

## PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

### LANSOPRAZOLE 15 MG GASTRO-RESISTANT CAPSULES, hard LANSOPRAZOLE 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 is and what it is used for
2. What you need to know before you take Lansoprazole
3. How to take Lansoprazole Capsules
4. Possible side effects
5. How to store Lansoprazole
6. Contents of the pack and other information

#### 1. WHAT LANSOPRAZOLE IS AND WHAT IT IS USED FOR

The active ingredient in Lansoprazole 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 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)
- Zollinger-Ellison syndrome.

Your doctor may have prescribed Lansoprazole 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

##### Do NOT take Lansoprazole:

- 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:

- 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 you use Lansoprazole 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 on a long-term basis (longer than 1 year) your doctor might need to keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.
- If **diarrhoea** occurs during the treatment with Lansoprazole contact your doctor **immediately**, as your medicine has been associated with a small increase in infectious diarrhoea
- if you are on Lansoprazole Teva Pharma 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.
- taking a proton pump inhibitor like lansoprazole, 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).

- 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.

#### Other medicines and Lansoprazole

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

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

- ketoconazole, itraconazole, rifampicin (used to treat infections)
- digoxin (used to treat heart problems)
- tacrolimus (used to prevent rejection of a transplant)
- theophylline, (used to treat asthma)
- 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)

#### Lansoprazole with food and drink

For the best results you should take Lansoprazole at least 30 minutes before food.

#### 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, fatigue and visual disturbances sometimes occur in patients taking Lansoprazole (see section 4). If you experience side effects like these you should take caution as your ability to react may be decreased.

Do NOT drive if you feel you are not in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration. Read all the information in this leaflet for guidance.

**Discuss with your doctor, nurse or pharmacist if you are unsure about anything.**

#### Lansoprazole 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

Always take this medicine exactly as your doctor 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 you 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. You may get best results if you take Lansoprazole first thing in the morning.
- 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 your medicine depends on your condition. The usual doses of Lansoprazole are given below. Your doctor will sometimes prescribe you a different dose and will tell you how long your treatment will last.

##### The recommended dose is:

**Treatment of heartburn and acid regurgitation:** one 15 mg or 30 mg lansoprazole every day for 4 weeks. If symptoms persist you should report them to your doctor. If your symptoms are not relieved within 4 weeks, please contact your doctor.

**Treatment of duodenal ulcer:** 30 mg lansoprazole every day for 2 weeks.

**Treatment of stomach ulcer:** 30 mg every day for 4 weeks.

**Treatment of inflammation in your oesophagus (reflux oesophagitis):** 30 mg lansoprazole every day for 4 weeks.

**Long-term prevention of reflux oesophagitis:** 15 mg lansoprazole every day, your doctor may adjust your dose to 30 mg lansoprazole every day.

**Treatment of duodenal or stomach ulcer in patients requiring continued NSAID treatment:** 30 mg lansoprazole every day for 4 weeks.

**Prevention of duodenal or stomach ulcer in patients requiring continued NSAIDs treatment:** 15 mg lansoprazole every day, your doctor may adjust your dose to 30 mg lansoprazole every day.

#### **Treatment of infection of Helicobacter pylori**

The usual dose is 30 mg lansoprazole in combination with two different antibiotics in the morning and 30 mg lansoprazole 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.

**Zollinger-Ellison syndrome:** The usual dose is 60 mg lansoprazole every day to start with, and then depending on how you respond to Lansoprazole, the dose may change, depending on what your doctor decides is best for you.

#### **Children and adolescents**

Lansoprazole should NOT be given to children.

#### **If you take more Lansoprazole than you should**

If you take more Lansoprazole than you have been told to, contact your doctor, pharmacist or your nearest hospital emergency department **immediately**.

#### **If you forget to take Lansoprazole**

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 a dose.

#### **If you stop taking Lansoprazole**

**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 product, 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 allergic reactions which need immediate medical attention:

- serious allergic reaction which causes swelling of the face or throat
- difficulty breathing or wheezing
- serious allergic reaction which causes difficulty in breathing or dizziness (anaphylactic shock)
- generally feeling weak

The following side effects are common (may affect up to 1 in 10 people):

- headache, dizziness
- dry or sore mouth or throat, feeling or being sick, diarrhoea, stomach pains, constipation, wind
- changes in liver function test values
- skin rash, itching
- tiredness.

The following side effects are uncommon (may affect up to 1 in 100 people):

- changes in blood cell counts
- depression
- muscle and joint pain
- fluid retention or swelling
- fracture of the hip, wrist or spine (see section 2 "Warnings and precautions").

The following side effects are rare (may affect up to 1 in 1,000 people):

- anaemia (paleness)
- hallucinations, confusion and difficulty in sleeping (insomnia), visual disturbances, vertigo
- candidiasis (fungal infection, may affect skin or the mucosa)
- change in the way things taste, loss of appetite, inflammation of the tongue (glossitis)
- inflammation of the liver (may be seen as yellow skin or eyes)
- skin reactions such as burning or pricking feeling under the skin, bruising, reddening and excessive sweating
- sensitivity to light
- hair loss
- breast swelling in males, impotence

- fever
- feelings of ants creeping over the skin (paresthesia), trembling
- kidney problems
- pancreatitis
- 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):

- reduction in number of white blood cells which may decrease your resistance to infection. 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).
- colitis (bowel inflammation)
- inflammation of the mouth (stomatitis)
- severe hypersensitivity reactions including shock. Symptoms of a hypersensitivity reaction may include fever, rash, swelling and sometimes a fall in blood pressure
- very severe skin reactions with reddening, blistering, severe inflammation and skin loss
- changes in test values such as sodium, cholesterol and triglyceride levels

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

- rash, possibly with pain in the joints
- low levels of magnesium in your blood (hypomagnesaemia) (see section 2 "Warnings and precautions"), severe hypomagnesaemia may result in low levels of calcium in your blood (hypocalcaemia)

#### **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 HPRC 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**

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

Do not store above 30°C.

Do not use Lansoprazole after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not throw away 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 contains;**

- The active substance is lansoprazole.
- Lansoprazole 15 mg Gastro-resistant Capsules, hard contain 15 mg lansoprazole and Lansoprazole 30 mg Gastro-resistant Capsules, hard contain 30 mg lansoprazole.
- The other ingredients are:

sugar spheres (sucrose and maize starch), sodium starch glycolate, sodium laurilsulfate, povidone, tri-sodium phosphate, hypromellose, methacrylic acid - ethyl acrylate copolymer 1:1, triethyl citrate, titanium dioxide (E171), talc.

The capsule shells contain: titanium dioxide (E171), water.

The printing ink on the capsules contains the following additional ingredients: shellac, ethyl alcohol anhydrous, isopropyl alcohol, propylene glycol, N-butyl alcohol, ammonium hydroxide, potassium hydroxide, black iron oxide (E172).

#### **What Lansoprazole look like and contents of the pack**

Each gastro-resistant capsule has a white cap marked with the letter L and a white body marked with the numbers 15 or 30, depending on the product strength. The capsules contain white to beige gastroresistant micropellets. Lansoprazole Capsules are supplied in Aluminium/Aluminium blisters of 28 capsules

#### **Product procured from within the EU, repackaged and distributed by:**

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

**Parallel Product Authorisation Holder;**

WPR Healthcare Limited, Unit 10, Ashbourne Business Park, Rath,  
Ashbourne, Co. Meath.

**PPA 565/63/1**

**PPA 565/63/2**

**Manufacturer:**

Teva Pharma S.L.U., Poligono Industrial Malpica, calle C, 50016  
Zaragoza, Spain.

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

<b>Belgium</b>	Lanosteva 15 & 30 mg maagsapresistente Capsules, hard/ gelules gastro-resistantes/ Magensaftresistente Hartkapseln
<b>Czech Republic</b>	Lansoprazol Teva 15 & 30 mg enterosolvetni Tvrde tobolky
<b>Germany</b>	Lansoprazol-ratiopharm 15 & 30 mg Magensaftresistente Hartkapseln
<b>Ireland</b>	Lansoprazole Teva Pharma 15 & 30 mg Gastro- Resistant Capsules, hard
<b>Italy</b>	Lansoprazolo Teva
<b>Luxembourg</b>	Lansoprazol-ratiopharm
<b>Netherlands</b>	Lansoprazol ratiopharm