14 December 2017
EMA/CHMP/817958/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Alkindi

hydrocortisone

On 14 December 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Alkindi, intended for replacement therapy of adrenal insufficiency in infants, children and adolescents. The applicant for this medicinal product is Diurnal Ltd.

Alkindi will be available as 0.5 mg, 1.0 mg, 2.0 mg and 5.0 mg granules in capsules for opening. The active substance of Alkindi is hydrocortisone, a corticosteroid for systemic use (ATC code: H02AB09). Hydrocortisone is the synthetic form of cortisol, the principal glucocorticoid secreted by the adrenal cortex. Hydrocortisone is given as replacement therapy in patients with adrenal insufficiency.

Alkindi is a hybrid medicine[2] of hydrocortisone 10 mg tablets which have been authorised in the EU since 1989. Alkindi contains the same active substance as hydrocortisone 10 mg tablets, but is available in a different form and different strengths. Alkindi has been developed as a paediatric-specific formulation (granules in capsules for opening) that allows for precise dosing and is designed to mask the bitter taste of the active substance. Studies have demonstrated the satisfactory quality of Alkindi, and its bioequivalence to the reference product.

The full indication is:
“Replacement therapy of adrenal insufficiency in infants, children and adolescents (from birth to < 18 years old).”

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact