Package leaflet: Information for the patient

Lansoprazole 15 mg orodispersible tablets

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
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)
- 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.

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:

- if you are allergic to lansoprazole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

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.

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.

Talk to your doctor before taking Lansoprazole:
- if 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 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 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 if you are taking, have recently taken or might take any other medicines, even those acquired 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:

- 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 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 from your medicines you should take Lansoprazole at least 30 minutes before food.

Pregnancy, 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 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, 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 medicine.

3. How to take Lansoprazole

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

Place the tablet on your tongue and suck gently. The tablet rapidly dissolves in the mouth, releasing microgranules which you should swallow without chewing with the help of a glass of water.
Your doctor might instruct you to take the tablet with a syringe, in case you have serious difficulties with swallowing.

The following instructions should be followed if administered via an oral syringe:
It is important that the appropriateness of the selected oral syringe is carefully tested.
- Remove the plunger of the syringe (at least 5 ml syringe for the 15 mg tablet and 10 ml syringe for the 30 mg tablet).
- Put the tablet into the barrel.
- Put the plunger back onto the syringe.
- For the 15 mg tablet: Draw 4 ml tap water into the syringe.
- For the 30 mg tablet: Draw 10 ml tap water into the syringe.
- Invert the syringe and draw an additional 1 ml of air into it.
- Shake the syringe gently for 10-20 seconds until the tablet is dispersed.
- The contents can be emptied directly into the mouth.
- Refill the syringe with 2-5 ml of tap water to flush the remnants out of the syringe into the mouth
- Repeat the precedent step if necessary

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 orodispersible tablet 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 orodispersible tablet every day for 2 weeks

Treatment of stomach ulcer: one 30 mg orodispersible tablet every day for 4 weeks

Treatment of inflammation in your oesophagus (reflux oesophagitis): one 30 mg orodispersible tablet every day for 4 weeks

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

Treatment of infection of *Helicobacter pylori*: The usual dose is one 30 mg orodispersible tablet in combination with two different antibiotics in the morning and one 30 mg orodispersible tablet 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 orodispersible tablet every day for 4 weeks.

Prevention of duodenal or stomach ulcer in patients requiring continued NSAID treatment: one 15 mg orodispersible tablet every day, your doctor may adjust your dose to one 30 mg orodispersible tablet every day.

Zollinger-Ellison syndrome: The usual dose is two 30 mg orodispersible tablets 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.

If you take more Lansoprazole than you should

If you take more Lansoprazole than you have been told to, seek medical advice quickly.

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 orodispersible tablets as normal. Do not take a double dose to make up for a forgotten orodispersible tablet.

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 medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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
- 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
- changes in blood cell counts.
- risks of fracture in 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
- feelings of ants creeping over the skin (paresthesiae), trembling
- anaemia (paleness)
- kidney problems
- pancreatitis
- inflammation of the liver (may be seen as yellow skin or eyes)
- breast swelling in males, impotence
- candidiasis (fungal infection, may affect skin or the mucosa)
- 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.

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

The following side effect occurs with frequency not known:
- 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.
- rash, possibly with pain in the joints
- visual hallucinations

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 the Yellow Card Scheme at: 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

Keep this medicine 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 after 'EXP'. The expiry date refers to the last day of that month.

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.

6. Contents of the pack and other information

What Lansoprazole contains

- The active substance is lansoprazole

- The other ingredients are sugar spheres (sucrose and maize starch), magnesium carbonate, hypromellose, polysorbate 80, macrogol 6000, triethyl citrate, talc, copolymer of methacrylic acid and ethyl acrylate, copolymer of methyl acrylate, methyl methacrylate and methacrylic acid, microcrystalline cellulose, hydroxypropyl cellulose, sodium saccharin, mannitol (E-421), tropical flavouring, malic acid and magnesium stearate.

What Lansoprazole looks like and contents of the pack
Lansoprazole 15 mg are flat, round, whitish orodispersible tablets speckled with microgranules.

Lansoprazole 15 mg are available in packs of 14, 28, 56 or 98 tablets.

Marketing Authorisation Holder
Sun Pharma UK Limited
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Manufacturer
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This medicinal product is authorised in the Member States of the EEA under the following names:

ES	Lansoprazol Flas Salvat 15 mg comprimidos bucodispersables Lansoprazol Flas Salvat 30 mg comprimidos bucodispersables
FR	Lansoprazole Salvat 15 mg comprimés orodispersibles Lansoprazole Salvat 30 mg comprimés orodispersibles
IT	Lansoprazolo Laboratori Alter 15 mg compresse orodispersibili Lansoprazolo Laboratori Alter 30 mg compresse orodispersibili
UK	Lansoprazole 15 mg orodispersible tablets Lansoprazole 30 mg orodispersible tablets
SE	Lansoprazol SUN 15 mg munsönderfallande tablett Lansoprazol SUN 30 mg munsönderfallande tablett

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