

MEDICATION GUIDE
ROWEEPRA (ROW ee pra) (Levetiracetam)
Tablets, USP

Read this Medication Guide before you start taking ROWEEPRA 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?

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

- Stopping ROWEEPRA 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?

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

ROWEEPRA 250 mg tablets are blue to light blue, oval, film-coated tablets, bisect debossed with logo “TL” and “622” on one side. The other side is blank.

ROWEEPRA 500 mg tablets are yellow to light yellow, oval, film-coated

tablets, bisect debossed with logo “OWP” and “500” on one side. The other side is blank.

ROWEEPRA 750 mg tablets are orange to light orange, oval, film-coated tablets, bisect debossed with logo “OWP” and “750” on one side. The other side is blank.

ROWEEPRA 1000 mg tablets are white, oval, film-coated tablets, bisect debossed with logo “OWP” and “1000” on one side. The other side is blank.

What should I tell my healthcare provider before starting ROWEEPRA?

Before taking ROWEEPRA, 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 will harm your unborn baby. You and your healthcare provider will have to decide if you should take ROWEEPRA while you are pregnant. If you become pregnant while taking ROWEEPRA, 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 and other antiepileptic medicine during pregnancy.
- are breast feeding. ROWEEPRA can pass into your milk and may harm your baby. You and your healthcare provider should discuss whether you should take ROWEEPRA 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 ROWEEPRA?

Take ROWEEPRA exactly as prescribed.

- Your healthcare provider will tell you how much ROWEEPRA to take and when to take it. ROWEEPRA is usually taken twice a day. Take ROWEEPRA 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 ROWEEPRA 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 ROWEEPRA, 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, call your local Poison Control Center or go to the nearest emergency room right away.

What should I avoid while taking ROWEEPRA?

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

What are the possible side effects of ROWEEPRA?

- See “What is the most important information I should know about ROWEEPRA?”

ROWEEPRA 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. 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 ROWEEPRA include:

- sleepiness
- weakness
- infection
- dizziness

The most common side effects seen in children who take ROWEEPRA 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 ROWEEPRA. 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 ROWEEPRA?

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

General information about ROWEEPRA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ROWEEPRA for a condition for which it was not prescribed. Do not give ROWEEPRA 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. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about ROWEEPRA that is written for health professionals. You can call 1-800-273-6729 to get information about ROWEEPRA.

What are the ingredients of ROWEEPRA?

ROWEEPRA tablets active ingredient: levetiracetam

Inactive ingredients: colloidal silicon dioxide, corn starch, hypromellose, lactose monohydrate, magnesium stearate, povidone, titanium dioxide, triacetin and additional agents listed below:

250 mg tablets: FD&C blue #2/indigo carmine aluminum lake

500 mg tablets: iron oxide yellow

750 mg tablets: FD&C yellow #6/sunset yellow FCF aluminum lake, iron oxide red

ROWEEPRA does not contain gluten.

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

Manufactured for:

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