Abbreviated Prescribing Information for Alkindi® 0.5 mg, 1 mg, 2 mg, and 5 mg granules in capsules for opening (Hydrocortisone)

Capsules for opening containing 0.5 mg, 1 mg, 2 mg or 5mg of hydrocortisone respectively.

Indication Replacement therapy of adrenal insufficiency in infants, children and adolescents (from birth to < 18 years old).

Dosage Dosage must be individualised according to the response of the patient: the lowest possible dosage should be used. Recommended replacement doses are 8-15 mg/m^2/day, in three or four divided doses. In minor illness or trauma, the total daily dose of Alkindi may need to be doubled or tripled. In more severe situations particularly with vomiting/diarrhoea, high fever or trauma/surgery parenteral administration of hydrocortisone and transfer to a facility with resuscitation facilities are necessary.

Administration The capsule shell must not be swallowed but carefully opened. The granules are either poured directly onto the child's tongue, or a spoon, with or without soft food, can be used to place the granules in the child's mouth. Immediately after administration fluid should be given orally.

Contraindications Hypersensitivity to the active substance or to any of the excipients. Patients with dysphagia or premature infants where oral feeding has not been established.

Warnings and precautions Where a child is vomiting or acutely unwell parenteral hydrocortisone should be started immediately. Sudden discontinuation of therapy risks adrenal crisis and death. Relative adrenal insufficiency may persist after discontinuation and in any stress situation therapy should be reinstated. Any signs of infection should be treated seriously, with an increased dose of Alkindi being started promptly. Inaccuracy in dosing possible with conventional oral hydrocortisone crushed or compounded formulations can lead to adrenal crisis when switching from these to Alkindi. Close monitoring of patients is recommended for a week after switch, and extra doses of Alkindi should be given if symptoms of adrenal insufficiency are seen. If this is required, an increase in the dose of Alkindi should be considered and immediate medical advice should be sought. Growth and/or bone mineral density may be retarded during infancy, childhood and adolescence. Psychiatric disturbances have been observed in adult patients taking replacement doses of hydrocortisone. If this occurs parents should seek medical advice immediately. Rarely anaphylactoid reactions have occurred in patients receiving corticosteroids. Visual disturbances of various types have been reported in patients receiving oral corticosteroids. Should this occur, consult an ophthalmologist. Granule cores may sometimes be seen in stools, no additional dose is required. Alkindi must not be administered through nasogastric tubes.

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

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

Adverse events A total of 30 healthy adult male subjects in two phase 1 studies and 24 paediatric patients with adrenal insufficiency in two phase 3 studies have been treated with Alkindi. There were no adverse reactions seen in any of the studies. In adult patients receiving hydrocortisone replacement therapy adverse events have been reported with unknown frequency: psychosis with hallucinations and delirium, mania, euphoria, gastritis, nausea, and hypokalaemic alkalosis.

Legal classification: POM

Product (50 capsule bottle)	Basic NHS Cost	MA Number
Alkindi 0.5 mg granules in capsules for opening	£33.75	PLGB 50616/0007 (UKNI) EU/1/17/1260/001
Alkindi 1 mg granules in capsules for opening	£67.50	PLGB 50616/0008 (UKNI) EU/1/17/1260/002
Alkindi 2 mg granules in capsules for opening	£135.00	PLGB 50616/0009 (UKNI) EU/1/17/1260/003
Alkindi 5 mg granules in capsules for opening	£337.50	PLGB 50616/0010 (UKNI) EU/1/17/1260/004

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

Approval Code: Inf EU-GB-0214
Date of preparation: January 2024

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