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

The medicine is dispensed with a doctor's prescription only

OMACOR® Soft capsules

Active ingredients:

Each capsule contains:

Omega-3-acid ethyl esters 90 1,000 mg, comprising 460 mg EPA ethyl ester and 380 mg DHA ethyl ester.

The total omega-3-acid ethyl ester is greater than 90%.

Inactive ingredients and allergens in the medicinal product – see section 2 under "Important information about some of the ingredients of the medicine" and section 6 "Further Information".

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THIS MEDICINE INTENDED FOR?

- Secondary preventive treatment after myocardial infarction, in addition to drug therapy (e.g., statins, antiplatelet medications, beta-blockers, ACE inhibitors).
- For treatment of high blood triglyceride levels, as a supplement to diet, when dietary measures alone are insufficient.

Therapeutic group: Omega-3 unsaturated fatty acids.

Omacor belongs to a group of medicines that lower cholesterol and triglycerides.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredients or to any of the other ingredients contained in the medicine. See section 6: "Further Information".
- you are allergic to peanuts or soya. Omacor contains soya oil.

Special warnings regarding use of the medicine

Before treatment with Omacor, tell the doctor or pharmacist if:

- you are due to undergo surgery or have recently undergone surgery
- you recently experienced trauma
- you have a kidney problem
- you have uncontrolled diabetes
- you have liver problems. The doctor will monitor the effect of Omacor on your liver via blood tests
- you are suffering, or have suffered in the past, from bleeding problems or coagulation problems and if you are being treated with anticoagulants. Patients receiving anticoagulants should be monitored and there may be a need to change the dosage of the medicine
- you are allergic to fish

Children and adolescents

Omacor is not intended for use in children and adolescents.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular if you are taking:

anticoagulants (e.g., warfarin) since you will need additional blood tests and there may be a need to change the dosage of the blood thinner.

Use of the medicine and food

Take the medicine with food, to lower the risk of side effects in the digestive system.

Pregnancy and breastfeeding

Do not use this medicine during pregnancy or when breastfeeding, unless the doctor decides that the treatment is essential. If you are pregnant or breastfeeding, consult the doctor or pharmacist before using the medicine.

Use in the elderly

Use Omacor with caution if you are over 70 years of age.

Driving and use of machines

This medicine is not expected to affect your ability to drive or to operate dangerous machinery.

Important information about some of the ingredients of the medicine

Omacor contains soya. If you are allergic to peanut or soya, do not use Omacor.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicinal product according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicinal product.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage for secondary preventive treatment after myocardial infarction is generally one capsule a day.

The usual dosage for high blood triglyceride levels is generally two capsules a day (if the desired response is not achieved, the doctor may increase the dosage up to four capsules a day).

Do not exceed the recommended dose.

Method of administration

Swallow the medicine with water.

Take the medicine with food to lower the risk of side effects in the digestive system.

If you accidentally took a higher dosage than you need, do not worry, as it is likely that no special treatment is necessary. Nonetheless, refer to a doctor or pharmacist for further advice.

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

If you forgot to take this medicine at the scheduled time, take the dose as soon as possible. If you remembered when it is almost time for the next dose, skip the forgotten dose, take the next dose at the regular time and consult the doctor. Do not take a double dose to compensate for the forgotten dose.

Adhere to the treatment as recommended by the doctor.

Even if there is an improvement in your condition, do not stop treatment without consulting the doctor.

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

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Omacor may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Common side effects – effects that occur in 1-10 users in 100:

- Abdominal problems, such as: abdominal distension, pain, constipation, diarrhea, dyspepsia, flatulence, belching, heartburn, nausea and vomiting

Uncommon side effects – effects that occur in 1-10 users in 1,000:

- High blood sugar levels
- Gout
- Dizziness
- Disturbances in sense of taste
- Headache
- Low blood pressure
- Nosebleed
- Bloody stools
- Rash

Rare side effects – effects that occur in 1-10 users in 10,000:

- Allergic reactions
- Urticaria (rash manifested by red, raised and itchy lesions)
- Liver disorders, with a possibility of changes in the results of certain blood tests

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Itching

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

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), which directs you to the online form for reporting side effects, or by entering the link:

https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the carton package and on the label. The expiry date refers to the last day of that month.
- Store below 25°C.
- Do not freeze.
- After first opening, can be used until the expiry date and stored below 25°C.
- Store in the original package.
- If you notice a change in the color or appearance of the capsules, consult the pharmacist.

6. FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains:
  Alpha-tocopherol (as an antioxidant), Gelatin, Glycerol, Purified water, Medium-chain triglycerides, Lecithin.
- What the medicine looks like and the contents of the pack:
  Omacor capsules are transparent soft gelatin capsules that contain a pale yellow oil.
  The medicine is available in bottles containing 28 or 100 capsules.
  Not all package sizes may be marketed.
- **License holder and its address:** Abbott Medical Laboratories Ltd., Kiryat Atidim, P.O.B. 58099, Tel-Aviv 6158002.
- **Manufacturer and its address:** Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover, Germany.
- Revised in March 2024.
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:**
  134-24-31088-00.

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