problems
- pancreatitis
- inflammation of the liver (may be seen as yellow skin or eyes)
- breast swelling in males, impotence
- candidiasis (fungal infection, may affect skin or the mucosa).

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

- inflammation of your mouth (stomatitis)
- colitis (bowel inflammation)
- changes in test values such as sodium, cholesterol and triglyceride levels.

The frequency of the following side effects is not known:

- rash, possibly with pain in the joints.
- visual hallucinations.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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

Keep out of the reach and sight of children.

Do not use Lansoprazole after the expiry date which is stated on the blister and carton. 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Lansoprazole contains

- The active substance is lansoprazole. Each gastro-resistant capsule contains either 15 mg or 30 mg of lansoprazole.
- The other ingredients are sugar spheres (maize starch, sucrose and purified water), sodium laurilsulphate, meglumine, mannitol (E421), hypromellose, macrogol 6000, talc, polysorbate 80, titanium dioxide (E171) and methacrylic acid-ethyl acrylate copolymer. The capsule shell contains gelatin, titanium dioxide (E171) and purified water. The 15 mg capsules also contain Quinoline Yellow (E104).

What Lansoprazole looks like and contents of the pack

The 15 mg gastro-resistant capsules are yellow and the 30 mg gastro-resistant capsules are white. They both contain white to off-white microgranules (beads).

Lansoprazole 15 mg and 30 mg gastro-resistant capsules are available in 28 and 98 capsule calendar packs and blister packs of 7, 14, 15, 28, 30, 35, 36, 56, 60 and 98 capsules. Not all pack sizes may be marketed. Your pharmacist will dispense the number of capsules prescribed by your doctor.

Marketing Authorisation Holder:

Mylan, Potters Bar, Hertfordshire, EN6 1TL, UK

Manufacturer

Generics [UK] Ltd, Potters Bar, Hertfordshire, EN6 1TL, UK

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