Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold with a doctor's prescription only

OMEPRA 20, OMEPRA 40
Capsules

Active ingredient:
Each capsule of Omepra 20 contains 20 mg Omeprazole
Each capsule of Omepra 40 contains 40 mg Omeprazole
For the list of the additional ingredients, see section 6. See also 'Important information about some of the medicine's ingredients' in section 2.

Read this entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.
This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if you think their medical condition is similar to yours.
This medicine is intended for children over one year of age and with a weight of 10 kilograms or more.

1. What is the medicine intended for?

The medicine inhibits acid secretion in the gastrointestinal tract.
The medicine is intended for:
- Treatment of gastric ulcer and duodenal ulcer.
- Combined treatment with antibiotics in Helicobacter pylori associated with peptic 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 poorly responsive peptic ulcer or severe reflux esophagitis.
- Treatment of severe reflux esophagitis in children from one year of age and older.
- 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 Inhibitor – PPI.

2. Before using the medicine

Do not use the medicine if:
- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (for the list of the additional ingredients, see section 6).
- You are sensitive (allergic) to medicines containing other proton pump inhibitors (PPI) (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- You are taking a medicine containing nelfinavir (medicine for the treatment of HIV infection).
- You suffer from difficulty or pain while swallowing food, from bloody vomit, or from bloody or black stools.
- You have heartburn accompanied by disorientation, sweating or dizziness.
- You have chest or shoulder pain accompanied by shortness of breath, sweating, pain radiating to the arms, neck or shoulders, or dizziness.
- You have frequent chest pain.

Special warnings regarding the use of this medicine
Severe skin reactions have been reported, including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP). Stop using Omepra and seek immediate medical attention if you notice symptoms related to these skin reactions, which are described in section 4.

The medicine may conceal symptoms of other diseases. Therefore, if you suffer from any of the following effects or if one of the conditions is relevant to you before you start taking Omepra or while you are taking Omepra, refer to the doctor immediately:
- You suffer from a severe loss of weight for no reason and/or you have problems swallowing. See also 'Do not use the medicine if' section.
- You suffer from stomach pain or indigestion.
- You vomit food or you have bloody vomit. See also 'Do not use the medicine if' section.
- You have bloody stools (black stools). See also 'Do not use the medicine if' section.
- You suffer from severe or persistent diarrhea, as the use of the medicine may slightly increase the risk of diarrhea as a result of an infection.
- You suffer from severe liver function problems.
- You have ever developed a skin reaction after using Omepra or a medicine similar to Omepra that reduces secretion of stomach acid.
- If you develop a rash on your skin, especially in areas exposed to the sun, report to the doctor as soon as possible, as you may need to stop using Omepra. Update the doctor also if you suffer from other symptoms of illness, such as joint pains.
- You are due to have a specific blood test (Chromogranin A).
- You suffer from heartburn for a period of over 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 take Omepra for a long period (longer than one year), the doctor may instruct you to be under regular medical surveillance. Report to the doctor any new and unusual symptom every time you see your doctor.
- Taking a medicine from the proton pump inhibitors group such as Omepra, especially for a period of more than one year, may slightly increase the risk of 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).
- Consult the doctor concerning regular monitoring of blood magnesium level during the treatment period with this medicine.

Drug interactions
If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell your doctor or pharmacist. Especially if you are taking:
- Nelfinavir (a medicine for the treatment of HIV infection) – do not take Omepra if you are taking a medicine containing nelfinavir.
- Ketoconazole, itraconazole, posaconazole, or voriconazole (for treatment of fungal infections).
- Digoxin (for the treatment of heart problems).
- Diazepam (for the treatment of anxiety, epilepsy or to relax muscles).
- Phenytoin (for the treatment of epilepsy). If you are taking phenytoin, your doctor may consider monitoring when you start or stop the treatment with Omepra.
- Anticoagulants (medicines for thinning of the blood) such as warfarin, or other vitamin K blockers. Your doctor may monitor you when you start or stop the treatment with Omepra.
- Rifampicin (for the treatment of tuberculosis).
- Atazanavir, saquinavir (medicines for the treatment of HIV infection).
- Tacrolimus or mycophenolate (given in cases of organ transplants).
- 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 used in high dosages to treat cancer) – if you are taking high dosages of methotrexate, the doctor will consider temporarily stopping the treatment with Omepra.
- Amoxicillin and clarithromycin (antibiotics): If the doctor prescribed these antibiotics concomitantly with Omepra to treat ulcers caused by Helicobacter pylori infection, it is very important that you inform your doctor about any other medicine you are taking.

Pregnancy, breastfeeding and fertility
- Consult the doctor or pharmacist before taking this medicine if you are pregnant, think you are pregnant, are planning a pregnancy or are breastfeeding.
- Omeprazole (the active ingredient in the medicine) is excreted in breastmilk but is not expected to affect the infant when taking the recommended dosage. The doctor will decide whether you can take Omepra while breastfeeding.

Use in children
Certain children with chronic illnesses may require long-term treatment, although it is not recommended.
This medicine is not intended for use in children under one year of age or weighing less than 10 kilograms.

Driving and use of machinery
The medicine 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 'Side effects' section). If you feel these effects, do not drive or operate machinery.

Important information about some of the medicine's ingredients:
- The medicine contains sucrose. If you have intolerance to some sugars, consult the doctor before taking the medicine.
- Each capsule contains less than 23 mg sodium, therefore the medicine is considered sodium-free.

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.
The dosage and the manner of treatment will be determined by the doctor only.
The standard dosage is usually:
Treatment for reflux esophagitis
Adults: capsule of 20 mg once a day for 4-8 weeks. The doctor may recommend to continue taking the capsules or increase the dosage if needed. To prevent recurrence of the symptoms, 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 and according to the child's weight. For children with swallowing difficulties see 'For patients with swallowing difficulties' below.
Treatment of duodenal ulcer and stomach (gastric) ulcer
Capsule of 20 mg once a day. The duration of the treatment will be determined by the doctor, and is usually for a period between 2 to 4 weeks. The doctor may recommend to continue taking the capsules or increase the dosage as per need, depending on your response to the treatment.
For prevention of peptic ulcer recurrence
To prevent recurrence of the ulcer, the usual dosage is in doses of 10 mg or 20 mg once a day. The doctor may increase the dosage if the symptoms recur.
Treatment and prevention of stomach ulcers or duodenal ulcers caused due to treatment with NSAIDs (Nonsteroidal Anti-Inflammatory Drugs)
If you suffered in the past from an ulcer, and you need to continue taking a medicine from the NSAIDs group, the usual dosage is a capsule of 20 mg once a day for 4-8 weeks.
Treatment and prevention of peptic ulcer caused by the Helicobacter pylori bacteria
The usual dose is a capsule of 20 mg twice a day for a week. The doctor may recommend to take two of the following antibiotics: amoxycillin, clarithromycin, metronidazole.
The usual treatment period is one week. Strictly follow the instructions on how to take the medicine and consult your doctor if you have any doubt.
Children: the dosage is based on the child's weight. For children with swallowing difficulties see 'For patients with swallowing difficulties' below.
Treatment of excess acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome)
The usual starting dose is 60 mg once a day. The doctor will guide you regarding the number of capsules, times to take them, and treatment duration.

Do not exceed the recommended dose.
- Take the medicine before the meal, preferably in the morning.
- Swallow the capsule whole with about half a glass of water.
- Do not chew or crush the capsule and the granules inside it, so as not to damage the coating of the granules which protects the medicine from being broken down by the acid in the stomach and is essential for the action of the medicine.

This medicine is not intended for infants under the age of 1 year.
If there is no improvement in your condition, refer to the doctor.

For patients with swallowing difficulties:
You can open the capsule, place the granules from inside the capsule on your tongue, and swallow immediately with about half a glass of water. For children and those who can't swallow the capsule whole or when necessary, the capsule can be opened, the contents mixed with soft acidic food (e.g. apple purée or yogurt) or an acidic drink (e.g. orange juice), and swallowed immediately (in this case, make sure that you have taken the entire dose of granules).

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

If you forgot to take the medicine
If you forgot to take the medicine at the required time, take the dose as soon as you remember; however, if it is nearly time to take the next dose, skip the forgotten dose. Do not take a double dose to compensate for the forgotten dose.
Adhere to the treatment as recommended by your doctor.
Even if your state of health improves, do not stop the treatment with the medicine without consulting your 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 concerning the use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, use of Omepra 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 Omepra and refer to your doctor immediately if you observed the following side effects which are rare (appear in 1-10 users out of 10,000) or very rare (appear in less than 1 user out of 10,000) but severe:
- Sudden wheezing, swelling of the lips, tongue, throat and/or other areas of the body, rash, fainting or difficulties with swallowing (severe allergic reaction) (rare).
- Reddening of the skin accompanied by blisters or peeling. Severe blisters and bleeding may also occur in the lips, eyes, mouth, nose and genitals. This condition may indicate 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 can be symptoms of liver problems (rare).

Additional side effects *(including frequencies)*
Common side effects (appear in 1-10 users out of 100):
- Headache.
- Effects on the stomach or intestine: diarrhea, abdominal pain, constipation, abdominal bloating, wind (flatulence).
- Nausea, vomiting.
- Benign polyps in the stomach.

Uncommon side effects (appear in 1-10 users out of 1,000):
- Swelling of the feet and ankles.
- Sleep disturbances (insomnia).
- Dizziness, tingling and prickling sensation, feeling drowsy.
- Feeling of dizziness (vertigo).
- Changes in liver function blood test results.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lack of energy.

Rare side effects (appear in 1-10 users out of 10,000):
- Problems in the blood system such as a decrease in the number of white cells or platelets, which may cause weakness, bruising or development of infections more easily.
- Low blood sodium levels – this may cause weakness, vomiting and cramps.
- Feeling agitated, confused or depressed.
- Changes in the sense of taste.
- Vision problems such as blurred vision.
- Sudden onset of wheezing or shortness of breath (bronchospasm).
- Dry mouth.
- Inflammation of the inside of the mouth.
- Fungal infection in the mouth which can affect the intestine.
- Hair loss (balding).
- Skin rash upon exposure to sunlight.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Severe kidney problems (Interstitial Nephritis).
- Increased sweating.

Very rare side effects (appear in less than 1 user out of 10,000):
- Changes in the blood count including agranulocytosis (lack of white blood cells). See further information below.
- Aggression.
- Hallucinations – seeing, feeling or hearing things that do not exist.
- Severe liver problems which cause liver failure and inflammation of the brain.
- Erythema multiforme.
- Muscle weakness.
- Enlarged breasts in men.

Side effects of unknown frequency (effects whose frequency has not yet been determined):
- Inflammation in the intestine (which causes diarrhea).
- If you are treated with Omepra for a period of more than three months, the magnesium levels in your blood may decrease. Low magnesium levels are manifested as tiredness, involuntary muscle cramps, confusion, spasms, dizziness or increase in heart rate. If you have any of these symptoms, please inform your doctor as soon as possible. Low magnesium levels can also cause a decrease in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor the magnesium levels in your blood.
- Rash, accompanied at times with joints pain.

In very rare cases the medicine may affect the white blood cells and cause an immune deficiency (damage the immune system). If you have an infection accompanied by symptoms such as fever with a severe decrease in your general state of health or fever with symptoms of a local infection such as pain in the throat, mouth or neck or difficulties in urinating, consult your doctor as soon as possible to rule out a lack of white blood cells (agranulocytosis) by a blood test. In this situation it is important you notify the doctor that you are taking Omepra.

If a side effect appears, 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 on side effects following medicinal treatment" on the Ministry of Health homepage (www.health.gov.il) that leads to an online form for reporting side effects, or by entering 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 (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Sucrose, corn starch, gelatin, hypromellose, talc, methacrylic acid-ethyl acrylate copolymer, water, mannitol, titanium dioxide (E171), macrogol 6000, polysorbate 80, disodium phosphate, sodium lauryl sulfate.
Each Omepra 20 capsule contains approximately 120 mg sugar (sucrose) and also in addition:
quinoline yellow (E104).
Each Omepra 40 capsule contains approximately 240 mg sugar (sucrose) and also in addition:
indigo carmine (E132).

What does the medicine look like and what does the pack contain?
Omepra 20: yellow capsules containing white granules.
14 or 28 capsules in blister packs. Not all pack sizes may be marketed.
Omepra 40: blue/white capsules containing white granules. 28 capsules in blister packs.
Registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.
Manufacturer: Liconsa SA, Spain.

Medicine registration numbers in the National Medicines Registry of the Ministry of Health:
Omepra 20: 136-80-31320
Omepra 40: 136-81-31380

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