

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lansoprazole 15 mg 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. 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 name of your medicine is Lansoprazole 15mg Gastro-Resistant Capsules (called Lansoprazole Capsules throughout this leaflet). 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 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.

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

Do not take Lansoprazole Capsules:

- If you are allergic (hypersensitive) to lansoprazole or to any of the other ingredients of Lansoprazole Capsules (see 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 Capsules:

- If you have low vitamin B12 levels or have risk factors for low vitamin B12 levels and receive long-term treatment with Lansoprazole Capsules. As with all acid reducing agents, Lansoprazole Capsules may lead to a reduced absorption of vitamin B12. 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 have serious liver disease. The doctor may have to adjust your dosage.

- If 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 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, 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 have ever had a skin reaction after treatment with a medicine similar to Lansoprazole Capsules that reduces stomach acid.

- If you are due to have a specific blood test (Chromogranin A).

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.

If you think any of these apply to you or you are unsure, talk to your doctor or pharmacist before taking lansoprazole. Do this even if they applied only in the past.

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.

Children

Lansoprazole Capsules should not be given to children.

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 if you are taking medicines containing any of the following active substances as Lansoprazole Capsules 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)
- corticosteroids

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 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 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 of 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 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.

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 Lansoprazole capsules 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 it 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 usual 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:** 15mg or 30mg once daily 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:** 30 mg once daily for 2 weeks

**Treatment of stomach ulcer:** 30 mg once daily for 4 weeks

**Treatment of inflammation in your oesophagus (reflux oesophagitis):** 30 mg once daily for 4 weeks

**Long-term prevention of reflux oesophagitis:** 15 mg once daily, your doctor may adjust your dose to 30 mg once daily.

**Treatment of infection of *Helicobacter pylori*:** The usual dose is 30 mg in combination with two different antibiotics in the morning and 30 mg 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:** 30 mg once daily for 4 weeks.

**Prevention of duodenal or stomach ulcer in patients requiring continued NSAID treatment:** 15 mg once daily, your doctor may adjust your dose to 30 mg once daily.

**Zollinger-Ellison syndrome:** The usual dose is 60 mg 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.

Take your medicine exactly as your doctor has told you. You should check with your doctor if you are not sure how to take your medicine.

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.

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 product, ask your doctor.

4. Possible side effects

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

Stop taking lansoprazole and see a doctor or go to a hospital straightaway if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria) This may mean you are having an **allergic reaction** to Lansoprazole capsules.
- You have blistering, peeling or bleeding of the skin around the lips, eyes, mouth, nose and genitals. You may also have flu-like symptoms and a high temperature. These could be signs of something called Stevens-Johnson syndrome
- You get a severe blistering rash in which layers of the skin may peel off to leave large areas of raw exposed skin over the body
- You get symptoms such as: yellowing of your skin or whites of your eyes, tiredness and fever. This may be due to inflammation of the liver or changes in the way your liver is working.

Tell your doctor as soon as possible if:

- You get long lasting diarrhoea and keep being sick. This can happen because lansoprazole lowers the natural acid in your stomach which would normally help to kill the bacteria there. This in turn, can lead to stomach infections
- You have changes in passing water (urine). This may be due to kidney problems or changes in the way your kidneys are working
- You bruise more easily than usual or you get more infections than usual. This could be due to a blood problem
- 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)

The following side effects are 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

The following side effects are uncommon (may affect up to 1 in 100 people):

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

The following side effects are rare (may affect up to 1 in 1,000 people):

- 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 prickling feeling under the skin, bruising, reddening and excessive sweating
- sensitivity to light
- hair loss

- feelings of ants creeping over the skin (paresthesiae), trembling
- anaemia (paleness)
- pancreatitis
- breast swelling in males, impotence
- candidiasis (fungal infection, may affect skin or the mucosa)

The following side effects are very rare (may affect up to 1 in 10,000 people):

- 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

The frequency of the following side effect is not known:

- if you are on lansoprazole for more than three months it is possible that the levels of magnesium in our 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.
- rash, possibly with pain in the joints.
- Visual hallucinations.

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 the Yellow Card Scheme: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lansoprazole Capsules

Keep out of the reach and sight of children. Do not use Lansoprazole Capsules after the expiry date which is stated on the blister and carton (Exp.). The expiry date refers to the last day of that month. HDPE bottle: Use within 6 months of opening.

Blister:

Do not store above 30°C.

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

Bottle:

Do not store above 30°C.

Keep the bottle tightly closed 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 to protect the environment.

6. Contents of the pack and other information

What Lansoprazole Capsules contain

The active substance is lansoprazole. Each capsule of Lansoprazole 15 mg Gastro-Resistant Capsules contains 15mg lansoprazole.

The other ingredients are:

**Capsule content:** Sugar spheres (sucrose and maize starch), Sodium laurilsulfate, Meglumine, Mannitol (E421), Hypromellose, Macrogol 6000, Talc, Polysorbate 80, Titanium dioxide (E171), Methacrylic Acid-Ethyl Acrylate Copolymer (1:1), Dispersion 30%

**Capsule shell:** Gelatin, Titanium dioxide (E171), Quinoline yellow (E104)

What Lansoprazole Capsules look like and contents of the pack

Lansoprazole 15 mg Gastro-Resistant Capsules are opaque yellow capsules. Lansoprazole Capsules are available in packs containing: Blister of 28 capsules. HDPE bottles of 100 capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Laboratorios Liconsa, S.A. C/Dulcinea S/N, 28805 Alcalá de Henares, Madrid, Spain

Manufacturer: LABORATORIOS LICONSA, S.A. Avda Miralcampo, N°7, Poligono Industrial Miralcampo, 19200 Azuqueca de Henares (Guadalajara), Spain

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