

PATIENT INFORMATION
Icosapent Ethyl Capsules
(eye koe' sa pent eth' il)

Patient Information Leaflet available at www1.apotex.com/products/us

What are icosapent ethyl capsules?

Icosapent ethyl capsules are a prescription medicine used:

- along with a low-fat and low-cholesterol diet to lower high levels of triglycerides (fats) in adults.

It is not known if icosapent ethyl capsules change your risk of having inflammation of your pancreas (pancreatitis).

It is not known if icosapent ethyl capsules are safe and effective in children.

Do not take icosapent ethyl capsules if you are allergic to icosapent ethyl or any of the ingredients in icosapent ethyl capsules. See the end of this leaflet for a complete list of ingredients in icosapent ethyl capsules.

Before taking icosapent ethyl capsules, tell your doctor 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.
- are allergic to fish or shellfish. It is not known if people who are allergic to fish or shellfish are also allergic to icosapent ethyl capsules.
- are pregnant, or planning to become pregnant. It is not known if icosapent ethyl capsules will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Icosapent ethyl can pass into your breastmilk, and may harm your baby. Talk to your doctor about the best way to feed your baby if you take icosapent ethyl capsules.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and dietary or herbal supplements.

Icosapent ethyl capsules can interact with certain other medicines that you are taking.

Especially tell your doctor if you take medicines that affect your blood clotting (anticoagulants or blood thinners).

How should I take icosapent ethyl capsules?

- Take icosapent ethyl capsules exactly as your doctor tells you to take it.
- Do not change your dose or stop taking icosapent ethyl capsules without talking to your doctor.
- Do not take more capsules than what is prescribed by your doctor.
 - If you are prescribed the 1 gram capsules, you should not take more than 4 capsules each day with food.
- Take icosapent ethyl capsules whole. Do not break, crush, dissolve, or chew icosapent ethyl capsules before swallowing.
- If you miss a dose of icosapent ethyl capsules, take it as soon as you remember. However, if you miss one day of icosapent ethyl capsules, do not double your dose when you take it.
- Your doctor may start you on a diet that is low in saturated fat, cholesterol,

carbohydrates, and low in added sugars before giving you icosapent ethyl capsules. Stay on this diet while taking icosapent ethyl capsules.

- Your doctor may do blood tests to check your triglyceride and other lipid levels while you take icosapent ethyl capsules.

What are the possible side effects of icosapent ethyl capsules?

Icosapent ethyl capsules may cause serious side effects, including:

- **Heart rhythm problems (atrial fibrillation and atrial flutter).** Heart rhythm problems which can be serious and cause hospitalization have happened in people who take icosapent ethyl capsules, especially in people who have heart (cardiovascular) disease or diabetes with a risk factor for heart (cardiovascular) disease, or who have had heart rhythm problems in the past. Tell your doctor if you get any symptoms of heart rhythm problems such as feeling as if your heart is beating fast and irregular, lightheadedness, dizziness, shortness of breath, chest discomfort, or you faint.
- **Possible allergic reactions if you are allergic to fish or shellfish.** Stop taking icosapent ethyl capsules and tell your doctor right away or get emergency medical help if you have any signs or symptoms of an allergic reaction.
- **Bleeding.** Serious bleeding can happen in people who take icosapent ethyl capsules. Your risk of bleeding may increase if you are also taking a blood thinner medicine.

If you have liver problems and are taking icosapent ethyl capsules, your doctor should do blood tests during treatment.

The most common side effect of icosapent ethyl capsules include:

- Muscle and joint pain.
- Swelling of the hands, legs, or feet.
- Constipation
- Gout
- Heart rhythm problems (atrial fibrillation).

These are not all the possible side effects of icosapent ethyl capsules. 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 icosapent ethyl capsules?

- Store icosapent ethyl capsules at 68°F to 77° F (20°C to 25°C).
- Safely throw away medicine that is out of date or no longer needed.

Keep icosapent ethyl capsules and all medicine out of the reach of children.

General information about the safe and effective use of icosapent ethyl capsules.

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

For more information, go to www.apotex.com or call 1-800-706-5575.

What are the ingredients in icosapent ethyl capsules?

Active Ingredient: icosapent ethyl

Inactive Ingredients: gelatin, glycerine, purified water and tocopherol. The capsule imprinting ink contains ammonium hydroxide, propylene glycol, shellac, simethicone, and titanium dioxide.

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

**APOTEX INC.
ICOSAPENT ETHYL CAPSULES
1 gram**

Manufactured by:
Accucaps Industries Limited
Windsor, Ontario
Canada N9C 3R5

Manufactured for:
Apotex Corp.
Weston, Florida
33326

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