QAZZO

COMPOSITION:

Qazzo 5mg tablets
Each tablet contains:
Rosuvastatin (as Calcium) U.S.P 5mg
Qazzo 10mg tablets
Each tablet contains:
Rosuvastatin (as Calcium) U.S.P 10mg
Qazzo 20mg tablets
Each tablet contains:
Rosuvastatin (as Calcium) U.S.P 20mg
Product conforms to the U.S.P Specifications.

DESCRIPTION:

Rosuvastatin (Qazzo) is a synthetic lipid lowering agent for oral administration. The chemical name for Rosuvastatin (as Calcium) is bis[(e)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl) amino] pyrimidin-5-yl](3r,5s)-3,5-dihydroxyhept-6-enoic acid] calcium salt with the empirical formula for Rosuvastatin (as Calcium) is (C22H27FN3O6S)2Ca and the molecular weight is 1001.14. Rosuvastatin (as Calcium) is a white amorphous powder that is sparingly soluble in water and methanol and slightly soluble in ethanol. Rosuvastatin (as Calcium) is a hydrophilic compound with a partition coefficient (Octanol/Water) of 0.13 at pH of 7.0.

INDICATIONS:

Hyperlipidemia and Mixed Dyslipidemia:
Rosuvastatin (Qazzo) is indicated as adjunctive therapy to diet to reduce elevated Total-C, LDL-C, ApoB, non HDL-C and Triglycerides and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia, lipid altering agents should be used in addition to a diet restricted in saturated fat and cholesterol when response to diet and non pharmacological interventions alone has been inadequate.
Hypertriglyceridemia:
Rosuvastatin (Qazzo) is indicated as adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia.
Primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia):
Rosuvastatin (Qazzo) is indicated as an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (type III hyperlipoproteinemia).
Homozygous Familial Hypercholesterolemia:
Rosuvastatin (Qazzo) is indicated as adjunctive therapy to other lipid lowering treatments (e.g. LDL apheresis) or alone if such treatments are unavailable to reduce LDL-C, Total-C and ApoB in adult patients with homozygous familial hypercholesterolemia.
Slowing of the Progression of Atherosclerosis:
Rosuvastatin (Qazzo) is indicated as adjunctive therapy to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels.
Limitations of Use:
The effect of Rosuvastatin (Qazzo) on cardiovascular morbidity and mortality has not been determined. Rosuvastatin (Qazzo) has not been studied in Fredrickson type I and V dyslipidemias.

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DOSAGE AND ADMINISTRATION:

The Dose Range for Rosuvastatin (Qazzo) is 5 to 40mg orally once daily.
Rosuvastatin (Qazzo) can be administered as a single dose at any time of day, with or without food.
When initiating Rosuvastatin (Qazzo) therapy or switching from another HMG-COA reductase inhibitor therapy, the appropriate Rosuvastatin (Qazzo) starting dose should first be utilized and only then titrated according to the patient's response and individualized goal of therapy. The 40mg dose of Rosuvastatin (Qazzo) should be used only for those patients who have not achieved their LDL-C goal utilizing the 20mg dose.
Hyperlipidemia, Mixed Dyslipidemia, Hypertriglyceridemia, Primary Dysbetalipoproteinemia (Type III Hyperlipoproteinemia) and slowing of the progression of Atherosclerosis.
The recommended starting dose of Rosuvastatin (Qazzo) is 10mg once daily. For patients with marked hyperlipidemia (LDL-C > 190 mg/dl) and aggressive lipid targets, a 20mg starting dose may be considered. After initiation or upon titration of Rosuvastatin (Qazzo), lipid levels should be analyzed within 2 to 4 weeks and the dosage adjusted accordingly. Homozygous Familial Hypercholesterolemia the recommended starting dose of Rosuvastatin (Qazzo) is 20mg once daily. Response to therapy should be estimated from Preapheresis LDL-C levels.

CONTRAINDICATIONS:

Rosuvastatin (Qazzo) is contraindicated in the following conditions:
Patients with a known hypersensitivity to any component of this product. Hypersensitivity reactions including rash, pruritus, urticaria and angioedema have been reported with Rosuvastatin (Qazzo).
Patients with active liver disease, which may include unexplained persistent elevations of hepatic transaminase levels.

USE IN PREGNANCY & LACTATION:

Pregnancy: Women who are pregnant or may become pregnant: because HMG-COA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol. Rosuvastatin (Qazzo) may cause fetal harm when administered to pregnant women. Additionally, there is no apparent benefit to therapy during pregnancy and safety in pregnant women has not been established. If the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus and the lack of known clinical benefit with continued use during pregnancy.
Lactation: Because another drug in this class passes into breast milk and because HMG-COA reductase inhibitors have the potential to cause serious adverse reactions in nursing infants, women who require Rosuvastatin (Qazzo) treatment should be advised not to nurse their infants.

ADVERSE DRUG REACTIONS:

The Following are the serious adverse reactions;
Rhabdomyolysis with myoglobinuria and acute renal failure and myopathy (including myositis)
Liver enzyme abnormalities
In the Rosuvastatin (Qazzo) controlled clinical trials database (placebo or active controlled) of patients with a mean treatment duration of 15 weeks, 1.4% of patients discontinued due to adverse reactions. The most common adverse reactions that led to treatment discontinuation were:
Myalgia

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Abdominal pain
Nausea
The most commonly reported adverse reactions (incidence > 2%) in the Rosuvastatin (Qazzo) controlled clinical trial database of patients were:
Headache
Asthenia
Myalgia
Nausea
Abdominal pain

OVER DOSAGE:

There is no specific treatment in the event of overdose. In the event of overdose, the patient should be treated symptomatically and supportive measures instituted as required. Hemodialysis does not significantly enhance clearance of Rosuvastatin.

INSTRUCTIONS:

Store in a cool and dry place below 25°C.
Protect from light, heat and moisture.
Keep out of reach of children.

PRESENTATION:

Qazzo 5mg tablets are available in blister pack of 30's
Qazzo 10mg tablets are available in blister pack of 10's
Qazzo 10mg tablets are available in blister pack of 20's
Qazzo 20mg tablets are available in blister pack of 10's