

## MEDICATION GUIDE

### KEPPRA XR® (KEPP-ruh XR) (levetiracetam) extended-release tablets

Read this Medication Guide before you start taking KEPPRA 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 KEPPRA XR?**

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

- Stopping KEPPRA 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 KEPPRA XR?**

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

500 mg KEPPRA XR tablets are white, oblong-shaped, film-coated tablets marked with “UCB 500XR” in red on one side.

750 mg KEPPRA XR tablets are white, oblong-shaped, film-coated tablets marked with “UCB 750XR” in red on one side.

### **What should I tell my healthcare provider before starting KEPPRA XR?**

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

Take KEPPRA XR exactly as prescribed.

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

### **What should I avoid while taking KEPPRA XR?**

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

### **What are the possible side effects of KEPPRA XR?**

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

KEPPRA 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 KEPPRA XR. There is no way to tell if a mild rash will become a serious reaction.

Common side effects seen in people who take KEPPRA XR and other formulations of KEPPRA 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 KEPPRA 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 KEPPRA XR?**

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

### **General information about the safe and effective use of KEPPRA XR.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use KEPPRA XR for a condition for which it was not prescribed. Do not give KEPPRA 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 KEPPRA XR. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about KEPPRA XR that is written for health professionals. You can also get information about KEPPRA XR at [www.keppraxr.com](http://www.keppraxr.com) or call 1- (844) 599-CARE (2273).

### **What are the ingredients of KEPPRA XR?**

**KEPPRA XR tablet** active ingredient: levetiracetam

Inactive ingredients: colloidal anhydrous silica, hypromellose, magnesium stearate, polyethylene glycol 6000, polyvinyl alcohol-partially hydrolyzed, titanium dioxide (E171), Macrogol/PEG3350, and talc. The imprinting ink contains shellac, FD&C Red #40, n-butyl alcohol, propylene glycol, titanium dioxide, ethanol, and methanol.

KEPPRA XR does not contain lactose or gluten.

**Rx Only**

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

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