

Important New Update to the Prescribing Information for TriCor® (fenofibrate) Tablets for Oral Use

In June 2021, the labeling information was updated for all fenofibrate and fenofibric acid products including the TriCor 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 TriCor 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 TriCor. 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 TriCor 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. TriCor 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 TriCor

Uses for TriCor® (fenofibrate) Tablets¹

- TriCor should only be used when other measures, such as diet and exercise, have not been enough.
- TriCor is a prescription medicine used along with diet in adults to lower triglycerides, total cholesterol, and LDL (bad) cholesterol, and to increase HDL (good) cholesterol.
- TriCor is also used along with diet in adults to lower severely high triglycerides. Improving blood sugar control in certain people with diabetes may prevent the need for cholesterol drug therapy.
- TriCor was not shown to reduce the risk of having heart problems in patients with type 2 diabetes.

Important Safety Information for TriCor¹

- TriCor should not be taken by people with liver, gallbladder, or severe kidney disease; nursing mothers; or those allergic to any product ingredient.
- TriCor has not been shown to lower your risk of having heart problems or a stroke.
- TriCor 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 TriCor to check for liver problems.
- TriCor can cause muscle problems. Unexplained muscle pain, tenderness, or weakness may be a sign of a serious but rare muscle problem and should be reported to your healthcare provider right away. The risk of a serious muscle problem may be higher when TriCor 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 TriCor.
- TriCor 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 all prescription and non-prescription medicines, vitamins and herbal supplements.
- TriCor 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 TriCor. It is not known if TriCor will harm your unborn baby.
- The most common side effects with TriCor include increases in liver or muscle enzymes measured by blood tests and congestion or allergy-like symptoms in the nose.

For more information, talk with your healthcare provider.

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