Pravachol (pravastatin sodium) - Drug Summary

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Pravastatin
(pravastatin sodium)

COMMON BRAND NAMES

Pravachol, Pravastatin

THERAPEUTIC CLASS

HMG-CoA reductase inhibitor (statin)

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Hyperlipidemia

Primary Hypercholesterolemia/Mixed Dyslipidemia/Primary Dysbetalipoproteinemia:
Initial: 40mg qd
Titrate: Increase to 80mg qd if 40mg qd does not achieve desired cholesterol levels

Maximal effect of a given dose is seen w/in 4 weeks; perform periodic lipid determinations at this time and adjust dose accordingly

Prevention of Cardiovascular Disease

Dose based on current clinical practice

PEDIATRIC DOSAGE & INDICATIONS

Heterozygous Familial Hypercholesterolemia

8-13 Years:
20mg qd
Doses >20mg have not been studied in this patient population

14-18 Years:
Initial: 40mg qd
Doses >40mg have not been studied in this patient population

DOSING CONSIDERATIONS

Concomitant Medications
Bile Acid Resins:
Administer pravastatin either 1 hr or more before or at least 4 hrs following the resin

Clarithromycin:
Limit pravastatin dose to 40mg qd

Immunosuppressive Drugs (eg, Cyclosporine):
Initial: 10mg qhs
Titrate: Increase dose cautiously
Max: 20mg/day

Renal Impairment
Significant:
Initial: 10mg qd

ADMINISTRATION

Oral route

Administer as a single dose at any time of the day, w/ or w/o food.

HOW SUPPLIED

Tab: 10mg; (Pravachol) 20mg, 40mg, 80mg

CONTRAINDICATIONS

Active liver disease or unexplained, persistent elevations of serum transaminases, women who are pregnant or may become pregnant, and nursing mothers.

WARNINGS/PRECAUTIONS

Rare cases of rhabdomyolysis w/ acute renal failure secondary to myoglobinuria reported. Increased risk of rhabdomyolysis w/ history of renal impairment; closely monitor for skeletal muscle effects. Uncomplicated myalgia and myopathy (including immune-mediated necrotizing myopathy [IMNM]) reported; d/c if markedly elevated CPK levels occur or myopathy is diagnosed/suspected. Temporarily withhold in any patient experiencing an acute or serious condition predisposing to development of renal failure secondary to rhabdomyolysis. May cause biochemical liver function abnormalities; perform LFTs prior to initiation of therapy and when clinically indicated. Caution in patients who have recent (<6 months) history of liver disease, have signs that may suggest liver disease, or are heavy alcohol users, or are elderly. Fatal and nonfatal hepatic failure reported (rare); 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. May blunt adrenal or gonadal steroid hormone production. Evaluate patients who display clinical evidence of endocrine dysfunction. Not studied in conditions where the major lipoprotein abnormality is elevation of chylomicrons (Fredrickson Types I and V). Not evaluated in patients w/ rare homozygous familial hypercholesterolemia; statins reported to be less effective because patients lack functional LDL receptors.

ADVERSE REACTIONS

Musculoskeletal pain/traumatism, URTI, chest pain, influenza, fatigue, cough, N/V, dizziness, sinus abnormality, rash, diarrhea, headache, muscle cramp, anxiety/nervousness.

DRUG INTERACTIONS

See Dosing Considerations. Increased risk of myopathy/rhabdomyolysis w/ cyclosporine, fibrates, niacin (nicotinic acid), erythromycin, clarithromycin, colchicine, and gemfibrozil; avoid w/ gemfibrozil and use caution w/ colchicine and other fibrates. Niacin may enhance risk of skeletal muscle effects; consider dose reduction of pravastatin. Caution w/ drugs that may diminish levels or activity of steroid hormones (eg, ketoconazole, spironolactone, cimetidine).

PREGNANCY AND LACTATION

Pregnancy: Category X.
Lactation: Not for use in nursing.

MECHANISM OF ACTION

HMG-CoA reductase inhibitor; inhibits 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 TGs and increases HDL.

PHARMACOKINETICS

Absorption: Absolute bioavailability (17%); T_{max}=1-1.5 hrs; (fasted) C_{max}=26.5ng/mL, AUC=59.8ng•hr/mL. **Distribution:** Plasma protein binding (50%); found in breast milk. **Metabolism:** Liver (extensive 1st pass), by isomerization and enzymatic ring hydroxylation; 3α-hydroxyisomeric metabolite (active). **Elimination:** Feces (70%), urine (20%); $T_{1/2}$=1.8 hrs.

ASSESSMENT

Assess for history of or active liver disease, unexplained persistent serum transaminase elevations, predisposing factors for myopathy, alcohol consumption, renal impairment, hypersensitivity to the drug, pregnancy/nursing status, and possible drug interactions. Obtain baseline lipid profile and LFTs.

MONITORING

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

PATIENT COUNSELING

Advise 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. Counsel females of childbearing potential on appropriate contraceptive methods while on therapy.

STORAGE

20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). Protect from light and moisture. **Pravachol:** 25°C (77°F); excursions permitted to 15-30°C (59-86°F). Protect from light and moisture.

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