

VIGABATRIN for oral solution USP 500 MG

S. No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Vigabatrin for oral solution is indicated for the treatment of: Refractory Complex Partial Seizures (CPS) and infantile spasms (IS)
2	Dosage	What is the recommended dosage?	<u>DOSAGE AND ADMINISTRATION</u> The vigabatrin for oral solution dosing regimen depends on the indication, age group, weight, and dosage form (tablets or for oral solution). Dosage Modifications are required upon experiencing Adverse Reactions. For complete details, please refer to Prescribing Information.
3	Administration	Use in Paediatric Population	The safety and effectiveness of vigabatrin as adjunctive treatment of refractory complex partial seizures in paediatric patients 2 to 16 years of age have been established. The safety and effectiveness of vigabatrin as monotherapy for paediatric patients with infantile spasms (1 month to 2 years of age) have been established. Safety and effectiveness as adjunctive treatment of refractory complex partial seizures in paediatric patients below the age of 2 and as monotherapy for the treatment of infantile spasms in paediatric patients below the age of 1 month have not been established.
4	Administration	Use in Geriatric Population	Vigabatrin is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function. For Dosage Modifications, please refer to Complete Prescribing Information.
5	Mechanism	Mechanism of Action	The precise mechanism of vigabatrin's anti-seizure effect is unknown, but it is believed to be the result of its action as an irreversible inhibitor of γ -aminobutyric acid transaminase (GABA-T), the enzyme responsible for the metabolism of the inhibitory neurotransmitter GABA. This action results in increased levels of GABA in the central nervous system.

6	Warning	Warnings and Precautions	Vigabatrin can cause permanent bilateral concentric visual field constriction, including tunnel vision that can result in disability. In some cases, vigabatrin may also decrease visual acuity (5.1). Risk increases with increasing dose and cumulative exposure, but there is no dose or exposure to vigabatrin known to be free of risk of vision loss (5.1). Risk of new and worsening vision loss continues as long as vigabatrin is used, and possibly after discontinuing vigabatrin (5.1). Baseline and periodic vision assessment is recommended for patients on vigabatrin. However, this assessment cannot always prevent vision damage (5.1). Vigabatrin is available only through a restricted program called the Vigabatrin REMS Program (5.2).
7	Lactation	Use in Lactation	Patients should let their doctor know if breastfeeding or plan to breastfeed. Patient and their doctor should decide if patient will take vigabatrin tablets.
8	Pregnancy	Use in Pregnancy	Patients should let their doctor know if pregnant or plan to become pregnant. Vigabatrin for oral solution can cause harm to unborn baby. Patient and healthcare provider will have to decide if patient should take vigabatrin for oral solution while pregnant.
9	Storage	Storage and Handling?	Store at 20°C to 25°C (68°F to 77°F)
10	Contraindication	What are the contraindications of (medication)?	None
Pharmaceutical Particulars			
11	Pharmaceutical Form	How Supplied	Vigabatrin for oral solution, USP is available as 500 mg packets containing a white to off white granular powder. They are supplied as follows: Carton of 50 packets: NDC 72205-093-50 (Single Packet: NDC 72205-093-61) The oral syringes are provided separately by the pharmacy.
12	Ingredients	Active and Inactive	Active ingredient: vigabatrin, USP Inactive ingredients: povidone
Miscellaneous			
13	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.
14	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
15	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
16	Miscellaneous	Why does my	Please check with your pharmacy as to why your

		pharmacy, that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	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
17	Miscellaneous	May I know where is this product manufactured?	<p>Manufactured by: MSN Laboratories Private Limited Telangana – 509 228, INDIA</p> <p>Distributed by: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714</p>