Zocor (simvastatin) - Drug Summary

Merck Sharp & Dohme Corp.

Related Drug Information ▼

Zocor
(simvastatin)

THERAPEUTIC CLASS

HMG-CoA reductase inhibitor (statin)

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Hyperlipidemia

Initial: 10mg or 20mg qpm
Usual Range: 5-40mg/day

High Risk for Coronary Heart Disease Events:
Initial: 40mg/day

Lipid determinations should be performed after 4 weeks of therapy and periodically thereafter

Homozygous Familial Hypercholesterolemia

40mg/day qpm

Lipid determinations should be performed after 4 weeks of therapy and periodically thereafter

PEDIATRIC DOSAGE & INDICATIONS

Heterozygous Familial Hypercholesterolemia

10-17 Years (At Least 1 Year Postmenarche):
Initial: 10mg qpm
Range: 10-40mg/day
Titrate: Adjust at ≥4-week intervals
Max: 40mg/day

DOSING CONSIDERATIONS

Concomitant Medications
Verapamil, Diltiazem, or Dronedarone:
Max: 10mg/day

Amiodarone, Amlodipine, or Ranolazine:
Max: 20mg/day

Lomitapide:
Homozygous Familial Hypercholesterolemia:
Reduce dose by 50% if initiating lomitapide
Max: 20mg/day (or 40mg/day for patients who have previously taken simvastatin 80mg/day chronically [eg, ≥12 months] w/o evidence of muscle toxicity)

Niacin-Containing Products:
Chinese Patients Taking Lipid-Modifying Doses (≥1g/day Niacin):
Caution w/ doses >20mg/day; do not give 80mg dose

Renal Impairment
Severe:
Initial: 5mg/day; use caution and monitor closely

Other Important Considerations
Restricted Dosing:

Use 80mg dose only in patients who have been taking simvastatin 80mg chronically (eg, ≥12 months) w/o evidence of muscle toxicity

If currently tolerating 80mg dose and needs to be initiated on a drug that is contraindicated or is associated w/ a dose cap for simvastatin, switch to an alternative statin w/ less potential for drug-drug interaction

In patients unable to achieve LDL goal utilizing the 40mg dose, place on alternative LDL-lowering treatment that provides greater LDL lowering; do not titrate therapy to 80mg dose

ADMINISTRATION

Oral route

HOW SUPPLIED

Tab: 5mg, 10mg, 20mg, 40mg, 80mg

CONTRAINDICATIONS

Concomitant administration of strong CYP3A4 inhibitors (eg, itraconazole, ketoconazole, posaconazole, voriconazole, HIV protease inhibitors, boceprevir, telaprevir, erythromycin, clarithromycin, telithromycin, nefazodone, cobicistat-containing products), gemfibrozil, cyclosporine, or danazol. Active liver disease, which may include unexplained persistent elevations in hepatic transaminases, women who are or may become pregnant, and nursing mothers.

WARNINGS/PRECAUTIONS

Myopathy (including immune-mediated necrotizing myopathy [IMNM]) and rhabdomyolysis reported; predisposing factors include advanced age (≥65 yrs of age), female gender, uncontrolled hypothyroidism, and renal impairment. Risk of myopathy, including rhabdomyolysis, is dose related and greater w/ 80mg doses. D/C if markedly elevated CPK levels occur or myopathy is diagnosed/suspected, and temporarily withhold in any patient experiencing an acute or serious condition predisposing to development of renal failure secondary to rhabdomyolysis. Persistent increases in serum transaminases reported. Fatal and nonfatal hepatic failure (rare) reported; promptly interrupt therapy if serious liver injury w/ clinical symptoms and/or hyperbilirubinemia or jaundice occurs and do not restart if no alternate etiology found. Increases in HbA1c and FPG levels reported. Caution w/ substantial alcohol consumption, history of liver disease, and in the elderly.

ADVERSE REACTIONS

Abdominal pain, headache, myalgia, constipation, nausea, atrial fibrillation, gastritis, diabetes mellitus, insomnia, vertigo, bronchitis, eczema, URTI, UTI(s).

DRUG INTERACTIONS

See Contraindications and Dosing Considerations. Due to the risk of myopathy/rhabdomyolysis, avoid grapefruit juice and caution w/ fibrates, lipid-modifying doses (≥1g/day) of niacin, colchicine, verapamil, diltiazem, dronedarone, lomitapide, amiodarone, amlodipine, and ranolazine. May slightly elevate digoxin concentrations; monitor patients taking digoxin when therapy is initiated. May potentiate effect of coumarin anticoagulants; determine PT before initiation and frequently during therapy.

PREGNANCY AND LACTATION

Category X, not for use in nursing.

MECHANISM OF ACTION

HMG-CoA reductase inhibitor; specific inhibitor of HMG-CoA reductase, the enzyme that catalyzes the conversion of HMG-CoA to mevalonate, an early and rate-limiting step in the biosynthetic pathway for cholesterol. Reduces VLDL and TG and increases HDL.

PHARMACOKINETICS

Absorption: T_{max}=1.3-2.4 hrs. **Distribution:** Plasma protein binding (95%). **Metabolism:** Liver (extensive 1st pass), by hydrolysis via CYP3A4; β-hydroxyacid, 6'-hydroxy, 6'-hydroxymethyl, and 6'-exomethylene derivatives (major active metabolites). **Elimination:** Feces (60%), urine (13%).

ASSESSMENT

Assess for history of or active liver disease, unexplained persistent hepatic transaminase elevations, predisposing factors for myopathy, renal impairment, alcohol consumption, drug hypersensitivity, any other conditions where treatment is contraindicated or cautioned, pregnancy/nursing status, and possible drug interactions. Assess lipid profile and LFTs.

MONITORING

Monitor for signs/symptoms of myopathy (including IMNM), rhabdomyolysis, liver dysfunction, increases in HbA1c and FPG levels, and other adverse reactions. Monitor lipid profile, LFTs when clinically indicated, and CPK levels.

PATIENT COUNSELING

Inform of benefits/risks of therapy. Advise to adhere to the National Cholesterol Education Program recommended diet, a regular exercise program, and periodic testing of a fasting lipid panel. Inform about substances that should be avoided during therapy, and advise to discuss all medications, both prescription and OTC, w/ physician. Instruct to report promptly any unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever or if these muscle signs or symptoms persist after discontinuation, or any symptoms that may indicate liver injury. Inform patients using the 80mg dose that the risk of myopathy, including rhabdomyolysis, is increased. Instruct women of childbearing age to use an effective

method of birth control to prevent pregnancy while on therapy, to d/c therapy and call physician if pregnant, and not to breastfeed while on therapy.

STORAGE

5-30°C (41-86°F).

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