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Dispense with Medication Guide available at: www.lupin.com/levetiracetamtab-mg.pdf

MEDICATION GUIDE
LEVETIRACETAM (LEE-ve-tye-RA-se-tam)
TABLETS USP
250 mg, 500 mg, 750 mg and 1000 mg
Rx only

Read this Medication Guide before you start taking levetiracetam 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 Tablets?

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

- Stopping Levetiracetam 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 Tablets?

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

Levetiracetam tablets are 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 tablets are 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 tablets provided below. Tell your pharmacist immediately if you think you have been given the wrong medicine.

Who should not take Levetiracetam Tablets?

Do not take levetiracetam tablets if you are allergic to levetiracetam.

What should I tell my healthcare provider before starting Levetiracetam Tablets?

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

- Take levetiracetam tablets exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much levetiracetam tablets to take and when to take it. Levetiracetam tablets are 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 tablets 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 you take too much levetiracetam tablets, 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 tablet affects you. Levetiracetam tablets may make you dizzy or sleepy.

What are the possible side effects of Levetiracetam Tablets?

Levetiracetam tablets can cause serious side effects including:

- See “What is the most important information I should know about Levetiracetam 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 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 Tablets include:

- | | |
|--------------|-------------|
| • sleepiness | • weakness |
| • infection | • dizziness |

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

- | | | | |
|---|--------------------|---|-------------------|
| • | 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 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 Tablets?

- Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature] away from heat and light.
- **Keep Levetiracetam Tablets and all medicines out of the reach of children.**

General information about safe and effective use of Levetiracetam Tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. 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. You can ask your pharmacist or healthcare provider information about levetiracetam tablets that is written for health professionals.

What are the ingredients of Levetiracetam Tablets?

Levetiracetam Tablets

active ingredient: levetiracetam

For 250 mg, 500 mg and 750 mg strengths:

Inactive ingredients: colloidal silicon dioxide, corn starch, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, talc, titanium dioxide, and additional agents listed below:

250 mg tablets: FD & C Blue No. 2/indigo carmine Aluminum Lake

500 mg tablets: Yellow Iron Oxide

750 mg tablets: FD & C Blue No. 2/indigo carmine Aluminum Lake, FD & C Yellow No. 6/sunset yellow FCF Aluminum Lake, iron oxide red

For 1000 mg strength:

Inactive ingredients: colloidal silicon dioxide, corn starch, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, talc and titanium dioxide.

Levetiracetam tablets do not contain lactose or gluten.

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



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