

MEDICATION GUIDE ROWEEPRA XR (ROW ee pra XR)(levetiracetam) extended-release tablets

Read this Medication Guide before you start taking ROWEEPRA XR 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 ROWEEPRA XR?

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

- Stopping ROWEEPRA XR 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 ROWEEPRA XR?

ROWEEPRA XR is a prescription medicine taken by mouth that is used with other medicines to treat partial onset seizures in people 12 years of age and older with epilepsy.

It is not known if ROWEEPRA XR is 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 ROWEEPRA XR provided below. Tell your pharmacist immediately if you think you have been given the wrong medicine.

500 mg ROWEEPRA XR tablets are white, oval, oblong tablets debossed with "LP332" on one side and blank on the other side.

750 mg ROWEEPRA XR tablets are white, oval, oblong tablets debossed with "LP79" on one side and blank on the other side.

What should I tell my healthcare provider before starting ROWEEPRA XR?

Before taking ROWEEPRA XR, 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 ROWEEPRA XR will harm your unborn baby. You and your healthcare provider will have to decide if you should take ROWEEPRA XR while you are pregnant. If you become pregnant while taking ROWEEPRA XR, 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 ROWEEPRA XR and other antiepileptic medicine during pregnancy.
- are breast feeding. ROWEEPRA XR can pass into your milk and may harm your baby. You and your healthcare provider should discuss whether you should take ROWEEPRA XR or breast feed; you should not do both.

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 ROWEEPRA XR?

Take ROWEEPRA XR exactly as prescribed.

- Your healthcare provider will tell you how much ROWEEPRA XR to take and when to take it. ROWEEPRA XR is usually taken once a day. Take ROWEEPRA XR at the same time each day.
- Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.
- Take ROWEEPRA XR with or without food.
- Swallow the tablets whole. Do not chew, break, or crush tablets.
- The inactive part of ROWEEPRA XR 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 miss a dose of ROWEEPRA XR, 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 ROWEEPRA XR, call your local Poison Control Center or go to the nearest emergency room right away.

What should I avoid while taking ROWEEPRA XR?

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

What are the possible side effects of ROWEEPRA XR?

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

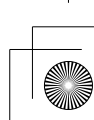
ROWEEPRA XR can cause serious side effects.

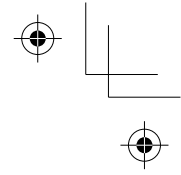
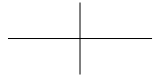
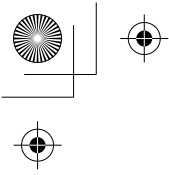
Call your healthcare provider right away if you have any of these symptoms:

- 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)
- a skin rash. Serious skin rashes can happen after you start taking ROWEEPRA XR. There is no way to tell if a mild rash will become a serious reaction.

Common side effects seen in people who take ROWEEPRA XR Tablets and other formulations of Levetiracetam include:

- sleepiness
- weakness
- infection
- dizziness





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 ROWEEPRA XR. For more information, ask your healthcare provider or pharmacist.

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

How should I store ROWEEPRA XR?



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

General information about the safe and effective use of ROWEEPRA XR.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ROWEEPRA XR for a condition for which it was not prescribed. Do not give ROWEEPRA XR 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 ROWEEPRA XR. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about ROWEEPRA XR that is written for health professionals.

What are the ingredients of ROWEEPRA XR?



ROWEEPRA XR tablet active ingredient: levetiracetam Inactive ingredients: colloidal silicon dioxide, ethylcellulose, glyceryl behenate, hypromellose 2910, lactose monohydrate, povidone K90, magnesium stearate, titanium dioxide and triacetin.

ROWEEPRA XR does not contain gluten.

Rx Only

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

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By:

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