NOVADOZ
AN MSN COMPANY

OLMESARTAN MEDOXOMIL TABLETS USP, 5 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Olmesartan medoxomil tablets are used to treat hypertension in adults and children aged six years and older. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, such as strokes and myocardial infarctions. However, there are no controlled trials specifically demonstrating risk reduction with olmesartan medoxomil.
2	Dosage	What is the recommended dosage?	**Adult Hypertension** • **Starting Dose:** 20 mg once daily • **Dose Range:** 20 - 40 mg once daily **Pediatric Hypertension (6 years and older)** **Weight 20 to <35 kg** • **Starting Dose:** 10 mg once daily • **Dose Range:** 10 - 20 mg once daily **Weight ≥35 kg** • **Starting Dose:** 20 mg once daily • **Dose Range:** 20 - 40 mg once daily
3	Administration	How do I take it?	Olmesartan medoxomil may be administered with or without food.
4	Formulation	Can tablet be crushed?	No
5	Administration	What do I do if I miss a dose?	If you miss a dose of Olmesartan medoxomil tablets continue your prescribed course of therapy, and contact your physician immediately.
6	Administration	Use in Pediatric Population	**Paediatric Use of Olmesartan Medoxomil** • **Effectiveness and Tolerability:** Evaluated in a randomized, double-blind study in paediatric

			patients aged 1 to 16 years. Olmesartan medoxomil was generally well tolerated with an adverse experience profile similar to that in adults. • **Age Restrictions:** Not shown to be effective in children under 6 years of age. Use in children under 1 year is not recommended due to potential impacts on kidney development from RAAS blockade, as seen in very young mice.
7	Administration	Use in Geriatric Population	In clinical studies, over 20% of patients receiving olmesartan medoxomil were aged 65 or older, and over 5% were 75 or older. No overall differences in effectiveness or safety were observed between elderly and younger patients. However, greater sensitivity in some older individuals cannot be ruled out.
8	Mechanism	Mechanism of Action	Olmesartan blocks the effects of angiotensin II, a key vasoconstrictor, by selectively inhibiting its binding to the AT1 receptor in vascular smooth muscle. This action is independent of angiotensin II synthesis pathways. Olmesartan has over 12,500 times greater affinity for the AT1 receptor than the AT2 receptor, which is not linked to cardiovascular regulation. Unlike ACE inhibitors, which also inhibit bradykinin degradation, olmesartan does not affect bradykinin levels as it does not inhibit ACE. This difference's clinical relevance is not yet known. Although olmesartan increases plasma renin activity and angiotensin II levels, these do not counteract its blood pressure-lowering effects.
9	Warning	Black Box Warning	**WARNING: Foetal Toxicity** • **Discontinue Use:** If pregnancy is detected, stop olmesartan medoxomil as soon as possible. • **Risk to foetus:** Drugs affecting the renin-angiotensin system can cause injury or death to the developing foetus.
10	Lactation	Use in Lactation	**Lactation** <u>Risk Summary</u> There is no information regarding the presence of olmesartan in human milk, the effects on the breastfed infant, or the effects on milk production. Olmesartan

			is secreted at low concentration in the milk of lactating rats. Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother. Data Presence of olmesartan in milk was observed after a single oral administration of 5 mg/kg olmesartan medoxomil to lactating rats.
11	Pregnancy	Use in Pregnancy	Olmesartan medoxomil can harm the fetus, particularly in the second and third trimesters, by impairing renal function and increasing the risk of fetal and neonatal complications. Animal studies show increased toxicity at doses lower than those causing maternal harm. Discontinue olmesartan medoxomil if pregnancy is detected and consider alternative treatments. The background risk of major birth defects and miscarriage in the U.S. is 2%-4% and 15%-20%, respectively. **Clinical Considerations:** • **Maternal and Foetal Risks:** Hypertension during pregnancy can lead to complications such as pre-eclampsia, gestational diabetes, and premature delivery, while increasing risks for intrauterine growth restriction and death. • **Foetal/Neonatal Adverse Reactions:** Oligohydramnios caused by renin-angiotensin system drugs can result in reduced renal function, lung hypoplasia, skeletal deformations, hypotension, and death. Monitor pregnant women with serial ultrasounds and fetal testing. Observe infants exposed in utero for hypotension, oliguria, and hyperkalaemia, and provide supportive measures if needed.
12	Precautions	Is there any interaction between medication and alcohol?	No
13	Interaction	Is there any interaction with	No

		food?	
14	Side effects	What are the common side effects?	**Adverse Reactions** The following adverse reactions have been reported are: • **Body as a Whole**: Asthenia, angioedema, anaphylactic reactions • **Gastrointestinal**: Vomiting, sprue-like enteropathy • **Metabolic and Nutritional Disorders**: Hyperkalaemia • **Musculoskeletal**: Rhabdomyolysis • **Urogenital System**: Acute renal failure, increased blood creatinine levels • **Skin and Appendages**: Alopecia, pruritus, urticaria
15	Storage	What are the storage conditions?	Store at 20-25°C (68-77°F)
16	Dispensing	How to Dispense?	As prescribed by the Physician
17	Contraindication	What are the contraindications of (medication).	Do not co-administer aliskiren with olmesartan medoxomil in patients with diabetes
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	Olmesartan medoxomil Tablets, USP are supplied as: • Olmesartan medoxomil 5 mg yellow colored, round shaped, biconvex, film-coated tablets, debossed with "MO" on one side and "5" on other side • Olmesartan medoxomil 20 mg white colored, round shaped, biconvex, film-coated tablets, debossed with "MO" on one side and "6" on other side • Olmesartan medoxomil 40 mg white colored, oval-shaped, biconvex, film-coated tablets, debossed with "MO" on one side and "7" on other side
19	Ingredients	Active and Inactive Ingredients	**Active**: OLMESARTAN MEDOXOMIL **Inactive**: HYDROXYPROPYL CELLULOSE, HYPROMELLOSES, LACTOSE MONOHYDRATE, HYDROXYPROPYL CELLULOSE, MAGNESIUM STEARATE, CELLULOSE, MICROCRYSTALLINE , TALC , TITANIUM DIOXIDE, FERRIC OXIDE YELLOW
20	Coating	What is the type of	film-coated tablets

		coating?	
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?	No
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
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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 Laboratories Private Limited** **Telangana – 509 228,** **INDIA** **Distributed by:** **Novadoz Pharmaceuticals LLC** **Piscataway, NJ 08854-3714**