PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed 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 the 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 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 the medicine:

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

- You have liver problems (the doctor may adjust the dosage).
- You suffer from osteoporosis or are taking corticosteroid 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 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 suffered from a skin reaction after treatment with medicines 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.
- If you take Lanton for more than three months, your blood magnesium levels may decrease. Symptoms of low magnesium levels: fatigue, involuntary muscle contractions, disorientation/confusion, convulsions, dizziness, increase in heart rate. If you observe one of these symptoms, tell your doctor as soon as possible. Low magnesium levels can also lead to a reduction in blood potassium or calcium levels. Your doctor may decide to perform regular blood tests to monitor your blood magnesium levels.
- Lanton may affect the effectiveness of vitamin B12 absorption, especially if you take it for a long period. Contact your doctor if you observe one of the following symptoms, which could indicate low vitamin B12 levels:
  - Extreme tiredness or lack of energy
  - Feeling of pins and needles
  - Pain or redness of the tongue, mouth ulcers
  - Muscle weakness
  - Disturbed vision
  - Memory problems, confusion, depression
- You suffer from new symptoms or the existing symptoms worsen.

Additional warnings:

- The doctor may refer you for an endoscopic examination to investigate the cause of 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 Lanton, additional medicines to treat your condition such as: antibiotics for treatment of Helicobacter pylori bacteria, or anti-inflammatory medicines: also read the patient leaflet of these medicines carefully.
- If you experience diarrhea during the treatment, refer to the 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, which could lead to stomach infections. See also 'Side effects' section.
- 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 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).
- Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in connection with Lanton treatment. Stop using Lanton and refer immediately for medical treatment if you observe one of the symptoms described in the side effects section 4.
- 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 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 getting osteoporosis (for instance, if you are taking steroids).
- When taking Lanton, kidney inflammation may occur. The symptoms are: decreased volume of urine, blood in the urine, hypersensitivity reactions manifested by fever, rash and stiff joints. Report these symptoms to the doctor.
- The use of the medicine may mask symptoms of other illnesses.
- 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 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 the 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 the doctor or pharmacist. Especially inform the 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 the 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: 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, are planning a pregnancy or are breastfeeding, consult the doctor before using the medicine.

- There is insufficient information on the use of the 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 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 the doctor before taking this medicine.

3. How to use this medicine?

Always use according to the doctor's instructions. Check with the 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 within 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 until 6 years of age and for patients with difficulty swallowing capsules), the capsule can be opened, the contents mixed with soft acidic food (for instance apple purée or yogurt) or an acidic drink (for instance orange juice) and swallowed immediately.

If you have accidentally taken a higher dosage or if a child has accidentally swallowed the medicine, refer immediately to a doctor or 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 the 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 the doctor.

If you stop taking the medicine before the time determined by the 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 the doctor or pharmacist.

4. Side effects

As with 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 to a doctor or 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), fever or a drop in blood pressure.
- Blistering, 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 could be signs of a severe, rare and life-threatening skin syndrome called Stevens-Johnson syndrome, toxic epidermal necrolysis or DRESS syndrome (frequency unknown).

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

- Persistent diarrhea without improvement. See also warnings.
- Intense and sudden abdominal pain which may radiate to the back and causes nausea and vomiting. This could be a sign of pancreas inflammation.
- Difficulties in passing urine or blood in the urine. These 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: fatigue, 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. The doctor may decide to perform regular blood tests to monitor your blood magnesium levels.
- You bruise easily. These symptoms can be a result of a blood problem. The doctor may refer you to perform a blood test.
- 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 the 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; 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 swelling of the arms and/or legs (edema); fractures 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; insomnia; vision problems; vertigo (spinning feeling); changes in taste, loss of appetite, tongue inflammation; excessive sweating; increased sensitivity

to light/sun; hair loss; feeling of pins and needles (paresthesia); shaking; anemia (may be manifested in paleness, tiredness, dizziness, fainting); kidney problems (inflammation, changes in urination, blood in the urine), 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 blood test values: such as decrease in sodium levels (symptoms include nausea, vomiting, headaches, drowsiness and fatigue, confusion, muscle weakness or spasms, irritability, seizures and coma), increase in cholesterol and triglyceride levels. The doctor may perform blood tests to monitor the blood sodium levels; Very severe skin reactions that can include reddening, blistering, severe inflammation, skin loss (Stevens-Johnson syndrome or toxic epidermal necrosis); reduction in the number of white blood cells (such as agranulocytosis, pancytopenia), collagenous colitis.

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.

Side effects and drug interaction in children:
Parents need to 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 the 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) 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 in the original package.

6. Additional information

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

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

Composition of the capsule:

Lanton 15: Gelatin, titanium dioxide, quinoline yellow, water.

Lanton 30: Gelatin, titanium dioxide, water.

- **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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