Delipid®

Gemfibrozil

Fibrate

COMPOSITION

Delipid® Capsule: Each capsule contains Gemfibrozil USP 300 mg.

PHARMACOLOGY

Delipid® containing Gemfibrozil is an anti-lipemic agent. Gemfibrozil decreases serum triglycerides in healthy individuals and patients with hyper-triglyceridemia. It decreases very low-density lipoprotein (VLDL)-triglyceride concentration and to a lesser extent, LDL-triglyceride concentration. HDL-triglyceride is usually decreased slightly. Gemfibrozil usually increases the HDL-cholesterol fraction in healthy individuals and patients with hyperlipoproteinemia, an action that may be beneficial in slowing the progression of atherosclerosis and in reducing the risk of coronary heart disease.

Gemfibrozil also inhibits synthesis of VLDL carrier apolipoprotein B, leading to a decrease in VLDL production. How gemfibrozil raises HDL concentration is not known. Gemfibrozil inhibits lipolysis of fat in adipose tissue and decreases the hepatic uptake of plasma free fatty acids, thereby reducing hepatic triglyceride production.

Gemfibrozil is rapidly and completely absorbed from the G. I. Tract. Peak concentration in plasma occurs within 1 to 2 hours; the half-life is about 1.5 hours. About 70% of a dose is excreted in the urine; little is excreted in the faeces.

INDICATION

Delipid® is used as a hypolipidemic agent in conjunction with dietary modification. It is recommended in the treatment of type IIa, type IIb, type III, type IV and type V hyperlipoproteinemia.

DOSAGE AND ADMINISTRATION

The usual dose by mouth is 1.2g daily in 2 divided doses given 30 minutes before morning and evening meal. The dosage range may vary between 0.9-1.5 g daily or as directed by the physician.

CONTRAINDICATION AND PRECAUTION

It is contraindicated in case of alcoholism, hepatic impairment, gallstone, and pregnancy and to patients hypersensitive to Gemfibrozil.

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Risk benefit must be considered in case of lactating mother. Before initiation long-term treatment lipid profile, blood counts, renal activity, annual eye examination and liver function tests should be done.

SIDE EFFECT

The most frequent adverse effect involves the G. I. Tract. Abdominal pain and epigastric pain or dyspepsia is common adverse G. I. effects. Other adverse reaction includes pruritus, rash, headache, dizziness, blurred vision, painful extremities and rarely myalgia.

DRUG INTERACTION

Concomitant anticoagulant dosage may need to be reduced and frequent determinations of prothrombin carried out to confirm that the desired prothrombin level has been re-established. There have been reports of severe myositis with marked elevation of creatinine kinase and myoglobinuria when Delipid® and lovastatin were used concomitantly. In most subjects who have had an unsatisfactory lipid response to either drug alone, the possible benefit of combined therapy with lovastatin and Delipid® does not outweigh the risks of severe myopathy, rhabdomyolysis and acute renal failure.

USE IN PREGNANCY AND LACTATION

Safe use in human pregnancy has not been established. It is not known whether gemfibrozil is secreted in human milk. Like most drugs, gemfibrozil should normally be avoided during pregnancy and lactation.

STORAGE CONDITION

It should be stored in a dry place at room temperature.

HOW SUPPLIED

Delipid® capsule: Box containing 3 x 10 capsules in strip pack.