Medication Guide

Fenofibric Acid (FEN-oh-FYE-bric AS-id) Delayed-Release Capsules

Read this Medication Guide before you start taking fenofibric acid delayed-release capsules and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about fenofibric acid delayed-release capsules?

Fenofibric acid delayed-release capsules can cause muscle pain, tenderness or weakness, which may be symptoms of a rare but serious muscle condition called rhabdomyolysis. In some cases rhabdomyolysis can cause kidney damage and death. The risk of rhabdomyolysis may be higher when fenofibric acid delayed-release capsules are given with statins. If you take a statin, tell your healthcare provider.

What are fenofibric acid delayed-release capsules?

Fenofibric acid delayed-release capsules are a prescription medicine used to treat cholesterol in the blood by lowering the total amount of triglycerides and LDL (bad) cholesterol, and increasing the HDL (good) cholesterol. **Fenofibric acid delayed-release capsules have not been shown to lower your risk of having heart problems or a stroke.** You should be on a low fat and low cholesterol diet while you take fenofibric acid delayed-release capsules.

The safety and effectiveness of fenofibric acid delayed-release capsules in children is not known.

Who should not take fenofibric acid delayed-release capsules?

Do not take fenofibric acid delayed-release capsules if you:

- are allergic to fenofibric acid, or any of the ingredients in fenofibric acid delayed-release capsules. See the end of this Medication Guide for a list of all the ingredients in fenofibric acid delayed-release capsules.
- have severe kidney disease.
- have liver disease.
- have gallbladder disease.
- are a nursing mother.

Talk to your healthcare provider before you take fenofibric acid delayed-release capsules if you have any of these conditions.

What should I tell my healthcare provider before taking fenofibric acid delayed-release capsules?

Before taking fenofibric acid delayed-release capsules, tell your healthcare provider about all your medical conditions, including if you:

- are allergic to any medicines.
- have ever had kidney problems.
- have ever had liver problems.
- have ever had gallbladder problems.
- are pregnant or if you plan to become pregnant. It is not known if fenofibric acid delayed-release capsules will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if fenofibric acid passes into your breast milk. You and your healthcare provider should decide if you will take fenofibric acid delayed-release capsules or breastfeed. You should not do both.

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

Using fenofibric acid delayed-release capsules with certain other medicines can affect the way these medicines work and other medicines may affect how fenofibric acid delayed-release capsules works. In some cases, using fenofibric acid delayed-release capsules with other medicines can cause serious side effects.

Know all the medicines you take. Keep a list of them and show it to your healthcare provider when you get a new medicine.

It is especially important to tell your healthcare provider if you take any of the medicines listed below:

- **anticoagulants,** also known as blood thinners (warfarin, Coumadin)
- **bile acid resins**
- **cyclosporine**

Ask your healthcare provider if you are not sure if your medicine is one of these.

How should I take fenofibric acid delayed-release capsules?

- You should be on a low fat and low cholesterol diet while you take fenofibric acid delayed-release capsules.
- Take fenofibric acid delayed-release capsules one time each day as prescribed by your healthcare provider.
- Take fenofibric acid delayed-release capsules with or without food.
- Swallow fenofibric acid delayed-release capsules whole. Do not break, crush, dissolve, or chew fenofibric acid delayed-release capsules before swallowing. If you cannot swallow fenofibric acid delayed-release capsules whole, tell your healthcare provider, you may need a different medicine.
- If you miss a dose of fenofibric acid delayed-release capsules, take it as soon as you remember. If it is almost time for your next dose, just skip the missed dose. Take the next dose at your regular time. If you are not sure about your dosing, call your healthcare provider. **Do not take more than one dose of fenofibric acid delayed-release capsules a day unless your healthcare provider tells you to.**

- If you take too much fenofibric acid delayed-release capsules, contact your healthcare provider or your local emergency department.
- Do not change your dose or stop fenofibric acid delayed-release capsules unless your healthcare provider tells you to.
- Your healthcare provider may do blood tests before you start taking fenofibric acid delayed-release capsules and during treatment. See your healthcare provider regularly to check your cholesterol and triglyceride levels and to check for side effects.

What are the possible side effects with fenofibric acid delayed-release capsules?

Fenofibric acid delayed-release capsules may cause serious side effects, including:

- **muscle pain, tenderness, or weakness.** See "What is the most important information that I should know about fenofibric acid delayed-release capsules?"
- **tiredness and fever.**
- **abdominal pain, nausea, or vomiting.** These may be signs of inflammation (swelling) of the gallbladder or pancreas.

Call your healthcare provider right away if you have any of these serious side effects.

The most common side effects with fenofibric acid delayed-release capsules include:

- headache
- heartburn (indigestion)
- nausea
- muscle aches
- increases in muscle or liver enzymes that are measured by blood tests

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of fenofibric acid delayed-release capsules. For more information, ask your healthcare provider or pharmacist.

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

How do I store fenofibric acid delayed-release capsules?

- Store fenofibric acid delayed-release capsules between 59° to 86°F (15° to 30°C).
- Protect fenofibric acid delayed-release capsules from moisture.

Keep fenofibric acid delayed-release capsules and all medicines out of the reach of children.

General information about the safe and effective use of fenofibric acid delayed-release capsules

Medicines are sometimes prescribed for conditions that are not mentioned in the Medication Guide. Do not use fenofibric acid delayed-release capsules for a condition for which it was not prescribed. Do not give fenofibric acid delayed-release capsules to other people, even if they have the same condition you have. It may harm them.

This Medication Guide summarizes the most important information about fenofibric acid delayed-release capsules. If you would like more information, talk to your healthcare provider. You can also ask your pharmacist or healthcare provider for information that is written for health professionals.

For more information call 1-866 210 9797.

What are the ingredients in fenofibric acid delayed-release capsules?

Active Ingredient: Fenofibric acid

Inactive Ingredients: Hypromellose, povidone, water, hydroxylpropyl cellulose, colloidal silicon dioxide, sodium stearyl fumarate, methacrylic acid copolymer, talc, triethyl citrate. The capsule shell of the 45 mg capsule contains the following inactive ingredients: gelatin, titanium dioxide, iron oxide yellow, and iron oxide red. The capsule shell of the 135 mg capsule contains the following inactive ingredients: gelatin, titanium dioxide, iron oxide yellow, and FD&C Blue #2. The capsule shells are printed with edible white ink and black ink. The edible white ink contains shellac, propylene glycol, potassium hydroxide, and titanium dioxide and the edible black ink contains shellac, propylene glycol, iron oxide black and, potassium hydroxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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