

Package leaflet: Information for the user

Lansoprazole Actavis 15 mg gastro-resistant capsules, hard Lansoprazole Actavis 30 mg gastro-resistant capsules, hard Lansoprazole

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

1. What Lansoprazole Actavis is and what it is used for

The active ingredient in Lansoprazole Actavis 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 Actavis 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 Actavis 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 Actavis

Do not take Lansoprazole Actavis:

- if you are allergic to lansoprazole or any of the other ingredients of this medicine (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 Actavis.

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

If your doctor has given you Lansoprazole Actavis 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 Actavis 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 Actavis, 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).

Talk to your doctor before taking Lansoprazole Actavis if you have ever had a skin reaction after treatment with a medicine similar to Lansoprazole Actavis 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 Actavis. Remember to also mention any other ill-effects like pain in your joints.

Tell your doctor before taking this medicine, if you are due to have a specific blood test (Chromogranin A).

Children and adolescents

Lansoprazole Actavis should not be given to children, especially to children less than 1 year of age.

Other medicines and Lansoprazole Actavis

Tell your doctor 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 Actavis 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)

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 Actavis. 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 Actavis contains 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.

3. How to take Lansoprazole Actavis

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 Actavis once a day, try to take it at the same time each day. You may get best results if you take Lansoprazole Actavis first thing in the morning
- If you are taking Lansoprazole Actavis twice a day, you should have the first dose in the morning and the second dose in the evening.

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

The dose of Lansoprazole Actavis depends on your condition. The usual doses of Lansoprazole Actavis 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 Actavis together with 250-500 mg clarithromycin and 1000 mg amoxicillin
- 30 mg Lansoprazole Actavis 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 Actavis the dose that your doctor decides is best for you.

If you take more Lansoprazole Actavis than you should

If you take more Lansoprazole Actavis than you have been told to, seek medical advice quickly.

If you forget to take Lansoprazole Actavis

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 Actavis

Do not stop treatment 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 (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.
- fractures of 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 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)
- 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 (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
- very severe skin reactions with reddening, blistering, severe inflammation and skin loss (Steven-Johnson syndrome and toxic epidermal necrolysis).
- very rarely Lansoprazole Actavis 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).

The frequency of the following side effects are not known (frequency cannot be estimated from the available data):

- If you are on Lansoprazole Actavis 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

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 Actavis

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister, bottle label and carton. 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 Actavis contains

- The active substance is lansoprazole. Lansoprazole Actaviscapsules contain 15 mg or 30 mg of lansoprazole.
- The other ingredients are:
 - Capsule content:* Sugar spheres (sucrose and maize starch), Sodium laurilsulphate, Meglumine, Mannitol (E421), Hypromellose, Macrogol, Talc, Polysorbate 80, Titanium dioxide (E171), Methacrylic Acid-Ethyl Acrylate Copolymer.
 - Capsule shell:* Gelatin, Titanium dioxide (E171)

Capsule shell of 15 mg also contains: Quinoline yellow (E104)

What Lansoprazole Actavis looks like and contents of the pack

- Lansoprazole Actavis 15 mg: opaque yellow cap and body capsules containing white or almost white spherical microgranules.
- Lansoprazole Actavis 30 mg: opaque white cap and body capsules containing white or almost white spherical microgranules.

Pack sizes:

The capsules are supplied in OPA-Al-PVC/Al blisters of 14 and 28 capsules; and in HDPE bottles of 14 and 28 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Actavis Group PTC ehf,
Reyjavíkurveg 76-78,
220 Hafnarfjörður,
Iceland

Manufacturer:

LABORATORIOS LICONSA, S.A.
Avda. Miralcampo, Nº 7, Polígono Industrial Miralcampo,
19200 Azuqueca de Henares (Guadalajara),
Spain

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

Denmark: Lansale, harde enterokapsler 15/30 mg
Italy: Lansoprazolo Aurobindo
Ireland: Lansoprazole Actavis 15/30 mg gastro-resistant capsules

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