25 March 2021
EMA/CHMP/176520/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Efmody

hydrocortisone

On 25 March 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Efmody[2], intended for the treatment of congenital adrenal hyperplasia (CAH) in patients aged 12 years and over.

The applicant for this medicinal product is Diurnal Europe BV.

Efmody will be available as modified-release hard capsules (5 mg, 10 mg and 20 mg). The active substance of Efmody 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.

Efmody has been developed as a modified-release formulation to mimic the physiological 24-hour profile of cortisol and is to be given twice daily. The benefit of Efmody compared to standard glucocorticoid therapy is its ability to reduce the early morning peak of 17-hydroxyprogesterone, a steroid precursor. The most common side effects are adrenal insufficiency (including acute events), fatigue, headache, increased appetite, dizziness and weight gain.

Efmody is a hybrid medicine[3] of hydrocortisone 20 mg tablets (Hydrocortone) which had been authorised in the EU since 1989. Efmody contains the same active substance as Hydrocortone, but is available in a different form and different strengths. Efmody is also authorised in a new indication.

The full indication is:

> Treatment of congenital adrenal hyperplasia (CAH) in adolescents aged 12 years and over and adults.

Efmody should be prescribed by physicians experienced in the treatment of CAH.

[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] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained
[3] 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.

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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.