Fibritor

Pemafibrate INN

COMPOSITION
Each film coated tablet contains Pemafibrate INN 0.1 mg.

PHARMACOLOGY
Pemafibrate activates PPARα by binding to this receptor and regulates the target gene expression, leading to decreased plasma triglyceride (TG), decreased triglyceride-rich lipoprotein, decreased apolipoprotein (Apo) C-3 and increased HDL-cholesterol.

INDICATION
It is indicated as adjunctive therapy to diet or other nonpharmacological treatment (e.g. exercise) to reduce TG and to increase HDL-C in patients with dyslipidemia characterised by high TG ≥150 mg/dL, particularly when there is evidence of associated risk such as hypertension and smoking.

DOSAGE AND ADMINISTRATION
The usual adult dosage is 0.1 mg (orally), twice daily in the morning and evening. The dose may be adjusted according to the patient's age and symptoms. The maximum dose is 0.2 mg twice daily.

CONTRAINDICATION
It is contraindicated in the following cases:
- In patients with known hypersensitivity to Pemafibrate or any of the excipients.
- In patients with severe hepatic disorder, Child-Pugh grade B or C cirrhosis or biliary obstruction.
- In patients with cholelithiasis.

WARNING & PRECAUTION
Patients need to be careful, in the following cases:
- Muscle toxicity, including very rare cases of rhabdomyolysis (with and without acute renal failure). In such cases, treatment with this medicine should be stopped. This medicine should be used with caution in patients receiving statins.
- Patients with hepatic disorder or those with a history of hepatic disorder.
- Patients with renal impairment. Renal function should be monitored periodically during treatment with this medicine.
- Patients with a history of cholelithiasis.

SIDE EFFECT
The most commonly reported side effects include cholelithiasis, diabetes mellitus and increased blood creatine phosphokinase.

USE IN PREGNANCY & LACTATION
The safety of this medicine has not been established for use during pregnancy. The use of this medicine should be avoided in breast-feeding women.

USE IN CHILDREN & ADOLESCENTS
No data is available.

DRUG INTERACTION
Concomitant administration of Cyclosporine or Rifampicin with Pemafibrate increased the plasma concentration of Pemafibrate.

OVERDOSAGE
There is no specific treatment in the event of overdose. The patient should be treated symptomatically and supportive measures instituted as required.

STORAGE
Store below 30°C temperature in a cool and dry place. Protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED
Each box contains 30 tablets in Alu-Alu blister pack.

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NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.