

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

The medicine is dispensed with a doctor's prescription only

Losec® 20 mg Rx 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.

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

This medicine is intended for children over the age of one and weighing 10 kg or more.

1. WHAT IS THE MEDICINE INTENDED FOR?

This medicine inhibits acid secretion in the gastrointestinal tract.

The medicine is intended for:

- Treatment of stomach ulcer and duodenal ulcer.
- Combination therapy with an antibiotic for Helicobacter pylori associated with gastric ulcer.
- Treatment of reflux esophagitis.
- Long-term treatment of reflux esophagitis and Zollinger Ellison syndrome. Maintenance treatment for the prevention of relapse in patients with a gastric ulcer that responds poorly or for severe reflux esophagitis.
- Treatment of severe reflux esophagitis in children aged one year and above.
- Treatment and prevention of stomach ulcer or duodenal ulcer as a result of NSAIDs treatment (non-steroidal anti-inflammatory drugs) in high-risk patients.

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 omeprazole 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.

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.

- If you are taking 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).

- If 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.

- The use of Losec may cause kidney inflammation. The symptoms may include a decrease in the amount of urine or blood in the urine and/or a hypersensitivity reaction such as fever, rash and joint stiffness. Report these signs to the treating doctor.

- Losec may affect the absorption of vitamin B₁₂, especially if Losec is taken for a prolonged period. Refer to the doctor if you notice the following symptoms, which indicate a low level of vitamin B₁₂:

- Extreme fatigue or lack of energy
- Tingling and numbing sensation
- Pain or redness of the tongue, mouth ulcers
- Muscle weakness
- Visual disturbances
- Memory impairment, confusion, depression

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 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 medicines 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

Certain children with chronic disease might need a long-term treatment, even though this is not recommended. This medicine is not intended for use in children under one year of age or who weigh less than 10 kg.

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

- Losec contains a sugar called lactose. If you have a sensitivity to certain sugars, consult your 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?

Always use the medicine according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is:

Treatment of reflux esophagitis:
Adults: One capsule of 20 mg once a day for a duration of 4-8 weeks. The doctor may recommend to continue taking the capsules or to increase the dosage as needed.

To prevent symptoms from recurring, the doctor may recommend to continue taking the medicine at doses of 10, 20, or 40 mg.

Children: The dosage will be determined by the doctor according to the child's weight. Children with swallowing difficulties, see information below.

Treatment of duodenal ulcer and stomach ulcer:

One capsule of 20 mg once a day. The duration of treatment will be determined by the doctor, and will

usually be for a period of 2 to 4 weeks. The doctor may recommend to continue taking the capsules or to increase the dosage as needed, depending on the response to the treatment.

Prevention of peptic ulcer relapse:

For the prevention of ulcer relapse, the accepted dosage is 10 mg or 20 mg once a day. The doctor may increase the dosage if the symptoms reoccur.

Treatment and prevention of stomach ulcer or duodenal ulcer as a result of NSAID treatment (non-steroidal anti-inflammatory drugs):

If you have previously suffered from an ulcer and there is a need to continue taking a non-steroidal anti-inflammatory medicine, the accepted dosage is a capsule of 20 mg once a day for 4-8 weeks.

Treatment and prevention of gastric ulcer caused by Helicobacter pylori bacteria:

The accepted dose is one capsule of 20 mg twice a day for one week. The doctor may recommend taking two of the following antibiotics: amoxicillin, clarithromycin and metronidazole. The standard duration of treatment is one week. Follow the instructions for taking the medicine strictly and consult the doctor in case of any doubt.

Children: the dosage should be determined according to weight. Children with swallowing difficulties, see below.

Treatment of excess stomach acid caused by a tumor in the pancreas (Zollinger Ellison Syndrome):

The accepted starting dose is 60 mg once daily. The doctor will instruct you regarding the number of capsules, when to take them, and the duration of treatment.

Do not exceed the recommended dose.

Take the 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.

This medicine is not intended for infants under one year of age.

If there is no improvement in your condition you should contact the doctor.

Children or patients with swallowing difficulties:

You can open the capsule and swallow its contents with a glass of water, 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. To ensure you have taken the entire dose, you should rinse the glass with half a cup of water and drink it again. Alternatively you can suck the capsule and swallow its contents.

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.

If you stop taking the medicine Do not stop taking the medicine without consulting the doctor or pharmacist.

Follow the treatment as recommended by the doctor.

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, abdominal bloating, 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 which 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 taking 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.
- A rash, 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, polyemullose, hydroxypropyl cellulose, microcrystalline cellulose, polyethylene glycol, disodium phosphate dihydrate, sodium lauril 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 license holder:
Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv.

The leaflet was revised in July 2023 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health:
050.66.26256

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