

Pyridostigmine Br Oral Solution, USP, 60 mg/5 mL

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Pyridostigmine bromide oral solution is useful in the treatment of myasthenia gravis.
2	Dosage	What is the recommended dosage?	The recommended dose of Pyridostigmine Bromide Oral Solution are : raspberry-flavoured, containing 60 mg pyridostigmine bromide per teaspoonful (5 mL). This form permits accurate dosage adjustment for children and “brittle” myasthenic patients who require fractions of 60 mg doses. It is more easily swallowed, especially in the morning, by patients with bulbar involvement. The average dose is ten 5 mL teaspoonfuls daily, spaced to provide maximum relief when maximum strength is needed. In severe cases as many as 25 teaspoonfuls a day may be required, while in mild cases one to six teaspoonfuls a day may suffice.
3	Administration	How do I take it?	The average dose is ten 5 mL teaspoonfuls daily, In severe cases as many as 25 teaspoonfuls a day may be required, while in mild cases one to six teaspoonfuls a day may suffice.
4	Formulation	Can tablet be crushed?	NO
5	Administration	What do I do if I miss a dose?	If you miss a dose of Pyridostigmine bromide oral solution continue your prescribed course of therapy, and contact your physician immediately.
6	Administration	Use in Pediatric Population	Safety and effectiveness in pediatric patients have not been established.
7	Administration	Use in Geriatric Population	There were too few elderly patients (n=18) in partial-onset seizure trials to assess if they respond differently from younger patients. No age-based dose adjustment for lacosamide is required, but elderly patients should start at a lower dose due to increased risks of decreased liver and kidney function, cardiac issues, and polypharmacy

8	Mechanism	Mechanism of Action	Pyridostigmine bromide inhibits the destruction of acetylcholine by cholinesterase and thereby permits freer transmission of nerve impulses across the neuromuscular junction. Pyridostigmine is an analog of neostigmine (Prostigmin), but differs from it in certain clinically significant respects; for example, pyridostigmine is characterized by a longer duration of action and fewer gastrointestinal side effects.
9	Warning	Black Box Warning	None
10	Lactation	Use in Lactation	The safety of pyridostigmine bromide during pregnancy or lactation in humans has not been established. Therefore, use of pyridostigmine bromide in women who may become pregnant requires weighing the drug's potential benefits against its possible hazards to mother and child.
11	Pregnancy	Use in Pregnancy	The safety of pyridostigmine bromide during pregnancy or lactation in humans has not been established. Therefore, use of pyridostigmine bromide in women who may become pregnant requires weighing the drug's potential benefits against its possible hazards to mother and child.
12	Precautions	Is there any interaction between medication and alcohol?	None
13	Interaction	Is there any interaction with food?	None
14	Side effects	What are the common side effects?	Side Effects of Pyridostigmine Bromide 1. Muscarinic Side Effects: • Nausea • Vomiting • Diarrhea • Abdominal cramps • Increased peristalsis • Increased salivation • Increased bronchial secretions • Miosis (pupil constriction) • Diaphoresis (excessive sweating) 2. Nicotinic Side Effects: • Muscle cramps • Fasciculation (muscle twitching) • Muscle weakness 3. Counteraction:

			- Muscarinic side effects can typically be counteracted with atropine; however, this approach carries some risks. 4. Skin Reactions: - Possible skin rash in some patients, usually subsiding after discontinuation of the medication. Note: Side effects are primarily related to overdosage.
15	Storage	What are the storage conditions?	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). [see USP Controlled Room Temperature]. Dispense in tight, light-resistant containers as defined by the USP.
16	Dispensing	How to Dispense?	As prescribed by the Physician
17	Contraindication	What are the contraindications of (medication).	Pyridostigmine bromide is contraindicated in mechanical intestinal or urinary obstruction, and particular caution should be used in its administration to patients with bronchial asthma. Care should be observed in the use of atropine for counteracting side effects,
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	Pyridostigmine Bromide Oral Solution USP, 60 mg pyridostigmine bromide per teaspoonful (5 mL) is available as a clear, raspberry flavored solution and 0.23% w/w alcohol. It is supplied as follows: Bottles of 16 fluid ounces, (1 pint, 473 mL) NDC 72205-098-72
19	Ingredients	Active and Inactive Ingredients	Active PYRIDOSTIGMINE BROMIDE Inactive: ALCOHOL, GLYCERIN, LACTIC ACID , SODIUM BENZOATE , SORBITOL, SUCROSE, WATER
20	Coating	What is the type of coating?	None
Allergens			
21	Ingredients	Is it Vegetarian?	yes
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain Dairy Products?	No
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
35	Ingredients	Does it contain Iodine?	No
36	Ingredients	Does it contain latex?	No
37	Ingredients	Does it contain alcohol?	Yes
38	Ingredients	Does it contain dyes?	No
39	Ingredients	Does it contain flavor?	No
40	Ingredients	Does it contain Lactose?	No
41	Ingredients	Does it contain Nuts?	No
42	Ingredients	Does it contain Preservatives?	Yes
43	Ingredients	Does it contain Soy products?	No
44	Ingredients	Does it contain peanut?	No
45	Ingredients	Does it contain nickel?	No
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Miscellaneous	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.
47	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
48	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.
49	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 .
50	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.
51	Miscellaneous	Manufacturer and Distributor	Manufactured by: MSN Pharmaceuticals Inc. Piscataway, NJ 08854 Distributed by: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714