ROVASTIN®
Tablets

Dear patient,
Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about ROVASTIN
ROVASTIN is available as 10 mg and 20 mg tablets for oral administration containing respectively rosuvastatin calcium equivalent to 10 mg and 20 mg rosuvastatin.
Excipients are: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, indigo blue for ROVASTIN 10 mg and red erythrosine for ROVASTIN 20 mg.
ROVASTIN is a lipid-lowering agent, inhibitor of (HMG-CoA) reductase, an enzyme involved in the biosynthesis of cholesterol.
ROVASTIN is indicated in the following conditions:
- As adjunctive therapy to diet to reduce elevated Total-C, LDL-C, ApoB, non-HDL-C, and triglycerides and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia. Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol when response to diet and non pharmacological interventions alone has been inadequate.
-As adjunctive therapy to diet to treat adult patients with hypertriglyceridemia.
-As adjunctive therapy to diet to treat patients with primary dysbetalipoproteinemia.
-As adjunctive therapy to other lipid-lowering treatments or alone in patients with homozygous familial
hypercholesterolemia.
-As adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels.
- In primary Prevention of Cardiovascular Disease to reduce the risk of stroke, myocardial infarction and the risk of arterial revascularization procedures.
-In pediatric patients 10 to 17 years of age (boys and girls who are at least 1 year post-menarche) with Heterozygous Familial Hypercholesterolemia (HeFH) as adjunct to diet to reduce Total-C, LDL-C and ApoB levels.
The way to take ROVASTIN
Take ROVASTIN as directed by your doctor. Do not discontinue the treatment without consulting your physician. ROVASTIN should be used in addition to a standard cholesterol-lowering diet restricted in saturated fat and cholesterol.
ROVASTIN can be administered as a single dose at any time of day, with or without food.
-The dose range for ROVASTIN is 5 to 40 mg orally once daily. The usual starting dose is 10-20 mg.
-The usual dose range of ROVASTIN in Heterozygous Familial Hypercholesterolemia in Pediatric Patients (10 to 17 years of age) is 5-20 mg/day; the maximum recommended dose is 20 mg/day.
-The recommended starting dose in Homozygous Familial Hypercholesterolemia is 20 mg once daily.
-For patients with severe renal impairment not on hemodialysis, dosing of ROVASTIN should be started at 5 mg once daily and not exceed 10 mg once daily.
-The dose of rosuvastatin should not exceed 5 mg once daily in patients taking cyclosporine.
-Initiate therapy with rosuvastatin 5 mg once daily in patients taking gemfibrozil; the dose of rosuvastatin should not exceed 10 mg once daily.
-Initiate therapy with rosuvastatin 5 mg once daily in patients taking lopinavir and ritonavir or atazanavir and ritonavir; the dose of rosuvastatin should not exceed 10 mg once daily.
Duration of treatment

The duration of treatment will be decided by your doctor. Do not discontinue therapy without consulting your doctor; you may require continuous treatment for quite some time. You should be periodically reassessed to determine the need for maintenance therapy with an appropriate dose.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in the following conditions:

-Known hypersensitivity to any of the components

-Active liver disease or unexplained persistent elevations of serum transaminases

-Pregnancy and lactation

Precautions

-Use with caution in patients with predisposing factors for myopathy and in patients with high risk of diabetes mellitus.

-This drug therapy should be discontinued if markedly elevated creatine kinase levels occur or myopathy is diagnosed or suspected; it should also be temporarily withheld in any patient with an acute, serious condition suggestive of myopathy or predisposing to the development of renal failure secondary to rhabdomyolysis.

-Consult your doctor at the first appearance of unexplained muscle pain, tenderness or weakness during the treatment.

-It is recommended that serum lipid levels and liver function tests be performed before initiation of treatment, and if signs or symptoms of liver injury occur; this drug should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of chronic liver disease.

-In patients taking coumarin anticoagulants concomitantly with this drug, INR should be determined before starting therapy with this rosuvastatin and frequently enough during early therapy to ensure that no significant alteration of INR occurs.

-A dose reduction should be considered for patients on this drug with unexplained persistent proteinuria and/or hematuria during routine urinalysis testing.

-Patients treated with rosuvastatin who develop clinical evidence of endocrine dysfunction should be evaluated appropriately; caution should be exercised if an HMG-CoA reductase is administered to patients receiving other drugs that may decrease the levels of endogenous steroid hormones (e.g. ketoconazole, spironolactone, cimetidine).

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

Co-administration of this drug with gemfibrozil should be avoided; if used together, the dose of rosuvastatin should be adjusted.

Dosage adjustment is needed in patients taking this drug with cyclosporine and protease inhibitors given in combination with ritonavir.

Use caution with oral anticoagulants, nicacin, fenofibrate, colchicine, and drugs that may decrease the levels or activity of endogenous steroid hormones.

Antacids containing aluminum, calcium or magnesium should not be taken within the two-hour period before or after taking this drug.

Adverse reactions

The most commonly reported adverse reaction include: myalgia, asthenia, abdominal pain, nausea, headache, and constipation.

Other reported adverse reactions include: dizziness, hypersensitivity, pancreatitis, liver enzyme abnormalities, elevated glucose, thyroid function abnormalities, rhabdomyolysis with myoglobinuria and acute renal failure, myopathy, proteinuria, and hematuria.

Please inform your doctor if any adverse reaction appears or becomes bothersome.

Storage

Store at controlled room temperature (below 30°C), protected from light and humidity, beyond the reach of children.
The expiry date is printed on the pack; don’t use this medicine after this date.

Pack Presentation

ROVASTIN, Rosuvastatin 20 mg, pack of 30 tablets
ROVASTIN, Rosuvastatin 10 mg, pack of 30 tablets

Revision date: 07/2014
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