

LOFIBRA[®] Important Safety Information

Indication

LOFIBRA[®] (fenofibrate capsules [micronized] and fenofibrate tablets) is a prescription medicine that, along with diet, reduces “bad” cholesterol (LDL) and triglycerides and increases “good” cholesterol (HDL) in your blood. While taking LOFIBRA[®], a diet low in saturated fat and cholesterol should be followed. The long term effect of LOFIBRA[®] on cardiovascular events and mortality has not been determined.

Important Safety Information

The use of LOFIBRA[®] should be considered only when non-drug methods, such as diet, exercise, and weight loss, have failed to obtain satisfactory results.

Tell your doctor about all the medications you are taking. Some medications are known to cause an increase in triglycerides in the blood.

You should not take LOFIBRA[®] if you have severe kidney disease, have liver or gallbladder disease, are nursing, or are allergic to LOFIBRA[®].

LOFIBRA[®] can cause liver or gallbladder problems. Your doctor may do blood tests to monitor your liver function or studies to check for gallstones.

Tell your doctor if you are taking any medications to slow the clotting of your blood (anticoagulants or blood thinners). LOFIBRA[®] may increase the effect of these medications, so your doctor may do frequent blood tests and may need to adjust your dose.

Call your doctor right away if you have unexplained muscle pain, tenderness, or weakness as these can be signs of a rare, but serious, side effect.

The most common side effects of LOFIBRA[®] are abdominal pain, abnormal liver tests, and respiratory symptoms.

Please see accompanying full prescribing information. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 800.FDA.1088.