

MEDICATION GUIDE

Trilipix®

(try-lip-iks)

(fenofibric acid, delayed release capsules)

Read this Medication Guide before you start taking Trilipix 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 Trilipix?

Trilipix can be used with other cholesterol-lowering medicines called statins. Statins include:

- atorvastatin (Lipitor, Caduet)
- pravastatin (Pravachol)
- fluvastatin (Lescol, Lescol XL)
- rosuvastatin (Crestor)
- lovastatin (Altoprev, Mevacor, Advicor)
- simvastatin (Zocor, Simcor, Vytorin)
- pitavastatin (Livalo)

Statins 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 Trilipix is given with statins. If you take a statin, tell your healthcare provider.

Other medicines or large amounts of grapefruit juice (more than a quart) may raise the levels of statins in your body, and could then raise the risk of muscle problems. Tell your healthcare provider if you are taking any medicines listed below.

- Heart medicine
- Stomach medicine
- Antibiotic
- Anti-fungal
- Cholesterol-lowering medicine
- Hormones
- HIV/AIDS medicine
- Antidepressant
- Immunosuppressant
- Anti-seizure medicine

Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure.

Tell your healthcare provider if you drink grapefruit juice.

What is Trilipix?

Trilipix is 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. **Trilipix has 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 Trilipix.

The safety and effectiveness of Trilipix in children is not known.

Who should not take Trilipix?

Do not take Trilipix if you:

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

Talk to your healthcare provider before you take Trilipix if you have any of these conditions.

What should I tell my healthcare provider before taking Trilipix?

Before taking Trilipix, 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 Trilipix will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Trilipix passes into your breast milk. You and your healthcare provider should decide if you will take Trilipix 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 Trilipix with certain other medicines can affect the way these medicines work and other medicines may affect how Trilipix works. In some cases, using Trilipix 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 mentioned in, "What is the most important information I should know about Trilipix?" or 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 Trilipix?

- You should be on a low fat and low cholesterol diet while you take Trilipix.

- Take Trilipix one time each day as prescribed by your healthcare provider.
- Take Trilipix with or without food.
- Swallow Trilipix capsules whole. Do not break, crush, dissolve, or chew Trilipix capsules before swallowing. If you cannot swallow Trilipix capsules whole, tell your healthcare provider, you may need a different medicine.
- If you take a medicine called a statin, you can take Trilipix® (fenofibric acid) and your statin at the same time of day.
- If you miss a dose of Trilipix, 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 Trilipix a day unless your healthcare provider tells you to.**
- If you take too much Trilipix, contact your healthcare provider or your local emergency department.
- Do not change your dose or stop Trilipix unless your healthcare provider tells you to.
- Your healthcare provider may do blood tests before you start taking Trilipix 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 Trilipix?

Trilipix may cause serious side effects, including:

- **muscle pain, tenderness, or weakness.** See "What is the most important information that I should know about Trilipix?"
- **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 Trilipix 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 Trilipix. 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 Trilipix?

- Store Trilipix between 59° to 86° F (15° to 30° C).
- Protect Trilipix from moisture.

Keep Trilipix and all medicines out of the reach of children.

General information about the safe and effective use of Trilipix

Medicines are sometimes prescribed for conditions that are not mentioned in the Medication Guide. Do not use Trilipix for a condition for which it was not prescribed. Do not give Trilipix 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 Trilipix. 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 go to www.Trilipix.com or call 1-800-633-9110.

What are the ingredients in Trilipix?

Active Ingredient: Fenofibric acid

Inactive Ingredients: Hypromellose, povidone, water, hydroxypropyl cellulose, colloidal silicon dioxide, sodium stearyl fumarate, methacrylic acid copolymer, talc, triethyl citrate, gelatin, titanium dioxide, and yellow iron oxide. Additionally, the 45 mg capsule shell contains black iron oxide and red iron oxide, and the 135 mg capsule shell contains FD&C Blue #2.

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by Fournier Laboratories Ireland Limited, Anngrove, Carrigtwohill Co. Cork, Ireland, or Abbott Pharmaceutical PR Ltd., Barceloneta, PR 00617.

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

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