Abbreviated Prescribing Information for Efmody® modified-release hard capsules (hydrocortisone) 5 mg and 10 mg

Modified-release hard capsules containing 5 mg and 10 mg of hydrocortisone respectively.

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

Dosage Dosage should be individualised according to response & the lowest possible dose used. ⅔ to ¾ of the dose should be given at bedtime and the rest on waking. During excessive stress, it may be necessary to increase the dose of Efmody or add additional hydrocortisone as oral or parenteral treatment.

Contraindications Hypersensitivity to the active substance or any of the excipients.

Warnings and precautions Patients should be advised of symptoms of acute adrenal insufficiency and adrenal crisis and the need to seek immediate medical attention. Sudden discontinuation of therapy risks adrenal crisis and death. During adrenal crisis parenteral hydrocortisone in high doses should be administered according to current guidelines. Infection should be taken seriously and an increase in steroid dose initiated, and expert advice sought early. Efmody is not recommended in patients with increased gastrointestinal motility. No data are available in patients with reduced gastrointestinal motility. Impaired glucose tolerance, growth retardation, early sexual maturation, diabetes and reduced bone mineral density may occur with long term use of corticosteroids. Excessive weight gain, decreased height velocity or symptoms of Cushing syndrome indicate excessive glucocorticoid treatment. Children should be assessed frequently and their dose adjusted according to individual response. Visual disturbances have been reported in patients receiving oral corticosteroids. Should this occur, consult an ophthalmologist. Patients should be informed that recovery of fertility may occur when starting treatment with Efmody so that they can consider using a method of contraception if necessary.

Fertility In both men and women who have lower fertility due to CAH, fertility may be restored shortly after beginning treatment with Efmody.

Interactions Hydrocortisone is metabolised by cytochrome P450 3A4 (CYP3A4). Concomitant administration of medicinal products or foodstuffs inhibiting or inducing CYP3A4 may require dose adjustment of Efmody and close monitoring.

Pregnancy and lactation Hydrocortisone for replacement therapy can be used during pregnancy and breast feeding.

Ability to drive and use machines Efmody has minor influence on ability to drive and use machines.

Adverse Events The commonest adverse events in the trial programme were fatigue, headache, increased appetite, dizziness and increased weight. The most common serious adverse event was acute adrenal insufficiency.

Legal classification: POM

Product (50 capsule bottle)	**Basic NHS Cost**	**MA Number**
Efmody 5 mg modified-release hard capsules	£135.00	PLGB 50616/0011
Efmody 10 mg modified-release hard capsules	£270.00	PLGB 50616/0012

Prescribers should refer to summary of product characteristics for full prescribing information.

Approval Code: CH EU-GB-0158
Date of preparation: January 2025

Marketing Authorisation Holder
Neurocrine Netherlands B.V.
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Adverse Events should be reported.
Reporting Forms and information can be found at www.mhra.gov.uk/yellowcard
Adverse Events should also be reported to Neurocrine UK on adverseeventsEU@neurocrine.com

Approval Certificate

Job Number CH EU-GB-0158

Product Chronocort EU

Item Name Efmody UK Prescribing Information V4 - Jan 2025

Objective

Intended Audience Healthcare Provider Prescriber

Certification and Release Declaration
I certify that I have examined the final form of this material and in my belief it is in accordance with the requirements of the ABPI Code of Practice.

Document Approvals	
Medical Practitioner Certification I certify that I have examined the final form of the material and in my belief it is in accordance with the requirements of the relevant regulations relating to advertising and the ABPI Code and any other relevant code, is not inconsistent with the marketing authorization and the summary of product characteristics, and is a fair and truthful presentation of the facts about the medicine. I certify the above is true	Anoop Kumar anoopkumar@diurnal.co.uk Medical Practitioner 12-Dec-2024 12:40:39 GMT+0000