

LACOSAMIDE ORALSOLUTION USP, 10mg/mL

S.No.	Category	Question	Answer
<b>Clinical Particulars</b>			
1	Use/Indication	What is the product indicated for?	<p>Lacosamide oral solution is indicated for:</p> <ul style="list-style-type: none"> <li>• Treatment of partial-onset seizures in patients 4 years of age and older.</li> <li>• Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older</li> </ul>
2	Dosage	What is the recommended dosage?	<p><b>Adults (17 years and older):</b></p> <ul style="list-style-type: none"> <li>• <b>For Monotherapy (Partial-Onset Seizures):</b> <ul style="list-style-type: none"> <li>○ Initial dosage: 100 mg twice daily</li> <li>○ Maximum recommended dosage: 200 mg twice daily</li> </ul> </li> <li>• <b>For Adjunctive Therapy (Partial-Onset Seizures or Primary Generalized Tonic-Clonic Seizures):</b> <ul style="list-style-type: none"> <li>○ Initial dosage: 50 mg twice daily</li> <li>○ Maximum recommended dosage: 200 mg twice daily</li> </ul> </li> </ul> <p><b>Pediatric Patients (4 to less than 17 years):</b></p> <ul style="list-style-type: none"> <li>• <b>Dosage:</b> <ul style="list-style-type: none"> <li>○ The recommended dosage is based on body weight and is administered orally twice daily.</li> <li>○ Dosage should be increased based on clinical response and tolerability, with adjustments made no more frequently than once per week.</li> </ul> </li> </ul> <p><b>Renal Impairment:</b></p> <ul style="list-style-type: none"> <li>• Dose adjustment is recommended for patients with severe renal impairment.</li> </ul> <p><b>Hepatic Impairment:</b></p> <ul style="list-style-type: none"> <li>• Dose adjustment is recommended for patients with mild or moderate hepatic impairment.</li> <li>• Use in patients with severe hepatic impairment is not recommended.</li> </ul>

3	Administration	How do I take it?	<ul style="list-style-type: none"> <li>• Take lacosamide oral solution exactly as your healthcare provider tells you.</li> <li>• Your healthcare provider will tell you how much lacosamide oral solution to take and when to take it.</li> <li>• Your healthcare provider may change your dose if needed.</li> <li>• Do not stop lacosamide oral solution without first talking to a healthcare provider. Stopping lacosamide oral solution suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).</li> <li>• Lacosamide oral solution may be taken with or without food.</li> <li>• If your healthcare provider has prescribed lacosamide oral solution, be sure to ask your pharmacist for a medicine dropper or medicine cup to help you measure the correct amount of lacosamide oral solution. Do not use a household teaspoon. Ask your pharmacist for instructions on how to use the measuring device the right way.</li> <li>• If you take too much lacosamide oral solution, call your healthcare provider or local Poison Control Center right away.</li> </ul>
4	Administration	Use in Pediatric Population	<ul style="list-style-type: none"> <li>• Lacosamide is safe and effective for treating partial-onset seizures in pediatric patients aged 4 to less than 17 years.</li> <li>• Safety and effectiveness in pediatric patients below 1 month of age have not been established</li> </ul>
5	Administration	Use in Geriatric Population	In elderly patients, titration should start at the lower end of the dosing range due to increased risk of hepatic and renal impairment, cardiac conduction issues, and polypharmacy.
6	Mechanism	Mechanism of Action	The precise mechanism by which lacosamide exerts its antiepileptic effects in humans remains to be fully elucidated. In vitro electrophysiological studies have shown that lacosamide selectively enhances slow inactivation of voltage-gated sodium channels, resulting in stabilization of hyperexcitable neuronal membranes and inhibition of repetitive neuronal firing.
7	Warning	Black Box Warning	None
8	Lactation	Use in Lactation	<ul style="list-style-type: none"> <li>• Lacosamide passes into breast milk.</li> <li>• Breastfeeding while taking lacosamide oral solution may cause increased sleepiness in your baby. If this occurs, contact your baby's healthcare provider.</li> <li>• Discuss with your healthcare provider the best approach for feeding your baby while using lacosamide oral solution.</li> </ul>
9	Pregnancy	Use in Pregnancy	<ul style="list-style-type: none"> <li>• The effects of lacosamide on an unborn baby are unknown. If you become pregnant while taking lacosamide oral solution, inform your healthcare provider immediately. Together, you will decide whether to continue treatment during pregnancy.</li> <li>• If you become pregnant while using lacosamide, discuss</li> </ul>

			enrolling in the North American Antiepileptic Drug Pregnancy Registry with your healthcare provider. You can register by calling 1-888-233-2334. This registry collects information to assess the safety of antiepileptic medications during pregnancy.
10	Precautions	Is there any interaction between medication and alcohol?	No
11	Interaction	Is there any interaction with food?	Lacosamide oral solution may be taken with or without food. Food does not affect the rate and extent of absorption.
12	Storage	What are the storage conditions?	Store lacosamide oral solution at room temperature between 68°F to 77°F (20°C to 25°C). Do not freeze lacosamide oral solution. Throw away any unused lacosamide oral solution 6 months after you first open the bottle.
13	Dispensing	How to Dispense?	As prescribed by the Physician
14	Contraindication	What are the contraindications of (medication).	None.
<b>Pharmaceutical Particulars</b>			
15	Pharmaceutical Form	How is it supplied?	Lacosamide Oral Solution, USP 10 mg/mL is a clear, colorless to yellow or yellow-brown, strawberry-flavored liquid. It is supplied as follows: <ul style="list-style-type: none"> <li>• 200 mL in PET bottles (NDC 72205-034-74)</li> <li>• 65 mL in PET bottles (NDC 72205-034-75)</li> </ul>
16	Ingredients	Active and Inactive Ingredients	<b>Active</b> LACOSAMIDE  <b>Inactive:</b> Acesulfame potassium, anhydrous citric acid, glycerin, methylparaben, polyethylene glycol, purified water, sodium carboxymethylcellulose, sodium chloride and sorbitol solution, strawberry flavor (including natural and artificial flavors, propylene glycol).
<b>Allergens</b>			
17	Ingredients	Is it Vegetarian?	yes
18	Ingredients	Does it contain Gluten?	No
19	Ingredients	Does it contain Dairy Products?	No
20	Ingredients	Does it contain Casein	No
21	Ingredients	Does it contain Whey?	No
22	Ingredients	Does it contain corn?	No
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?	No
31	Ingredients	Does it contain Iodine?	No
32	Ingredients	Does it contain latex?	No
33	Ingredients	Does it contain alcohol?	Yes (Lacosamide API contains Methonal NMT 3000 PPM & Ethanol NMT 5000 PPM, 2-Propanol NMT 5000 PPM)
34	Ingredients	Does it contain dyes?	No
35	Ingredients	Does it contain flavor?	Yes (strawberry flavor including natural and artificial flavors, propylene glycol).
36	Ingredients	Does it contain Lactose?	No
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
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	<b>Manufactured by: MSN Pharmaceuticals Inc 20 Duke Road, Piscataway-08854, NJ, USA</b>

