ROSUVASTATIN

Class: Antilipemic Agent, HMG-CoA Reductase Inhibitor

Indications: **Treatment of dyslipidemias:**

Used with dietary therapy for hyperlipidemias to reduce elevations in total cholesterol (TC), LDL-C, apolipoprotein B, nonHDL-C, and triglycerides (TG) in patients with primary hypercholesterolemia (elevations of 1 or more components are present in Fredrickson type IIa, IIb, and IV hyperlipidemias); increase HDL-C; treatment of primary dysbetalipoproteinemia (Fredrickson type III hyperlipidemia); treatment of homozygous familial hypercholesterolemia (FH); to slow progression of atherosclerosis as an adjunct to diet to lower TC and LDL-C

Heterozygous familial hypercholesterolemia (HeFH): In adolescent patients (10-17 years of age, females >1 year postmenarche) with HeFH having LDL-C >190 mg/dL or LDL >160 mg/dL with positive family history of premature cardiovascular disease (CVD), or ≥2 other CVD risk factors.

Primary prevention of cardiovascular disease: To reduce the risk of stroke, myocardial infarction, or arterial revascularization procedures in patients without clinically evident coronary heart disease or lipid abnormalities but with all of the following: 1) an increased risk of cardiovascular disease based on age ≥50 years old in men and ≥60 years old in women, 2) hsCRP ≥2 mg/L, and 3) the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease.

Secondary prevention of cardiovascular disease: To slow progression of atherosclerosis

Available dosage form in the hospital: 10MG TAB, 20MG TAB

Dosage:**Note:** Doses should be individualized according to the baseline LDL-cholesterol levels, the recommended goal of therapy, and patient response; adjustments should be made at intervals of 4 weeks or more.

-Hyperlipidemia, mixed dyslipidemia, hypertriglyceridemia, primary dysbetalipoproteinemia, slowing progression of atherosclerosis: Oral:

-Initial dose:

-General dosing: 10 mg once daily; 20 mg once daily may be used in patients with severe hyperlipidemia (LDL >190 mg/dL) and aggressive lipid targets

-Conservative dosing: Patients requiring less aggressive treatment or predisposed to myopathy (including patients of Asian descent): 5 mg once daily

Titration: After 2 weeks, may be increased by 5-10 mg once daily; dosing range: 5-40 mg daily (maximum dose: 40 mg once daily).

Note: The 40 mg dose should be reserved for patients who have not achieved goal cholesterol levels on a dose of 20 mg daily, including patients switched from another HMG-CoA reductase inhibitor.

-Homozygous familial hypercholesterolemia (FH): Oral: Initial: 20 mg once daily (maximum dose: 40 mg daily).

-Dosage adjustment with concomitant medications: Oral:

-Cyclosporine: Rosuvastatin dose should not exceed 5 mg once daily

-Gemfibrozil: Avoid concurrent use; if unable to avoid concurrent use, initiate rosuvastatin at 5 mg once daily; dose should not exceed 10 mg once daily

-Atazanavir/ritonavir or lopinavir/ritonavir: Initiate rosuvastatin at 5 mg once daily; dose should not exceed 10 mg once daily.

-Canadian labeling:

-Cyclosporine: Concomitant use is contraindicated

-Gemfibrozil: Rosuvastatin dose should not exceed 20 mg daily

-Dosage adjustment for hematuria and/or persistent, unexplained proteinuria while on 40 mg daily: Reduce dose and evaluate causes.

Renal Impairment:

Mild-to-moderate impairment: No dosage adjustment required.

Cl_{cr} <30 mL/minute/1.73 m^2: Initial: 5 mg once daily; do not exceed 10 mg once daily

Hepatic Impairment:

Active hepatic disease, including unexplained persistent transaminase elevations: Use is contraindicated.

Canadian labeling:

-Active hepatic disease or unexplained persistent transaminase >3 x ULN: Use is contraindicated.

-Mild-to-moderate impairment: No dosage adjustment required.

-Severe impairment: Initial: 5 mg daily; do not exceed 20 mg once daily.

Common side effect: >10%: Neuromuscular & skeletal: Myalgia (3% to 13%)

2% to 10%:Central nervous system: Headache (6%), dizziness (4%)

Gastrointestinal: Nausea (3%), abdominal pain (2%), constipation (2%)

Hepatic: ALT increased (2%; >3 times ULN)

Neuromuscular & skeletal: Arthralgia (4% to 10%), CPK increased (3%; >10 x ULN: Children 3%), weakness (3%)

Pregnancy Risk Factor: X