**LEVETIRACETAM TABLETS (250 mg, 500 mg, 750 mg, 1000 mg)**

| S.No. | Category | Question | Answer |
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| **Clinical Particulars** | | | |
| 1. | Use/Indication | What is the product indicated for? | • Levetiracetam tablets are indicated for the treatment of partial-onset seizures in patients 1 month of age and older.<br>• Levetiracetam tablets are also indicated as adjunctive therapy for the treatment of:<br>• Myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy.<br>• Primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy |
| 2. | Dosage | What is the recommended dosage? | • Use the oral solution for pediatric patients with body weight ≤ 20 kg<br>• For pediatric patients, use weight-based dosing for the oral solution with a calibrated measuring device (not a household teaspoon or tablespoon)<br>***Partial-Onset Seizures (monotherapy or adjunctive therapy):***<br>• 1 Month to < 6 Months: 7 mg/kg twice daily; increase by 7 mg/kg twice daily every 2 weeks to recommended dose of 21 mg/kg twice daily<br>• 6 Months to < 4 Years: 10 mg/kg twice daily; increase by 10 mg/kg twice daily every 2 weeks to recommended dose of 25 mg/kg twice daily<br>• 4 Years to < 16 Years: 10 mg/kg twice daily; increase by 10 mg/kg twice daily every 2 weeks to recommended dose of 30 mg/kg twice daily<br>• Adults 16 Years and Older: 500 mg twice daily; increase by 500 mg twice daily every 2 weeks to a recommended dose of 1,500 mg twice daily<br>***Myoclonic Seizures in Adults and Pediatric Patients 12 Years and Older***:<br>• 500 mg twice daily; increase by 500 mg twice daily every 2 weeks to recommended dose of 1,500 mg twice daily<br>***Primary Generalized Tonic-Clonic Seizures:***<br>• 6 Years to < 16 Years: 10 mg/kg twice daily, increase in increments of 10 mg/kg twice daily every 2 weeks to recommended dose of 30 mg/kg twice daily<br>• Adults 16 Years and Older: 500 mg twice daily, increase by 500 mg twice daily every 2 weeks to recommended dose of 1,500 mg twice daily<br>***Adult Patients with Impaired Renal Function:***<br>• Dose adjustment is recommended, based on the patient's estimated creatinine clearance |

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| 3. | Administration | How do I take it? | ✓ Take levetiracetam tablets exactly as your healthcare provider tells you to take it.<br>✓ Your healthcare provider will tell you how much levetiracetam tablets to take and when to take it. Levetiracetam tablets is usually taken 2 times each day.<br>✓ Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.<br>✓ Take levetiracetam tablets with or without food.<br>✓ Swallow the tablets whole. Do not chew or crush tablets. Ask your healthcare provider for levetiracetam oral solution if you cannot swallow tablets. |
| 4. | Formulation | Can tablet be crushed? | Do not crush or chew the tablets |
| 5. | Administration | Use in Pediatric Population | The safety and effectiveness of levetiracetam for treating partial-onset seizures in infants under 1 month, myoclonic seizures in children under 12, and primary generalized tonic-clonic seizures in children under 6 have not been established. |
| 6. | Administration | Use in Geriatric Population | Levetiracetam is primarily excreted by the kidneys, and the risk of adverse reactions may be higher in patients with impaired renal function. Since elderly patients are more likely to have reduced renal function, dose selection should be cautious, and monitoring of renal function may be necessary. |
| 7. | Mechanism | Mechanism of Action | The precise mechanism(s) by which levetiracetam exerts its antiepileptic effect is unknown. A saturable and stereoselective neuronal binding site in rat brain tissue has been identified for levetiracetam. Experimental data suggest that this binding site is the synaptic vesicle protein SV2A, which is thought to be involved in the regulation of vesicle exocytosis. Although the molecular significance of levetiracetam binding to SV2A is not fully understood, levetiracetam and related analogs have shown a rank order of affinity for SV2A that correlates with the potency of their antiseizure activity in audiogenic seizure-prone mice. These findings suggest that levetiracetam's interaction with the SV2A protein may contribute to its antiepileptic mechanism of action. |
| 8. | Warning | Warning | Do not drive, operate machinery or do other dangerous activities until you know how levetiracetam tablets affects you. Levetiracetam tablets may make you dizzy or sleepy. |
| 9. | Lactation | Use in Lactation | Levetiracetam can pass into breast milk. It is not known whether the levetiracetam in breast milk could harm your baby. |
| 10. | Pregnancy | Use in Pregnancy | Inform your healthcare provider if you become pregnant or plan to become pregnant during levetiracetam therapy. |
| 11. | Precautions | Is there any interaction between medication and alcohol? | NO |
| 12. | Interaction | Is there any interaction with other medication? | No |

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| 13. | Interaction | Is there any interaction with food? | NO |
| 14. | Storage | What are the storage conditions? | Store at 20°C to 25°C (68°F to 77°F); excursions are allowed between 15°C to 30°C (59°F to 86°F). |
| 15. | Dispensing | How to Dispense? | Dispense in a tight, light-resistant container with a child-resistant closure. |
| 16. | Contraindication | What are the contraindications of (medication). | Levetiracetam tablets are contraindicated in patients with hypersensitivity to levetiracetam, as reactions may include anaphylaxis and angioedema. |
| **Pharmaceutical Particulars** | | | |
| 17. | Pharmaceutical Form | How is it supplied? | ***Levetiracetam Tablets, USP:***<br>• **250 mg:** White to off-white, oblong, biconvex, film-coated tablets debossed with "ML" and "7" on either side of the functional score on one side, plain on the other.<br>Bottles of 120 NDC 72205-094-92<br>• **500 mg:** Light yellow to yellow, oblong, biconvex, film-coated tablets debossed with "ML" and "8" on either side of the functional score on one side, plain on the other.<br>Bottles of 120 NDC 72205-095-92<br>• **750 mg:** Orange, oblong, biconvex, film-coated tablets debossed with "ML" and "9" on either side of the functional score on one side, plain on the other.<br>Bottles of 120 NDC 72205-096-92<br>• **1,000 mg:** White to off-white, oblong, biconvex, film-coated tablets debossed with "ML" and "10" on either side of the functional score on one side, plain on the other.<br>Bottles of 30 NDC 72205-097-30 |
| 18. | Ingredients | Active and Inactive Ingredients | **Active:** Levetiracetam Tablets<br><br>**Inactive:** Corn starch, colloidal silicon dioxide, croscarmellose sodium, povidone K30, talc, magnesium stearate, microcrystalline cellulose, titanium dioxide, polyethylene glycol, polyvinyl alcohol, and additional agents listed below:<br>• 500 mg tablets: Iron oxide yellow<br>• 750 mg tablets: FD&C Yellow No. 6 aluminum lake |
| **Allergens** | | | |
| 19. | Ingredients | Is it Vegetarian? | yes |
| 20. | Ingredients | Does it contain Gluten? | No |
| 21. | Ingredients | Does it contain Dairy Products? | No |
| 22. | Ingredients | Does it contain Casein | No |

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| 23. | Ingredients | Does it contain Whey? | No |
| 24. | Ingredients | Does it contain corn? | No |
| 25. | Ingredients | Does it contain rye? | No |
| 26. | Ingredients | Does it contain sugar? | No |
| 27. | Ingredients | Does it contain Oats? | No |
| 28. | Ingredients | Does it contain wheat? | No |
| 29. | Ingredients | Does it contain spelt? | No |
| 30. | Ingredients | Does it contain barley? | No |
| 31. | Ingredients | Does it contain rennet? | No |
| 32. | Ingredients | Does it contain starch? | Yes |
| 33. | Ingredients | Does it contain Iodine? | No |
| 34. | Ingredients | Does it contain latex? | No |
| 35. | Ingredients | Does it contain alcohol? | Yes; API contains solvents within the limits as per ICH |
| 36. | Ingredients | Does it contain dyes? | No |
| 37. | Ingredients | Does it contain flavor? | No |
| 38. | Ingredients | Does it contain Lactose? | No |
| 39. | Ingredients | Does it contain Nuts? | No |
| 40. | Ingredients | Does it contain Preservatives? | No |
| 41. | Ingredients | Does it contain Soy products? | No |
| 42. | Ingredients | Does it contain peanut? | No |
| 43. | Ingredients | Does it contain nickel? | No |
| **Miscellaneous** | | | |
| 44. | 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. |
| 45. | Miscellaneous | May I know about return, refunds and reimbursement? | Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500 |
| 46. | 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. |
| 47. | 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. |
| 48. | Miscellaneous | Why does my pharmacy that used to fill your generic formulation of a | 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) |

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| | | particular medicine, no longer fills my prescription with Novadoz formulation? | page to learn where to find our products. |
| 49. | Miscellaneous | Manufacturer and Distributor | **MSN Pharmaceuticals Inc**<br>**MSN life sciences unit-2 Nandigama** |