Indications and Usage

Severe Hypertriglyceridemia

FIBRICOR is indicated as adjunctive therapy to diet for treatment of severe hypertriglyceridemia (≥500 mg/dl). Improving glycemic control in diabetic patients showing fasting chylomicronemia will usually obviate the need for pharmacologic intervention.

Markedly elevated levels of serum triglycerides > 2000 mg/dL may increase the risk of developing pancreatitis. The effect of fenofibrate therapy on reducing this risk has not been adequately studied.

Primary Hypercholesterolemia or Mixed Dyslipidemia

FIBRICOR is indicated as adjunctive therapy to diet to reduce elevated low-density lipoprotein cholesterol (LDL-C), total cholesterol (Total-C), triglycerides (TG), and apolipoprotein B (Apo B), and to increase high-density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia or mixed dyslipidemia.

Important Limitations of Use

Fenofibrate at a dose equivalent to 105 mg of FIBRICOR was not shown to reduce coronary heart disease morbidity and mortality in patients with type 2 diabetes mellitus.

Important Safety Information

FIBRICOR is contraindicated in patients with severe renal impairment including those on dialysis, with active liver disease including primary biliary cirrhosis and unexplained persistent liver function abnormalities and with gallbladder disease. FIBRICOR is also contraindicated in nursing mothers and patients with hypersensitivity to fenofibric acid or fenofibrate.

The most commonly reported adverse reactions (>2% and at least 1% greater than placebo) are abnormal liver tests, increased AST, increased ALT, increased CPK, and rhinitis.

Fenofibrate can increase serum transaminases. Monitor liver tests, including ALT, periodically during therapy. In addition, myopathy and rhabdomyolysis have been reported in patients taking fenofibrate. Fibrates increase the risk for myopathy and have been associated with rhabdomyolysis. The risk for serious muscle toxicity appears to be increased in elderly patients and in patients with diabetes, renal failure, or hypothyroidism. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness particularly if accompanied by malaise or fever. Creatine phosphokinase (CPK) levels should be assessed in these patients. Treatment should be discontinued if markedly elevated CPK levels occur or myopathy/myositis is suspected or diagnosed. Fenofibrate can reversibly increase serum creatinine levels. The clinical relevance of these findings is unknown. Patients with renal impairment and those at risk for renal insufficiency should be periodically monitored. Fenofibrates may increase cholesterol excretion into the bile, leading to risk of cholelithiasis. If cholelithiasis is suspected, gallbladder studies are indicated. Discontinue treatment if gallstones are found.

Please see accompanying full Prescribing Information