NOVADOZ
AN MSN COMPANY

Levetiracetam Injection USP 500 mg 5mL (100 mg,mL) Single dose vials

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	1. **Partial-Onset Seizures:** Indicated for the treatment of partial-onset seizures in patients aged 1 month and older. 2. **Adjunctive Therapy:** • **Myoclonic Seizures:** For patients aged 12 years and older with juvenile myoclonic epilepsy. • **Primary Generalized Tonic-Clonic Seizures:** For patients aged 6 years and older with idiopathic generalized epilepsy. 3. **Intravenous Use:** Levetiracetam injection is for intravenous use only when oral administration is temporarily not feasible.
2	Dosage	What is the recommended dosage?	**Levetiracetam Injection (Intravenous Use Only)** **1. Partial-Onset Seizures (Monotherapy or Adjunctive Therapy):** • **1 Month to < 6 Months:** Start at 7 mg/kg twice daily, increase by 7 mg/kg twice daily every 2 weeks to a maximum of 21 mg/kg twice daily. • **6 Months to < 4 Years:** Start at 10 mg/kg twice daily, increase by 10 mg/kg twice daily every 2 weeks to a maximum of 25 mg/kg twice daily. • **4 Years to < 16 Years:** Start at 10 mg/kg twice daily, increase by 10 mg/kg twice daily every 2 weeks to a maximum of 30 mg/kg twice daily. • **Adults 16 Years and Older:** Start at 500 mg twice daily, increase by 500 mg twice daily every 2 weeks to a maximum of 1,500 mg twice daily. **2. Myoclonic Seizures (Adults and Pediatric Patients 12 Years and Older):** Start at 500 mg twice daily, increase by 500 mg twice daily every 2 weeks to a maximum of 1,500 mg twice daily. **3. Primary Generalized Tonic-Clonic Seizures:** • **6 Years to < 16 Years:** Start at 10 mg/kg

			twice daily, increase by 10 mg/kg twice daily every 2 weeks to a maximum of 30 mg/kg twice daily. • **Adults 16 Years and Older:** Start at 500 mg twice daily, increase by 500 mg twice daily every 2 weeks to a maximum of 1,500 mg twice daily. **4. Switching Between Oral and Intravenous Levetiracetam:** When switching from or to oral levetiracetam, the total daily dosage and frequency of levetiracetam injection should match the oral dosage regimen.
3	Administration	How do I take it?	• Levetiracetam injection should be diluted in 100 mL of a compatible diluent prior to administration. For smaller volumes (e.g., pediatric patients), the amount of diluent should be adjusted to ensure the final concentration does not exceed 15 mg/mL. Additionally, consider the patient's total daily fluid intake. • The injection should be administered as a 15-minute IV infusion. • Levetiracetam injection can be mixed with compatible diluents and antiepileptic drugs, and stored in polyvinyl chloride (PVC) bags. • The diluted solution should not be stored for more than 4 hours at controlled room temperature (15-30°C or 59-86°F).
4	Administration	Use in Pediatric Population	The safety and effectiveness of levetiracetam for the treatment of partial-onset seizures in pediatric patients under 1 month of age, adjunctive therapy for myoclonic seizures in pediatric patients under 12 years of age, and adjunctive therapy for primary generalized tonic-clonic seizures in pediatric patients under 6 years of age have not been established.
5	Administration	Use in Geriatric Population	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.
6	Mechanism	Mechanism of Action	The exact mechanism by which levetiracetam exerts its antiepileptic effect is unknown. It binds to the synaptic vesicle protein SV2A in the brain, which is involved in regulating vesicle exocytosis. While the molecular significance of this binding is unclear, experimental data suggest that the affinity of levetiracetam for SV2A correlates with its potency in controlling seizures, indicating that this interaction may contribute to its antiepileptic effects.
7	Warning	Black Box Warning	None
8	Lactation	Use in Lactation	Levetiracetam is excreted in human milk. However, there are no data on its effects on the breastfed infant or milk production. The benefits of breastfeeding should be weighed against the mother's clinical need for levetiracetam and any potential risks to the infant from the drug or the mother's underlying condition.

9	Pregnancy	Use in Pregnancy	• Prolonged experience with levetiracetam in pregnant women has not identified any drug-associated risks of major birth defects or miscarriage. However, the background risk of major birth defects and miscarriage in the general population is unknown. • Advise patients to notify their healthcare provider if they become pregnant or intend to become pregnant during levetiracetam therapy. Encourage patients to enroll in the North American Antiepileptic Drug (NAAED) pregnancy registry if they become pregnant
10	Precautions and Warnings	While using the medication	▪ Behavioral abnormalities including psychotic symptoms, suicidal ideation, irritability, and aggressive behavior have been observed; monitor patients for psychiatric signs and symptoms. ▪ Monitor for somnolence and fatigue; advise patients not to drive or operate machinery until they have sufficient experience on levetiracetam. ▪ Serious Dermatological Reactions: Discontinue levetiracetam at the first sign of rash unless clearly not drug related. ▪ Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan Hypersensitivity: Discontinue if no alternative etiology. ▪ Coordination Difficulties: Monitor for ataxia, abnormal gait, and incoordination. ▪ Withdrawal Seizures: Levetiracetam must be gradually withdrawn.
11	Storage	What are the storage conditions?	Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).
12	Dispensing	How to Dispense?	As prescribed by the Physician
13	Contraindication	What are the contraindications of (medication).	Levetiracetam is contraindicated in patients with a known hypersensitivity to the drug. Severe allergic reactions, including angioedema and anaphylaxis, have been reported.
Pharmaceutical Particulars			
14	Pharmaceutical Form	How is it supplied?	***Levetiracetam Injection, USP 500 mg/5 mL:*** Levetiracetam injection is a clear, colorless, sterile solution supplied in single-dose 5 mL vials. It is available in the following packaging options: • **Carton of 10 vials** (NDC 72205-120-07) • **Carton of 25 vials** (NDC 72205-120-25)
15	Ingredients	Active and Inactive Ingredients	**Active**: Levetiracetam **Inactive**: water, acetic acid, sodium chloride, sodium acetate.
Allergens			
16	Ingredients	Is it Vegetarian?	Yes

17	Ingredients	Does it contain Gluten?	No
18	Ingredients	Does it contain Dairy Products?	No
19	Ingredients	Does it contain Casein	No
20	Ingredients	Does it contain Whey?	No
21	Ingredients	Does it contain corn?	No
22	Ingredients	Does it contain rye?	No
23	Ingredients	Does it contain sugar?	No
24	Ingredients	Does it contain Oats?	No
25	Ingredients	Does it contain wheat?	No
26	Ingredients	Does it contain spelt?	No
27	Ingredients	Does it contain barley?	No
28	Ingredients	Does it contain rennet?	No
29	Ingredients	Does it contain starch?	No
30	Ingredients	Does it contain Iodine?	No
31	Ingredients	Does it contain latex?	No
32	Ingredients	Does it contain alcohol?	Yes
33	Ingredients	Does it contain dyes?	No
34	Ingredients	Does it contain flavor?	No
35	Ingredients	Does it contain Lactose?	No
36	Ingredients	Does it contain Nuts?	No
37	Ingredients	Does it contain Preservatives?	No
38	Ingredients	Does it contain Soy products?	No
39	Ingredients	Does it contain peanut?	No
40	Ingredients	Does it contain nickel?	No
Miscellaneous			
41	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.
42	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
43	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.

44	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.
45	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.
46	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**