

Vilazodone hydrochloride tablets USP, 10 mg and 40 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Vilazodone hydrochloride tablets are indicated for the treatment of major depressive disorder (MDD) in adults.
2	Dosage	What is the recommended dosage?	<ul style="list-style-type: none"> Recommended target dosage: 20 mg to 40 mg once daily with food. To titrate: start with initial dosage of 10 mg once daily for 7 days, followed by 20 mg once daily. The dose may be increased up to 40 mg once daily after a minimum of 7 days between dosage increases. Prior to initiating vilazodone hydrochloride, screen for bipolar disorder. When discontinuing vilazodone hydrochloride, reduce dosage gradually
3	Administration	How do I take it?	<ul style="list-style-type: none"> Start with an initial dosage of 10 mg once daily with food for 7 days, Then increase to 20 mg once daily with food. The dose may be increased up to 40 mg once daily with food after a minimum of 7 days between dosage increases.
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 Vilazodone hydrochloride tablets acetate tablets continue your prescribed course of therapy, and contact your physician immediately.
6	Administration	Use in Pediatric Population	The safety and effectiveness of vilazodone hydrochloride for treating major depressive disorder (MDD) in pediatric patients have not been established. Antidepressants may increase the risk of suicidal thoughts and behaviors in this population.
7	Administration	Use in Geriatric Population	No dosage adjustment for vilazodone hydrochloride is recommended based on age. A pharmacokinetic study showed similar results in geriatric subjects (> 65 years) compared to younger subjects (24 to 55 years) after a single 20 mg dose. Clinical studies included only a small number of patients

			<p>aged 65 and over—65 out of 3,007 (2.2%). Of these, 378 patients (12.6%) were aged 55 to 64. For elderly patients, a conservative dose selection is recommended, starting at the lower end of the dosing range due to potential hepatic, renal, or cardiac function decline.</p> <p>Serotonergic antidepressants have been linked to clinically significant hyponatremia in elderly patients, who may be at greater risk for this adverse effect. No other differences in adverse reactions were noted between geriatric and younger patients.</p>
8	Mechanism	Mechanism of Action	<p>The mechanism of action of vilazodone in the treatment of major depressive disorder is not fully understood, but is thought to be related to its enhancement of serotonergic activity in the CNS through selective inhibition of serotonin reuptake. Vilazodone is also a partial agonist at serotonergic 5-HT_{1A} receptors; however, the net result of this action on serotonergic transmission and its role in vilazodone's antidepressant effect are unknown.</p>
9	Warning	Black Box Warning	<p>Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening and for emergence of suicidal thoughts and behaviors. Vilazodone hydrochloride tablets is not approved for use in pediatric patients</p>
10	Lactation	Use in Lactation	<p>There are no data on vilazodone in human milk or its effects on breastfed infants and milk production. However, vilazodone is excreted in rat milk. The benefits of breastfeeding should be weighed against the mother's clinical need for vilazodone and any potential risks to the breastfed child from the drug or the mother's underlying condition.</p>
11	Pregnancy	Use in Pregnancy	<p>Adequate studies of vilazodone hydrochloride in pregnant women are lacking. The background risk of major birth defects is 2-4%, and miscarriage is 15-20% in the U.S.</p> <p>General population Clinical Considerations</p> <p>Women with major depressive disorder who discontinue antidepressants during pregnancy may have a higher risk of relapse. Consider the risks of untreated depression when adjusting treatment.</p> <p>Fetal/Neonatal Adverse Reactions</p> <p>Exposure to SSRIs and SNRIs, including vilazodone, late in pregnancy may increase the risk of neonatal complications requiring prolonged hospitalization, respiratory support, and persistent pulmonary hypertension of the newborn (PPHN). Monitor neonates exposed in the third trimester for these complications.</p> <p>Neonates exposed to SSRIs or SNRIs in late pregnancy</p>

			have experienced complications such as respiratory distress and seizures. These may occur immediately upon delivery and could be due to direct toxicity or withdrawal. There is an increased risk of PPHN with SSRI exposure after the 20th week of gestation, significantly higher compared to unexposed infants. Studies indicate a risk ratio for PPHN of approximately 6-fold for infants exposed to SSRIs late in pregnancy.
12	Precautions	Is there any interaction between medication and alcohol?	None
13	Interaction	Is there any interaction with food?	The absolute bioavailability of vilazodone was 72% with food. Vilazodone AUC and C _{max} in the fasted state can be decreased by approximately 50% and 60%, respectively, compared to the fed state. Administration without food can result in inadequate drug concentrations and may reduce effectiveness.
14	Side effects	What are the common side effects?	<p>Possible Side Effects of Vilazodone Hydrochloride</p> <ul style="list-style-type: none"> Agitation Hallucinations (seeing or hearing things that aren't real) Confusion Coma Fast heartbeat Blood pressure changes Dizziness Sweating Flushing Hyperthermia (high body temperature) Tremors, stiff muscles, or twitching Loss of coordination Seizures Nausea, vomiting, diarrhea Increased Bleeding Risk Taking vilazodone with aspirin, NSAIDs, warfarin, or other blood thinners may increase bleeding risk. Report any unusual bleeding or bruising to your healthcare provider immediately. <p>Mania or Hypomania</p> <p>In individuals with a history of bipolar disorder, symptoms may include:</p> <ul style="list-style-type: none"> Increased energy Severe insomnia Racing thoughts Reckless behavior Grandiose ideas Excessive happiness or irritability Rapid speech

15	Storage	What are the storage conditions?	Store at 25°C (77°F); allowed excursions from 15°C to 30°C (59°F to 86°F).
16	Dispensing	How to Dispense?	As prescribed by the Physician
17	Contraindication	What are the contraindications of (medication).	Patients taking, or within 14 days of stopping, monoamine oxidase inhibitors (MAOIs), including MAOIs such as linezolid or intravenous methylene blue, because of an increased risk of serotonin syndrome
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	<p>10 mg: Pink, ellipse-shaped, biconvex, film-coated tablets, debossed with “MV” on one side and “14” on the other.</p> <p>NDC: 72205-260-30 (30-count bottles)</p> <p>20 mg: Orange, ellipse-shaped, biconvex, film-coated tablets, debossed with “MV” on one side and “15” on the other.</p> <p>NDC: 72205-261-30 (30-count bottles)</p> <p>40 mg: Blue, ellipse-shaped, biconvex, film-coated tablets, debossed with “MV” on one side and “16” on the other.</p> <p>NDC: 72205-262-30 (30-count bottles)</p>
19	Ingredients	Active and Inactive Ingredients	<p>Active: VILAZODONE HYDROCHLORIDE</p> <p>Inactive: FERRIC OXIDE RED, TALC POLYETHYLENE GLYCOL 8000, TITANIUM DIOXIDE, POLYVINYL ALCOHOL, SILICON DIOXIDE, MAGNESIUM STEARATE, CELLULOSE, MICROCRYSTALLINE, LACTOSE MONOHYDRATE</p>
20	Coating	What is the type of coating?	Uncoated tablets
Allergens			
21	Ingredients	Is it Vegetarian?	No, Lactose produced from milk, that has been sourced from healthy cows is used as inactive ingredient.
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain Dairy Products?	Lactose used as diluent in the FP products and sourced from cows’ milk
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 contain povidone?	No
36	Ingredients	Does it contain Iodine?	No
37	Ingredients	Does it contain latex?	No
38	Ingredients	Does it contain alcohol?	API contains solvents within the limits as per ICH
39	Ingredients	Does it contain dyes?	No
40	Ingredients	Does it contain flavor?	No
41	Ingredients	Does it contain Lactose?	Yes, Lactose produced from milk, that has been sourced from healthy cows is used as inactive ingredient.
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 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.
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 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.
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	<p>Manufactured by: MSN Laboratories Private Limited Telangana – 509 228, INDIA</p> <p>Distributed by: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714 Issued on: June 2023</p>