

**LEVETIRACETAM TABLET, FILM COATED 250 mg, 500mg, 750mg and 1000mg**

S.No.	Category	Question	Answer
<b>Clinical Particulars</b>			
1	Use/Indication	What is the product indicated for?	<p>Levetiracetam tablets are indicated for the treatment of partial-onset seizures in patients 1 month of age and older.</p> <p>Levetiracetam tablets are indicated for adjunctive therapy for the treatment of:</p> <ul style="list-style-type: none"> <li>• Myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy.</li> <li>• Primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy.</li> </ul>
2	Administration	How do I take it?	<p>Levetiracetam tablets are given orally with or without food. Levetiracetam tablets should be swallowed as a whole. Tablets should not be chewed or crushed.</p>
3	Formulation	Can tablet be crushed?	Tablets should not be chewed or crushed.
4	Administration	What do I do if I miss a dose?	<p>Avoid abrupt withdrawal from levetiracetam tablets in order to reduce the risk of increased seizure frequency and status epilepticus.</p> <p><i>In case, if you miss a dose, please contact your treating physician.</i></p>
5	Administration	Use in Pediatric Population	<p>Safety and effectiveness for the treatment of partial-onset seizures in pediatric patients below the age of 1 month; adjunctive therapy for the treatment of myoclonic seizures in pediatric patients below the age of 12 years; and adjunctive therapy for the treatment of primary generalized tonic-clonic seizures in pediatric patients below the age of 6 years have not been established.</p>
6	Administration	Use in Geriatric Population	<p>Levetiracetam is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function.</p> <p>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.</p>
7	Mechanism	Mechanism of Action	The precise mechanism(s) by which levetiracetam exerts its antiepileptic effect is unknown.
8	Warning	Black Box Warning	None
9	Lactation	Use in Lactation	Before taking levetiracetam tablets, tell your healthcare provider if you are breastfeeding or planning to breastfeed. levetiracetam can pass into your breast milk. Talk to your

			doctor about the best way to feed your baby while you receive levetiracetam tablets.
10	Pregnancy	Use in Pregnancy	Before taking levetiracetam tablets, tell your healthcare provider if you are pregnant or planning to become pregnant. It is not known if levetiracetam tablets will harm your unborn baby. You and your healthcare provider will have to decide if you should take levetiracetam tablets while you are pregnant.
11	Interaction	Is there any interaction with food?	Take levetiracetam tablets with or without food. Food does not affect the extent of absorption of levetiracetam but it decreases $C_{max}$ by 20% and delays $T_{max}$ by 1.5 hours.
12	Side effects	What are the common side effects?	Most common adverse reactions (incidence $\geq$ 5% more than placebo) include:  <u>Adult patients:</u> somnolence, asthenia, infection and dizziness <u>Pediatric patients:</u> fatigue, aggression, nasal congestion, decreased appetite, and irritability.
13	Storage	What are the storage conditions?	Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F). Dispense in a tight, light-resistant container with a child-resistant closure.
14	Dispensing	How to Dispense?	Dispense in a tight, light-resistant container with a child-resistant closure.
15	Contraindication	What are the contraindications of (medication).	Levetiracetam tablets are contraindicated in patients with a hypersensitivity to levetiracetam. Reactions have included anaphylaxis and angioedema.  <i>Please refer to Prescribing Information for complete details</i>
<b>Pharmaceutical Particulars</b>			
16	Pharmaceutical Form	How is it supplied?	<p><u>250 mg:</u> White to off white colored, oblong shaped, biconvex, film-coated tablets debossed with “ML” and “7” on either side of functional score on one side and plain surface on the other side. Bottles of 120: NDC 72205-094-92</p> <p><u>500 mg:</u> Light yellow to yellow colored, oblong shaped, biconvex, film-coated tablets debossed with “ML” and “8” on either side of functional score on one side and plain surface on the other side. Bottles of 120: NDC 72205-095-92</p> <p><u>750 mg:</u> Orange colored, oblong shaped, biconvex, film-coated tablets debossed with “ML” and “9” on either side of functional score on one side and plain surface on the other side. Bottles of 120: NDC 72205-096-92</p> <p><u>1000 mg:</u> White to off white colored, oblong shaped, biconvex, film-coated tablets debossed with “ML” and “10” on either side of functional score on one side and plain surface on the other side. Bottles of 60: NDC 72205-097-60</p>

17	Ingredients	Active and Inactive Ingredients	<p><b>Active:</b> LEVETIRACETAM</p> <p><b>Inactive:</b> 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: 500 mg tablets: iron oxide yellow 750 mg tablets: FD&amp;C yellow No. 6 aluminum lake.</p>
<b>Miscellaneous</b>			
18	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.
19	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
20	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.
21	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.
22	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.
23	Miscellaneous	Manufacturer and Distributor	<p><b>Manufactured by:</b> MSN Laboratories Private Limited Ranga Reddy (Dt.) Telangana – 509 228, INDIA</p> <p><b>Distributed by:</b> Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714</p>