

PACKAGE LEAFLET:
 INFORMATION FOR THE USER
OMACOR®
 1000 mg soft capsules
 Omega-3-acid ethyl esters 90

8030185 Laetus 260

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

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 gastrointestinal 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.

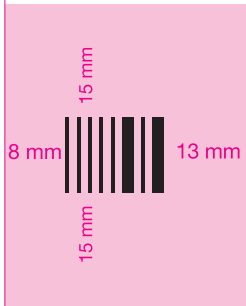
If you take more Omacor than you should

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.

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Component Type	Leaflet (Insert)	Site Barcode/DataMatrix	260	No. of colours	1	Page Count	1 of 2
Affiliate Item Code	3248053	Viatrix SAP No.	400540359, 400541486, 400542258	Colours	Black		
Superseded Affiliate Item Code	2149302	Vendor Job No.	N.A.	Non-Print Colours	Keyline		
TrackWise/GLAMS Job No.	3248053	Artwork Proof No.	1	Equate CMYK with			
MA No.	PL 15905/0001 and PA 1099/1/1	Client Market	Ireland, United Kingdom	Main Font	Helvetica Neue	Body Text Size	8.5 pt
Supplier SAP No.	N.A.	Barcode Info	N.A.	Dimensions	240x180mm	Min Text Size used	8.5 pt
New Supplier Code	8030185	3D Render ID	N.A.	Keyline/Drawing No.	N.A.		
Superseded Supplier Code	8030150						
Packing Site/Printer	GMPack ApS (Hadsund - DK)						
Sign-offs							
V3 MAY 2023							

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
- 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 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 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 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. 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 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
BASF AS
P.O. Box 420
NO-1327 Lysaker
Norway.

Manufacturer
BASF AS
Framnesveien 41
NO-3222 Sandefjord
Norway

or
Pierre Fabre Médicament Production
Le Payrat
FR- 46000 Cahors
France

This leaflet was last updated: September 2023.
Omacor is supplied in the UK by Viatris UK Healthcare Limited, 20 Station Close, Potters Bar, Hertfordshire, EN6 1TL.
Omacor is supplied in Ireland by Mylan IRE Healthcare Limited, Newenham Court, Northern Cross, Malahide Road, Dublin 17, Ireland.

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