

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using OMACOR?

OMACOR contains the active ingredient Omega-3-acid ethyl esters 90 (includes EPA & DHA). OMACOR is used, along with a low fat and low-cholesterol diet, to lower very high triglycerides (fats) in blood.

For more information, see Section [1. Why am I using OMACOR?](#) in the full CMI.

2. What should I know before I use OMACOR?

Do not use if you have ever had an allergic reaction to OMACOR or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use OMACOR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with OMACOR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use OMACOR?

- Your doctor will decide what dose you will receive.
- The dose to lower triglyceride levels is 4 capsules daily.

More instructions can be found in Section [4. How do I use OMACOR?](#) in the full CMI.

5. What should I know while using OMACOR?

Things you should do	<ul style="list-style-type: none">• 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 should not do	<ul style="list-style-type: none">• 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.
Looking after your medicine	<ul style="list-style-type: none">• Keep OMACOR in a cool dry place where the temperature stays below 30°C. Do not refrigerate. Do not freeze.• Do not store it in the bathroom, near a sink, on a window sill or leave it in the car.• Keep it where young children cannot reach it.

For more information, see Section [5. What should I know while using OMACOR?](#) in the full CMI.

6. Are there any side effects?

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.

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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

OMACOR®

Active ingredient(s): *Omega-3-acid ethyl esters 90 (includes EPA & DHA)s*

Consumer Medicine Information (CMI)

This leaflet provides important information about using OMACOR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using OMACOR.**

Where to find information in this leaflet:

- [1. Why am I using OMACOR?](#)
- [2. What should I know before I use OMACOR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use OMACOR?](#)
- [5. What should I know while using OMACOR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using OMACOR?

OMACOR contains the active ingredient **Omega-3-acid ethyl esters 90 (includes EPA & DHA)**. 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.

OMACOR is 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.

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.

2. What should I know before I use OMACOR?

Warnings

Do not use OMACOR if:

- you are allergic to Omega-3-acid ethyl esters 90, or any of the ingredients listed at the end of this leaflet.**
Always check the ingredients to make sure you can use this medicine.
- 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.
- the packaging is torn or shows signs of tampering.**
- the expiry date (EXP) printed on the pack has passed.** 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.

Check with your doctor if you:

- take any medicines for any other condition
- have any allergies or sensitivity to any other medicines or any other substances, such as foods, preservatives or dyes.**
- you have, or have had, any other medical conditions, including:**
 - liver problems
 - a history of bleeding disorders
 - diabetes
 - are over 70 years of age

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether OMACOR passes into breast milk.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect OMACOR.

4. How do I use OMACOR?

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.
- The dose to lower triglyceride levels is 4 capsules daily.

When to take OMACOR

- **OMACOR should be taken 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 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.

How long to take it

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

Omacor 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.

If you forget to use OMACOR

OMACOR should be used regularly at the same time each day.

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 you missed.

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

If you use too much OMACOR

If you think that you have used too much OMACOR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while using OMACOR?

Things you should 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.**
- Remind any doctor, dentist or pharmacist you visit that you are using OMACOR.

Things you should 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.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

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.

Store away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • belching or flatulence • nausea or vomiting • taste disturbance • gastrointestinal discomfort or pain. • diarrhoea or constipation <p>These are mild side effects of the medicine, and usually short-lived.</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • swelling of the face, or tongue • shortness of breath • skin rash. <p>These are very serious side effects. They may need urgent medical attention. These side effects are rare.</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What OMACOR contains

Active ingredient (main ingredient)	<p>Each OMACOR capsule contains 900 mg Omega-3-acid ethyl esters 90 including:</p> <p>Eicosapentaenoic Acid (EPA) about 460mg</p> <p>Docosahexaenoic Acid (DHA) about 380 mg</p>
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Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • gelatin • glycerol • purified water • d-alpha-Tocopherol
Potential allergens	OMACOR may contain soya bean products and traces of sulfites and fish products.

Do not take this medicine if you are allergic to any of these ingredients.

What OMACOR looks like

OMACOR capsules are soft, oblong, transparent gelatin capsules containing pale yellow oil. (AUST R 155717).

Who distributes OMACOR

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

Viatrix Pty Ltd
 Level 1, 30 The Bond
 30-34 Hickson Road
 Millers Point NSW 2000
www.viatrix.com.au
 Phone: 1800 274 276

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