Pivalo™

Pitavastatin

PRESENTATION
Pivalo™2: Each film coated tablet contains Pitavastatin Calcium INN equivalent to Pitavastatin 2 mg.

Pivalo™4: Each film coated tablet contains Pitavastatin Calcium INN equivalent to Pitavastatin 4 mg.

PHARMACOLOGY
Pitavastatin lowers plasma cholesterol and lipoprotein levels by inhibiting HMG-CoA reductase and cholesterol synthesis in the liver and increases the number of hepatic LDL receptors on the cell surface for enhanced uptake and catabolism of LDL.

PHARMACOKINETICS
Absorption: Pitavastatin peak plasma concentrations are achieved about 1 hour after oral administration. The absolute bioavailability of Pitavastatin is 51%. Administration of Pitavastatin with a high fat meal (50% fat content) decreases Pitavastatin Cmax by 43% but does not significantly reduce Pitavastatin AUC. The Cmax and AUC of Pitavastatin did not differ following evening or morning drug administration.

Distribution: Pitavastatin is more than 99% protein bound in human plasma, mainly to albumin and alpha-1 acid glycoprotein and the mean volume of distribution is approximately 148 L.

Metabolism: Pitavastatin is marginally metabolized by CYP2C9 and to a lesser extent by CYP2C8.

Excretion: The mean plasma elimination half-life is approximately 12 hours.

INDICATION
Pitavastatin is indicated as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG) and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia.

DOSAGE & ADMINISTRATION
The dose range for Pitavastatin is 1 to 4 mg orally once daily at any time of the day with or without food. The recommended starting dose is 2 mg and the maximum dose is 4 mg. After initiation or upon titration of Pitavastatin, lipid levels should be analyzed after 4 weeks and the dosage adjusted accordingly.

Dosage in Patients with Renal Impairment:
Patients with moderate renal impairment and end–stage renal disease receiving hemodialysis should receive a starting dose of Pitavastatin 1 mg once daily and a maximum dose of Pitavastatin 2 mg once daily. Pitavastatin should not be used in patients with severe renal impairment.

CONTRAINDICATION
Patients with a known hypersensitivity to any component of this product. Hypersensitivity reactions including rash, pruritus and urticaria have been reported with Pitavastatin. Patients with active liver disease which may include unexplained persistent elevations of hepatic transaminase levels.

USE IN PREGNANCY AND LACTATION
Pregnancy Category X. Pitavastatin is contraindicated in women who are or may become pregnant. It is not known whether Pitavastatin is excreted in human milk, however, it has been shown that a small amount of another drug in this class passes into human milk.

DRUG INTERACTION
Cyclosporine: Co-administration of cyclosporine with Pitavastatin is contraindicated.

Erythromycin: Erythromycin significantly increased Pitavastatin exposure. In patients taking erythromycin, a dose of Pitavastatin 1 mg once daily should not be exceeded.

Rifampin: Rifampin significantly increased Pitavastatin exposure. In patients taking rifampin, a dose of Pitavastatin 2 mg once daily should not be exceeded.

Fibrates: Pitavastatin should be administered with caution when used concomitantly with gemfibrozil or other fibrates.

Warfarin: Pitavastatin had no significant pharmacokinetic interaction with warfarin.

SIDE EFFECT
Rhabdomyolysis, myopathy and Liver enzyme abnormalities.

OVERDOSE
There is no known specific treatment in the event of overdose of Pitavastatin. In the event of overdose, the patient should be treated symptomatically and supportive measures instituted as required. Hemodialysis is unlikely to be of benefit due to high protein binding ratio of Pitavastatin.

PRECAUTION
Pitavastatin should be prescribed with caution in patients with predisposing factors for myopathy. These factors include advanced age (>65 years), renal impairment, and inadequately treated hypothyroidism. Increase in serum transaminases have been reported with HMG-CoA reductase inhibitors, including Pitavastatin. In most cases, the elevations were transient and resolved or improved on continued therapy or after a brief interruption in therapy.

STORAGE
Store in a cool and dry place, protect from light & moisture . Keep out of the reach of children.

HOW SUPPLIED
Pivalo™ 2: Each box contains 30 tablets in blister pack.
Pivalo™ 4: Each box contains 20 tablets in blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
Pabna, Bangladesh