

**LURASIDONE HYDROCHLORIDE FILM COATED TABLETS 20mg, 40mg, 60mg, 80mg and 120mg**

S.No.	Category	Question	Answer
<b>Clinical Particulars</b>			
1	Use/Indication	What is the product indicated for?	Lurasidone hydrochloride tablets are an atypical antipsychotic indicated for the treatment of: <ul style="list-style-type: none"> <li>• Schizophrenia in adults and adolescents (13 to 17 years)</li> <li>• Depressive episode associated with Bipolar I Disorder (bipolar depression) in adults and pediatric patients (10 to 17 years) as monotherapy</li> <li>• Depressive episode associated with Bipolar I Disorder (bipolar depression) in adults as adjunctive therapy with lithium or valproate</li> </ul>
2	Dosage	What is the recommended dosage?	For Schizophrenia, the recommended dose is Adults - 40 mg to 160 mg per day Adolescents (13 to 17 years) - 40 mg to 80 mg per day  For Bipolar Depression, the recommended dose is Adults - 20 mg to 120 mg per day Pediatric patients (10 to 17 years) - 20 mg to 80 mg per day  For more information, please refer to the Prescribing Information
3	Administration	How do I take it?	<ul style="list-style-type: none"> <li>• Take lurasidone hydrochloride tablets exactly as your healthcare provider tells you to take it. Do not change the dose or stop taking lurasidone hydrochloride tablets without first talking to your healthcare provider.</li> <li>• Take lurasidone hydrochloride tablets by mouth, with food (at least 350 calories).</li> <li>• If you take too much lurasidone hydrochloride tablets, call your healthcare provider or poison control center or go to the nearest hospital emergency room right away.</li> </ul> For more information, please refer to the Prescribing Information
4	Administration	What do I do if I miss a dose?	Take lurasidone hydrochloride tablets exactly as your healthcare provider tells you to take it. Do not change the dose or stop taking lurasidone hydrochloride tablets without first talking to your healthcare provider.  In case, if you miss a dose, please contact your treating physician.
5	Administration	Use in Pediatric Population	The safety and effectiveness of lurasidone hydrochloride has not been established in pediatric patients less than 13 years of age with schizophrenia.

			<p>The safety and effectiveness of lurasidone hydrochloride has not been established in pediatric patients less than 10 years of age with bipolar depression.</p> <p>The effectiveness of lurasidone hydrochloride in pediatric patients for the treatment of irritability associated with autistic disorder has not been established.</p>
7	Administration	Use in Geriatric Population	Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Lurasidone hydrochloride tablets are not approved for the treatment of patients with dementia-related psychosis.
8	Mechanism	Mechanism of Action	The mechanism of action of lurasidone in the treatment of schizophrenia and bipolar depression is unclear. However, its efficacy in schizophrenia and bipolar depression could be mediated through a combination of central dopamine D2 and serotonin Type 2 (5HT2A) receptor antagonism.
9	Warning	Black Box Warning	<p>Increased Mortality in Elderly Patients with Dementia-Related Psychosis; Suicidal Thoughts and Behaviors</p> <p>See full prescribing information for complete boxed warning.</p>
10	Lactation	Use in Lactation	Before taking lurasidone hydrochloride tablets, tell your healthcare provider if you are breastfeeding or plan to breastfeed. It is not known if lurasidone hydrochloride passes into breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with lurasidone hydrochloride tablets.
11	Pregnancy	Use in Pregnancy	<p>Before taking lurasidone hydrochloride tablets, tell your healthcare provider if you are pregnant or plan to become pregnant. It is not known if lurasidone hydrochloride tablets will harm your unborn baby. Talk to your healthcare provider about the risk to your unborn baby if you take lurasidone hydrochloride tablets during pregnancy.</p> <p>Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with lurasidone hydrochloride.</p>
14	Side effects	What are the common side effects?	<p>Commonly observed adverse reactions were:</p> <p><u>Adult patients with schizophrenia:</u> somnolence, akathisia, extrapyramidal symptoms, and nausea</p> <p><u>Adolescent patients (13-17 years) with schizophrenia:</u> somnolence, nausea, akathisia, EPS (non-akathisia), rhinitis (80 mg only), and vomiting</p> <p><u>Adult patients with bipolar depression:</u> akathisia, extrapyramidal symptoms, and somnolence</p> <p><u>Pediatric patients (10-17 years) with bipolar depression:</u> nausea, weight increase, and insomnia.</p> <p>See full prescribing information for complete information regarding adverse reactions.</p>

15	Storage	What are the storage conditions?	Store lurasidone hydrochloride tablets at 20° to 25°C (68° to 77°F).
16	Dispensing	How to Dispense?	As prescribed by the Physician
17	Contraindication	What are the contraindications of (medication).	<ul style="list-style-type: none"> <li>• Known hypersensitivity to lurasidone hydrochloride or any components in the formulation</li> <li>• Concomitant use with a strong CYP3A4 inhibitor (e.g., ketoconazole)</li> <li>• Concomitant use with a strong CYP3A4 inducer (e.g., rifampin)</li> </ul> <p>See full prescribing information for complete information</p>
<b>Pharmaceutical Particulars</b>			
18	Pharmaceutical Form	How is it supplied?	<p>Lurasidone hydrochloride tablets are available as follows:</p> <p>20 mg tablets are available in bottles of 30, 90 and 500 tablets. (72205-207-30   72205-207-90   72205-207-05)</p> <p>40 mg tablets are available in bottles of 30, 90 and 500 tablets. (72205-208-30   72205-208-90   72205-208-05)</p> <p>60 mg tablets are available in bottles of 30, 90 and 500 tablets. (72205-209-30   72205-209-90   72205-209-05)</p> <p>80 mg tablets are available in bottles of 30, 90 and 500 tablets. (72205-210-30   72205-210-90   72205-210-05)</p> <p>120 mg tablets are available in bottles of 30, 90 and 500 tablets. (72205-211-30   72205-211-90   72205-211-05)</p>
19	Ingredients	Active and Inactive Ingredients	<p><b>Active ingredient:</b> lurasidone hydrochloride</p> <p><b>Inactive ingredients:</b> carnauba wax, citric acid anhydrous, croscarmellose sodium, Hypromellose, lactose monohydrate, magnesium stearate, mannitol, polyethylene glycol, povidone, pregelatinized starch, and titanium dioxide</p>
<b>Miscellaneous</b>			
20	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
21	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500.
22	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
23	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.
24	Miscellaneous	Why does my pharmacy that used to fill your generic	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized

		formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	distributor of record) page to learn where to find our products.
25	Miscellaneous	Manufacturer and Distributor	<b>Manufactured by:</b> MSN Laboratories Private Limited Telangana – 509 228, INDIA <b>Distributed by:</b> MSN Pharmaceuticals Inc. Piscataway, NJ 08854-3714 Issued on: January 2023