

Tiginor® EZ

Atorvastatin and Ezetimibe Tablet

Presentation

Tiginor® EZ 10/10: Each film coated tablet contains Atorvastatin Calcium Trihydrate USP equivalent to Atorvastatin 10 mg and Ezetimibe USP 10 mg.

Tiginor® EZ 20/10: Each film coated tablet contains Atorvastatin Calcium Trihydrate USP equivalent to Atorvastatin 20 mg and Ezetimibe USP 10 mg.

Description

Tiginor® EZ contains Atorvastatin, a 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitor and Ezetimibe, a selective inhibitor of intestinal cholesterol and related phytylsterol absorption.

Indications

Primary Hyperlipidemia: Tiginor® EZ is indicated 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) hyperlipidemia or mixed hyperlipidemia.

Homozygous Familial Hypercholesterolemia (HoFH): Tiginor® EZ is indicated for the reduction of elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia, as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable.

Dosage and Administration

The recommended starting dose of Tiginor® EZ is 10/10 mg or 20/10 mg daily. Tiginor® EZ can be administered as a single dose at any time of the day, with or without food. The recommended starting dose for patients who require a larger reduction in LDL-C (greater than 55%) is 40/10 mg daily. After initiation and/or upon titration of Tiginor® EZ, lipid levels should be analyzed within 2 or more weeks and dosage adjusted accordingly.

Patients with Homozygous Familial Hypercholesterolemia: The dosage of Tiginor® EZ in patients with homozygous familial hypercholesterolemia is 40/10 mg or 80/10 mg daily. Tiginor® EZ should be used as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) in these patients or if such treatments are unavailable.

Patients with Hepatic Impairment: Tiginor® EZ is contraindicated in patients with active liver disease or unexplained persistent elevations in hepatic transaminase levels.

Patients with Renal Impairment: In patients with renal impairment, no dosage adjustment of Tiginor® EZ is necessary.

Use in Special Population

Pregnancy: Pregnancy Category X. Tiginor® EZ is contraindicated in women who are or may become pregnant.

Nursing Mothers: Because of the potential for adverse reactions in nursing infants, women taking Tiginor® EZ should not breastfeed.

Pediatric Use: Safety and effectiveness have not been established in pediatric patients.

Geriatric Use: In geriatric patients, no dosage adjustment of Tiginor® EZ is necessary.

Side Effects

Common side effects are rhabdomyolysis, myopathy, liver enzyme abnormalities, myalgia, abdominal pain, increased hepatic enzymes.

Contraindications

Active liver disease or unexplained persistent elevations of transaminase
Hypersensitivity to any component of Tiginor® EZ.

Warning and Precautions

Cases of myopathy, including rhabdomyolysis, have been reported with atorvastatin coadministered with colchicine, and caution should be exercised when prescribing Tiginor® EZ with colchicine. Tiginor® EZ therapy should be temporarily withheld or discontinued in any patient with an acute, serious condition suggestive of myopathy or having a risk factor predisposing to the development of renal failure secondary to rhabdomyolysis.

Liver Enzymes: It is recommended that liver enzyme tests be obtained prior to initiating therapy with Tiginor® EZ and repeated as clinically indicated. If serious liver injury with symptoms and/or hyperbilirubinemia or jaundice occurs during treatment with Tiginor® EZ, promptly interrupt therapy. If an alternate etiology is found, do not restart Tiginor® EZ. Active liver disease or unexplained persistent transaminase elevations are contraindicated to the use of Tiginor® EZ.

Endocrine Function: Cautions should be exercised if Tiginor® EZ is administered concomitantly with drugs that may decrease the levels or activity of endogenous steroid hormones, such as ketoconazole, spironolactone and cimetidine.

Drug Interactions

The risk of myopathy during treatment with statins is increased with concurrent administration of fibric acid derivatives, lipid-modifying doses of niacin, cyclosporine, or strong CYP3A4 inhibitors (e.g., clarithromycin, HIV protease inhibitors, and itraconazole). The coadministration of Tiginor® EZ with cyclosporine should be avoided. Due to an increased risk of myopathy/rhabdomyolysis when HMG-CoA reductase inhibitors are coadministered with gemfibrozil, concomitant administration of Tiginor® EZ with gemfibrozil should be avoided. The risk of skeletal muscle effects may be enhanced when Tiginor® EZ is used in combination with niacin. Patients taking digoxin should be monitored appropriately. The increase in AUC values for norethindrone and ethinyl estradiol should be considered when selecting an oral contraceptive for a woman taking Tiginor® EZ. Caution should be exercised when prescribing Tiginor® EZ with colchicine. If Tiginor® EZ is added to warfarin, a coumarin anticoagulant, the International Normalized Ratio (INR) should be appropriately monitored.

Overdosage

No specific treatment of overdosage with Tiginor® EZ can be recommended. In the event of an overdose, the patient should be treated symptomatically, and supportive measures instituted as required.

Storage

Do not store above 30° C. Keep away from light and out of the reach of children.

Commercial Pack

Tiginor® EZ 10/10 tablet: Each box contains 3 blister strips of 10 tablets.

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Manufactured by

 **Incepta Pharmaceuticals Ltd**

Savar, Dhaka, Bangladesh

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