

MEDICATION GUIDE

Levetiracetam

(lee" va tye ra' se tam)

Tablets, USP and Oral Solution, USP

Read this Medication Guide before you start taking levetiracetam 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?

Like other antiepileptic drugs, levetiracetam 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 without first talking to a healthcare provider.

- Stopping levetiracetam 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?

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

- partial onset seizures in people 1 month of age and older with epilepsy
- 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 is safe or effective in children under 1 month of age.

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.

Levetiracetam Tablets USP, 250 mg are blue, film coated caplet shape tablets, scored on one side, engraved with "LVT" on the left of the score and "250" on the right, and "TARO" on the other side.

Levetiracetam Tablets USP, 500 mg are yellow, film coated caplet shape tablets, scored on one side, engraved with "LVT" on the left of the score and "500" on the right, and "TARO" on the other side.

Levetiracetam Tablets USP, 750 mg are peach, film coated caplet shape tablets, scored on one side, engraved with "LVT" on the left of the score and "750" on the right, and "TARO" on the other side.

Levetiracetam Tablets USP, 1000 mg are white to off-white, film coated caplet shaped tablets, scored on one side, engraved with "LVT" on the left of the score and "1000" on the right, and "TARO" on the other side.

Levetiracetam Oral Solution USP, 100 mg/mL is a clear to yellowish, grape-flavored liquid.

Who should not take levetiracetam?

Do not take levetiracetam if you are allergic to levetiracetam.

What should I tell my healthcare provider before starting levetiracetam?

Before taking levetiracetam, 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 will harm your unborn baby. You and your healthcare provider will have to decide if you should take levetiracetam while you are pregnant. If you become pregnant while taking levetiracetam, 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. The purpose of this registry is to collect information about the safety of levetiracetam and other antiepileptic medicine during pregnancy.
- are breast feeding. Levetiracetam can pass into your milk and may harm your baby. You and your healthcare provider should discuss whether you should take levetiracetam or breast-feed; you should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription 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?

Take levetiracetam exactly as prescribed.

- Your healthcare provider will tell you how much levetiracetam to take and when to take it. Levetiracetam is usually taken twice a day. Take levetiracetam at the same times each day.
- Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.
- Take levetiracetam with or without food.

- Swallow the tablets whole. Do not chew or crush tablets. Ask your healthcare provider for levetiracetam oral solution if you cannot swallow tablets.
- 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 miss a dose of levetiracetam, take it as soon as you remember. If it is almost time for your next dose, just skip the missed dose. Take the next dose at your regular time. **Do not take two doses at the same time.**
- If you take too much levetiracetam, call your local Poison Control Center or go to the nearest emergency room right away.

What should I avoid while taking levetiracetam?

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

What are the possible side effects of levetiracetam?

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

Levetiracetam can cause serious side effects.

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
- problems with muscle coordination (problems walking and moving)
- 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. There is no way to tell if a mild rash will become a serious reaction.

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

- sleepiness
- weakness
- infection
- dizziness

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

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

These side effects can happen at any time but happen more often within the first 4 weeks of treatment except for infection.

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. 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?

- Store levetiracetam at room temperature, 68°F to 77°F (20°C to 25°C) away from heat and light.
- **Keep levetiracetam and all medicines out of the reach of children.**

General information about levetiracetam.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use levetiracetam for a condition for which it was not prescribed. Do not give levetiracetam to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about levetiracetam. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about levetiracetam that is written for health professionals. You can also get information about levetiracetam at www.taro.com or call 1-866-923-4914.

What are the ingredients of levetiracetam?

Levetiracetam Tablet, USP

Active ingredient: levetiracetam USP

Inactive ingredients: colloidal silicon dioxide, corn starch, magnesium stearate, povidone, talc and additional agents listed below:

250 mg tablets: opadry blue 03B20463 (contains FD&C Blue #2/indigo carmine aluminum lake, hypromellose, polyethylene glycol and titanium dioxide)

500 mg tablets: opadry yellow 03B32441 (contains hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, and titanium dioxide)

750 mg tablets: opadry pink 03B34672 (contains hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, and titanium dioxide)

1000 mg tablets: opadry white Y-1-7000 (contains hypromellose polyethylene glycol and titanium dioxide)

Levetiracetam Oral Solution, USP

Active ingredient: levetiracetam USP

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

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

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

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