

MEDICATION GUIDE Brivaracetam (briv' a ra' se tam) tablets CV for oral use
What is the most important information I should know about Brivaracetam tablets? Brivaracetam is a federally controlled substance (CV) because it can be abused or lead to dependence. Keep brivaracetam tablets in a safe place to prevent misuse and abuse. Selling or giving away brivaracetam tablets may harm others and is against the law. Like other antiepileptic drugs, brivaracetam tablets 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 tablets without first talking to a healthcare provider. - Stopping brivaracetam tablets suddenly can cause serious problems. - Stopping a seizure medicine suddenly can cause seizures that will not stop (status epilepticus).
What is brivaracetam tablets? Brivaracetam tablets are prescription medicine used to treat partial-onset seizures in people 1 month of age and older. It is not known if brivaracetam tablets are safe and effective in children younger than 1 month of age.
Who should not take brivaracetam tablets? Do not take brivaracetam tablets if you are allergic to brivaracetam or any of the ingredients in brivaracetam tablets. See the end of this Medication Guide for a complete list of ingredients in brivaracetam tablets.
What should I tell my healthcare provider before starting brivaracetam tablets? Before taking brivaracetam tablets, 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 tablets will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking brivaracetam tablets. You and your healthcare provider will have to decide if you should take brivaracetam tablets 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 tablets. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Brivaracetam tablets may affect the way other medicines work, and other medicines may affect how brivaracetam tablets 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 tablets? - Take brivaracetam tablets exactly as your healthcare provider tells you. - Your healthcare provider will tell you how much brivaracetam tablets 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 tablets with or without food. - Swallow brivaracetam tablets whole with a liquid. Do not chew or crush brivaracetam tablets before swallowing. If you take too much brivaracetam tablets, call your Poison Control Center or go to the nearest emergency room right away.
What should I avoid while taking brivaracetam tablets? Do not drive or operate machinery until you know how brivaracetam tablets affects you. Brivaracetam tablets may cause drowsiness, tiredness, dizziness, and problems with your balance and coordination.
What are the possible side effects of brivaracetam tablets? Brivaracetam tablets may cause serious side effects, including: - See “What is the most important information I should know about brivaracetam tablets?” Nervous system problems. Drowsiness, tiredness, and dizziness are common with brivaracetam tablets, but can be severe. See “What should I avoid while taking brivaracetam tablets?” brivaracetam tablets can also cause problems with balance and coordination. Mental (psychiatric) symptoms. Brivaracetam tablets 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 tablets, and can be severe. People who take brivaracetam tablets 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 tablets 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 tablets 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 tablets without first talking to your healthcare provider. The most common side effects of brivaracetam tablets in adults include: - sleepiness - feeling tired - dizziness - nausea and vomiting Side effects of brivaracetam tablets 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 tablets. 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 tablets? Store brivaracetam tablets at room temperature between 59°F to 86°F (15°C to 30°C). Keep BRIVARACETAM and all medicines out of the reach of children.
General information about the safe and effective use of brivaracetam tablets. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use brivaracetam tablets for a condition for which it was not prescribed. Do not give brivaracetam tablets 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 tablets. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about brivaracetam tablets that is written for health professionals.
What are the ingredients in brivaracetam tablets? Active ingredient: brivaracetam Tablet inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and film coating agent contains polyethylene glycol 3350, polyethylene glycol 8000, polyvinyl alcohol, talc, and titanium dioxide.
Manufactured by: ScieGen Pharmaceuticals Inc Hauppauge, NY 11788 USA For more information, call ScieGen Pharmaceuticals at 1-855-724-3436.

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