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

The dispensing of this medicine is upon doctor's prescription only

OMEPRA 20, OMEPRA 40
Capsules

Active ingredient:

Each Omepra 20 capsule contains 20 mg Omeprazole

Each Omepra 40 capsule contains 40 mg Omeprazole

For a list of the inactive ingredients in this preparation, see section 6 – "Further information". See also 'Important information on some of the ingredients of the medicine' in section 2.

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.
This medicine was prescribed to treat your ailment. Do not pass it on to others. It may harm them, even if their medical state seems similar to yours. This medicine is not intended for administration in children under 1 year of age.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Inhibits acid secretion in the gastrointestinal tract.
This medicine is indicated for:
Treatment of gastric ulcer and duodenal ulcer.
Combined treatment with antibiotics in Helicobacter pylori associated peptic ulcer disease.
Long-term management of reflux oesophagitis and Zollinger-Ellison syndrome.
Severe reflux oesophagitis in children from one year of age and older.
Maintenance treatment for the prevention of relapse in patients with poorly responsive peptic ulcer or severe reflux oesophagitis.
Treatment and prevention of gastric ulcer and duodenal ulcer caused by the treatment with NSAID in high-risk patients.

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 medicine (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).

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 Omepra 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 Omepra. 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 feces).
- You experience severe or persistent diarrhea, as omeprazole has been associated with a small increase in infectious diarrhea.
- You suffer or have suffered from intolerance to some sugars.
- If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

Additional precautions

Do not exceed the recommended duration of treatment.

Taking a proton pump inhibitor like Omepra, 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.

Drug interactions:

Inform your doctor or pharmacist if you are taking or have recently taken other medicines, including non-prescription medicines or dietary supplements,

especially if you are taking:

- Medicines 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 Omepra.
- 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 Omepra.
- 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 Omepra 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, are planning to become pregnant or are breastfeeding, ask your doctor or pharmacist for advice before taking this medicine.

Use in children
This medicine is not intended for administration in children under 1 year of age.

Driving and use of machinery
The medicine 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.

Important information about some of the medicine's ingredients:
The medicine contains sucrose. If you suffer from intolerance to some sugars, consult your doctor before taking the medicine.

3. HOW SHOULD YOU USE THIS MEDICINE?
Always use the medicine according to the doctor's instructions. If you are unsure as regards the dosage and method of treatment with the medicine, refer to your doctor or pharmacist.
Method of treatment and dosing are determined only by the doctor.

- This medicine should be taken before a meal, preferably in the morning.
- Do not chew the capsule contents.
- Swallow the capsules with half a glass of water.

This medicine is not intended for children under one year of age.

Do not chew or crush the capsule and the granules in it in order not to damage the granule coating which is essential for the action of the medicine. You may open the capsule, place the granules in the capsule on your tongue and immediately drink with half a glass of water. For children or when necessary, you can open the capsule, mix the contents with soft acidic food (e.g. apple purée or yogurt) or an acidic drink (e.g. orange juice), and swallow immediately. If there is no improvement in your condition consult your doctor.

Recommended dosage is usually as follows:
Treatment for reflux oesophagitis
Adults: capsule of 20 mg once a day for 4-8 weeks. Your doctor may recommend that you continue taking the capsules or increase the dose if needed. To prevent recurrence of the symptoms, the doctor may recommend that you continue taking the medicine at a dose of 10, 20 or 40 mg.
Children: the dose is based on the child's weight. For children with swallowing difficulties see above.
Treatment for gastric ulcer and duodenal ulcer
Capsule of 20 mg once a day. Your doctor will tell you for how long to take the medicine, usually between 2 to 4 weeks. Your doctor may recommend that you continue taking the capsules or increase the dose depending on your response to the treatment. To prevent recurrence of the ulcer, the usual dose is 10 mg or 20 mg once a day. Your doctor may increase the dose if your symptoms return.
Treatment and prevention of stomach ulcers or duodenal ulcers caused due to treatment with NSAIDs (Nonsteroidal Anti-Inflammatory Drugs)
If you have suffered from an ulcer in the past, and you need to continue taking NSAIDs, the usual dose is a capsule of 20 mg once a day for 4-8 weeks.
Treatment and prevention of peptic ulcer caused by the bacteria Helicobacter pylori
The usual dose is a capsule of 20 mg twice a day. The doctor may recommend that you take two of the following antibiotics: amoxycillin, clarithromycin, metronidazole. The usual treatment period is one week. Follow strictly the instructions on how to take your medicine and consult your doctor if you have any doubt.
Children: the dose is based on the child's weight. For children with swallowing difficulties see above.
Treatment of too much 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 instruct you how many capsules to take, when to take them and for how long.

Do not exceed the recommended dosage.

If you accidentally took a **higher dose:** 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 medicine package 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 do not take a double dose on the same day. Take the next capsule at the usual time and consult the doctor.

You must continue treatment as recommended by your doctor.

Even if you feel improvement in your health, do not stop treatment without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take your medicine. Wear glasses if you need them.

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

4. SIDE EFFECTS

As with any medicine, use of Omepra 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 any of the following reactions occur:

- An allergic or anaphylactic reaction (characterized by shortness of breath, sudden wheezing, and swelling of the body, face, lips, tongue or throat, rash, fainting or difficulties in swallowing).
- Reddening of the skin, accompanied by blisters or peeling. Severe blistering and bleeding may also occur in the lips, eyes, mouth, nose and genitals.
- Jaundice (yellow eyes, skin and nails and dark urine) and tiredness, which may be indicative of liver problems.
- Cramps, dizziness, irregular heartbeats or arrhythmias, restlessness, nervousness, sudden spasms or tremor, muscular weakness, cramps in hands and feet, muscular cramps or muscular pain, cramps in the throat (signs of low blood sodium and magnesium levels) - stop treatment and refer to the doctor.
- Severe diarrhea which is persistent or is accompanied by severe abdominal pain and fever.

Additional side effects

Common side effects (appear in 1 to 10 users out of 100):

Headache, diarrhea, constipation, stomachache, nausea (feeling sick), vomiting, flatulence.

*Uncommon side effects (appear in 1 to 10 users out of 1,000)**:***

Swelling of the feet and ankles, sleepiness; trouble sleeping, dizziness; pins and needles; vertigo, feeling faint; increase in liver enzymes, rash; itching; dermatitis, generally feeling unwell, weakness.

Rare side effects (appear in 1 to 10 users out of 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, bleeding or 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, 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 esophagus (gullet)
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness
- Unusual hair loss or thinning
- Skin hypersensitivity to light
- Painful swollen joints; aching muscles or muscle weakness
- Kidney disease
- Increased sweating

Very rare side effects (appear in less than 1 user out of 10,000):

- Changes in blood count including agranulocytosis (lack of white blood cells)
- Aggression
- Seeing or feeling things that are not there (hallucinations)
- 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.
- Gastroenteritis, leading to acute diarrhea that does not stop or accompanied by intense abdominal pain and fever.
- If you are on Omepra for more than three months it is possible that the magnesium levels in your blood may fall. Low magnesium levels may cause fatigue, involuntary muscle cramps, disorientation, spasms, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low magnesium

levels 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 magnesium levels.

The medicine 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://sideeffects.health.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 and sight 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 (exp. date) mentioned on the pack. The expiry date refers to the last day of the indicated month.
Storage conditions: store below 25ºC.

6. FURTHER INFORMATION

Aside from the active ingredient, this 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.
Every Omepra 20 capsule contains 120 mg sugar (sucrose) and also: quinoline yellow (E104).
Every Omepra 40 capsule contains 240 mg sugar (sucrose) and also: indigo carmine (E132).

What the medicine looks like and contents of the package
Omepra 20: yellow capsules containing white granules. 14 or 28 capsules in blister pack. Not all pack sizes may be marketed.
Omepra 40: blue-azure capsules containing white granules. 28 capsules in blister pack.
LICENSE HOLDER: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.
MANUFACTURER: Liconsa SA, Spain.

This leaflet from January 2020 is in the format determined by the Ministry of Health and its contents is in accordance with the innovative medicine's leaflet that was checked and approved by the Ministry of Health in May 2016.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
Omepra 20: 136-80-31320
Omepra 40: 136-81-31380