Lipicon® EZ

Atorvastatin Calcium USP and Ezetimibe USP
Film Coated Tablet

DESCRIPTION

Lipicon® EZ is a combined preparation of Atorvastatin, a 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitor and Ezetimibe, a selective inhibitor of intestinal cholesterol and related phytosterol absorption. Plasma cholesterol is derived from intestinal absorption and endogenous synthesis. 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, Niemann-Pick C1-Like 1 (NPC1L1), which is involved in the intestinal uptake of cholesterol and phytosterols. Ezetimibe does not inhibit cholesterol synthesis in the liver or increase bile acid excretion. Ezetimibe localizes at the brush border of the small intestine and inhibits the absorption of cholesterol, leading to a decrease in the delivery of intestinal cholesterol to the liver. This causes a reduction of hepatic cholesterol stores and an increase in clearance of cholesterol from the blood; this distinct mechanism is complementary to that of statins.

INDICATIONS

- Reduce elevated total-C, LDL-C, Apo B, TG, and non-HDL-C, and to increase HDL-C in patients with primary (heterozygous familial and non-familial) hyperlipidemia or mixed hyperlipidemia.

- Reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), as an adjunct to other lipid-lowering treatments.

DOSAGE AND ADMINISTRATION

- Dosage range is 10/10 mg/day through 80/10 mg/day.
- Recommended starting dose is 10/10 mg/day or 20/10 mg/day.
- Recommended starting dose is 40/10 mg/day for patients requiring a >55% reduction in LDL-C.
- Dosing of Atorvastatin & Ezetimibe should occur either ≥2 hours before or ≥4 hours after administration of a bile acid sequestrant.

CONTRAINDICATIONS

- Active liver disease or unexplained persistent elevations of hepatic transaminase levels.
- Hypersensitivity to any component of Atorvastatin & Ezetimibe.
- Women who are pregnant or may become pregnant
- Nursing mothers.

SIDE EFFECTS

- Increased ALT • Increased AST • Musculoskeletal pain

PRECAUTION AND WARNING

Patients should be advised to report promptly any unexplained and/or persistent muscle pain, tenderness or weakness. Atorvastatin & Ezetimibe should be discontinued immediately if myopathy is diagnosed or suspected.

Persistent elevations in hepatic transaminase can occur. Check liver enzyme tests before initiating therapy and as clinically indicated thereafter.

USE IN SPECIAL POPULATION

Pregnancy: Pregnancy category X: Atorvastatin & Ezetimibe is contraindicated in women who are or may become pregnant. There are no adequate and well-controlled studies of Atorvastatin & Ezetimibe use during pregnancy. There have been rare reports of congenital anomalies following intrauterine exposure to statins.

Lactation: It is not known whether atorvastatin is excreted in human milk, but a small amount of another drug in this class does pass into breast milk. Because of the potential for adverse reactions in nursing infants, women taking Atorvastatin & Ezetimibe should not breast-feed.

PHARMACEUTICAL PRECAUTION

Do not store above 25 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Lipicon® EZ 10/10 Tablet:

Box containing 2 strips of 10 tablets each. Each film-coated tablet contains Atorvastatin Calcium USP equivalent to Atorvastatin 10 mg and Ezetimibe USP 10 mg.

Lipicon® EZ 20/10 tablet:

Box containing 1 strip of 10 tablets. Each film-coated tablet contains Atorvastatin Calcium USP equivalent to Atorvastatin 20 mg and Ezetimibe USP 10 mg.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH

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