

MEDICATION GUIDE

Levetiracetam Tablets

250 mg, 500 mg, 750 mg, 1000 mg

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 4 years 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 4 years 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. Contact your pharmacist immediately if you believe a dispensing error may have occurred.

250 mg levetiracetam tablets are pink, oblong-shaped, bi-convex, scored film coated tablets, debossed “SLC 221” on either side of the score and plain on the other side.

500 mg levetiracetam tablets are pink, oblong-shaped, bi-convex, scored film coated tablets, debossed “SLC 222” on either side of the score and plain on the other side.

750 mg levetiracetam tablets are pink, oblong-shaped, bi-convex, scored film coated tablets, debossed “SLC 223” on either side of the score and plain on the other side.

1000 mg levetiracetam tablets are white to off-white, modified capsules shaped, bi-convex, scored film-coated tablets debossed “SLC 224” on either side of the score and plain on the other side.

What should I tell my healthcare provider before starting levetiracetam?

Before starting 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 Tablets?

Take Levetiracetam tablets exactly as prescribed.

- Your healthcare provider will tell you how much levetiracetam to take and when to take it.
- Take levetiracetam tablets with or without food. Swallow the tablets whole. Do not chew or crush tablets.
- 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. Use the 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 or overdose, call your local Poison Control Center or go to the nearest emergency room right away.

What should I avoid while taking Levetiracetam tablets?

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

What are the possible side effects of levetiracetam tablets?

- 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)

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

- sleepiness
- weakness
- dizziness
- infection

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

- accidental injury
- irritability
- hostility

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 tablets?

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

General information about levetiracetam tablets.

Medicines are sometimes prescribed for purposes other than those described in patient information leaflets. Do not use levetiracetam tablets for a condition for which it was not prescribed. Do not

give levetiracetam tablets 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 tablets. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about levetiracetam tablets that is written for health professionals.

What are the ingredients of levetiracetam tablets?

Levetiracetam tablets contain the labeled amount of levetiracetam. Inactive ingredients: colloidal silicon dioxide, corn starch, magnesium stearate, povidone, talc, and additional agents listed below:

250 mg, 500 mg, Opadry II Pink 40L94198, which and 750 mg tablets: contains D&C Red No. 21; FD&C Blue No. 2; FD&C Red No. 40; FD&C Yellow No. 6; hypromellose 2910 3cP, 6cP, and 50cP; polydextrose FCC; polyethylene glycol 800; titanium dioxide; and triacetin.

1000 mg tablets: Opadry II white Y-22-7719, which contains hypromellose 2910 3cP, 6cP, and 50cP; polydextrose FCC; polyethylene glycol 800; titanium dioxide; and triacetin.

Levetiracetam tablets do not contain lactose or gluten.

Call your doctor for medical advice about side effects. To report SUSPECTED ADVERSE REACTIONS, contact Legacy Pharmaceuticals Puerto Rico, LLC or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Rx Only

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

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* Repeat of the Medication Guide in its entirety.

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