

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lansoprazole 15mg Gastro-resistant Capsules (lansoprazole)

Your medicine is available using the above name but will be referred to as Lansoprazole Capsules throughout this leaflet.

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 symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- What Lansoprazole Capsules are and what they are used for
- Before you take Lansoprazole Capsules
- How to take Lansoprazole Capsules
- Possible side effects
- How to store Lansoprazole Capsules
- 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 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. Before you take Lansoprazole Capsules

Do NOT take Lansoprazole Capsules:

- if you are allergic (hypersensitive) to lansoprazole or any of the other ingredients of Lansoprazole Capsules
- if you are taking a medicine containing the active substance atazanavir (used in the treatment of HIV). Lansoprazole Capsules should not be given to children.

Take special care with Lansoprazole Capsules

It is important to:

- Speak with your doctor if you have serious liver disease. The doctor may have to adjust your dosage
- read the package leaflets of any other medicines your doctor has given you intended for the treatment of *Helicobacter pylori* infection (antibiotics) or together with anti-inflammatory medicines to treat your pain or rheumatic disease
- report any new and exceptional symptoms and circumstances whenever you see your doctor if you take Lansoprazole on a long-term basis (longer than 1 year). Your doctor will probably keep you under regular surveillance.
- if you have ever had a skin reaction after treatment with a medicine similar to Lansoprazole Capsules that reduces stomach acid.

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.

Your doctor may perform or have performed an additional investigation called an endoscopy in order to diagnose your condition and/or exclude malignant disease.

Taking other medicines

Please tell your doctor 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 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)
- atazanavir (used in the treatment of HIV). Please refer to section 'Do not take Lansoprazole Capsules'.

Taking Lansoprazole Capsules 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 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, nurse or pharmacist if you are unsure about anything.

Important information about some of the ingredients of Lansoprazole Capsules

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.

3. How to take Lansoprazole Capsules

Swallow the capsule whole with a glass of water. You may get best results if you take Lansoprazole Capsules first thing in the morning, at least 30 minutes before having food.

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.

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 for adults are given below. Your doctor will sometimes prescribe you a different dose and will tell you how long your treatment will last.

If you take Lansoprazole on a long-term basis (longer than 1 year) please refer to section 'Take special care with Lansoprazole Capsules'.

Treatment of heartburn and acid regurgitation:

one 15mg or 30mg 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 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 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 usual dose is two 30mg capsules every day to start with, then depending on how you respond to Lansoprazole the dose that your doctor decides is best for you.

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 improved. 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 can cause side effects, although not everybody will experience them.

If you experience any of the following side effects, seek immediate medical attention:

- swollen face, tongue or throat, difficulty to swallow, hives and difficulties to breath (angiodema)
- severe or persistent diarrhoea, as lansoprazole has been associated with a small increase in infectious diarrhoea
- 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/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).

Other possible side effects are:

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.

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 (paresthesiae), 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):

- 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.

Other side effects, the frequency of which is unknown:

- 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.
- Rash, possibly with pain in the joints.

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).

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 HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@hpra.ie

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**
- Store below 30°C.
- Do not use this medicine after the expiry date (Exp) which is marked on the carton and blister strips. This refers to the last day of that month.
- If your doctor decides to stop your treatment, return any leftover medicine to your pharmacist.
- Do not use this medicine if you notice discoloration, damage or any other signs of deterioration.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any 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 lansoprazole 15mg.

The other ingredients are:

sugar spheres (sucrose and maize starch), sodium starch glycolate (type A), sodium laurilsulfate, 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 contains shellac (lacca), propylene glycol, ammonium hydroxide, potassium hydroxide and black iron oxide (E172).

What Lansoprazole Capsules look like and contents of the pack

Lansoprazole are hard, cellulose capsules with a white opaque cap marked with "L" in black ink and a white opaque body marked with "15" in black ink, filled with white to beige micropellets.

Lansoprazole Capsules are available in packs of 28 capsules.

Manufacturer

Manufactured by: Teva Pharma S.L.U.,
Poligono Industrial Malpica, calle C, Numero 4,
50016 Zaragoza, Spain.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall,
Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park,
Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business
Park, Santry, Dublin 9.

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