

PATIENT INFORMATION

KEPPRA[®] (pronounced *KEPP-ruh*) (levetiracetam)

250 mg, 500 mg, 750 mg, and 1000 mg tablets and 100 mg/mL oral solution

Read the Patient Information that comes with KEPPRA before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your condition or your treatment.

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 provided below. Contact your pharmacist immediately if you believe a dispensing error may have occurred.

250 mg KEPPRA tablets are blue, oblong-shaped, scored, film-coated tablets marked with “ucb 250” on one side.

500 mg KEPPRA tablets are yellow, oblong-shaped, scored, film-coated tablets marked with “ucb 500” on one side.

750 mg KEPPRA tablets are orange, oblong-shaped, scored, film-coated tablets marked with “ucb 750” on one side.

1000 mg KEPPRA tablets are white, oblong-shaped, scored, film-coated tablets marked with “ucb 1000” on one side.

KEPPRA oral solution is a clear, colorless, grape-flavored liquid.

What is KEPPRA?

KEPPRA is a medicine taken by mouth that is used with other medicines to treat:

- partial onset seizures in patients 4 years of age and older with epilepsy
- myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy
- primary generalized tonic-clonic seizures in adults and children 6 years of age and older with idiopathic generalized epilepsy.

Who should not take KEPPRA?

Do not take KEPPRA if you are allergic to any of its ingredients. The active ingredient is levetiracetam. See the end of this leaflet for a list of all the ingredients in KEPPRA.

What should I tell my healthcare provider before starting KEPPRA?

Tell your healthcare provider about all of your medical conditions, including if you:

- **have kidney disease.** You may need a lower dose of KEPPRA.
- **are pregnant or planning to become pregnant.** It is not known if KEPPRA can harm your unborn baby. If you use KEPPRA while you are pregnant, ask your healthcare provider about being in the KEPPRA Pregnancy Registry. You can join this registry by calling (888) 537-7734 (toll free). You may also join the North American Antiepileptic Drug Pregnancy Registry by calling (888) 233-2334 (toll free).

- **are breast feeding.** KEPPRA can pass into your milk and may harm your baby. You should choose to either take KEPPRA or breast feed, but not both.

Tell your healthcare provider about all the medicines you take, including prescription, nonprescription, vitamins, and herbal supplements.

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?

- Take KEPPRA exactly as prescribed. KEPPRA is usually taken twice a day. Once in the morning and once at night. Take KEPPRA at the same times each day.
- Your healthcare provider may start you on a lower dose of KEPPRA and increase it as your body gets used to the medicine.
- Take KEPPRA with or without food. Swallow the tablets whole. Do not chew or crush tablets. Use the KEPPRA oral solution if you cannot swallow tablets. Use a medicine dropper or medicine cup to measure KEPPRA oral solution. Do not use a teaspoon. Ask your pharmacist for a medicine dropper or medicine cup to help you measure KEPPRA. If your healthcare provider has given you KEPPRA oral solution for your child, be sure to ask your pharmacist for a medicine syringe to help you measure the correct amount of KEPPRA oral solution. Ask your pharmacist for instructions on how to properly use the medicine syringe or dosing device that has been provided to you.
- If you miss a dose of KEPPRA, do not double your next dose to make up for the missed dose. If it has only been a few hours since your missed dose, take KEPPRA as soon as you remember then return to your regular schedule. If it is almost time for the next dose, skip the missed dose and resume your regular schedule. Talk with your healthcare provider for more detailed instructions.
- If you take too much KEPPRA or overdose, call your local Poison Control Center or emergency room right away.
- Do not stop taking KEPPRA or any other seizure medicine unless your healthcare provider told you to. Stopping a seizure medicine all at once can cause seizures that will not stop (status epilepticus), a very serious problem.
- Tell your healthcare provider if your seizures get worse or if you have any new types of seizures.

What should I avoid while taking KEPPRA?

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

What are the possible side effects of KEPPRA?

Adults

KEPPRA may cause the following serious problems in adults. Call your healthcare provider right away if you get any of the following symptoms:

- extreme sleepiness, tiredness, and weakness
- problems with muscle coordination (problems walking and moving)
- 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. A few people may get thoughts of suicide (thoughts of killing yourself).

The most common side effects with KEPPRA in adults are:

- sleepiness
- weakness
- dizziness
- infection

These side effects could happen at any time but happen most often within the first four weeks of treatment except for infection.

Children

KEPPRA may cause the following serious problems in children. Call your child's healthcare provider right away if they get any of the following symptoms:

- extreme sleepiness, tiredness, and weakness
- mood and behavior changes such as aggression, agitation, anger, anxiety, apathy, depression, hostility, and irritability

The most common side effects with KEPPRA in children, in addition to those seen in adults are:

- sleepiness
- accidental injury
- hostility
- irritability
- weakness

These side effects could happen at any time.

These are not all the side effects of KEPPRA. For more information, ask your healthcare provider or pharmacist. If you get any side effects that concern you, call your healthcare provider.

How should I store KEPPRA?

- Store KEPPRA at room temperature away from heat and light.
- **Keep KEPPRA and all medicines out of the reach of children.**

General information about KEPPRA.

Medicines are sometimes prescribed for conditions other than those described in patient information leaflets. Do not use KEPPRA for a condition for which it was not prescribed. Do not give your KEPPRA to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarizes the most important information about KEPPRA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about KEPPRA that is written for healthcare professionals. You can also get information about KEPPRA at www.keppra.com.

What are the ingredients of KEPPRA?

KEPPRA tablets contain the labeled amount of levetiracetam. Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, polyethylene glycol 3350, polyethylene glycol 6000, polyvinyl alcohol, talc, titanium dioxide, 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

KEPPRA oral solution contains 100 mg of levetiracetam per mL. Inactive ingredients: ammonium glycyrrhizinate, citric acid monohydrate, glycerin, maltitol solution, methylparaben, potassium acesulfame, propylparaben, purified water, sodium citrate dihydrate and natural and artificial flavor.

KEPPRA does not contain lactose or gluten. KEPPRA oral solution does contain carbohydrates. The liquid is dye-free.

Rx Only

This patient leaflet has been approved by the US Food and Drug Administration.

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