

# Lanzor<sup>®</sup> 30 mg

lansoprazole

gastro-resistant hard capsules

## Read all of this leaflet carefully before you start using 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## In this leaflet:

1. What Lanzor 30 mg gastro-resistant hard capsules are and what they are used for
2. Before you take Lanzor 30 mg gastro-resistant hard capsules
3. How to take Lanzor 30 mg gastro-resistant hard capsules
4. Possible side effects
5. How to store Lanzor 30 mg gastro-resistant hard capsules
6. Further information

## 1. WHAT Lanzor 30 mg gastro-resistant hard capsules ARE AND WHAT THEY ARE USED FOR

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.

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 with a dose different from the dose indicated in this package leaflet. Please follow your doctor's instructions for taking your medicine.

## 2. BEFORE YOU TAKE Lanzor 30 mg gastro-resistant hard capsules

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

### Do not take Lanzor 30 mg gastro-resistant hard capsules:

- 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 substance atazanavir (used in the treatment of AIDS).

### Take special care with Lanzor 30 mg gastro-resistant hard capsules:

#### Special warnings

- Please 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 undergo an additional investigation 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, please also read the package leaflets of these medicines carefully.
- If you take Lanzor on a long-term basis (more than 1 year) your doctor will probably regularly monitor your condition. You should report any unusual new symptoms to your doctor.

- This medicine contains sucrose. You should not take this medicine if you have fructose intolerance, glucose and galactose malabsorption syndrome or sucrose-isomaltase deficiency (rare hereditary diseases).

### Taking/using other medicines

Please 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, 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).

### Taking Lanzor 30 mg gastro-resistant hard capsules with food and drink

To ensure that Lanzor is as effective as possible, take it at least 30 minutes before a meal.

### Pregnancy and 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. Due to these effects or undesirable 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 30 mg gastro-resistant hard capsules

List of excipients with specific effects: sucrose.

## 3. HOW TO TAKE Lanzor 30 mg gastro-resistant hard capsules

The hard capsule should be swallowed 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, you should 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. If symptoms persist you should consult your doctor. If your symptoms are not relieved within 4 weeks, please 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:

- 30 mg of Lanzor together with 250 mg to 500 mg of clarithromycin and 1 000 mg of amoxicillin;
- 30 mg of Lanzor together 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-Elison syndrome:**

The usual recommended 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 30 mg gastro-resistant hard capsules than you should:**

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

**If you forget to take Lanzor 30 mg gastro-resistant hard 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 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 a forgotten dose.

**If you stop taking Lanzor 30 mg gastro-resistant hard capsules:**

Do not stop treatment because your symptoms have improved. Your condition may not have been fully cured and symptoms may reoccur.

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 30 mg gastro-resistant hard capsules 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 swelling,
- 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; you should consult your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue or pharynx, difficulty swallowing, hives and 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 fall 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).

If any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

## 5. HOW TO STORE Lanzor 30 mg gastro-resistant hard capsules

Keep out of the reach and sight 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.

Store at a temperature no higher than 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 medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

**What Lanzor 30 mg gastro-resistant hard capsules contain**

**The active substance is:** lansoprazole.

**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 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 14 and 15 hard capsules in bottles.

Not all pack sizes may be marketed.

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