

| | | EMLc | ATC codes: H02AA02 |
|--------------------------|---|------------------|--------------------|
| Indication | Adrenocortical insufficiency | ICD11 code: 5A74 | |
| INN | Fludrocortisone | | |
| Medicine type | Chemical agent | | |
| List type | Core (EML) (EMLc) | | |
| Formulations | Oral > Solid: 100 µg (acetate) | | |
| 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 | Fludrocortisone  | | |
| DrugBank | Fludrocortisone  | | |

Summary of evidence and Expert Committee recommendations

The EMLc Subcommittee considered an 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. Fludrocortisone was also added to the EML to provide concordance with the EMLc since it was noted by the Expert Committee that it would be essential for the treatment of congenital adrenal hypoplasia and adrenal failure in adults. 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.

