

Package leaflet: Information for the user

Lansoprazole Teva Pharma 15 mg gastro-resistant capsules, hard **Lansoprazole Teva Pharma 30mg 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 Teva Pharma is and what it is used for
2. What you need to know before you take Lansoprazole Teva Pharma
3. How to take Lansoprazole Teva Pharma
4. Possible side effects
5. How to store Lansoprazole Teva Pharma
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1. What Lansoprazole Teva Pharma is and what it is used for

The active ingredient in Lansoprazole Teva Pharma 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 Teva Pharma for the following indications in adults:

- 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 Lansoprazole Teva Pharma 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 Lansoprazole Teva Pharma

Do not take Lansoprazole Teva Pharma

- 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 or pharmacist before taking Lansoprazole Teva Pharma:

- if you have **serious liver disease**. The doctor may have to adjust your dosage.

- if you have **low vitamin B12 levels or have risk factors for low vitamin B12 levels** and receive long-term treatment with Lansoprazole Teva Pharma. As with all acid reducing agents, Lansoprazole Teva Pharma may lead to a reduced absorption of vitamin B12.
- 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 Teva Pharma 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 Teva Pharma. 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 Lansoprazole Teva Pharma treatment. Stop using Lansoprazole Teva Pharma 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.

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 Teva Pharma contact your doctor **immediately**, as your medicine has been associated with a small increase in infectious diarrhoea

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

If you take Lansoprazole Teva Pharma 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.

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.

Other medicines and Lansoprazole Teva Pharma

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use 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 Lansoprazole Teva Pharma 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 rejection of a transplant)
- 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 and fertility

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. 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 or pharmacist if you are unsure about anything.

Lansoprazole Teva Pharma contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Lansoprazole Teva Pharma contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Lansoprazole Teva Pharma

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

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

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 Teva Pharma once a day, try to take it at the same time each day. You may get best results if you take Lansoprazole Teva Pharma first thing in the morning.
- If you are taking Lansoprazole Teva Pharma 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 recommended doses of Lansoprazole Teva Pharma 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

15 mg or 30 mg lansoprazole every day for 4 weeks. 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 lansoprazole 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 ulcers in patients requiring continued NSAID 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 recommended 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 recommended dose is 60 mg lansoprazole every day to start with, and then depending on how you respond to Lansoprazole Teva Pharma, the dose may change, depending on what your doctor decides is best for you.

Use in children

Lansoprazole Teva Pharma should NOT be given to children.

If you take more Lansoprazole Teva Pharma than you should

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

If you forget to take Lansoprazole Teva Pharma

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 dose.

If you stop taking Lansoprazole Teva Pharma

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 taking Lansoprazole Teva Pharma and seek medical attention immediately if you notice any of the following symptoms

- **angioedema:** symptoms may include swollen face, tongue or pharynx, difficulty to swallow, hives and difficulties to breath (rare side effect: may affect up to 1 in 1,000 people)
- **severe hypersensitivity reactions including anaphylactic shock:** symptoms may include fever, rash, swelling and sometimes a fall in blood pressure (very rare side effect: may affect up to 1 in 10,000 people)
- **very severe skin reactions** with 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 (very rare side effects: may affect up to 1 in 10,000 people)
- **very severe skin reactions** with widespread rash, high body temperature and enlarged lymph nodes: DRESS syndrome or drug hypersensitivity syndrome (frequency not known).
- **very severe skin reactions** with symmetrical, red raised skin areas evolving into target lesions or further confluent patches, that can appear all over the body, typically on hands and feet, and/or mucous membranes lesions: erythema multiforme (rare side effect: may affect up to 1 in 1,000 people).
- **inflammation of the liver:** may be seen as yellow skin or eyes (rare side effect: may affect up to 1 in 1,000 people).

Common side effects (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, benign polyps in the stomach
- skin rash, itching
- changes in liver function test values
- tiredness.

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 section 2 “Warnings and precautions”).

Rare side effects (may affect up to 1 in 1,000 people):

- fever
- hallucinations, confusion and difficulty in sleeping (insomnia), visual disturbances, vertigo, restlessness, drowsiness
- candidiasis (fungal infection, may affect skin or the mucosa)
- change in the way things taste, loss of appetite, inflammation of the 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

- pancreatitis
- 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):

- inflammation of your mouth (*stomatitis*)
- bowel inflammation (*colitis*)
- changes in test values such as sodium, cholesterol and triglyceride levels
- very rarely Lansoprazole Teva Pharma may cause a reduction in the 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).
- coexisting abnormal reduction in the number of red and white blood cells, as well as platelets (pancytopenia) .

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

- low levels of magnesium in your blood (hypomagnesaemia) (see section 2 ‘Warnings and precautions’). Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood (hypokalaemia, hypocalcaemia)
- 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, pharmacist or nurse. 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.

5. How to store Lansoprazole Teva Pharma

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

Store below 30° C.

[Lansoprazole Teva Pharma 15 mg gastro-resistant capsules, hard]

Lansoprazole Teva Pharma should be used no longer than 56 days after first opening of the bottle.

[Lansoprazole Teva Pharma 30 mg gastro-resistant capsules, hard]

[HDPE bottles- 7, 14 or 28 capsules]

Lansoprazole Teva Pharma should be used no longer than 28 days after first opening of the bottle.

[HDPE bottles- 49, 50 or 56 capsules]

Lansoprazole Teva Pharma should be used no longer than 56 days after first opening of the bottle.

Do not use this medicine after the expiry date which is stated on the outer packaging and blister strip bottle label after EXP. The expiry date refers to the last day of that month.

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 protect the environment.

6. Contents of the pack and other information

What Lansoprazole Teva Pharma contains

- The active substance is lansoprazole. Each capsule contains either 15 mg or 30 mg of the active substance.
- The other ingredients are sugar spheres (sucrose, corn starch), povidone, sodium laurilsulfate, sodium starch glycolate (type A), trisodium phosphate, hypromellose, talc, methacrylic acid ethylacrylate copolymer (1:1) dispersion 30 per cent, triethyl citrate, titanium dioxide (E171).
- The capsule shells contain: gelatine, titanium dioxide (E171).
- The printing ink contains shellac, propylene glycol, ammonium hydroxide, potassium hydroxide black iron oxide (E172).

What Lansoprazole Teva Pharma looks like and contents of the pack

- [Lansoprazole Teva Pharma 15 mg Gastro-resistant Capsules, hard] A hard gelatine capsule with an opaque white cap and opaque white body, filled with white to beige micropellets. The capsules have been marked using black ink with the letter “L” on the cap and the number “15” on the body.
- [Lansoprazole Teva Pharma 30 mg Gastro-resistant Capsules, hard] A hard gelatine capsule with an opaque white cap and opaque white body, filled with white to beige micropellets. The capsules have been marked using black ink with the letter “L” on the cap and the number “30” on the body.

Lansoprazole Teva Pharma is available in blister packs of 7, 7x1, 10, 10x1, 14, 14x1, 28, 28x1, 30, 30x1, 50, 50x1, 50x1 (hospital pack), 56, 56x1, 60, 60x1, 90, 90x1, 98, 98x1, 100, 100x1 gastro-resistant capsules (blisters) or bottles with 7, 14, 28, 49, 50, 56, 98 (2x49), 100 (2x50) gastro-resistant capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Teva B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturer:

TEVA PHARMA S.L.U., C/C, n. 4, Poligono Industrial Malpica, Zaragoza, 50016, Spain.
Merckle GmbH, Ludwig-Merckle-Straße 3, Blaubeuren, 89079, Germany.
Teva Pharma B.V., Swensweg 5, 2031 GA Haarlem, The Netherlands.

This medicine is authorised in the Member States of the European Economic Area under the following names:

Belgium	Lansoprazole Teva 15 & 30 mg maagsapresistente capsules, hard/ gélules gastro-résistantes/ magensaftresistente Hartkapseln
Finland	Gasterix 15 & 30 mg enterokapseli, kova
Germany	Lansoprazol-ratiopharm 15 & 30 mg magensaftresistente Hartkapseln
Ireland	Lansoprazole Teva Pharma 15 & 30 mg Gastro-resistant Capsules, hard
Luxembourg	Lansoprazol-ratiopharm

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