

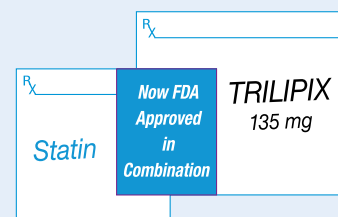
# FDA Approves TRILIPIX

Dear Pharmacist:

Abbott is pleased to introduce a new treatment option for mixed dyslipidemia. **NEW TRILIPIX is the FIRST and ONLY fibrate with an FDA-approved indication in combination with statins in high-risk patients\***. TRILIPIX prescribed in combination with a statin allows for comprehensive treatment of the lipid profile, which includes low HDL-C, high triglycerides (TGs), and high LDL-C.

## Combination Indication: The FIRST and ONLY fibrate with an FDA-approved indication in combination with statins<sup>1</sup>

- ◆ An advancement in the use of fibrate therapy
- ◆ 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



## Comprehensive Efficacy: Substantial improvements across all three key lipids through Week 12 with TRILIPIX + a statin (rosuvastatin, atorvastatin, or simvastatin); sustained results up to Week 64<sup>1,2</sup>

- ◆ TRILIPIX + a low- or moderate-dose statin met all primary endpoints for LDL-C, HDL-C, and TGs through Week 12 (n=2698) in clinical trials
- ◆ Up to 64-week long-term clinical efficacy data of TRILIPIX + a moderate-dose statin (n=1895) with sustained improvements in LDL-C, HDL-C, and TGs

## Demonstrated Safety in Clinical Trials: TRILIPIX + a statin demonstrated clinical safety in 2201 patients up to Week 64<sup>1,2</sup>

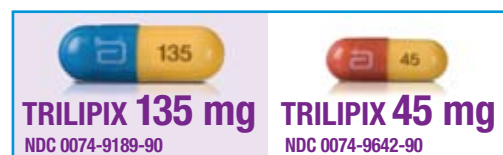
- ◆ The most commonly reported adverse events ( $\geq 4\%$  of patients receiving TRILIPIX or TRILIPIX co-administered with a statin) were dyspepsia, nausea, nasopharyngitis, upper respiratory tract infection, arthralgia, back pain, pain in extremity, dizziness, and headache

## Available in the Following Dosage Strengths<sup>1</sup>:

- ◆ 135 mg
- ◆ 45 mg

## Monotherapy Indications: Monotherapy in mixed dyslipidemia, primary hyperlipidemia, or hypertriglyceridemia<sup>1</sup>

- ◆ Indicated as an adjunct to diet to reduce TG in patients with severe hypertriglyceridemia
- ◆ 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
- ◆ The most common adverse reactions reported by  $\geq 3\%$  of patients treated with fenofibrate and greater than placebo were abdominal pain, back pain, headache, abnormal liver function tests, increased CPK, and respiratory disorder



Capsules shown are not actual size.

## TRILIPIX Stocking Information

Abbott supports TRILIPIX with over 2200 sales representatives and targeted efforts to managed care organizations to ensure formulary access. Please see the accompanying stocking sheet for detailed ordering information. You can order your new TRILIPIX capsules in your usual manner, or contact Abbott Customer Service at 1-800-255-5162.

Limitation of Use: No incremental benefit of TRILIPIX on cardiovascular morbidity and mortality over and above that demonstrated for statin monotherapy has been established.

For additional information, please call Abbott Medical Information at 1-800-633-9110.

Sincerely,

Darryl J. Sleep, MD  
Global Project Head  
Dyslipidemia Franchise  
Global Pharmaceutical Research and Development

\* High-risk patients are those with CHD or CHD risk equivalent.

**Please see Indications and Important Safety Information on next page.**  
**For full Prescribing Information, click on link or visit**  
[www.rxabbott.com/pdf/trilipix\\_pi.pdf](http://www.rxabbott.com/pdf/trilipix_pi.pdf)

**NEW**  
**TRILIPIX™**  
(fenofibric acid)  
delayed-release capsules  
135 mg and 45 mg

Solvay  
Pharmaceuticals



**Abbott**  
A Promise for Life

## Indications

- ◆ 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.
- ◆ TRILIPIX is indicated as an adjunct to diet to reduce LDL-C, Total-C, TG, and Apo B and increase HDL-C in patients with primary hyperlipidemia or mixed dyslipidemia.
- ◆ **No incremental benefit of TRILIPIX on cardiovascular morbidity and mortality over and above that demonstrated for statin monotherapy has been established.**

## Important Safety Information

- ◆ TRILIPIX is contraindicated in patients with severe renal impairment; active liver disease or unexplained persistent liver function abnormalities; preexisting gallbladder disease; in nursing mothers; or in patients with hypersensitivity to fenofibric acid, choline fenofibrate or fenofibrate.
- ◆ **Fibrate and statin monotherapy increase the risk of myositis or myopathy, and have been associated with rhabdomyolysis. Data from observational studies suggest that the risk for rhabdomyolysis is increased when fibrates are co-administered with a statin. The risk for serious muscle toxicity appears to be increased in elderly patients and in patients with diabetes, renal failure, or hypothyroidism.**
- ◆ Myopathy should be considered in patients with muscle pain, tenderness, or weakness. If markedly elevated CPK levels occur or myopathy/myositis is diagnosed, TRILIPIX and statin therapy should be discontinued.
- ◆ Reversible elevations in serum creatinine have been reported in patients receiving TRILIPIX as monotherapy or co-administered with statins, as well as in patients receiving fenofibrate. Renal function should be monitored in patients with or at risk for renal insufficiency.
- ◆ TRILIPIX at a dose of 135 mg once daily administered as monotherapy or co-administered with statins has been associated with increases in serum transaminases. Regular liver function monitoring should be performed for the duration of therapy with TRILIPIX, and therapy discontinued 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 potentiate the effects of oral coumarin anticoagulants. Dosage adjustment based on frequent prothrombin time/INR determinations is recommended.
- ◆ Pancreatitis, hypersensitivity reactions, hematological changes, and venothromboembolic events have been reported with the use of fibrates.
- ◆ Co-administration with the maximum dose of a statin has not been evaluated in clinical studies and should be avoided unless the benefits are expected to outweigh the risks.
- ◆ The most commonly reported adverse events ( $\geq 4\%$  of patients receiving TRILIPIX or TRILIPIX co-administered with a statin) were dyspepsia, nausea, nasopharyngitis, upper respiratory tract infection, arthralgia, back pain, pain in extremity, dizziness, and headache. The most common adverse reactions reported by  $\geq 3\%$  of patients treated with fenofibrate and greater than placebo were abdominal pain, back pain, headache, abnormal liver function tests, increased CPK, and respiratory disorder.

References: 1. TRILIPIX [package insert]. North Chicago, IL: Abbott Laboratories. 2. Data on file, Abbott Laboratories.

For full Prescribing Information, click on link or visit  
[www.rxabbott.com/pdf/trilipix\\_pi.pdf](http://www.rxabbott.com/pdf/trilipix_pi.pdf)

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032-186503 December 2008

NEW  
 **TRILIPIX**<sup>™</sup>  
(fenofibric acid)  
delayed-release capsules  
135 mg and 45 mg

Solvay  
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