Abbreviated prescribing information for Efmody® 5mg and 10mg modified-release hard capsules (hydrocortisone).

Modified-release hard capsules containing 5mg and 10mg 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. 2/3 to 3/4 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.

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.

Fertility, pregnancy and lactation: Hydrocortisone for replacement therapy can be used during pregnancy and breast feeding. No data are available for any effect on fertility.

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 5mg modified-release hard capsules	£135.00	PLGB 50616/0011 EU/1/21/1549/001
Efmody 10mg modified-release hard capsules	£270.00	PLGB 50616/0012 EU/1/21/1549/002

Marketing Authorisation Holder
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Prescribers should refer to summary of product characteristics for full prescribing information.
Approval Code: CH EU-GB-0046
Date of preparation: July 2021

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 Diurnal on adverse-events@diurnal.co.uk
Telephone +44 (0) 7917 334899