

PATIENT INFORMATION
Omega-3-acid ethyl esters
(oh-MAY-ga 3 AS-id eth-il es-ters)
Capsules, USP

What are omega-3-acid ethyl esters capsules?

Omega-3-acid ethyl esters capsules are a prescription medicine used along 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 inflammation of your pancreas (pancreatitis).

It is not known if omega-3-acid ethyl esters prevents you from having a heart attack or stroke.

It is not known if omega-3-acid ethyl esters are safe and effective in children.

Who should not take omega-3-acid ethyl esters capsules?

Do not take omega-3-acid ethyl esters capsules 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.

Before taking omega-3-acid ethyl esters, tell your healthcare provider about all of your medical conditions, including 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 people who are allergic to fish or shellfish are also allergic to omega-3-acid ethyl esters capsules.
- are pregnant or plan to become pregnant. It is not known if omega-3-acid ethyl esters will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Omega-3-acid ethyl esters can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take omega-3-acid ethyl esters capsules.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Omega-3-acid ethyl esters capsules can interact with certain other medicines that you are taking. Using omega-3-acid ethyl esters capsules with medicines that affect blood clotting (anticoagulants or blood thinners) may cause serious side effects.

How should I take omega-3-acid ethyl esters capsules?

- Take omega-3-acid ethyl esters capsules exactly as your healthcare provider tells you to take it.
- You should not take more than 4 capsules of omega-3-acid ethyl esters capsules each day. Either take all 4 capsules at one time or 2 capsules two times a day.
- Do not change your dose or stop omega-3-acid ethyl esters capsules without talking to your healthcare provider.
- Take omega-3-acid ethyl esters capsules with food.
- Take omega-3-acid ethyl esters capsules whole. Do not break, open, crush, dissolve, or chew omega-3-acid ethyl esters capsules before swallowing. If you cannot swallow omega-3-acid ethyl esters capsules whole, tell your healthcare provider. You may need a different medicine.
- If you miss a dose of omega-3-acid ethyl esters capsules, take the missed dose as soon as you remember. If you miss one day of omega-3-acid ethyl esters capsules, **do not** double your dose the next time you take it.
- Your healthcare provider may start you on a cholesterol-lowering diet before giving you omega-3-acid ethyl esters capsules. Stay on this diet while taking omega-3-acid ethyl esters capsules.
- Your healthcare provider should do blood tests to check your triglyceride, bad cholesterol (LDL-C), and liver function (ALT and AST) levels while you take omega-3-acid ethyl esters capsules.

What are the possible side effects of omega-3-acid ethyl esters capsules?

Omega-3-acid ethyl esters capsules may cause serious side effects, including:

- **changes in certain blood tests.** Omega-3-acid ethyl esters may cause an increase in the results of blood tests used to check your liver function and your bad cholesterol levels.
- **increased risk of a heart rhythm problem in people who have a heart rhythm problem.** Omega-3-acid ethyl esters may cause an increase in the frequency of a heart rhythm problem (atrial fibrillation or flutter), especially in the first few months of taking omega-3-acid ethyl esters, if you already have a heart rhythm problem.

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

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

These are not all the possible side effects of omega-3-acid ethyl esters. 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 esters capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not freeze omega-3-acid ethyl esters capsules.
- Safely throw away medicine that is out of date or no longer needed.

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

General information about the safe and effective use of omega-3-acid ethyl esters capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use omega-3-acid ethyl esters capsules for a condition for which it was not prescribed. Do not give omega-3-acid ethyl esters capsules to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about omega-3-acid ethyl esters capsules that is written for health professionals.

What are the ingredients in omega-3-acid ethyl esters capsules, USP?

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

Inactive Ingredients: gelatin, glycerin, 4.4 mg α -tocopherol, soybean oil and purified water. The capsules are printed with white imprinting ink containing titanium dioxide, hypromellose 2910 and propylene glycol.

Manufactured by:

Ascent Pharmaceuticals, Inc.
Central Islip, NY 11722

Manufactured for:

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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