

LIPITRIN[®] Tablets.
(Simvastatin/Ezetimibe)**COMPOSITION:**

Lipitrin is available as tablets in 3 dosage forms :

LIPITRIN^{10/10}

Each Tablet contains : 10 mg Simvastatin & 10 mg Ezetimibe.

LIPITRIN^{20/10}

Each tablet contains : 20 mg Simvastatin & 10 mg Ezetimibe.

LIPITRIN^{40/10}

Each tablet contains : 40 mg Simvastatin & 10 mg Ezetimibe.

PROPERTIES :

LIPITRIN is a lipid -lowering product that selectively inhibits the intestinal absorption of cholesterol and related plant sterols and inhibits the endogenous synthesis of cholesterol.

INDICATIONS :

Primary Hypercholesterolemia

LIPITRIN is indicated as adjunctive therapy to diet for the reduction of elevated total cholesterol (total-C), low- density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and non-high-density lipoprotein cholesterol (non-HDL-C), and to increase high-density lipoprotein cholesterol (HDL-C) in patients with primary (heterozygous familial and non-familial) hypercholesterolemia or mixed hyperlipidemia.

Homozygous Familial Hypercholesterolemia (HoFH) :

LIPITRIN is indicated for the reduction of elevated total-C levels in patient with HoFH. Patients may also receive adjunctive treatments (e.g. LDL apheresis).

DOSAGE AND ADMINISTRATION :

The patient should be placed on a standard cholesterol-lowering diet before receiving LIPITRIN and should continue on this diet treatment with LIPITRIN.

The dosage should be individualized according to the baseline LDL-C level, the recommended goal of therapy, and response. LIPITRIN should be taken as a single daily dose in the evening, with or without food.

The recommended usual starting dose is 20/10 mg/day.

Initiation of therapy with 10/10 mg/day may be considered for patients requiring less aggressive LDL-C reductions.

Patients who require a larger reduction in LDL-C (greater than 55%) may be started at 40/10 mg/day.

After initiation of therapy, Lipid levels may be analyzed after 2 or more weeks and dosage adjusted, if needed.

Dosage in Patients with Homozygous Familial Hypercholesterolemia :

The recommended dosage for patients with homozygous familial hypercholesterolemia is LIPITRIN 40/10 mg/day or 80/10 mg/day in the evening. LIPITRIN Should be used as an adjunct to other lipid-lowering treatments (e.g.,LDL apheresis) in these patients or if such treatments are unavailable.

Use in the Elderly :

No dosage adjustment is required for elderly patients.

Use in Hepatic Impairment :

No dosage adjustment is required in mild hepatic insufficiency . Treatment with LIPITRIN is not recommended in patients with moderate or severe liver dysfunction.

Use in Renal Impairment :

No dosage adjustment is required for patients with moderate renal insufficiency.

If treatment in patients with severe renal insufficiency (creatinine clearance ≤ 30 ml/min) is deemed necessary, dosages above 10/10 mg/day should be implemented cautiously.

Coadministration with other medicines :

In patients taking amiodarone or verapamil concomitantly with LIPITRIN the dose of LIPITRIN should not exceed 20/10 mg/day.

The safety and effectiveness of ezetimibe administered with fibrates have not been established. Therefore, the combination of LIPITRIN and fibrates should be avoided .

There is an increased risk of myopathy when simvastatin is used concomitantly with fibrates (especially gemfibrozil). Therefore, although not recommended, if lipitrin is used in combination with gemfibrozil, the dose should not exceed 10/10 mg daily .

Concomitant administration of ezetimibe (10 mg once daily) had no significant effect on bioavailability of warfarin and prothrombin time.

CONTRAINDICATIONS :

Hypersensitivity to the active substances or to any of the excipients. Active liver disease or unexplained persistent elevations of serum transaminases.

Pregnancy and nursing.

PRECAUTIONS :

Myopathy/Rhabdomyolysis

Simvastatin, like other inhibitors of HMG-CoA reductase, occasionally causes myopathy/Rhabdomyolysis

The risk of myopathy/rhabdomyolysis is increased by concomitant use of Lipitrin with the following:

Potent inhibitors of CYP3A4, e.g., itraconazole, ketoconazole, erythromycin, clarithromycin, telithromycin, HIV protease inhibitors, or nefazodone, particularly with higher doses of LIPITRIN.

SIDE EFFECTS :

Gastrointestinal disorders: flatulence

Musculoskeletal and connective tissue: myalgia

Nervous system disorders: headache

PRESENTATION :

LIPITRIN 10/10: strip of 7 tablets.

LIPITRIN 20/10: strip of 7 tablets.

LIPITRIN 40/10: strip of 7 tablets.

STORAGE :

Store below 30 C.

Produced by:
Chemipharm Pharmaceutical Industries
6th October City - Egypt
