MEDICATION GUIDE
Levetiracetam (LEE-ve-tye-RA-se-tam) Oral Solution, USP

Read this Medication Guide before you start taking levetiracetam oral solution and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about levetiracetam oral solution?

Like other antiepileptic drugs, levetiracetam oral solution may cause suicidal thoughts or actions in a very small number of people, about 1 in 500 people taking it.

Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

Do not stop levetiracetam oral solution without first talking to a healthcare provider.

- Stopping levetiracetam oral solution suddenly can cause serious problems. Stopping a seizure medicine suddenly can cause seizures that will not stop (status epilepticus).
- Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.

Call your healthcare provider between visits as needed, especially if you are worried about symptoms

What is levetiracetam oral solution?

Levetiracetam oral solution is a prescription medicine taken by mouth that is used to treat partial-onset seizures in people 1 month of age and older.

Levetiracetam oral solution is a prescription medicine taken by mouth that is used with other medicines to treat:

- myoclonic seizures in people 12 years of age and older with juvenile myoclonic epilepsy.
- primary generalized tonic-clonic seizures in people 6 years of age and older with certain types of generalized epilepsy.

It is not known if levetiracetam oral solution is safe or effective in children under:

- 1 month of age to treat partial-onset seizures
- 12 years of age to treat myoclonic seizures
- 6 years of age to treat primary generalized tonic-clonic seizures

Before taking your medicine, make sure you have received the correct medicine. Compare the name above with the name on your bottle and the appearance of your medicine with the description of levetiracetam provided below. Tell your pharmacist immediately if you think you have been given the wrong medicine.

Who should not take levetiracetam oral solution?

Do not take levetiracetam oral solution if you are allergic to levetiracetam.

What should I tell my healthcare provider before starting levetiracetam oral solution?

Before taking levetiracetam oral solution, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had depression, mood problems or suicidal thoughts or behavior.
- have kidney problems.
- 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. If you become pregnant while taking levetiracetam oral solution, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334 or go to http://www.aedpregnancyregistry.org. The purpose of this registry is to collect information about the safety of levetiracetam oral solution and other antiepileptic medicine during pregnancy.
- are breastfeeding or plan to breastfeed. Levetiracetam oral solution can pass into your breast milk. It is not known if the levetiracetam oral solution 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.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Do not start a new medicine without first talking with your healthcare provider.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine.

How should I take levetiracetam oral solution?

- Take levetiracetam oral solution exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much levetiracetam oral solution to take and when to take it. Levetiracetam oral solution is usually taken 2 times each day.
- Your healthcare provider may change your dose. **Do not** change your dose without talking to your healthcare provider.
- Take levetiracetam oral solution with or without food.
- If your healthcare provider has prescribed levetiracetam oral solution, be sure to ask your pharmacist for a medicine dropper or medicine cup to help you measure the correct amount of levetiracetam oral solution. Do not use a household teaspoon. Ask your pharmacist for instructions on how to use the measuring device the right way.
- If you take too much levetiracetam oral solution, call your local Poison Control Center or go to the nearest emergency room right away.

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What should I avoid while taking levetiracetam oral solution?

Do not drive, operate machinery or do other dangerous activities until you know how levetiracetam oral solution affects you. Levetiracetam oral solution may make you dizzy or sleepy.

What are the possible side effects of levetiracetam oral solution?

Levetiracetam oral solution can cause serious side effects including:

- See **"What is the most important information I should know about levetiracetam oral solution?**

Call your healthcare provider right away if you have any of these symptoms:

- mood and behavior changes such as aggression, agitation, anger, anxiety, apathy, mood swings, depression, hostility, and irritability. A few people may get psychotic symptoms such as hallucinations (seeing or hearing things that are really not there), delusions (false or strange thoughts or beliefs) and unusual behavior.
- extreme sleepiness, tiredness, and weakness
- allergic reactions such as swelling of the face, lips, eyes, tongue, and throat, trouble swallowing or breathing, and hives.
- a skin rash. Serious skin rashes can happen after you start taking levetiracetam oral solution. There is no way to tell if a mild rash will become a serious reaction.
- a serious allergic reaction that may affect your skin or other parts of your body such as your liver, kidneys, heart, or blood cells. This allergic reaction can be life-threatening and can cause death, particularly if it is not treated as early as possible. Call your healthcare provider right away if you have:
  - a skin rash
  - fever or swollen glands that do not go away
  - swelling of your face
  - shortness of breath
  - dark urine
  - yellowing of the skin or whites of the eyes
- problems with muscle coordination (problems walking and moving)

The most common side effects seen in people who take levetiracetam oral solution include:

- sleepiness
- weakness
- infection
- dizziness

The most common side effects seen in children who take levetiracetam oral solution include, in addition to those listed above include:

- tiredness
- acting aggressive
- decreased appetite
- nasal congestion
- irritability

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of levetiracetam oral solution. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store levetiracetam oral solution?

- **Store levetiracetam oral solution** at room temperature, between 59°F to 86°F (15°C to 30°C) away from heat and light.
- **Keep levetiracetam oral solution and all medicines out of the reach of children.**

General information about the safe and effective use of levetiracetam oral solution.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use levetiracetam oral solution for a condition for which it was not prescribed. Do not give levetiracetam oral solution to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider information about levetiracetam oral solution that is written for health professionals.

What are the ingredients in levetiracetam oral solution, USP?

Active ingredient: Levetiracetam, USP

Inactive ingredients: acesulfame potassium, ammonium glycyrrhizinate, citric acid monohydrate, glycerin, maltitol solution, methylparaben, propylparaben, purified water, sodium citrate dihydrate and natural and artificial flavor.

Levetiracetam oral solution does not contain lactose or gluten. Levetiracetam oral solution does contain carbohydrates. The liquid is dye-free.

Manufactured by:
Strides Pharma Science Limited
Bengaluru – 562106, India

Distributed by:
Strides Pharma Inc.
East Brunswick, NJ 08816

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

Medication Guide available at: www.strides.com/levetiracetam-os/

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ARTWORK DETAIL LABEL

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Buyer/Country	STRIDES PHARMA INC - US	Component	Medication Guide		
Dimension	**240 x 300 mm**			Pack	–
New Item Code	**1040432**	Old Item Code	NA		
Colour Shades	BLACK			No. of Colours	1

Change Control No.	NA	Artwork Version	1.0
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