Pravalip

Pravastatin Sodium BP

Composition

Pravalip 10 Tablet: Each tablet contains Pravastatin Sodium BP 10 mg.
Pravalip 20 Tablet: Each tablet contains Pravastatin Sodium BP 20 mg.

Pharmacology

Pravastatin is a reversible inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (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. In addition, pravastatin reduces VLDL and TG and increases HDL-C.

Indications

Pravalip is an HMG-CoA reductase inhibitor (statin) indicated as an adjunctive therapy to diet to:

- Reduce the risk of Myocardial Infarction (MI), revascularization, and cardiovascular mortality in hypercholesterolemic patients without clinically evident Coronary Heart Disease (CHD).
- Reduce the risk of total mortality by reducing coronary death, Myocardial Infarction (MI), revascularization, stroke/Transient Ischemic Attack (TIA), and the progression of coronary atherosclerosis in patients with clinically evident Coronary Heart Disease (CHD).
- Reduce elevated Total Cholesterol (TC), Low Density Lipoprotein Cholesterol (LDL-C), Apolipoprotein B (ApoB) and Triglycerides (TG) levels and to increase High Density Lipoprotein Cholesterol (HDL-C) in patients with primary hypercholesterolemia and mixed dyslipidemia.
- Reduce elevated serum Triglycerides (TG) levels in patients with hypertriglyceridemia.
- Treat patients with primary dysbetalipoproteinemia who are not responding to diet.
- Treat children and adolescent patients ages 8 years and older with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy.

Dosage & Administration

Adults: The recommended starting dose is 40 mg once daily. Use 80 mg dose only for patients not reaching LDL-C goal with 40 mg.
Significant renal impairment: The recommended starting dose of pravastatin is 10 mg once daily.
Children (ages 8 to 13 years): The recommended starting dose is 20 mg once daily.
Adolescents (ages 14 to 18 years): The recommended starting dose is 40 mg once daily **or as directed by the physicians**.

Contraindication

Pravastatin is contraindicated to patients with hypersensitivity to any component of this medication, active liver disease or unexplained, persistent elevation of serum transaminase.

Warnings & Precautions

Effects on skeletal muscle: Patients should be advised to promptly report to their physicians about any unexplained and/or persistent muscle pain, tenderness, or weakness. Pravastatin therapy should be discontinued if myopathy is diagnosed or suspected.
Immune-Mediated Necrotizing Myopathy (IMNM): There have been rare reports of IMNM, an autoimmune myopathy, associated with statin use. IMNM is characterized by: proximal muscle weakness and elevated serum creatine kinase, which persist despite discontinuation of statin treatment, positive anti-HMG CoA reductase antibody, muscle biopsy showing necrotizing myopathy and improvement with immunosuppressive agents.
Liver enzyme abnormalities: persistent elevations in hepatic transaminases can occur. Check liver enzyme tests before initiating therapy and as clinically indicated thereafter.

Side Effects

In short-term clinical trials, the most commonly reported side effetcs ($\geq$2% and > placebo) regardless of causality are musculoskeletal pain, nausea/vomiting, upper respiratory infection, diarrhea and headache.

Use In Pregnancy & Lactation

Pravastatin is contraindicated for use in pregnant woman because of the potential for foetal harm. As safety in pregnant women has not been established and there is no apparent benefit to therapy with Pravastatin during pregnancy, Pravastatin should be immediately discontinued as soon as pregnancy is recognized.
Pravastatin use is contraindicated during breastfeeding.

Use In Children & Adolescents

The safety and effectiveness in paediatric patients have not been established.

Drug interactions

Concomitant lipid-lowering therapies: Use with fibrates or lipid-modifying doses ($\geq$1 g/day) of niacin increases the risk of adverse skeletal muscle effects. Caution should be used when prescribing with Pravastatin Cyclosporine. Combination increases exposure. Limit pravastatin to 20 mg once daily. Clarithromycin combination increases exposure. Limit pravastatin to 40 mg once daily.

Overdosage

To date, there has been limited experience with overdosage of pravastatin. If an overdose occurs, it should be treated symptomatically with laboratory monitoring and supportive measures should be instituted as required.

Storage

Store below 30°C, protected from light & in a dry place. Keep all medicines out of the reach of children.

Packing

Pravalip 10 Tablet: Each box contains 3 X 10 tablets in Alu-Alu blister pack and an insert.
Pravalip 20 Tablet: Each box contains 3 X 10 tablets in Alu-Alu blister pack and an insert.

Manufactured by:
Navana Pharmaceuticals Ltd.
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