Noficon®

Fenofibrate BP Capsule

DESCRIPTION

Noficon® capsule contains Fenofibrate (micronised). It is a fibric acid derivative. Fenofibrate is rapidly hydrolyzed after oral ingestion to its pharmacologically active form, Fenofibric Acid. Fenofibric Acid produces reductions in total cholesterol, LDL cholesterol, apo-lipoprotein B, total triglycerides and triglyceride rich lipoprotein (VLDL) in treated patients. In addition, treatment with Fenofibrate results in increases in HDL and apoproteins apo AI and apo AII. Fenofibrate also reduces serum uric acid levels in hyperuricemic and normal individuals by increasing the urinary excretion of uric acid. The micronised form of Fenofibrate has enhanced absorption over the non-micronised formulation.

INDICATIONS

Noficon® is indicated for the treatment of hyperlipidaemias of types IIa, IIb, III, IV and V in patients who have not responded adequately to diet and other appropriate measures .

DOSAGE AND ADMINISTRATION

The initial adult dose of the micronized formulation is one 200 mg capsule once daily. Patients should be placed on an appropriate lipid-lowering diet before receiving **Noficon®** and should continue during treatment. **Noficon®** should be given with meals, thereby optimizing the bioavailability of the medication.

PHARMACOKINETICS

Absorption and Distribution: Fenofibrate is well absorbed from the gastro-intestinal 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 by approximately 35%. In healthy volunteers, steady-state plasma levels of fenofibric acid were shown to be achieved within 5 days of dosing. Serum protein binding was approximately 99% in normal and hyperlipidemic subjects.

Metabolism and Excretion: Following oral administration, Fenofibrate is rapidly hydrolyzed by esterases to the active metabolite, Fenofibric Acid; no unchanged Fenofibrate is detected in plasma. In vivo metabolism data indicate that neither Fenofibrate nor Fenofibric Acid undergo oxidative metabolism (e.g., cytochrome P450) to a significant extent. After absorption, Fenofibrate is mainly excreted in the urine in the form of metabolites, primarily Fenofibric Acid and Fenofibric Acid Glucuronide, after administration of radiolabelled Fenofibrate, approximately 60% of the dose appeared in the urine and 25% was excreted in the feces. The mean plasma half-life is 22.1 h (Range: 19.6-26.6 h) in healthy young adults, allowing once daily administration in a clinical setting.

CONTRAINDICATIONS

Fenofibrate is contraindicated in patients with hypersensitivity to Fenofibrate, hepatic or severe renal dysfunction, including primary biliary cirrhosis and patients with unexplained persistent liver function abnormality. Fenofibrate is also contraindicated in patients with preexisting gallbladder disease.

SIDE-EFFECTS

Gastro-intestinal (e.g. nausea, anorexia, gastric pain), pruritus, urticaria, impotence, also headache, dizziness, vertigo, fatigue, hair loss and myotoxicity (with myasthenia or myalgia), anaemia, leucopenia, thrombocytopenia.

PRECAUTIONS

Precautions of Fenofibrate include risks of pancreatitis and myopathy. Transient hematologic changes have been reported in some cases. Thrombocytopenia and agranulocytosis have been reported rarely. Fenofibrate dose should be reduced in presence of renal insufficiency.

USE IN PREGNANCY & LACTATION

Fenofibrate is not recommended for pregnant women. Fenofibrate is not recommended in nursing mothers and the safety and efficacy of the drug has not been established in pediatric patients.

DRUG INTERACTIONS

Fenofibrate potentiate the action of oral anticoagulants. In patients receiving oral anticoagulant therapy, the dose should be reduced by one third on starting Fenofibrate and then adjusted according to the international normalized ratio (Prothrombin time). Fenofibrate should not be used in combination with perhexiline maleate or with monoamine oxidase inhibitors (MAOIs). Fenofibrate has been given in combination with statins in resistant hyperlipidemias but the incidence of muscle problems and rhabdomyolysis is increased and care must be exercised.

PHARMACEUTICAL PRECAUTION

Store in a dry place, away from light. Keep out of reach of children.

PACKAGING

Noficon® Capsule : Box containing 4 strips of 10 capsules each. Each capsule contains Fenofibrate BP 200 mg.

SK+F
Manufactured by
ESKAYEF BANGLADESH LIMITED
GAZIPUR, BANGLADESH
® REGD. TRADEMARK

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