

Fenofibrate BP 200 mg

COMPOSITION

Each capsule contains micronized Fenofibrate BP 200 mg.

PHARMACOLOGY

Lipidof® (Fenofibrate) is a lipid-regulating agent. 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.

INDICATION

Lipidof® (Fenofibrate) is indicated as adjunctive therapy to diet for the treatment of hypertriglyceridemia (Fredrickson Types IV and V) and also for primary hypercholesterolemia or mixed dyslipidemia (Fredrickson Types IIa, IIb) who are at risk of pancreatitis and who do not respond adequately to dietary effort.

DOSAGE AND ADMINISTRATION

Route of Administration : Orally.

Patients should be placed on an appropriate lipid lowering diet before receiving Fenofibrate, and should continue this diet during treatment with it. It should be taken with meal for better absorption.

The recommended dose is 200 mg capsule per day.

Treatment with Lipidof® should be initiated at a dose of 67 mg/day in patients having impaired renal function, and increased only after evaluation of the effects on renal function and triglyceride levels at this dose. In the elderly, the initial dose should likewise be limited to 67 mg/day.

OR AS DIRECTED BY THE PHYSICIAN.

CONTRAINDICATION

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

WARNING & PRECAUTION

During Fenofibrate therapy regular monitoring of liver function tests should be performed and therapy should be discontinued if enzyme levels persist above three times the normal limit.

The benefits and risks of using Fenofibrate with immunosuppressants and other potentially nephrotoxic agents should be carefully considered, and the lowest effective dose should be employed.

SIDE EFFECT

Common side effects: The most common side effects of Fenofibrate therapy are gastrointestinal upsets including nausea, anorexia, and gastric disorder.

Rare side effects: Other adverse effects reported to occur less frequently include pruritus, urticaria, headache, dizziness, vertigo, fatigue, hair loss, myotoxicity (with myasthenia or myalgia), skin rash, anemia, leucopenia, and thrombocytopenia.

USE IN PREGNANCY & LACTATION

Pregnancy: Fenofibrate is not recommended for pregnant women.

Lactation: Fenofibrate should not be used in lactating mothers because of its potential for tumorigenicity seen in animal studies.

USE IN CHILDREN & ADOLESCENTS

Safety and effectiveness in children have not been established.

DRUG INTERACTION

Anticoagulant: Fenofibrate may enhance the effects of oral anticoagulants; thus the dose of anticoagulants should be reduced to maintain the Prothrombin Time at the desired level to prevent bleeding complications when treatment with Fenofibrate is started, and then adjusted gradually if necessary.

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.

OVERDOSAGE

There is no specific treatment for overdose with Fenofibrate. General supportive care of the patients is indicated, including monitoring of vital signs and observation of clinical status, should an overdose occur. Because Fenofibrate is highly bound to plasma proteins, hemodialysis should not be considered.

STORAGE

Store below 30° C temperature & dry place, protected from light.

Keep all medicines out of reach of children.

PACKING

Each box contains 3 x 10 capsules in blisters.

* Further information is available on request.



Manufactured by:

The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh

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