

## **PATIENT INFORMATION**

### **OMACOR (ō-mă-kōr)**

#### **Capsules (omega-3-acid ethyl esters)**

Read the Patient Information that comes with OMACOR before you start taking it, and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment.

### **WHAT IS OMACOR?**

OMACOR is a prescription medicine for adults called a lipid-regulating medicine. OMACOR is made of omega-3 fatty acids. Omega-3 fatty acids are natural substances that your body needs. They are found naturally in some plants and in the oil of certain fish, such as salmon and mackerel.

OMACOR is used along with a low-fat and low-cholesterol diet to lower very high triglycerides (fats) in your blood. The following should be done to lower high blood fats before OMACOR or other lipid-regulating medicines are used:

- lose weight
- increase physical exercise
- lowering alcohol use
- treat diseases such as diabetes and low thyroid (hypothyroidism)
- stop other medicines that raise triglyceride levels such as certain blood pressure medicines and estrogens

Treatment with OMACOR has not been shown to prevent heart attacks or strokes.

OMACOR has not been studied in children under the age of 18 years.

### **Who should not take OMACOR?**

Do not take OMACOR if you:

- **are allergic to OMACOR or any of its ingredients.** See the end of this leaflet for a complete list of ingredients in OMACOR.

### **What should I tell my doctor before taking OMACOR:**

**Tell your doctor about all of your medical conditions, including if you:**

- **drink more than 2 glasses of alcohol daily**
- **have diabetes**
- **have a thyroid problem** called hypothyroidism
- **have a liver problem**
- **have a pancreas problem**
- **are allergic to fish.**  
OMACOR may not be right for you.
- **are pregnant, or planning to become pregnant.** It is not known if OMACOR can harm your unborn baby.
- **are breastfeeding.** It is not known if OMACOR passes into your milk and if it can harm your baby.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicine, vitamins and herbal supplements. OMACOR and certain other medicines can interact causing serious side effects. Especially tell your doctor if you take medicines:

- to reduce clotting – known as anticoagulants or blood thinners. These include aspirin, warfarin, coumarin and clopidogrel (Plavix).

Know all the medicines you take. Keep a list of them with you to show your doctor and pharmacist.

### ***How should I take OMACOR?***

- Take OMACOR exactly as prescribed. Do not change your dose or stop OMACOR without talking to your doctor.
- The usual dose of OMACOR is 4 capsules:
  - Take all 4 capsules at the same time, or
  - Take 2 capsules two times a day
- Take OMACOR at the same time or times each day
- Take OMACOR with or without food. You may find it easier to take OMACOR with food.
- Do not take more than 4 capsules a day. Taking more than 4 capsules per day may increase the chance of side effects.

- Your doctor should start you on a low-fat and low-cholesterol diet before giving you OMACOR. Stay on this low-fat and low-cholesterol diet while taking OMACOR.
- Your doctor should do blood tests to check your triglyceride and cholesterol levels, and liver function during treatment with OMACOR. Your dose of OMACOR may be changed based on these blood tests.
- If you miss a dose of OMACOR, take it as soon as you remember. However, if you miss one day of OMACOR, do not double your dose when you next take it.
- If you take too much OMACOR or overdose, call your doctor or Poison Control Center right away.

### ***What are the possible side effects of OMACOR?***

- The most common side effects with OMACOR are burping, infection, flu symptoms, upset stomach, a change in your sense of taste, back pain and skin rash.
- OMACOR may affect certain blood tests. It may change:
  - one of the tests to check liver function (ALT)
  - one of the tests to measure cholesterol levels (LDL-C)

Talk to your doctor if you have side effects that bother you or that will not go away.

These are not all the side effects with OMACOR. Ask your doctor or pharmacist for a complete list.

### ***How should I store OMACOR?***

- Store OMACOR at room temperature, 59° to 86° F (15° to 30° C).
- Do not keep medicine that is out of date or that you no longer need.
- **Keep OMACOR out of the reach of children.** Be sure that if you throw medicines away, it is out of the reach of children.

### ***General information about OMACOR.***

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use OMACOR for a condition for which it was not prescribed. Do not give OMACOR to other people, even if they have the same problem you have. It may harm them.

This leaflet summarizes the most important information about OMACOR. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about OMACOR that is written for health professionals or go to [www.OMACORrx.COM](http://www.OMACORrx.COM).

### ***What are the ingredients in OMACOR?***

Active Ingredient: Omega-3-Acid Ethyl Esters

Inactive Ingredients: gelatin, glycerol, purified water, alpha-tocopherol (in partially hydrogenated vegetable oils, including soybean oil)

### ***Rx Only***

Manufactured for:

Reliant Pharmaceuticals, Inc.  
Liberty Corner, NJ 07938

By:

Cardinal Health  
St. Petersburg, FL 33716