

FINACOR® **160 mg Capsules**

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about FINACOR

Each FINACOR capsule for oral administration contains fenofibrate micronized 160 mg.

Other ingredients: hydroxy propyl methyl cellulose, dimethicone, purified talc.

Fenofibrate is a fibric acid derivative, a lipid lowering agent that produces reductions in total cholesterol, LDL cholesterol, apolipoprotein B, total triglycerides and triglyceride rich lipoprotein (VLDL) in treated patients by the activation of peroxisome proliferator activated receptor α (PPAR α).

Fenofibrate also induces an increase in HDL cholesterol and reduces serum uric acid levels and C Reactive Protein levels.

FINACOR is indicated in the following conditions:

- As adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia
- As adjunctive therapy to diet for the reduction of LDL-C, total cholesterol, triglycerides and Apo B and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidemia

The way to take FINACOR

Take FINACOR as directed.

The usual recommended dose for the treatment of adult patients with primary hypercholesterolemia, mixed hyperlipidemia or hypertriglyceridemia is one capsule of 160 mg per day with sufficient water during a meal.

Lower initial doses may be recommended in patients with impaired renal function.

In geriatric patients, the dose is selected on the basis of renal function.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in the following conditions:

- Hypersensitivity to any of the components
- Severe renal dysfunction
- Hepatic dysfunction
- Pre-existing gallbladder disease
- Nursing mothers

Precautions

- This drug must be used with caution in case of hepatic or renal disease.
- Baseline and periodic monitoring of liver function and serum lipids should be performed for the duration of therapy with this drug.
- Inform your doctor if you complain of muscle pain, tenderness or weakness during therapy with this drug.
- Fenofibrate was not shown to reduce coronary heart disease morbidity and mortality in patients with type 2 diabetes mellitus
- Inform your doctor before using this medication in case of pregnancy or lactation. Safe use in pregnancy has not been established. This drug should not be used in nursing mothers.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

Caution should be exercised when anticoagulants, cyclosporine or nephrotoxic agents are given in conjunction with this drug.

Take FINACOR at least 1 hour before or 4-6 hours after a bile acid binding resin to avoid impeding fenofibrate absorption.

Adverse reactions

This drug is usually well tolerated when used as directed. Some reported adverse reactions include: abnormal liver tests, increase in serum transaminases, dyspepsia, flatulence, nausea, vomiting, diarrhea, rash, pruritus, hypersensitivity reactions, photosensitivity, hematologic changes, headache, rhinitis, muscle pain and biliary lithiasis.

Inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

FINACOR, fenofibrate micronized 160 mg, pack of 30 capsules

Revision date: 02/2013

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FINACOR is manufactured by Mediphar Laboratories –Lebanon
Under license from Zeon-Health Industries -India