

## ROSUVASTATIN CALCIUM TABLETS 5mg, 10mg, 20mg and 40mg

S.No.	Category	Question	Answer
<b>Clinical Particulars</b>			
1	Use/Indication	What is the product indicated for?	<p>Rosuvastatin Calcium is an HMG Co-A reductase inhibitor indicated for:</p> <ul style="list-style-type: none"> <li>• adult patients with hypertriglyceridemia as an adjunct to diet</li> <li>• adult patients with primary dysbetalipoproteinemia (Type III hyperlipoproteinemia) as an adjunct to diet.</li> <li>• adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C, total-C, and ApoB</li> </ul> <p>Limitations of use: Rosuvastatin calcium tablets has not been studied in Fredrickson Type I and V dyslipidemias.</p>
2	Dosage	What is the recommended dosage?	<ul style="list-style-type: none"> <li>• Rosuvastatin Calcium tablets can be taken with or without food, at any time of day.</li> <li>• Dose range: 5 to 40 mg once daily. The usual starting dose is 10 to 20 mg once daily. Use 40 mg dose only for patients not reaching LDL-C goal with 20 mg.</li> <li>• Adult homozygous familial hypercholesterolemia (HoFH): Starting dose 20 mg/day</li> </ul>
3	Administration	How do I administer Rosuvastatin tablets?	Rosuvastatin tablets can be administered as a single dose at any time of day, with or without food. The tablet should be swallowed whole.
4	Administration	What do I do if I miss a dose?	If you miss a dose of rosuvastatin tablets, take it as soon as you remember. However, do not take 2 doses of rosuvastatin tablets within 12 hours of each other.
3	Administration	Use in Paediatric Population	Pediatric use information for patients 7 to 17 years of age is approved for AstraZeneca's CRESTOR (rosuvastatin calcium) tablets. However, due to AstraZeneca's marketing exclusivity rights, this drug product is not labeled with that pediatric information.
4	Administration	Use in Geriatric Population	No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Elderly patients are at higher risk of myopathy and rosuvastatin calcium should be prescribed with caution in the elderly.
5	Side Effects	What are the most common side effects?	The most common side effects with Rosuvastatin are: headache, muscle aches and pains, abdominal pain, weakness, and nausea. Additional side effects that have been reported with rosuvastatin tablets include memory loss and confusion.

5	Mechanism	Mechanism of Action	Rosuvastatin is a selective and competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl coenzyme A to mevalonate, a precursor of cholesterol. In vivo studies in animals and in vitro studies in cultured animal and human cells have shown rosuvastatin to have a high uptake into, and selectivity for, action in the liver, the target organ for cholesterol lowering. In in vivo and in vitro studies, 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.
6	Warning	Black Box Warning	None
7	Lactation	Use in Lactation	Advise women not to breastfeed during treatment with rosuvastatin calcium.
8	Pregnancy	Use in Pregnancy	Rosuvastatin calcium is contraindicated for use in pregnant women since safety in pregnant women has not been established and there is no apparent benefit to therapy with rosuvastatin calcium during pregnancy. Rosuvastatin calcium should be discontinued as soon as pregnancy is recognized.
9	Precautions	Is there any interaction between medication and alcohol.	Rosuvastatin calcium should be used with caution in patients who consume substantial quantities of alcohol. Tell your doctor if you drink more than 2 glasses of alcohol daily.
10	Storage	What are the storage conditions?	Store at controlled room temperature, 20-25°C (68-77°F). Protect from moisture.
11	Dispensing	How to Dispense?	As prescribed by the Physician
12	Contraindication	What are the contraindications of (medication).	<ul style="list-style-type: none"> <li>• Known hypersensitivity to product components</li> <li>• Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels</li> <li>• Pregnancy</li> <li>• Lactation</li> </ul>

#### Pharmaceutical Particulars

13	Pharmaceutical Form	How Supplied	<p>Rosuvastatin Calcium Tablets 5 mg are available as white, round shaped, biconvex, film coated tablets debossed with "R5" on one side and plain on other side. Bottle of 90 tablets NDC-72205-027-90; Bottle of 500 tablets NDC-72205-027-05; Bottle of 1000 tablets NDC-72205-027-99; Cartons of 100 (10 x 10) unit-dose tablets NDC-72205-027-06.</p> <p>Rosuvastatin Calcium Tablets 10 mg are available as Pink, round shaped, biconvex, film coated tablets debossed with "R10" on one side and plain on other side. Bottle of 90 tablets NDC-72205-003-90; Bottle of 500 tablets NDC-72205-003-05; Bottle of 1000 tablets NDC-72205-003-99; Cartons of 100 (10 x 10) unit-dose tablets NDC-72205-003-06.</p> <p>Rosuvastatin Calcium Tablets 20 mg are available as Pink, round shaped, biconvex, film coated tablets debossed with "R20" on one side and plain on other side. Bottle of 90 tablets NDC-72205-004-90; Bottle of 500 tablets NDC-72205-004-05; Bottle of 1000 tablets NDC-72205-004-99;</p>
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14	Ingredients	Active and Inactive	<p>Active Ingredient: rosuvastatin as rosuvastatin calcium</p> <p>Inactive Ingredients: crospovidone, hypromellose, lactose monohydrate, magnesium stearate, mannitol, meglumine, microcrystalline cellulose, pregelatinized starch, titanium dioxide and triacetin. Additionally, 10 mg, 20 mg and 40 mg tablets contain FD&amp;C red No. 40/allura 12 red AC aluminum lake, FD&amp;C blue No. 2/indigo carmine aluminum lake and FD&amp;C yellow No.6/sunset yellow FCF aluminum lake.</p>
15	Miscellaneous	Manufacturer and Distributor	<p>Manufactured by:  MSN Laboratories Private Limited  Mahabubnagar (Dt.)  Telangana – 509 216,  INDIA</p> <p>Distributed by:  Novadoz Pharmaceuticals LLC  Piscataway, NJ 08854-3714</p>
<b>Miscellaneous</b>			
16	Ingredients	Does it contain Gluten?	No
17	Ingredients	Does it contain alcohol?	No
18	Ingredients	Does it contain dyes?	Yes
19	Ingredients	Does it contain Lactose?	Yes, Lactose produced from milk, that has been sourced from healthy cows is used as inactive ingredient.
20	Ingredients	Does it contain Nuts?	No
21	Ingredients	Does it contain Preservatives?	No
22	Ingredients	Does it contain Soy products?	No
23	Ingredients	Does it contain peanut?	No
24	Ingredients	Does it contain any derivatives from tree nuts or	No

		any other type of nuts?	
25	Color Change	Why color of Rosuvastatin Tablets, USP 5 mg was changed? (Yellow to White)	Ingredient Tartrazine was removed from Rosuvastatin Tablets, USP 5 mg. Tablets with Tartrazine are yellow in color and without Tartrazine, are in white color. However, there are 3 batches which are manufactured with old NDC which are white in color. All future batches will be white in color with new NDC
<b>Additional Questions</b>			
26	Miscellaneous	May I know the product availability ?	Novadoz Pharma sells national wholesalers and retail chains and does not sell any medications to patients directly. Please contact retail pharmacies for the product.
27	Miscellaneous	May I know about return, refunds and reimbursement ?	Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714
28	Miscellaneous	May I know where is this product manufactured ?	Manufactured by: MSN Laboratories Private Limited Telangana – 509 216, INDIA Distributed by: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714
29	Miscellaneous	Do you have any patient's assistance program ?	As a generics medications manufacturer, MSN Laboratories Private Limited, currently does not offer a patient assistance program.
30	Miscellaneous	How do I report an adverse drug effect or reaction to Novadoz medication?	To report SUSPECTED ADVERSE REACTIONS, contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1-800-FDA-1088 or <a href="http://www.fda.gov/medwatch">www.fda.gov/medwatch</a> .
31	Miscellaneous	What ingredients are in your products?	Please see our Prescription info for a detailed view of ingredients.
32	Miscellaneous	Is there gluten in your product?	Please see our Prescription info for a detailed view of ingredients.
33	Miscellaneous	Where are your drugs manufactured?	Please refer to the package label for manufacturing location information. Manufactured by: MSN Laboratories Private Limited Telangana – 509 228, INDIA Distributed by: Novadoz Pharmaceuticals Inc. Piscataway, NJ 08854-3714
34	Miscellaneous	When is the launching date of a given product?	October 10, 2018 is the launch date for Rosuvastatin.
35	Miscellaneous	Can I purchase my medicine from Novadoz Pharma directly?	Novadoz Pharma sells only to national wholesalers and retail chains and does not sell any medications to patients directly.
36	Miscellaneous	Why does my pharmacy, that used to fill your generic formulation of a particular medicine, no longer fills my	Please check with your pharmacist or doctor to ensure that only Novadoz Pharma branded pharmaceuticals are dispensed to you at any time your prescription needs to be filled.

		prescription with Novadoz formulation?	
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