

PACKAGE LEAFLET: INFORMATION FOR THE USER

Omacor® 1000 mg soft capsules Omega-3-acid ethyl esters 90

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Omacor is and what it is used for
2. What you need to know before you take Omacor
3. How to take Omacor
4. Possible side effects
5. How to store Omacor
6. Contents of the pack and other information

1. WHAT OMACOR IS AND WHAT IT IS USED FOR

Omacor contains highly purified omega-3 polyunsaturated fatty acids.

Omacor belongs to a group of so called reducers of cholesterol and triglycerides.

Omacor is used:

- to treat certain forms of increased triglycerides (fats) in the blood after changes to the diet have not worked.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE OMACOR

Do not take Omacor:

- if you are allergic (hypersensitive) to the active substances or any of the other ingredients of Omacor (listed in section 6: Contents of the pack and other information).

If any of the above applies to you, do not take this medicine, and talk to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Omacor.

- if you are due to have or have had surgery recently
- if you have had a trauma recently
- if you have a kidney problem
- if you have diabetes which is not controlled
- if you have problems with your liver. Your doctor will monitor any effects Omacor may have on your liver with blood tests.
- if you are allergic to fish.
- if you have, or have had, heart problems.

- if you develop light-headedness, asthenia (feeling of weakness), palpitations or shortness of breath as these may be symptoms of an irregular and often very rapid heart rhythm (atrial fibrillation).

Other medicines and Omacor

If you are using a medicine to stop blood clotting in your arteries, such as warfarin you may need extra blood tests and your usual dose of your blood thinning medicine may have to be changed.

Please tell your doctor or pharmacist if you are using, have recently used or might use any other medicines including medicines obtained without prescription.

Omacor with food and drink

You should take the capsules at meal times. This is to help lower the chances of side effects that affect the area in and around the stomach (the gastro-intestinal area).

Elderly Use Omacor with care if you are over 70 years.

Children Children should not take this medicine.

Pregnancy and breast-feeding

You should not take this medicine if you are pregnant or breast-feeding, unless your doctor decides it is absolutely necessary.

Ask your doctor or pharmacist for advice before using any medicine.

Driving and using machines

This medicine is not likely to affect you being able to drive or use any tools or machines.

Omacor contains soya oil

Omacor contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

3. HOW TO TAKE OMACOR

Always take Omacor exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Swallow the capsules with a drink of water.
- You may take the capsules at meal times to help reduce gastro-intestinal side effects.
- Your doctor will decide how long you should take this medicine.

Dose to treat high blood triglyceride levels (high levels of fat in the blood or hypertriglyceridaemia)

The usual dose is 2 capsules a day, as recommended by a doctor.

If the medicine is not working well enough at this dose, your doctor may increase this to 4 capsules a day.

If you take more Omacor than you should

If you accidentally take more of this medicine than you should, do not worry, as this is unlikely to need special treatment. However, you should contact your doctor or pharmacist for further advice.

If you forget to take Omacor

If you miss a dose, take it when you remember unless it is almost time for your next dose, in which case take the next dose as usual. Do not take a double dose (twice the dose recommended by your doctor) to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Omacor can cause side effects, although not everybody gets them. The following are side effects that may happen with this medicine:

Common side effects (may affect up to 1 in 10 people):

- irregular, rapid rhythm of the heart
- stomach problems like abdominal distension, pain, constipation, diarrhoea, indigestion (dyspepsia), gas, belching (eructation), acid reflux, feeling sick (nausea) and being sick (vomiting)

Uncommon side effects (may affect up to 1 in 100 people):

- high blood sugar levels
- gout
- dizziness
- problems with taste
- headache
- low blood pressure
- nose bleed
- blood in your stools
- rash

Rare side effects (may affect up to 1 in 1,000 people):

- allergic reactions
- itchy rash (hives or urticaria)
- liver disorders, with possible changes in the results of certain blood tests

Other side effects have occurred in a very small number of people but their exact frequency is unknown.

- itching

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website:

www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE OMACOR

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month

Do not store above 25°C. Do not freeze.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Omacor contains

The active substances are omega-3-acid ethyl esters, 1000 mg of omega-3-acid ethyl esters 90 comprising 460 mg eicosapentaenoic acid (EPA), 380 mg docosahexaenoic acid (DHA) ethyl esters (these substances are called omega-3 polyunsaturated fatty acids) and including also 4 mg d-alpha- tocopherol (mixed with a vegetable oil e.g. soya oil) as antioxidant.

The soft capsule shell is made up of gelatine, glycerol, medium-chain triglycerides, lecithin (soya) and purified water.

What Omacor looks like and contents of the pack

Omacor capsules are transparent soft gelatin capsules containing pale yellow oil.

Omacor is available in packs of 28 capsules.

Parallel Product Authorisation Holder

IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland

Manufacturer

BASF AS, N-1327 Lysaker, Norway or BASF AS, Framnesveien 41, NO-3222 Sandefjord, Norway or Pierre Fabre Médicament Production, Le Payrat, FR-46000 Cahors, France.

Repackaged by

Cast Healthcare Ltd, Unit E, The Business Centre, 5-7 Tobermore Road, Draperstown, Magherafelt, BT45 7AG, UK(NI) or IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland

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