Anzitor® *EZ*

Atorvastatin & Ezetimibe

COMPOSITION: Anzitor® *EZ* 10/10: Each Film coated tablet contains Atorvastatin 10 mg (as Atorvastatin Calcium Trihydrate Ph. Eur.) and Ezetimibe USP 10 mg.
Anzitor® *EZ* 20/10: Each Film coated tablet contains Atorvastatin 20 mg (as Atorvastatin Calcium Trihydrate Ph. Eur.) and Ezetimibe USP 10 mg.

PHARMACOLOGY: *Atorvastatin:* Atorvastatin lowers plasma cholesterol and lipoprotein levels by inhibiting HMG-CoA reductase and cholesterol synthesis in the liver and by increasing the number of hepatic LDL receptors on the cell-surface to enhance uptake and catabolism of LDL; Atorvastatin reduces LDL production and the number of LDL particles. *Ezetimibe:* Ezetimibe reduces blood cholesterol by inhibiting the absorption of cholesterol by the small intestine. The molecular target of Ezetimibe has been shown to be the sterol transporter, which is involved in the intestinal uptake of cholesterol and phytosterols.

INDICATIONS: *Primary Hyperlipidemia:* **Anzitor® *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:* **Anzitor® *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 dosage range of **Anzitor® *EZ*** is 10/10 mg/day to 80/10 mg/day. The recommended starting dose of **Anzitor® *EZ*** is 10/10 mg/day or 20/10 mg/day. **Anzitor® *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/day. After initiation and/or upon titration of **Anzitor® *EZ***, lipid levels should be analyzed within 2 or more weeks and dosage adjusted accordingly. Patients should swallow **Anzitor® *EZ*** tablet whole. Tablets should not be crushed, dissolved, or chewed. The dosage of **Anzitor® *EZ*** in patients with homozygous familial hypercholesterolemia is 10/40 mg/day or 10/80 mg/day. **Anzitor® *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.

CONTRAINDICATIONS: Active liver disease or unexplained persistent elevations of hepatic transaminase levels. Hypersensitivity to any component of **Anzitor® *EZ*** .

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

PRECAUTIONS: *Skeletal muscle effects (e.g., myopathy and rhabdomyolysis):* Risks increase with higher doses and concomitant use of certain CYP3A4 inhibitors, fibric acid derivatives and cyclosporine. Predisposing factors include advanced age (>65), uncontrolled hypothyroidism and renal impairment. Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported. *Liver enzyme abnormalities:* Persistent elevations in hepatic transaminase can occur. Check liver enzyme tests before initiating therapy and as clinically indicated thereafter.

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 co-administration with cyclosporine should be avoided. Due to an increased risk of myopathy/rhabdomyolysis when HMG-CoA reductase inhibitors are co-administered with gemfibrozil, concomitant administration with gemfibrozil should be avoided. The risk of skeletal muscle effects may be enhanced when 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. Caution should be exercised when prescribing with colchicine. If added to warfarin, a coumarin anticoagulant, the International Normalized Ratio (INR) should be appropriately monitored.

USE IN SPECIAL POPULATION: *Pregnancy:* **Anzitor® *EZ*** is contraindicated in women who are or may become pregnant. *Lactation:* Because of the potential for adverse reactions in nursing infants, women taking **Anzitor® *EZ*** should not breast-feed. *Pediatric Use:* Safety and effectiveness have not been established in pediatric patients. *Geriatric Use:* No dosage adjustment is necessary. *Patients with Hepatic Impairment:* Contraindicated in patients with active liver disease or unexplained persistent elevations in hepatic transaminase levels. *Patients with Renal Impairment:* A history of renal impairment may be a risk factor for statin-associated myopathy. These patients need closer monitoring for skeletal muscle effects. In patients with renal impairment, no dosage adjustment is necessary.

STORAGE: Store below 30° C temperature. Keep all medicine out of the reach of children.

HOW SUPPLIED : Anzitor® *EZ* 10/10: Each box contains 30 tablets in Alu-Alu blister pack.
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Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH