Lopid (gemfibrozil) - Drug Summary

Parke-Davis Division of Pfizer Inc

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Lopid
(gemfibrozil)

THERAPEUTIC CLASS

Fibric acid derivative

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Coronary Heart Disease

Adjunctive therapy to diet to reduce risk of developing coronary heart disease only in Type IIb patients w/o history of or symptoms of existing coronary heart disease who have had an inadequate response to weight loss, dietary therapy, exercise, and other pharmacologic agents and who have the triad of low HDL, elevated LDL, and elevated TG levels

1200mg in 2 divided doses 30 min before am and pm meals

Hypertriglyceridemia

Adjunctive therapy to diet for treatment of adults w/ very high elevations of serum TG levels (Types IV and V hyperlipidemia) who present a risk of pancreatitis and who do not respond adequately to diet

1200mg in 2 divided doses 30 min before am and pm meals

ADMINISTRATION

Oral route

Take 30 min before am and pm meals

HOW SUPPLIED

Tab: 600mg* *scored

CONTRAINDICATIONS

Severe renal dysfunction, hepatic dysfunction (including primary biliary cirrhosis), preexisting gallbladder disease, combination therapy with repaglinide or simvastatin.

WARNINGS/PRECAUTIONS

Cholelithiasis reported; perform gallbladder studies if cholelithiasis is suspected and d/c therapy if gallstones are found. May be associated with myositis; d/c if myositis is suspected/diagnosed. Control any medical problems (eg, diabetes mellitus [DM], hypothyroidism) that contribute to lipid abnormalities before initiating therapy. D/C if lipid response is inadequate after 3 months of therapy. Mild Hgb, Hct, and WBC decreases, and severe anemia, leukopenia, thrombocytopenia, and bone marrow hypoplasia reported; periodically monitor blood counts during the first 12 months of therapy. Abnormal LFTs reported; periodically monitor LFTs and d/c if abnormalities persist. Worsening renal insufficiency reported upon the addition of therapy in patients with baseline plasma creatinine >2mg/dL. Estrogen therapy is associated with massive rises in plasma TGs; discontinuation of estrogen therapy may obviate the need for specific drug therapy of hypertriglyceridemia.

ADVERSE REACTIONS

Dyspepsia, abdominal pain, diarrhea, fatigue.

DRUG INTERACTIONS

See Contraindications. Caution with anticoagulants; reduce anticoagulant dose and frequently monitor prothrombin until it has been definitely determined that prothrombin level has stabilized. Increased risk of myopathy and rhabdomyolysis with HMG-CoA reductase inhibitors. Reduced exposure with resin-granule drugs (eg, colestipol); administer ≥2 hrs apart. May potentiate myopathy with colchicine; caution when prescribing with colchicine, especially in elderly patients or patients with renal dysfunction.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Fibric acid derivative; not established. Inhibits peripheral lipolysis and decreases hepatic extraction of free fatty acids, thus reducing hepatic TG production. Inhibits synthesis and increases clearance of VLDL carrier apolipoprotein B, leading to a decrease in VLDL production.

PHARMACOKINETICS

Absorption: Complete. T_{max}=1-2 hrs. **Distribution:** Plasma protein binding (highly bound). **Metabolism:** Oxidation to form a hydroxymethyl and a carboxyl metabolite. **Elimination:** Urine (70%, <2% unchanged), feces (6%).

ASSESSMENT

Assess for hepatic/renal dysfunction, gallbladder disease, other medical conditions (eg, DM, hypothyroidism), hypersensitivity to drug, pregnancy/nursing status, and possible drug interactions. Obtain lipid levels.

MONITORING

Monitor for signs/symptoms of cholelithiasis, myositis, worsening renal insufficiency, and other adverse reactions. Periodically monitor serum lipids levels, CBC, and LFTs. Frequently monitor prothrombin with anticoagulants. Closely observe patients with significantly elevated TGs during therapy.

PATIENT COUNSELING

Inform about potential risks/benefits of therapy. Advise to report to physician any muscle pain/tenderness/weakness, or other adverse reactions. Instruct to notify physician if pregnant/nursing or planning to become pregnant.

STORAGE

20-25°C (68-77°F). Protect from light and humidity.

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