



Alkindi® Sprinkle (hydrocortisone) – New orphan drug approval

- On September 30, 2020, [Eton Pharmaceuticals announced the FDA approval of Alkindi Sprinkle \(hydrocortisone\)](#), as replacement therapy in pediatric patients with adrenocortical insufficiency.
- Pediatric adrenocortical insufficiency is a rare disease characterized by an inability to synthesize and release cortisol, and sometimes aldosterone. This causes excessive androgens (abnormal sexual development in females, premature puberty, premature growth termination and short stature). Diminished cortisol in the system may result in adrenal crisis.
 - Eton estimates that pediatric adrenocortical insufficiency affects between 5,000 and 11,000 children in the U.S.
- Alkindi Sprinkle is the first FDA-approved granular hydrocortisone formulation for the treatment of adrenocortical insufficiency specifically designed for use in children.
 - Oral hydrocortisone is also available generically as a [tablet](#).
- Warnings and precautions for Alkindi Sprinkle include adrenal crisis, infections, growth retardation, Cushing's syndrome due to use of excessive doses of corticosteroids, decrease in bone mineral density, psychiatric adverse reactions, ophthalmic adverse reactions, and gastrointestinal adverse reactions.
- The most common adverse reactions with corticosteroid use include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain.
- The dose of Alkindi Sprinkle should be individualized for each patient, with the lowest possible dosage being used. The recommended starting replacement dosage is 8 to 10 mg/m²/day orally daily. Higher doses may be needed based on patient's age and symptoms of the disease. Use of lower starting doses may be sufficient in patients with residual but decreased endogenous cortisol production.
 - The dose should be rounded to the nearest 0.5 mg or 1 mg. The contents of more than one capsule may be needed to supply the required dose.
 - The total daily dose should be divided in 3 doses and administered 3 times daily. Older pediatric patients may have their daily dose divided by 2 and administered twice daily.
- Eton Pharmaceuticals plans to launch Alkindi Sprinkle in the fourth quarter 2020. Alkindi Sprinkle will be available as 0.5 mg, 1 mg, 2 mg, and 5 mg oral granules in capsules.



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