IN HYPERTENSION

When a complex regimen reduces compliance... It's time for TENORETIC.

One-tablet-a-day TENORETIC is the simplest regimen available. It's easy, convenient therapy that works round-the-clock to effectively lower blood pressure without added tablets or added side effects that discourage patient compliance.

TENORETIC is not indicated for the initial therapy of hypertension. See next page for brief summary of prescribing information.
Low HDL with elevated LDL and triglycerides: A common denominator of many heart attack victims

Mixed hyperlipidemias—elevated cholesterol and triglycerides—are common among heart attack victims, and nearly two thirds of people who developed myocardial infarction in the PROCAM Trial had a low (< 35 mg/dL) baseline level of HDL cholesterol. LOPID (gemfibrozil) is not indicated for the treatment of patients with low HDL cholesterol as their only lipid abnormality.

HEART ATTACK PATIENTS (PROCAM TRIAL):

- HDL over 35 mg/dL: 36%
- HDL under 35 mg/dL: 64%
LOPID is indicated for reducing the risk of coronary heart disease in type IIB patients with low HDL, in addition to elevated LDL and triglycerides, and who have had an inadequate response to weight loss, diet, exercise, and other pharmacologic agents such as bile acid sequestrants and nicotinic acid.

Raised low HDL 25%
in patients whose baseline HDL was < 35 mg/dL and median baseline LDL was 186 mg/dL in the landmark Helsinki Heart Study (HHS).1

Reduced heart attack incidence up to 62%*
in these HHS patients.3 Incidence of serious coronary events was similar for LOPID and placebo subgroups with baseline HDL above the median (46.4 mg/dL).3

RAISES HDL, LOWERS LDL AND TRIGLYCERIDES DRAMATICALLY REDUCES HEART ATTACK
Contraindicated in patients with hepatic or severe renal dysfunction, including primary biliary cirrhosis, preexisting gallbladder disease, or hypersensitivity to gemfibrozil. LOPID may increase cholesterol secretion into the bile, leading to cholelithiasis. Caution should be exercised when anticoagulants are given in conjunction with LOPID.

*Defined as a combination of definite coronary death and/or definite myocardial infarction. 

P = 0.013; 95% CI 13.3 to 111.3.


Please see last page of this advertisement for warnings, contraindications, and brief summary of prescribing information.
Lopid® (Gemfibrozil Capsules and Tablets)

Before prescribing, please see full prescribing information.

A Brief Summary follows.

CONTRAINDICATIONS. 1. Hepatic or severe renal dysfunction, including primary biliary cirrhosis.

2. Pre-existing gallbladder disease (See WARNINGS).

3. Hypersensitivity to gemfibrozil.

WARNINGS. 1. Because of chemical, pharmacological, and clinical similarities between gemfibrozil and clofibrate, the adverse findings with clofibrate, including fatalities, in clinical studies may also apply to gemfibrozil. In the first of these studies, the Coronary Drug Project, 1003 subjects with previous myocardial infarction were treated for five years with 1 g daily of either clofibrate or placebo. A higher incidence of worsening of pre-existing cardiac disease, and of 3000 placebo-treated subjects, there were 12 cases of cardiovascular deaths, 3 with clofibrate and 3 without. A lower incidence of pre-existing cardiac disease treated with clofibrate for five years and followed one year beyond. There was a statistically significant, 29%, higher total mortality in the clofibrate-treated group than in the placebo control group. The excess mortality was due to a 33% increase in noncardiovascular causes, including malignancy, post-cholesterolcompeting complications, and pancreatitis. The higher risk of clofibrate-treated subjects, and the other group treated with clofibrate. Both clofibrate and gemfibrozil have the potential to cause myopathy, rhabdomyolysis, and acute renal failure. Electron microscopy studies have demonstrated a florid hepatic peroxisome proliferation following Lopid administration to the male rat. An adequate study to test for peroxisome proliferation has not been done in humans but changes in peroxisome proliferation have been described in rats. Rhabdomyolysis has been reported to occur in humans with either of two other drugs of the fibrates class when liver biopsies were compared before and after treatment in the same individual. Acidemia resulting from human dose to male rats for 10 weeks resulted in a dose-related decrease of tensility. Subsequent studies demonstrated that this effect was reversed after a drug-free period of about eight weeks, and it was not transmit-

5. Pregnancy Category B— Reproduction studies have been performed in the rat at doses 3 and 9 times the human dose, and in the rabbit at 2 and 0.7 times the human dose. The results of these studies have revealed no evidence of impaired fertility in male and female rats, and of any medical problems such as diabetes mellitus and rhabdomyolysis, markedly elevated creatine kinase (CK) levels, and more frequent prothrombin determinations are recommended in patients treated with gemfibrozil. The dos.age of the anticoagulant should be reduced to prevent bleeding complications.

6. Nursing Mothers —Because of the potential for tumorigenicity shown for gem-

7. Use in Children— Safety and efficacy in children have not been established.

ADVERSE REACTIONS. In the double-blind controlled phase of the Helsinki Heart Study, 2046 patients received Lopid for up to 5 years. In this study, the incidence of adverse reactions that were more common among Lopid treatment group subjects but not different statistically from the incidence of a drug therapy should be discontinued if gallstones are found.

2. Since a reduction of mortality from coronary artery disease has not been demonstrated in the Helsmki Heart Study, the incidence of gallbladder surgery was observed for the Lopid group (17 of 115 subjects, a 15% excess). The result of this study is not statistically significant, but it suggests a possible increase in the incidence of gallbladder surgery in patients on gemfibrozil. The dos.age of the anticoagulant should be reduced to prevent bleeding complications.

4. Concomitant Anticoagulants— Caution should be exercised when anticoagulants are given in conjunction with Lopid. The dosage of the anticoagulant should be reduced to prevent bleeding complications. These include heparin, phenprocoumon, dicoumarol, warfarin, meclofenamic acid, and dipyridamole. Frequent prothrombin determinations are advisable until it has been definitely determined that the prothrombin level has stabilized.

5. Glucose—Hyperglycemia has been noted in some patients, although this is a known complication of decreased carbohydrate utilization in certain patients. It has been observed in rats, Lopid should be administered only to those patients described in the INDICATIONS AND USAGE section. If a significant serum lipid response is not obtained, Lopid should be discontinued.

6. Cataracts—Suggestive evidence of a possible association of cataracts with Lopid administration has been observed in male and female mice, there were no statistically significant differences in the incidence of cataracts or other ocular abnormalities. These studies have revealed no evidence of impaired fertility in male and female rats, and of any medical problems such as diabetes mellitus and rhabdomyolysis, markedly elevated creatine kinase (CK) levels, and more frequent prothrombin determinations are recommended in patients treated with gemfibrozil. The dos.age of the anticoagulant should be reduced to prevent bleeding complications.

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Vascular: Atenolol is excreted in human breast milk at a ratio of 1:4 to 6:1 as compared to the concentration in plasma. Caution should be exercised when atenolol is administered to a nursing woman. Clinically significant hypoglycemia has been reported in breast-fed infants. Premature infants and infants receiving intravenous fluids or medication may be at greater risk of developing adverse effects.

Dermatologic: Atenolol has been reported to be associated with an increased risk of developing HIV in patients receiving atenolol or placebo. However, the role of TENORETIC therapy in the development of HIV is uncertain.

Allergic: No significant effects of TENORETIC therapy have been observed for TENORETIC therapy patients in any of the studies conducted in the clinical treatment of hypertension. This fixed dose combination drug is not indicated for initial therapy of hypertension. If the fixed dose combination represents the dose appropriate to the individual patient, TENORETIC should be administered as the fixed dose combination for at least 3 weeks before dose titration.

IN PATIENTS WITHOUT A HISTORY OF CARDIAC FAILURE, continuous administration of the drugs in the same dosage regimen in combination with other antihypertensive drugs is recommended in patients with isolated systolic hypertension. In patients with isolated systolic hypertension, the treatment of primary hypertension, and in patients with severe hypertension, TENORETIC should be administered as the fixed dose combination for at least 2 weeks before dose titration.

IN PATIENTS WITH A HISTORY OF CARDIAC FAILURE, continuous administration of the drugs in the same dosage regimen in combination with other antihypertensive drugs is recommended in patients with isolated systolic hypertension. In patients with isolated systolic hypertension, the treatment of primary hypertension, and in patients with severe hypertension, TENORETIC should be administered as the fixed dose combination for at least 2 weeks before dose titration.

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