

## **Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986**

This medicine is sold with a doctor's prescription only

### **Lanton 15 Lanton 30 Capsules**

#### **Active ingredient:**

Each Lanton 15 capsule contains: Lansoprazole 15 mg

Each Lanton 30 capsule contains: Lansoprazole 30 mg

For the list of the additional ingredients, see section 6.

See also 'Important information about some of the medicine's ingredients' in section 2.

#### **Read the entire leaflet carefully before using the medicine.**

This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.

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

## **1. What is the medicine intended for?**

The medicine reduces stomach acid secretion.

The medicine is intended for:

- Treatment of gastric (stomach) ulcers and duodenum ulcers.
- Treatment and recurrence prevention of reflux esophagitis .
- Combined treatment with antibiotic therapy to eradicate the Helicobacter pylori (H.Pylori) bacteria associated with ulcers in the digestive system.
- Treatment and prevention of ulcers in the stomach and/or the duodenum caused as a result of treatment with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).
- Treatment of symptomatic Gastroesophageal Reflux Disease (GERD).
- Treatment of Zollinger-Ellison syndrome.

#### **Therapeutic group:**

Proton pump inhibitors (PPIs).

## **2. Before using the medicine**

#### **Do not use the medicine if:**

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (for the list of the additional ingredients, see section 6). Symptoms of an allergic reaction can include: a rash, breathing and/or swallowing problems, swelling of the face, lips, throat or tongue.

#### **Special warnings regarding the use of this medicine:**

##### **Before (and during) treatment with Lanton tell your doctor if:**

- You have liver problems (your doctor may adjust the dosage).
- You suffer from osteoporosis or are taking corticosteroids medicines (which can increase the risk of osteoporosis). Taking medicines from the proton pump inhibitor group (PPIs), such as Lanton, especially over a period of more than one year and/or in high dosage, may slightly increase the risk of fracture in the hip, wrist or spine. The doctor may recommend taking vitamin D and calcium supplements.
- You have ever suffered from a skin reaction after treatment with a medicine similar to Lanton that are used for reduction of stomach acid.
- You need to perform a blood test for Chromogranin A, since Lanton might interfere with interpretation of the results.

- You have low vitamin B12 levels or have risk factors for low vitamin B12 levels. Long-term treatment with Lanton (as with other acid-reducing medicines) may lead to a reduced absorption of vitamin B12.
- You suffer from new symptoms or the symptoms worsen.

**Additional warnings:**

- Your doctor may refer you for an endoscopic examination to investigate the cause for the symptoms you suffer from. This examination can also rule out more serious causes of the symptoms (such as stomach cancer).
- The doctor may have prescribed for you together with the Lanton additional medicines to treat your condition such as: antibiotics for treatment of Helicobacter pylori bacteria, or anti-inflammatory medicines: you should also read the patient leaflet of these medicines carefully.
- If you experience diarrhea during the treatment, refer to your doctor immediately, as the use of Lanton could slightly increase the risk of infectious diarrhea. Lanton reduces the natural stomach acidity that normally helps destroy bacteria, and this could lead to stomach infections. See also 'Side effects' section.
- If a skin rash develops, especially in areas exposed to the sun, refer to your doctor as soon as you possible, as your doctor may recommend stopping treatment with the medicine. In addition, tell the doctor if you experience additional reactions such as joint pains. (These symptoms may be related to a skin form of lupus).
- Taking medicines from the proton pump inhibitor group (PPIs), such as Lanton, especially over a period of more than one year and/or in high dosage, may slightly increase the risk of fracture in the hip, wrist or spine.
- The use of the medicine may mask symptoms of other illnesses.
- If after two weeks your condition does not improve, contact your doctor.

**Use in Children:**

The use of the medicine is not recommended in children since there is insufficient information on the use of the medicine in children.

Do not give this medicine to children under the age of 1 year.

See also 'Manner of use' in section 3.

**Tests and follow-up:**

- Consult with your doctor on the need to perform blood tests for blood magnesium levels (before and during the treatment), since the medicine may cause a reduction in the magnesium level. See also 'Side effects' section.
- If you are treated with Lanton for a long period (over one year), the doctor may monitor your condition and evaluate the necessity of treatment continuation.

**Drug interactions: If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell your doctor or pharmacist.** Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list indicates the active ingredients in the medicines. If you are unsure whether you are using one of these medicines, please consult with your doctor or pharmacist):

- Medicines from the HIV protease inhibitors group such as atazanavir, nelfinavir (anti-HIV virus medicines).
- Methotrexate.
- Ketoconazole, itraconazole, rifampicin (for treatment of infections).
- Digoxin (for treatment of heart problems).
- Warfarin (blood anticoagulant medicine).
- Theophylline (for treatment of asthma).

- Tacrolimus (for the prevention of transplant rejection).
- Fluvoxamine (for treatment of depression or other mental problems).
- Antacids (used for instance for heartburn) or sucralfate: you should take Lanton at least one hour after taking these medicines.
- The hypericum plant (also known as St. John's Wort).
- Medicines that might cause a decrease in the blood magnesium level, such as diuretics.

**Use of this medicine and food:**

It is recommended to take the medicine at least 30 minutes before food.

**Pregnancy and breastfeeding:**

If you are pregnant, think you are pregnant, planning a pregnancy or if you are breastfeeding, consult your doctor before using the medicine.

- There is insufficient information on the use of this medicine during pregnancy and therefore its use is not recommended.
- It is not known whether the medicine passes into the breastmilk. The usage is not recommended during the breastfeeding period.

**Driving and use of machinery:**

The use of this medicine may cause side effects such as dizziness, sleepiness, tiredness, vertigo (a feeling of spinning), headache or visual disturbances, which might impair the ability to drive and to operate machinery. If you feel these effects, do not drive or operate machinery. Employ caution in any activity requiring alertness.

**Important information about some of the medicine's ingredients:**

Each Lanton 15 capsule contains about 110 mg sucrose (a type of sugar).

Each Lanton 30 capsule contains about 220 mg sucrose (a type of sugar).

If you have intolerance to certain sugars, inform your doctor before taking this medicine.

### 3. How to use this medicine?

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.

The dosage, duration of treatment and manner of treatment will be determined by the doctor only.

Make sure to use this medicine at set times as determined by the attending doctor.

**The standard dosage is usually:**

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

If you are taking Lanton once a day, in the absence of any other instruction by the doctor, it is recommended to take the capsule every morning before breakfast.

If you are taking Lanton twice a day, it is recommended to take one dose in the morning before breakfast, and a second dose in the evening.

**Do not exceed the recommended dose.**

**Manner of use:**

Take the medicine at least 30 minutes before food.

Swallow the capsule with a glass of water.

Do not chew or crush the capsule and the granules inside it so as not to damage the coating of the granules which is essential for the action of the medicine. You can open the capsule, place the granules from within the capsule on your tongue and drink with water immediately. If necessary (for instance for children from 1 year of age until 6 years of age and for patients who have difficulty

swallowing capsules), you can open the capsule, mix the contents with soft acidic food (for instance apple purée or yogurt) or an acidic drink (for instance orange juice) and swallow immediately.

**If you have accidentally taken a higher dosage** or if a child has accidentally swallowed the medicine, go immediately to a doctor or a hospital emergency room and bring the medicine package with you.

**If you forgot to take the medicine** at the set time, take the 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 make up for a forgotten dose.

Adhere to the treatment as recommended by your doctor. Relief of the symptoms appears usually before final recovery. Even if your state of health improves, do not stop the treatment with the medicine without consulting your 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 each time you take a medicine. Wear glasses if you need them.

If you have further questions concerning the use of the medicine, consult your doctor or pharmacist.

#### **4. Side effects**

As for any medicine, the use of Lanton may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

**Stop the treatment and refer the doctor or a hospital emergency room immediately, if the following serious side effects appear** (affect up to 1 out of 1000 users):

- **Angioedema and/or allergic reaction.** The symptoms can include: swelling of the hands, feet, ankles; swelling of the face, lips, tongue, pharynx and/or throat, swallowing difficulties, shortness of breath and/or breathing difficulties; raised and itchy rash (urticaria/hives).
- Blistering, peeling or bleeding of the skin around the lips, eyes, mouth, nose and genitals. You may also have flu-like symptoms and a high temperature. These could be signs of Stevens-Johnson syndrome.
- A severe rash accompanied by blisters which may cause peeling of the skin and exposure of inner layers. This could be a sign of toxic epidermal necrolysis.
- Symptoms such as yellowing of the skin and/or whites of the eyes, tiredness, fever. These symptoms can be a result of inflammation of the liver or changes in liver functions.

**Refer to your doctor immediately if the following side effects appear** (affect up to 1 out of 1000 users):

- Long-lasting diarrhea without improvement. See also warnings.
- Severe abdominal pain which may reach through to your back. This could be a sign of pancreas inflammation.
- Difficulties in passing urine or blood in the urine. This symptoms may indicate kidney problems or changes in kidney functions.
- Decrease in magnesium levels: there may be a decrease in blood magnesium levels, especially if the medicine is used for longer than 3 months. This can be manifested in symptoms such as: tiredness, involuntary muscle contractions, disorientation/confusion, convulsions, dizziness, increased

heart rate (or other heart rate problems). Low magnesium levels could also cause a reduction in blood potassium or calcium levels. See also 'Tests and follow-up' in section 2.

- If you bruise easily. These symptoms can be a result of a blood problem. Your doctor may refer you to carry out a blood test.
- If you suffer from an infection or signs that could indicate an infection such as fever and serious deterioration in your general condition; or fever accompanied by signs of a local infection such as pain in the mouth, pharynx and throat; or problems in the urinary system. These reactions could indicate a decrease in white blood cells and in the body's resistance to infections. In a blood test the doctor will be able to check whether there is a white blood cells deficiency (agranulocytosis).

Additional side effects (including frequencies):

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

Headache, dizziness, tiredness, generally feeling unwell; diarrhea, constipation, abdominal pains, nausea, vomiting, flatulence; dry or sore mouth or throat, polyps in the stomach; itching, skin rash, urticaria; changes in liver functions (seen in blood tests, for instance in an increase in liver enzymes).

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

Despondency/depression; muscle or joint pains; water retention which may cause swollen arms and/or legs (edema); fracture in the hip, wrist and/or spine (especially if used with a high dosage and/or over a long time period - see also warnings above in the leaflet); changes in blood count (such as thrombocytopenia, eosinophilia, leukopenia).

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

Fever; restlessness, drowsiness, confusion; seeing or hearing things that are not realistic (hallucinations); skin reactions such as numbness, tingling, pricking, burning, bruises, red or purple spots that may be itchy, blistering; difficulty sleeping (insomnia); vision problems; vertigo (spinning feeling); changes in taste, loss of appetite, tongue inflammation; excessive sweating; increased sensitivity to light/sun; hair loss; shaking; anemia (may be manifested in paleness, tiredness, dizziness); kidney problems, pancreas inflammation, inflammation of the liver or jaundice (may be manifest in yellowing of the skin or the eyes), swelling of the breasts in men, erection problems (impotence); fungal infection (such as one which may affect the esophagus); angioedema.

*Very rare side effects (appear in less than 1 user out of 10,000):*

Severe hypersensitivity reactions including anaphylactic shock (the symptoms can include: fever, rash, swelling, fall in blood pressure), mouth inflammation (stomatitis); bowel inflammation (colitis); changes in test values (such as sodium, cholesterol and triglyceride levels), very severe skin reactions that can include reddening, blistering, severe inflammation, skin loss; reduction in the number of white blood cells (such as agranulocytosis, pancytopenia).

*Side effects of unknown frequency (effects whose frequency has not yet been determined):*

Rash, possibly with pain in the joints; skin-related forms of lupus or a lupus rash; visual hallucinations; decrease in magnesium, calcium and potassium levels; collagenous colitis.

**Side effects and drug interaction in children:**

Parents must inform the attending doctor about any side effect, as well as any additional medicine that is given to the child. See above for detailed side effects and drug interactions.

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

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) which leads to an online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

## 5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 25°C.

## 6. Additional information

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

Sucrose, corn starch, gelatin, methacrylic acid – ethyl acrylate copolymer (Eudragit), hypromellose, mannitol, talc, macrogol 6000, titanium dioxide (E-171), polysorbate 80, N-methylglucamine, sodium lauryl sulfate.

Each capsule of Lanton 15 also contains quinoline yellow.

- **What does the medicine look like and what does the package contain?**  
Lanton 15: yellow capsules containing white granules. 28 capsules in blister packs.  
Lanton 30: white capsules containing white granules, 28 capsules in blister packs.

**Registration holder:** Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

**Manufacturer:** Laboratorios Liconsa SA, Spain.

**Medicine registration number in the National Medicines Registry of the Ministry of Health:**

Lanton 15: 131 08 30988

Lanton 30: 129 25 30761

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