

Levetiracetam Oral Solution 100 mg/mL

S.No.	Category	Question	Answer
Clinical Particulars			
1.	Use/Indication	What is the product indicated for?	<p>Levetiracetam oral solution is indicated for the treatment of partial-onset seizures in patients 1 month of age and older.</p> <p>Levetiracetam oral solution is indicated for adjunctive therapy for the treatment of:</p> <ul style="list-style-type: none"> • Myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy. • Primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy.
2.	Dosage	What is the recommended dosage?	<p>Use the oral solution for pediatric patients with body weight ≤ 20 kg</p> <p>For pediatric patients, use weight-based dosing for the oral solution with a calibrated measuring device (not a household teaspoon or tablespoon).</p> <p><u>Partial-Onset Seizures (monotherapy or adjunctive therapy):</u></p> <ul style="list-style-type: none"> • 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. • 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. • 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. • 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. <p><u>Myoclonic Seizures in Adults and Pediatric Patients 12 Years and Older:</u></p> <ul style="list-style-type: none"> • 500 mg twice daily; increase by 500 mg twice daily every 2 weeks to recommended dose of 1,500 mg twice daily. <p><u>Primary Generalized Tonic-Clonic Seizures:</u></p> <ul style="list-style-type: none"> • 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. • Adults 16 Years and Older: 500 mg twice daily, increase

			<p>by 500 mg twice daily every 2 weeks to recommended dose of 1,500 mg twice daily.</p> <p>Adult Patients with Impaired Renal Function:</p> <ul style="list-style-type: none"> Dose adjustment is recommended, based on the patient's estimated creatinine clearance.
3.	Administration	How do I take?	Take levetiracetam with or without food.
4.	Administration	What do I do if I miss a dose?	Take levetiracetam exactly as your healthcare provider tells you to take it. Do not change the dose or stop taking levetiracetam without first talking to your healthcare provider.
5.	Side effects	What are the most common and possible side effects?	Adult patients: somnolence, asthenia, infection and dizziness. Pediatric patients: fatigue, aggression, nasal congestion, decreased appetite, and irritability.
6.	Administration	Use in Pediatric Population	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.
7.	Administration	Use in Geriatric Population	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. 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.
8.	Mechanism	Mechanism of Action	The precise mechanism(s) by which levetiracetam exerts its antiepileptic effect is unknown.
9.	Warning	Black Box Warning	No Black Box warning
10.	Lactation	Use in Lactation	<p>The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for levetiracetam and any potential adverse effects on the breastfed infant from levetiracetam or from the underlying maternal condition.</p> <p>Tell healthcare provider before starting levetiracetam oral solution if you are breastfeeding or plan to breastfeed. Levetiracetam can pass into your breast milk. It is not known if the levetiracetam that passes into your breast milk can harm your baby. Talk to your doctor about the best way to feed your baby while you receive levetiracetam oral solution.</p>
11.	Pregnancy	Use in Pregnancy	Tell healthcare provider before starting levetiracetam oral solution if you are pregnant or planning to become pregnant. It is not known if levetiracetam oral solution will harm your unborn baby. You and your healthcare provider will have to decide if you should take levetiracetam oral solution while you are pregnant.
12.	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.
13.	Dispensing	How to Dispense?	Dispense in a tight, light-resistant container with a child-resistant closure.
14.	Contraindication	What are the contraindications	Levetiracetam oral solution is contraindicated in patients with a hypersensitivity to levetiracetam. Reactions have included

		of (medication)?	anaphylaxis and angioedema. See Prescribing Information for complete details
Pharmaceutical Particulars			
15.	Pharmaceutical Form	How Supplied	Levetiracetam is supplied as 100 mg/mL: a clear, colorless, grape-flavored liquid. It is supplied in 16 fl. oz. white HDPE bottles (NDC 72205-037-72).
16.	Ingredients	Active and Inactive	<p>Active ingredient: Levetiracetam, USP</p> <p>Inactive ingredients: Ammonium glycyrrhizinate, artificial grape flavour, citric acid monohydrate, glycerin, maltitol syrup, methylparaben, potassium acesulfame, propylparaben, sodium citrate dihydrate and purified water.</p> <p>Levetiracetam oral solution does not contain lactose or gluten. Levetiracetam oral solution does contain carbohydrates. The liquid is dye-free.</p>
Miscellaneous			
17.	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
18.	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
19.	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
20.	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
21.	Miscellaneous	May I know where is this product manufactured?	<p>Manufactured by: MSN pharmaceuticals Inc. Piscataway, NJ 08854.</p> <p>Distributed by: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714 TEL: 855-NOVADOZ (668-2369)</p>