LURASIDONE HYDROCHLORIDE TABLET, USP 20 mg, 40 mg, 60 mg, 80 mg, 120 mg

S.No.	Category	Question	Answer
		Clinical Particulars	
1.	Use/Indication	What is the product indicated for?	***Lurasidone hydrochloride tablets are a prescription medicine used:*** • To treat people 13 years of age or older with schizophrenia. • Alone to treat people 10 years of age and older with depressive episodes that happen with Bipolar I Disorder (bipolar depression). • With the medicine lithium or valproate to treat adults with depressive episodes that happen with Bipolar I Disorder (bipolar depression).
2.	Dosage	What is the recommended dosage?	• ***Moderate and Severe Renal Impairment****:* Recommended starting dose is 20 mg per day, and the maximum recommended dose is 80 mg per day. • ***Moderate and Severe Hepatic Impairment***: Recommended starting dose is 20 mg per day. The maximum recommended dose is 80 mg per day in moderate hepatic impairment and 40 mg per day in severe hepatic impairment. • ***Concomitant Use of a Moderate CYP3A4 inhibitor (e.g., diltiazem)****:* Lurasidone hydrochloride tablets dose should be reduced to half of the original dose level. Recommended starting dose is 20 mg per day. Maximum recommended dose is 80 mg per day • ***Concomitant Use of a Moderate CYP3A4 Inducer:*** It may be necessary to increase the dose of lurasidone hydrochloride tablets
3.	Administration	How do I take it?	• 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. • Take lurasidone hydrochloride tablets by mouth, with food (at least 350 calories). • 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.
4.	Administration	Use in Pediatric Population	Safety and effectiveness have not been evaluated less than 13 years of age with schizophrenia, less than 10 years of age with bipolar depression.

5.	Administration	Use in Geriatric Population	• Clinical studies with lurasidone hydrochloride did not include sufficient numbers of patients aged 65 and older to determine whether or not they respond differently from younger patients. • It is unknown whether dose adjustment is necessary on the basis of age alone.
6.	Mechanism	Mechanism of Action	The mechanism of action 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.
7.	Warning	Black Box Warning	**INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS; SUICIDAL THOUGHTS AND BEHAVIORS:** • 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. • Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients. Closely monitor for clinical worsening and emergence of suicidal thoughts and behaviors.
8.	Lactation	Use in Lactation	Studies have not been conducted to assess the presence of lurasidone in human milk, the effects on the breastfed infant, or the effects on milk production.
9.	Pregnancy	Use in Pregnancy	▪ If you are pregnant or plan to become pregnant, it is not known if Lurasidone hydrochloride tablets will harm your unborn baby. ▪ Advise patients that lurasidone hydrochloride tablets may cause extrapyramidal and/or withdrawal symptoms in a neonate. ▪ Advise patients to notify their healthcare provider with a known or suspected pregnancy. ▪ Advise patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to lurasidone hydrochloride tablets during pregnancy.
10.	Interaction	Is there any interaction with other medication?	No Clinically Important Interactions with Lurasidone Hydrochloride.
11.	Precautions	Is there any interaction between medication and alcohol?	No
12.	Storage	What are the storage conditions?	• Store lurasidone hydrochloride tablets at room temperature between (68° to 77°F).

13.	Dispensing	How to Dispense?	• As prescribed by Physician.
14.	Contraindication	What are the contraindications of (medication).	• Known hypersensitivity to lurasidone HCl or any components in the formulation. Angioedema has been observed with lurasidone. • Strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil, etc.) Strong CYP3A4 inducers (e.g., rifampin, avasimibe, St. John's wort, phenytoin, carbamazepine, etc.)
Pharmaceutical Particulars			
15.	Pharmaceutical Form	How is it supplied?	1. ***Lurasidone hydrochloride 20 mg tablets***: • white colored, round shaped, biconvex, film-coated tablets • Debossed with "20" on one side and "ML" on other side. • Supplied as: • NDC 72205-207-30, bottle of 30 tablets • NDC 72205-207-90, bottle of 90 tablets • NDC 72205-207-05, bottle of 500 tablets 2. ***Lurasidone hydrochloride 40 mg tablets***: • white colored, round shaped, biconvex, film-coated tablets • Debossed with "40" on one side and "ML" on other side. • Supplied as: ▪ NDC 72205-208-30, bottle of 30 tablets ▪ NDC 72205-208-90, bottle of 90 tablets ▪ NDC 72205-208-05, bottle of 500 tablets 3. ***Lurasidone hydrochloride 60 mg tablets:*** • white colored, oval shaped, biconvex, film-coated tablets • Debossed with "60" on one side and "ML" on other side. • Supplied as: • NDC 72205-209-30, bottle of 30 tablets • NDC 72205-209-90, bottle of 90 tablets • NDC 72205-209-05, bottle of 500 tablets ***4. Lurasidone hydrochloride 80 mg tablets:*** • white colored, oval shaped, biconvex, film-coated

			tablets • Debossed with “80” on one side and “ML” on other side. • Supplied as: • NDC 72205-210-30, bottle of 30 tablets • NDC 72205-210-90, bottle of 90 tablets • NDC 72205-210-05, bottle of 500 tablets ***5. Lurasidone hydrochloride 120 mg tablets:*** • white colored, oval shaped, biconvex, film-coated tablets • Debossed with “120” on one side and “ML” on other side. • Supplied as: • NDC 72205-211-30, bottle of 30 tablets • NDC 72205-211-90, bottle of 90 tablets • NDC 72205-211-05, bottle of 500 tablets
16.	Ingredients	Active and Inactive Ingredients	**Active**: Lurasidone hydrochloride. **Inactive:** carnauba wax, citric acid anhydrous, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, mannitol, polyethylene glycol, povidone, pregelatinized starch, and titanium dioxide.
Allergens			
17.	Ingredients	Is it Vegetarian?	No (Lactose produced from milk, that has been sourced from healthy cows.)
18.	Ingredients	Does it contain Gluten?	No
19.	Ingredients	Does it contain Dairy Products?	Yes (Lactose used as diluent in the FP products and sourced from Cow’s milk)
20.	Ingredients	Does it contain Casein	No
21.	Ingredients	Does it contain Whey?	No
22.	Ingredients	Does it contain corn?	Yes (Contains starch)
23.	Ingredients	Does it contain rye?	No
24.	Ingredients	Does it contain sugar?	No
25.	Ingredients	Does it contain Oats?	No
26.	Ingredients	Does it contain wheat?	No
27.	Ingredients	Does it contain spelt?	No
28.	Ingredients	Does it contain barley?	No
29.	Ingredients	Does it contain rennet?	No

30.	Ingredients	Does it contain starch?	Yes
31.	Ingredients	Does it contain Iodine?	No
32.	Ingredients	Does it contain latex?	No
33.	Ingredients	Does it contain alcohol?	Yes: API contains solvents within the limits as per ICH
34.	Ingredients	Does it contain dyes?	No
35.	Ingredients	Does it contain flavor?	No
36.	Ingredients	Does it contain Lactose?	Yes: Lactose produced from milk, that has been sourced from healthy cows.
37.	Ingredients	Does it contain Nuts?	No
38.	Ingredients	Does it contain Preservatives?	No
39.	Ingredients	Does it contain Soy products?	No
40.	Ingredients	Does it contain peanut?	No
41.	Ingredients	Does it contain nickel?	No
Miscellaneous			
42.	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.
43.	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
44.	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.
45.	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.
46.	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.
47.	Miscellaneous	Manufacturer and Distributor	**MSN Pharmaceuticals Inc** **Manufactured by:** MSN Laboratories Private Limited, Unit – II, Formulations Division, Nandigama **Distributed by:** Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714