Spritam® (levetiracetam)
Tablets for Oral Suspension

Now Approved for NG-Tube and G-Tube Administration

SPRITAM is the only levetiracetam formulation with FDA-approved labeling for NG-tube and G-tube administration

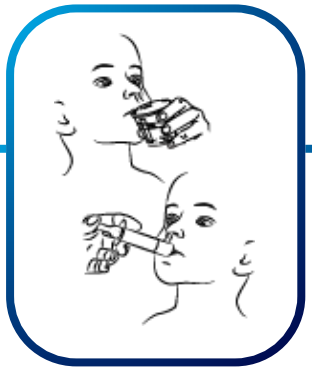
Three Options for Administering SPRITAM

SPRITAM (levetiracetam) offers three flexible administration options to support individualized patient care. Now approved for Nasogastric (NG) and Gastrostomy (G) tube delivery, SPRITAM can be administered orally, in a small amount of liquid in a cup, or through a feeding tube, offering versatility in administration options.

Option 1

Take SPRITAM with a Sip of Liquid

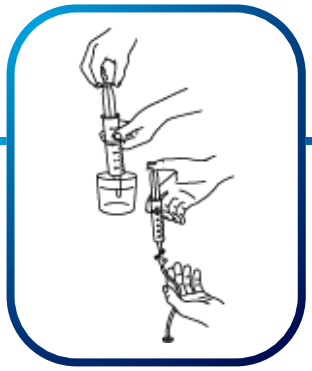
Spritam is intended to disintegrate in the mouth when taken with a sip of liquid, one tablet at a time. Place tablet on the tongue and follow with a sip of liquid before swallowing.



Option 2

Dissolve SPRITAM in a Small Volume of Liquid for Oral Administration

Add whole tablet(s) to a small volume of liquid in a cup and swirl gently. Swallow right after the tablet(s) disintegrate, by mouth using a cup or oral syringe. If any medicine is left in the cup, rinse with a small volume of liquid, swirl gently and swallow the liquid by cup or oral syringe.



Option 3

Dissolve SPRITAM in a Small Volume of Water for Nasogastric or Gastrostomy Feeding Tube Administration

Place the prescribed whole tablet(s) in a small dosing cup, with 10 mL room temperature water. Gently swirl the cup. Draw up mixture into an oral syringe, hold in vertical position and administer immediately via feeding tube. Flush the feeding tube (2x) after administration, by adding water to the dosing cup that contained the dispersion and administering the mixture through the feeding tube. See full instructions below.

INSTRUCTIONS FOR HANDLING TABLETS

Do NOT push the tablet through the foil. **Bend up and lift the peel tab** around the blister seal. Empty the exposed tablet into a dry hand. Partial tablets should not be administered.

INDICATIONS AND USAGE

SPRITAM (levetiracetam) is a prescription medicine used to treat partial-onset seizures in patients 4 years of age and older. SPRITAM is also used as adjunctive therapy to treat myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy, and primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy. SPRITAM is recommended for use in patients weighing more than 44 pounds (20 kilograms).

IMPORTANT SAFETY INFORMATION

SPRITAM may not be for everyone. SPRITAM is contraindicated in patients with a hypersensitivity to levetiracetam. Reactions have included anaphylaxis and angioedema.

Important Safety Information continued on next page.

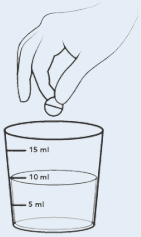
Spritam® (levetiracetam)
Tablets for Oral Suspension

Administering SPRITAM (levetiracetam) through a Nasogastric or Gastrostomy Tube

Important Preparation and Administration Instructions

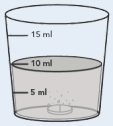
SPRITAM (levetiracetam) Tablets for Oral Suspension may be given through Nasogastric or Gastrostomy tube in sizes of 10-14 French as determined by a healthcare provider. See instructions below.

REMINDER: The foil should be peeled away from the blister by bending up and lifting the peel tab around the blister seal. Do not push the tablet through the foil when opening the blister seal.



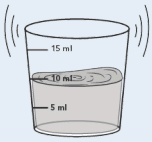
1

Place the number of whole tablets needed for the prescribed dose in a small dosing cup. Do not use partial tablets.



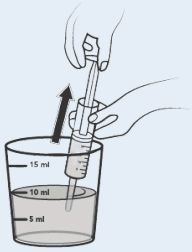
2

Add approximately 10 mL of room temperature water.



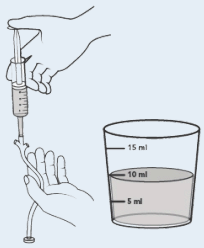
3

Gently swirl the cup until the tablet(s) disperse.



4

Draw up the mixture into a 10 mL oral catheter-tip syringe, hold the syringe in a vertical position, and administer immediately via feeding tube.



5

After administration, flush the feeding tube twice, as follows:

- Add another 10 mL of room temperature water to the dosing cup that contained the dispersion.
- Swirl the cup to re-suspend any tablet residue.
- Draw up the mixture into the same oral syringe and immediately push through the feeding tube.

See the U.S. Full Prescribing Information and Medication Guide for complete administration instructions. Including, how to administer Spritam by mouth.

IMPORTANT SAFETY INFORMATION *(continued)*

WARNINGS AND PRECAUTIONS

SPRITAM may cause behavioral abnormalities including psychotic symptoms, suicidal ideation, irritability and aggressive behavior. Patients treated with SPRITAM should be monitored for psychiatric signs and symptoms.

Antiepileptic drugs, including SPRITAM, may cause suicidal thoughts or actions in a very small number of patients, about 1 in 500. Advise patients to contact you right away if they experience new or worsening symptoms of depression, any unusual changes in mood or behavior, or suicidal thoughts, behavior, or thoughts about self-harm they have never had before or which may be worse than before.

WARNINGS AND PRECAUTIONS (*continued*)
SPRITAM may cause extreme sleepiness, tiredness, and weakness, and problems with muscle coordination. Patients should be instructed not to drive, operate machinery or do other dangerous activities until they know how SPRITAM affects them.

SPRITAM can cause anaphylaxis or angioedema after the first dose or at any time during treatment. Advise your patients to discontinue SPRITAM and seek immediate medical attention if they have allergic reactions such as swelling of the face, lips, eyes, tongue and throat, trouble swallowing or breathing, and hives.

Serious dermatological reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), can occur after your patients start taking SPRITAM. There is no way to tell if a mild rash will become a serious reaction. SPRITAM should be discontinued at the first sign of rash unless clearly not drug related.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as multiorgan hypersensitivity, can occur in patients taking SPRITAM, and can be fatal or life-threatening, particularly if diagnosis and treatment do not occur as early as possible. DRESS may present with symptoms of fever, rash, lymphadenopathy and/or facial swelling associated with signs of other organ system involvement (e.g., hepatitis, nephritis, myocarditis, myositis, or hematological abnormalities [eosinophilia]). Advise your patients to seek immediate medical attention if any of these symptoms develop. SPRITAM should be discontinued immediately if a serious hypersensitivity reaction is suspected.

Advise patients not to stop SPRITAM unless instructed by you. Stopping a seizure medication suddenly can cause more frequent seizures or seizures that will not stop.

SPRITAM can cause hematologic abnormalities. A complete blood count is recommended in patients experiencing significant weakness, pyrexia, recurrent infections, or coagulation disorders.

Instruct patients to contact you right away if they become pregnant or intend to become pregnant.

COMMON ADVERSE REACTIONS
In clinical trials, the most common side effects seen in adults 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.

To report SUSPECTED ADVERSE REACTIONS, contact Aprecia Pharmaceuticals, LLC at 1-844-882-7732 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

ADMINISTRATION
SPRITAM is intended to disintegrate in the mouth when taken with a sip of liquid, one tablet at a time. As a primary method of administration, instruct patients to place a tablet on their tongue with a dry hand, and then take a sip of liquid. SPRITAM should be swallowed only after the tablet disintegrates in the mouth. SPRITAM should not be swallowed intact. Partial tablet(s) should not be administered.

Alternately, patients can add whole SPRITAM tablet(s) to a small volume of liquid in a cup (one tablespoon or enough to cover the medicine), swirl gently and swallow immediately after the tablet(s) disintegrate. If there is any medicine left in the cup, instruct patients to rinse with a small volume of liquid, swirl and swallow the remaining contents.

SPRITAM may also be administered via nasogastric or gastrostomy feeding tube (French size 10 to 14). Place the required number of whole tablets in a dosing cup with approximately 10 mL of room temperature water and gently swirl until the tablets disperse. Draw up the mixture into a 10 mL oral catheter-tip syringe, hold the syringe vertically, and administer immediately via feeding tube. Flush the feeding tube twice after administration by repeating this method with an additional 10 mL of room temperature water in the same dosing cup to ensure complete delivery of any remaining tablet residue, in the feeding tube.

For additional safety information, please see **U.S. Full Prescribing Information** and **Medication Guide**.

Manufactured by Aprecia Pharmaceuticals, LLC, Mason, OH 45040 USA.
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