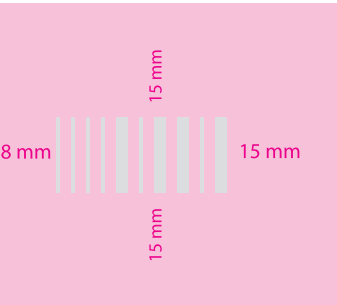


PACKAGE LEAFLET:
INFORMATION FOR THE USER

OMACOR[®]

1000 mg soft capsules

Omega-3-acid ethyl esters 90



Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may want to read it again. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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.

In this leaflet:

- 1. What Omacor is and what it is used for**
- 2. Before you take Omacor**
- 3. How to take Omacor**
- 4. Possible side effects**
- 5. How to store Omacor**
- 6. Further 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:

- together with other medicines for treatment after a heart attack.
- to treat certain forms of increased triglycerides (fats) in the blood after changes to the diet have not worked.

2. BEFORE YOU TAKE OMACOR

Do not take Omacor, if

- you are allergic (hypersensitive) to the main ingredient or any of the other ingredients of Omacor (see Section: Important information about some of the ingredients, and Section 6: Further Information).

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

Take special care with Omacor if:

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

If any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

Using other medicines

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 or have recently used other medicines including medicines obtained without prescription.

Taking Omacor with food or 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).

Use in elderly

Use Omacor with care if you are over 70 years.

Use in 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.

Important Information about some of the ingredients

Omacor may contain soya-bean 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 after a heart attack

The usual dose is one capsule a day.

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 of 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

(occur in 1 to 10 users in 100):

- 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

(occur in 1 to 10 users in 1,000):

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

Rare side effects

(occur in 1 to 10 users in 10,000):

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

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 the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

In the UK:

The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

In Ireland:

Reports may be made via freepost, to the following address:

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

5. HOW TO STORE OMACOR

- Keep out of the reach and sight of children.
- Do not use Omacor after the expiry date which is printed on the carton and the label. The expiry date refers to the last day of the month.
- Do not store Omacor above 25°C. Do not freeze.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER 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) and 380 mg docosahexaenoic acid (DHA) ethyl esters (these substances are called omega-3 polyunsaturated fatty acids) including as antioxidant 4 mg d-alpha-tocopherol (mixed with a vegetable oil e.g. soya-bean oil).

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

What Omacor looks like and contents of the pack

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

Omacor is available in the following pack sizes:

- 1 x 20 capsules
- 1 x 28 capsules
- 1 x 30 capsules
- 1 x 60 capsules
- 1 x 100 capsules
- 10 x 28 capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder and manufacturer of Omacor is:

Pronova BioPharma Norge AS

P.O. Box 420

NO-1327 Lysaker

Norway.

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Omacor is supplied in the United Kingdom by Mylan UK Healthcare Limited., 20 Station Close, Potters Bar, Hertfordshire, EN6 1TL, UK.

Omacor is supplied in Ireland by Mylan IRE Healthcare Limited., Newenham Court, Northern Cross, Malahide Road, Dublin 17, Ireland.

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