SPRITAM® KEY FACTS

What is SPRITAM®?

SPRITAM® levetiracetam for oral use is a prescription adjunctive therapy for the treatment of partial onset seizures, myoclonic seizures and primary generalized tonic-clonic seizures in adults and children with epilepsy.[1] SPRITAM are unitary porous structures produced by a three-dimensional printing process (3DP) that binds the powders without compression.[1]

The approval of SPRITAM marks the first time a drug product manufactured with this 3DP technology has been approved by the U.S. Food and Drug Administration (FDA).

What are the FDA-approved indications for SPRITAM?

SPRITAM is indicated for adjunctive therapy in the treatment of:

- 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

What is the dosage and administration for SPRITAM?

SPRITAM is administered orally, with or without food, with a sip of liquid. Patients should take only whole tablets. The SPRITAM dosing regimen depends on the indication, age group and renal function. SPRITAM disintegrates at a mean time of 11 seconds (ranging from 2 to 27 seconds) in the mouth when taken with a sip of liquid. SPRITAM should not be swallowed intact.

Patients should not push the tablet through the foil. The foil should be peeled from the blister by bending and lifting the peel tab around the blister seal. Patients should place the tablet on the tongue with a dry hand and follow with a sip of liquid. The tablet should be swallowed only after it disintegrates.

What is the SPRITAM Important Safety Information?

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

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 a healthcare provider right away with any 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. Call your healthcare provider right away if you have 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.

Do not stop taking SPRITAM unless instructed by your healthcare provider. Stopping a seizure medication all at once can cause seizures that will not stop, a very serious problem.

Common Adverse Reactions

In clinical trials, the most common side effects (incidence ≥5% more than placebo) seen in people who take SPRITAM include sleepiness, weakness, dizziness, and infection. In addition to those previously listed, the most common side effects seen in children who take 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. Full Prescribing Information and Medication Guide at www.SPRITAM.com

This information does not take the place of talking with your healthcare provider about your condition or your treatment.

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[1] SPRITAM [package insert]. East Windsor, N.J. Aprecia Pharmaceuticals Company; 2015.