

Package leaflet: Information for the patient

Lansoprazole 15 mg orodispersible tablets

Lansoprazole 30 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 orodispersible tablets are and what they are used for
2. What you need to know before you take Lansoprazole orodispersible tablets
3. How to take Lansoprazole orodispersible tablets
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1. What Lansoprazole orodispersible tablets are and what they are used for

The active ingredient in Lansoprazole 15 mg and 30 mg orodispersible tablets is lansoprazole, which is a proton pump inhibitor. Proton pump inhibitors reduce the amount of acid that your stomach makes.

Lansoprazole orodispersible tablets are used to treat adults.

Your doctor may prescribe Lansoprazole orodispersible tablets 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 orodispersible tablets 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 orodispersible tablets

Do not take Lansoprazole orodispersible tablets:

- 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 orodispersible tablets;

- If you have serious liver disease. The doctor may have to adjust your dosage.
- If you have ever had a skin reaction after treatment with a medicine similar to Lansoprazole orodispersible tablets that reduces stomach acid.
- If 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 orodispersible tablets.

Remember to also mention any other ill-effects like pain in your joints.

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 orodispersible tablets contact your doctor immediately, as Lansoprazole orodispersible tablets have been associated with a small increase in infectious diarrhoea.

If your doctor has given you Lansoprazole orodispersible tablets 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 orodispersible tablets, 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 orodispersible tablets 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.

Other medicines and Lansoprazole orodispersible tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 orodispersible tablets may affect the way these drugs work:

- 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)
- diuretics (used to elevate the rate of urination).

Lansoprazole orodispersible tablets with food and drink

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you might 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 orodispersible tablets. 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 orodispersible tablets contain aspartame and benzyl alcohol

15 mg orodispersible tablets:

This medicine contains 5.25 mg of aspartame in each orodispersible tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicine contains 0.032 mg of benzyl alcohol in each orodispersible tablet. Benzyl alcohol may cause allergic reactions. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

30 mg orodispersible tablets:

This medicine contains 10.5 mg of aspartame in each orodispersible tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicine contains 0.063 mg of benzyl alcohol in each orodispersible tablet. Benzyl alcohol may cause allergic reactions. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

3. How to take Lansoprazole orodispersible tablets

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

Place the tablet on your tongue and suck gently. The tablet rapidly dissolves in the mouth, releasing pellets which you should swallow without chewing. You can also swallow the tablet whole with a glass of water.

Your doctor might instruct you to take the tablet with an oral syringe, in case you have serious difficulties with swallowing.

The following instructions should be followed if administered via 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 water into the syringe
- For the 30 mg tablet: Draw 10 ml 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
- After the tablet has dispersed, administer the contents within 15 minutes
- The contents can be emptied directly into the mouth
- Refill the syringe with approximately 2 ml (5 ml for the 30 mg tablet) of water, shake gently, and administer any remaining contents.

If you are taking Lansoprazole orodispersible tablets once a day, try to take it at the same time each day. You may get best results if you take Lansoprazole orodispersible tablets first thing in the morning.

If you are taking Lansoprazole orodispersible tablets twice a day, you should have the first dose in the morning and the second dose in the evening.

The dose of Lansoprazole orodispersible tablets depends on your condition. The usual doses of Lansoprazole orodispersible tablets 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 orodispersible tablets together with 250-500 mg clarithromycin and 1000 mg amoxicillin
- 30 mg Lansoprazole orodispersible tablets 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 orodispersible tablets the dose that your doctor decides is best for you.

Use in children and adolescents

Lansoprazole orodispersible tablets should not be given to children.

If you take more Lansoprazole orodispersible tablets than you should

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

If you forget to take Lansoprazole orodispersible tablets

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 orodispersible tablets

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.

If diarrhoea occurs during the treatment with Lansoprazole orodispersible tablets contact your doctor immediately, as Lansoprazole orodispersible tablets have been associated with a small increase in infectious diarrhoea.

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

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

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

- depression
- joint or muscle pain
- fluid retention or swelling
- changes in blood cell counts

- risk of fracture in the hip, wrist or spine.

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

- 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 (paraesthesiae), 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 (may affect 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 orodispersible tablets 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 (frequency cannot be estimated from the available data):

- hypomagnesaemia (abnormally low levels of magnesium in the blood)
- rash, possibly with pain in the joints
- visual hallucinations.

If you are on Lansoprazole orodispersible tablets or 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.

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 national reporting system: 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 orodispersible tablets

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.

Store below 25°C.

Store in the original package in order to protect from moisture.

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 orodispersible tablets contain

- The active substance is lansoprazole.

Each orodispersible tablet contains 15 mg of lansoprazole.

Each orodispersible tablet contains 30 mg of lansoprazole.

- The other ingredients are:

Tablet core: microcrystalline cellulose, light magnesium carbonate, low-substituted hydroxypropyl cellulose, hydroxypropyl cellulose (E463).

Coating: hypromellose 3 cps (E464), low substituted hydroxypropyl cellulose, talc (E553b), titanium dioxide (E171), mannitol (E421), methacrylic acid ethyl acrylate copolymer dispersion (1:1), polyacrylate dispersion, glycerol monostearate, polyethylene glycol 6000, triethyl citrate, polysorbate 80, citric acid (E330), ferric oxide yellow (E172), ferric oxide red (E172), talc (E553b).

Compressed tablet: F-melt type C (contains mannitol, xylitol, microcrystalline cellulose, crospovidone, anhydrous dibasic calcium phosphate), crospovidone, microcrystalline cellulose, aspartame (E951), strawberry flavour (contains flavouring, maize maltodextrin, propylene glycol, benzyl alcohol), magnesium stearate (vegetable grade) (E470b).

What Lansoprazole orodispersible tablets looks like and contents of the pack

15 mg orodispersible tablets:

White to yellowish white, uncoated tablets, speckled with orange to dark brown pellets, debossed with “15” on one side of the tablet and plain on the other side.

30 mg orodispersible tablets:

White to yellowish white, uncoated tablets, speckled with orange to dark brown pellets, debossed with “30” on one side of the tablet and plain on the other side.

Each 15 mg and 30 mg orodispersible tablet is strawberry flavoured.

The orodispersible tablets are packed in an aluminium/aluminium blister with aluminium lidding foil or a cold form desiccant blister with aluminium lidding foil, which is further packed into cartons. The orodispersible tablets are available in packs of 7, 14, 28, 56, and 98 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Lupin (Europe) Limited, Victoria Court, Bexton Road, Knutsford, Cheshire WA16 0PF, United Kingdom.

LEK Pharmaceuticals d.d., Verovškova ulica 57, 1526 Ljubljana, Slovenia.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, Barleben, Sachsen-Anhalt, 39179, Germany.

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

Ireland: Lansoprazole 15 mg and 30 mg orodispersible tablets

Italy: Lansoprazolo Sandoz GmbH

Spain: Lansoprazol Flas Sandoz 15mg, 30mg comprimidos bucodispersables EFG

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