

PATIENT LEAFLET: INFORMATION FOR THE USER

LANSOPRAZOLE 15 mg & 30 mg GASTRO-RESISTANT CAPSULES

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, 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 become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT LANSOPRAZOLE IS FOR

The active ingredient in Lansoprazole 15 mg and 30 mg gastro-resistant capsules 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)
- Treatment of 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. BEFORE YOU TAKE LANSOPRAZOLE

Do not take Lansoprazole and tell your doctor if you:

- are allergic (hypersensitive) to lansoprazole or any of the other ingredients of these capsules, (listed in section 6 of this leaflet)
- are taking a medicine containing the active substance atazanavir (used in the treatment of HIV).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Lansoprazole.

Warning and precautions

Talk to your doctor before taking lansoprazole, if:

- 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).

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-effect like pain in your joints.

Take special care with Lansoprazole

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

If 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 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 or if you are taking corticosteroids (which can increase the risk of osteoporosis).

If you take Lansoprazole 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 not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Lansoprazole.

Taking other medicines

Please tell your doctor 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 Lansoprazole may affect the way these drugs work, and these medicines may affect the way Lansoprazole works:

- 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 Lansoprazole with food and drink

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

Pregnancy and breast-feeding

If you are pregnant, breast-feeding or if there is a chance you might be pregnant, ask your doctor or pharmacist for advice before taking any 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, nurse or pharmacist if you are unsure about anything.

Important information about some of the ingredients of Lansoprazole capsules

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

3. HOW TO TAKE LANSOPRAZOLE

Swallow the capsule whole with a glass of water. If you find the capsules difficult to swallow your doctor may advise 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 Lansoprazole depends on your condition. The usual doses of Lansoprazole 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:

one 15 mg or 30 mg capsule every day for 4 weeks. If symptoms persist you should report to your doctor. If your symptoms are not relieved within 4 weeks, please contact your doctor.

Treatment of duodenal ulcer:

one 30 mg capsule every day for 2 weeks

Treatment of stomach ulcer:

one 30 mg capsule every day for 4 weeks

Treatment of inflammation in your oesophagus (reflux oesophagitis):

one 30 mg capsule every day for 4 weeks

Long-term prevention of reflux oesophagitis:

one 15 mg capsule every day, your doctor may adjust your dose to one 30 mg capsule every day.

Treatment of infection of *Helicobacter pylori*:

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

Treatment of duodenal or stomach ulcer in patients requiring continued NSAID treatment:

one 30 mg capsule every day for 4 weeks.

Prevention of duodenal or stomach ulcer in patients requiring continued NSAID treatment:

one 15 mg capsule every day, your doctor may adjust your dose to one 30 mg capsule every day.

Zollinger-Ellison syndrome:

The usual dose is two 30 mg capsules every day to start with, then depending on how you respond to Lansoprazole the dose that your doctor decides is best for you.

Use in Children

Lansoprazole should **not** be given to children.

Take your medicine exactly as your doctor has told you. You should check with your doctor if you are not sure how to take your medicine.

If you take more Lansoprazole than prescribed

If you take more Lansoprazole than you have been told to, seek medical advice quickly. Contact your doctor or the nearest hospital casualty department immediately. Take this leaflet and the package with you so they know what has been taken.

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 capsule.

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.

4. POSSIBLE SIDE EFFECTS

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

If you get any of the following side effects, STOP TAKING Lansoprazole and tell your doctor immediately or go to the nearest hospital emergency department:

- an allergic reaction to Lansoprazole. You may experience some of the following symptoms; swelling of the face, tongue or throat which may cause difficulty swallowing or breathing, red, raised, lumpy rash (hives)
- reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals you may also have a high temperature swollen glands or joint pain. This could be 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'.

Talk to your doctor straight away if you notice any of the following serious side effects:

- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely. A blood test can be taken to check.
- Severe kidney problems (interstitial nephritis)
- Severe stomach or back pain. These could be signs of pancreatitis, (an inflammation of the pancreas).
- High temperature, tiredness, loss of appetite, stomach pain, feeling sick (nausea), yellowing of the skin or eyes (jaundice) and liver failure. These are symptoms of hepatitis (inflammation of the liver).

Tell your doctor or pharmacist if you notice any of the following side effects:

The following side effects are common (occur in more than 1 in 100 patients):

- headache, dizziness
- diarrhoea, constipation, stomach pains, feeling or being sick, wind, dry or sore mouth or throat
- skin rash, itching
- changes in liver function test values shown by a blood test
- tiredness
- benign polyps in the stomach

The following side effects are uncommon (occur in less than 1 in 100 patients):

- depression
- joint or muscle pain
- fluid retention or swelling
- fracture of the hip, wrist or spine

The following side effects are rare (occur in less than 1 in 1000 patients):

- fever
- restlessness, drowsiness, confusion, hallucinations, insomnia, visual disturbances, 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, reddening and excessive sweating
- sensitivity to light
- hair loss
- anaemia (paleness)
- feelings of ants creeping over the skin (paresthesia), trembling
- breast swelling in males, impotence
- candidiasis (fungal infection, may affect skin or the mucosa)

The following side effects are very rare (occur in less than 1 in 10000 patients):

- inflammation of your mouth (stomatitis)
- colitis (bowel inflammation)
- changes in test values such as sodium, cholesterol and triglyceride levels

Frequency not known

- rash, possibly with pain in the joints
- 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.

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

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 Yellow Card Scheme:

www.mhra.gov.uk/yellowcard.

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

5. HOW TO STORE LANSOPRAZOLE

Keep out of the sight and reach of children.

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

Store below 25°C.

Store in the original package to help protect 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 Lansoprazole capsules contains

The active substance is lansoprazole. Each capsule contains either 15 mg or 30 mg of lansoprazole.

The other ingredients are:

- *Capsule content:* Sugar spheres (sucrose and maize starch), Sodium laurylsulphate, Meglumine, Mannitol (E421), Hypromellose, Macrogol, Talc, Polysorbate 80, Titanium dioxide (E171), Methacrylic Acid-Ethyl Acrylate Copolymer (1:1), Dispersion 30%
- *Capsule shell:* Gelatine, Titanium dioxide (E171)
Capsule shell of 15 mg also contains: Quinoline yellow (E104)

What Lansoprazole capsules looks like and contents of the pack

Lansoprazole 15 mg gastro-resistant capsules: opaque yellow cap and body capsules.

Lansoprazole 30 mg gastro-resistant capsules: opaque white cap and body capsules.

Each capsule contains white or almost white spherical microgranules.

These capsules are available in blister packs containing 7, 14, 28, 56 or 98 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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