



SPRITAM® key facts

- SPRITAM[®] (levetiracetam) tablets for oral suspension, is a prescription medicine used with other medicines for the treatment of certain types of epileptic seizures in adults and children with epilepsy.¹
- SPRITAM rapidly disintegrates in the mouth with a sip of liquid, in an average time of 11 seconds (range 2-27 seconds), and offers a new option for patients, including those who may struggle to take their medicine.
- Now available in the U.S., SPRITAM is the first and only prescription medicine manufactured using 3D printing that has been approved by the U.S. Food and Drug Administration (FDA).

Indications

SPRITAM is indicated for use with other epilepsy medicines for the treatment of:¹

- Partial onset seizures in patients with epilepsy 4 years of age and older weighing more than 20 kg
- Myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy
- Primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy weighing more than 20 kg

Dosage and Administration

- As a primary method of administration, SPRITAM tablets for oral suspension are administered with a sip of liquid.
 - Place a tablet on the tongue with a dry hand, and then take a sip of liquid.
 SPRITAM should be swallowed only after the tablet disintegrates in the mouth.
- Alternately, add whole SPRITAM tablet(s) to a small volume of liquid in a cup and swirl gently. Swallow right after the tablet(s) disintegrate.
- The SPRITAM dosing regimen depends on the indication, age group and renal function. It is available in unit dose strengths of 250 mg, 500 mg, 750 mg and 1,000 mg.¹
- The full tablet should be consumed partial quantities should not be taken.

Important Safety Information

SPRITAM may not be for everyone. Ask a healthcare provider if SPRITAM is right for you.

Warnings and Precautions

Antiepileptic drugs, including SPRITAM, may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call your healthcare provider right away if you have new or worsening symptoms of depression, any unusual changes in mood or behavior, or suicidal thoughts behavior, or thoughts about self-harm that you have never had before or may be worse than before.

SPRITAM may cause extreme sleepiness, tiredness, and weakness, and problems with muscle coordination. You should not drive, operate machinery or do other dangerous activities until you know how SPRITAM affects you.

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.

Do not stop taking SPRITAM unless instructed by your healthcare provider. Stopping a seizure medication suddenly can cause you to have seizures more often or seizures that will not stop, a very serious problem. If you become pregnant or intend to become pregnant, contact your healthcare provider right away.

Common Adverse Reactions

In clinical trials, the most common side effects seen in adults taking SPRITAM include sleepiness, weakness, dizziness, and infection. In addition to those previously listed, the most common side effects seen in children taking SPRITAM include tiredness, acting aggressive, nasal congestion, decreased appetite, and irritability.

Talk to your healthcare provider about other possible side effects with SPRITAM. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For additional safety information, please see U.S. <u>Full Prescribing Information</u> and <u>Medication Guide</u>. This information does not take the place of talking with your healthcare provider about your condition or your treatment.

¹ SPRITAM U.S. Full Prescribing Information. Aprecia Pharmaceuticals Company.