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

The medicine is dispensed without a doctor's prescription

LOSEC®
Capsules
20 mg

Composition
Each capsule contains:
Omeprazole 20 mg

For a list of the inactive ingredients in this preparation, see section 6 – "Further information".

Read the package insert carefully and in its entirety before using the medicine. This package insert includes concise information about the medicine. If you have further questions, refer to your doctor or to a pharmacist.

You must use this medicine in a correct manner. Consult the pharmacist if you need additional information. In the event signs of the disease (symptoms) get worse or are not improving, refer to the physician.

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

1. WHAT IS THIS MEDICINE INTENDED FOR?

Inhibits acid secretion in the gastro intestinal tract.

Losec capsules are intended for relief of reflux-like symptoms (e.g., heartburn) which occur at a frequency of two or more times per week in patients over 18 years of age.

Therapeutic group:
Proton pump inhibitors (PPI).

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:
- you are sensitive (allergic) to the active ingredient or to any other ingredient in the preparation (see section 6), or to other proton pump inhibitors (PPI) e.g., pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- you suffer from pain while swallowing food, vomiting with blood, bloody or black stools.
- you are taking nelfinavir (a medicine used to treat HIV).
- Do not use this medicine in children and adolescents under 18 years of age.

Special precautions regarding the use of this medicine

❗ Before you start to take this medicine talk to your doctor if:
- you have ever had a skin reaction after treatment with a medicine similar to Losec that reduces stomach acid. If you get a rash on your skin, especially in areas exposed to the sun, tell your doctor as soon as you can, as you may need to stop your treatment with Losec. Remember to also mention any other ill-effects like pain in your joints.
- you are suffering or if you have suffered in the past from severe liver function problems, heartburn for over three months or you have been taking medicines for the treatment of heartburn or indigestion for a prolonged period.
- you are suffering or if you have suffered in the past from unexplained weight loss, have problems swallowing, nausea or vomiting, stomach pain, heartburn with lightheadedness, sweating or dizziness, pain in the chest or shoulders accompanied by shortness of breath, sweating, pain radiating to the arms, neck or shoulders, disorientation or dizziness, frequent chest pain, frequent wheezing, particularly if accompanied with heartburn.
- you begin to vomit food or blood.
- you pass black stools (blood-stained faeces).
- you experience severe or persistent diarrhoea, as use of omeprazole slightly increases the risk of infection-associated diarrhoea.
- you suffer or have suffered from an intolerance to some sugars.
- you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.
- The preparation contains lactose and may cause an allergic reaction in patients sensitive to lactose.

❗ Additional precautions
Do not exceed the recommended duration of treatment.

Taking a proton pump inhibitor like Losec, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Consult your doctor concerning monitoring blood magnesium levels during treatment with this medicine.

You must inform your doctor if you are about to undergo laboratory tests; the doctor may instruct you to stop treatment with the medicine temporarily.

❗ Inform your doctor or pharmacist if you are taking or have recently taken other medicines, including non-prescription medicines or dietary supplements; especially inform the doctor or the pharmacist if you are taking the following medicines:
- drugs affecting the central nervous system (such as phenytoin [for epilepsy], medicines for insomnia or anxiety such as diazepam). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking Losec.
- anticoagulants (such as warfarin), or other vitamin K blockers (for thinning of the blood). Your doctor will need to monitor you when you start or stop taking Losec.
- cilostazol (for leg pain).
- digoxin (for the heart).
- ketoconazole, itraconazole, posaconazole, or voriconazole (for fungal infections).
- clarithromycin (antibiotic).
- rifampicin (for tuberculosis).
- tacrolimus (used in organ transplants).
- preparations containing iron.
- disulfiram (detoxifier).
- atazanavir, saquinavir, ritonavir (medicines to treat HIV).
- erlotinib (anti cancer).
- St. John's wort (antidepressant).
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your Losec treatment.

It has been reported that medicines belonging to this group (PPI) may reduce the effect of clopidogrel, which is used to inhibit blood platelet aggregation. Use of this medicine together with clopidogrel should be avoided.

❗ Pregnancy and breastfeeding
If you are pregnant, think you may be pregnant, planning to become pregnant or are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

❗ Use in children
This medicine is not intended for administration in children and adolescents under 18 years of age.

❗ Driving
Losec is not likely to affect your ability to drive or use any tools or machines. Yet, side effects such as dizziness and visual disturbances may occur. If affected, you should not drive or operate machinery.

3. HOW SHOULD YOU USE THIS MEDICINE?

Strictly follow the instructions for use detailed below. If you are unsure, refer to your doctor or pharmacist.

This medicine should be taken before a meal, preferably in the morning.

The contents of the capsule should not be chewed. Swallow the capsules with a glass of water.

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

For patients with swallowing difficulties, the capsule might be opened and the contents swallowed or suspended in a slightly acidic fluid e.g., orange juice or yogurt. The suspended contents should be taken within 30 minutes. Alternatively these patients can suck the capsule and swallow the contents.

Children who are unable to swallow the capsule whole might swallow the contents of the opened capsule, or suck the capsule and swallow its contents. The contents must be suspended in a slightly acidic fluid, e.g., orange juice or yogurt, and taken within 30 minutes. Remember to stir the mixture before each drinking. To make sure that you have drunk all of the medicine, rinse it down with half a glass of water and drink it.

Recommended dosage for adults above the age of 18 years unless otherwise prescribed by your physician:

1 capsule once a day before a meal for a period of 14 days.

Do not exceed the recommended daily dosage.

You may repeat a 14 days course every 4 months. Do not take the medicine for more than 14 days or more often than one course (14 days) every 4 months unless instructed to do so by a physician. If there is no improvement in your condition after 14 days and/or the symptoms return frequently or worsen, contact your physician.

If you accidentally took an overdose of this medicine or if a child accidentally swallowed from this medicine, refer to your doctor or a hospital emergency room immediately and bring the package of the medicine with you.

If you forget to take the medicine
If you forget to take this medicine at the specified time, take the dose as soon as you remember, but never take a double dose on the same day. Take the next capsule at the usual time and consult the doctor.

How can you contribute to the success of the treatment?
Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have additional inquiries regarding use of the medicine, consult the physician or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of this medicine can cause side effects among some users. Do not be alarmed by the list of side effects; you may not suffer from any of them.

Refer to a doctor immediately if:
- An allergic or anaphylactic reaction develops (characterized by shortness of breath, sudden wheezing, and swelling of the body, facial area, lips, tongue or throat, rash, fainting or difficulties in swallowing).
- Reddening of the skin occurs, accompanied by blisters or peeling. Severe blistering and bleeding may also occur in the lips, eyes, mouth, nose and genitals.
- You develop jaundice (yellow eyes, skin and nails and dark urine) and tiredness, which may be indicative of liver problems.
- Contractions, dizziness, irregular heart beats or arrhythmias, restlessness, nervousness, sudden convulsions or tremor, muscular weakness, contractions in hands and feet, muscular contractions or muscular pain, contractions in the throat occur (signs of low blood sodium and magnesium levels) - stop treatment and refer to the doctor.
- There is severe diarrhea which is persistent or is accompanied by severe abdominal pain and fever.

Additional side effects
Common side effects (affect 1 to 10 users in 100)
Headache, diarrhea, constipation, stomach ache, nausea (feeling sick), vomiting, flatulence.

Uncommon side effects (affect 1 to 10 users in 1,000)
Swelling of the feet and ankles, sleepiness, trouble sleeping, dizziness, pins and needles, vertigo, feeling faint, increase in liver enzymes, rash, itching, hives, dermatitis, generally feeling unwell and weakness.

Rare side effects (affect 1 to 10 users in 10,000)
- Blood problems such as a reduced number of white cells or platelets, which may sometimes lead to infections with symptoms of fever, severe chills, sore throat, mouth ulcers, bruising more easily than normal or tiredness
- Allergic reactions sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing
- Low blood sodium levels. This may cause weakness, being sick (vomiting) and cramps
- Blurred vision; taste disturbance
- Feeling agitated, confused or depressed
- Suddenly feeling wheezy or short of breath (bronchospasm)
- Dry mouth
- An inflammation of the inside of the mouth
- Thrush in the mouth or gullet
- Liver problems, including jaundice which can cause yellow skin, dark urine and tiredness
- Unusual hair loss or thinning
- Skin sensitivity to light
- Painful swollen joints; aching muscles or muscle weakness
- Kidney disease
- Increased sweating

Very rare side effects (affect less than 1 user in 10,000)
- Changes in blood count including agranulocytosis (lack of white blood cells)
- Aggression
- Hallucinations (seeing or feeling things that are not there)
- Liver failure leading to brain damage
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (erythema multiforme, Stevens-Johnson's syndrome, toxic epidermal necrolysis)
- Muscle weakness
- Enlarged breasts in men

Side effects of unknown frequency
- Rash, possibly with pain in the joints.
- Inflammation in the gut, leading to acute diarrhea that does not stop or accompanied by intense abdominal pain and fever.
- If you are on Losec for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Losec may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a severely reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that damage to the immune system (agranulocytosis) can be ruled out by a blood test.

Consult with your doctor if a side effect occurs, if any of the side effects worsens, or if you experience a side effect not mentioned in this leaflet.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW TO STORE THIS MEDICINE?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use after the expiry date mentioned on the pack. The expiration date refers to the last day of the indicated month.

Store this medicine in a dry place, below 25ºC.

Store in the original package in order to protect from light.

This medicine may be used for 3 months following first opening of the bottle.

Close the bottle tightly after use in order to prevent penetration of air and humidity.

6. FURTHER INFORMATION

Aside from the active ingredient, this medicine also contains:
Capsule content
Mannitol, methacrylic acid copolymer, lactose anhydrous, hydroxypropylmethyl cellulose (hypromellose), hydroxypropylcellulose, microcrystalline cellulose, polyethylene glycol, disodium hydrogen phosphate dihydrate, sodium laurilsulfate, magnesium stearate.
Capsule shell
Gelatin, red iron oxide, titanium dioxide, water.
Each capsule of Losec 20 mg contains 8 mg lactose and 0.25 mg sodium.

What the medicine looks like and contents of the package
Capsules with opaque pink body and reddish-brown cap. The capsules contain white to slightly beige enteric coated pellets.

LICENSE HOLDER
Abic Ltd., P.O. Box 8077, Kiryat Nordau, Netanya.

MANUFACTURER AND ADDRESS
Teva Pharmaceutical Industries Ltd., P.O. Box 3190, Petah-Tikva.

This leaflet was checked and approved by the Ministry of Health in May 2016.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 139.78.31879

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