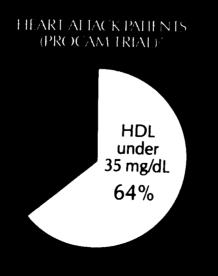


# Low HDL with elevated LDL and triglycerides: A common denominator of many heart attack victims

Mixed hyperlipidemias – elevated cholesterol *and* triglycerides – are common "among heart attack victums," and nearly two thirds of people who developed "myocardial intarction in the PROCAM Irial had a low (< 35 mg/dL) baseline "level of HDL cholesterol – LOPID - igenitibrozil) is not indicated for the treatment "of patients with low HDL cholesterol as their only lipid abnormality.



**PARKE-DAVIS** 



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 below 35 mg/dL in the landmark Helsinki Heart Study (HHS).<sup>3</sup>

# Reduced heart attack incidence up to 62%\*

—in these HHS patients. Incidence of serious coronary events was similar for LOPID and placebo subgroups with baseline HDL above the median (46.4 mg/dL).<sup>3</sup>

### 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* = .013; 95% CI 13.3-111.5.

 References 1. Goldstein JL, Hazzard WR, Schrott HG, Bierman EL, Motulsky AG. Hyperlipidemia in coronary heart disease. I. Lipid levels in 500 survivors of myocardial infarction. J Clin Invest. 1973;52:1533-1543.
Assmann G, Schulte H. PROCAM-Trial: Prospective Cardiovascular Münster Trial. Zürich: Panscientia Verlag; 1966:B-9. 3. Data on file, Medical Affairs Dept, Parke-Davis.

Please see last page of this advertisement for warnings, contraindications, and brief summary of prescribing information.

## Before prescribing, please see full prescribing information. A Brief Summary follows.

CONTRAINDICATIONS. 1. Hepatic or severe renal dysfunction, including primary biliary cirrhosis. 2. Preexisting gallbladder disease (See WARNINGS)

Hypersensitivity to gemfibrozil.

WARNINGS. 1. Because of chemical, pharmacological, and clinical similarities between gemfibrozil and clofibrate, the adverse findings with clofibrate in two large clinical studies may also apply to gemfibrozii. In the first of those studies, the Coronary Drug Project, 1000 subjects with previous myocardial infarction were treated for five years with clofibrate. There was no difference in mortality between the clofibrate-treated subjects and 3000 placebo-treated subjects, but twice as many clofibrate-treated subjects developed choleithiasis and cholecystilis requiring surgery. In the other study, con-ducted by the World Health Organization (WHO), 5000 subjects without known cor-onary heart disease were treated with clofibrate for five years and followed one year beyond. There was a statistically significant, 29%, higher total mortality in the clofibratetreated than in a comparable placebo-treated control group. The excess mortality was due to a 33% increase in noncardiovascular causes, including malignancy, post-cholecystectomy complications, and pancreatitis. The higher risk of clofibrate-treated subjects for gallbladder disease was confirmed.

During the Helsinki Heart Study and in the 1/2 year follow-up period since the trial was completed, mortality from any cause was 59 (2.9%) in the Lopid group and 55 (2.7%) in the placebo group. Mortality from any cause during the double-blind portion of the study was 44 deaths in the Lopid group and 43 in the placebo group. Because of the more limited size of the Helsinki Heart Study, this result is not statisticallysignificantly different from the 29% excess mortality seen in the clofibrate group in the separate WHO study. Noncoronary hear disease related mortality showed a 58% greater trend in the Lopid group (43 vs 27 patients in the placebo group, p=0.056). In the Helsinki Heart Study, the incidence of total malignancies discovered during the

trial and in the 1½ years since the trial was completed was 39 in the Lopid group and 29 in the placebo group (difference not statistically significant). This includes 5 basal cell carcinomas in the Lopid group and none in the placebo group (p=0.06; historical data predicted an expected 4.7 cases in the placebo group). GI malignancies and deaths

from malignancies were not statistically different between Lopid and placebo subgroups. Follow-up of the Helsinki Heart Study participants will provide further infor-mation on cause-specific mortality and cancer morbidity.

2. A gallstone prevalence substudy of 450 Helsinki Heart Study participants showed a trend toward a greater prevalence of gallstones during the study within the Lopid treatment group (7.5% vs 4.9% for the place bo group, a 55% excess for the gemfibrozil group). A trend toward a greater incidence of gallbladder surgery was observed for the Lopid group (17 vs 11 subjects, a 54% excess). This result did not differ statistically

from the increased incidence of cholecystectomy observed in the WHO study in the group treated with clofibrate. Both clofibrate and gemfibrozil may increase cholesterol excretion into the bile leading to cholelithiasis. If cholelithiasis is suspected, gallbladder studies are indicated. Lopid therapy should be discontinued if gallstones are found.

 Since a reduction of mortality from coronary artery disease has not been demonstrated and because liver and interstitial cell testicular tumors were increased 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.

4. Concomitant Anticoagulants – Caution should be exercised when anticoagulants are given in conjunction with Lopid. The dosage of the anticoagulant should be reduced to maintain the prothrombin time at the desired level to prevent bleeding complications. Frequent prothrombin determinations are advisable until it has been definitely determined that the prothrombin level has stabilized

 Concomitant therapy with Lopid and Mevacor® (lovastatin) has been associated with rhabdomyolysis, markedly elevated creatine kinase (CK) levels and myoglobinuria, leading in a high proportion of cases to acute renal failure. In most subjects who have had an unsatisfactory lipid response to either drug alone, the possible benefit of combined therapy with lovastatin and gemfibrozil does not outweigh the risks of severe myopathy, rhabdomyolysis, and acute renal failure (See Drug Interactions). The use of fibrates alone, including Lopid, may occasionally be associated with myositis. Patients receiving Lopid and complaining of muscle pain, tenderness, or weakness should have prompt medical evaluation for myositis, including serum creatine kinase level determination. If myositis is suspected or diagnosed, Lopid therapy should be withdrawn. 6. Cataracts – Subcapsular bilateral cataracts occurred in 10%, and unilateral in 6.3%

rats treated with gemfibrozil at 10 times the human dose

PRECAUTIONS. 1. Initial Therapy – Laboratory studies should be done to ascertain that the lipid levels are consistently abnormal. Before instituting Lopid therapy, every attempt should be made to control serum lipids with appropriate diet, exercise, weight loss in obese patients, and control of any medical problems such as diabetes mellitus and hypothyroidism that are contributing to the lipid abnormalities.

 Continued Therapy – Periodic determination of serum lipids should be obtained, and the drug withdrawn if lipid response is inadequate after 3 months of therapy.
Drug Interactione – (A) Lovestatin: Rhabdomyolysis has occurred with combined gemiltrozi and lovestatin therapy. It may be seen as early as 3 weeks after initiation of combined therapy or after several months. In most subjects who have had an unsatisfac-ultication of the several months. tory lipid response to either drug alone, the possible benefit of combined therapy with lovastatin and gemfibrozil does not outweigh the risks of severe myopathy, rhab

Iovastatin and gemilorozil does not outweigh the risks of severe myopathy, rhab-domyolysis, and acute renal failure. There is no assurance that periodic monitoring of creatine kinase will prevent the occurrence of severe myopathy and kidney damage. (B) **Anticoegulants:** CAUTION SHOULD BE EXERCISED WHEN ANTICOAGU-LANTS ARE GIVEN IN CONJUNCTION WITH LOPID. THE DOSAGE OF THE ANTI-COAGULANT SHOULD BE REDUCED TO MAINTAIN THE PROTHROMBIN TIME AT THE DESIRED LEVEL TO PREVENT BLEEDING COMPLICATIONS. FREQUENT PROTHROMBIN DETERMINATIONS ARE ADVISABLE UNTIL IT HAS BEEN DEFINITY DETERMINATIONS ARE ADVISABLE UNTIL IT HAS DEEN DEFINITELY DETERMINED THAT THE PROTHROMBIN LEVEL HAS STABILIZED.

4. Carcinogenesis, Mutagenesis, Impairment of Fertility - Long-term studies have been conducted in rats and mice at one and ten times the human dose. The inci-dence of benign liver nodules and liver carcinomas was significantly increased in high dose male rats. The incidence of liver carcinomas increased also in low dose males, but this increase was not statistically significant (p=0.1). In high dose female rats, there was a significant increase in the combined incidence of benign, and malignant liver neoplasms. In male and female mice, there were no statistically significant differences

#### Lopid® (Gemfibrozil Capsules and Tablets)

from controls in the incidence of liver tumors, but the doses tested were lower than those shown to be carcinogenic with other fibrates

Male rats had a dose-related and statistically significant increase of benign Levdig cell tumors at 1 and 10 times the human dose.

Electron microscopy studies have demonstrated a florid hepatic peroxisome prolifera-tion following Lopid administration to the male rat. An adequate study to test for perox-isome proliferation has not been done in humans but changes in peroxisome

morphology have been observed. Peroxisome proliferation has been shown to occur in humans with either of two other drugs of the fibrate class when liver biopsies were com-

pared before and after treatment in the same individual. Administration of approximately three or ten times the human dose to male rats for 10 weeks resulted in a dose-related decrease of fertility. Subsequent studies demonstrated that this effect was reversed after a drug-free period of about eight weeks, and it was not transmit-

ted to the offspring. 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 6.7 times the human dose. These studies have revealed no evidence of impaired fertility in females or harm to the fetus due to Lopid. Minor fetotoxicity was manifested by reduced birth rates observed at the high dose levels. No significant malformations were found among almost 400 off-spring from 36 litters of rats and 100 fetuses from 22 litters of rabbits.

There are no studies in pregnant women. In view of the fact that Lopid is tumorigenic in male and female rats, the use of Lopid in pregnancy should be reserved for those pa-tients where the benefit clearly outweighs the possible risk to the patient or fetus. 6. Nursing Mothers – Because of the potential for tumorigenicity shown for gem-fibrozil in rats, a decision should be made whether to discontinue nursing or discontinue

the drug, taking into account the importance of the drug to the mother.

7. Hematologic Changes – Mild hemoglobin, hematocrit and white blood cell decreases have been observed in occasional patients following initiation of Lopid therapy. However, these levels stabilize during long-term administration. Rarely, severe anemia, leukopenia, thrombocytopenia, and bone marrow hypoplasia have been reported. Therefore, periodic blood counts are recommended during the first 12 months of Lopid administration.

8. Liver Function - Abnormal liver function tests have been observed occasionally

during Lopid administration, including eleva-tions of AST (SGOT), ALT (SGPT), LDH, bili-rubin, and alkaline phosphatase. These are usually reversible when Lopid is discon-tinued. Therefore periodic liver function studies are recommended and Lopid therapy should be terminated if abnormalities persis

 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 that study, the following adverse reactions LAND IRIGLYCEKIDES CES HEART ATTACK (23.8%): dyspepsia, 19.6% (11.9%); abdominal pain, 9.8% (5.6%); acute appendicitis

(histologically confirmed in most cases where data are available), 1.2% (0.6%); atrial fibrillation, 0.7% (0.1%).

tibrillation, 0.7% (0.1%). Adverse events reported by more than 1% of subjects, but without a significant difference between groups (placebo incidence in parentheses) were: diarrhea, 7.2% (6.5%); fatigue, 3.8% (3.5%); nausea/vomiting, 2.5% (2.1%); eczema, 1.9% (1.2%); rash, 1.7% (1.3%); vertigo, 1.5% (1.3%); constipation, 1.4% (1.3%); headache, 1.2% (1.1%). (13%); Vertigo, 13% (13%), consupation, 14% (14%), notated in 1,2% (13%). **Galibladder surgery** was performed in 0.9% of Lopid and 0.5% of placebo subjects, a 64% excess, which is not statistically different from the excess of galibladder surgery observed in the clofibrate compared to the placebo group of the WHO study.

Nervous system and special senses adverse reactions were more common in the Lopid group. These included hypesthesia, paresthesias, and taste perversion. Other Lopid group. These includes hyperinear, particular particular by the section of the adverse reactions that were more common among Lopid treatment group subjects but where a causal relationship was not established include cataracts, peripheral vascular disease, and intracerebral hemorrhage.

disease, and intracerebral nemorrhage. From other studies it seems probable that Lopid is causally related to the occurrence of musculoskeletal symptoms (See WARNINGS), and to abnormal liver function tests and hematologic changes (See PRECAUTIONS). Reports of viral and bacterial infections (common cold, cough, urinary tract infections) were more common in gernfibrozil-treated patients in other controlled clinical trials of 050 patients.

Additional adverse reactions that have been reported for gemfibrozil are listed below

by system. These are categorized according to whether a causal relationship to treat-ment with Lopid is probable or not established:

CAUSAL RELATIONSHIP PROBABLE: Gastrointestinal: cholestatic jaundice; Central Nervous System: dizziness, somnolence, paresthesia, peripheral neuritis, decreased libido, depression, headache; Eye: blurred vision; Genitourinary: impotence; Musuloskeletal: myopathy, myasthenia, myalgia, painful extremites, arthraigia, synovitis, rhabdomyolysis (see WARNINGS and Drug Interactions under PRECAU-TIONS): *Clinical Laboratory*: increased creatine phosphokinase, increased bilirubin, in-creased liver transaminases (AST [SGOT], ALT [SGPT]), increased alkaline phosphatase; *Hematopoietic*: anemia, leukopenia, bone marrow hypoplasia, eosinophilia; *Im*munologic: angioedema, laryngeal edema, urticaria; Integumentary: exfoliative der-

matitis, rash, dermatitis, pruritus. CAUSAL RELATIONSHIP NOT ESTABLISHED: General: weight loss; Cardiac: extrasystoles; Gastrointestinal: pancreatitis, hepatoma, colitis; Central Nervous System: confu-sion, convulsions, syncope; Eye: retinal edema; Genitourinary: decreased male fertility; Clinical Laboratory: positive antinuclear antibody; Hernatopoletic: thrombocytopenia; Immunologic: anaphylaxis, Lipus-like syndrome, vasculitis; Integumentary: alopecia. DOSAGE AND ADMINISTRATION. The recommended dose for adults is 1200 mg administered in two divided doses 30 minutes before the morning and evening meal. MANAGEMENT OF OVERDOSE. While there has been no reported case of over dosage, symptomatic supportive measures should be taken should it occur.

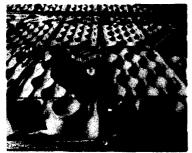
References: 1. Frick MH, Elo O, Haapa K, et al: Helsinki Heart Study: Primary nreven. Hererences: 1. Frick MH, Elo U, Haapa K, et al: Helsinki Heart Study: Primary prevention trial with gemfibrozil in middle-aged men with dyslipidemia. N Engl J Med 1987;317:1237:1245 2. Manninen V, Elo O, Frick MH, et al: Lipid alterations and decline in the incidence of coronary heart disease in the Helsinki Heart Study. JAMA 1988; 260:641-651. 3. Nikkila EA: Familial lipoprotein lipase deficiency and related disorders of chylomicron metabolism. In Stanbury J. B. et al. (eds.): The Metabolic Basis of Inherited Disease, 5th ed., McGraw-Hill, 1983, Chap. 30, pp. 622-642.

### PARKE-DAVIS

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# Food Fight Erupts in Neighborhood Supermarket



Produce section after recent food fight.

Carrots, broccoli, tomatoes, even brussels sprouts were flying into grocery carts as **The Great American Food Fight Against Cancer** broke out in area supermarkets.

Consumers are reacting to studies which show that foods high in vitamins A and C, high in fiber and low in fat, may help reduce cancer risk.

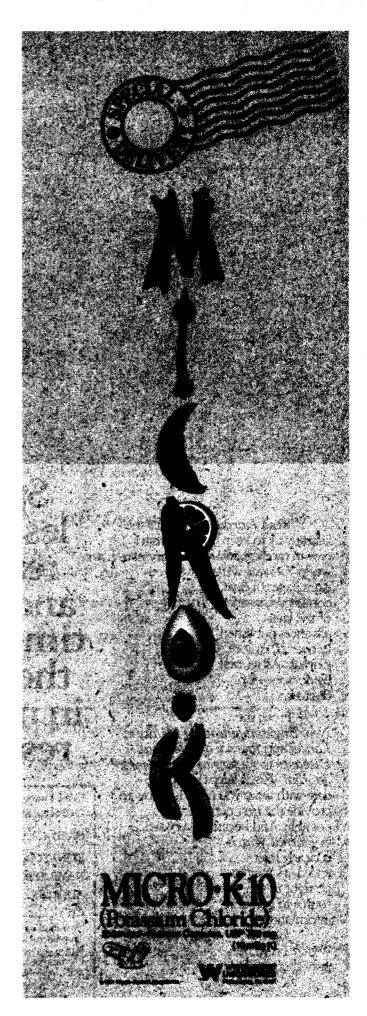
"My husband is getting whole grain toast tomorrow morning," one shopper declared. A mother was seen throwing carrots into her bag. "Snacks for the kids," she said.

Grocers are, of course, delighted. "This food fight is pretty exciting," said one produce manager, "and there's nothing for me to clean up!"

The American Cancer Society, sponsor of the Food Fight, has more information. Call **1-800-ACS-2345**.

And, be on the lookout for Community Crusade volunteers armed with shopping lists.





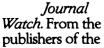
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- Pellegrin FA, Ramcharan S, Fisch IR, Phillips NR. The noncontraceptive effects of oral contraceptive drugs: the Kaiser-Permanente Study. In: Ramcharan S, ed. The Walnut Creek Contraceptive Drug Study: a prospective study of the side effects of oral contraceptives. Vol. 1. Bethesda, Md.: National Institutes of Health, 1974:1-19. (DHEW publication no. (NIH)74-562).

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Verapamil without the food variable

# ENGINEERED WITH A NEW PATENTED<sup>®</sup> DELIVERY TECHNOLOGY FOR HYPERTENSION

## New absorption profile

Controlled and predictable absorption over 24 hours with or without food

## Advanced convenience

With VERELAN, food intake is not required for consistent absorption. Traditional SR verapamil imust be taken with food to achieve the desired absorption profile.

## Advanced dosing simplicity

Once a day dosing for all dosages, even for patients requiring dosages over 240 mg a day.

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