

Consumer Medication Information Leaflet (RiMUP)

OMACOR[®] 1000MG SOFT CAPSULES

Omega-3-Acid Ethyl Esters 90 (1000mg)

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What Omacor[®] is used for

Omacor[®] is used to treat certain forms of increased triglycerides (fats) in the blood after changes to the diet have not worked.

How Omacor[®] works

Omacor[®] contains highly purified omega-3 polyunsaturated fatty acids. It works by reducing cholesterol and triglycerides.

Before you use Omacor[®]

- When you must not use it

Do not take Omacor[®] if: You are allergic (hypersensitive) to Omega- 3-Acid Ethyl Esters 90 or any of the other ingredients of Omacor[®]

Do not use Omacor[®] if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Omacor[®].

- Before you start to use it

Talk to your doctor or pharmacist before taking Omacor[®] if you suffer from any medical conditions or illnesses, in particular:

- if you are due to have or have had surgery recently
- if you have a kidney and liver problem
- if you are allergic to fish

- Taking other medicines

It is particularly important to tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This also concerns medicines obtained without a prescription including herbal medicines. Tell your doctor or pharmacist if you are taking any of the following medicines:

- aspirin (acetylsalicylic acid)
- warfarin or other medicines, used to prevent blood clots

How to use Omacor[®]

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The capsules may be taken with food to avoid gastrointestinal disturbances.

Increased triglycerides (high levels of fats in the blood)

Initial treatment two capsules daily. If adequate response is not obtained, the dose may be increased to four capsules daily.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Omacor[®] for as long as your doctor or pharmacist recommends.

- If you forget to use it

Do not take a double dose to make up for the forgotten dose. Take the next dose at your regular time on the next day. If you are worried about this, talk to your doctor or pharmacist.

- If you use too much (overdose)

If you take more Omacor[®] than you should, stop taking Omacor[®] and talk to a doctor or pharmacist.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Talk to your doctor or pharmacist before taking this medicine if you are pregnant, might become pregnant or are breast-feeding. Omacor[®] can be used during pregnancy and when breast-feeding if necessary.

- Things to be careful of

Omacor[®] contains traces of soya lecithin. If you have been told by your doctor that you have an intolerance to soya, talk to your doctor before taking this medicine.

Side effects

Like all medicines, Omacor[®] can cause side effects, although not everybody gets them.

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Common (may affect more than 1 in 100 people):

Abdominal pain, constipation, diarrhea, indigestion, flatulence, acid reflux, nausea, vomiting, and atrial fibrillation.

Uncommon (may affect less than 1 in 100 people):

High blood sugar levels, gout, headache, low blood pressure, rash, nose bleed, and blood in your stool

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Omacor[®]

- Storage

Keep this medicine out of the sight and reach of children. Do not use Omacor[®] after the expiry date which is stated on the carton and the bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Do not freeze.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Omacor[®] is a transparent soft oblong gelatin capsules containing pale yellow oil.

Omacor[®] is available in bottle of 28's and 100's.

- Ingredients

- Active ingredient(s)
Omega-3-Acid Ethyl Esters 90

- Inactive ingredients

Alpha-tocopherol, Gelatin, Glycerol, Purified water, Medium-chain triglycerides, Lecithin (soya)

- MAL number:

Omacor[®] 1000mg Soft Capsules:
MAL12115077XC

Manufacturer

Patheon Softgels B.V.
De Posthoornstraat 7,
5048 AS Tilburg
Netherlands

Product Registration Holder

Abbott Laboratories (M) Sdn. Bhd.
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47400 Petaling Jaya, Selangor
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