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.

Please refer to the Summary of Product Characteristics (SmPC) before prescribing Efmody.

Indication Treatment of congenital adrenal hyperplasia (CAH) in adolescents aged 12 years and over and adults.
Dosage Should be individualised according to response & the lowest possible dose used. Recommended replacement doses of hydrocortisone are 10-15 mg/m^2/day in adolescents aged 12 years and over who have not completed growth, and 15-25 mg/day in adolescents who have completed growth and adult patients with CAH. In patients with some remaining endogenous cortisol production a lower dose may be sufficient. 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 Acute adrenal insufficiency may develop in patients with known adrenal insufficiency who are on inadequate daily doses or in situations with increased cortisol need. 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. Pre-operatively, anaesthetists must be informed if the patient is taking or has previously taken corticosteroids. Parenteral administration of hydrocortisone is warranted during transient illness episodes such as severe infections, in particular gastroenteritis associated with vomiting and/or diarrhoea, high fever or extensive physical stress, such as serious accidents and surgery under general anaesthesia. If so, the patient should be treated in a facility with resuscitation facilities. All infections should be taken seriously and an increase in steroid dose initiated, and expert advice sought early. Supra-physiological dosages of hydrocortisone can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. Potassium levels should be monitored to rule out hypokalaemia. Long-term treatment with higher than physiological hydrocortisone doses can lead to clinical features resembling Cushing's syndrome and thus result in an increased risk of cardiovascular morbidity and mortality. Patients should be warned of the signs of diabetes and to seek medical advice if they occur. Long-term therapy may reduce bone mineral density. Risk of potentially severe psychiatric adverse reactions. Euphoria, mania, psychosis with hallucinations and delirium have been seen in adult patients. Patients should seek medical advice if symptoms develop, especially depressed mood or suicidal ideation. Psychiatric disturbances may also occur either during or immediately after dose tapering/withdrawal of systemic steroids. Rare instances of anaphylactoid reactions have occurred in patients receiving corticosteroids and immediate medical advice should be sought if symptoms develop. Not recommended in patients with increased gastrointestinal motility. May cause growth retardation in childhood and adolescence; may be irreversible. Treatment should be limited to the minimum dose required. Children require frequent assessment to assess growth, blood pressure, and general well-being. Adolescents with CAH may show accelerated sexual maturation and needs close monitoring; if there are signs of it, an increase in dose should be considered. Visual disturbances have been reported. Should this occur, consider referral to an ophthalmologist. In men and women who have lower fertility due to CAH, fertility may be restored shortly after beginning treatment with Efmody. Patients should be informed so that they can consider contraceptive measures if required.
Interactions with other products 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. Please refer to the SmPC for further information on other medicinal interactions.
Pregnancy & lactation 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. Fatigue and dizziness have been reported. Untreated and poorly replaced adrenal insufficiency may affect the ability to drive and use machines.
Adverse Events
Serious adverse events: acute adrenal insufficiency (4.2% pf patients treated with Efmody) and hypokalaemia.
Very common (frequency ≥ 1/10): fatigue.
Common (≥ 1/100 to < 1/10): adrenal insufficiency including acute events, increased appetite, decreased appetite, impaired fasting glucose, insomnia, abnormal dreams, sleep disorder, depressed mood, headache, dizziness, carpal tunnel syndrome, paraesthesia, nausea, upper abdominal pain, acne, abnormal hair growth, arthralgia, myalgia, muscle fatigue, pain in extremity, asthenia, hypokalaemia, low density lipoprotein increased, renin increased and increased weight.
Legal classification: POM

Product (50 capsule bottle)	Cost	Basic NHS 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.

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Adverse Events should be reported. Reporting Forms and information can be found at https://yellowcard.mhra.gov.uk Adverse Events should also be reported to Neurocrine UK on adverseeventsEU@neurocrine.com