

**Atorvastatin Calcium Tablets 10 mg, 20 mg, 40 mg, 80 mg**

S.No	Category	Question	Answer
<b>Clinical Particulars</b>			
1	Use/Indication	What is the product indicated for?	<p>Atorvastatin calcium tablets is an HMG-CoA reductase inhibitor indicated as an adjunct therapy to diet to:</p> <ul style="list-style-type: none"> <li>• Reduce the risk of MI, stroke, revascularization procedures, and angina in adult patients without CHD, but with multiple risk factors.</li> <li>• Reduce the risk of MI and stroke in adult patients with type 2 diabetes without CHD, but with multiple risk factors.</li> <li>• Reduce the risk of non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for CHF, and angina in adult patients with CHD.</li> <li>• Reduce elevated total-C, LDL-C, apo B, and TG levels and increase HDL-C in adult patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia.</li> <li>• Reduce elevated TG in adult patients with hypertriglyceridemia and primary dysbetalipoproteinemia.</li> <li>• Reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH).</li> <li>• Reduce elevated total-C, LDL-C, and apo B levels in pediatric patients, 10 years to 17 years of age, with heterozygous familial hypercholesterolemia (HeFH) after failing an adequate trial of diet therapy.</li> </ul>
2	Dosage	What is the recommended dosage?	<p>The recommended starting dose of atorvastatin calcium tablets is 10 or 20 mg once daily. Patients who require a large reduction in LDL-C (more than 45%) may be started at 40 mg once daily. The dosage range of atorvastatin calcium tablets is 10 to 80 mg once daily.</p>
3	Administration	How to administer?	<p>Take atorvastatin calcium tablets each day at any time of day at about the same time each day. Atorvastatin calcium tablets can be taken with or without food</p>
4	Formulation	Can tablet be crushed?	No
5	Administration	What do I do if I miss a dose?	<p>If you miss a dose of atorvastatin calcium tablets, take it as soon as you remember. Do not take atorvastatin calcium tablets if it has been more than 12 hours since you missed your last dose. Wait and take the next dose at your regular time. Do not take 2 doses of atorvastatin calcium tablets at the same time.</p>
6	Administration	Use in Pediatric Population	<p>In Heterozygous Familial Hypercholesterolemia (HeFH): The safety and effectiveness of atorvastatin calcium has been established in pediatric patients, 10 years to 17 years of age. However, due to Pfizer's marketing exclusivity rights, this drug product is not labeled with that pediatric information</p>
7	Administration	Use in Geriatric Population	<p>Since advanced age (<math>\geq 65</math> years) is a predisposing factor for myopathy, atorvastatin calcium should be prescribed with caution in the elderly.</p>

8	Side effects	What are the possible side effects of Atorvastatin Calcium Tablets?	<ul style="list-style-type: none"> <li>• Muscle problems</li> <li>• Nausea and vomiting</li> <li>• Passing brown or dark-colored urine</li> <li>• You feel more tired than usual</li> <li>• Your skin and whites of your eyes get yellow.</li> <li>• Stomach pain.</li> <li>• Allergic skin reactions</li> </ul>
9	Mechanism	Mechanism of Action	Atorvastatin is a selective, competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methyl glutaryl-coenzyme A to mevalonate, a precursor of sterols, including cholesterol. In animal models, atorvastatin calcium lowers plasma cholesterol and lipoprotein levels by inhibiting HMG-CoA reductase and cholesterol synthesis in the liver and by increasing the number of hepatic LDL receptors on the cell surface to enhance uptake and catabolism of LDL; atorvastatin calcium also reduces LDL production and the number of LDL particles.
10	Warning	Black Box Warning	None.
11	Lactation	Use in Lactation	Atorvastatin calcium use is contraindicated during breastfeeding.
12	Pregnancy	Use in Pregnancy	Atorvastatin calcium is contraindicated for use in pregnant women.
13	Precautions	Is there any interaction between medication and alcohol.	Atorvastatin should be used with caution in patients who consume substantial quantities of alcohol.
14	Storage	What are the storage conditions?	Store at controlled room temperature 20° to 25°C (68° to 77°F).
15	Dispensing	How to Dispense?	As prescribed by the Physician
16	Contraindication	What are the contraindications of (medication).	<ul style="list-style-type: none"> <li>• Atorvastatin is contraindicated in active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels</li> <li>• Hypersensitivity to any component of atorvastatin calcium</li> <li>• Pregnancy</li> <li>• Lactation</li> </ul>
<b>Pharmaceutical Particulars</b>			
17	Pharmaceutical Form	How is it supplied?	<p><b>10 mg tablets (10 mg of atorvastatin):</b> coded "MA" on one side and "1" on other side. NDC 72205-022-30 bottles of 30 NDC 72205-022-90 bottles of 90 NDC 72205-022-05 bottles of 500</p> <p><b>20 mg tablets (20 mg of atorvastatin):</b> coded "MA" on one side and "2" on other side. NDC 72205-023-30 bottles of 30 NDC 72205-023-90 bottles of 90 NDC 72205-023-05 bottles of 500</p> <p><b>40 mg tablets (40 mg of atorvastatin):</b> coded "MA" on one side and "3" on other side. NDC 72205-024-30 bottles of 30 NDC 72205-024-90 bottles of 90 NDC 72205-024-05 bottles of 500</p> <p><b>80 mg tablets (80 mg of atorvastatin):</b> coded "MA" on one side and "4" on other side. NDC 72205-025-30 bottles of 30 NDC 72205-025-90 bottles of 90 NDC 72205-025-05 bottles of 500</p>
18	Coating	What is the type of coating?	Film-coated
19	Ingredient	Active and Inactive	<b>Active Ingredient:</b> Atorvastatin calcium

	ts	ingredients	<b>Inactive Ingredients:</b> Croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, magnesium aluminometasilicate, microcrystalline cellulose, polysorbate 80, precipitated calcium carbonate, polyvinyl alcohol, titanium dioxide, talc, polyethylene glycol and lecithin.
<b>Allergens</b>			
20	Ingredients	Does it contain peanut?	No
21	Ingredients	Is it Vegetarian?	Yes
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain alcohol?	Yes
24	Ingredients	Does it contain dyes?	Yes
25	Ingredients	Does it contain Lactose?	Yes
26	Ingredients	Does it contain Nuts?	No
27	Ingredients	Does it contain Preservatives?	No
28	Ingredients	Does it contain Soy products?	No
<b>Miscellaneous</b>			
29	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
30	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
31	Miscellaneous	Do you have any Patient/Financial 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
32	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> .
33	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
34	Miscellaneous	Manufacturer and Distributor	<b>Manufactured by:</b> MSN Laboratories Private Limited Telangana – 509 228, INDIA  <b>Distributed by:</b> Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714