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:
Omepradex caplets 10 mg
Omeprazole 10 mg
Omepradex caplets 20 mg
Omeprazole 20 mg
Omepradex caplets 40 mg
Omeprazole 40 mg

The list of inactive ingredients appears in section 6.

Read this entire leaflet carefully before you start using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the physician 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 similar.

This medicine is not intended for children under 6 years of age.

1. What is the medicine intended for?

The medicine inhibits acid secretion in the gastrointestinal tract.
- Treatment of severe gastric ulcer, severe duodenal ulcer, reflux oesophagitis, and Zollinger-Ellison syndrome.
- Maintenance treatment for the prevention of relapse in patients with poorly responsive peptic ulcer or with severe reflux oesophagitis.
- Treatment of severe reflux oesophagitis in children over 6 years of age.
- Treatment and prevention of gastric and duodenal ulcer caused by use of non-steroidal anti-inflammatory drugs (NSAIDs) in high risk patients.
- Combined treatment with antibiotics in Helicobacter pylori related peptic ulcer.

Therapeutic group: proton pump inhibitors (PPI).

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (Omeprazole) or any of the additional ingredients the medicine contains or other proton pump inhibitors (PPI) (such as: pantoprazole, lansoprazoe, rabeprazole, esomeprazole).
- You are taking nelfinavir (a medicine for treating HIV).

Special warnings regarding the use of this medicine
- **Before treatment with Omepradex, tell the physician if:**
  - You are pregnant, might be pregnant, planning to become pregnant or you are breastfeeding. (see "Pregnancy and breastfeeding" section).
  - You have suffered in the past from a gastric ulcer or you have previously undergone gastrointestinal surgery.
  - You suffer, or have suffered in the past, from liver problems, heartburn for a period longer than 3 months or if you are taking medicines for treatment of heartburn or indigestion for a prolonged period of time.
  - You are above 55 years of age with new symptoms or symptoms that have recently changed.
  - You have been told that you have low levels of magnesium in the blood. Consult the physician regarding monitoring of blood magnesium levels during the treatment with this medicine.
  - You suffer from nausea, from heartburn accompanied by blurriness, sweating or dizziness; chest or shoulderpain accompanied by shortness of breath, sweeting, pain radiating to the arms, neck or shoulders, blurriness or dizziness; from frequent chest pain; from frequent wheezing (breathing difficulties), mainly if accompanied by heartburn.
  - You are hypersensitive to any kind of food or medicine.
- If you are using Omepradex for a prolonged period (more than a year), your physician may monitor your medical condition regularly. Report any new and exceptional symptoms and medical circumstances every time you have a visit to the physician.
- The use of a preparation from the proton pump inhibitors (PPI) group such as Omepradex, especially for more than a year, may slightly increase the risk of hip, wrist and spine fractures. Tell the physician if you suffer from osteoporosis or you are taking corticosteroids (that may increase the risk of osteoporosis).
- Omepradex reduces the level of gastric acidity. Gastric acidity is required for the absorption of vitamin B_{12}. If you are taking the medicine for a prolonged period, consult the physician regarding the possibility of vitamin B_{12} deficiency.

The medicine may hide the symptoms of other diseases, **therefore, if you suffer from the following symptoms before or during the treatment,** refer to a physician immediately and inform him of this:
- Weight loss with no apparent reason, problem swallowing (such as difficulty or pain)
- Abdominal pain or indigestion
- Vomiting food or blood
- Black stools (bloody stools)
- Severe or persistent diarrhea (omeprazole has been associated with small increase in infectious diarrhea)

Tell the physician or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements. Especially if you are taking:
- Nelfinavir (a medicine for treating HIV), see "Do not use the medicine" section
- Clopidogrel (for the prevention of blood clots (thrombosis)), it has been reported that medicines of this group (PPI), such as omeprazole, may reduce the activity of clopidogrel and therefore, avoid taking the medicine with clopidogrel
- Atazanavir, saquinavir, ritonavir (medicines for treating HIV)
- Ketoconazole, itraconazole, posaconazole and vorconazole (medicines for treating fungal infections)
- Digoxin (for heart diseases)
- Medicines that affect the central nervous system (such as phenytoin [for epilepsy], diazepam [for treatment of anxiety or epilepsy and muscle relaxation]. If you are taking phenytoin, medical surveillance will be necessary at the beginning of treatment with Omepradex caplets and at the end of it
- Blood thinners such as warfarin and other vitamin K blockers. Medical surveillance will be necessary at the beginning of treatment and at the end of it.
- Cilostazol (for leg pain)
- Tacrolimus, mycophenolate mofetil (immunosuppressants)
- Iron containing preparations
- Disulfiram (for withdrawal)
- A herbal medicine containing hypericum perforatum (St. John's wort, used for the treatment of depression)
- Erlotinib (for treating cancer)
- Methotrexate – your physician may temporarily stop the treatment with Omepradex caplets
- Antibiotics such as clarithromycin, ampicillin
- Rifampicin (for the treatment of tuberculosis)

If the physician has instructed you to take Omepradex with antibiotics (clarithromycin, amoxicillin) for a combined treatment of gastric ulcer associated with Helicobacter pylori, it is especially important to report to the physician about any additional medicine you are taking.

Use of this medicine and food

Take the medicine before a meal, preferably in the morning.

Pregnancy and breastfeeding

Do not take the medicine without consulting a physician if you are pregnant, might be pregnant, planning pregnancy or if you are breastfeeding.

Driving and use of machinery

Use of the medicine may cause side effects such as dizziness and vision disturbances (see "Side effects" section). If these side effects occur, avoid driving a car and operating heavy machinery.

Important information about some of the ingredients of this medicine

This medicine contains lactose. If you have been told in the past by a physician that you have an intolerance to certain sugars, consult a physician before starting treatment with this medicine.

3. How to use this medicine?

Always use according to the physician's instructions. Check with the physician or pharmacist if you are not sure. The dosage and administration will be determined by the physician only. The usual recommended dosage is:

Treatment of reflux oesophagitis:
Adults: A 20 mg caplet once daily for 4-8 weeks. The physician may recommend that you continue to take the caplets or increase the dosage as needed. To prevent recurrence of symptoms, the physician may recommend continued treatment with the medicine in a dose of 10, 20 or 40 mg.
Children: Dosage will be determined according to weight.

Treatment of duodenal and gastric ulcer:
A 20 mg caplet once daily. Duration of treatment will be determined by the physician, usually for a period of 4 to 8 weeks. The physician may recommend that you continue to take the caplets or increase the dosage as needed, according to your response to the treatment. To prevent recurrence of the ulcer, the recommended dosage is a 10 or 20 mg caplet once daily. The physician may increase the dosage if the symptoms recur.

Treatment and prevention of NSAID-associated duodenal and gastric ulcers:
If you have sufferec in the past from an ulcer and there is a need to continue taking nonsteroidal anti-inflammatory drugs, the recommended dosage is a 20 mg caplet once daily. Duration of treatment will be determined by the physician.

Treatment of peptic ulcer caused by the bacterium Helicobacter pylori:
Adults: A 20 mg caplet twice daily for a week. Additionally, the physician may recommend that you take one or two of the following antibiotics: amoxicillin, clarithromycin, metronidazole.
Make sure to take the medicine accurately and according to the instructions and consult the physician if you have any doubt.

Treatment of excess gastric acid caused by a tumor in the pancreas (Zollinger-Ellison Syndrome)
The recommended dose is 60 mg once daily. The physician will adjust the dosage and duration of treatment, according to your condition.

Do not exceed the recommended dosage.

Swallow the caplet whole with a glass of water. Do not halve, crush or chew the caplet, in order to maintain the coating of the caplet (the coating prevents the digestive juices in the stomach from breaking down the caplet, so that the active ingredient will be released only in the intestine, where it is absorbed into the body).
If there is no improvement in your condition, contact the physician.

Tests and follow up

Inform the physician if you are about to undergo lab tests, the physician may instruct you to stop the treatment with the medicine two weeks before the tests.
Consult the physician regarding monitoring of blood magnesium levels during treatment with this medicine.
If you are taking phenytoin or blood thinners your physician will refer you for tests at the beginning and end of treatment.

If you have accidently taken a higher dosage or if a child has accidentally swallowed the medicine, proceed immediately to a physician or a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting unless explicitly instructed to do so by the physician.

If you forgot to take this medicine at the required time, take a dose as soon as you remember. However, if it is almost time for your next dose, skip the forgotten dose and resume your regular dosing schedule. Never take two doses together!
Continue with the treatment as recommended by the physician. Even if there is an improvement in your health, do not stop the treatment of this medicine without consulting the physician.

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 any further questions regarding the use of this medicine, consult a physician or pharmacist.

4. Side effects

Like any medicine, the use of Omepradex 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 use of this medicine and refer to a physician immediately if:
- An allergic or anaphylactic reaction has developed (manifested by shortness of breath, sudden wheezing and swelling of the body, the facial area, lips, tongue or throat, rash, fainting or difficulties in swallowing). This reaction can sometimes be very severe.
- You suffer from redness of the skin with blistering or peeling of the skin, severe blistering or bleeding in the lips, eyes, mouth, nose and genitals. Can be accompanied by fever and joint pain.
- You suffer from jaundice (yellowing of the skin, eyes and yellow nails, dark urine), tiredness (may be signs of liver problems).
- Signs of low levels of sodium and magnesium in the blood such as: cramps, dizziness, irregular heart rate or arrhythmia, restlessness, irritability, sudden spasm or tremor, muscle weakness, cramps in the hands and legs, muscle cramps or muscle pain, throat tightness.
- Acute diarrhea that does not cease or is accompanied by strong abdominal pain and fever.

Additional side effects:
Common side effects (appear in 1-10 users out of 100): Headache, abdominal pain, constipation, diarrhea, flatulence, nausea, vomiting.
Uncommon side effects (appear in 1-10 users out of 1,000): Swelling of the legs and ankles, dizziness, vertigo, fainting, tingling sensation, drowsiness, sleep problems, rash, itching, hives, skin inflammation (dermatitis). Generally feeling unwell and lacking energy, changes in blood tests (changes in liver functions).

Rare side effects (appear in 1-10 users out of 10,000):
- Problems in the blood system (such as: decrease in white blood cell count or in platelets) that may cause weakness, tiredness, bruising, bleeding or frequent infections accompanied by fever and severe trembling, throat ache, mouth ulcers
- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever and wheezing
- Low levels of sodium in the blood - may cause weakness, vomiting, cramps
- Blurred vision, taste changes
- Irritability, restlessness, confusion or depression
- Sudden wheezing or shortness of breath (bronchospasm)
- Dry mouth
- Pain in the mouth, inflammation inside the mouth
- Fungal infection in the mouth and esophagus
- Fungal infections which may affect the intestine
- Liver problems, including jaundice, manifested by yellow skin, dark urine and tiredness
- Hypersensitivity of the skin to light, may be manifested as rash
- Unusual hair loss or thinning of hair
- Joint swelling accompanied by pain, muscle pain or muscle weakness
- Severe kidney problems
- Excessive sweating

Very rare side effects (appear in less than 1 out of 10,000 users):
- Changes in blood count including lack of white blood cells (agranulocytosis)
- Aggression
- Hallucinations (seeing or feeling things that do not exist)
- Severe liver problems causing liver failure and inflammation of the brain
- Sudden onset of a severe rash or blisters or peeling of the skin. May be accompanied by fever and joint pain (erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis)
- Enlarged breasts in men

Side effects with unknown frequency:
- Intestinal inflammation that causes acute diarrhea that does not cease or is accompanied by severe abdominal pain and fever.
- If omeprazole has been used for a period longer than 3 months, there may be a decrease in your blood magnesium levels. Low magnesium levels are manifested by tiredness, involuntary muscle contractions, confusion, convulsions, dizziness, or increase in heartbeat. If you experience one of these effects, tell the physician as soon as possible. Low levels of magnesium in the blood may also cause a decrease in blood potassium or calcium levels. The physician will consider performing blood tests regularly in order to monitor your blood magnesium levels.

Omepradex may very rarely affect the level of white blood cells, damaging the immune system. If you suffer from an infectious disease manifested by fever and severe deterioration in your general health or fever with symptoms of local infection such as pain in the neck, throat or mouth, or difficulty urinating, **you must consult the physician as soon as possible** in order to exclude possible damage to the immune system (agranulocytosis) by performing blood tests.

If a side effect appears, if any of the side effects worsens or when you suffer from a side effect not mentioned in this leaflet, consult the physician.

Report side effects to the Ministry of Health using the online form in the following link:
http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic%40moh.health.gov.il

5. How to store the medicine

- Avoid poisoning! This medicine, and any other medicine, must be stored in a safe 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 physician.
- 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.
- Do not store at a temperature above 25°C. Store in the original package.

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, Titanium dioxide, Sodium hydroxide, Sodium laurilsulfate, Red iron oxide (E-172), Hypromellose 2910, Yellow iron oxide (E-172), Carnauba wax.

Each caplet of Omepradex 10 mg contains approximately 96 mg lactose.
Each caplet of Omepradex 20 mg contains approximately 193 mg lactose.
Each caplet of Omepradex 40 mg contains approximately 386 mg lactose.

What the medicine looks like and what the package contains:

Omepradex 10 mg and 20 mg - pinkish brown caplet. Approved package sizes: 10, 14, 20, 28, 30 caplets.
Omepradex 40 mg - pinkish brown caplet. Approved package sizes: 7, 10, 14, 20, 28, 30 caplets.

Not all package sizes may be marketed.

This leaflet was checked and approved by the Ministry of Health in July 2015.

Drug registration numbers at the national medicines 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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