

Silodosin Capsules, 4 mg and 8 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Silodosin capsule, an alpha-1 adrenergic receptor antagonist, is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). Silodosin Capsule is not indicated for the treatment of hypertension.
2	Dosage	What is the recommended dosage?	The recommended dosage 8 mg capsules taken orally once daily with a meal.
3	Administration	How do I take it?	Take orally once daily with a meal to reduce risk of adverse events.
4	Administration	Can Capsule be crushed or powdered?	Patients who have difficulty swallowing pills and capsules may carefully open the silodosin capsule and sprinkle the powder inside on a table spoonful of applesauce. The applesauce should be swallowed immediately (within 5 minutes) without chewing and followed with an 8oz glass of cool water to ensure complete swallowing of the powder. The applesauce used should not be hot, and it should be soft enough to be swallowed without chewing. Any powder/applesauce mixture should be used immediately (within 5 minutes) and not stored for future use. Subdividing the contents of a silodosin capsule is not recommended
5	Administration	Use in Pediatric Population	Silodosin is not indicated for use in pediatric patients. Safety and effectiveness in pediatric patients have not been established.
6	Administration	Use in Geriatric Population	There were no significant differences in safety or effectiveness between older and younger patients
7	Side effects	What are the common side effects of silodosin	The most common side effects seen with silodosin is an orgasm with reduced or no semen. This side effect does not pose a safety concern and is reversible with discontinuation of the product.
8	Mechanism	Mechanism of Action	Silodosin is a selective antagonist of post-synaptic alpha-1 adrenoreceptors, which are located in the human prostate, bladder base, bladder neck, prostatic capsule, and prostatic urethra. Blockade of these alpha-1 adrenoreceptors can cause smooth muscle in these tissues to relax, resulting in an improvement in urine flow and a reduction in BPH symptoms. An in vitro study results demonstrated that silodosin binds with high affinity to the alpha-1A subtype.
9	Warning	Black Box Warning	No black box warning
10	Lactation	Use in Lactation	Silodosin is not indicated for use in women.
11	Pregnancy	Use in Pregnancy	Silodosin is not indicated for use in women.
12	Precautions	Is there any interaction between medication and alcohol.	Not available
13	Storage	What are the storage conditions?	Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F).Protect from light and moisture.
14	Dispensing	How to Dispense?	As prescribed by the Physician

15	Contraindication	What are the contraindications of (medication).	<ul style="list-style-type: none"> • Patients with severe renal impairment [Creatinine Clearance (CCr < 30 mL/min)]. • Patients with severe hepatic impairment (Child-Pugh score ≥ 10). • Concomitant administration with strong Cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ketoconazole, clarithromycin, itraconazole, ritonavir). • Patients with a history of hypersensitivity to silodosin or any of the ingredients of silodosin.
Pharmaceutical Particulars			
16	Pharmaceutical Form	How is it supplied?	<p>White, opaque, hard gelatin 8 mg capsules. Cap is imprinted with “S” in black ink. Body is imprinted with “8 mg”. 8 mg capsules are supplied as:</p> <ul style="list-style-type: none"> • 30 capsules (NDC 72205-010-30) • 90 capsules (NDC 72205-010-90) <p>Bottles of 30 and 90 capsules are supplied with child-resistant closures.</p> <p>White, opaque, hard gelatin 4 mg capsules. Cap is imprinted with “S” in black ink. Body is imprinted with “4 mg”. 4 mg capsules are supplied as:</p> <ul style="list-style-type: none"> • 30 capsules (NDC 72205-009-30) <p>Bottles of 30 capsules are supplied with child-resistant closures.</p>
17	Ingredients	Active and Inactive ingredients	<p>Active Ingredient: silodosin</p> <p>Inactive ingredients: magnesium stearate, magnesium aluminometasilicate, mannitol, polysorbate 80 and pregelatinized starch. The hard gelatin capsules contain gelatin and titanium dioxide. The capsules are printed with edible ink containing shellac, propylene glycol, black iron oxide and potassium hydroxide.</p>
18	Coating	What is the type of coating?	It is capsule. No coating
Allergens			
19	Ingredients	Does it contain Gluten?	No
20	Ingredients	Does it contain alcohol?	No
21	Ingredients	Does it contain dyes?	No
22	Ingredients	Does it contain Lactose?	No
23	Ingredients	Does it contain Nuts?	No
24	Ingredients	Does it contain Preservatives?	No
25	Ingredients	Does it contain Soy products?	No
26	Ingredients	Does it contain peanut?	No
27	Ingredients	Does it contain any derivatives from tree nuts or any other type of nuts?	No
Miscellaneous			
28	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
29	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500

30	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
31	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 .
32	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
33	Miscellaneous	Manufacturer and Distributor	<p>Manufactured by: MSN Laboratories Private Limited Telangana – 509 216, INDIA</p> <p>Distributed by: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714</p>