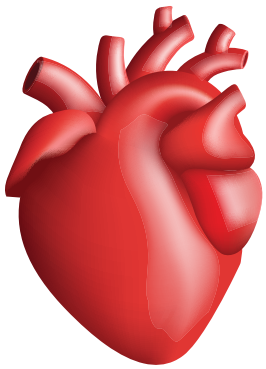


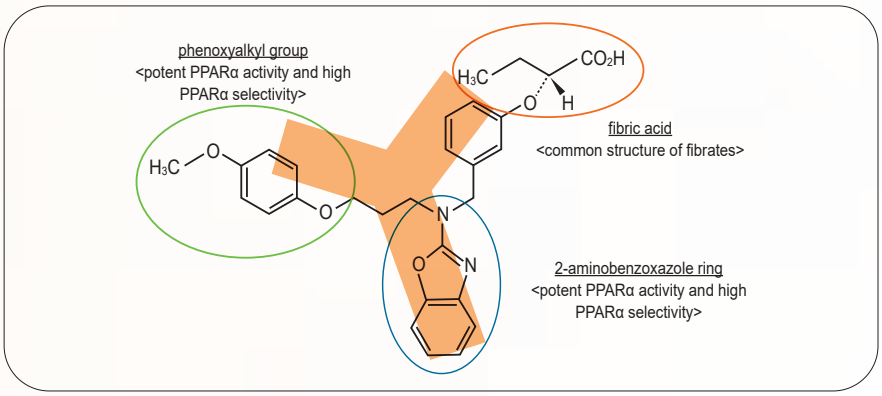
# Managing
# Hypertriglyceridemia

## Setting a new standard through
## Structural Superiority

Hypertriglyceridemia along with reduced HDL-C are risk factors of Atherosclerotic Cardiovascular Disease (ASCVD). Factors such as sedentary lifestyle, lipid-rich diet etc. makes it more difficult to control high triglyceride (TG).

Fibrates are considered as the preferred treatment for reducing TG. They act primarily by binding to and activating peroxisome proliferator activated receptor alpha (PPARα), a nuclear receptor. But conventional fibrates have low selectivity and potency for binding to PPARα. As a result, sometimes they fail to achieve desired TG level and often associated with various side effects.[1]

**Pemafibrate**, a new selective PPARα modulator, is strongly effective in treating hypertriglyceridemia and low HDL-C levels. Its unique Y-shaped structure allows it to bind tightly to the PPARα receptor.




Pemafibrate structure contains benzoxazole and phenoxyalkyl side-chains along with common fibric acid group, which ensures-

- High selectivity for PPARα
- Strong interaction with the receptor
- Maximum activation of the receptor

Thus, Pemafibrate shows over 2,500-fold greater potency for PPARα compared to conventional fibrates and provides better therapeutic outcome.[2]

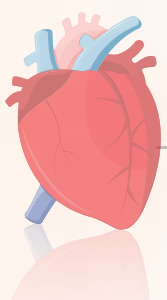
*Incepta introduces,*

# Pemafate™

## Pemafibrate INN 0.1 mg

1ST Time in Bangladesh

Structurally advanced fibrate
to manage ***Hypertriglyceridemia***



# Pemafate™

Pemafibrate INN 0.1 mg

Structurally advanced fibrate to manage ***Hypertriglyceridemia***

## Significantly decreases TG and increases HDL-C Level[3]

**Study type:** Randomized, double blind, active-controlled phase-III trial

**No. of patients:** 225

**Duration:** 24 weeks

**Drug used:** Pemafibrate

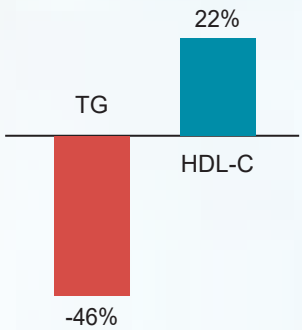



Fig: % change in TG and HDL-C level

## *Ensures improvement of lipid profile in dyslipidemic patients*

## Safer than Fenofibrate in treating Hypertriglyceridemia[4]

**Study type:** Multicenter, placebo-controlled, double-blind, randomized phase-III trial; **No. of patients:** 489; **Duration:** 12 weeks; **Drug used:** Pemafibrate and Fenofibrate


Fig: comparative reduction (%) of AE and ADR of Pemafibrate than Fenofibrate

## *Offers safer treatment option than Fenofibrate in reducing TG*

# Pemafate™

Pemafibrate INN 0.1 mg

Structurally advanced fibrate
to manage ***Hypertriglyceridemia***

- *Ensures strong binding with PPARα due to unique Y-shape structure*
- *Shows 2,500-fold greater potency for PPARα activation compared to conventional fibrates*
- *Ensures improvement of lipid profile in dyslipidemic patients*
- *Offers safer treatment option than Fenofibrate in reducing TG*


The recommended dose is
0.1 mg twice daily

## PRESCRIBING INFORMATION

**Presentation:** Pemafate Tablet: Each film coated tablet contains pemafibrate INN 0.1 mg. **Description:** Pemafibrate binds to PPARα with high selectivity and potency. Binding to PPARα regulates the target gene expression, leading to decreased plasma triglyceride (TG) concentration, decreased triglyceride-rich lipoprotein,decreased apolipoprotein (Apo) C-3 and increased HDL-cholesterol. Pemafibrate may modulate inflammation and oxidative stress by inhibiting the expression of pro-inflammatory cytokines and adhesion molecules. This anti-inflammatory action can further contribute to cardiovascular protection by reducing the inflammatory component of atherosclerosis, a condition characterized by the buildup of fatty deposits in the arterial walls. **Indication:** Pemafibrate is indicated as adjunctive therapy to diet to reduce TG in patients with dyslipidemia, including familial hyperlipidemia. **Dosage and Administration:** *Adult dose:* The usual adult dosage is 0.1 mg of pemafibrate orally administered twice daily. The dose may be individualized according to the patient's age and symtoms. Pemafibrate can be taken with or without food. *Use in children:* The safety of Pemafibrate in children has not been established. *Renal impairment:* Pemafibrate should be used with caution in patients with renal impairment defined as estimated glomerular filtration rate (eGFR) less than 30 mg/min/1.73 m2 .A lower starting dose or prolong dosing intervals should be considered. The maximum dose is 0.2 mg daily. *Hepatic impairment:* Pemafibrate should be used with caution in patients with severe hepatic disorder. **Side-effects:** Gastro-intestinal disorder (e.g. nausea, diarrhoea, abdominal pain), jaundice, skin rashes, gallstones, myotoxicity. **Pre-caution:** An increased risk of rhabdomyolysis has been reported with other fibrates when co-administered with an HMG-CoA reductase inhibitor (statin), especially in case of pre-existing muscular disease. Pemafibrate should be used with caution in patients receiving statins. Muscle toxicity should be suspected in patients presenting diffuse myalgia, myositis, muscle cramps and weakness and/or marked increase in (CK>5 times the upper limit of normal range [ULN]). In such cases, treatment with Pemafibrate should be stopped. Pemafibrate should be used with caution in patients with hepatic disorder or those with history of hepatic disorder. Abnormal liver function tests may occur. The plasma concentration of Pemafibrate may increase in patients with hepatic disorder (Child-Pugh grade A cirrhosis, etc). Liver function should be monitored periodically during treatment. Since cholelithiasis has been reported, Pemafibrate should be used with caution in patients with a history of cholelithiasis. Since increase in LDL-cholesterol levels may occur, LDL-cholesterol levels should be monitored periodically during treatment. **Contraindication**: Pemafibrate is contraindicated in • patients with known hypersensitivity to Pemafibrate or to any of the excipients. • patients with severe hepatic disorder, Child-Pugh grade B or C cirrhosis, or biliary obstruction • patients with cholelithiasis • pregnant or possibly pregnant women • patients receiving concomitant cyclosporine or rifampicin **Use in pregnancy and lactation:** *Pregnancy:* Pemafibrate is contraindicated in pregnant or possibly pregnant women. The safety of Pemafibrate has not been established for use during pregnancy. *Breast-feeding:* The use of Pemafibrate should be avoided in beast-feeding women. If the administration of Pemafibrate is unavoidable, breast-feeding should be discontinued. **Drug Interactions:** *Other fibrates:* The risk or severity of adverse effects can be increased when Pemafibrate is combined with other fibrates. *HMG CoA reductase inhibitors:* Concurrent use with statins, which are commonly prescribed for lipid management, may increase the risk of muscle-related side effects such as myopathy or rhabdomyolysis. *Oral anticoagulant therapy:* Patients taking anticoagulants such as warfarin should also be cautious, as Pemafibrate can potentiate the effects of these medications, increasing the risk of bleeding. Regular monitoring of coagulation parameters is recommended to adjust the anticoagulant dose as needed. **Storage:** Do not store above 30°C. Keep away from light and out of the reach of children. **Commercial Pack:** Pemafate Tablet: Each box contains 5 Alu Alu blister strips of 10 tablets.

**Incepta Pharmaceuticals Ltd**
Tejgaon, Dhaka, Bangladesh
www.inceptapharma.com
™ Trademark

Prescribing Information is available on request

References:
**1.** DOI: 10.1007/s11883-020-0823-5 **2.** DOI: 10.5551/jat.48918 **3.** DOI: 10.5551/jat.44412
**4.** DOI: 10.1016/j.jacl.2017.10.006

PTG: D8-245/131025/50000 MAS 15033370 / PFTGLIT---1