

## CLINICAL UPDATE

<b>Brand Name</b>	Alkindi® Sprinkle
<b>Generic Name</b>	hydrocortisone
<b>Drug Manufacturer</b>	Eton Pharmaceuticals, Inc.

### Clinical Update

#### TYPE OF CLINICAL UPDATE

Clinical Update - New Dosage Form (0.5mg, 1mg, 2mg, 5mg)

#### FDA APPROVAL DATE

September 29, 2020

#### LAUNCH DATE

FDA Date Added – 10/15/2020

#### REVIEW DESIGNATION

Standard; Orphan

#### TYPE OF REVIEW

Type 3 - New Dosage Form

#### DISPENSING RESTRICTIONS

N/A

### Overview

#### INDICATION(S) FOR USE

Alkindi® Sprinkle is a corticosteroid indicated as replacement therapy in pediatric patients with adrenocortical insufficiency.

#### MECHANISMS OF ACTION

Hydrocortisone is a glucocorticoid. Glucocorticoids and adrenocortical steroids cause varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli.

#### DOSAGE FORM(S) AND STRENGTH(S)

Oral granules: 0.5 mg, 1 mg, 2 mg, 5 mg contained in capsules.

#### DOSE & ADMINISTRATION

Individualize the dose for each patient, using the lowest possible dosage.

The recommended starting replacement dosage is 8 to 10 mg/m<sup>2</sup> 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.

Round the dose to the nearest 0.5 mg or 1 mg. More than one capsule may be needed to supply the required dose.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

## CLINICAL UPDATE

Divide the total daily dose in 3 doses and administer 3 times daily. Older patients may have their daily dose divided by 2 and administered twice daily.

### EFFICACY

Alkindi® Sprinkle was supported by six clinical studies, including the first and only interventional Phase III study of oral hydrocortisone for Pediatric AI in neonates to children under eight years of age. Many pediatric patients require significantly lower doses and the flexibility of precision titration. It will be available in 0.5mg, 1mg, 2mg, and 5mg strengths, allowing clinicians greater flexibility to individualize dosing based on each patient's needs in accordance with the instructions for dosage and administration.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.