Omega-3-Acid Ethyl Esters Capsules USP

Read this Patient Information before you start taking omega-3-acid ethyl esters, and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is Omega-3-Acid Ethyl Esters Capsules?
Omega-3-acid ethyl esters is a prescription medicine, usually taken with a low fat and low cholesterol diet to lower very high triglyceride (fat) levels in adults. It is not known if omega-3-acid ethyl esters changes your risk of having an arrhythmia or other drug affecting coagulation (e.g., aspirin, dipyridamole, warfarin).

Who should not take Omega-3-Acid Ethyl Esters Capsules?
Do not take omega-3-acid ethyl esters if you are allergic to omega-3-acid ethyl esters or any of the ingredients in omega-3-acid ethyl esters capsules. See the end of this leaflet for a complete list of ingredients in omega-3-acid ethyl esters capsules.

What should I tell my doctor before taking Omega-3-Acid Ethyl Esters Capsules?
Before you take omega-3-acid ethyl esters, tell your doctor if you:

- have diabetes
  - have a low thyroid problem (hypothyroidism)
  - have a liver problem
  - have a pancreas problem
  - have a certain heart rhythm problem called atrial fibrillation or flutter
  - are allergic to fish or shellfish. It is not known if omega-3-acid ethyl esters will harm your unborn baby.

How should I take Omega-3-Acid Ethyl Esters Capsules?
Capsules USP

- Take omega-3-acid ethyl esters exactly as your doctor tells you to take them. If you do not take them as directed, they may not work well.
- You should not take more than 4 capsules of omega-3-acid ethyl esters each day. Do not take all 4 capsules at one time, or 2 capsules twice a day.
- Do not change your dose or stop omega-3-acid ethyl esters without talking to your doctor.
- Take omega-3-acid ethyl esters with or without food. Take omega-3-acid ethyl esters capsules whole. Do not break, crush, dissolve, or chew omega-3-acid ethyl esters capsules.
- Your doctor may start you on a diet that is low in saturated fat, cholesterol, and low in added sugars before giving you omega-3-acid ethyl esters for 2 to 6 weeks and may have you continue this diet during treatment with omega-3-acid ethyl esters.
- If you cannot get enough omega-3 fatty acids in your diet, you may be able to get omega-3 fatty acids by taking omega-3-acid ethyl esters capsules. They should be used as part of a diet that is low in fat and low in cholesterol.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Omega-3-acid ethyl esters can interact with certain other medicines that you are taking. Using omega-3-acid ethyl esters and other medicines together may affect the amount of each medicine in your body, which may increase the risk of side effects or cause your medicine not to work.

Know the medicines you take. Keep a list of them with you to show your doctor and pharmacist when you get a new medicine.
Omega-3-acid ethyl esters may cause serious side effects, including:

- fluctuations in the results of blood tests used to check your liver function (ALT and AST) and your bad cholesterol levels (LDL-C).
- increases in the frequency of a heart rhythm problem (atrial fibrillation or flutter) which may especially happen in the first few weeks of taking omega-3-acid ethyl esters if you already have that problem.

The most common side effects of omega-3-acid ethyl esters include:

- diarrhea
- upset stomach
- a change in your sense of taste

Talk to your doctor if you have a side effect that bothers you or does not go away.

These are not all the possible side effects of omega-3-acid ethyl esters. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Omega-3-Acid Ethyl Esters Capsules?

- Store omega-3-acid ethyl ester capsules at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Protect from light.
- Do not freeze omega-3-acid ethyl esters.
- Safely throw away medicine that is out of date or no longer needed.

Keep omega-3-acid ethyl esters and all medicines out of reach of children.

General information about the safe and effective use of omega-3-acid ethyl esters: Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use omega-3-acid ethyl esters for a condition for which it was not pre-

scribed. Do not give omega-3-acid ethyl esters to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information Leaflet summarizes the most important information about omega-3-acid ethyl esters. If you would like more information, ask your doctor or pharmacist. You can ask your doctor or pharmacist for information about omega-3-acid ethyl esters that is written for health professionals.

For more information call Par Pharmaceuticalat 1-800-928-9093.

What are the ingredients in Omega-3-Acid Ethyl Esters Capsules?

Active Ingredient: omega-3-acid ethyl esters, mostly EPA and DHA

Inactive Ingredients: gelatin, gelatin, and purified water, n-tocopherol, 3.8-4.2 mg/capsule (components of the capsule shell), alcohol, ammonium hydroxide, isopropyl alcohol, polyethylene glycol, polyvinyl acetate phthalate, propylene glycol, titanium dioxide. May also contain shellac glaze, simethicone, and n-butyl alcohol.

This patient labeling has been approved by the U.S. Food and Drug Administration.

Distributed by:
Par Pharmaceutical Companies, Inc.
Chestnut Ridge, New York 10977

What are the possible side effects of Omega-3-Acid Ethyl Esters Capsules? Omega-3-acid ethyl esters may cause serious side effects, including:

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PATIENT INFORMATION

Information for Patients

Omega-3-acid ethyl esters should be used with caution in patients with known sensitivity or allergy to fish and/or shellfish. [see Warnings and Precautions (1.1)].

Patients should not be taking omega-3-acid ethyl esters as prescribed if a dose has been missed. Advise patients to take as soon as they remember. However, if more than 2 hours have passed since the missed dose, they should not double the dose when they take it.

Information for Parthen 75% (77°F) capsules permitted to 10° to 30°C (50° to 86°F) [see USP Controlled Room Temperature]. Protect from light.

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