Patient package insert according to Pharmacists' Regulations (Preparations), 1986.

This medicine can be sold without a physician's prescription.

Omepradex Z- caplets, 20 mg

Each caplet contains: Omeprazole 20 mg

The list of inactive ingredients appears in section 6.

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the physician or pharmacist.
The medicine is intended for adults over 18 years of age. Take it in the correct manner. Consult the pharmacist if you need additional information. Duration of treatment is up to 14 days. Refer to the physician if the symptoms of the illness worsen or do not improve after 14 days.

1. What is the medicine intended for?

Omepradex Z caplets are intended for the relief of symptoms derived from backflow of acid from the stomach into the esophagus (e.g.: heartburn) that appear at a frequency of at least twice a week, in adults over 18 years of age.

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), to any of the additional ingredients the medicine contains or proton pump inhibitors (PPI) (such as: pantoprazole, lansoprazole, rabeprazole or esomeprazole).
- If you are taking nelfinavir (for treating HIV).

Special warnings regarding the use of this medicine:

- **Before treatment with Omepradex Z, tell the physician if:**
  - You are pregnant, might be pregnant, planning to become pregnant or breastfeeding (see "Pregnancy and breastfeeding" section).
  - You have suffered in the past from a gastric ulcer or if you have undergone gastrointestinal surgery in the past.
  - You continuously take medicines for the symptomatic treatment of heartburn or indigestion for 4 weeks or more.
  - You have been suffering from difficulties in digestion for 4 weeks or more (it could indicate a more severe condition).
  - You are suffering or have suffered in the past from impaired liver function or from liver disease or jaundice.
  - You are over 55 years of age with new symptoms or symptoms that have recently changed.
  - You suffer from nausea, heartburn accompanied by lightheadedness, sweating or dizziness; chest pain accompanied with shortness of breath, sweating, pain spreading to arms, neck or shoulders, lightheadedness or dizziness; frequent chest pain; frequent wheezing (breathing difficulties), mainly if accompanied by heartburn.
  - You were told you have low levels of magnesium in the blood. Consult the physician about monitoring the levels of magnesium in the blood during treatment with this medicine.
  - You are allergic to any kind of food or medicine.
- The duration of treatment with this medicine is up to 14 days. Do not take the medicine for more than 14 days or more than one treatment (14 days) every 4 months. Do not take the medicine as preventive treatment. If you do not feel relief or if the heartburn continues or worsens or the symptoms you suffer from worsen, stop the treatment and consult a physician.
- The use of a medicine from the proton pump inhibitors PPI group, like Omepradex, especially for over a year, may slightly increase the risk of hip, wrist and spine fractures. Tell the physician if you suffer from osteoporosis or if you are taking corticosteroids (which may increase the risk of osteoporosis).
- Omepradex decreases the levels of gastric acidity. Gastric acid is needed for the absorption of vitamin B_{12}. If you are continuously taking the medicine, consult the physician about 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 the treatment or during it,** refer immediately to a physician and tell him of this:
- Weight loss for no apparent reason and troubles swallowing (such as difficulty or pain)
- Abdominal pain or indigestion
- Vomiting food or vomiting blood
- Black stools (bloody stools)
- Severe or persistent diarrhea (omeprazole has been associated with minor increase in infectious diarrhea)

Tell the doctor 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 if" section.
- Clopidogrel [for the prevention of blood clots (thrombosis)], it has been reported that medicines of this group (PPI), like 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 voriconazole (medicines for treating fungal infections).
- Digoxn (for heart diseases).
- Medicines that affect the central nervous system (such as phenytoin [for epilepsy], diazepam [anxiety, muscle relaxing or epilepsy]). If you are taking phenytoin, a medical monitoring will be necessary at the beginning of treatment with Omepradex Z and at the end of it.
- Blood thinners such as warfarin, other vitamin K blockers. There will be a need for medical monitoring at the beginning of treatment and at the end of it.
- Cilostazol (for leg pain).
- Tacrolimus, mycophenolate mofetil (immunosuppressants).
- Iron containing medicines.
- Disulfiram (for withdrawal).
- A herbal medicine containing hypericum perforatum (St. John's wort, used for treating depression).
- Erlotinib (for treating cancer).
- Methotrexate – your physician may temporarily stop the treatment with Omepradex Z.
- Antibiotics such as clarithromycin, ampicillin.
- Rifampicin (for the treatment of tuberculosis).

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 to pregnancy or breastfeeding.

Driving and use of machinery:

Use of the medicine may cause side effects such a 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?

Check with the physician or pharmacist if you are not sure.
This medicine is not intended for children and adolescents under 18 years of age. **The usual recommended dosage** for adults over 18 years of age is: one caplet, once daily before a meal, for a period of 14 days.

Do not exceed the recommended dose

Swallow the caplet whole with a full glass of water. Do not crush, halve or chew the caplet, in order to maintain the caplet coating (the coating prevents the breaking down of the caplet by the stomach acids so that the active ingredient is released only in the intestine where it is absorbed by the body).

Duration of treatment:

Up to 14 days. It is possible that 2-3 days will pass until the medicine takes full effect. If there is no improvement in you condition after 14 days, refer to a physician. The 14 day treatment can be repeated every 4 months. Do not take the medicine for more than 14 days or more than one treatment (14 days) every 4 months, unless instructed to do so by a physician. If the symptoms recur often or worsen, refer to a 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 a 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 necessary 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.

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 Z 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, of the facial area, lips, tongue or throat, rash, fainting or swallowing problems). This reaction can often be very severe.
- You suffer from redness of the skin with blistering or skin peeling; 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 sodium and magnesium levels such as: cramps, dizziness, irregular heart rate and arrhythmia, restlessness, irritation, sudden spasm or tremor, muscle weakness, arm and leg cramps, muscle cramps or muscle pain, throat tightness.
- Acute diarrhea which is consistent or is accompanied by strong abdominal pain and fever.

Additional side effects:

Common side effect (appear in 1-10 users out of 100):
Headache, abdominal pain, constipation, diarrhea, flatulence, nausea, vomiting.

Uncommon side effect (appear in 1-10 users out of 1,000):
Swelling of the legs and ankles, dizziness, vertigo, feeling of fainting , tingling sensation, drowsiness, sleep problems, rash, itching, hives, skin inflammation (dermatitis). General unwell feeling and lack of 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 lead to weakness, tiredness, bruising, bleeding or to frequent infections accompanied by fever and severe trembling, throat ache, mouth ulcers.
- Allergic reactions, often very severe, including swelling of the lips, tongue and throat, fever and tinnitus.
- Low blood sodium levels - may cause weakness, vomiting, spasms.
- Blurred vision, taste changes.
- Irritation, restlessness, confusion or depression.
- Sudden wheezing or shortness of breath (bronchspasm).
- Dry mouth.
- Pain in the mouth, inflammation inside the mouth.
- Oral or esophageal candidiasis.
- 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.
- Hair loss or unusual thinning.
- 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 outburst 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).
- Breast enlargement 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 blood magnesium levels may also cause a decrease in blood potassium and calcium levels. The physician will consider performing blood tests regularly in order to monitor your blood magnesium levels.

Omepradex Z 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 neck, throat, or mouth pain 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.

Side effects can be reported to the Ministry of Health via the link "Report Side Effects of Drug Treatment" found on the website of the Ministry of Health (www.health.gov.il), which refers to the online form for reporting side effects, or via the following link: http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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 25ºC. 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, Trietyl 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 contains approximately 193 mg lactose.

What the medicine looks like and what the package contains:
Omepradex Z is a pinkish brown caplet.
Approved package sizes:7 , 14, 28 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:
131 25 30841 00

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Manufacturer and registration holder:

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