NOVADOZ®
VALUE IN EVERY DOSE

Droxidopa Capsules, 100 mg, 200 mg, and 300 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Droxidopa capsules are indicated for the treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension (nOH) caused by primary autonomic failure (Parkinson's disease [PD], multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy.
2	Dosage	What is the recommended dosage?	The recommended starting dose of droxidopa capsules is 100 mg, taken orally three times daily: upon arising in the morning, at midday, and in the late afternoon at least 3 hours prior to bedtime (to reduce the potential for supine hypertension during sleep).
3	Administration	How do I take it?	Administer droxidopa capsules consistently, either with food or without food.
4	Formulation	Can tablet be crushed?	Take droxidopa capsule whole. They should not be crushed or chewed.
5	Administration	What do I do if I miss a dose?	Patients who miss a dose of droxidopa capsules should take their next scheduled dose. *Please contact your physician for further queries.*
6	Administration	Use in Pediatric Population	The safety and effectiveness of droxidopa in pediatric patients have not been established.
7	Administration	Use in Geriatric Population	No overall differences in safety or effectiveness is observed between elderly patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out.
8	Mechanism	Mechanism of Action	The exact mechanism of action of droxidopa in the treatment of neurogenic orthostatic hypotension is unknown. Droxidopa is a synthetic amino acid analog that is directly metabolized to norepinephrine by dopa-decarboxylase, which is extensively distributed throughout the body. Droxidopa is believed to exert its pharmacological effects through norepinephrine and not through the parent molecule or other metabolites. Norepinephrine increases blood pressure by inducing peripheral arterial and venous vasoconstriction. Droxidopa in humans induces small and transient rises in plasma norepinephrine.
9	Warning	Black Box Warning	SUPINE HYPERTENSION. *See full prescribing information for complete boxed warning.*
10	Lactation	Use in Lactation	Advise women not to breastfeed during treatment with droxidopa.

11	Pregnancy	Use in Pregnancy	There are no available data on use of droxidopa in pregnant women and risk of major birth defects or miscarriage.
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?	**Headache, Dizziness, Nausea and Hypertension**
15	Storage	What are the storage conditions?	Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
16	Dispensing	How to Dispense?	As prescribed by the Physician
17	Contraindication	What are the contraindications of (medication).	Droxidopa is contraindicated in patients who have a history of hypersensitivity to the drug or its ingredients.
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	Droxidopa capsules are supplied in the following dosage strengths. *100 mg:* White to light brown powder filled in Size"4" hard gelatin capsules with white opaque body with black color band and Light blue opaque cap imprinted with "MD 10" in black ink. *200 mg:* White to light brown powder filled in Size "2" hard gelatin capsules with white opaque body with black color band and Light yellow opaque cap imprinted with "MD 9" in black ink. *300 mg:* White to light brown powder filled in Size "1" hard gelatin capsules with white opaque body with black color band and Light green opaque cap imprinted with "MD 8" in black ink. They are supplied in bottle as: 100 mg 90-count bottle (NDC code # 72205-072-90) 100 mg 500-count bottle (NDC code # 72205-072-05) 200 mg 90-count bottle (NDC code # 72205-073-90) 200 mg 500-count bottle (NDC code # 72205-073-05) 300 mg 90-count bottle (NDC code # 72205-074-90) 300 mg 500-count bottle (NDC code # 72205-074-05).
19	Ingredients	Active and Inactive Ingredients	**Active**: Droxidopa **Inactive**: magnesium stearate, mannitol and pre gelatinized starch. The capsule shell is printed with black ink. The black ink contain black iron oxide, propylene glycol, potassium hydroxide and shellac. The capsule shell contains the following inactive ingredients: 100 mg-gelatin, titanium oxide, iron oxide red, iron oxide black, FD&C Blue2, 200 mg – gelatin, titanium dioxide, iron oxide black and iron oxide yellow, 300 mg – gelatin, titanium dioxide, FD&C BLUE 1, D&C YELLOW 10.

20	Coating	What is the type of coating?	Capsule
Allergens			
21	Ingredients	Is it Vegetarian?	No. Contains Gelatin sourced from healthy bovine
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?	Yes (corn starch)
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?	Yes
35	Ingredients	Does it contain povidone?	No
36	Ingredients	Does it contain Iodine?	No
37	Ingredients	Does it contain latex?	No
38	Ingredients	Does it contain alcohol?	Yes (present in API)
39	Ingredients	Does it contain dyes?	No
40	Ingredients	Does it contain flavor?	No
41	Ingredients	Does it contain Lactose?	No
42	Ingredients	Does it contain Nuts?	No
43	Ingredients	Does it contain Preservatives?	No
44	Ingredients	Does it contain Soy products?	No
45	Ingredients	Does it contain peanut?	No
46	Ingredients	Does it contain nickel?	No
Miscellaneous			
47	Miscellaneous	May I know the	Novadoz Pharmaceuticals products are only available

		product availability?	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 offers Droxidopa Copay Assistance Program. Novadoz Pharmaceutical Copay Assistance Program can help eligible commercial patients with their out-of-pocket expenses for Droxidopa. For full details, visit NovadozPharma.com for more details.
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:** MSN Pharmaceuticals Inc. Piscataway, NJ 08854-3714 Issued on: 12/2019