Administration Tips



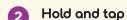


Check expiration and prepare

Check the expiration date on the ALKINDI SPRINKLE bottle. **Do not** use after the expiration date listed on the bottle.

Then, remove the prescribed dose of ALKINDI SPRINKLE capsules from the bottle.





Hold capsule with the writing at the top. Tap the capsule to make sure the granules fall to the bottom.



Squeeze

Gently squeeze the bottom of the capsule to loosen the top from the bottom.



Twist and remove

Carefully twist off the top of the capsule.



Sprinkle

ALKINDI SPRINKLE can be given by spoon with soft food or sprinkled directly into your child's mouth.



👩 Tap

Tap the capsule to ensure all the granules are removed. Avoid wetting the capsule on the tongue or soft food as this may result in granules remaining in the capsule.



Give fluids

After giving ALKINDI SPRINKLE, give your child a sip of fluids, such as water, milk, breast milk, or formula, right away to ensure all granules are swallowed.



ALKINDI SPRINKLE has a texture that may be new to most children.

Here are some useful suggestions on how to give ALKINDI SPRINKLE to your child.

ON A SPOON WITH FOOD

Pour all granules onto a spoonful of soft, cold or room-temperature food, like yogurt or applesauce, or any other food your child will eat, and give within 5 minutes.

DIRECTLY INTO YOUR CHILD'S MOUTH

Pour all granules of the prescribed dose directly into your child's mouth.

Visit AlkindiSprinkle.com/resources to access useful videos for giving ALKINDI SPRINKLE to your child.

ALKINDI SPRINKLE granules may sometimes be seen in stools since the center of the granule is not absorbed in the gut after the drug has been released.



Call the specialty pharmacy hotline to ask questions about ALKINDI SPRINKLE, available Monday through Friday, 8 AM-5 PM CT, at 1-833-343-2500

USE

ALKINDI SPRINKLE is a prescription medicine used in children from birth to less than 17 years old as replacement therapy when the adrenal gland is not making enough cortisol.

IMPORTANT SAFETY INFORMATION

Always give ALKINDI SPRINKLE exactly as your doctor has directed.

Do not take ALKINDI SPRINKLE if you are allergic to hydrocortisone or any of its other ingredients.

Adrenal Crisis: giving too low a dose or stopping medication can cause low levels of cortisol, which can result in serious illness or death. Treatment with intravenous hydrocortisone should be started immediately. When switching from another type of hydrocortisone to ALKINDI SPRINKLE, watch your child closely for any changes. If your child doesn't get the entire dose of ALKINDI SPRINKLE because of vomiting or spitting some granules out, contact your doctor to see if another dose is needed.

Immunosuppression and Increased Risk of Infection with Use of a Dosage Greater Than Replacement: Use of a greater than replacement dosage can suppress the immune system and increase the risks of new infections or exacerbation of latent infections with any pathogen, including viral, bacterial, fungal, protozoan, or helminthic infections. Monitor patients for signs and symptoms of infections.

Growth Retardation: the long-term use of corticosteroids in high doses may cause growth retardation in children.

Decrease in Bone Density: corticosteroids can affect your child's bone growth and strength.

Cushing's Syndrome Due to High Doses of Corticosteroids: treatment with high doses of corticosteroids can cause Cushing's Syndrome. Treatment should be limited to the smallest dose required, and your child's growth and development monitored appropriately.

Changes in Vision: tell your doctor if your child has blurred vision or other vision problems during treatment with ALKINDI SPRINKLE.

Psychiatric Changes: corticosteroids can change your child's behavior or mood. Tell your doctor if your child has periods of extreme happiness, extreme sadness, hallucinations, or depression.

Gastrointestinal Reactions: tell the doctor if your child has stomach pain, upset stomach, black, tarry stools, or vomiting of blood. These could be signs of ulcers or tears in the stomach or intestines. Taking anti-inflammatory nonsteroidal drugs, like ibuprofen, naproxen, or aspirin, can increase the risk of ulcers or tears.

The most common side effects of ALKINDI SPRINKLE include retaining fluids, changes in glucose tolerance, high blood pressure, behavioral and mood changes, greater appetite, and weight gain.

Vaccination: Administration of live vaccines may be acceptable in ALKINDI SPRINKLE-treated pediatric patients with adrenocortical insufficiency who receive replacement corticosteroids.

Please visit ALKINDISPRINKLE.com/patient for more information

You are encouraged to report negative side effects of prescription drugs by contacting Eton Pharmaceuticals, Inc. at <u>1-855-224-0233</u> or the U.S. Food and Drug Administration (FDA) at <u>www.fda.gov/safety/medwatch</u> or call <u>1-800-FDA-1088</u>.

Please see <u>full Prescribing Information</u> for more information.



