

**MEDICATION GUIDE**  
**Brivaracetam (briv" a ra' se tam) CV**  
**oral solution**

**What is the most important information I should know about brivaracetam oral solution?**

**Brivaracetam oral solution is a federally controlled substance (CV) because it can be abused or lead to dependence. Keep brivaracetam oral solution in a safe place to prevent misuse and abuse. Selling or giving away brivaracetam oral solution may harm others and is against the law.**

**Like other antiepileptic drugs, brivaracetam oral solution 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
- new or worse depression
- feeling agitated or restless
- trouble sleeping (insomnia)
- acting aggressive, feeling angry, or being violent
- an extreme increase in activity and talking (mania)
- attempts to commit suicide
- new or worse anxiety
- panic attacks
- new or worse irritability
- acting on dangerous impulses
- other unusual changes in behavior or mood

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.

**Do not stop brivaracetam oral solution without first talking to a healthcare provider.**

- Stopping brivaracetam oral solution suddenly can cause serious problems.
- Stopping a seizure medicine suddenly can cause seizures that will not stop (status epilepticus).

**What is brivaracetam oral solution?**

Brivaracetam oral solution is a prescription medicine used to treat partial-onset seizures in people 1 month of age and older. It is not known if brivaracetam oral solution is safe and effective in children younger than 1 month of age.

**Who should not take brivaracetam oral solution?**

Do not take brivaracetam oral solution if you are allergic to brivaracetam or any of the ingredients in brivaracetam oral solution. See the end of this Medication Guide for a complete list of ingredients in brivaracetam oral solution.

**What should I tell my healthcare provider before starting brivaracetam oral solution?**

**Before taking brivaracetam oral solution, tell your healthcare provider about all of your medical conditions, including if you:**

- have or had depression, mood problems, or suicidal thoughts or behavior.
- have liver problems.
- have abused or been dependent on prescription medicines, street drugs, or alcohol.
- are pregnant or plan to become pregnant. It is not known if brivaracetam oral solution will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking brivaracetam oral solution. You and your healthcare provider will have to decide if you should take brivaracetam oral solution while you are pregnant.
- are breastfeeding or plan to breastfeed. Brivaracetam passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take brivaracetam oral solution.

**Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Brivaracetam oral solution may affect the way other**

medicines work, and other medicines may affect how brivaracetam oral solution works. 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 brivaracetam oral solution?**

- Take brivaracetam oral solution exactly as your healthcare provider tells you.
- Your healthcare provider will tell you how much brivaracetam oral solution to take and when to take it.
- Your healthcare provider may change your dose if needed. Do not change your dose without talking to your healthcare provider.
- Take brivaracetam oral solution with or without food.
- If your healthcare provider has prescribed brivaracetam oral solution, be sure to ask your pharmacist for a medicine dropper or medicine cup to help you measure the correct amount of brivaracetam oral solution. Do not use a household teaspoon or tablespoon. Ask your pharmacist for instructions on how to use the measuring device the right way.
- If you take too much brivaracetam oral solution, call your Poison Control Center or go to the nearest emergency room right away.

**What should I avoid while taking brivaracetam oral solution?**

Do not drive or operate machinery until you know how brivaracetam oral solution affects you. Brivaracetam oral solution may cause drowsiness, tiredness, dizziness, and problems with your balance and coordination.

**What are the possible side effects of brivaracetam oral solution?**

**Brivaracetam oral solution may cause serious side effects, including:**

- See “**What is the most important information I should know about brivaracetam oral solution?**”
- **Nervous system problems.** Drowsiness, tiredness, and dizziness are common with brivaracetam oral solution, but can be severe. See “**What should I avoid while taking brivaracetam oral solution?**”. Brivaracetam oral solution can also cause problems with balance and coordination.
- **Mental (psychiatric) symptoms.** Brivaracetam oral solution can cause mood and behavior changes such as aggression, agitation, anger, anxiety, apathy, mood swings, depression, hostility, and irritability. Irritability and anxiety are common with brivaracetam oral solution, and can be severe. People who take brivaracetam oral solution can also 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.
- **Serious allergic reactions.** Stop taking brivaracetam oral solution and call your healthcare provider right away if you have any of these signs of a serious allergic reaction:
  - swelling of your face, mouth, lips, gums, tongue, throat, or neck
  - trouble breathing
- **Serious skin rashes.** Brivaracetam oral solution may cause a severe rash with blisters and peeling skin. This may occur around the mouth, nose, eyes, and genitals or over much of the body. A mild rash may become a serious reaction and may cause death. Call your healthcare provider right away if you have a rash, skin blisters, sores in the mouth, or hives.  
Do not stop taking brivaracetam oral solution without first talking to your healthcare provider.

**The most common side effects of brivaracetam oral solution in adults include:**

- |              |                       |
|--------------|-----------------------|
| • sleepiness | • feeling tired       |
| • dizziness  | • nausea and vomiting |

Side effects of brivaracetam oral solution in children 1 month to less than 16 years of age are similar to those seen in adults.

These are not all the possible side effects of brivaracetam oral solution. For more information, ask your healthcare provider or pharmacist. Tell your healthcare provider about any side effect that bothers you or that does not go away. 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 brivaracetam oral solution?**

- Store brivaracetam oral solution at room temperature between 59°F to 86°F (15°C to 30°C).
- Do not freeze brivaracetam oral solution.
- Safely throw away any opened bottle of brivaracetam oral solution after 5 months of first opening the bottle, even if there is medicine left in the bottle.

**Keep brivaracetam oral solution and all medicines out of the reach of children.****General information about the safe and effective use of brivaracetam oral solution.**

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

**What are the ingredients in brivaracetam oral solution?**

**Active ingredient:** brivaracetam

**Oral solution inactive ingredients:** sodium citrate (trisodium citrate dihydrate), anhydrous citric acid, methylparaben, sodium carboxymethylcellulose, sucralose, non-crystallizing sorbitol solution, anhydrous glycerol, raspberry flavor, and purified water. Raspberry flavor also contains maltodextrin, propylene glycol and modified waxy maize starch.

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

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