



## Medicine: hydrocortisone modified-release capsules (brand name: Efmody®)

Diurnal Europe BV

The Scottish Medicines Consortium (SMC) has assessed hydrocortisone modified-release capsules for the treatment of congenital adrenal hyperplasia (CAH) in patients aged 12 years and older. This document summarises the SMC decision and what it means for patients.

### What has SMC said?

After careful consideration, SMC has not recommended hydrocortisone modified-release for treating CAH as described above.

SMC was unable to accept hydrocortisone modified-release because the evidence provided by the company was not strong enough to satisfy the committee that it offers value for money to NHSScotland. This was despite using a more [flexible approach\\*](#) in the assessment, as it is for a rare condition.

### What does SMC's decision mean for patients?

Hydrocortisone modified-release should not normally be prescribed on the NHS in Scotland for use as described above. If a patient's healthcare professional thinks a particular patient would benefit from it, they can make a request to prescribe hydrocortisone modified-release. All health boards have procedures in place to consider these requests. For further information see:

Medicines in Scotland: What's the right treatment for me?

[www.healthcareimprovementscotland.org/medicinesbooklet.aspx](http://www.healthcareimprovementscotland.org/medicinesbooklet.aspx)



### What is hydrocortisone modified-release used for?

Hydrocortisone modified-release is used to treat CAH, which is a group of rare inherited conditions where the adrenal glands are larger than usual. In the main types of CAH the production of cortisol (a hormone which is essential for life and which plays a key role in the body's response to stress) and often aldosterone (a hormone that controls blood pressure by affecting the amount of salt in the body), is low. People with untreated CAH are at risk of life-threatening adrenal crises (where cortisol levels are too low, leading to symptoms such as profound weakness, low blood pressure and dehydration). CAH can also cause differences in sexual development due to the body producing excess testosterone to compensate for the low levels of cortisol and aldosterone.

\*<https://www.scottishmedicines.org.uk/how-we-decide/pace/>

## How does hydrocortisone modified-release work?

People with CAH are unable to make enough of a hormone called cortisol. Hydrocortisone modified-release is an artificial form of cortisol. The modified release aspect means that it is released gradually in the body in a similar pattern to the natural daily secretion of cortisol. This helps to create a more normal hormone balance and reduce the effects of CAH.

## How does SMC make its decision?

SMC carefully considers every new medicine to make sure it benefits patients and is considered to be an acceptable use of the limited resources in NHSScotland.

To do this SMC considers the following:

- Evidence from the company about how well the medicine works compared with current treatments available in Scotland, in relation to how much they will cost to buy and administer.
- Information from patient groups about the potential impact of the medicine on patients and carers.
- Advice from healthcare professionals about any benefits of the new medicine compared to current treatment, along with how the new medicine is likely to be used.

When SMC assesses a medicine it takes account of the needs of all patients in NHSScotland, not only those who may be treated with the medicine under consideration.

You can find more detailed information about the SMC assessment of hydrocortisone modified-release by looking at the SMC Detailed Advice Document (SMC2414).

## More information

The organisation below can provide more information and support for people with CAH and their families. SMC is not responsible for the content of any information provided by external organisations.

### CAH Support Group



<https://www.livingwithcah.com>

You can find out more about hydrocortisone modified-release capsules (Efmody®) in the European public assessment report (EPAR) summary for the public by searching for the medicine name on the European Medicines Agency (EMA) website.



<https://www.ema.europa.eu/en>