Lipired®

Fenofibrate

Fibrate

COMPOSITION

Lipired® Capsule: Each capsule contains micronised Fenofibrate BP 200 mg.

PHARMACOLOGY

Fenofibric acid, the active metabolite of fenofibrate, lowers plasma triglycerides apparently by inhibiting triglyceride synthesis, resulting in a reduction of VLDL released into the circulation, and also by stimulating the catabolism of triglyceride-rich lipoprotein (i.e., VLDL). Fenofibrate also reduces serum uric acid levels in hyperuricemic and normal individuals by increasing the urinary excretion of uric acid.

PHARMACOKINETIC

Comparisons of blood level following oral administration of both formulations in healthy volunteers demonstrate that a single capsulecontaining 67 mg of the "micronised" formulation is bioequivalent to 100 mg of the "non-micronised" formulation. Absorption : Fenofibrate is well absorbed from the gastrointestinal tract and Peak plasma levels of fenofibric acid occur within 6 to 8 hours afteradministration. The absorption of fenofibrate is increased when administered with food. With micronised fenofibrate, the absorption is increased by approximately 35% under fed as compared to fasting conditions. Distribution : In healthy volunteers, steady-state plasma levels of fenofibric acid were shown to be achieved within 5 days of dosing and did not demonstrate accumulation across time following multiple dose administration. Serum protein binding was approximately 99% in normal and hyperlipidemic subjects. Metabolism : Following oral administration, fenofibrate 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 then excreted in urine. Excretion : After absorption, fenofibrate is mainly excreted in the urine in the form of metabolites, primarily fenofibric acid and fenofibric acid glucuronide. The compound is eliminated with a half-life of 20 hours, allowing once daily administration in a clinical setting.

INDICATION

Fenofibrate (fenofibrate capsules), micronised, is indicated as adjunctive therapy to diet for treatment of hyperlipidemias of Type IIa, IIb, III, IV and V who do not respond adequately to a determined dietary effort or other ppropriate measures to control them.

DOSAGE & ADMINISTRATION

The dose is one 200 mg capsule per day. Dosage should be individualized according to patient response, and should be increased sequentially if necessary following repeat serum triglyceride estimations at 4 to 8 week intervals. 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.

CONTRAINDICATION

1. Hepatic or severe renal dysfunction, including primary biliary cirrhosis, and patients with unexplained persistent liver function abnormality.
2. Preexisting gallbladder disease.
3. Hypersensitivity to fenofibrate.

SPECIAL POPULATION

Geriatrics : This indicates that a similar dosage regimen can be used in the elderly, without increasing accumulation of the drug or metabolites. Pediatrics : No data are available. Fenofibrate is not indicated for use in the pediatric population. Gender : No pharmacokinetic difference between male and female has been observed for fenofibrate. Renal insufficiency : The dosage of fenofibrate should be minimized in patients who have severe renal impairment, while no modification of dosage is required in patients having moderate renal impairment. Hepatic insufficiency : No pharmacokinetic study has been conducted in patients having hepatic insufficiency.

SIDE EFFECT

Digestive: hepatitis, cholelithiasis, cholecystitis, hepatomegaly Musculoskeletal: myalgia, myasthenia, rhabdomyolysis Skin and appendages: photosensitivity, eczema Cardiovascular: peripheral edema, angina, palpitations, tachycardia, and migraine

DRUG INTERACTION

Oral Anticoagulants: Caution should be exercised when anticoagulants are given in conjunction with fenofibrate. The dosage of the anticoagulants should be reduced to maintain the prothrombin time at the desired level to prevent bleeding complications. Resins: Since bile acid sequestrants may bind other drugs given concurrently, patients should take fenofibrate at least 1 hour before or 4-6 hours after a bile acid binding resin to avoid impending its absorption. Cyclosporine: Because cyclosporine can produce nephrotoxicity with decreases in creatinine clearance and rises in serum creatinine, and because renal excretion is the primary elimination route of fibrate drugs including fenofibrate, there is a risk that an interaction will lead to deterioration.

PREGNANCY

Pregnancy Category C. Fenofibrate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHER

Fenofibrate should not be used in nursing mothers. Because of the potential for tumorigenicity seen in animal studies, a decision should be made whether to discontinue nursing or to discontinue the drug.

STORAGE

Store at cool & dry place. Protect from light and moisture.

HOW SUPPLIED

Lipired® capsule: Each box containing 3 x 10 capsules in blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH