FENOLIP CAPSULE 300mg

DESCRIPTION: Opaque white/Opaque white colored size 1 hard gelatin capsule.

COMPOSITION: Each capsule contains Fenofibrate 300mg.

ACTIONS & PHARMACOLOGY:
Hypolipidemic. Studies with fenofibrate on lipoprotein fractions show decrease in levels of LDL- and VLDL-cholesterol. HDL-cholesterol levels are frequently increased; LDL- and VLDL-triglycerides are reduced. The overall effect is a decrease in the ratio of low and very low density lipoproteins to high density lipoproteins, which epidemiological studies have correlated with a decrease in atherogenic risk. Fenofibrate has a uricosuric effect and is therefore of additional benefit to type IV hyperlipidemic patients. Poorly and less well absorbed from an empty stomach, hence should always be taken with food. The plasma half-life of elimination of fenofibric acid is approximately 20 hours, Kinetic studies after multiple dosing show the absence of accumulation of the product.

INDICATIONS:
Fenofibrate reduces elevated serum cholesterol and triglycerides and is of benefit in the treatment of severe hyperlipidemias found in some patients, in whom dietary measures alone have failed to produce an adequate response. Fenofibrate is therefore indicated in appropriate cases of type IIa, IIb, III, IV and V hyperlipidemia.

CONTRAINDICATION:
Contraindicated in patients with severe liver dysfunction, existing gall bladder disease, severe renal disorders and in patients hypersensitive to fenofibrate.

SIDE EFFECTS:
Adverse reactions observed during fenofibrate treatment are infrequent, and are generally minor, transient and do not interfere with treatment.
Most commonly reported are mild gastrointestinal disturbances, skin reactions, headache, fatigue, and vertigo. Sexual asthenia and muscle cramps are less frequently reported. Probably causally related: Hepatitis, rhabdomyolysis.

WARNING AND PRECAUTIONS:
Dose reduction should be considered in elderly patients and those with impaired renal and hepatic functions. If satisfactory reduction of serum concentration of lipids is not obtained after 3 to 6 months of treatment, other therapeutic means (complementary or different) must be envisaged. Systematic verification of transaminases every 3 months, over the first 12 months of treatment should be done. Patients who develop signs of muscle toxicity should be monitored closely and CPK levels checked. Treatment with fenofibrate should be stopped if myopathy is suspected or if CPK rises to greater than or equal 10 times the upper limit of normal.

DRUG INTERACTIONS:
Fenofibrate potentiates oral anticoagulants and enhances the haemorrhagic risk through displacement of their binding with the plasma proteins. Possible interaction with oral hypoglycaemic agents should also be considered. Concurrent use of Lovastatin (or other HMG-CoA reductase inhibitors) may cause severe myositis and myoglobinuria.

PREGNANCY & LACTATION:
Fenofibrate has not been shown to be teratogenic in animals. However, signs of embryotoxicity have been seen in rats and it is therefore recommended that fenofibrate should not be given to women who are pregnant or are breastfeeding.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
Fenofibrate has no or negligible influence on the ability to drive and use machines.

ROUTE OF ADMINISTRATION:
Oral

DOSAGE & ADMINISTRATION:
The recommended initial dose of fenofibrate is 300 mg daily (in divided doses). In children the dose level is 5 mg per kg bodyweight per day.

Dietary restrictions should be continued. Response to therapy should be monitored by determination of serum lipid values, and dosage altered within 200-400 mg daily when necessary. Treatment should be discontinued if appropriate response has not been achieved within 3 months.

OVERDOSAGE & TREATMENT:
No reports of ill effects from overdose have been reported. There are no specific antidotes and treatment of acute overdosage should be symptomatic. Gastric lavage, and appropriate supportive care may be instituted if necessary.

PRESENTATION:
Blisters of 10 capsules. Box of 30, 60, 100, 250, 500 and 1000 capsules.

STORAGE:
Store in a cool dry place below 30°C.
Protect from light.
Keep medicine out of reach of children.

MANUFACTURED BY: **Noripharma Sdn Bhd** **200701034604 (792633-A)**
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Date of revision: August 2022