NOVADOZ
AN MSN COMPANY

LISDEXAMFETAMINE DIMESYLATE CHEWABLE TABLETS 10 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Lisdexamfetamine dimesylate chewable tablets are a central nervous system (CNS) stimulant indicated for the treatment of: • Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older • Moderate to severe binge eating disorder (BED) in adults
2	Dosage	What is the recommended dosage?	The recommended dose of Lisdexamfetamine dimesylate chewable tablets are: **ADHD Treatment:** • **Starting Dosage:** 30 mg once daily in the morning. • **Adjustment:** Increase in 10 mg or 20 mg increments weekly. • **Maximum Dosage:** 70 mg once daily. **Moderate to Severe BED Treatment:** • **Starting Dosage:** 30 mg once daily. • **Adjustment:** Increase in 20 mg increments weekly. • **Target Dosage:** 50 mg to 70 mg once daily. • **Maximum Dosage:** 70 mg once daily. **Renal Impairment:** • **Severe Impairment (GFR 15-<30):** Max 50 mg once daily. • **End-Stage Renal Disease (ESRD, GFR <15):** Max 30 mg once daily. **Drug Interactions:** • **Acidifying Agents:** Decrease blood levels. • **Alkalinizing Agents:** Increase blood levels. • **Adjust dosage accordingly.**

3	Administration	How do I take it?	Administration: Take orally in the morning with or without food. Avoid afternoon doses to prevent insomnia. Chewing Instructions: Chew thoroughly before swallowing.
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 Lisdexamfetamine dimesylate chewable tablets continue your prescribed course of therapy, and contact your physician immediately.
6	Administration	Use in Pediatric Population	ADHD in Pediatric Patients (6-17 years): Safety and effectiveness established. Not established for children under 6 years. A study in 4-5-year-olds showed higher exposure and increased adverse reactions like weight loss and insomnia. BED in Pediatric Patients: Safety and effectiveness not established for those under 18 years. Growth Monitoring: Monitor growth during treatment. Treatment may need to be interrupted if growth is not as expected.
7	Administration	Use in Geriatric Population	**Clinical Studies:** Insufficient data for patients aged 65 and over. **Pharmacokinetics:** No identified differences in response between elderly and younger patients. **Dosing:** Start at the low end of the dosing range due to potential decreased hepatic, renal, or cardiac function and other factors.
8	Mechanism	Mechanism of Action	Lisdexamfetamine is a prodrug of dextroamphetamine. Amphetamines are non-catecholamine sympathomimetic amines with CNS stimulant activity. The exact mode of therapeutic action in ADHD and BED is not known.
9	Warning	Black Box Warning	WARNING: ABUSE, MISUSE, AND ADDICTION See full prescribing information for complete boxed warning. Lisdexamfetamine dimesylate has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including lisdexamfetamine dimesylate, can result in overdose and death (5.1, 9.2, 10): Before prescribing lisdexamfetamine dimesylate, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout treatment, reassess each patient's risk and

			frequently monitor for signs and symptoms of abuse, misuse, and addiction.
10	Lactation	Use in Lactation	Lisdexamfetamine is a pro-drug of dextroamphetamine. Based on limited case reports in published literature, amphetamine (d-or d, 1-) is present in human milk, at relative infant doses of 2% to 13.8% of the maternal weight-adjusted dosage and a milk/plasma ratio ranging between 1.9 and 7.5. There are no reports of adverse effects on the breastfed infant. Long-term neurodevelopmental effects on infants from amphetamine exposure are unknown. It is possible that large dosages of dextroamphetamine might interfere with milk production, especially in women whose lactation is not well established. Because of the potential for serious adverse reactions in nursing infants, including serious cardiovascular reactions, blood pressure and heart rate increase, suppression of growth, and peripheral vasculopathy, advise patients that breastfeeding is not recommended during treatment with lisdexamfetamine dimesylate.
11	Pregnancy	Use in Pregnancy	Pregnancy Exposure Registry: Monitors outcomes for women exposed to ADHD medications. Register at 1-866-961-2388 or online here. Risk Summary: Limited data on lisdexamfetamine dimesylate's risk for birth defects or miscarriage. Adverse outcomes such as premature delivery and low birth weight have been reported in amphetamine-dependent mothers. Animal studies showed no effects on embryo-fetal development, but amphetamine exposure in rats affected pup survival, weight, and developmental milestones. Clinical Considerations: Amphetamines may reduce placental blood flow and increase risk of premature delivery. Monitor infants for withdrawal symptoms like feeding difficulties and irritability.
12	Precautions	Is there any interaction between medication and alcohol?	None
13	Interaction	Is there any interaction with food?	Take orally in the morning with or without food. Avoid afternoon doses to prevent insomnia.
14	Side effects	What are the common side effects?	Common Side Effects in Children (6-17 years) and Adults with ADHD: Loss of appetite, anxiety, weight loss, diarrhea, dizziness, dry mouth, irritability, trouble sleeping, nausea, stomach pain, vomiting. Common Side Effects in Adults with BED:

			Dry mouth, trouble sleeping, decreased appetite, increased heart rate, constipation, jitteriness, anxiety.
15	Storage	What are the storage conditions?	• **Container:** Dispense in a tight, light-resistant container. • **Temperature:** Store at room temperature (20ºC to 25ºC or 68ºF to 77ºF). Allowed range: 15ºC to 30ºC (59ºF to 86ºF).
16	Dispensing	How to Dispense?	As prescribed by the Physician
17	Contraindication	What are the contraindications of (medication).	Hypersensitivity: Known allergy to amphetamines or other ingredients. Postmarketing reports include severe reactions like anaphylaxis and Stevens-Johnson Syndrome. MAOIs: Concurrent use or within 14 days of stopping MAOIs (including linezolid and intravenous methylene blue) due to risk of hypertensive crisis.
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	How Supplied: 10 mg: White/off-white, mottled, round, debossed 'm169', bottles of 100, NDC 72205-132-91 20 mg: White/off-white, mottled, hexagonal, debossed 'm170', bottles of 100, NDC 72205-133-91 30 mg: White/off-white, mottled, arc triangular, debossed 'm171', bottles of 100, NDC 72205-134-91 40 mg: White/off-white, mottled, capsule-shaped, debossed 'm172', bottles of 100, NDC 72205-135-91 50 mg: White/off-white, mottled, arc square, debossed 'm173', bottles of 100, NDC 72205-136-91 60 mg: White/off-white, mottled, arc diamond, debossed 'm174', bottles of 100, NDC 72205-137-91
19	Ingredients	Active and Inactive Ingredients	**Active**: lisdexamfetamine dimesylate **Inactive**: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, mannitol, microcrystalline cellulose and gaur gum, sucralose, N-C strawberry flavorart.
20	Coating	What is the type of coating?	Uncoated tablets
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?	No
43	Ingredients	Does it contain Soy products?	No
44	Ingredients	Does it contain peanut?	No
45	Ingredients	Does it contain nickel?	No
46			
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.