

INDICATION

ROWEEPRA XR (levetiracetam) 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.

IMPORTANT SAFETY INFORMATION

ROWEEPRA XR may not be for everyone. Ask your healthcare provider if ROWEEPRA XR is right for you. Do not take ROWEEPRA XR if you are allergic to levetiracetam.

WARNINGS AND PRECAUTIONS

ROWEEPRA XR may cause behavioral abnormalities and psychotic symptoms.

Antiepileptic drugs (AEDs), including ROWEEPRA XR, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Talk to your doctor about the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

Call your healthcare provider immediately at the first sign of a skin rash. Serious dermatological reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in patients treated with levetiracetam. ROWEEPRA XR should be discontinued at the first sign of a rash, unless the rash is clearly not drug-related. If signs or symptoms suggest SJS/TEN, use of this drug should not be resumed and alternative therapy should be considered.

Do not stop taking ROWEEPRA XR unless instructed to by your healthcare provider. Anti-epileptic drugs, including ROWEEPRA XR, should be withdrawn gradually to minimize the potential of increased seizure frequency.

ROWEEPRA XR can cause hematologic abnormalities. Hematologic abnormalities occurred in clinical trials and included decreases in red blood cell (RBC) counts, hemoglobin, and hematocrit, and increases in eosinophil counts. Decreased white blood cell (WBC) and neutrophil counts also occurred in clinical trials. Cases of agranulocytosis have been reported in the postmarketing setting.

ADVERSE REACTIONS

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.

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 at any time 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.

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

USE IN SPECIFIC POPULATIONS

Children and Adolescents

ROWEEPRA XR is not indicated for use in children and adolescents below 12 years of age.

Pregnancy and Breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to become pregnant, ask your doctor for advice before taking this medicine.

ROWEEPRA XR should not be used during pregnancy unless the potential benefits justify the potential risk to the baby. A risk of birth defects for your unborn child cannot be completely excluded. ROWEEPRA XR has shown unwanted reproductive effects in animal studies at dose levels similar to or higher than you would need to control your seizures. Breast-feeding is not recommended during treatment.

Renal Impairment

Talk to your doctor before taking this medicine if you have kidney problems. Dose adjustment is recommended for patients with impaired renal function.

Driving and Using Machines

ROWEEPRA XR may impair your ability to drive or operate any tools or machinery, as it may make you feel sleepy. This is more likely at the beginning of treatment or after an increase in the dose. You should not drive or use machines until it is established that your ability to perform such activities is not affected.