

Khindivi[™] (hydrocortisone) - New drug approval

- On May 28, 2025, <u>Eton Pharmaceuticals announced</u> the FDA approval of <u>Khindivi</u>
 (<u>hydrocortisone</u>), as <u>replacement therapy in pediatric patients 5 years of age and older with adrenocortical insufficiency</u>.
 - Khindivi is not approved for increased dosing during periods of stress or acute events. A
 different hydrocortisone-containing drug product should be used for stress dosing.
- Khindivi is a corticosteroid and the first oral solution formulation of hydrocortisone.
- Warnings and precautions for Khindivi include adrenal crisis; systemic adverse reactions due to
 inactive ingredients; immunosuppression and increased risk of infection with use of a dosage
 greater than replacement; growth retardation; Cushing's syndrome due to use of excessive doses
 of corticosteroids; decrease in bone mineral density; psychiatric adverse reactions; ophthalmic
 adverse reactions; gastrointestinal adverse reactions; risk of Kaposi's sarcoma with use of a
 dosage greater than replacement; and vaccination.
- 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.
- The recommended starting replacement dosage of Khindivi is 8 to 10 mg/m² daily administered orally with or without food. Higher doses may be needed based on the patient's age and symptoms of the disease. Use of a lower starting dose may be sufficient in patients with residual but decreased endogenous cortisol production.
 - The total daily dose should be divided into 3 doses and administered 3 times daily. Older pediatric patients may have their daily dose divided by 2 and administered twice daily.
 - Refer to the Khindivi drug label for complete dosing and administration recommendations.
- Eton Pharmaceuticals plans to launch Khindivi in the week of June 2nd. Khindivi will be available as a 1 mg/mL oral solution.



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