

Lanzor[®] 15 mg, gastro-resistant hard capsules

Lanzor[®] 30 mg, gastro-resistant hard capsules

lansoprazole

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 or are unsure of anything, ask your doctor or pharmacist for more information.
- 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 any of the side effects become serious or if you notice any side effects not listed in this leaflet, talk to your doctor or pharmacist.

What is in this leaflet:

1. What LANZOR is and what it is used for
2. What you need to know before you take LANZOR
3. How to take LANZOR
4. Possible side effects
5. How to store LANZOR
6. Further information

1. WHAT Lanzor IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group

The active substance in LANZOR is lansoprazole, which is a proton pump inhibitor. Proton pump inhibitors reduce the amount of acid excreted by your stomach.

Therapeutic indications

Your doctor may prescribe LANZOR for:

- treatment of duodenal and stomach ulcer,
- treatment of inflammation of the esophagus (reflux esophagitis),
- prevention of reflux esophagitis,
- treatment of heartburn and acid regurgitation,
- treatment of infections caused by *Helicobacter pylori* bacteria when given in combination with antibiotic therapy,
- treatment or prevention of duodenal or stomach ulcer in patients requiring continuous NSAID treatment (NSAIDs are used to treat pain or inflammation),
- treatment of Zollinger-Ellison syndrome.

Your doctor may have prescribed LANZOR for another indication or prescribed a dose that is different from the one stated in this package leaflet. Follow your doctor's instructions for taking your medicine.

TAKE LANZOR

If your doctor has told you that you are intolerant to certain sugars, contact him/her before taking this medicine.

Contraindications

Never take LANZOR in the following situations:

- if you are allergic (hypersensitive) to lansoprazole or to any of the other ingredients of LANZOR,
- if you are taking a medicine containing the active

- Tell your doctor if you have serious liver disease. The doctor may have to adjust the dosage.
- Your doctor may ask or may already have asked you to have an additional examination called an endoscopy in order to diagnose your condition and/or exclude malignant disease.
- If diarrhea occurs during treatment with LANZOR, contact your doctor immediately, as the drug has been associated with a slight increase in infectious diarrhea.
- If your doctor has given you LANZOR in addition to other medicines intended to treat *Helicobacter pylori* infection (antibiotics), or together with anti-inflammatory medicines to treat your pain or rheumatic disease, also read the package leaflets of these medicines carefully.
- If you have been taking LANZOR for a long time (over a year) your doctor will probably regularly monitor your condition. You should report any unusual new symptoms to your doctor.

Use of a proton pump inhibitor such as LANZOR, particularly for over a year, can slightly increase the risk of hip, wrist or spine fracture. Inform your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis). Use of this medicine is not recommended if you have fructose intolerance, glucose and galactose malabsorption syndrome or sucrase-isomaltase deficiency (rare hereditary diseases).

Taking/using other medicines

Tell your doctor or pharmacist 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 LANZOR may affect the properties of these medicines:

- ketoconazole, itraconazole, rifampin (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).

Food and drink

For best results, take LANZOR at least 30 minutes before a meal.

Pregnancy – Breast-feeding

If you are pregnant, if you are breast-feeding or if you may be pregnant, ask your doctor for advice before taking this medicine.

Driving and using machines

Side effects such as drowsiness, dizziness, tiredness and visual disturbances sometimes occur in patients taking this medicine. If you experience these effects, be careful as your alertness may be decreased. You alone are responsible for deciding whether you are capable of driving or performing other tasks that require a high level of concentration. Because of these effects or side effects, taking this medicine may reduce your ability to do these things safely.

A description 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 still unsure of anything.

Important information about some of the ingredients of LANZOR:

Excipient with known effect: sucrose.

3. HOW TO TAKE Lanzor

Swallow the hard capsule whole with a glass of water. If you find the hard capsules difficult to swallow, your doctor may recommend other ways of taking the medicine. Do not crush or chew the hard capsules or capsule contents since this would affect their properties.

If you are taking LANZOR once a day, try to take it at the same time each day. Best results can be obtained if you take LANZOR when you get up in the morning. If you are taking LANZOR twice a day, take the first dose in the morning, and the second in the evening.

The dosage depends on your condition. The usual doses of LANZOR for adults are given below. Your doctor may 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 hard capsule every day for 4 weeks. Consult your doctor if symptoms persist. If your symptoms are not relieved within 4 weeks, contact your doctor.

Treatment of duodenal ulcer:

One 30 mg hard capsule every day for 2 weeks.

Treatment of stomach ulcer:

One 30 mg hard capsule every day for 4 weeks.

Treatment of inflammation of the esophagus (reflux esophagitis):

One 30 mg hard capsule every day for 4 weeks.

Long-term prevention of reflux esophagitis:

One 15 mg hard capsule every day; your doctor may adjust your dose to one 30 mg hard capsule every day.

Treatment of *Helicobacter pylori* infection:

The usual dose is one 30 mg hard capsule in combination with two different antibiotics in the morning, and one 30 mg hard capsule in combination with two different antibiotics in the evening. Treatment should be taken every day, usually for 7 days.

The recommended combinations of antibiotics are:

- LANZOR with 250 to 500 mg of clarithromycin and 1 000 mg of amoxicillin;
- LANZOR with 250 mg of clarithromycin and 400 mg to 500 mg of 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 obtain the best results with your medication, take it at the right time and **do not miss a dose.**

Treatment of duodenal or stomach ulcer in patients requiring continuous NSAID (Non-Steroidal Anti-Inflammatory Drugs) treatment:
One 30 mg hard capsule every day for 4 weeks.

Prevention of duodenal or stomach ulcer in patients requiring continuous NSAID (Non-Steroidal Anti-Inflammatory Drugs) treatment:
One 15 mg hard capsule every day; your doctor may adjust your dose to one 30 mg hard capsule every day.

Zollinger-Ellison syndrome:
The recommended initial dose is two 30 mg hard capsules every day to start with, then depending on how you respond to the treatment, your doctor may decide to adjust the dose.

USE IN CHILDREN:
LANZOR must not be given to children.
Always take the dose prescribed by your doctor. If you are not sure, consult your doctor.

If you take more LANZOR than you should:
If you take more LANZOR than you should, consult your doctor rapidly.

If you forget to take LANZOR:
If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. If it is almost time, skip the missed dose, and take the remaining hard capsules as planned. Do not take a double dose to make up for the dose you forgot to take.

If you stop taking LANZOR:
Do not stop treatment because your symptoms have improved. Your condition may not have been fully cured and symptoms may recur.
If you have any further questions on how to use this medicine, ask your doctor for more information.

4. POSSIBLE SIDE EFFECTS

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

- ▶ The following side effects are common (more than 1 in 100 patients):
 - headache, drowsiness,
 - diarrhea, constipation, stomach pain, nausea, bloating, dry or sore mouth or throat,
 - extensive skin rash, itching,
 - changes in liver function test values,
 - tiredness.
- ▶ The following side effects are uncommon (less than 1 in 100 patients):
 - depression,
 - joint or muscle pain,
 - water retention or edema,
 - changes in blood cell counts.
- ▶ The following side effects are rare (less than 1 in 1 000 patients):
 - fever,
 - restlessness, drowsiness, confusion, hallucinations, insomnia, visual disturbances, dizziness,
 - changes in taste, loss of appetite, inflammation of the tongue (glossitis),
 - skin reactions such as burning or pricking sensations, bruising, reddening and excessive sweating,
 - sensitivity to light (strong skin reaction on exposure to sun and UV rays),
 - hair loss,
 - tingling (paresthesia), tremor,
 - anemia (paleness),
 - kidney problems,
 - pancreatitis,
 - hepatitis, jaundice,
 - breast swelling in men, impotence,
 - candidiasis (fungal infection affecting skin or the mucosa),
 - angioedema; contact your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue or pharynx, difficulty swallowing, hives or difficulty breathing.
- ▶ The following side effects are very rare (less than 1 in 10 000 patients):
 - severe allergic reactions including shock. Symptoms of an allergic reaction may include fever, extensive skin rash, edema and sometimes a drop in blood pressure,
 - inflammation of the mouth (stomatitis),
 - bowel inflammation (colitis),
 - changes in blood sodium, cholesterol and triglyceride levels,
 - very severe skin reactions with reddening, blistering, severe inflammation and peeling,
 - very rarely LANZOR may reduce the number of white blood cells affecting resistance to infection. If you

develop 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 consult your doctor immediately. A blood test will be done to check possible reduction of white blood cells (agranulocytosis).

▶ **Unknown frequency:**
If you have been taking LANZOR for more than 3 months, magnesium levels in your blood may decrease. Low magnesium levels can result in tiredness, involuntary muscle contractions, disorientation, seizures, a feeling of being dizzy and accelerated heart rate. If you have any of these symptoms, tell your doctor immediately. Low magnesium levels can also cause a decrease in potassium or calcium levels in the blood. Your doctor may ask you to have regular blood tests to monitor your magnesium levels.

Reporting side effects
If you notice any side effects, whether or not they are listed in this leaflet, immediately tell your doctor, pharmacist or other healthcare professional (e.g. a nurse). By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LANZOR

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
Do not use LANZOR after the expiry date which is stated on the blister or box. The expiry date refers to the last day of that month.

Do not store above 25 °C.
Keep the bottle tightly closed and away from moisture. Keep the blisters in their box and away from moisture. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of unused medicines. These measures will help protect the environment.

6. FURTHER INFORMATION

What LANZOR 15 mg gastro-resistant hard capsules contain the active substance is:
Lansoprazole.....15 mg
for one gastro-resistant hard capsule.

The other ingredients are:
heavy magnesium carbonate, neutral microgranules (sucrose, maize starch), sucrose, maize starch, low-substituted hydroxypropyl cellulose, hydroxypropyl cellulose, copolymer of methacrylic acid and ethyl acrylate (1: 1) (30% dispersion) (Eudragit L30 D-55), talc, macrogol 6000, titanium dioxide, polysorbate 80, colloidal anhydrous silica.
Hard capsule coating: capsule cap (orange): gelatin, titanium dioxide, erythrosin, yellow iron oxide.
Capsule body (blue): gelatin, titanium dioxide, indigotin.

What LANZOR 30 mg gastro-resistant hard capsules contain the active substance is:
Lansoprazole.....30 mg
for one gastro-resistant hard capsule.

The other ingredients are:
heavy magnesium carbonate, neutral microgranules (sucrose, maize starch), sucrose, maize starch, low-substituted hydroxypropyl cellulose, hydroxypropyl cellulose, copolymer of methacrylic acid and ethyl acrylate (1: 1) (30% dispersion) (Eudragit L30 D-55), talc, macrogol 6000, titanium dioxide, polysorbate 80, colloidal anhydrous silica.
Hard capsule coating: capsule cap (orange): gelatin, titanium dioxide, erythrosin, yellow iron oxide.
Capsule body (white): gelatin, titanium dioxide.

What LANZOR 15 mg gastro-resistant hard capsules look like and contents of the pack
This medicine is available as hard capsules; each hard capsule contains white to brownish-white gastro-resistant microgranules.
Boxes of 7, 14, 15, 28, 30 and 60 hard capsules in blisters. Boxes of 14, 15, 28 and 30 hard capsules in bottles. Some pack sizes may not be marketed.

What LANZOR 30 mg gastro-resistant hard capsules look like and contents of the pack
This medicine is available as hard capsules; each hard capsule contains white to brownish-white gastro-resistant microgranules.
Boxes of 7, 14, 28 and 60 hard capsules in blisters. Boxes of 14 and 15 hard capsules in bottles. Some pack sizes may not be marketed.

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