

Package Leaflet: Information for the patient

Lanzol 15 mg hard gastro-resistant capsules

Lanzol 30 mg hard gastro-resistant capsules

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

1 What Lanzol is and what it is used for

The active substance in Lanzol is lansoprazole, which is a proton pump inhibitor. Proton pump inhibitors reduce the amount of acid that your stomach makes.

Your doctor may prescribe Lanzol 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 (nonsteroidal anti-inflammatory drugs) treatment (NSAID treatment is used against pain or inflammation)
- Treatment of Zollinger-Ellison syndrome.

Your doctor may have prescribed Lanzol for another indication or with a dose different from that which is written in this information leaflet. Please take your medicine in consultation with your doctor.

You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

2 What you need to know before you take Lanzol

Do not take Lanzol:

- if you are allergic to lansoprazole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before taking Lanzol if you have serious liver disease. The doctor may have to adjust your dose.

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 you are on this medicine 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 (see “Possible side effects”).

If diarrhoea occurs during the treatment with Lanzol contact your doctor immediately, as Lanzol has been associated with a small increase in infectious diarrhoea.

If your doctor has given you Lanzol 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 Lanzol, 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 (reduced bone density) or if your doctor has told you that you are at risk of getting osteoporosis (for example, if you are taking steroids).

If you take Lanzol 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.

Talk to your doctor before taking lansoprazole:

- If you have low vitamin B₁₂ levels or have risk factors for low vitamin B₁₂ levels and receive long-term treatment with lansoprazole. As with all acid reducing agents, lansoprazole may lead to a reduced absorption of vitamin B₁₂. 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 are due to have a specific blood test (Chromogranin A)
- If you have ever had a skin reaction after treatment with a medicine similar to lansoprazole 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. Remember to also mention any other ill-effects like pain in your joints.
- Serious skin reactions [Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS)] have been reported in association with Lanzol treatment. Stop using Lanzol and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- 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.

Other medicines and Lanzol

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

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

- HIV protease inhibitors such as atazanavir and nelfinavir (used to treat HIV)
- methotrexate (used to treat autoimmune disease and cancer)
- ketoconazole, itraconazole, rifampicin (used to treat infections)
- digoxin (used to treat heart problems)
- warfarin (used to treat blood clots)
- 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)

Lanzol with food and drink

For the best results from your medicine, you should take Lanzol at least 30 minutes before food with a glass of water.

Pregnancy and breast-feeding

If you are pregnant, 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.

Pregnancy

Use of Lanzol is not recommended during pregnancy, as there is no adequate experience on the use of lansoprazole during pregnancy.

Breast-feeding

There is insufficient experience with use of lansoprazole during breast-feeding. Based on the results of animal studies, it is thought that lansoprazole crosses into the breast milk.

When making a decision as to whether breast-feeding or therapy with Lanzol should be continued or discontinued, your treating physician will consider the benefits of breast-feeding for your child and the benefits of therapy with Lanzol for you.

Driving and using machines

Side effects such as dizziness, vertigo, tiredness and visual disturbances sometimes occur in patients taking Lanzol. 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.

Lanzol contains sucrose and sodium

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 (23 mg) sodium per hard gastro-resistant capsule, that is to say essentially 'sodium-free'.

3 How to take Lanzol

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The dose of Lanzol depends on your condition. The recommended doses of Lanzol 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 of Lanzol 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

Two 15 mg capsules or one 30 mg capsule of Lanzol every day for 2 weeks.

Treatment of stomach ulcer

Two 15 mg capsules or one 30 mg capsule of Lanzol every day for 4 weeks.

Treatment of inflammation in your oesophagus (reflux oesophagitis)

Two 15 mg capsules or one 30 mg capsule of Lanzol every day for 4 weeks.

Long-term prevention of reflux oesophagitis

One 15 mg capsule of Lanzol every day, your doctor may adjust your dose to two 15 mg capsules or one 30 mg capsule of Lanzol every day.

Treatment of infection of *Helicobacter pylori*

The usual dose is two 15 mg capsules or one 30 mg capsule of Lanzol in combination with two different antibiotics in the morning and two 15 mg capsules or one 30 mg capsule of Lanzol 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

Two 15 mg capsules or one 30 mg capsule of Lanzol every day for 4 weeks.

Prevention of duodenal or stomach ulcer in patients requiring continued NSAID treatment

One 15 mg capsule of Lanzol every day, your doctor may adjust your dose to two 15 mg capsules or one 30 mg capsule of Lanzol every day.

Zollinger-Ellison syndrome

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

Use in children

Lanzol should not be given to children.

Taking this medicine

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 Lanzol once a day, try to take it at the same time each day. You may get best results if you take Lanzol first thing in the morning, at least 30 minutes before food.

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

If you take more Lanzol than you should

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

If you forget to take Lanzol

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 Lanzol

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.

Stop using Lanzol and seek medical attention immediately if you notice any of the following symptoms

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- 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 breathe.
- Severe hypersensitivity reactions including shock. Symptoms of a hypersensitivity reaction may include fever, rash, swelling and sometimes a fall in blood pressure.
- Very rarely this medicine 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).

Common side effects (may affect up to 1 in 10 people):

- headache, dizziness
- tiredness
- diarrhoea, constipation, stomach pain, feeling or being sick, wind, dry or sore mouth or throat

- skin rash, itching
- changes in liver function test values
- benign polyps in the stomach.

Uncommon side effects (may affect up to 1 in 100 people):

- depression
- joint or muscle pain
- fluid retention or swelling
- changes in blood cell counts
- fracture of the hip, wrist or spine (see “Warnings and precautions”).

Rare side effects (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 (paraesthesia), trembling
- anaemia (paleness)
- kidney problems
- inflammation of pancreas (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).

Very rare side effects (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.

Frequency not known (frequency cannot be estimated from the available data):

- If you are on Lanzol 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 (see “Warnings and precautions”).
- Low levels of sodium in the blood. Common symptoms include nausea and vomiting, headache, drowsiness and fatigue, confusion, muscle weakness or spasms, irritability, seizures, coma.
- 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 HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

Keep this medicine out of the sight and reach of children.

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

In addition for HDPE containers:

Keep the container tightly closed in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6 Contents of the pack and other information

What Lanzol contains

- The active substance is lansoprazole. Each capsule contains 15 mg lansoprazole or 30 mg lansoprazole respectively.
- The other ingredients are:
Sugar spheres (sucrose and maize starch), Sodium laurilsulfate, Meglumine, Mannitol (E421), Hypromellose, Macrogol 6000, Talc, Polysorbate 80, Titanium dioxide (E171), Methacrylic acid ethylacrylate copolymer (1:1)-dispersion 30%
- Capsule shell: Gelatine, Titanium dioxide (E171), Quinoline yellow (15 mg only) (E104).

What Lanzol looks like and contents of the pack

Lanzol 15 mg

Opaque, yellow hard gelatine capsule, containing white to almost white pellets with enteric coating.

Lanzol 30 mg

Opaque, white hard gelatine capsule, containing white to almost white pellets with enteric coating.

Lanzol 15 mg is available in blister packs of 7, 10, 14, 15, 20, 28, 30, 35, 50, 56, 60, 84, 98, 100 and 250 capsules or HDPE containers of 28 capsules

Lanzol 30 mg is available in blister packs of 2, 7, 10, 14, 15, 20, 28, 30, 35, 42, 50, 56, 60, 84, 98, 100 and 250 capsules or HDPE containers of 28 capsules

Not all packs sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Liconsa S.A., Avda. Miralcampo, No. 7 Poligono, Industrial Miralcampo, 19200 Azuqueca de Henares, (Guadalajara), Spain.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.

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

Ireland: Lanzol 15 mg hard gastro-resistant capsules

Lanzol 30 mg hard gastro-resistant capsules

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