

Package leaflet: Information for the user

Lansoprazole Teva 15 mg orodispersible tablets Lansoprazole Teva 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 Teva orodispersible tablets are and what they are used for
2. What you need to know before you take Lansoprazole Teva orodispersible tablets
3. How to take Lansoprazole Teva orodispersible tablets
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1. What Lansoprazole Teva orodispersible tablets are and what they are used for

The active ingredient in Lansoprazole Teva 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 Teva orodispersible tablets for the following indications in adults:

- 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 Teva 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.

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 Teva orodispersible tablets

Do not take Lansoprazole Teva orodispersible tablets

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Lansoprazole Teva orodispersible tablets

- if you have serious liver disease. The doctor may have to adjust your dosage.
- if you have low vitamin B12 levels or have risk factors for low vitamin B12 levels and receive long-term treatment with Lansoprazole Teva orodispersible tablets. As with all acid reducing agents, Lansoprazole Teva orodispersible tablets may lead to a reduced absorption of vitamin B12.
- if you are due to have a specific blood test (Chromagranin A).
- if you have ever had a skin reaction after treatment with a medicine similar to Lansoprazole Teva 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 Teva 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 Teva orodispersible tablets contact your doctor immediately, as Lansoprazole Teva orodispersible tablets has been associated with a small increase in infectious diarrhoea.

If your doctor has given you Lansoprazole Teva 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 Teva 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 Teva 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.

If you are on Lansoprazole Teva 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.

Other medicines and Lansoprazole Teva orodispersible tablets

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

In particular tell your doctor or pharmacist if you are taking medicines containing any of the following active substances as Lansoprazole Teva orodispersible tablets may affect the way these medicines 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)

- theophylline (used to treat asthma)
- warfarin (used to treat blood clots)
- 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 Teva orodispersible tablets with food and drink

For the best results you should take Lansoprazole Teva 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 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. 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 or pharmacist if you are unsure about anything.

Lansoprazole Teva orodispersible tablets contain lactose, sucrose and aspartame

Lansoprazole Teva 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 medicinal product.

Lansoprazole Teva 15 mg orodispersible tablets contains 6.5 mg aspartame in each tablet.

Lansoprazole Teva 30 mg orodispersible tablets contains 13 mg aspartame in each 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.

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

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

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

The dose of Lansoprazole Teva orodispersible tablets depends on your condition. The recommended doses of Lansoprazole Teva 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

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

Treatment of duodenal ulcer

30 mg lansoprazole every day for 2 weeks.

Treatment of stomach ulcer

30 mg lansoprazole every day for 4 weeks.

Treatment of inflammation in your oesophagus (reflux oesophagitis)

30 mg lansoprazole every day for 4 weeks.

Long-term prevention of reflux oesophagitis

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

Treatment of infection of *Helicobacter pylori*

The recommended dose is 30 mg lansoprazole in combination with two different antibiotics in the morning and 30 mg lansoprazole 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 Teva orodispersible Tablet together with 250-500 mg clarithromycin and 1000 mg amoxicillin

- 30 mg Lansoprazole Teva orodispersible Tablet 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

30 mg lansoprazole every day for 4 weeks.

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

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

Zollinger-Ellison syndrome

The recommended dose is 60 mg lansoprazole every day to start with, and then depending on how you respond to Lansoprazole Teva orodispersible tablets the dose may change, depending on what your doctor decides is best for you.

Use in children

Lansoprazole Teva orodispersible tablets should not be given to children.

If you take more Lansoprazole Teva orodispersible tablets than you should

If you take more Lansoprazole Teva orodispersible tablets than you have been told to, contact your doctor, pharmacist or your nearest hospital emergency department immediately.

If you forget to take Lansoprazole Teva 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 Teva 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 you get any of the following side effects, stop taking Lansoprazole Teva orodispersible tablets and tell your doctor immediately, or contact the casualty department at your nearest hospital:

- **angioedema** (symptoms may include swollen face, tongue or pharynx, difficulty to swallow, hives and difficulties to breath)
- **severe hypersensitivity reactions including anaphylactic shock** (symptoms may include fever, rash, swelling and sometimes a fall in blood pressure)
- **very severe skin reactions** with reddening, blistering, severe inflammation and skin loss (Stevens-Johnson-Syndrome, toxic epidermal necrolysis, erythema multiforme)
- **inflammation of the liver** (may be seen as yellow skin or eyes).

The following side effects are 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, benign polyps in the stomach
- 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
- fracture of the hip, wrist or spine (see section 2 “Warnings and precautions”).

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

- fever
- restlessness, drowsiness, confusion, hallucinations, insomnia, visual disturbances, vertigo
- 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
- breast swelling in males, impotence
- candidiasis (fungal infection, may affect skin or the mucosa).

The following side effects are very rare (may affect up to 1 in 10,000 people):

- inflammation of your mouth (stomatitis)
- colitis (bowel inflammation)
- changes in test values such as sodium, cholesterol and triglyceride levels
- reduction in the number of white blood cells which may decrease your resistance to infection. 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).

Frequency not known (cannot be estimated from the available data):

- rash, possibly with pain in the joints
- low levels of magnesium in your blood (hypomagnesaemia) (see section 2 ‘Warnings and precautions’), severe hypomagnesaemia may result in low levels of calcium in your blood (hypocalcaemia)
- 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 HPRAs 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 Teva 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 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 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 Teva orodispersible tablets contains

- The active substance is lansoprazole.
Each 15 mg orodispersible tablet contains 15 mg lansoprazole.
Each 30 mg orodispersible tablet contains 30 mg 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 Teva orodispersible tablets looks like and contents of the pack

Lansoprazole Teva 15 mg orodispersible tablets: White to off-white, flat beveled 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 Teva 30 mg orodispersible tablets: White to off white, flat beveled round tablet debossed with "30" on one side of the tablet and plain on the other side. Each orodispersible tablet contains white to greyish gastro-resistant granules.

Lansoprazole Teva orodispersible tablets are available in aluminium – aluminium blister packs:

Lansoprazole Teva 15 mg orodispersible tablets: 1, 7, 14, 28, 30, 30 (3 x 10), 50, 56, 98 & 100 orodispersible tablets

Lansoprazole Teva 30 mg orodispersible tablets: 1, 2, 7, 14, 28, 30, 30 (3 x 10), 50, 56, 98 & 100 orodispersible tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva Pharma B.V.
Swensweg 5
2031 GA Haarlem
The Netherlands

Manufacturer

Teva UK Ltd., Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG, United Kingdom

Pharmachemie BV, Swensweg 5, Postbus 552, 2003 RN Haarlem, The Netherlands
Teva Czech Industries s.r.o., Ostravská 29, č.p. 305, 747 70 Opava-Komárov, Czech Republic

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

Austria	Lansoprazol Teva 15 mg & 30 mg Schmelztabletten
Hungary	Lansoprazol-Teva Sol 15 mg & 30 mg szájban diszpergálódó tableta
Ireland	Lansoprazole Teva 15 mg & 30 mg orodispersible tablets
Portugal	Lansoprazol Teva (15 & 30 mg)
Spain	Lanzol Teva 15 mg & 30 mg comprimidos bucodispersables
Sweden	Lansoprazol Teva 15 mg & 30 mg munsönderfallande tablett
United Kingdom	Lansoprazole 15 mg & 30 mg orodispersible tablet

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