LACOSAMIDE INJECTION USP, 200 mg20 mL (10 mgmL) Single-Dose Vials

S.No.	Category	Question	Answer
		Clinical Particulars	
1.	Use/Indication	What is the product indicated for?	To treat partial-onset seizures in patients aged 17 years and older. It is not known if lacosamide injection is safe and effective for partial-onset seizures in children under 1 month of age.
2.	Dosage	What is the recommended dosage?	**Adults (17 years and older):** **1. Monotherapy for Partial-Onset Seizures:** • **Initial Dosage:** 100 mg twice daily • **Maximum Dosage:** 200 mg twice daily • Increase dosage based on clinical response and tolerability, no more frequently than once per week. **2. Adjunctive Therapy for Partial-Onset Seizures:** • **Initial Dosage:** 50 mg twice daily • **Maximum Dosage:** 200 mg twice daily • Increase dosage based on clinical response and tolerability, no more frequently than once per week. 3. **Intravenous (IV) Administration:** For cases where oral administration is temporarily not feasible, the recommended IV dosage is administered two or three times daily over 15 to 60 minutes. • **Note:** Obtain an ECG before initiation for certain patients. **4. Dose Adjustments:** • **Renal Impairment:** Dose adjustment is recommended for severe renal impairment. • **Hepatic Impairment:** Dose adjustment is recommended for mild or moderate hepatic impairment. Use is not recommended in patients with severe hepatic impairment.
3.	Administration	How do I take it?	• Take lacosamide injection exactly as your healthcare provider tells you. • Your healthcare provider will tell you how much lacosamide injection to take and when to take it. • Your healthcare provider may change your dose if needed. • Do not stop lacosamide injection without first talking to a healthcare provider.

			Stopping lacosamide injection suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus). • Lacosamide injection may be taken with or without food. • If you take too much lacosamide injection, call your healthcare provider or local Poison Control Center right away.
4.	Mechanism	Mechanism of Action	The exact mechanism by which lacosamide produces its antiepileptic effects in humans is not fully understood. However, in vitro electrophysiological studies have demonstrated that lacosamide selectively enhances the slow inactivation of voltage-gated sodium channels. This action helps stabilize hyperexcitable neuronal membranes and inhibits repetitive neuronal firing.
5.	Warning	Black Box Warning	None
6.	Lactation	Use in Lactation	• Lacosamide passes into breast milk. • Breastfeeding while receiving lacosamide injection may cause increased sleepiness in your baby. If this occurs, contact your baby's healthcare provider. • Consult your healthcare provider to discuss the best feeding options for your baby while taking lacosamide injection.
7.	Pregnancy	Use in Pregnancy	▪ It is not known whether lacosamide injection can harm your unborn baby. If you become pregnant while using lacosamide injection, inform your healthcare provider immediately. Together, you will determine whether you should continue the treatment during pregnancy. ▪ If you become pregnant while taking lacosamide injection, discuss registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll by calling 1-888-233-2334. The registry collects information to assess the safety of antiepileptic medications during pregnancy.
8.	Warnings	While using the medication	▪ Monitor patients for signs of suicidal thoughts or behavior. ▪ Lacosamide may cause dizziness and ataxia. ▪ An ECG is recommended before starting treatment and after titration to steady-state maintenance in patients with underlying proarrhythmic conditions or those taking medications affecting cardiac conduction. These patients should be closely monitored. ▪ Lacosamide may cause syncope (fainting). ▪ To minimize the risk of increased seizure frequency, lacosamide should be gradually withdrawn. ▪ Discontinue lacosamide if no alternate etiology is identified.
9.	Storage	What are the storage conditions?	• Store lacosamide injection at room temperature between 68ºF to 77ºF (20ºC to 25ºC).

			• Do not freeze lacosamide injection.
10.	Dispensing	How to Dispense?	As prescribed by the Physician
11.	Contraindication	What are the contraindications of (medication).	None
Pharmaceutical Particulars			
12.	Pharmaceutical Form	How is it supplied?	**Lacosamide Injection, USP 200 mg/20 mL** is a clear, colorless, sterile solution supplied in 20 mL single-dose glass vials. • **Packaging:** 200 mg/20 mL vials, available in cartons containing 10 vials. • **NDC:** 72205-220-07.
13.	Ingredients	Active and Inactive Ingredients	**Active**: Lacosamide **Inactive**: sodium chloride (7.60 mg/mL), water for injection, hydrochloric acid (for pH adjustment).
Allergens			
14.	Ingredients	Is it Vegetarian?	Yes
15.	Ingredients	Does it contain Gluten?	No
16.	Ingredients	Does it contain Dairy Products?	No
17.	Ingredients	Does it contain Casein	No
18.	Ingredients	Does it contain Whey?	No
19.	Ingredients	Does it contain corn?	No
20.	Ingredients	Does it contain rye?	No
21.	Ingredients	Does it contain sugar?	No
22.	Ingredients	Does it contain Oats?	No
23.	Ingredients	Does it contain wheat?	No
24.	Ingredients	Does it contain spelt?	No
25.	Ingredients	Does it contain barley?	No
26.	Ingredients	Does it contain rennet?	No
27.	Ingredients	Does it contain starch?	No
28.	Ingredients	Does it contain Iodine?	No
29.	Ingredients	Does it contain latex?	No
30.	Ingredients	Does it contain alcohol?	Yes; API contains solvents within the limits as per ICH
31.	Ingredients	Does it contain dyes?	No

32.	Ingredients	Does it contain flavor?	No
33.	Ingredients	Does it contain Lactose?	No
34.	Ingredients	Does it contain Nuts?	No
35.	Ingredients	Does it contain Preservatives?	No
36.	Ingredients	Does it contain Soy products?	No
37.	Ingredients	Does it contain peanut?	No
38.	Ingredients	Does it contain nickel?	No
39.	Ingredients	Does it contain Latex?	No; Free from latex
Miscellaneous			
40.	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.
41.	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
42.	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.
43.	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.
44.	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.
45.	Miscellaneous	Manufacturer and Distributor	**Manufactured by:** **MSN laboratories pvt Ltd,** **Formulation divisions unit -II nandigama. INDIA** **Distributed by:** **Novadoz Pharmaceuticals LLC** **Piscataway, NJ 08854-3714**