Solifenacin Succinate Tablets, 5 mg and 10 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Solifenacin succinate tablet is a muscarinic antagonist indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency
2	Dosage	What is the recommended dosage?	• 5 mg tablet taken once daily, and if well tolerated may be increased to 10 mg once daily. • Do not exceed 5 mg tablet once daily in patients with: Severe renal impairment [Creatinine Clearance] (CLcr <30 ml/min). Moderate hepatic impairment (Child-Pugh B). Concomitant use of potent CYP3A4 inhibitors. • Use of solifenacin succinate tablets is not recommended in patients with severe hepatic impairment (Child-Pugh C)
3	Administration	What do I do if I miss a dose?	If you miss a dose of solifenacin succinate tablets, begin taking solifenacin succinate tablets again the next day. Do not take 2 doses of solifenacin succinate tablets the same day.
4	Administration	Use in Pediatric Population	The safety and effectiveness of solifenacin succinate in pediatric patients have not been established.
5	Administration	Use in Geriatric Population	No overall differences in safety and efficacy were observed between these patients and younger patients.
6	Mechanism	Mechanism of Action	Solifenacin is a competitive muscarinic receptor antagonist. Muscarinic receptors play an important role in several major cholinergically mediated functions, including contractions of urinary bladder smooth muscle and stimulation of salivary secretion.
7	Warning	Black Box Warning	No black box warning
8	Lactation	Use in Lactation	Solifenacin succinate should not be administered during nursing. A decision should be made whether to discontinue nursing or to discontinue solifenacin succinate in nursing mothers.
9	Pregnancy	Use in Pregnancy	Solifenacin succinate should be used during pregnancy only if the potential benefit for the mother justifies the potential risk to the fetus.
10	Precautions	Is there any interaction between medication and alcohol?	No interactions.
11	Storage	What are the storage conditions?	Store at 25ºC (77ºF) with excursions permitted from 15ºC to 30ºC (59°F to 86°F).
12	Dispensing	How to Dispense?	As prescribed by the Physician
13	Contraindication	What are the contraindications of (medication).	Solifenacin succinate is contraindicated in patients with: • urinary retention, • gastric retention, • uncontrolled narrow-angle glaucoma and • in patients who have demonstrated hypersensitivity to the drug

Pharmaceutical Particulars			
14	Pharmaceutical Form	How is it supplied?	Solifenacin succinate tablets are supplied as round, film-coated tablets, available in bottles as follows: Each 5 mg tablet is light yellow colored, round shaped, biconvex, film-coated tablets, debossed with 'S 5' on one side and plain on other side and is available as follows: Bottle of 30 NDC 72205-020-3 Bottle of 90 NDC 72205-020-90 Bottle of 1000 NDC 72205-020-99 Each 10 mg tablet is light pink colored, round shaped, biconvex, film-coated tablets, debossed with 'S 10' on one side and plain on other side and is available as follows: Bottle of 30 NDC 72205-021-30 Bottle of 90 NDC 72205-021-90 Bottle of 1000 NDC 72205-021-99
15	Ingredients	Active and Inactive ingredients	**Active ingredient:** solifenacin succinate I**nactive ingredients:** Hypromellose, lactose monohydrate, magnesium Stearate, talc, titanium dioxide and triacetin with yellow ferric oxide (5 mg solifenacin succinate tablet) or red ferric oxide (10 mg solifenacin succinate tablet).
16	Coating	What is the type of coating?	Film coating
Allergens			
17	Ingredients	Does it contain Gluten?	No
18	Ingredients	Does it contain alcohol?	No
19	Ingredients	Does it contain dyes?	Yes
20	Ingredients	Does it contain Lactose?	Yes
21	Ingredients	Does it contain Nuts?	No
22	Ingredients	Does it contain Preservatives?	No
23	Ingredients	Does it contain Soy products?	No
24	Ingredients	Does it contain peanut?	No
25	Ingredients	Does it contain any derivatives from tree nuts or any other type of nuts?	No
26	Ingredients	Does it contain nickel?	No
Miscellaneous			
27	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.
28	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.
31	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.
32	Miscellaneous	Manufacturer and Distributor	**Manufactured by:** MSN Laboratories Private Limited Ranga Reddy (Dt.) Telangana – 509 228, INDIA **Distributed by:** Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714