

Rosuvastatin Calcium Tablets 5mg, 10mg, 20mg

| S.No. | Category | Question | Answer |
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| Clinical Particulars | | | |
| 1 | Use/Indication | What is the product indicated for? | Rosuvastatin Calcium is an HMG Co-A reductase inhibitor for: <ul style="list-style-type: none"> • adult patients with hypertriglyceridemia as an adjunct to diet • adult patients with primary dysbetalipoproteinemia (Type III hyperlipoproteinemia) as an adjunct to diet. • adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C, total-C, and ApoB (1.5) Limitations of use: Rosuvastatin calcium tablets have not been studied in Fredrickson Type I and V dyslipidemias. |
| 2 | Dosage | What is the recommended dosage? | <ul style="list-style-type: none"> • Rosuvastatin Calcium tablets can be taken with or without food, at any time of day. • 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. • Adult homozygous familial hypercholesterolemia (HoFH): Starting dose 20 mg/day |
| 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 Pediatric 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. <i>In vivo</i> studies in animals and <i>in vitro</i> 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. <i>In vivo</i> and <i>in vitro</i> 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 | No black box warning |

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| 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"> • Known hypersensitivity to product components • Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels • Pregnancy • Lactation |
| Pharmaceutical Particulars | | | |
| 13 | Pharmaceutical Form | How is it 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; Cartons of 100 (10 x 10) unit-dose tablets NDC-72205-004-06.</p> <p>Rosuvastatin Calcium Tablets 40 mg are available as: Pink, oval shaped, biconvex, film coated tablets debossed with "R" on one side and "40" on other side. Bottle of 30 tablets NDC-72205-005-30; Bottle of 90 tablets NDC-72205-005-90; Bottle of 500 tablets NDC-72205-005-05; Bottle of 1000 tablets NDC-72205-005-99; Cartons of 100 (10 x 10) unit-dose tablets NDC-72205-005-06.</p> |

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| 14 | Ingredients | Active and Inactive ingredients | Active Ingredient: rosuvastatin as rosuvastatin calcium 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&C red No. 40/allura 12 red AC aluminum lake, FD&C blue No. 2/indigo carmine aluminum lake and FD&C yellow No.6/sunset yellow FCF aluminum lake. |
| Allergens | | | |
| 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? | No |
| 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 any other type of nuts? | No |
| Miscellaneous | | | |
| 26 | Miscellaneous | May I know the product availability? | Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products |
| 27 | Miscellaneous | May I know about return, refunds and reimbursement ? | Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500. |
| 29 | Miscellaneous | Do you have any patient's assistance program? | Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company |
| 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 www.fda.gov/medwatch. |
| 36 | Miscellaneous | Why does my pharmacy that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation? | Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products. |
| 28 | Miscellaneous | May I know where is this product | Manufactured by: MSN Laboratories Private Limited |

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| | | manufactured? | Telangana – 509 216, INDIA Distributed by: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714 |
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