ATORVASTATIN CALCIUM TABLETS 10 mg, 20 mg, 40 mg, 80 mg

S.No.	Category	Question	Answer
Clinical Particulars			

1	Use/Indication	What is the product indicated for?	***Atorvastatin calcium tablets are an HMG-CoA reductase inhibitor (statin) indicated:***
			
			• To reduce the risk of:
			  ○ Myocardial infarction (MI), stroke, revascularization procedures, and angina in adults with multiple risk factors for coronary heart disease (CHD) but without clinically evident CHD.
			  ○ MI and stroke in adults with type 2 diabetes mellitus with multiple risk factors for CHD but without clinically evident CHD.
			  ○ Non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure, and angina in adults with clinically evident CHD.
			• As an adjunct to diet to reduce low-density lipoprotein (LDL-C) in:
			  ○ Adults with primary hyperlipidemia.
			  ○ Adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH).
			• As an adjunct to other LDL-C-lowering therapies to reduce LDL-C in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia.
			• As an adjunct to diet for the treatment of adults with:
			  ○ Primary dysbetaliproteinemia.
			  ○ Hypertriglyceridemia.

2	Dosage	What is the recommended dosage?	Assess LDL-C when clinically appropriate, as early as 4 weeks after initiating atorvastatin calcium tablets, and adjust dosage if necessary. ***Adults:***

			• Recommended starting dosage is 10 or 20 mg once daily; dosage range is 10 mg to 80 mg once daily. • Patients requiring LDL-C reduction >45% may start at 40 mg once daily. ***Pediatric Patients Aged 10 Years of Age and Older with HeFH:*** • Recommended starting dosage is 10 mg once daily; dosage range is 10 to 20 mg once daily. ***Pediatric Patients Aged 10 Years of Age and Older with HoFH:*** • Recommended starting dosage is 10 to 20 mg once daily; dosage range is 10 to 80 mg once daily.
3	Administration	How do I take it?	✓ Take atorvastatin calcium tablets exactly as your doctor tells you to take it. ✓ Do not change your dose or stop atorvastatin calcium tablets without talking to your doctor. ✓ Your doctor may do blood tests to check your cholesterol levels during your treatment with atorvastatin calcium tablets. ✓ Your dose of atorvastatin calcium tablets may be changed based on these blood test results. ✓ Take atorvastatin calcium tablets each day at any time of day. ✓ Atorvastatin calcium tablets can be taken with or without food. ✓ Your doctor may start you on a cholesterol-lowering diet before giving you atorvastatin calcium tablets. Stay on this low-fat diet when you take atorvastatin calcium tablets.
4	Formulation	Can tablet be crushed?	Do not crush or chew the tablets
5	Administration	What do I do if I miss a dose?	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. If you take too much atorvastatin calcium tablets or overdose, call your doctor or Poison Control Center or go to the nearest emergency room right away.
6	Administration	Use in Pediatric Population	The safety and effectiveness of atorvastatin calcium have not been established in pediatric patients younger than 10 years of age with HeFH or HoFH, or in pediatric

			patients with other types of hyperlipidemia (other than HeFH or HoFH).
7	Administration	Use in Geriatric Population	• No overall differences in safety or effectiveness were observed between these patients and younger patients. • Advanced age (≥65 years) is a risk factor for atorvastatin calcium -associated myopathy and rhabdomyolysis.
8	Mechanism	Mechanism of Action	Atorvastatin is a selective, competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl-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.
9	Warnings and Precautions	Warnings	***Myopathy and Rhabdomyolysis:*** • Risk factors include age 65 years or greater, uncontrolled hypothyroidism, renal impairment, concomitant use with certain other drugs, and higher atorvastatin calcium dosage. • Discontinue atorvastatin calcium if markedly elevated CK levels occur or if myopathy is diagnosed or suspected. • Temporarily discontinue atorvastatin calcium in patients experiencing an acute or serious condition at high risk of developing renal failure secondary to rhabdomyolysis. • Inform patients of the risk of myopathy and rhabdomyolysis when starting or increasing atorvastatin calcium dosage. • Instruct patients to promptly report unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever. ***Immune-Mediated Necrotizing Myopathy (IMNM):*** • Rare reports of IMNM, an autoimmune myopathy, have been reported with statin use. • Discontinue atorvastatin calcium if IMNM is suspected. ***Hepatic Dysfunction:*** • Increases in serum transaminases have occurred, some persistent. Rare reports of fatal and non-

			fatal hepatic failure have occurred. • Consider testing liver enzymes before initiating therapy and as clinically indicated thereafter. • If serious hepatic injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs, promptly discontinue atorvastatin calcium.
10	Lactation	Use in Lactation	Breastfeeding not recommended during treatment with atorvastatin calcium
11	Pregnancy	Use in Pregnancy	• Advise pregnant patients and patients who can become pregnant of the potential risk to a fetus (May cause foetal harm). • Advise patients to inform their healthcare provider of a known or suspected pregnancy to discuss if atorvastatin calcium should be discontinued
12	Precautions	Is there any interaction between medication and alcohol?	No
13	Interaction	Is there any interaction with food/Medications?	• Avoid drinking more than 1.2 liters of grapefruit juice each day in patients taking atorvastatin • Rifampin: May reduce atorvastatin plasma concentrations. Administer simultaneously with atorvastatin calcium. • Oral Contraceptives: May increase plasma levels of norethindrone and ethinyl estradiol; consider this effect when selecting an oral contraceptive. • Digoxin: May increase digoxin plasma levels; monitor patients appropriately.
14	Storage	What are the storage conditions?	• Store atorvastatin calcium tablets at room temperature between 68ºF to 77ºF (20ºC to 25ºC). • Do not keep medicine that is out of date or that you no longer need. • Keep atorvastatin calcium tablets and all medicines out of the reach of children.
15	Dispensing	How to Dispense?	As prescribed by the Physician
16	Contraindication	What are the contraindications of (medication).	• Acute liver failure or decompensated cirrhosis. • Hypersensitivity to atorvastatin or any excipient in atorvastatin calcium.
Pharmaceutical Particulars			
17	Pharmaceutical Form	How is it supplied?	***Atorvastatin calcium tablets, USP are supplied as follows:*** **10 mg of atorvastatin:** White colored, oval-shaped, biconvex, film-coated tablets with "MA" on one side

			and "1" on the other side. • **Bottles of 30:** NDC 72205-022-30 • **Bottles of 90:** NDC 72205-022-90 • **Bottles of 500:** NDC 72205-022-05 • **Bottles of 1000:** NDC 72205-022-99 **20 mg of atorvastatin:** White colored, oval-shaped, biconvex, film-coated tablets with "MA" on one side and "2" on the other side. • **Bottles of 30:** NDC 72205-023-30 • **Bottles of 90:** NDC 72205-023-90 • **Bottles of 500:** NDC 72205-023-05 • **Bottles of 1000:** NDC 72205-023-99 **40 mg of atorvastatin:** White colored, oval-shaped, biconvex, film-coated tablets with "MA" on one side and "3" on the other side. • **Bottles of 30:** NDC 72205-024-30 • **Bottles of 90:** NDC 72205-024-90 • **Bottles of 500:** NDC 72205-024-05 • **Bottles of 1000:** NDC 72205-024-99 **80 mg of atorvastatin:** White colored, oval-shaped, biconvex, film-coated tablets with "MA" on one side and "4" on the other side. • **Bottles of 30:** NDC 72205-025-30 • **Bottles of 90:** NDC 72205-025-90 • **Bottles of 500:** NDC 72205-025-05 • **Bottles of 1000:** NDC 72205-025-99
18	Ingredients	Active and Inactive Ingredients	**Active:** Atorvastatin calcium **Inactive:** 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.
19	Coating	What is the type of coating?	Film-coated tablets
Allergens			

21	Ingredients	Is it Vegetarian?	No
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain Dairy Products?	Yes (Lactose used as diluent in the FP products and sourced from Cow's milk)
24	Ingredients	Does it contain Casein	No
25	Ingredients	Does it contain Whey?	No
26	Ingredients	Does it contain corn?	No
27	Ingredients	Does it contain rye?	No
28	Ingredients	Does it contain sugar?	No
29	Ingredients	Does it contain Oats?	No
30	Ingredients	Does it contain wheat?	No
31	Ingredients	Does it contain spelt?	No
32	Ingredients	Does it contain barley?	No
33	Ingredients	Does it contain rennet?	No
34	Ingredients	Does it contain starch?	No
36	Ingredients	Does it contain Iodine?	No
37	Ingredients	Does it contain latex?	No
38	Ingredients	Does it contain alcohol?	Yes (API contains solvents within the limits as per ICH)
39	Ingredients	Does it contain dyes?	No
40	Ingredients	Does it contain flavor?	No
41	Ingredients	Does it contain Lactose?	Yes
42	Ingredients	Does it contain Nuts?	No
43	Ingredients	Does it contain Preservatives?	No
44	Ingredients	Does it contain Soy products?	Yes
45	Ingredients	Does it contain peanut?	No
46	Ingredients	Does it contain nickel?	No
Miscellaneous			
47	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.
48	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500

49	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.
50	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.
51	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.
52	Miscellaneous	Manufacturer and Distributor	**Manufactured by:** MSN Laboratories Private Limited Telangana – 509 228, INDIA **Distributed by:** Novadoz Pharmaceuticals LLC Piscataway, NJ 08854 -3714