**Patient package insert according to Pharmacists' Regulations (Preparations) – 1986**

This medicine can be sold with a physician's prescription only

# Omepradex® caplets, 10,20,40 mg

Each caplet contains: Omeprazole 10, 20, or 40 mg respectively.

Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

**Read this entire leaflet carefully before using this medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

**This medicine is intended for use in children over 6 years of age.**

## 1. What is the medicine intended for?

The medicine inhibits acid secretion in the gastrointestinal tract.

This medicine is intended for:

- Treatment of gastric ulcer and duodenal ulcer.
- Combination treatment with antibiotics for Helicobacter pylori associated with gastrointestinal ulcer.
- Treatment of inflammation of the esophagus due to reflux (reflux esophagitis).
- Long-term treatment of reflux esophagitis.
- Treatment of Zollinger-Ellison Syndrome.
- Maintenance treatment for the prevention of relapse in patients with poorly responsive peptic ulcer or severe reflux esophagitis.
- Treatment of severe reflux esophagitis in children over 6 years of age.
- Treatment and prevention of gastric ulcer or duodenal ulcer caused by treatment with NSAIDs (non-steroidal anti inflammatory drugs) in high risk patients.

**Therapeutic group:**
Proton pump inhibitors (PPIs).

## 2. Before using the medicine

**Do not use the medicine if:**

- You are hypersensitive (allergic) to the active ingredient (omeprazole) or to any of the other ingredients this medicine contains (see section 6 "Additional information").
- You are hypersensitive (allergic) to medicines that contain other proton pump inhibitors (PPI) (e.g., pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- You are taking a medicine that contains nelfinavir (a medicine used to treat HIV infections).
- You suffer from difficulty or pain while swallowing food, from bloody vomiting, bloody or black stool.
- You have heartburn accompanied by lightheadedness, sweating or dizziness.
- You have chest or shoulder pain 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**

Serious skin reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP), have been reported. Stop using **Omepradex** and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions, described in section 4.

**Omepradex may mask the symptoms of other diseases. Therefore, you should contact your doctor immediately if you suffer from one of the following symptoms before starting treatment with Omepradex or during treatment with Omepradex:**

- You are suffering from a significant unexplained weight loss and have problems swallowing.
- You are suffering from stomach pain or digestion difficulties.
- You vomit food or have bloody vomiting.
- You pass bloody stool (black stool).
- You suffer from severe or persistent diarrhea, as use of **Omepradex** can slightly increase the risk of diarrhea as a result of an infection.
- You suffer from severe liver function problems.
- You have ever had a skin reaction after treatment with a medicine similar to **Omepradex** that reduces acid secretion in the stomach.
- You are about to undergo a specific blood test (Chromogranin A).
- You suffer from heartburn for a period of more than 3 months, this may indicate a more serious problem.
- You suffer from frequent wheezing, particularly if it is accompanied by heartburn.
- You suffer from nausea or vomiting.
- You are taking **Omepradex** for a long period (for more than a year), the doctor may instruct you to be under regular medical supervision. Report any new and unusual symptom each time you see your doctor.
- The use of a medicine from the proton pump inhibitors group, such as **Omepradex**, especially for a period of more than one year may slightly increase your risk of a fracture in the hip, wrist or spine. Tell your doctor if you suffer from osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).
- You develop a skin rash, especially in areas exposed to the sun. Inform the doctor as soon as possible, as you may need to stop using **Omepradex**. Also inform the doctor if you suffer from any other symptoms of disease such as joint pain.
- Consult the doctor about regular monitoring of blood magnesium levels during 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 pharmacist.** The doctor or pharmacist should be informed especially if you are taking the following medicines:

- **Nelfinavir** (a medicine to treat HIV infections) – **Omepradex** should not be taken if you are taking a medicine that contains Nelfinavir.
- Ketoconazole, itraconazole, posaconazole or voriconazole (to treat fungal infections).
- Digoxin (to treat heart problems).
- Diazepam (to treat anxiety, relax muscles or in epilepsy).
- Phenytoin (to treat epilepsy). If you are taking phenytoin, the doctor will need to monitor you when you start or stop treatment with **Omepradex**.
- Blood-thinning medicines such as warfarin or other vitamin K blockers. The doctor may need to monitor you when you start or stop treatment with **Omepradex**.
- Rifampicin (to treat tuberculosis).
- Atazanavir, saquinavir (medicines to treat HIV infection).
- Tacrolimus or mycophenolate (in cases of organ transplantation).
- St. John's wort plant (hypericum perforatum) to treat depression.
- Cilostazole (to treat intermittent claudication).
- Clopidogrel (prevents clotting).
- Erlotinib (to treat cancer).
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking high doses of methotrexate, the doctor may consider to temporarily stop the treatment with **Omepradex**.
- Amoxicillin and clarithromycin (antibiotics) – if the doctor prescribed you these antibiotics together with **Omepradex** to treat ulcers caused by Helicobacter pylori infection, it is very important that you tell your doctor about any other medicine that you are taking.

**Use of the medicine and food**
Take the medicine before a meal.

**Pregnancy, breastfeeding and fertility**
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor or pharmacist before using this medicine.
Omeprazole (the active ingredient in the medicine) is excreted in breast milk, but is not expected to affect the baby when the recommended dosage is taken. The doctor will decide if you can take **Omepradex** while breastfeeding.

**Use in children**
Certain children who are chronically ill may require long-term treatment, even though this is not recommended.
This medicine is intended for use in children above 6 years of age.

**Driving and using machines**
**Omepradex** is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur (see section 4 "Side effects"). If affected, you should not drive or operate machinery.

**Important information about some of the ingredients of the medicine**
**Omepradex** contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per caplet, that is to say essentially "sodium-free".

## 3. How should you use the medicine?

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.
The dosage and manner of treatment will be determined by the doctor only. The usual recommended dosage is:

Treatment of reflux esophagitis
Adults: a caplet of 20 mg once a day for 4-8 weeks. The doctor may recommend to continue taking the caplets or to increase the dosage as needed.
To prevent the recurrence of symptoms, the doctor may recommend to continue taking the medicine in doses of 10, 20 or 40 mg.
Children: The dosage will be determined by the doctor and according to the child's weight.

Treatment of duodenal ulcer and gastric ulcer
20 mg caplet once daily. The duration of treatment will be determined by the doctor, and usually will be for a period of 2 to 4 weeks.
The doctor may recommend that you continue taking the caplets or increase the dosage as needed depending on your response to treatment.

To prevent recurrence of peptic ulcer
To prevent recurrence of the ulcer, the usual dose is 10 mg or 20 mg once daily. The doctor may increase the dosage if the symptoms return.

Treatment and prevention of gastric ulcer or duodenal ulcer caused by treatment with NSAIDs
If you have previously suffered from an ulcer and there is a need to continue taking a non-steroidal anti-inflammatory drug, the usual dose is a 20 mg caplet once daily for 4-8 weeks.

Treatment and prevention of a gastrointestinal ulcer caused by the bacteria Helicobacter Pylori
The usual dose is a 20 mg caplet twice daily for a week. The doctor may recommend taking two of the following antibiotics: amoxicillin, clarithromycin and metronidazole.
The usual duration of treatment is one week. Accurately adhere to the instructions for taking the medicine and consult the doctor if there is any doubt.

Treatment of excess acid in the stomach caused by a tumor in the pancreas (Zollinger-Ellison Syndrome)
The usual initial dose is 60 mg once daily. The doctor will guide you regarding the amount of caplets, the times to take them and the duration of treatment.

**Do not exceed the recommended dose.**

This medicine should be taken before a meal. It is recommended to take the medicine in the morning. The caplet should be swallowed whole with a glass of water.
The caplet should not be halved, crushed or chewed, in order to maintain the caplet's coating (the coating prevents the digestive juices in the stomach from breaking down the caplet so that the active ingredient is released only in the intestine, where the active ingredient is absorbed into the body).
This medicine is intended for children over 6 years of age.
If your condition does not improve, contact a doctor.

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

**If you forgot to take the medicine**
If you forgot to take this medicine at the designated time, take a dose as soon as you remember; but if it is almost time to take the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

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

Continue with the treatment as recommended by the doctor.

**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 on the use of this medicine, consult the doctor or pharmacist.**

## 4. Side effects

Like any medicine, the use of **Omepradex** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Stop taking Omepradex and refer to the doctor immediately if you have noticed the following rare (effects that occur in 1-10 out of 10,000 users) or very rare (effects that occur in less than 1 in 10,000 users) but serious side effects:**

- Sudden wheezing, swelling of the lips, tongue and throat or of the body, rash, fainting or difficulties in swallowing (severe allergic reaction).(rare)
- Reddening of the skin accompanied by blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'. (very rare)
- Generalized rash, high fever and enlarged lymph nodes (DRESS syndrome, drug reaction with eosinophilia and systemic symptoms or hypersensitivity to the medicine). (rare)
- Generalized rash characterized by red skin, with scaling, and bumpy skin with blisters accompanied by fever. The symptoms usually occur at the beginning of treatment (Acute Generalizd Exanthematous Pustulosis). (rare)
- Yellowing of the skin, dark urine and tiredness which can be symptoms of liver problems. (rare)

**Additional side effects**
**Common side effects** (effects that occur in 1-10 out of 100 users):

- Headache.
- Effects on the stomach or gut: diarrhea, stomach pain, constipation, wind (flatulence).
- Nausea or vomiting.
- Benign polyps in the stomach.

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

- Swelling of the feet and ankles.
- Trouble sleeping (insomnia).
- Dizziness, sensation of tingling and numbness, drowsiness.
- Dizziness (vertigo).
- Changes in blood tests that check liver functions.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lacking energy.

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

- Problems in the blood system such as a reduced number of white blood cells or platelets that can cause weakness, bruising or make infections more likely.
- Low blood sodium levels – this may cause weakness, vomiting and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Dry mouth.
- An inflammation inside the mouth.
- A fungal infection in the mouth which can affect the gut.
- Hair loss (balding).
- Skin rash on exposure to sunlight.
- Joint pain (arthralgia) or muscle pain (myalgia).
- Severe kidney problems (interstitial nephritis).
- Increased sweating.

**Very rare side effects** (effects that occur in less than 1 in 10,000 users):

- Changes in blood count including agranulocytosis (lack of white blood cells).
- Aggression.
- Hallucinations – seeing, feeling or hearing things that do not actually exist.
- Severe liver problems leading to liver failure and inflammation of the brain.
- Erythema multiforme.
- Muscle weakness.
- Enlarged breasts in men.

**Side effects with unknown frequency** (effects for which a frequency has not yet been determined):

- Inflammation in the gut (leading to diarrhea).
- If you are treated with **Omepradex** for a period of more than 3 months, it is possible that the levels of magnesium in your blood may decrease. 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, you should inform the 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 blood magnesium levels.
- Rash, sometimes accompanied by pain in the joints.

**Omepradex** may in very rare cases affect the white blood cells leading to immune deficiency (damage to the immune system). If you have an infection accompanied by symptoms such as fever with a severely reduced general health or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult a doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to inform your doctor about your medicine in this situation.

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.**

**Reporting side effects**
Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via 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 (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store above 25°C.

## 6. Additional information

**In addition to the active ingredient, the medicine also contains:**
Lactose monohydrate, hypromellose acetate succinate, magnesium carbonate heavy, sodium starch glycolate, talc, sodium stearyl fumarate, triethyl citrate, propylene glycol, purified water, titanium dioxide (E171), sodium hydroxide, sodium laurilsulfate, red iron oxide (E172), hypromellose 2910, yellow iron oxide (E172), carnauba wax.

**What the medicine looks like and what the package contains:**
Brownish-pink caplet.

Approved package sizes:
**Omepradex Caplets 10 mg, 40 mg**: 20, 30 caplets.
**Omepradex Caplets 20 mg**: 14, 20, 30 caplets.
Not all package sizes may be marketed.

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**Drug registration number at the national drug registry of the Ministry of Health:**
**Omepradex Caplets 10 mg**: 123-66-30228-00
**Omepradex Caplets 20 mg**: 120-19-30048-00
**Omepradex Caplets 40 mg**: 123-65-30268-00

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**Manufacturer and registration holder:**
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