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MEDICATION GUIDE

LEVETIRACETAM (LEE-ve-tye-RA-se-tam) EXTENDED-RELEASE TABLETS USP, for oral use

Rx Only

Read this Medication Guide before you start taking levetiracetam extended-release tablets 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 extended-release tablets?

Like other antiepileptic drugs, levetiracetam extended-release tablets 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 extended-release tablets without first talking to a healthcare provider.

- Stopping levetiracetam extended-release tablets 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 are levetiracetam extended-release tablets?

Levetiracetam extended-release tablets are a prescription medicine taken by mouth that is used to treat partial-onset seizures in people 12 years of age and older.

It is not known if levetiracetam extended-release tablets are safe or effective in people under 12 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 extended-release tablets provided below. Tell your pharmacist immediately if you think you have been given the wrong medicine.

Who should not take levetiracetam extended-release tablets?

Do not take levetiracetam extended-release tablets if you are allergic to levetiracetam.

What should I tell my healthcare provider before starting levetiracetam extended-release tablets?

Before taking levetiracetam extended-release tablets, 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 extended-release tablets will harm your unborn baby. You and your healthcare provider will have to decide if you should take levetiracetam extended-release tablets while you are pregnant. If you become pregnant while taking levetiracetam extended-release tablets, 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 extended-release tablets and other antiepileptic medicine during pregnancy.
- 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.

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 extended-release tablets?

- Take levetiracetam extended-release tablets exactly as your healthcare provider tells you to take it.

- Your healthcare provider will tell you how much levetiracetam extended-release tablets to take and when to take it. Levetiracetam extended-release tablet is usually taken 1 time each day.
- Your healthcare provider may change your dose. **Do not** change your dose without talking to your healthcare provider.
- Take levetiracetam extended-release tablets with or without food.
- Swallow the tablets whole. **Do not** chew, break, or crush tablets.
- The inactive part of levetiracetam extended-release tablets may not dissolve after all the medicine has been released in your body. You may sometimes notice something in your bowel movement that looks like swollen pieces of the original tablet. This is normal.
- If you take too much levetiracetam extended-release tablets, call your local Poison Control Center or go to the nearest emergency room right away.

What should I avoid while taking levetiracetam extended-release tablets?

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

What are the possible side effects of levetiracetam extended-release tablets?

Levetiracetam extended-release tablets can cause serious side effects including:

- See “**What is the most important information I should know about levetiracetam extended-release tablets?**”

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 extended-release tablets. 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
 - swelling of your face
 - dark urine
 - fever or swollen glands that do not go away
 - shortness of breath
 - 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 extended-release tablets include:

- sleepiness
- 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 extended-release tablets. 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.

You may also report side effects to Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

How should I store levetiracetam extended-release tablets?

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

General information about the safe and effective use of levetiracetam extended-release tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use levetiracetam extended-release tablets for a condition for which it was not prescribed. Do not give levetiracetam extended-release tablets 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 for information about levetiracetam extended-release tablets that is written for health professionals.

What are the ingredients in levetiracetam extended-release tablets?

Levetiracetam extended-release tablet active ingredient: levetiracetam

Inactive ingredients: colloidal silicon dioxide, dibasic calcium phosphate anhydrous, hydrogenated vegetable oil, hypromellose, lactose anhydrous, magnesium stearate, polyvinyl alcohol, polyethylene glycol, talc and titanium dioxide. The imprinting ink contains shellac, iron oxide black and propylene glycol.

Levetiracetam extended-release tablet does not contain gluten.

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

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