

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Lansoprazole Teva 30 mg Capsules

Composition:

Each capsule contains:
Lansoprazole 30 mg

For information regarding inactive ingredients and allergens, see section 2 - "Important information about some ingredients of the medicine" and section 6 - "Additional information".

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. What is the medicine intended for?

- Lansoprazole Teva inhibits the secretion of gastric acid and is therefore effective in treating acid-related disorders in the upper gastrointestinal tract.
- For the treatment of gastric ulcer, duodenal ulcer, reflux oesophagitis, gastroesophageal reflux disease (GERD).
- For prolonged and maintenance treatment to prevent recurrence of gastroesophageal reflux disease (GERD) or duodenal ulcer.
- For combined treatment with antibiotics for the eradication of *Helicobacter pylori* (*H. pylori*), which is one of the main causes of peptic ulcer and gastritis.
- For short-term treatment (up to 4 weeks) of dyspeptic effects caused by excessive gastric acidity, such as heartburn and/or upper abdominal pain.
- For long-term treatment in hypersecretory conditions, including Zollinger-Ellison syndrome.
- For the treatment and prophylaxis of peptic ulcer caused by treatment with non-steroidal anti-inflammatory drugs (NSAIDs), and for the relief of symptoms in patients receiving prolonged treatment with NSAIDs.

Therapeutic class

Proton pump inhibitors (PPI).

2. Before using the medicine:

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (Lansoprazole) or to any of the other ingredients this medicine contains (see section 6 - "Additional information"). Symptoms of an allergic reaction may include: rash, breathing and/or swallowing problems, swelling of the face, lips, throat or tongue.

Special warnings regarding the use of the medicine:

Before starting treatment with Lansoprazole Teva (and during the course of treatment) tell your doctor if:

- You have liver problems (the doctor may adjust the dosage).
- You suffer from osteoporosis or are taking corticosteroid medicines (which may increase the risk of osteoporosis). Taking medicines from the class of proton pump inhibitors (PPIs) such as Lansoprazole Teva, especially for a period of more than a year and/or at high dosages, may slightly increase the risk of fractures in the hip, wrist or spine. The doctor may recommend to take vitamin D and calcium supplements.
- You have ever developed a skin reaction after treatment with Lansoprazole Teva or similar medicines intended to inhibit the secretion of gastric acid. If you develop a rash on the skin, especially in areas exposed to the sun, tell your doctor as soon as possible, as you may need to stop using Lansoprazole Teva. You should also tell your doctor if you have other symptoms such as joint pain (these symptoms may be related to a skin form of lupus).
- You are due to have a blood test for Chromogranin A, as Lansoprazole Teva may interfere with the interpretation of the results.
- You have low B12 levels or have risk factors for low B12 levels. Long-term treatment with Lansoprazole Teva (as with other acid reducing medicines) may cause a decrease in vitamin B12 absorption.
- You suffer from new symptoms or if the symptoms worsen.

Additional warnings:

- Your doctor may send you for an endoscopic test to find out the cause of your symptoms. This test may also rule out more serious causes of your symptoms (such as stomach cancer).
- Your doctor may have prescribed for you, along with Lansoprazole Teva, additional medicines to treat your condition such as antibiotics for the treatment of *Helicobacter pylori* or anti-inflammatory medicines. Read carefully the leaflet of these medicines as well.
- If you experience diarrhea during the treatment, refer to the doctor immediately, as the use of Lansoprazole Teva may slightly increase the risk of infectious diarrhea. Lansoprazole Teva reduces the natural acidity of the stomach that usually helps to eradicate bacteria, which may lead to stomach infections. See also section 4 - "Side effects".
- The use of the medicine may conceal symptoms of other diseases.
- If after two weeks your condition does not improve, refer to the doctor.

Use in children

The use of the medicine is not recommended in children as there is not enough information regarding the use of the medicine in children.

Do not give the medicine to children under one year of age.

See also section 3 - "Method of use".

Tests and follow-up

- Consult your doctor about the need to perform blood tests for blood magnesium level (before and during treatment), as the medicine may lower magnesium levels. See also section 4 - "Side effects".
- If you are being treated with Lansoprazole Teva for a prolonged period of time (over a year), your doctor may monitor your condition and consider the necessity of continuing the treatment.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking (note that the list below indicates the active ingredients in the medicines. If you are not sure whether you are taking any of these medicines, please consult the doctor or pharmacist):

- Medicines from the class of HIV protease inhibitors such as atazanavir, nelfinavir (medicines against the HIV virus)
- Methotrexate

- Ketoconazole, itraconazole, rifampicin (for treatment of infections)
- Digoxin (for the treatment of heart problems)
- Warfarin (anticoagulant)
- Theophylline (for treatment of asthma)
- Tacrolimus (to prevent transplant rejection)
- Fluvoxamine (for the treatment of depression or other mental problems)
- Antacids (used for heartburn, for example) or sucralfate. Lansoprazole Teva should be taken at least one hour after taking these medicines
- Medicines that may cause a decrease in blood magnesium levels, such as diuretics
- Hypericum plant (also called St. John's wort)
- There have been reports that lansoprazole, like other medicines in the PPIs class, may reduce the activity of clopidogrel, which is used to inhibit platelet aggregation, and therefore taking Lansoprazole Teva with clopidogrel should be avoided.

Use of the medicine and food

Take the medicine at least 30 minutes before eating.

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant, are planning to become pregnant or are breastfeeding, consult the doctor before taking this medicine.

- Not enough information is available regarding the use of the medicine in pregnancy, and therefore its use is not recommended.

- It is not known whether the medicine passes into breast milk. The use of the medicine is not recommended during the period of breastfeeding.

Driving and operating machinery

The use of this medicine may cause side effects such as dizziness, sleepiness, tiredness, vertigo (sensation of giddiness), headache or visual disturbances, which may impair the ability to drive and operate machinery. If you experience these effects, do not drive or operate machinery. Caution should be exercised in any activity that requires alertness.

Important information about some of the ingredients of the medicine

Lansoprazole Teva contains sugar (sucrose). If you have been told by a doctor that you have an intolerance (sensitivity) to certain sugars, consult your doctor before taking this medicine. See also section 6 - "Additional information".

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation. The dosage, duration of treatment and method of use will be determined by the doctor only. The generally accepted dosage is:

The daily dose and duration of treatment will be determined by the doctor according to the purpose of the treatment, your condition and your response to the treatment.

- If you are taking Lansoprazole Teva once a day, unless otherwise instructed by your doctor, it is recommended that you take the capsule every morning before breakfast.
- If you are taking Lansoprazole Teva twice a day, it is recommended that you take one dose in the morning before breakfast and a second dose in the evening.

Be sure to use this medicine at set intervals as determined by the treating doctor.

Do not exceed the recommended dose Method of use

Take the medicine at least 30 minutes before eating.

The capsule should be swallowed with a glass of water.

Do not chew or crush the capsule and the granules within so as not to damage the coating of the granules, which is essential for the medicine's activity.

If you accidentally took a higher dosage
If you took an overdose or if a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the required time, take a dose as soon as you remember, however, if it is nearly time for the next dose, skip the forgotten dose and take the next dose on time. Do not take a double dose to compensate for a forgotten dose.

Follow the treatment as recommended by the doctor.

Symptom relief usually appears before the final healing. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking the medicine before the time determined by your doctor, the symptoms may return.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Lansoprazole Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Discontinue the treatment and refer to a doctor or a hospital emergency room immediately if the following severe side effects occur (affecting up to 1 in 1,000 people):

- Angioedema and/or allergic reaction. The symptoms may include: swelling of the arms, legs, ankles; swelling of the face, lips, tongue, pharynx and/or throat, difficulty swallowing, shortness of breath and/or difficulty breathing; raised itchy rash (urticaria).
- Blisters, peeling or bleeding of the skin around the lips, eyes, mouth, nose and genitals. You may also have flu-like symptoms and high fever. These may be signs of Stevens-Johnson syndrome.
- Severe rash accompanied by blisters that may cause peeling of the skin and exposure of inner layers. This effect may be a sign of toxic epidermal necrolysis.
- Symptoms such as yellowing of the skin and/or the whites of the eyes, fatigue, fever. These symptoms may be the result of inflammation of the liver or of changes in liver function.

Refer to a doctor immediately if the following side effects occur (affecting up to 1 in 1,000 people):

- Prolonged diarrhea without relief. See also section 2 - "Additional warnings".
- Severe abdominal pain that may radiate to the back. It may be a sign of inflammation of the pancreas.
- Difficulty urinating or blood in the urine. These symptoms may indicate kidney problems or changes in kidney function.
- Decreased blood magnesium levels, especially if the medicine is used for more than 3 months. This may be manifested in symptoms such as tiredness, involuntary muscle contractions, disorientation/confusion, convulsions, dizziness, increased heart rate (or other rhythm

problems). Low magnesium levels may also cause a decrease in potassium or calcium levels in the blood. See also section 2 - "Tests and follow-up".

- If you bruise easily. These symptoms may be the result of a blood problem. The doctor may refer you to undergo a blood test.

- If you suffer from an infection or signs that could indicate an infection, such as fever and severe deterioration in your general condition, fever accompanied by signs of local infection such as pain in the mouth, pharynx and throat or urinary tract problems. These symptoms may indicate a decrease in white blood cell count and in the body's resistance to infections. Through a blood test, the doctor will be able to check whether there is a lack of white blood cells (agranulocytosis).

Additional side effects

Common side effects (occur in 1-10 out of 100 users):

- Headache, dizziness, tiredness, general malaise
- Diarrhea, constipation, abdominal pain, nausea, vomiting, flatulence
- Dryness or pain in the mouth or throat
- Gastric polyps
- Itch, skin rash, urticaria
- Changes in liver function (seen in blood tests, for example as an increase in liver enzymes)

Uncommon side effects (occur in 1-10 out of 1,000 users):

- Gloominess/depression
- Muscle or joint aches
- Fluid retention that may cause swelling of the arms and/or legs (edema)
- Fractures in the hip, wrist and/or spine (especially when used at a high dosage and/or for a long period, see also section 2 - "Special warnings")
- Changes in blood count (such as thrombocytopenia, eosinophilia, leucopenia)

Rare side effects (occur in 1-10 out of 10,000 users):

- Fever
- Restlessness, drowsiness, confusion, seeing or hearing non-existing things (hallucinations)
- Skin reactions, such as loss of sensation, numbness, burning or tingling sensation, bruising, red or purple spots that may itch, blisters
- Sleeping difficulties (insomnia)
- Visual problems, vertigo (spinning sensation)
- Changes in the sense of taste, loss of appetite, inflammation of the tongue
- Increased sweating
- Increased sensitivity to light/sun
- Hair loss
- Tremor
- Anemia (may manifest as pallor, fatigue, dizziness)
- Renal disorders
- Pancreatitis
- Inflammation of the liver or jaundice (may manifest as yellowing of the skin or eyes)
- Swelling of the breasts in men, erectile dysfunction (impotence)
- Fungal infection (such as one that may affect the esophagus)
- Angioedema

Very rare side effects (occur in less than 1 out of 10,000 users):

- Hypersensitivity reaction including anaphylactic shock (its symptoms may include: fever, rash, swelling, drop in blood pressure)
- Inflammation of the mouth and lips (stomatitis)
- Inflammation of the intestine (colitis)
- Changes in test values (such as sodium, cholesterol, and triglyceride levels)
- Very severe skin reactions that may include redness, blisters, severe inflammation, skin separation
- Decreased white blood cell count (such as agranulocytosis, pancytopenia)

Side effects with unknown frequency (side effects whose frequency has not yet been determined):

- A rash, sometimes accompanied by joint pain
- Skin form of lupus or a lupus-related rash
- Visual hallucinations
- Decreased levels of magnesium, calcium and potassium
- Collagenous colitis

Side effects and drug interactions in children:

Parents need to report to the treating doctor any side effect and any additional medicine given to the child. See the side effects and drug interactions detailed above.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- **Avoid poisoning!** This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- **Store in a dry place, below 25°C.**
- For the bottle packaging only – once the bottle is opened for the first time, the preparation may be used for 60 days. The desiccant should be left inside the bottle, and the bottle should be closed tightly after each use.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Sugar spheres (sucrose, maize starch), talc, methacrylic acid copolymer dispersion, hydroxypropyl methylcellulose, magnesium carbonate, triethyl citrate, titanium dioxide.

Capsule composition:
Gelatin, titanium dioxide, red iron oxide, black iron oxide, printing ink

Each 30 mg Lansoprazole Teva capsule contains approximately 165.6 mg of sucrose.

What does the medicine look like and what are the contents of the package:
An opaque, light gray and beige capsule, with the numbers 93 and 7351 printed on each part of the capsule.

The package contains 30 capsules in blister trays or bottles. Not all package types may be marketed.

Name and address of marketing authorization holder and manufacturer:
Teva Israel Ltd,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

The leaflet was revised in August 2021 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 133.19.30999

Lansoprazole PIL MW1221