

MEDICATION GUIDE
SPRITAM® (SPREE-tam)
(levetiracetam)
tablets for oral suspension

What is the most important information I should know about SPRITAM?

Like other antiepileptic drugs, SPRITAM 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, being angry, or violent
- an extreme increase in activity or 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

Do not stop SPRITAM without first talking to a healthcare provider.

- Stopping SPRITAM suddenly can cause you to have seizures more often.
- 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 SPRITAM?

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

- partial onset seizures in people 4 years of age and older weighing more than 20 kg (44 pounds) with epilepsy
- myoclonic seizures in people 12 years of age and older with juvenile myoclonic epilepsy
- primary generalized tonic-clonic seizures in people 6 years of age and older weighing more than 20 kg with certain types of generalized epilepsy.

SPRITAM tablets disintegrate in the mouth on average within 11 seconds (ranging from 2-27 seconds) when taken with a sip of liquid.

Before taking your medicine, make sure you have received the correct medicine. Compare the name above with the name on your package and the appearance of your medicine with the description of SPRITAM provided below. Tell your pharmacist immediately if you think you have been given the wrong medicine.

250 mg SPRITAM is a round tablet marked with "  " on one side.

500 mg SPRITAM is a round tablet marked with "  " on one side.

750 mg SPRITAM is a round tablet marked with "  " on one side.

1000 mg SPRITAM is a round tablet marked with "  " on one side.

What should I tell my healthcare provider before starting SPRITAM?

Before taking SPRITAM, 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 SPRITAM will harm your unborn baby. You and your healthcare provider will have to decide if you should take SPRITAM while you are pregnant. If you become pregnant while taking SPRITAM, 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 the registry is to collect information about the safety of SPRITAM and other antiepileptic medicine during pregnancy.
- are breast feeding. SPRITAM can pass into your milk and may harm your baby. You and your healthcare provider should discuss whether you should take SPRITAM 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 SPRITAM?

- Take SPRITAM exactly as prescribed.
- Your healthcare provider will tell you how much SPRITAM to take and when to take it. SPRITAM is usually taken 2 times each day. Take SPRITAM at the same times each day.
- Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.
- **As a primary method of administration, SPRITAM is intended to disintegrate in your mouth when taken with a sip of liquid.**
- Alternately, SPRITAM may be taken by adding the whole tablet to a small volume of liquid in a cup.
 - **How to take SPRITAM with a sip of liquid:**
 - Take SPRITAM as shown on the SPRITAM carton (box).
 - Make sure your hands are dry before you remove the SPRITAM tablet(s).
 - Peel the foil away from the blister. Do not push the tablet(s) through the foil packaging.
 - Peel the foil away from the blister by bending up and lifting the peel tab around the blister seal.
 - Empty the tablet into your **dry hand**.
 - Place the SPRITAM tablet on your tongue and follow with a sip of liquid. **Let the tablet disintegrate all the way on your tongue before swallowing.**
 - SPRITAM disintegrates in an average time of 11 seconds (ranging from 2 to 27 seconds) in the mouth when taken with a sip of liquid.
 - **How to take SPRITAM with a small volume of liquid in a cup:**
 - Make sure your hands are dry before you remove the SPRITAM tablet(s).
 - Peel the foil away from the blister. Do not push the tablet through the foil packaging.
 - Peel the foil away from the blister by bending up and lifting the peel tab around the blister seal.
 - Add whole SPRITAM tablet(s) to a small volume of liquid in a cup (1 tablespoon or enough to cover the medicine), and swirl gently.
 - Swallow right after the tablet(s) disintegrates.
 - If there is any medicine left in the cup, add a small volume of liquid to the cup, swirl gently, and swallow the liquid.
- SPRITAM can be taken with or without food.
- If you take too much SPRITAM, call your Poison Control Center at 1-800-222-1222 or go to the nearest emergency room right away.
- As shown on the SPRITAM carton (box), do not push the tablet through foil. The foil should be peeled away from the blister. Bend up and lift the peel tab, pulling open the seal around the blister.

What should I avoid while taking SPRITAM?

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

What are the possible side effects of SPRITAM?

- See "What is the most important information I should know about SPRITAM?"

SPRITAM 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
- a skin rash. Serious skin rashes can happen after you start taking SPRITAM. There is no way to tell if a mild rash will become a serious reaction. Call your healthcare provider right away if you get a rash while taking SPRITAM.
- problems with muscle coordination (problems walking and moving)

The most common side effects seen in adults who take SPRITAM include sleepiness, infection, weakness, or dizziness.

The most common side effects seen in children who take SPRITAM include the side effects above and tiredness, decreased appetite, acting aggressive, irritability, and nasal congestion.

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 SPRITAM. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to Aprecia Pharmaceuticals Company at 1-844-882-7732 or FDA at 1-800-FDA-1088.

How should I store SPRITAM?

- Store SPRITAM at room temperature, 59°F to 86°F (15°C to 30°C).
- Keep SPRITAM and all medicines out of the reach of children.

General information about the safe and effective use of SPRITAM.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SPRITAM for a condition for which it was not prescribed. Do not give SPRITAM 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 SPRITAM. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about SPRITAM that is written for health professionals. You can also get information about SPRITAM at 1-844-882-7732.

What are the ingredients of SPRITAM?

Active ingredient: levetiracetam

Inactive ingredients: colloidal silicon dioxide, glycerin, mannitol, microcrystalline cellulose, polysorbate 20, povidone, sucralose, butylated hydroxyanisole, and natural and artificial spearmint flavor.

Manufactured by Aprecia Pharmaceuticals Company, East Windsor, NJ 08520

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

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