

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS

(PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Losec® 20 mg Capsules

Composition

Each capsule contains: Omeprazole 20 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.

You should take this medicine in accordance with the instructions in the dosage section of this leaflet. Consult the pharmacist if you need more information. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve.

This medicine is not intended for children and adolescents under the age of 18.

1. What is the medicine intended for?

This medicine inhibits acid secretion in the gastrointestinal tract.

Losec is intended for the relief of reflux symptoms (such as heartburn) that occur at a frequency of twice a week or more in patients over 18 years old.

Therapeutic class:

Proton pump inhibitors (PPI).

2. Before using the medicine

Do not use the preparation if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (see section 6 – "Additional information").
- You are sensitive (allergic) to medicines that contain other proton pump inhibitors (PPI) (such as: pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- You are taking a medicine that contains nelfinavir (a medicine for treatment of HIV infections).
- You suffer from difficulty or pain while swallowing food, bloody vomit or bloody or black stool.
- You have heartburn accompanied by lightheadedness, sweating or dizziness.
- You have pain in the chest or shoulders accompanied by shortness of breath, sweating, pain that radiates to the arms, neck or shoulders, or dizziness.
- You frequently have chest pain.
- You are under 18 years of age.

Special warnings regarding the use of the medicine

Severe skin reactions have been reported, including: Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms syndrome (DRESS) and acute generalized exanthematous pustulosis (AGEP). Stop using Losec and seek immediate medical treatment if you notice symptoms related to these severe skin reactions, which are described in section 4.

Losec may hide the symptoms of other diseases. Therefore, you should talk to your doctor immediately if you suffer from any of the following symptoms before starting the treatment with Losec or during the treatment with Losec:

- You suffer from unexplained severe weight loss and you have problems swallowing.
- You suffer from abdominal pain or indigestion.
- You vomit food or you have bloody vomit.
- You have bloody stool (black stool).
- You suffer from severe or persistent diarrhea, as the use of Losec can slightly increase the risk of diarrhea as a result of an infection.
- You suffer from severe problems in your liver function.
- You have ever developed a skin reaction after the use of a medicine similar to Losec that decreases acid secretion in the stomach.
- You are about to have a specific blood test (chromogranin A).
- You suffer from heartburn for a period of over 3 months, this might indicate a more serious problem.
- You suffer from frequent wheezing, particularly if accompanied by heartburn.
- You suffer from nausea or vomiting.
- You take Losec for a long period (more than a year), the doctor may keep you under regular surveillance. You should report to the doctor any new or exceptional symptom every time you see your doctor.
- Taking medicines from the class of proton pump inhibitors, such as Losec, especially for a period of more than a year, may slightly increase the risk of fracture in the hip, wrist or spine. You should

tell your doctor if you suffer from osteoporosis or if you are taking corticosteroid medicines (which may increase the risk of osteoporosis).

- You develop a skin rash, especially in areas exposed to the sun, you should report this to your doctor as soon as possible, as you may need to stop using Losec. You should also inform your doctor if you suffer from other disease symptoms such as joint pain.
- You should consult the doctor about regularly testing your blood magnesium level during the treatment with this medicine.

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 inform the doctor or pharmacist if you are taking any of the following medicines:

- Nelfinavir (a medicine for the treatment of HIV infection) – do not take Losec if you take a medicine that contains Nelfinavir.
- Ketoconazole, itraconazole, posaconazole or voriconazole (for the treatment of fungal infections).
- Digoxin (for treatment of cardiac problems).
- Diazepam (for the treatment of anxiety, as a muscle relaxant or for epilepsy).
- Phenytoin (for treatment of epilepsy). If you are taking phenytoin, the doctor will monitor you when you start or stop the treatment with Losec.
- Blood thinning medicines such as warfarin or other vitamin K blockers. Your doctor may monitor you when you start or stop the treatment with Losec.
- Rifampicin (for the treatment of tuberculosis).
- Atazanavir, saquinavir (medicines for the treatment of HIV infection).
- Tacrolimus or mycophenolate (in cases of organ transplantation).
- St. John's Wort plant (hypericum perforatum) for the treatment of depression.
- Cilostazol (for the treatment of intermittent claudication).
- Clopidogrel (anticoagulant).
- Erlotinib (for the treatment of esophageal cancer).
- Methotrexate (a chemotherapy medicine that is used in high doses for the treatment of cancer) – if you are taking high doses of methotrexate, the doctor may consider temporarily stopping the treatment with Losec.
- Amoxicillin and clarithromycin (antibiotics) – if the doctor prescribed these antibiotics for you together with Losec for the treatment of ulcers that are caused by Helicobacter pylori infection, it is very important to tell your doctor about any other medicine you are taking.

Pregnancy, breastfeeding and fertility

You should consult the doctor or pharmacist before using the medicine if you are pregnant, think you might be pregnant, planning to become pregnant or breastfeeding. Omeprazole (the active ingredient in this medicine) is secreted in breastmilk, however it is not expected to affect the infant when taking the recommended dose. The doctor will decide whether you can take this medicine while breastfeeding.

Use in children

This medicine is not intended for children and adolescents under the age of 18 years.

Driving and operating machinery Losec is not supposed to affect your ability to drive, use machines or operate machinery. Side effects such as dizziness and visual disturbances may occur (see section 4). If you experience these effects do not drive or operate machinery.

Important information about some of the ingredients of the medicine

- The medicine Losec contains a sugar called lactose. If you have been told by your doctor that you have a sensitivity to certain sugars, consult the doctor before taking this medicine.
- This medicine contains less than 23 mg of sodium per capsule, and is therefore considered sodium-free.

3. How should you use the medicine?

This medicine is not intended for children and adolescents under 18 years of age.

Follow the instructions for use as detailed below. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The recommended dosage for adults aged 18 years and over, in the absence of other instructions from the doctor, is:

- One capsule once a day before a meal for a duration of 14 days.
- You can repeat a 14-day treatment every 4 months.
- Do not take this medicine for more than 14 days or more than one course of treatment (14 days) every 4 months, unless instructed by the doctor.
- If there is no improvement in your condition after 14 days and/or the symptoms recur frequently or worsen, you should contact the doctor.

Do not exceed the recommended dose.

Take this medicine before a meal. It is recommended to take the

medicine in the morning.

Swallow the capsule whole with a glass of water.

Do not chew or crush the capsule and/or its contents, as the capsule contains coated pellets which prevent the medicine from being broken down by the acid in the stomach.

Patients with swallowing difficulties:

You can open the capsule and swallow its contents or alternatively, you can mix the capsule contents with a slightly acidic drink (such as orange juice) or with yogurt, and take it within 30 minutes. Alternatively you can suck the capsule and swallow its contents. To ensure you have taken the entire dose, you should rinse the glass with half a cup of water and drink it again.

Children who cannot swallow the capsule whole, can swallow the contents of the opened capsule or suck the capsule and swallow its contents. You can mix the capsule contents with a slightly acidic drink such as orange juice or with yogurt, and take it within 30 minutes.

To ensure the child has taken the entire dose, you should rinse the glass with half a cup of water and drink it again.

If you have accidentally taken an overdose of the medicine, or if a child has accidentally swallowed the medicine, refer immediately to the doctor or to a hospital emergency room and take the package of the medicine with you.

If you have forgotten 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 missed dose. Do not take a double dose to compensate for a missed dose.

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 Losec 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. **Stop taking Losec and refer to the doctor immediately if you notice any of the following side effects, that are rare (affect up to 1 patient out of 1,000 patients) or very rare (affect up to 1 patient out of 10,000 patients) but severe:**

- Sudden wheezing while breathing, swelling of the lips, tongue and throat or of the body, rash, fainting or difficulties swallowing (severe allergic reaction) (rare).
- Redness of the skin that is accompanied by blisters or peeling. Severe blisters and bleeding may also occur in the lips, eyes, mouth, nose and genitals. This condition could be "Stevens-Johnson syndrome" or toxic epidermal necrolysis (toxic necrosis of the skin) (very rare).
- Extensive rash, high fever and enlarged lymph nodes (DRESS syndrome – drug reaction with eosinophilia and systemic symptoms syndrome or hypersensitivity to the medicine) (rare).
- Extensive rash characterized by red, scaly skin and lumpy skin with blisters accompanied by fever. The symptoms usually appear at the beginning of the treatment (Acute Generalized Exanthematous Pustulosis) (rare).
- Yellowing of the skin, dark urine and tiredness which may be symptoms of liver problems (rare).

Additional side effects

Common side effects (affect up to 1 patient out of 10 patients):

- Headache.
- Effects on the stomach or the intestine: diarrhea, abdominal pain, constipation, swelling in the stomach (flatulence).
- Nausea or vomiting.
- Benign gastric polyps.

Uncommon side effects (affect up to 1 patient out of 100 patients):

- Swelling of the legs and ankles.
- Sleep problems (insomnia).
- Dizziness, tingling and numbing sensation, feeling drowsy.
- Sensation of dizziness (vertigo).
- Change in liver function blood tests.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lack of energy.

Rare side effects (affect up to 1 patient out of 1,000 patients):

- Blood disorders such as a decrease in the number of white blood cells or platelets that may cause weakness, bruising or make you develop infections more easily.
- Low levels of sodium in the blood – may cause weakness, vomiting and cramps.
- Feeling agitated, confused or depressed.
- Changes in the sense of taste.
- Vision problems such as blurred vision.
- Sudden wheezing or shortness of breath (bronchospasm).
- Dry mouth.
- An inflammation of the inside the mouth.
- Fungal infection in the mouth that may affect the intestine.
- Hair loss (balding).

- Skin rash on exposure to sunshine.
- Joint pain (arthralgia) or muscle pain (myalgia).
- Severe kidney problems (Interstitial Nephritis).
- Increased sweating.

Very rare side effects (affect up to 1 patient out of 10,000 patients):

- Changes in blood count including agranulocytosis (lack of white blood cells).
- Aggressiveness.
- Hallucinations – seeing, sensing or hearing non-existing things.
- Severe liver problems that cause liver failure and brain inflammation.
- Erythema multiforme.
- Muscle weakness.
- Breast enlargement in men.

Side effects with unknown frequency (side effects whose frequency cannot be estimated from the available data):

- Inflammation in the gut (leading to diarrhea).
- If you are being treated with Losec for a period of more than 3 months your blood magnesium level may decrease. Low magnesium levels can manifest as tiredness, involuntary muscle contractions, confusion, spasms, dizziness or increased heart rate. If you have any of these symptoms, you should inform the doctor as soon as possible. Low levels of magnesium may also cause a decrease in the levels of potassium or calcium in the blood. Your doctor may decide to perform regular blood tests to monitor your blood magnesium levels.
- Arash, sometimes accompanied by joint pain.

In very rare cases Losec may affect the white blood cells and cause an immunodeficiency (impairment of the immune system). If you have an infection accompanied by symptoms such as fever with a severe decline in your general state of health or fever with symptoms of local infection such as pain in the neck, throat or mouth or difficulty urinating, you should consult the doctor as soon as possible to rule out a lack of white blood cells (agranulocytosis) by a blood test. In such a case it is important to let the doctor know about your medicine.

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 this medicine in a dry place, below 25°C. Keep in the original package to protect from light.**
- **Close the bottle tightly after every use.**
- **The medicine can be used for up to 3 months after first opening the bottle, but no later than the expiry date of the medicine.**

6. Additional information

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

Capsule contents: Mannitol, methacrylic acid copolymer, lactose anhydrous, hypromellose, hydroxypropyl cellulose, microcrystalline cellulose, polyethylene glycol, disodium phosphate dihydrate, sodium lauryl sulfate, magnesium stearate.

Capsule composition: Gelatin, red iron oxide, titanium dioxide, water.

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

The capsule is made up of an opaque pink part marked with the number "20" and a reddish brown part marked with "A LOSEC®". The capsules contain white to slightly yellowish enteric coated pellets. Package sizes: 7, 14, 28 and 30 capsules. Not all package sizes may be marketed.

Name and address of the manufacturer and marketing authorization holder:

Teva Israel Ltd., 124 Dvora HaNe'eva St., Tel Aviv 6944020.

The leaflet was revised in July 2022 in accordance with the Ministry of Health guidelines.

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

139.78.31879