

OMACOR[®] capsules

Omega-3-acid ethyl esters 90 (includes EPA & DHA)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Omacor.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Omacor against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Omacor is used for

Omacor reduces the risk of experiencing another heart attack in people who have already had a heart attack in addition to other standard therapy.

Omacor is also used, along with a low-fat and low-cholesterol diet, to lower very high triglycerides (fats) in blood. High levels of triglycerides may increase your risk of developing coronary heart disease. In most people there are no symptoms of high triglycerides. Your doctor can measure your triglyceride levels with a simple blood test.

How Omacor works

Omacor contains highly purified omega-3 polyunsaturated fatty acids. These fatty acids are natural substances found in the body oil of fat fish species that your body needs in sufficient amounts to provide energy. However, as the body cannot make enough on its own, the balance needs to be obtained in the diet.

Ask your doctor if you have any questions about why Omacor has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that this medicine is addictive.

Omacor is only available with a doctor's prescription.

Before you take it

When you must not take it

Do not take Omacor if you are allergic to it or to any of the ingredients listed at the end of this leaflet.

Do not take Omacor if you are allergic to peanut or soya (including soya milk or soya beans).

- Symptoms of an allergic reaction may include skin rash, itching, difficulty breathing or swelling of the face.

Do not take it if the packaging is torn or shows signs of tampering.

Do not take it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

If you are not sure whether you should start taking Omacor, talk to your doctor.

Do not give Omacor to a child under 18 years.

The safety and effectiveness of this medicine in children have not been established.

Before you start to take it

Tell your doctor if:

- 1. you have any allergies or sensitivity to any other medicines or any other substances, such as foods, preservatives or dyes.**
- 2. you are pregnant or intend to become pregnant.**

It is not known if Omacor can harm your unborn baby.

3. you are breast-feeding or intend to breast-feed.

It is not known whether Omacor passes into breast milk.

4. you have, or have had, any other medical conditions, including:

- liver or kidney problems
- a history of bleeding disorders
- diabetes
- over 70 years of age

If you have not told your doctor about any of the above, tell them before you take any Omacor.

Taking other medicines

Tell your doctor if you are taking any other medicines or remedies, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by Omacor, or they may affect how well Omacor works. These include medicines used to prevent clotting, such as aspirin and warfarin.

If you are taking these medicines, you may need additional blood tests, and the dose may need to be changed.

Please talk with your doctor or pharmacist for further information.

How to take it

Follow your doctor's instructions about how and when to take this medicine. These directions may differ from the information contained in this leaflet.

How much to take

Take Omacor only when prescribed by your doctor.

Follow the directions your doctor has given you on how many capsules to take each day. These will be printed on the pharmacy label on the container.

If you are taking Omacor after experiencing a heart attack, the usual dose is 1 capsule daily.

The dose to lower triglyceride levels is 4 capsules daily.

How to take it

Swallow the capsules whole with a glass of water.

Omacor capsules must be taken with a meal.

Taking your capsules with meals helps to avoid any stomach upset.

Take Omacor at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take the capsules.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Omacor helps to reduce your risk of another heart attack, if you have had one already. It also helps to lower very high triglyceride (fat) levels in your blood. It does not cure your condition. Therefore you need to take it for as long as directed by your doctor if you wish to keep those levels down. You may need to take this medicine for the rest of your life. If you stop taking Omacor your triglyceride levels may rise again, or you may have another heart attack.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your capsules, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Australian Poisons Information Centre (telephone 13 11 26), or go to the Accident and Emergency department at your nearest hospital if you think you or anyone else may have taken too much Omacor.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep telephone numbers for these handy.

While you are taking it

Things you must do

Have your blood triglyceride level checked regularly when your doctor says to make sure Omacor is working.

Tell your doctor if you become pregnant while you are taking Omacor.

Tell your doctor and pharmacist if you start or stop any new medicine.

Things you must not do

Do not give Omacor to anyone else even if they have the same condition as you.

Do not use Omacor to treat any other complaints unless your doctor tells you to.

Things that may help your condition

People who have high triglyceride (fat) levels in their blood have an increased chance of developing coronary heart disease. Other factors which may contribute to this condition include high blood pressure, cigarette smoking, diabetes, excessive weight and a family history of coronary heart disease.

Some self-help measures suggested below may help lower your high triglyceride levels.

Talk to your doctor, pharmacist or dietitian about them:

- a low-fat and low-cholesterol diet
- losing weight, if you are overweight
- making physical exercise, such as walking, a part of your routine
- stopping smoking.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking Omacor.

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- belching or flatulence
- nausea or vomiting
- taste disturbance
- gastrointestinal discomfort or pain.
- diarrhoea or constipation

These are mild side effects of the medicine, and usually short-lived.

Stop taking Omacor and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you experience any of the following:

- swelling of the face, or tongue
- shortness of breath
- skin rash.

These are very serious side effects. They may need urgent medical attention. These side effects are rare.

Other side effects not listed above may also occur in some people.

Ask your doctor or pharmacist to answer any questions you may have.

After taking it

Storage

Keep your capsules in the bottle until it is time to take them.

If you take the capsules out of the bottle they may not keep well.

Keep Omacor in a cool dry place where the temperature stays below 30°C. Do not refrigerate. Do not freeze.

Do not store it or any other medicine in the bathroom, near a sink or on a window sill.

Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is good place to store medicines.

Disposal

If your doctor tells you to stop taking Omacor or the capsules have passed their expiry date, return any unused medicine to your pharmacist.

Product description

What it looks like

Soft, oblong, transparent gelatin capsules containing pale yellow oil.

Ingredients

Active ingredient:

Each Omacor capsule contains about 900 mg Omega-3-acid ethyl esters 90 including:

Eicosapentaenoic Acid (EPA) about 460mg

Docosahexaenoic Acid (DHA) about 380 mg

Inactive ingredients:

Each capsule also contains:

- gelatin
- glycerol
- purified water
- medium chain triglycerides
- d-alpha-Tocopherol
- lecithin (soya)

Omacor does not contain gluten, lactose monohydrate, sucrose, tartrazine or any other azo dyes.

It may contain traces of soya (lecithin).

Manufacturer/Sponsor

Omacor capsules are made in Europe and supplied in Australia by:

Mylan Health Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: 1800 314 527

This leaflet was updated in June 2018.

Australian Registration Number:

AUST R 155717