FADZ
PHARMA INC.

Drug/ Drug Class: Fenofibrate

Fenofadz®
200 mg Capsule
Lipid Modifying Agent

Pharmacodynamics

Fenofibrate 200 mg capsules is a formulation containing 200 mg of Fenofibrate; the administration of this product results in effective plasma concentrations identical to those obtained with 3 capsules of Fenofibrate 67 mg capsules containing 67 mg of Fenofibrate.

The lipid-lowering properties of Fenofibrate seen in clinical practice have been explained in vivo in transgenic mice and in human hepatocyte cultures by activation of Peroxisome Proliferator Activated Receptor ß (PPARß). Through this mechanism, Fenofibrate increases lipolysis and elimination of triglyceride-rich particles from plasma by activating lipoprotein lipase and reducing production of Apoprotein C-III. Activation of PPARß also induces an increase in the synthesis of Apoprotein A-I, A-II and of HDL cholesterol.

Epidemiological studies have demonstrated a positive correlation between abnormally increased serum lipid levels and an increased risk of coronary heart disease. The control of such dyslipidaemias forms the rationale for treatment with Fenofibrate. However, the possible beneficial and adverse long-term consequences of drugs used in the management of dyslipidaemia are still the subject of scientific discussion. Therefore, the presumptive beneficial effect of Fenofibrate 200 mg capsules on cardiovascular morbidity and mortality is as yet unproven. There is evidence that treatment with fibrates may reduce coronary heart disease events but they have not been shown to decrease all-cause mortality in the primary or secondary prevention of cardiovascular disease.

The Action to Control Cardiovascular Risk in Diabetes (ACCORD) lipid trial was a randomized placebo-controlled study of 5518 patients with type 2 diabetes mellitus treated with Fenofibrate in addition to simvastatin. Fenofibrate plus simvastatin therapy did not show any significant differences compared to simvastatin monotherapy in the composite primary outcome of non-fatal myocardial infarction, non-fatal stroke, and cardiovascular death (hazard ratio [HR] 0.92, 95% CI 0.79-1.08, p = 0.32 ; absolute risk reduction: 0.74%). In the prespecified subgroup of dyslipidaemic patients, defined as those in the lowest tertile of HDL-C (≤34 mg/dL or 0.88 mmol/L) and highest tertile of TG (≥ 204 mg/dL or 2.3 mmol/L) at baseline, fenofibrate plus simvastatin therapy demonstrated a 31% relative reduction compared to simvastatin monotherapy for the composite primary outcome (hazard ratio [HR] 0.69, 95% CI 0.49-0.97, p = 0.03 ; absolute risk reduction: 4.95%). Another prespecified subgroup analysis identified a statistically significant treatment-by-gender interaction (p = 0.01) indicating a possible treatment benefit of combination therapy in men (p=0.037) but a potentially higher risk for the primary outcome in women treated with combination therapy compared to simvastatin monotherapy (p=0.069). This was not observed in the aforementioned subgroup of patients with dyslipidaemia but there was also no clear evidence of benefit in dyslipidaemic women treated with Fenofibrate plus simvastatin, and a possible harmful effect in this subgroup could not be excluded.

Studies with Fenofibrate on lipoprotein fractions show decreases in levels of LDL and VLDL cholesterol. HDL cholesterol levels are frequently increased. LDL and VLDL triglycerides levels are also reduced. The overall effect is a decrease in the

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ratio of low and very low-density lipoproteins to high density lipoproteins, which epidemiological studies have correlated with a decrease in atherogenic risk. Apolipoprotein-A and apolipoprotein-B levels are altered in parallel with HDL and LDL and VLDL levels respectively.
Regression of xanthomata has been observed during fenofibrate therapy. Plasma uric acid levels are increased in approximately 20% of hyperlipidaemic patients, particularly in those with type IV phenotype. Fenofibrate 200 mg capsules have a uricosuric effect and is therefore of additional benefit in such patients. Patients with raised levels of fibrinogen and Lp(a) have shown significant reductions in these measurements during clinical trials with fenofibrate.

Formulation

Each hard gelatin capsule contains:
Fenofibrate BP.....200 mg

Availability

Alu/Alu Blister Pack x 10's
(Box of 50's

Pharmacokinetics

Fenofibrate is readily absorbed from the gastrointestinal tract when taken with food; absorption may be reduced if Fenofibrate is given on an empty stomach, although this depends on the formulation. It is rapidly hydrolysed to its active metabolite fenofibric acid which is about 99% bound to plasma albumin. The plasma elimination half-life is about 20 hours. Fenofibric acid is excreted mainly in the urine, mainly as the glucuronide conjugate, but also as a reduced form of fenofibric acid and its glucuronide. It is not removed haemodialysis.

Dosage & Administration

200 mg once daily. Or as prescribed by the physician.

Indication

It is used to reduce low-density lipoprotein (LDL)- cholesterol, total cholesterol, triglycerides, and apolipoprotein B, and to increase high-density lipoprotein (HDL)-cholesterol, in the management of hyperlipidaemias, including type IIa, type IIb, type III, type IV, and type V hyperlipoproteinaemias.

Contraindication

Hypersensitivity to active ingredient or any component of the formulation

Pregnancy and Lactation

Fenofibrate **should not be administered** to women who are pregnant.
There are no data on the excretion of Fenofibrate and/or its metabolites into breast milk. It is therefore recommended that Fenofibrate should not be administered to women who are breastfeeding.

Storage Condition

Store at temperatures not exceeding 30°C

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