

Package Leaflet : Information For the patient

LANSOPRAZOLE 15 MG & 30 MG [AND ASSOCIATED NAMES]

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 of the 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 [and associated names] Capsules are and what they are used for
2. What you need to know before you take Lansoprazole [and associated names] Capsules
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1. What Lansoprazole [and associated names] Capsules are and what they are used for

The active ingredient in Lansoprazole [and associated names] 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 [and associated names] 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 NSAID treatment (NSAID treatment is used against pain or inflammation)
- Treatment of Zollinger-Ellison syndrome.

Your doctor may have prescribed Lansoprazole [and associated names] 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 [and associated names] Capsules

Do not take Lansoprazole [and associated names]:

- if you are allergic to lansoprazole or any of the other ingredients of Lansoprazole [and associated names] (listed in section 6)
- if you are taking a medicine containing the active substance atazanavir (used in the treatment of HIV).

Warnings and precautions

Talk to your doctor or pharmacist before taking Lansoprazole [and associated names] Capsules. 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 [and associated names] contact your doctor immediately, as lansoprazole has been associated with a small increase in infectious diarrhoea.

If your doctor has given you Lansoprazole [and associated names] 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.

Taking a proton pump inhibitor like Lansoprazole Capsules, 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).

If you take Lansoprazole [and associated names] 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.

Children

Lansoprazole [and associated names] should not be given to children.

Other medicines and Lansoprazole [and associated names] Capsules

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

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 infections)
- 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)

Lansoprazole [and associated names] Capsules with food and drink

For the best results from your medicines you should take Lansoprazole [and associated names] at least 30 minutes before food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or 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 [and associated names]. 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 [and associated names] 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 medicine.

3. How to take Lansoprazole [and associated names] Capsules

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

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

The dose of Lansoprazole [and associated names] depends on your condition. The recommended dose of Lansoprazole [and associated names] is 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 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 [and associated names] together with 250-500 mg clarithromycin and 1000 mg amoxicillin

- 30 mg Lansoprazole [and associated names] 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 [and associated names] the dose that your doctor decides is best for you.

Use in children

Lansoprazole [and associated names] should not be given to children.

If you take more Lansoprazole [and associated names] Capsules than you should

If you take more Lansoprazole [and associated names] than you have been told to, seek medical advice quickly.

If you forget to take Lansoprazole [and associated names] 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 [and associated names] 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.

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

- 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 or muscle pain
- fluid retention or swelling
- changes in blood cell counts
- fracture of 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)
- skin reactions such as burning or pricking feeling under the skin, bruising, reddening and excessive sweating
- sensitivity to light
- hair loss
- feelings of ants creeping over the skin (paresthesia), 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)
- angioedema; 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):

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

Frequency not known:

- an autoimmune disease of the skin known as Cutaneous lupus erythematosus

If you are on 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.

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 Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IRL - Dublin , Tel: +353 1 6764971, Fax: +353 1 6767836, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lansoprazole [and associated names] Capsules

Keep this medicine out of the sight and reach of children.
Store below 30°C.

Do not use this medicine after the expiry date that is stated on the label and carton after 'EXP:'. The expiry date refers to the last day of that month.

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 to protect the environment.

6. Contents of the pack and other information

What Lansoprazole [and associated names] Capsules contains

- The active substance is lansoprazole.
- The other ingredients are:
sugar spheres (sucrose and maize starch), sodium starch glycolate (type A), sodium laurilsulfate (type A), povidone (K30), potassium oleate, oleic acid, hypromellose, methacrylic acid - ethyl acrylate copolymer 1:1, triethyl citrate, titanium dioxide (E171), talc, carrageenan, Potassium chloride and carnauba wax.. The printing ink on the capsules contains the following additional ingredients: shellac (lacca), propylene glycol, ammonium hydroxide, potassium hydroxide, black iron oxide (E172).

What Lansoprazole [and associated names] Capsules look like and contents of the pack

Each hard, cellulose capsule has a white cap marked with the letter L and a white body marked with the numbers 15 or 30, depending on the product strength. The capsules contain white to beige gastro-resistant micropellets containing either 15 mg or 30 mg lansoprazole.

Lansoprazole [and associated names] Capsules are supplied in Aluminium/Aluminium blisters of 7, 14, 28, 30, 56 and 98 capsules*.

*Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Portugal	- Lansoprazol Teva 15mg & 30mg Cápsulas gastrorresistentes
United Kingdom	- Lansoprazole 15 & 30 mg Gastro-resistant Capsules
Netherlands	- Lansoprazol 15 & 30 mg Teva Maagsapresistente Capsules
Germany	- Lansoprazol-ratiopharm 15 & 30 mg Magensaftresistente Hartkapseln
Italy	- Lansoprazolo GERMED 15 & 30 mg Capsula Gastroresistente
Ireland	- Lansoprazole 15 & 30 mg Gastro-resistant Capsules

This leaflet was last revised in June 2013

Information highlighted in Grey will only appear in Members States where there is no existing patent