

Important New Update to the Prescribing Information for TRILIPIX® (fenofibric acid) Delayed-Release Capsules for Oral Use

In June 2021, the labeling information was updated for all fenofibrate and fenofibric acid products including the TRILIPIX Prescribing Information (PI), and key highlights are listed below. These highlights do not include all the changes; please refer to the complete PI to review additional changes.

The following describe the important changes in the TRILIPIX PI:

Warnings and Precautions:

In the updated Warnings and Precautions subsection, “Liver Function” was retitled to “Hepatotoxicity” and described that serious drug induced liver injury, including liver transplantation and death, has been reported postmarketing with TRILIPIX. Drug induced liver injury has been reported within the first few weeks of treatment or after several months of treatment and in some cases has reversed when TRILIPIX was discontinued. Patients with drug induced liver injury experienced signs and symptoms including dark urine, abnormal stool, jaundice (yellowing of the skin or whites of the eyes), malaise (feeling of discomfort, illness, or uneasiness), abdominal pain, myalgia (muscle pain), weight loss, pruritus (itching), and nausea. Inform your healthcare provider if you have any of these signs and symptoms of liver injury. Many patients also had elevations in liver enzyme levels, serum alanine transaminase (ALT), and aspartate transaminase (AST) including total bilirubin.

Your physician should monitor your liver function, including liver enzymes ALT, AST, and total bilirubin, before you start treatment and periodically for the duration of your treatment. TRILIPIX should be discontinued if you develop signs or symptoms of liver injury or if you have increased liver enzyme levels that persist.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088 (1-800-332-1088).

Uses and Important Safety Information for TRILIPIX

Uses for TRILIPIX® (fenofibric acid) delayed-release capsules¹

- TRILIPIX should only be used when other measures, such as diet and exercise, have not been enough.
- 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. You should be on a low fat and low cholesterol diet while you take TRILIPIX.
- TRILIPIX is also used along with diet to lower severely high triglycerides. Improving blood sugar control in certain people with diabetes may prevent the need for cholesterol drug therapy.
- **TRILIPIX has not been shown to lower your risk of having heart problems or a stroke.**

Important Safety Information for TRILIPIX¹

- TRILIPIX should not be taken by people with liver, gallbladder, or severe kidney disease, nursing mothers, or those allergic to any product ingredient.
- TRILIPIX can cause serious liver injury, including liver transplantation and death. Tell your doctor if you have signs or symptoms of liver injury including dark urine, abnormal stool, jaundice (yellowing of the skin or whites of the eyes), malaise (feeling of discomfort, illness, or uneasiness), abdominal pain, myalgia (muscle pain), weight loss, pruritus (itching), or nausea. Blood tests are needed before and during treatment with TRILIPIX to check for liver problems.
- TRILIPIX 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.
- Some people require blood tests to check for kidney problems while taking TRILIPIX.
- TRILIPIX may cause inflammation (swelling) of the gallbladder or pancreas. Contact your healthcare provider if you experience abdominal pain, nausea, or vomiting.
- Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.
- TRILIPIX may cause serious allergic-type reactions, blood clots, and possible changes in some blood test values.
- If you are pregnant or may become pregnant, talk with your healthcare provider about TRILIPIX. It is not known if TRILIPIX will harm your unborn baby.
- The most common side effects with TRILIPIX include headache, heartburn (indigestion), nausea, muscle aches, and increases in muscle or liver enzymes that are measured by blood tests.

For more information, talk with your healthcare provider.

Please [click here](#) for full Prescribing Information.