

BRIVARACETAM ORAL SOLUTION 10mg/mL

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Brivaracetam oral solution is indicated for the treatment of partial-onset seizures in patients 1 month of age and older
2	Dosage	What is the recommended dosage?	- Adults (≥ 16 years): Starting dose is 50 mg twice daily (100 mg/day). Based on tolerability and response, the dose may be adjusted between 25 mg twice daily (50 mg/day) and 100 mg twice daily (200 mg/day). - Pediatric patients (1 month to <16 years): Dosage is based on body weight and administered twice daily. - Hepatic impairment: Dose adjustment is recommended for all stages of hepatic impairment.
3	Administration	How do I take it?	- Take brivaracetam oral solution exactly as your healthcare provider tells you. - Your healthcare provider will tell you how much brivaracetam oral solution to take and when to take it. - Your healthcare provider may change your dose if needed. Do not change your dose without talking to your healthcare provider. - Take brivaracetam oral solution with or without food. - If your healthcare provider has prescribed brivaracetam oral solution, be sure to ask your pharmacist for a medicine dropper or medicine cup to help you measure the correct amount of brivaracetam oral solution. Do not use a household teaspoon or tablespoon. Ask your pharmacist for instructions on how to use the measuring device the right way. - If you take too much brivaracetam oral solution, call your Poison Control Center or go to the nearest emergency room right away.
4	Precaution to be taken	What should I avoid while taking brivaracetam oral solution?	Do not drive or operate machinery until you know how brivaracetam oral solution affects you. Brivaracetam oral solution may cause drowsiness, tiredness, dizziness, and problems with your balance and coordination.

5	Administration	What do I do if I miss a dose?	If you miss a dose of Brivaracetam oral solution continue your prescribed course of therapy, and contact your physician immediately.
6	Administration	Use in Pediatric Population	- Brivaracetam oral solution is approved for use in children aged 1 month to less than 16 years to treat partial-onset seizures. Its use in children is supported by studies done in adults, information on how the medicine works and moves through the body in both adults and children, and safety information collected from children. - However, for babies younger than 1 month old, there is not enough information available to know if the medicine is safe and works well, so it is not established for this age group.
7	Administration	Use in Geriatric Population	- There were not enough people aged 65 years and older included in the studies to clearly determine how well brivaracetam works in older adults with epilepsy. - For elderly patients, doctors usually start with a lower dose and adjust carefully if needed. This is because older adults are more likely to have reduced liver, kidney, or heart function, may have other health conditions, or may be taking other medicines that could affect treatment.
8	Mechanism	Mechanism of Action	The precise mechanism by which brivaracetam exerts its anticonvulsant activity is not known. Brivaracetam displays a high and selective affinity for synaptic vesicle protein 2A (SV2A) in the brain, which may contribute to the anticonvulsant effect.
9	Warning	Black Box Warning	- Brivaracetam and other anti-seizure (epilepsy) medicines may increase the risk of suicidal thoughts or unusual behavior in some people, even when used for different conditions. Patients should be monitored for new or worsening depression, suicidal thoughts, mood changes, or unusual behavior. - Studies showed that people taking these medicines had about twice the risk of suicidal thoughts or behavior compared with people taking placebo (inactive treatment), but the overall risk was still low (less than 1%). This means there was about 1 extra case for every 530 patients treated. - This risk was seen as early as 1 week after starting treatment and continued during the time studied.

			The risk appeared to be similar across different anti-seizure medicines and across all age groups studied. • Patients and caregivers should watch for changes in mood, behavior, depression, or thoughts of self-harm and contact a doctor if these occur.
10	Lactation	Use in Lactation	• Data from published literature indicate that brivaracetam is present in human milk. There is insufficient information on the effects of brivaracetam on the breastfed infant or on milk production. • The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for brivaracetam and any potential adverse effects on the breastfed infant from brivaracetam or from the underlying maternal condition.
11	Pregnancy	Use in Pregnancy	All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. Currently, there is not enough information in pregnant women to know whether brivaracetam increases the risk of birth defects, miscarriage, or other pregnancy problems.
12	Precautions	Is there any interaction between medication and alcohol?	None
13	Interaction	Is there any interaction with food?	No
14	Side effects	What are the common side effects?	The most common side effects of brivaracetam oral solution in adults include: • sleepiness • feeling tired • dizziness • nausea and vomiting
15	Storage	What are the storage conditions?	• Store brivaracetam oral solution at room temperature (20°C–25°C / 68°F–77°F). Short periods between 15°C–30°C (59°F–86°F) are allowed. • Do not freeze the medicine. • Throw away any unused oral solution 5 months after opening the bottle.
16	Dispensing	How to Dispense?	As prescribed by the Physician

17	Contraindication	What are the contraindications of (medication).	Hypersensitivity to brivaracetam or any of the inactive ingredients in brivaracetam oral solution (bronchospasm and angioedema have occurred).
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	Brivaracetam Oral Solution 10 mg/mL is a slightly viscous, clear, colorless to yellowish, raspberry-flavored liquid. It is supplied in amber glass bottles: 300 mL bottles. - NDC 72205-033-73
19	Ingredients	Active and Inactive Ingredients	Active Brivaracetam oral solution Inactive: artificial raspberry flavor, citric acid anhydrous, glycerin, methyl paraben, sodium carboxy methyl cellulose, sodium citrate dihydrate, sorbitol, sucralose and purified water.
20	Coating	What is the type of coating?	None
Allergens			
21	Ingredients	Is it Vegetarian?	Yes
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain Dairy Products?	No
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 Iodine?	No
36	Ingredients	Does it contain latex?	No
37	Ingredients	Does it contain alcohol?	Yes (API contains ICH residual solvents and which are controlled with ICH limits).
38	Ingredients	Does it contain dyes?	No

39	Ingredients	Does it contain flavor?	No
40	Ingredients	Does it contain Lactose?	No
41	Ingredients	Does it contain Nuts?	No
42	Ingredients	Does it contain Preservatives?	Yes (Methyl paraben)
43	Ingredients	Does it contain Soy products?	No
44	Ingredients	Does it contain peanut?	No
45	Ingredients	Does it contain nickel?	No
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Miscellaneous	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.
47	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
48	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.
49	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 .
50	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.
51	Miscellaneous	Manufacturer and Distributor	Manufactured by: MSN Pharmaceuticals Inc. 20 Duke Road, Piscataway- 08854, NJ, USA.