Hydrocortisone

Essential medicine status ✓

Section: 18. Medicines for endocrine disorders > 18.1. Adrenal hormones and synthetic substitutes

EMLc | ATC codes: H02AB09

Indication	Adrenocortical insufficiency ICD11 code: 5A74
INN	Hydrocortisone
Medicine type	Chemical agent
List type	Core (EML) (EMLc)
Formulations	Oral > Solid: 5 mg ; 10 mg ; 20 mg
EML status history	First added in 1977 (TRS 615) Changed in 1979 (TRS 641) Removed in 2003 (TRS 920) Added in 2009 (TRS 958)
Sex	All
Age	Also recommended for children
Therapeutic alternatives	The recommendation is for this specific medicine
Patent information	Patents have expired in most jurisdictions Read more about patents.
Wikipedia	Hydrocortisone
DrugBank	Hydrocortisone

Summary of evidence and Expert Committee recommendations

The EMLc Subcommittee considered the application for the inclusion of the adrenal hormones fludrocortisone and hydrocortisone to the EMLc. Numerous external comments in support of the proposal were received from health professionals, associations and individuals. The Subcommittee noted that hydrocortisone and fludrocortisone are used in the management of primary and secondary aldosterone deficiency caused by congenital adrenal hyperplasia and Addison disease, that both medications are licensed for use in all ages, and that treatment should be of lifelong duration. It was noted that fludrocortisone is currently the only mineralocorticoid available for aldosterone replacement in congenital adrenal hyperplasia, and that consequently there are no comparative efficacy or safety studies for the management of mineralocorticoid deficiency in congenital adrenal hyperplasia. The application identified a retrospective study of 484 patients from five European countries, which demonstrated a decrease in mortality rate from 11.9% in untreated patients to 4.3% in those patients who were treated with fludrocortisone (1). Only one small study (2) of nine patients comparing hydrocortisone with prednisone for the management of congenital adrenal hyperplasia was included in the application. It showed that prednisolone had significantly greater adverse effects on growth than hydrocortisone. It was acknowledged however that the use of other glucocorticoids such as dexamethasone and prednisolone is generally avoided in children due to adverse effects on growth. The Subcommittee agreed that fludrocortisone and hydrocortisone are both essential medicines for the management of congenital adrenal hyperplasia and adrenal insufficiency in children, and included them on the EMLc. Hydrocortisone was also added to the EML to provide concordance with the EMLc. References: 1. Kovacs J et al. Lessons from 30 years of clinical diagnosis and treatment of congenital adrenal hyperplasia in five middle-European countries. Journal of Clinical Endocrinology and Metabolism, 2001, 86:2958–64. 2. Spritzer P et al. Cyproterone acetate versus hydrocortisone treatment in late-onset adrenal hyperplasia. Journal of Clinical Endocrinology and Metabolism, 1990, 70:642–6.