Dear Pharmacist:

At a time when patients are struggling with economic challenges, FIBRICOR is a low-cost alternative to TriCor or TriLipix.  

**Generic (fenofibric acid) tablets are now available!**

With the introduction of fenofibric acid tablets, the authorized generic for FIBRICOR, most patients can have their FIBRICOR prescription filled affordably with a generic at a Tier-1 copay.

**When should you dispense fenofibric acid?**

1. Fenofibric acid tablets should be dispensed as the generic for FIBRICOR prescriptions.
2. For patients prescribed TriCor or TriLipix, please let them know that there is a low-cost alternative available, often with a Tier-1 copay, and suggest that they contact their doctor to prescribe FIBRICOR.
3. For patients prescribed TriCor or TriLipix, we also kindly ask you to assist them in contacting their doctor to suggest a cost-savings prescription for FIBRICOR.

**FIBRICOR: An alternative to TriCor and TriLipix**

- FIBRICOR and TriCor are bioequivalent under fasted conditions and following a standard meal.
- Like TriCor and TriLipix, FIBRICOR can be taken without regard to meals.
- Fenofibric acid, the active ingredient of FIBRICOR, is the same active ingredient found in TriLipix.

*FIBRICOR is not AB-rated to TriCor or TriLipix.
Copays are determined by the patient’s pharmacy benefit insurance carrier.
Following oral administration of FIBRICOR (105 mg) or TriCor (145 mg) in healthy volunteers, mean peak plasma levels of fenofibric acid occurred approximately 2.5 hours after administration. FIBRICOR was bioequivalent to TriCor in terms of rate and extent of absorption under fasted conditions and following a standard breakfast meal consisting of 36% fat and 575 kcal. fenofibric acid is the only pharmacologically active moiety following administration of TriLipix.

Please see Important Safety Information on next page.
Please see accompanying full Prescribing Information.
A switch to generic (fenofibric acid) tablets can save patients money!

For easy reference, the strengths and NDC numbers for both FIBRICOR™ and the low-cost generic-equivalent (fenofibric acid) tablets are listed below:

<table>
<thead>
<tr>
<th>Description</th>
<th>Strength</th>
<th>Fill Size</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand: FIBRICOR</td>
<td>105 mg</td>
<td>30</td>
<td>13310-102-07</td>
</tr>
<tr>
<td></td>
<td></td>
<td>90</td>
<td>13310-102-90</td>
</tr>
<tr>
<td></td>
<td>35 mg</td>
<td>30</td>
<td>13310-101-07</td>
</tr>
<tr>
<td>Authorized generic:</td>
<td>105 mg</td>
<td>30</td>
<td>53489-678-07</td>
</tr>
<tr>
<td>fenofibric acid (Mutual)</td>
<td></td>
<td>90</td>
<td>53489-678-90</td>
</tr>
<tr>
<td></td>
<td>35 mg</td>
<td>30</td>
<td>53489-677-07</td>
</tr>
</tbody>
</table>

To learn more about FIBRICOR and fenofibric acid tablets, please refer to the attached sales brochure and visit www.fibricor.com/info or call 1.866.415.7675.

Kindest regards,

Gregory K. Hayer
Sr. VP of Sales

FIBRICOR is a peroxisome proliferator receptor alpha (PPARα) activator indicated:

- To reduce triglyceride (TG) levels in patients with severe hypertriglyceridemia (≥ 500 mg/dl)
- To reduce elevated total cholesterol (TC), low-density-lipoprotein cholesterol (LDL-C), TG and apolipoprotein (Apo) B and to increase high-density lipoprotein cholesterol (HDL-C) in patients with primary hyperlipidemia or mixed dyslipidemia

**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, choline fenofibrate or fenofibrate.

The most commonly reported adverse reactions (> 2% and greater than placebo) are increases in liver test values, abdominal pain, back pain, and headache.

Fenofibrate can increase serum transaminases, so patients should be monitored for AST or ALT changes periodically for the duration of the therapy. In addition, myopathy and rhabdomyolysis have been reported in patients taking fenofibrate. The risks of myopathy and rhabdomyolysis may be increased in patients who are elderly, have diabetes, renal failure, or hypothyroidism. Patients should be advised to report unexplained muscle pain, tenderness or weakness promptly, especially if accompanied by malaise or fever. Creatine phosphokinase (CPK) levels should be assessed in these patients. Fenofibrate can reversibly increase serum creatinine levels. Patients with renal impairment and those at risk for renal insufficiency should be periodically monitored. Fenofibrate increases cholesterol excretion into the bile, leading to risk of cholelithiasis. If cholelithiasis is suspected, gallbladder studies are indicated.

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.


TriCor® and TriLipix® are registered trademarks of Fournier Industrie et Santé Corporation, France.

Please see accompanying full Prescribing Information.
FENOFIBRIC ACID TABLETS

FULL PRESCRIBING INFORMATION

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use fenofibric acid tablets safely and effectively. See full prescribing information for fenofibric acid tablets.

- For complete prescribing information, see Full Prescribing Information.

Indications and Usage

Fenofibric acid tablets are a peroxisome proliferator-activated receptor (PPARα) activator indicated for:

- To reduce total cholesterol levels (TC), low-density lipoprotein cholesterol (LDL-C), and triglyceride levels in patients with severe hypertriglyceridemia (5.0-15.0 mmol/L (400-1350 mg/dL)).
- To reduce low-density lipoprotein cholesterol (LDL-C) levels in patients with primary hypercholesterolemia (10.0 mmol/L (400 mg/dL)).

- Use fenofibric acid tablets in combination with diet and other lipid-lowering medications for the management of hypercholesterolemia and hypertriglyceridemia.

Contraindications

Fenofibric acid tablets are contraindicated in patients with severe hepatic impairment, severe renal impairment, and in patients who have experienced an acute systemic inflammatory reaction such as disseminated intravascular coagulation or severe sepsis. Fenofibric acid tablets should not be used in patients with known intolerance to fenofibric acid or fenofibrate.

Warnings and Precautions

- Use fenofibric acid tablets with caution in patients with liver disease and in those with a history of liver disease. Monitor liver function tests regularly.
- Use fenofibric acid tablets with caution in patients with a history of gallbladder disease, as gallbladder disease has been reported in patients taking fenofibric acid tablets.
- Use fenofibric acid tablets with caution in patients with a history of myopathy, as myopathy and rhabdomyolysis have been reported in patients taking fenofibric acid tablets.
- Use fenofibric acid tablets with caution in patients with a history of pancreatitis, as pancreatitis has been reported in patients taking fenofibric acid tablets.
- Use fenofibric acid tablets with caution in patients with a history of diabetes, as diabetes mellitus has been reported in patients taking fenofibric acid tablets.

Drug Interactions

- Use fenofibric acid tablets with caution in patients taking drugs that are metabolized by the cytochrome (CYP) P450 isoforms CYP3A4, CYP2D6, CYP2E1, or CYP1A2, as use of these medications may increase the risk of myopathy and rhabdomyolysis.

Adverse Reactions

- Adverse reactions reported in patients taking fenofibric acid tablets include gastrointestinal reactions such as diarrhea, dyspepsia, nausea, and vomiting.
- Adverse reactions reported in patients taking fenofibric acid tablets include cutaneous reactions such as rash, pruritus, and urticaria.

Drug Use During Pregnancy

Fenofibric acid tablets should not be used during pregnancy. Fenofibric acid tablets are teratogenic in rats. The use of fenofibric acid tablets in pregnant women has not been established.

Drug Use During Lactation

Fenofibric acid tablets are excreted in breast milk. The use of fenofibric acid tablets in nursing mothers has not been established.

OVERDOSAGE

Fenofibric acid tablets are not expected to cause significant systemic effects at overdosage. Overdosage is unlikely to cause serious harm.

PATIENT COUNSELING INFORMATION

- Instruct patients to take fenofibric acid tablets as prescribed and to report any adverse reactions immediately.
- Inform patients that fenofibric acid tablets should be taken with or after meals to minimize gastrointestinal side effects.

FULL PRESCRIBING INFORMATION

1. indications and Usage

Fenofibric acid tablets are a peroxisome proliferator-activated receptor (PPARα) activator indicated for:

- To reduce total cholesterol levels (TC), low-density lipoprotein cholesterol (LDL-C), and triglyceride levels in patients with severe hypertriglyceridemia (5.0-15.0 mmol/L (400-1350 mg/dL)).
- To reduce low-density lipoprotein cholesterol (LDL-C) levels in patients with primary hypercholesterolemia (10.0 mmol/L (400 mg/dL)).

- Use fenofibric acid tablets in combination with diet and other lipid-lowering medications for the management of hypercholesterolemia and hypertriglyceridemia.

Contraindications

Fenofibric acid tablets are contraindicated in patients with severe hepatic impairment, severe renal impairment, and in patients who have experienced an acute systemic inflammatory reaction such as disseminated intravascular coagulation or severe sepsis. Fenofibric acid tablets should not be used in patients with known intolerance to fenofibric acid or fenofibrate.

Warnings and Precautions

- Use fenofibric acid tablets with caution in patients with liver disease and in those with a history of liver disease. Monitor liver function tests regularly.
- Use fenofibric acid tablets with caution in patients with a history of gallbladder disease, as gallbladder disease has been reported in patients taking fenofibric acid tablets.
- Use fenofibric acid tablets with caution in patients with a history of myopathy, as myopathy and rhabdomyolysis have been reported in patients taking fenofibric acid tablets.
- Use fenofibric acid tablets with caution in patients with a history of pancreatitis, as pancreatitis has been reported in patients taking fenofibric acid tablets.
- Use fenofibric acid tablets with caution in patients with a history of diabetes, as diabetes mellitus has been reported in patients taking fenofibric acid tablets.

Drug Interactions

- Use fenofibric acid tablets with caution in patients taking drugs that are metabolized by the cytochrome (CYP) P450 isoforms CYP3A4, CYP2D6, CYP2E1, or CYP1A2, as use of these medications may increase the risk of myopathy and rhabdomyolysis.

Adverse Reactions

- Adverse reactions reported in patients taking fenofibric acid tablets include gastrointestinal reactions such as diarrhea, dyspepsia, nausea, and vomiting.
- Adverse reactions reported in patients taking fenofibric acid tablets include cutaneous reactions such as rash, pruritus, and urticaria.

Drug Use During Pregnancy

Fenofibric acid tablets should not be used during pregnancy. Fenofibric acid tablets are teratogenic in rats. The use of fenofibric acid tablets in pregnant women has not been established.

Drug Use During Lactation

Fenofibric acid tablets are excreted in breast milk. The use of fenofibric acid tablets in nursing mothers has not been established.

OVERDOSAGE

Fenofibric acid tablets are not expected to cause significant systemic effects at overdosage. Overdosage is unlikely to cause serious harm.

PATIENT COUNSELING INFORMATION

- Instruct patients to take fenofibric acid tablets as prescribed and to report any adverse reactions immediately.
- Inform patients that fenofibric acid tablets should be taken with or after meals to minimize gastrointestinal side effects.
Table 2 describes the effects of co-administered drugs on fenofibric acid systemic exposure.

<table>
<thead>
<tr>
<th>Drug Administered</th>
<th>Drug Co-Administered</th>
<th>AUC % Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>Placebo</td>
<td>100%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Rosiglitazone</td>
<td>26%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Simvastatin</td>
<td>36%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Fluvastatin</td>
<td>29%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Pravastatin</td>
<td>36%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Ezetimibe</td>
<td>26%</td>
</tr>
</tbody>
</table>

Table 3 describes the effects of co-administered drugs on fenofibric acid systemic exposure from fenofibric acid tablets.

<table>
<thead>
<tr>
<th>Drug Administered</th>
<th>Drug Co-Administered</th>
<th>AUC % Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>Placebo</td>
<td>100%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Rosiglitazone</td>
<td>26%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Simvastatin</td>
<td>36%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Fluvastatin</td>
<td>29%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Pravastatin</td>
<td>36%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Ezetimibe</td>
<td>26%</td>
</tr>
</tbody>
</table>

Table 4 describes the effects of fenofibrate on patients with clinical hypertriglyceridemia.

<table>
<thead>
<tr>
<th>Drug Administered</th>
<th>Drug Co-Administered</th>
<th>AUC % Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>Placebo</td>
<td>100%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Rosiglitazone</td>
<td>26%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Simvastatin</td>
<td>36%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Fluvastatin</td>
<td>29%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Pravastatin</td>
<td>36%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Ezetimibe</td>
<td>26%</td>
</tr>
</tbody>
</table>

14.2 Primary Hyperlipoproteinemia Familial and Mixed Dyslipidemia

The effects of fenofibrate on baseline triglyceride levels in hypertriglyceridemic patients were compared to placebo in a 21-month study in CF-1 mice, demonstrating a significant increase in triglycerides.

Table 5 describes the mean percent change in lipid parameters at end of fenofibrate treatment.

<table>
<thead>
<tr>
<th>Lipid Parameter</th>
<th>Treatment</th>
<th>Placebo</th>
<th>Rosiglitazone</th>
<th>Simvastatin</th>
<th>Fluvastatin</th>
<th>Pravastatin</th>
<th>Ezetimibe</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDL Cholesterol</td>
<td>80 mg QD</td>
<td>100%</td>
<td>6%</td>
<td>12%</td>
<td>15%</td>
<td>16%</td>
<td>17%</td>
</tr>
<tr>
<td>VLDL Triglycerides</td>
<td>80 mg QD</td>
<td>100%</td>
<td>43%</td>
<td>6%</td>
<td>15%</td>
<td>16%</td>
<td>17%</td>
</tr>
<tr>
<td>HDL Cholesterol</td>
<td>80 mg QD</td>
<td>100%</td>
<td>11%</td>
<td>12%</td>
<td>15%</td>
<td>16%</td>
<td>17%</td>
</tr>
<tr>
<td>Total Cholesterol</td>
<td>80 mg QD</td>
<td>100%</td>
<td>43%</td>
<td>6%</td>
<td>15%</td>
<td>16%</td>
<td>17%</td>
</tr>
</tbody>
</table>

In a subset of the subjects, measurement of Apo B was conducted. Fenofibrate treatment significantly reduced Apo B from baseline to endpoint as compared with placebo (-25.1% vs. 2.4%, p < 0.0001, n=213 and 143 respectively).

Table 6 describes the effects of co-administered drugs on fenofibrate systemic exposure.

<table>
<thead>
<tr>
<th>Drug Administered</th>
<th>Drug Co-Administered</th>
<th>AUC % Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>Placebo</td>
<td>100%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Rosiglitazone</td>
<td>26%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Simvastatin</td>
<td>36%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Fluvastatin</td>
<td>29%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Pravastatin</td>
<td>36%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Ezetimibe</td>
<td>26%</td>
</tr>
</tbody>
</table>

14.6 Pharmacokinetic Properties

The effects of fenofibrate on serum triglycerides were studied in two randomized, double-blind, placebo-controlled clinical trials of 18 hypertensive/obese patients. Patients were treated for eight weeks with placebo (n=114) or fenofibrate (n=110) at a dose of 100 mg/day. The mean percent change in triglycerides was significantly greater with fenofibrate than placebo (63.8% vs. 3.3%, p < 0.0001).

Table 7 describes the effects of co-administered drugs on fenofibrate systemic exposure.

<table>
<thead>
<tr>
<th>Drug Administered</th>
<th>Drug Co-Administered</th>
<th>AUC % Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>Placebo</td>
<td>100%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Rosiglitazone</td>
<td>26%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Simvastatin</td>
<td>36%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Fluvastatin</td>
<td>29%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Pravastatin</td>
<td>36%</td>
</tr>
<tr>
<td>Placebo</td>
<td>Ezetimibe</td>
<td>26%</td>
</tr>
</tbody>
</table>

16.4 How Supplied/Storage and Handling

Fenofibric Acid Tablets or Fenofibrate Administration

Dosage Regimen of Fenofibrate

- 145 mg TID for 10 days
- 160 mg QD for 10 days
- 54 mg TID for 10 days

Dosage Regimen of Fenofibric Acid Tablets

- 432 mg TID for 10 days
- 860 mg QD for 10 days
- 208 mg TID for 10 days

For more information, please see the prescribing information for Fenofibrate tablets or Fenofibric Acid Tablets.

17. Patient Counseling Information

Patients should be advised to:

- take fenofibric acid tablets exactly as directed.
- to continue to follow an appropriate lipid-modifying diet while taking fenofibric acid tablets.
- to stop taking fenofibric acid tablets if they do not work.
- if they experience any unusual signs or symptoms while taking fenofibric acid tablets.
- to tell their healthcare provider if they are pregnant, plan to become pregnant, or breastfeed.
- to tell their healthcare provider about other medications they are taking.
- to tell their healthcare provider if they have kidney disease.
- to tell their healthcare provider if they have liver disease.
- to tell their healthcare provider about any other conditions they may have.
- to tell their healthcare provider about any allergies they may have.
- to follow the directions provided by their healthcare provider.
- to return to the dose of fenofibric acid tablets that worked best before.
- to stop taking fenofibric acid tablets if they experience any unusual signs or symptoms while taking fenofibric acid tablets.
- to tell their healthcare provider if they are pregnant, plan to become pregnant, or breastfeed.
- to tell their healthcare provider about other medications they are taking.
- to tell their healthcare provider about any other conditions they may have.
- to tell their healthcare provider about any allergies they may have.
- to follow the directions provided by their healthcare provider.
- to return to the dose of fenofibric acid tablets that worked best before.
- to stop taking fenofibric acid tablets if they experience any unusual signs or symptoms while taking fenofibric acid tablets.
- to tell their healthcare provider if they are pregnant, plan to become pregnant, or breastfeed.
- to tell their healthcare provider about other medications they are taking.
- to tell their healthcare provider about any other conditions they may have.
- to tell their healthcare provider about any allergies they may have.
- to follow the directions provided by their healthcare provider.
- to return to the dose of fenofibric acid tablets that worked best before.
- to stop taking fenofibric acid tablets if they experience any unusual signs or symptoms while taking fenofibric acid tablets.
- to tell their healthcare provider if they are pregnant, plan to become pregnant, or breastfeed.
- to tell their healthcare provider about other medications they are taking.
- to tell their healthcare provider about any other conditions they may have.
- to tell their healthcare provider about any allergies they may have.
- to follow the directions provided by their healthcare provider.
- to return to the dose of fenofibric acid tablets that worked best before.
- to stop taking fenofibric acid tablets if they experience any unusual signs or symptoms while taking fenofibric acid tablets.