



Bharat Parenterals Limited

Registered Office & Works:
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CIN NO: U24231GJ1992PLC018237

Rostor 10-SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product:

Generic Name/INN Name:

Rosuvastatin Tablets 10 mg

Trade Name:

Rostor 10

2. Strength:

Each film coated tablet contains:

Rosuvastatin Calcium eq. to.

Rosuvastatin 10 mg

Excipients q.s.

Colour: Lake Quinoline Yellow and Titanium Dioxide

3. Pharmaceutical form:

Solid oral dosage form, Tablet

2. Qualitative and Quantitative Composition:

Each tablet contains: Rosuvastatin Calcium eq. to. Rosuvastatin 10 mg

Sr. No.	Ingredients	Specification	Standard Quantity/ Tablet (mg)	% w/w	Function
1.	Rosuvastatin Calcium eq to Rosuvastatin 10 mg	In house	10.000	3.450	Active
2.	Microcrystalline Cellulose grade 102	BP	230.000	79.310	Diluent
3.	Sodium Starch Glycollate	BP	20.000	6.896	Super -Disintegrant
4.	Purified talc	BP	10.000	3.448	Lubricant
5.	Colloidal Anhydrous Silica	BP	3.000	1.034	Glidant
6.	Magnesium stearate	BP	7.000	2.414	Lubricant
Total weight of Uncoated tablet			280.000		
7.	Elegance Coat EL-Q-01839 Yellow	In house	10.00	3.448	Colouring agent
8.	Dichloromethane	BP	112.492	-	Coating solvent
9.	Isopropyl alcohol	BP	78.984	-	Coating solvent
Total weight of Film coated tablet			290.000	100.000	

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3. Pharmaceutical form:

Dosage Form:

Solid oral dosage form, Tablet

Visual & Physical characteristics of the product:

A yellow coloured, round shape, biconvex film coated tablets.

4. Clinical particulars:

4.1 Therapeutic indications:

Rosuvastatin tablets 10 mg is indicated in

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.

4.2 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, using current consensus guidelines.

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

Treatment of hypercholesterolaemia

The recommended start dose is 5 or 10 mg orally once daily in both statin naïve or patients switched from another HMG CoA reductase inhibitors. 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.

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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.

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.

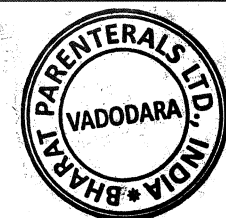
Dosage in patients with renal insufficiency

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 of <60 ml/min).

Dosage in patients with hepatic impairment

There was no increase in systemic exposure to rosuvastatin in subjects with Child-Pugh scores of 7 or below. However, increased systemic exposure has been observed in subjects with Child-Pugh scores of 8 and 9. In these patients an assessment of renal function should be

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considered. There is no experience in subjects with Child-Pugh scores above 9. 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 pre-disposing factors to myopathy

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

Concomitant therapy

Rosuvastatin is a substrate of various transporter proteins (e.g. OATP1B1 and BCRP). The risk of myopathy (including rhabdomyolysis) is increased when rosuvastatin is administered concomitantly with certain medicinal products that may increase the plasma concentration of rosuvastatin due to interactions with these transporter proteins (e.g. ciclosporin and certain protease inhibitors including combinations of ritonavir with atazanavir, lopinavir, and/or tipranavir;.

4.3 Contraindications:

Rosuvastatin is contraindicated:

- in patients with hypersensitivity to rosuvastatin or to any of the excipients, listed in section 6.1
- in patients with active liver disease including unexplained, persistent elevations of serum transaminases and any serum transaminase elevation exceeding 3 times 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. The 40 mg dose is contraindicated in patients with pre-disposing factors for myopathy/ rhabdomyolysis. Such factors include:

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- moderate renal impairment (creatinine clearance < 60 ml/min)
- hypothyroidism
- personal or family history of hereditary muscular disorders
- previous history of muscular toxicity with another HMG-CoA reductase inhibitor or fibrate
- alcohol abuse
- situations where an increase in plasma levels may occur
- Asian patients
- concomitant use of fibrates.

4.4 Special warnings and precautions for use:

Renal Effects

Proteinuria, detected by dipstick testing and mostly tubular in origin, has been observed in patients treated with higher doses of rosuvastatin, in particular 40 mg, where it was transient or intermittent in most cases. Proteinuria has not been shown to be predictive of acute or progressive renal disease. The reporting rate for serious renal events in post-marketing use is higher at the 40 mg dose. 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. Very rare cases of rhabdomyolysis have been reported with the use of ezetimibe in combination with HMG-CoA reductase inhibitors. A pharmacodynamic interaction cannot be excluded and caution should be exercised with their combined use.

As with other HMG-CoA reductase inhibitors, the reporting rate for rhabdomyolysis associated with rosuvastatin in post-marketing use is higher at the 40 mg dose.

Creatine Kinase Measurement

Creatine Kinase (CK) should not be measured following strenuous exercise or in the presence of a plausible alternative cause of CK increase which may confound interpretation of the result. If CK levels are significantly elevated at baseline (>5xULN) a confirmatory test should be carried out within 5 – 7 days. If the repeat test confirms a baseline CK>5xULN, treatment should not be started.

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