rosuvastatin (roe-soo-va-sta-tin)

Classification
Therapeutic: Lipid-lowering agents
Pharmacologic: HMG-CoA reductase inhibitors (statins)

Pregnancy Category X

Indications
Adjunctive management of primary hypercholesterolemia and mixed dyslipidemias. Adjunctive management of primary hypertriglyceridemia. Homozygous familial hypercholesterolemia. Slows the progression of atherosclerosis as adjunct to diet. Adjunctive therapy to diet and exercise for the reduction of LDL cholesterol in children 10–17 yrs with heterozygous familial hypercholesterolemia if diet therapy fails (LDL cholesterol remains >190 mg/dL or remains >160 mg/dL with family history of premature cardiovascular disease or ≥2 risk factors for cardiovascular disease); may be used alone or in combination with statin. Primary prevention of cardiovascular disease (reduces risk of stroke, myocardial infarction, and revascularization) in patients without clinically evident coronary heart disease but with an increased risk of cardiovascular disease because of age (<50 yr for men; <60 yr for women), hsCRP ≥2 mg/L, and the presence of ≥1 risk factor for cardiovascular disease (hypertension, low HDL-C, smoking, or premature family history of coronary heart disease).

Action
Inhibits 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase, an enzyme which is responsible for catalyzing an early step in the synthesis of cholesterol. Therapeutic Effects: Lowering of total and LDL cholesterol and triglycerides. Slightly increases HDL cholesterol. Slows the progression of coronary atherosclerosis.

Pharmacokinetics
Absorption: 20% absorbed following oral administration.
Distribution: Unknown.
Metabolism and Excretion: 10% metabolized, 90% excreted unchanged in feces.

Half-life: 19 hr

TIME/ACTION PROFILE (effect on lipids)

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<th>ROUTE</th>
<th>ONSET</th>
<th>PEAK</th>
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<td>PO</td>
<td>unknown</td>
<td>2–4 wk</td>
<td>unknown</td>
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Contraindications/Precautions
Contraindicated in: Hypersensitivity; Active liver disease or unexplained persistent elevations in AST & ALT; OB, Lactation: Pregnancy or lactation.

Use Cautiously in: History of liver disease; Alcoholism; Renal impairment; Patients with Asian ancestry (may have q blood levels and q risk of rhabdomyolysis); Concurrent use of gemfibrozil, azole antifungals, protease inhibitors, niacin, cyclosporine, amiodarone, or verapamil (higher risk of myopathy/rhabdomyolysis); OB: Women of childbearing age; Pedi: Safety not established.

Adverse Reactions/Side Effects
CNS: amnesia, confusion, memory loss, weakness.
GI: abdominal pain, constipation, drug-induced hepatitis, liver function tests, nausea.
Derm: rash.
Endo: hyperglycemia.
Hemat: thrombocytopenia.
Metab: RHABDOMYOLYSIS, immune-mediated necrotizing myopathy, myalgia.

Interactions
Drug-Drug: Antacids p absorption (administer 2 hr after rosuvastatin). Risk of myopathy when used with cyclosporine, lopinavir/ritonavir, atazanavir/ritonavir, colchicine, fibrates, or large doses of niacin; concurrent use of gemfibrozil should be avoided, if possible; use c doses with cyclosporine, lopinavir/ritonavir, and atazanavir/ritonavir. Levels of norgestrel and ethinyl estradiol may risk of bleeding with warfarin; monitor INR.

Route/Dosage
PO (Adults): 10 mg once daily initially (range 5–20 mg initially). (20 mg initial dose may be considered for patients with LDL-C >190 mg/dL or homozygous familial hypercholesterolemia); dose may be adjusted at 2–4 wk intervals, some patients may require up to 40 mg/day, however this dose is associated with q risk of rhabdomyolysis. Patients with renal anemia—initial dose should be ≤5 mg. Concomitant cyclosporine therapy—Dose should not exceed 5 mg/day. Concomitant lopinavir/ritonavir or atazanavir/ritonavir therapy—Dose should not exceed 10 mg/day;
Concurrent gemfibrozil therapy—Dose should not exceed 10 mg/day (avoid if possible).

PO (Children 10–17 yr): 5–20 mg once daily.

Renal Impairment

PO (Adults): CCr <30 mL/min—5 mg once daily initially, may be 7 to 10 mg/day.

NURSING IMPLICATIONS

Assessment

● Obtain a diet history, especially with regard to fat consumption.

● Lab Test Considerations: Evaluate serum cholesterol and triglyceride levels before initiating, after 2–4 wk of therapy, and periodically thereafter.

● Monitor liver function tests before initiation of therapy and as clinically indicated. If symptoms of serum liver injury, hepatic fibrosis, or jaundice occur, discontinue rosvustatin and do not restart. May also cause ↑ alkaline phosphatase, γ-glutamyl transpeptidase, and bilirubin levels.

● If patient develops muscle tenderness during therapy, CK levels should be monitored. If CK levels are markedly ↑ or myopathy occurs, discontinue therapy.

● May cause proteinuria and microscopic hematuria; if persistent, may require dose reduction.

Potential Nursing Diagnoses

Noncompliance (Patient/Family Teaching)

Implementation

● PO: Administer once daily without regard to food. Swallow tablets whole; do not crush, break, or chew.

● If magnesium or aluminum-containing antacids are used concurrently, administer antacid at least 2 hr after rosuvastatin.

● Avoid grapefruit and grapefruit juice during therapy; may increase risk of toxicity.

● Advise patient to take medication as directed, notice skip doses or double up on missed doses. Take missed doses as soon as remembered but not within 12 hr of next dose. Medication helps control but does not cure elevated serum cholesterol levels.

Patient/Family Teaching

● Advise patient to notify health care professional if unexplained muscle pain, tenderness, or weakness occurs, especially if accompanied by fever or malaise.

● Advise patient to take magnesium or aluminum-containing antacids, if needed, at least 2 hr after rosuvastatin.

● Advise female patients to notify health care professional promptly if pregnancy is planned or suspected.

● Advise patient to notify health care professional if all Rx or OTC medications, vitamins, or herbal products being taken and consult health care professional before taking any new medications.

● Advise patient to notify health care professional of medication regimen before treatment or surgery.

● Instruct patient to notify health care professional if pregnancy is planned or suspected or if she is breast feeding.

● Advise patient to notify health care professional if unexplained muscle pain, tenderness, or weakness occurs, especially if accompanied by fever or malaise.

● Advise patient to take magnesium or aluminum-containing antacids, if needed, at least 2 hr after rosuvastatin.

● Instruct female patient to inform health care professional if pregnancy is planned or suspected or if she is breast feeding.

● Emphasize the importance of follow-up exams to determine effectiveness and to monitor for side effects.

Evaluation/Desired Outcomes

● Decrease in LDL, total cholesterol levels.

● Increase in HDL cholesterol levels.

● Decrease in triglyceride levels.

● Slowing of the progression of coronary artery disease.

Why was this drug prescribed for your patient?