

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lansoprazole 15mg Orodispersible Tablets (lansoprazole)

Your medicine is available using the above name but will be referred to as Lansoprazole Orodispersible Tablets throughout this leaflet.

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:

- What Lansoprazole Orodispersible Tablets are and what they are used for
- What you need to know before you take Lansoprazole Orodispersible Tablets
- How to take Lansoprazole Orodispersible Tablets
- Possible side effects
- How to store Lansoprazole Orodispersible Tablets
- Contents of the pack and other information

1. What Lanzoprazole Orodispersible Tablets are and what they are used for

The active ingredient in Lansoprazole Orodispersible Tablets 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 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 ever had a skin reaction after treatment with a medicine similar to Lansoprazole Orodispersible Tablets 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 Orodispersible Tablets. Remember to also mention any other ill-effects like pain in your joints.

- 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 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.
 - 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.

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).

Children

The use of Lansoprazole Orodispersible Tablets is not recommended in children as clinical data are limited. Treatment of small children below one year of age should be avoided as available data have not shown beneficial effects in the treatment of gastro-oesophageal reflux disease.

Other medicines and Lansoprazole Orodispersible Tablets

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

- 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)

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 and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or 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 lactose, sucrose and aspartame.

Lansoprazole Orodispersible Tablets contain lactose and 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 Orodispersible Tablets contain aspartame. Aspartame is a source of phenylalanine, which may be harmful for people with phenylketonuria.

3. How to take Lansoprazole Orodispersible Tablets

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

The orodispersible tablets are for oral use.

The tablets break easily, so you should handle the tablets carefully. Do not handle the tablets with wet hands as the tablets may break up.

Place the tablet on your tongue and suck gently. The tablet rapidly dissolves in the mouth, releasing microgranules 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 a syringe, in case you have serious difficulties with swallowing.

- The following instructions should be followed if administered via syringe:
- It is important that the appropriateness of the selected 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.

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 15mg or 30mg orodispersible tablet 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 30mg orodispersible tablet every day for 2 weeks

Treatment of stomach ulcer:

one 30mg orodispersible tablet every day for 4 weeks

Treatment of inflammation in your oesophagus (reflux oesophagitis):

one 30mg orodispersible tablet every day for 4 weeks

Long-term prevention of reflux oesophagitis:

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

Treatment of infection of *Helicobacter pylori*:

The usual dose is one 30mg orodispersible tablet in combination with two different antibiotics in the morning and one 30mg 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:

- 30mg Lansoprazole Orodispersible Tablet together with 250-500mg clarithromycin and 1000mg amoxicillin
- 30mg Lansoprazole Orodispersible Tablet together with 250mg clarithromycin and 400-500mg 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 30mg orodispersible tablet every day for 4 weeks.

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

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

Zollinger-Ellison syndrome:

The usual dose is two 30mg orodispersible tablet 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.

Children:

Lansoprazole Orodispersible Tablets 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 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 dose.

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.

Common: 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
- skin rash, itching
- changes in liver function test values
- tiredness.

Uncommon: may affect up to 1 in 100 people

- depression
- joint or muscle pain
- fluid retention or swelling
- changes in blood cell counts
- slight increase in the risk of hip, wrist or spine fractures if you take Lansoprazole Orodispersible Tablets over a period of more than one year.

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 (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 breath.

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).

Not known: frequency cannot be estimated from the available data

- if you are on Lansoprazole Orodispersible Tablets 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.

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, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@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 store above 25°C.
- Store in the original package to protect from moisture.
- Do not use Lansoprazole Orodispersible Tablets after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.
- If your doctor decides to stop your treatment, return any leftover medicine to your pharmacist.
- If your medicine appears to be discoloured, damaged or shows any other signs of deterioration, please return to your pharmacist who will advise you.
- 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 to protect the environment.

6. Contents of the pack and other information

What Lansoprazole Orodispersible Tablets contain

The active substance of Lansoprazole Orodispersible Tablets is lansoprazole.
Each orodispersible tablet contains 15mg of lansoprazole.

The other ingredients are: sugar spheres (sucrose and maize starch), hypromellose, talc, magnesium carbonate, methacrylic acid-ethyl acrylate copolymer (1:1) triethyl citrate, titanium dioxide (E 171), colloidal anhydrous silica, lactose monohydrate, maize starch, aspartame, strawberry flavour and magnesium stearate.

What Lansoprazole Orodispersible Tablets look like and contents of the pack

Lansoprazole Orodispersible are white to off-white, flat bevelled round tablet debossed with "15" on one side of the tablet and plain on the other side. Each orodispersible tablet contains white to greyish gastro-resistant granules.

Lansoprazole Orodispersible Tablets are available in calendar blister packs of 28 tablets.

Manufacturer

Manufactured by: TEVA UK Limited, Eastbourne, BN22 9AG, UK.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/206/3

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

Austria	Lansoprazol Teva 15 mg Schmelztabletten
Greece	Lanziop 15 mg δισκία διασπειρόμενα στο στόμα
Hungary	Lansoprazol-Teva Sol 15 mg szájban diszpergálódó tabletta
Ireland	Lansoprazole Teva 15 mg Orodispersible Tablets
Portugal	Lansoprazol Teva (15 mg)
Spain	Lanzol Teva 15 mg comprimidos bucodispersables
Sweden	Lansoprazol Teva 15 mg munsönderfallande tablett
United Kingdom	Lansoprazole 15 mg Orodispersible tablet