

PACKAGE LEAFLET: INFORMATION FOR THE USER

LANSOPRAZOLE 15MG & 30MG GASTRO-RESISTANT CAPSULES

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
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 name of your medicine is Lansoprazole 15 mg & 30 mg gastro-resistant capsules (called lansoprazole throughout this leaflet). It belongs to a group of medicines called proton pump inhibitors. Lansoprazole works by lowering the amount of acid in your stomach. It can be used for:

- Healing ulcers in your stomach or duodenum (gut)
- Healing and preventing ulcers caused by medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). This includes medicines like aspirin, ibuprofen, ketoprofen and piroxicam
- Gastro-Oesophageal Reflux Disease (GORD). This happens when acid from your stomach escapes into your food pipe (oesophagus) causing damage and inflammation

Lansoprazole can relieve symptoms that can happen with the above conditions and stop them from coming back. It can also be used to treat:

- The pain of indigestion or heartburn caused by too much acid (acid-related dyspepsia) in your stomach
- Illnesses, such as Zollinger-Ellison Syndrome, where the stomach makes large amounts of acid. This can lead to diarrhoea and pain in the stomach
- Infections caused by the bacteria *Helicobacter pylori* when given in combination with antibiotic therapy.

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

**Do not take lansoprazole and tell your doctor if:**

- You are allergic to lansoprazole or any of the other ingredients of these capsules (see Section 6: Contents of the pack and other information)

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

Do not take lansoprazole if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

**Warnings and Precautions**

Talk to your doctor or pharmacist before taking lansoprazole if:

- You have liver problems. Your doctor may want to adjust your dose.
- You have osteoporosis or are taking a type of medicine called corticosteroids (which can increase the risk of osteoporosis). 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.
- Your doctor may arrange for you to have an endoscopic examination (where a very small camera is inserted down your oesophagus (food pipe) to look into your stomach). This will help find out what is causing your symptoms. It can help to exclude more serious causes of your symptoms such as stomach cancer.
- Your doctor has given you lansoprazole in addition to other medicines intended for the treatment of *Helicobacter pylori* infection (antibiotics) or together with anti-inflammatory medicines to treat pain or rheumatic disease please also read the package leaflets of these medicines carefully.
- You take lansoprazole on a long-term basis (longer than 1 year) your doctor will probably ask to see you regularly so he can check how well you are doing. Tell your doctor if you notice any new symptoms or if any of your symptoms are getting worse.
- You have ever had a skin reaction after treatment with a medicine similar to lansoprazole that reduces stomach acid.
- You are due to have a specific blood test (Chromogranin A).
- 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.

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

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.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking lansoprazole. Do this even if they applied only in the past.

**Other medicines and Lansoprazole**

Please tell your doctor or pharmacist if you are taking or have recently or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because lansoprazole can affect the way some other medicines work. Also, some medicines can have an affect on the way lansoprazole works. In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- 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 problems)
- Antacids (used to treat heartburn or acid regurgitation)
- Sucralfate (used for healing ulcers)
- St John’s wort, sometimes called *Hypericum perforatum* (used to treat mild depression)

If you are not sure, talk to your doctor or pharmacist before taking lansoprazole.

**Taking lansoprazole with food and drink**

You should take lansoprazole at least 30 minutes before food.

**Pregnancy, breast-feeding and fertility**

Talk to your doctor or pharmacist for advice before taking lansoprazole if:

- You are pregnant, think you may be pregnant or are planning to have a baby
- You are breast-feeding

**Driving and using machines**

You may feel dizzy, tired, sick, have a headache or problems with your eyesight while taking lansoprazole. If this happens, do not drive or use any tools or machines.

**Important information about some of the ingredients in Lansoprazole gastro-resistant capsules**

Lansoprazole gastro-resistant capsules contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE LANSOPRAZOLE

- If you are taking lansoprazole once a day, take it at the same time every morning before breakfast.
- If you are taking lansoprazole twice a day, take the first dose in the morning before breakfast and the second dose in the evening.

The usual doses for adults are:

**Stomach ulcers:**

- One 30 mg capsule every day for 4 weeks

**Ulcers of the duodenum:**

- One 30 mg capsule every day for 2 weeks to heal the ulcer
- Your doctor may then decide you need one 15mg capsule every day to stop it coming back

**Ulcers of the stomach and duodenum caused by an NSAID:**

- One 30 mg capsule every day for 4 weeks to heal the ulcer
- Your doctor may then decide to give you one 15mg or 30mg capsule every day to stop the ulcer or your symptoms coming back
- Your doctor will tell you when to stop taking lansoprazole

**Preventing an ulcer and relief of symptoms while taking NSAID:**

- One 15mg or 30mg capsule every day
- Your doctor will tell you when to stop taking lansoprazole

**Treatment of infection of *Helicobacter pylori*:**

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

**Gastro-oesophageal reflux disease (GORD):**

- One 30mg capsule every day for 4 weeks to heal your food pipe (oesophagus) and/or relieve symptoms
- Your doctor may then decide you need one 15mg or 30mg capsule a day to stop your illness coming back

**Indigestion caused by too much acid (acid-related dyspepsia):**

- One 15mg or 30mg capsule every day for 2 to 4 weeks
- Talk to your doctor once you have completed this course or if your symptoms are not getting better

**Zollinger-Ellison syndrome:**

- Two 30mg capsules every day to start with
- Your doctor will then decide the dose which is best for you depending on how you respond to treatment with lansoprazole

**Patients with liver problems**

If you have severe liver problems your doctor may keep your dose to one capsule a day.



Children

Do not give lansoprazole to children.

If you take more lansoprazole than you should

Tell your doctor or go to your nearest hospital straight away. Remember to take with you any lansoprazole capsules that are left and the pack as well. This is so the doctor knows what you have taken.

If you forget to take lansoprazole

If you forget to take a dose, take it as soon as you remember, unless it is time for your next dose.

If it is time for your next dose then skip the missed dose and continue with your next dose as normal.

Do not take a double dose to make up for a forgotten dose.

If you stop taking lansoprazole

Keep taking the medicine until your doctor tells you to stop. Do not stop taking lansoprazole just because you feel better. If you do stop taking lansoprazole your illness may get worse again.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lansoprazole gastro-resistant capsules can cause side effects, although not everybody gets them.

Stop taking lansoprazole and see a doctor or go to a hospital straightaway if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria) This may mean you are having an **allergic reaction** to Lansoprazole gastro-resistant capsules.
- You have blistering, peeling or bleeding of the skin around the lips, eyes, mouth, nose and genitals. You may also have flu-like symptoms and a high temperature. These could be signs of something called Stevens-Johnson syndrome
- You get a severe blistering rash in which layers of the skin may peel off to leave large areas of raw exposed skin over the body. These could be signs of toxic epidermal necrolysis
- You get symptoms such as yellowing of your skin or whites of your eyes, tiredness and fever. This may be due to inflammation of the liver or changes in the way your liver is working

While these are serious side effects that require urgent medical attention, they are all rare or very rare (affect up to 1 in 1000 people)

Talk to your doctor as soon as possible if:

- You get long lasting diarrhoea and keep being sick. This can happen because lansoprazole lowers the natural acid in your stomach which would normally help to kill bacteria. This can lead to stomach infections.
- You get severe stomach pain which may reach through to your back. This could be a sign of pancreatitis.
- You have difficulty in passing water (urine) or you notice blood in your urine. This may be due to kidney problems or changes in the way your kidneys are working.

- You bruise more easily than usual or you get more infections than usual. This could be due to a blood problem. Your doctor may want to carry out a blood test.

The above side effects are all rare or very rare (affect up to 1 in 1000 people).

If any of the following side effects gets serious or lasts longer than a few days, tell your doctor or pharmacist.

Common (affects up to 1 in 10 people)

- headaches, feeling dizzy or tired, or a general feeling of being unwell
- diarrhoea, constipation, stomach pains, feeling sick (nausea) or being sick (vomiting), wind
- dry or sore mouth or throat, benign polyps in the stomach
- skin rash, itching
- changes in the way your liver is working (shown by a blood test)

Uncommon (affects up to 1 in 100 people)

- low mood (depression)
- joint or muscle pain
- water retention which may cause swollen arms or legs
- fracture of the hip, wrist or spine (if lansoprazole is used in high doses and over a long period of time)
- changes in blood cell counts

Rare (affects up to 1 in 1000 people)

- fever
- feeling restless, drowsy or confused
- seeing or hearing things which are not there (hallucinations)
- numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- difficulty sleeping (insomnia)
- problems with your vision
- feeling dizzy, possibly with a “spinning” feeling (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, red or purple spots which may be itchy or blister.
- excessive sweating
- being more sensitive to the sun than usual
- hair loss (alopecia)
- trembling
- feeling tired, faint, dizzy, having pale skin. These could be symptoms of anaemia.
- kidney problems
- pancreatitis
- inflammation of the liver (may be seen as yellow skin or eyes)
- swelling of the breasts in men, being unable to get or keep an erection (impotence)
- candidiasis fungal infection, such as thrush, which may affect your oesophagus (food pipe)
- 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.

Very rare (affects 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
- very severe skin reactions with reddening, blistering, severe inflammation and skin loss
- very rarely lansoprazole 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).

Not known (frequency cannot be estimated from the available data)

- rash, possibly with pain in the joints
- skin-related forms of lupus or a lupus rash
- If you are on lansoprazole 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.
- 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LANSOPRAZOLE

Blister packs

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which you will find on the pack.
- Store in the original package.
- Do not store above 30°C.
- 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.

Bottles

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which you will find on the pack.
- Any capsules remaining 28 days after first opening should either be discarded safely or returned to your pharmacist
- Keep the bottle tightly closed to protect from moisture
- Do not store above 25°C.
- 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 gastro-resistant capsules contain

The active substance is Lansoprazole. Each 15 mg capsule contains 15 mg Lansoprazole. Each 30 mg capsule contains 30 mg Lansoprazole. The other ingredients are hypromellose (E-464), talc (E-553b), titanium dioxide (E-171), metacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 %, triethylcitrate (E-1505), sugar spheres (sucrose and maize starch), gelatine and black ink (Shellac and Black Iron Oxide (E-172)).

What Lansoprazole gastro-resistant capsules look like and contents of the pack

Lansoprazole 15mg gastro-resistant capsules are white and imprinted with LAN 15. Lansoprazole 30mg gastro-resistant capsules are white and imprinted with LAN 30. They are supplied in blister packs of 7, 14, 28, 42 and 56 capsules or bottle packs of: 7, 14, 28 and 56 (28x2) capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK.

Manufacturer

Esteve Pharmaceuticals S.A., C/ San Martí 75-97, Martorelles, 08107 Barcelona, Spain.

This leaflet was last revised in February 2019

This leaflet does not contain all the information about your medicine. If you have any questions or you are not sure about anything ask your doctor or pharmacist.

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