fenofibric acid  (feen-oh-fye-brik-as-id)

Fibricor, TriLipix

Classification
Therapeutic: lipid-lowering agents
Pharmacologic: thioctic acid derivatives

Indications
With a statin to reduce triglycerides (TG) and increase high density lipoprotein-C (HDL-C) in patients with mixed dyslipidemias and CHD or a CHD risk equivalent who are on statin therapy to achieve their low-density lipoprotein-C (LDL-C) goal (TriLipix only). As monotherapy to reduce TG in patients with severe hypertriglyceridemia. As monotherapy to reduce elevated LDL-C, total cholesterol (Total-C), TG and apolipoprotein B (Apo B), and increase HDL-C in patients with primary hyperlipidemia or mixed dyslipidemia. Part of a comprehensive program to decrease cardiovascular risk factors.

Action
Activates the peroxisome proliferator activated receptor (PPAR), resulting in increased lipolysis and elimination of triglycerides from plasma. Activation of PPAR also increases production of HDL. Therapeutic Effects: Improvement in lipid profile with lowered triglycerides and LDL cholesterol, and increased HDL cholesterol.

Pharmacokinetics
Absorption: Well absorbed following oral administration.

Distribution: Unknown.

Protein Binding: 99%.

Metabolism and Excretion: Fenofibric acid is the active metabolite of fenofibrate. It is mostly metabolized by glucuronidation and the metabolites are mostly excreted by the kidneys.

Half-life: 20 hr.

Contraindications/Precautions
Contraindicated in:
Hypersensitivity to fenofibric acid, choline fenofibrate or fenofibrate; Severe renal impairment (CCr < 30 mL/min); Active liver or gallbladder disease. Use Cautiously in:
Mild/moderate renal impairment (dose adjustment necessary for CCr 30– 80 mL/min); Concurrent use with statins in elderly patients, patients with diabetes, renal failure, or hypothyroidism (risk of myopathy/rhabdomyolysis); Geri: Consider age-related decreases in renal function, concurrent illnesses and drug therapy; OB: Use only if the potential benefit justifies the potential risk to the fetus; Pedi: Safety and effectiveness not established.

Adverse Reactions/Side Effects
CNS: Headache.

GI: Diarrhea, nausea, cholelithiasis, q liver enzymes, pancreatitis.

GU: Serum creatinine.

Metab: HDL levels.

MS: Myopathy/rhabdomyolysis, myalgia, back pain.

Interactions
Drug-Drug: Effects and risk of bleeding with warfarin; monitor prothrombin time/INR. Bile acid sequestrants may reduce absorption and effectiveness; administer at least 1 hr before or 4–6 hr after a bile acid sequestrant. Concurrent use with nephrotoxic drugs including cyclosporine may impair renal function and excretion, risk of adverse reactions. Concurrent use with colchicine may risk of cholestatic chills.

Route/Dosage
Mixed Dyslipidemia
PO (Adults): TriLipix—135 mg once daily; Aligatorin—15–135 mg once daily.

Hypertriglyceridemia
PO (Adults): Fibricor—55–105 mg once daily; TriLipix—45–135 mg once daily.

TIME/ACTION PROFILE (effects on blood lipids)
ROUTE ONSET PEAK DURATION
PO unknown 4–5 hr† unknown
†Blood levels
Primary Hypercholesterolemia or Mixed Dyslipidemia

PO (Adults): Fenofibric Acid—105 mg once daily; TriLipix—135 mg once daily.

Renal Impairment

PO (Adults): CCr 20–39 mL/min—Fibricor: Initiate with 35 mg once daily; may titrate cautiously; TriLipix: Initiate with 45 mg once daily; may titrate cautiously; CCr <20 mL/min—Contraindicated.

NURSING IMPLICATIONS

Assessment

● Obtain a diet history, especially with regard to fat consumption. Every attempt should be made to obtain normal serum triglyceride levels with diet, exercise, and weight loss in obese patients before fenofibric acid therapy is instituted.

● Assess patient for cholelithiasis. If symptoms occur, gallbladder studies are indicated.

● Lab Test Considerations: Monitor serum lipids before therapy to determine consistent elevations, then monitor periodically during therapy.

● Monitor serum AST and ALT periodically during therapy. May cause levels. Discontinue therapy if levels rise 3 times the normal limit.

● If patient develops muscle tenderness during therapy, CPK levels should be monitored. If CPK levels are markedly elevated or myopathy occurs, therapy should be discontinued.

● May cause reversible increase in serum creatinine. Monitor renal function in patients at risk for renal insufficiency (elderly, diabetics).

● May cause edema in lower legs, feet, and ankles; hematoma, and WBCs. Monitor periodically during first 12 mo of therapy. Levels usually stabilize during long-term therapy.

● Monitor prothrombin time and INR monitored frequently until levels stabilize in patients taking anticoagulants concurrently.

Potential Nursing Diagnoses

Noncompliance (Patient/Family Teaching)

Implementation

● Patients should be placed on a triglyceride-lowering diet before therapy and remain on this diet throughout therapy.

● PO: Administer without regard to meals. Swallow capsules whole; do not open, crush, or chew. May be administered at same time as statin dose.

Patient/Family Teaching

● Instruct patient in taking medication as directed. Take missed doses as soon as remembered; if time for next dose, skip dose and take next dose at regular time. Do not double doses. Medication helps control but does not cure elevated serum triglyceride levels. Advise patient to read Medication Guide before starting and with each Rx refill; new information may be available.

● Advise patient that this medication should be used in conjunction with diet restrictions (fat, cholesterol, carbohydrates, alcohol), exercise, and cessation of smoking.

● Instruct patient to notify health care professional of unexplained muscle pain, tenderness, weakness, tinnitus, fever, nausea, vomiting, or abdominal pain occurs, especially if accompanied by fever or malaise.

● Instruct female patients to notify health care professional promptly if pregnancy is planned or suspected.

● Advise patient to notify health care professional of all Rx or OTC medications, vitamins, or herbal products being taken and to consult with health care professional before taking other medications.

● Advise patient to notify health care professional of medication regimen before treatment or surgery.

Evaluation/Desired Outcomes

● Decrease in serum triglycerides and LDL cholesterol to normal levels with an increase in HDL levels.

Why was this drug prescribed for your patient?