

Size : 85 x 120 mm (fron & back) Colour : BLACK

Fenofibrate

Lofibra

200 mg Capsule
Anti-hypertriglyceridemia

FORMULATION:

Each capsule contains:
Fenofibrate BP (micronized) 200 mg

PHARMACOKINETICS:

Fenofibrate is well absorbed from the gastrointestinal tract. Peak plasma levels of fenofibric acid occur within 6 to 8 hours after administration. The absorption of Fenofibrate is increased when administered with food. With micronized Fenofibrate, the absorption is increased by approximately 35% under fed as compared to fasting condition. Steady state plasma levels of Fenofibric acid were shown to be achieved within 5 days of dosing with single oral doses equivalent to 67 mg and did not demonstrate accumulation across time following multiple dose administration. Serum protein binding was approximately 99% in normal and hyperlipidemic subjects. It is rapidly hydrolyzed by esterases to the active metabolite, Fenofibric acid; no unchanged Fenofibrate is detected in plasma. Fenofibric acid is primarily conjugated with glucuronic acid and excreted in the urine in the form of metabolites, primarily Fenofibric acid and Fenofibrate glucuronide. The compound is eliminated with a half-life of 20 hours, allowing once daily administration in a clinical setting.

INDICATIONS:

Fenofibrate capsules, micronized, is indicated as adjunctive therapy to diet for treatment of adult patients with very high elevations of serum triglyceride levels (Type IV and V hyperlipidemia) who are at risk of pancreatitis and who do not respond adequately to a determined dietary effort to control them.

CONTRAINDICATIONS :

Contraindicated with known hypersensitivity to this product or any of its component.

DRUG INTERACTION:

Potiation of coumarin-type anticoagulants has been observed with prolongation of the prothrombin time. The dosage of the anticoagulants should be reduced to maintain the prothrombin time at the desired level to prevent bleeding complications.

ADVERSE REACTIONS:

Digestive: hepatitis, cholelithiasis, cholecystitis, hepatomegaly, dyspepsia and rise in transaminases;

Skin and appendages: cutaneous allergic reactions, photosensitivity and eczema. Other events reported in less than 2% of studied cases were:

Respiratory: allergic pulmonary alveolitis.

PRECAUTION:

Laboratories studies should be done ascertain that the lipid levels are consistently abnormal before instituting Fenofibrate 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. Medications known to exacerbate hypertriglyceridemia (beta-blockers, thiazides, estrogens) should be continued or changed if possible prior to consideration of triglyceride-lowering therapy. Therapy should be withdrawn in patients who do not have an adequate response after two months of treatment with the maximum recommended dose of 200 mg per day.

DOSAGE AND ADMINISTRATION:

Patients should be placed on an appropriate triglyceride-lowering diet before receiving Fenofibrate, and should continue this diet during treatment with Fenofibrate. Fenofibrate should be given with meals, thereby optimizing the bioavailability of the medication. The initial dose is 200 mg per day. Doses may be adjusted according to response to between 200 and 400 mg per day. Children may be given 5 mg / kg body weight daily. Daily maintenance doses of 200 mg per day may be given after the triglyceride levels have stabilized. Or as prescribed by the physician.

AVAILABILITY :

Fenofibrate (Lofibra) 200 mg Capsule packed in blister foil x 10's (box of 50's)

CAUTION:

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

Manufactured by:

Micro Labs Limited

Unit III, 63/3 & 4, Thiruvandar Koil, Pondicherry-605 102, India

Imported by :

OE P PHILIPPINES, INC.

Rm. 606 SEDCCO I Bldg., cor. Rada & Legaspi Sts.,
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Distributed by :

Zuellig Pharma Corporation

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