Only for the use of Medical Professionals

Rosetor®

Rosuvastatin

Description

Rosetor® is a preparation of Rosuvastatin which is a lipid lowering agent. It is a selective & competitive inhibitor of HMG-CoA reductase, the rate limiting enzyme that converts 3-hydroxy-3-methylglutaryl coenzyme A to Mevalonate, a precursor of sterols, including cholesterol. Rosuvastatin produces its lipid modifying effects in two ways. First, it increases the number of hepatic LDL receptors on the cell surface to enhance uptake and catabolism of LDL. Second, Rosuvastatin inhibits hepatic synthesis of VLDL, which reduces the total number of VLDL and LDL particles.

Indications

Rosetor® is indicated for the treatment of-

- Hyperlipidemia and mixed dyslipidemia
- Hypertriglyceridemia
- Primary prevention of cardiovascular disease such as-
  - Reduce the risk of stroke
  - Reduce the risk of myocardial infarction
  - Reduce the risk of arterial revascularization procedures
- Slowing the progression of atherosclerosis
- Primary dysbetalipoproteinemia (Type III hyperlipoproteinemia)
- Heterozygous familial hypercholesterolemia (Pediatric patients 10 to 17 years of age)
- Homozygous familial hypercholesterolemia

Dosage and administration

The dose range for **Rosetor®** is 5 to 40 mg orally once daily. The usual starting dose is 5 to 10 mg. **Rosetor®** can be administered as a single dose at any time of the day, with or without food. When initiating **Rosetor®** therapy or switching from another HMG-CoA reductase inhibitor therapy, the appropriate **Rosetor®** starting dose first be utilized and only then titrated according to the patients' response and individualized goals of therapy. After initiation or upon titration of **Rosetor®** lipid level should be analyzed within 2 to 4 weeks and the dosage adjusted accordingly.

Specific populations	Dose
Heterozygous familial hypercholesterolemia in pediatric patients (10 to 17 years of age)	• Usual dose range: 5-20 mg/day • Maximum recommended dose: 20 mg/day
Homozygous familial hypercholesterolemia	Starting dose: 20 mg/day
With cyclosporine therapy	Maximum dose: 5 mg/day
With lopinavir/ ritonavir or atazanavir/ ritonavir therapy	Maximum dose: 10 mg/day
With mild to moderate renal impairment (CLcr ≥ 30 ml/ min/ 1.73 m^2)	No dosage adjustment required
With severe renal impairment (CLcr < 30 ml/ min/ 1.73 m^2) not on hemodialysis	Starting dose: 5 mg/day Maximum dose: 10 mg/day

Patients with hepatic impairment: Rosuvastatin is contraindicated in patients with active liver disease, which may include unexplained persistent elevations of hepatic transaminase levels. Chronic alcohol liver disease is known to increase rosuvastatin exposure. Rosuvastatin should be used with caution in these patients.

Geriatric use: No overall differences in safety or effectiveness were observed between elderly and younger subjects, but greater sensitivity of some older patients cannot be ruled out. Since advanced age is a predisposing factor for myopathy, rosuvastatin should be prescribed with caution in the elderly.

Children and adolescents: Safety and effectiveness in patients 10 to 17 years of age with heterozygous familial hypercholesterolemia have been evaluated in a controlled clinical trial of 12 weeks duration followed by 40 weeks of open label exposure. There was no detectable effect of rosuvastatin on growth, weight, BMI, or sexual maturation. Doses greater than 20 mg have not been studied in this patient population. Rosuvastatin has not been studied in controlled clinical trials involving pre-pubertal patients or patients younger than 10 years of age.

Use in pregnancy and lactation

Pregnancy: Rosuvastatin is pregnancy category X drug. Rosuvastatin is contraindicated in women who are or may become pregnant.

Lactation: It is not known whether rosuvastatin is excreted in human milk, but a small amount of another drug in this class passes into breast milk. Statins have a potential to cause serious adverse reactions in nursing infants, women requiring rosuvastatin treatment should be advised not to nurse their infants.

Side effects

The most common side effects of rosuvastatin are headache, myalgia, abdominal pain, asthenia and nausea.

Contraindications

Rosuvastatin is contraindicated in patients who are hypersensitive to any component of this product or to any of its ingredients. It is also contraindicated in patients with active liver disease, which may include unexplained persistent elevations of hepatic transaminase levels.

Warnings and precautions

Caution should be exercised when anticoagulants are given in conjunction with rosuvastatin. It should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of liver disease. This drug should be prescribed with caution in patients with predisposing factors for myopathy (e.g., age 65 years, inadequately treated hypothyroidism, renal impairment).

Drug interactions

Concomitant use of rosuvastatin with some drugs like cyclosporine, gemfibrozil and other lipid lowering products, protease inhibitors and itraconazole may be resulted in increased AUC. However, no clinically relevant interactions have been observed between rosuvastatin and either fluconazole or ketoconazole. On the contrary, concomitant use of rosuvastatin with antacid or erythromycin results in decreased AUC. Adverse effects caused by simultaneous use of rosuvastatin and ezetimibe cannot be ruled out. As with other HMG-CoA reductase inhibitors, the initiation of treatment or dosage up-titration of rosuvastatin in patients treated concomitantly with vitamin K antagonists (e.g., warfarin or another coumarin anticoagulant) may result in an increase in International Normalised Ratio (INR). Discontinuation or down titration of rosuvastatin may result in a decrease in INR. In such situations, appropriate monitoring of INR is desirable.

Overdose

There is no specific treatment in the event of overdose. In the event of overdose, the patient should be treated symptomatically and supportive measures instituted as required. Liver function and creatine kinase levels should be monitored. Haemodialysis is unlikely to be of benefit.

Pharmaceutical precautions

Store in a cool (below 30°C) and dry place protected from light.

Presentation

Rosetor® 5 tablet: Each coated tablet contains Rosuvastatin Calcium BP 5.21 mg equivalent to 5 mg Rosuvastatin.
Rosetor® 10 tablet: Each coated tablet contains Rosuvastatin Calcium BP 10.42 mg equivalent to 10 mg Rosuvastatin.
Rosetor® 20 tablet: Each coated tablet contains Rosuvastatin Calcium BP 20.84 mg equivalent to 20 mg Rosuvastatin.

Package quantities

Rosetor® 5 tablet: Carton of 30 tablets in blister pack.
Rosetor® 10 tablet: Carton of 20 tablets in blister pack.
Rosetor® 20 tablet: Carton of 20 tablets in blister pack.

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ACI Limited
Godnyl, Narayanganj, Bangladesh