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RoZenon®

Rosuvastatin Calcium USP

50102

Presentation:
Rozenon 5 mg tablet: Each film coated tablet contains Rosuvastatin Calcium 5.2 mg equivalent to 5 mg Rosuvastatin
Rozenon 10 mg tablet: Each film coated tablet contains Rosuvastatin Calcium 10.4 mg equivalent to 10 mg Rosuvastatin
Rozenon 20 mg tablet: Each film coated tablet contains Rosuvastatin Calcium 20.8 mg equivalent to 20 mg Rosuvastatin

Indications:
Treatment of hypercholesterolaemia-
Adults, adolescents and children aged 6 years or older with primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia) or mixed dyslipidaemia (type IIb) as an adjunct to diet when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate.
Adults, adolescents and children aged 6 years or older with homozygous familial hypercholesterolaemia as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis) or if such treatments are not appropriate.

Prevention of cardiovascular events-
Prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.

Posology and method of administration:
Before treatment initiation the patient should be placed on a standard cholesterol-lowering diet that should continue during treatment. The dose should be individualised according to the goal of therapy and patient response.

Posology:
Treatment of hypercholesterolaemia:
The recommended start dose is 5 mg or 10 mg orally once daily in both statin naive or patients switched from another HMG-CoA reductase inhibitor. Administration of a 5 mg dose can be achieved by halving a 10 mg tablet with the breakline.
The choice of start dose should take into account the individual patient's cholesterol level and future cardiovascular risk as well as the potential risk for adverse reactions. A dose adjustment to the next dose level can be made after 4 weeks, if necessary.

Prevention of cardiovascular events:
In the cardiovascular events risk reduction study, the dose used was 20 mg daily.

Paediatric population:
Paediatric use should only be carried out by specialists.

Children and adolescents 6 to 17 years of age (Tanner Stage < II-V):

Heterozygous familial hypercholesterolaemia.
In children and adolescents with heterozygous familial hypercholesterolaemia the usual start dose is 5 mg daily.

• In children 6 to 9 years of age with heterozygous familial hypercholesterolaemia, the usual dose range is 5 10 mg orally once daily. Safety and efficacy of doses greater than 10 mg have not been studied in this population.
• In children 10 to 17 years of age with heterozygous familial hypercholesterolaemia, the usual dose range is 5-20 mg orally once daily. Safety and efficacy of doses greater than 20 mg have not been studied in this population.

Homozygous familial hypercholesterolaemia
In children 6 to 17 years of age with homozygous familial hypercholesterolaemia, the recommended maximum dose is 20 mg once daily.
A starting dose of 5 to 10 mg once daily depending on age, weight and prior statin use is advised. Titration to the maximum dose of 20 mg once daily should be conducted according to the individual response and tolerability in paediatric patients, as recommended by the paediatric treatment recommendations. Children and adolescents should be placed on standard cholesterol-lowering diet before rosuvastatin treatment initiation; this diet should be continued during rosuvastatin treatment. There is limited experience with doses other than 20 mg in this population.

Children younger than 6 years
The safety and efficacy of use in children younger than 6 years has not been studied. Therefore, rosuvastatin is not recommended for use in children younger than 6 years.

Use in the elderly:
A start dose of 5 mg is recommended in patients > 70 years. No other dose adjustment is necessary in relation to age.

Dosage in patients with renal insufficiency
No dose adjustment is necessary in patients with mild to moderate renal impairment. The recommended start dose is 5 mg in patients with moderate renal impairment (creatinine clearance < 60 ml/min). The use of rosuvastatin in patients with severe renal impairment is contraindicated for all doses.

Dosage in patients with hepatic impairment
Rosuvastatin is contraindicated in patients with active liver disease.

Race
Increased systemic exposure has been seen in Asian subjects. The recommended start dose is 5 mg for patients of Asian ancestry.

Genetic polymorphisms
Specific types of genetic polymorphisms are known that can lead to increased rosuvastatin exposure. For patients who are known to have such specific types of polymorphisms, a lower daily dose of rosuvastatin is recommended.

Dosage in patients with predisposing factors to myopathy
The recommended start dose is 5 mg in patients with predisposing factors to myopathy.

Method of administration
Rosuvastatin may be given at any time of day, with or without food.

Contraindications:
Rosuvastatin is contraindicated:
- in patients with hypersensitivity to the active substance or to any of the excipients.
- in patients with active liver disease including unexplained, persistent elevations of serum transaminases and any serum transaminase elevation exceeding 3× the upper limit of normal (ULN).
- in patients with severe renal impairment (creatinine clearance < 30 ml/min).
- in patients with myopathy.
- in patients receiving concomitant ciclosporin.
- during pregnancy and lactation and in women of childbearing potential not using appropriate contraceptive measures.

Special warnings and precautions for use:
• Renal effects
An assessment of renal function should be considered during routine follow-up of patients treated with a dose of 40 mg.
• Skeletal muscle effects
Effects on skeletal muscle e.g. myalgia, myopathy and, rarely, rhabdomyolysis have been reported in rosuvastatin-treated patients with all doses and in particular with doses > 20 mg.
• Creatine kinase measurement
Creatine kinase should not be measured following strenuous exercise or in the presence of a plausible alternative cause of Creatine kinase increase which may confound interpretation of the result. If Creatine kinase levels are significantly elevated at baseline (> 5× ULN) a confirmatory test should be carried out within 5 – 7 days. If the repeat test confirms a baseline Creatine kinase > 5× ULN, treatment should not be started.
• Liver effects
In patients with secondary hypercholesterolaemia caused by hypothyroidism or nephrotic syndrome, the underlying disease should be treated prior to initiating therapy with rosuvastatin.
• Protease inhibitors
Increased systemic exposure to rosuvastatin has been observed in subjects receiving rosuvastatin concomitantly with various protease inhibitors in combination with ritonavir. The concomitant use with certain protease inhibitors is not recommended unless the dose of rosuvastatin is adjusted.
• Interstitial lung disease
Exceptional cases of interstitial lung disease have been reported with some statins, especially with long term therapy. Presenting features can include dyspnoea, non-productive cough and deterioration in general health (fatigue, weight loss and fever). If it is suspected that a patient has developed interstitial lung disease, statin therapy should be discontinued.
• Diabetes mellitus
Some evidence suggests that statins as a class raise blood glucose and in some patients, at high risk of future diabetes, may produce a level of hyperglycaemia where formal diabetes care is appropriate. This risk, however, is outweighed by the reduction in vascular risk with statins and therefore should not be a reason for stopping statin treatment. Patients at risk (fasting glucose 5.6 to 6.9 mmol/l, BMI > 30 kg/m2, raised triglycerides, hypertension) should be monitored both clinically and biochemically according to national guidelines.
In the JUPITER study, the reported overall frequency of diabetes mellitus was 2.8% in rosuvastatin and 2.3% in placebo, mostly in patients with fasting glucose 5.6 to 6.9 mmol/l.
• Paediatric population
The evaluation of linear growth (height), weight, BMI (body mass index), and secondary characteristics of sexual maturation by Tanner staging in paediatric patients 6 to 17 years of age taking rosuvastatin is limited to a two-year period. After two years of study treatment, no effect on growth, weight, BMI or sexual maturation was detected.

Fertility, pregnancy and lactation:
Rosuvastatin is contraindicated in pregnancy and lactation.

Women of child bearing potential should use appropriate contraceptive measures. Since cholesterol and other products of cholesterol biosynthesis are essential for the development of the fetus, the potential risk from inhibition of HMG-CoA reductase outweighs the advantage of treatment during pregnancy. Animal studies provide limited evidence of reproductive toxicity. If a patient becomes pregnant during use of this product, treatment should be discontinued immediately.

Rosuvastatin is excreted in the milk of rats. There are no data with respect to excretion in milk in humans.

Effects on ability to drive and use machines:
Studies to determine the effect of rosuvastatin on the ability to drive and use machines have not been conducted. However, based on its pharmacodynamic properties, rosuvastatin is unlikely to affect this ability. When driving vehicles or operating machines, it should be taken into account that dizziness may occur during treatment.

Undesirable effects:
The adverse reactions seen with rosuvastatin are generally mild and transient. In controlled clinical trials, less than 4% of rosuvastatin-treated patients were withdrawn due to adverse reactions.

MedDRA System organ class	Frequency	Undesirable effect
Blood and lymphatic system disorders	Rare	Thrombocytopenia
Immune system disorders	Rare	Hypersensitivity reactions including angioedema
Endocrine disorders	Common	Diabetes mellitus1
Nervous system disorders	Common	Headache, Dizziness
	Very rare	Polyneuropathy, Memory loss
Gastrointestinal disorders	Common	Constipation, Nausea, Abdominal pain
Hepatobiliary disorders	Rare	Increased hepatic transaminases
	Very rare	Jaundice, Hepatitis
Skin and subcutaneous tissue disorders	Uncommon	Pruritus, Rash, Urticaria
Musculoskeletal and connective tissue disorders	Common	Myalgia
	Rare	Myopathy (including myositis) Rhabdomyolysis
	Very rare	Arthralgia
Renal and urinary disorders	Very rare	Haematuria
Reproductive system and breast disorders	Very rare	Gynaecomastia
General disorders and administration site conditions	Common	Asthenia

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 CK levels should be monitored. Haemodialysis is unlikely to be of benefit.

Storage conditions:
Store below 25°C in a dry place.

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Package quantities:
Rozenon 5 mg tablet: Box of 3 x 10 x 5 mg in Blister Packs.
Rozenon 10 mg tablet: Box of 3 x 10 x 10 mg in Blister Packs.
Rozenon 20 mg tablet: Box of 1 x 10 x 20 mg in Blister Packs.

Manufactured by:
synovia
Synovia Pharma PLC., Station Road, Tongi, Gazipur.
A Subsidiary of BEXIMCO PHARMACEUTICALS LTD.

547948

Direction Slip artwork legend

Product Name	:	RoZenon
Code number	:	547948
Dimension	:	L 11.86 x W 14.97 inches
Min. size of text	:	8 pt
Used Colors	:	Black C ■ Pantone 186 C ■