

Flexible dosing options designed for individualized treatment accuracy

Alkindi Sprinkle®
(hydrocortisone)
oral granules

Combine the 4 low-dose strengths of ALKINDI SPRINKLE® (hydrocortisone) oral granules for individualized and accurate pediatric dosing of rapidly growing patients.^{1,2}

- Color coded for easy identification
- Known accuracy is dependent on assurance that the entire dose is administered and consumed when and as directed

Please see Important Safety Information below and on back.



Example Dose 0.5 mg	Example Dose 1.0 mg	Example Dose 1.5 mg	Example Dose 2.0 mg	Example Dose 2.5 mg
Example Dose 3.0 mg	Example Dose 3.5 mg	Example Dose 4.0 mg	Example Dose 4.5 mg	Example Dose 5.0 mg

Capsules shown are not actual size.



Scan to see how ALKINDI SPRINKLE delivers individualized dosing and accurate administration to pediatric patients.

INDICATION AND IMPORTANT SAFETY INFORMATION

Contraindication

Hypersensitivity to hydrocortisone or any of the ingredients in ALKINDI SPRINKLE.

Please see additional Important Safety Information for ALKINDI SPRINKLE on back.

INDICATION AND IMPORTANT SAFETY INFORMATION (cont)

Warnings and Precautions

- **Adrenal Crisis:** Undertreatment or sudden discontinuation of therapy may lead to symptoms of adrenal insufficiency, adrenal crisis, and death. Adrenal crisis may also be induced by stressor events, such as infections or surgery. Monitor patients closely when switching from other forms of hydrocortisone to ALKINDI SPRINKLE. Instruct patients and/or caregivers to contact their healthcare provider if the full dose of ALKINDI SPRINKLE is not administered, as a repeat dose may be required. Increase the dose during periods of stress. Switch patients who are vomiting, severely ill, or unable to take oral medications to parenteral corticosteroid formulations.
- **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:** Long-term use in excessive doses may cause growth retardation. Use the minimum dosage of ALKINDI SPRINKLE to achieve desired clinical response and monitor the patient's growth.
- **Cushing's Syndrome Due to Use of Excessive Doses of Corticosteroids:** Prolonged use with supraphysiologic doses may cause Cushing's syndrome. Monitor patients for signs and symptoms of Cushing's syndrome every 6 months; pediatric patients under one year of age may require more frequent monitoring.
- **Decrease in Bone Mineral Density:** Corticosteroids decrease bone formation and increase bone resorption, which may lead to inhibition of bone growth and development of osteoporosis. Use the minimum dosage of ALKINDI SPRINKLE to achieve desired clinical response.
- **Psychiatric Adverse Reactions:** Use may be associated with severe psychiatric adverse reactions, such as euphoria, mania, psychosis with hallucinations and delirium, or depression. Symptoms typically emerge within a few days or weeks of starting the treatment. Most reactions resolve after either dose reduction or withdrawal, although specific treatment may be necessary. Monitor patients for behavioral and mood disturbances during treatment. Instruct caregivers and/or patients to seek medical advice if psychiatric symptoms develop.
- **Ophthalmic Adverse Reactions:** Cataracts, glaucoma, and central serous chorioretinopathy have been reported with prolonged use of high doses. Monitor patients for blurred vision or other visual disturbances, and if they occur, refer them to an ophthalmologist.
- **Gastrointestinal Adverse Reactions:** There is an increased risk of gastrointestinal perforation in patients with certain gastrointestinal disorders. Signs of gastrointestinal perforation, such as peritoneal irritation, may be masked in patients receiving corticosteroids. Corticosteroids should be used with caution if there is a probability of impending perforation, abscess, or other pyogenic infections; diverticulitis; fresh intestinal anastomoses; and active or latent peptic ulcer.
Concurrent administration of corticosteroids with nonsteroidal anti-inflammatory drugs (NSAIDs) may increase the risk of gastrointestinal adverse reactions. Monitor patients receiving corticosteroids and concomitant NSAIDs for gastrointestinal adverse reactions.
- **Risk of Kaposi's Sarcoma with Use of a Dosage Greater Than Replacement:** Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid therapy, most often for chronic conditions at a dosage greater than replacement (supraphysiologic dosage). If patients take a supraphysiologic chronic dosage of ALKINDI SPRINKLE, they are at increased risk of developing Kaposi's sarcoma.
- **Vaccination:** Administration of live vaccines may be acceptable in ALKINDI SPRINKLE-treated pediatric patients with adrenocortical insufficiency who receive replacement corticosteroids.



Adverse Reactions

Common adverse reactions for corticosteroids include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite, and weight gain.

To report a suspected adverse event related to ALKINDI SPRINKLE, contact Eton Pharmaceuticals, Inc. at 1-855-224-0233 or the U.S. Food and Drug Administration (FDA) at <http://www.fda.gov/MedWatch> or call 1-800-FDA-1088.

INDICATION

ALKINDI SPRINKLE is a corticosteroid indicated for replacement therapy in pediatric patients with adrenocortical insufficiency.

Please see full Prescribing Information for more information.

References: **1.** ALKINDI SPRINKLE. Package insert. Eton Pharmaceuticals, Inc; 2024. **2.** Whitaker MJ, Spielmann S, Digweed D, et al. Development and testing in healthy adults of oral hydrocortisone granules with taste masking for the treatment of neonates and infants with adrenal insufficiency. *J Clin Endocrinol Metab.* 2015;100(4):1681-1688. doi:10.1210/jc.2014-4060



PHARMACEUTICALS

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