



3 Important Questions to Consider before Recommending a Generic

Dear Pharmacist:

Over the past 20 years there have been dramatic changes in the generic and brand prescription market. It is estimated that by 2012, that generics will account for ~83% of all dispensed prescription medications. While cost savings and financial incentives may contribute to increased generic utilization there are three important questions to consider before recommending a generic alternative for TRILIPIX® (fenofibric acid):

- 1 Is the generic classified as a therapeutic equivalent to TRILIPIX?
- 2 Does the generic drug have the same indication(s) as TRILIPIX?
- 3 Is the generic pharmaceutically equivalent to TRILIPIX?

1 TRILIPIX has no AB-rated generic therapeutic equivalent.¹

- According to the FDA, drugs are considered to be therapeutic equivalents only if they are pharmaceutical equivalents of one another and if they can be expected to have the same clinical effect and safety profile when administered to patients.²

2 TRILIPIX is the ONLY fibrate with an FDA-approved indication for use in combination with statins.

- Indicated as an adjunct to diet in combination with a statin to reduce TG and increase HDL-C in patients with mixed dyslipidemia and CHD or a CHD risk equivalent who are on optimal statin therapy to achieve their LDL-C goal.³
- Important Limitations of Use: No incremental benefit of TRILIPIX on cardiovascular morbidity and mortality over and above that demonstrated for statin monotherapy has been established.** Fenofibrate at a dose equivalent to 135 mg of TRILIPIX was not shown to reduce coronary heart disease morbidity and mortality in 2 large trials of patients with type 2 diabetes mellitus.
- Safety Information:** TRILIPIX is contraindicated in patients with severe renal impairment, active liver disease, gallbladder disease, and in nursing mothers. TRILIPIX is associated with myopathy, rhabdomyolysis, increases in serum transaminases and serum creatinine levels, and risk of cholelithiasis. The risks for myopathy and rhabdomyolysis are increased when fibrates are co-administered with a statin. TRILIPIX may increase the effects of oral coumarin anticoagulants. Pancreatitis, hypersensitivity reactions, hematological changes, and venothromboembolic events have also been reported with fibrates.

3 TRILIPIX is available in 135mg and 45mg dosage strengths.

- TRILIPIX 135mg is not therapeutically equivalent to fenofibrate 134mg.
- There are no products pharmaceutically equivalent to TRILIPIX.

Indications for TRILIPIX® (fenofibric acid) delayed-release capsules³

- ▶ Every reasonable attempt should be made to control serum lipids with diet, other disease-state management, and other non-drug methods before and during treatment with TRILIPIX.
- ▶ TRILIPIX is indicated as an adjunct to diet in combination with a statin to reduce TG and increase HDL-C in patients with mixed dyslipidemia and CHD or a CHD risk equivalent who are on optimal statin therapy to achieve their LDL-C goal.
- ▶ TRILIPIX is indicated as an adjunct to diet to reduce TG in patients with severe hypertriglyceridemia. Improving glycemic control in diabetics with fasting chylomicronemia will usually obviate the need for drug therapy. The effect of TRILIPIX on pancreatitis risk reduction in patients with markedly elevated serum TG has not been adequately studied.
- ▶ TRILIPIX is indicated as an adjunct to diet to reduce LDL-C, Total-C, TG, and Apo B and to increase HDL-C in patients with primary hyperlipidemia or mixed dyslipidemia.
- ▶ **Important Limitations of Use: No incremental benefit of TRILIPIX on cardiovascular morbidity and mortality over and above that demonstrated for statin monotherapy has been established.** Fenofibrate at a dose equivalent to 135 mg of TRILIPIX was not shown to reduce coronary heart disease morbidity and mortality in 2 large trials of patients with type 2 diabetes mellitus.

Important Safety Information for TRILIPIX³

- ▶ TRILIPIX is contraindicated in patients with severe renal impairment; active liver disease, including those with unexplained persistent liver function abnormalities; gallbladder disease; in nursing mothers; and in patients with hypersensitivity to fenofibric acid or fenofibrate.
- ▶ **Fibrate and statin monotherapy increase the risk of myositis or myopathy and have been associated with rhabdomyolysis. The risks for myopathy and rhabdomyolysis are increased when fibrates are co-administered with a statin, particularly in the elderly and in patients with diabetes, renal failure, or hypothyroidism.**
- ▶ Tell patients to promptly report unexplained muscle pain, tenderness, or weakness. If markedly elevated CPK levels occur or myopathy/myositis is diagnosed, TRILIPIX and statin therapy should be discontinued.
- ▶ TRILIPIX can cause reversible elevations in serum creatinine. Monitor renal function periodically in patients with or at risk for renal insufficiency.
- ▶ TRILIPIX can increase serum transaminases. Monitor liver function tests regularly, and discontinue therapy if enzyme levels persist above 3 times the upper limit of normal.
- ▶ TRILIPIX may lead to cholelithiasis. If cholelithiasis is confirmed, TRILIPIX should be discontinued.
- ▶ TRILIPIX may increase the effects of oral coumarin anticoagulants. Monitoring and dosage adjustment of the anticoagulant are recommended.
- ▶ Pancreatitis, hypersensitivity reactions, hematological changes, and venothromboembolic events have been reported with the use of fibrates.
- ▶ The effect of TRILIPIX on coronary heart disease morbidity and mortality and non-cardiovascular mortality has not been established.
- ▶ Co-administration with the maximum dose of a statin has not been evaluated and should be avoided unless the benefits are expected to outweigh the risks.
- ▶ Adverse events reported by $\geq 4\%$ of patients receiving TRILIPIX alone or co-administered with a statin in controlled clinical trials were dyspepsia, nausea, nasopharyngitis, upper respiratory tract infection, arthralgia, back pain, pain in extremity, dizziness, and headache.

References: 1. Drugs@FDA [database online]. US Food and Drug Administration. Available at: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>. Accessed November 23, 2011. 2. Drugs@FDA. Glossary of terms. US Food and Drug Administration. Available at: <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm>. Updated January 7, 2010. Accessed November 23, 2011. 3. TRILIPIX [package insert]. North Chicago, IL: Abbott Laboratories.

 **TRILIPIX**[®]
(fenofibric acid)
delayed-release capsules
135 mg and 45 mg

Full Prescribing Information available at www.rxabbott.com/pdf/trilipix_pi.pdf or www.trilipix.com.

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