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

The medicine is dispensed with a doctor's prescription only

Lanso Teva 30 mg

Gastro-resistant capsules

Composition:

Each capsule contains:

Lansoprazole 30 mg

For information regarding inactive ingredients and allergens, see section 2 – "Important information about some of the 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?

The medicine decreases acid secretion in the stomach.

The medicine is intended for:

- Treatment of stomach ulcer and duodenal ulcer.
- Treatment and prevention of recurrence of reflux esophagitis.
- Combined treatment with antibiotics for the eradication of the bacterium Helicobacter pylori (H. pylori) which is associated with ulcers in the gastrointestinal system.
- Treatment and prevention of stomach and/or duodenal ulcers caused as a result of treatment with nonsteroidal anti-inflammatory drugs (NSAIDs).
- Treatment of symptomatic gastroesophageal reflux disease (GERD).
- Treatment of Zollinger-Ellison syndrome.

Therapeutic class

Proton pump inhibitors (PPIs).

2. BEFORE USING THE MEDICINE:

Do not use the 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 Lanso 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 Lanso 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 taking vitamin D and calcium supplements.
- You have ever developed a skin reaction after using Lanso Teva or similar medicines intended to inhibit the secretion of gastric acid.
- You are due to have a blood test for chromogranin A, as Lanso Teva may affect the test results.
- If you are taking Lanso Teva for more than three months, the levels of magnesium in your blood may decrease. Symptoms of low magnesium levels: tiredness, involuntary muscle contractions, disorientation/confusion, convulsions, dizziness, increased heart rate. If you notice any of these symptoms, tell your doctor as soon as possible. Low magnesium levels may also cause a decrease in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your blood magnesium levels.
- Lanso Teva may affect the effectiveness of vitamin B12 absorption, especially in prolonged use. Contact the treating doctor if you notice any of the following symptoms, which may indicate low levels of vitamin B12:
  - Extreme fatigue or lack of energy
  - Tingling and numbness sensation
  - Tongue pain or redness, mouth ulcers
  - Muscle weakness
  - Visual disturbances
  - Memory problems, confusion, depression
- 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 Lanso 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 Lanso Teva may slightly increase the risk of infectious diarrhea. Lanso 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".
- If a skin rash develops, especially in areas exposed to the sun, refer to the doctor as soon as possible, as the doctor may recommend that you stop the treatment with the medicine. In addition, also tell your doctor if you have other symptoms such as joint pain (these symptoms may be related to a skin form of lupus).
- Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in connection with treatment with lansoprazole. Stop using Lanso Teva and seek medical attention immediately if you notice any of the symptoms described in the side effects in section 4.
- Taking medicines from the class of proton pump inhibitors (PPIs) such as Lanso 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. Tell your doctor if you have osteoporosis (reduced bone density) or if your doctor has told you that you are at risk of developing osteoporosis (e.g., if you are taking steroids).
- While taking Lanso Teva, kidney inflammation may occur. The symptoms are – decrease in urine volume, blood in the urine, hypersensitivity reactions manifested by fever, rash and joint stiffness. Report these symptoms to the doctor.
- 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 in 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 Lanso 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. In particular, you should inform the doctor or pharmacist if you are taking any of the following medicines (the following list mentions the active ingredients in the medicines. If you are not sure whether you are using any of these medicines, please consult the doctor or pharmacist):

- Medicines from the class of HIV protease inhibitors such as atazanavir and nelfinavir (medicines against the HIV virus)
- Methotrexate
- Ketoconazole, itraconazole, rifampicin (for treatment of infections)
- Digoxin (for treatment of heart problems)
- Warfarin (anticoagulant medicine)
- Theophylline (for treatment of asthma)
- Tacrolimus (to prevent transplant rejection)
- Fluvoxamine (for treatment of depression or other mental problems)
- Antacids (e.g., used for heartburn) or sucralfate. Lanso 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
- The Hypericum plant (also called St. John's wort)

Use of the medicine and food

Take the medicine at least 30 minutes before a meal.

Pregnancy and breastfeeding

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

- Not enough information is available regarding the use of this medicine in pregnancy, and therefore its use is not recommended if you are pregnant.
- 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 (spinning sensation), 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

Lanso 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".

Each Lanso Teva 30 mg capsule contains approximately 120.03 mg of sucrose.

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 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 Lanso 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 Lanso 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 scheduled times as determined by the treating doctor.

Do not exceed the recommended dose

Method of use

Take the medicine at least 30 minutes before food.

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 to a hospital emergency room 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 at the usual time. Do not take a double dose to compensate for a missed 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 condition, 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 <u>every time</u> you take a 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 Lanso 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 serious 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), fever or drop in blood pressure.
- 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 or DRESS syndrome.
- 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 and lead to nausea and vomiting. 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". The doctor may decide to perform regular blood tests to monitor blood magnesium levels.
- If you bruise easily. This symptom 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 effects may indicate a decrease in white blood cell count and in the body's resistance to infections. The doctor will be able to check whether there is a lack of white blood cells (agranulocytosis) through a blood test.

Additional side effects

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

- 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 users out of 1,000):

- 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, leukopenia)

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

- Fever
- Restlessness, drowsiness, confusion, seeing or hearing non-existing things (hallucinations)
- Skin reactions, such as: lack of sensation, numbness, burning or tingling sensations, bruises, 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
- Numbness (paresthesia)
- Tremor
- Anemia (may manifest as pallor, fatigue, dizziness, fainting)
- Renal disorders (inflammation, changes in urination, blood in the urine)
- 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 user out of 10,000):

- Severe hypersensitivity reactions including anaphylactic shock (the symptoms may include: fever, rash, swelling, drop in blood pressure)
- Inflammation of the mouth (stomatitis)
- Inflammation of the intestine (colitis)
- Changes in test values such as: decrease in sodium levels (hyponatremia). Symptoms include nausea, vomiting, headaches, drowsiness and tiredness, confusion, muscle weakness or spasms, nervousness, fits and coma. The doctor may perform blood tests to monitor blood sodium levels
- Increased levels of cholesterol and triglycerides
- Very severe skin reactions that may include redness, blisters, severe inflammation, skin separation
- Decreased white blood cell count (such as: agranulocytosis, pancytopenia)
- Collagenous colitis

Side effects with unknown frequency (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

Side effects and drug interactions in children:

Parents should 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.

<u>Reporting side effects</u>

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 (<u>http://www.health.gov.il</u>), which will direct you to the online form for reporting side effects, or by clicking on the following link: <u>https://sideeffects.health.gov.il</u>

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 below 25°C.**

6. ADDITIONAL INFORMATION

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

Sugar spheres (sucrose, corn starch), hypromellose, methacrylic acid-ethyl acrylate copolymer, povidone, sodium lauryl sulphate, sodium starch glycolate, talc, triethyl citrate, titanium dioxide, trisodium phosphate.

Capsule composition:

Gelatin, titanium dioxide, printing black ink (shellac, propylene glycol, strong ammonia solution, potassium hydroxide, and black iron oxide).

What does the medicine look like and what are the contents of the package?

An opaque, white capsule. The number 1 and the letter L are printed on the cap of the capsule and the number 30 is printed on the body of the capsule.

The package contains 28 gastro-resistant capsules in blister trays.

Name and address of the license holder and manufacturer:

Teva Israel Ltd.,

124 Dvora HaNevi'a St., Tel Aviv 6944020.

The leaflet was revised in June 2024.

Registration number of the medicine in the national drug registry of the Ministry of Health: 174-29-36849-99

LANSO-TEVA PIL MW0624

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