



Medicine: hydrocortisone granules in capsules (brand name: Alkindi®) for adrenal insufficiency

Diurnal Limited

What is adrenal insufficiency?

Adrenal insufficiency is a condition where the body's adrenal glands do not make enough of a hormone called cortisol. Cortisol is needed to control many of the body's processes so symptoms can be varied and include: weight loss, tiredness, muscle weakness and low blood pressure.

How does hydrocortisone work?

Hydrocortisone is the same as cortisol. It can replace the cortisol missing in people with adrenal insufficiency, which reduces symptoms. Alkindi is granules of hydrocortisone inside capsules that are opened and is specifically for treating children with adrenal insufficiency.

What has SMC said?

SMC has accepted hydrocortisone granules for restricted use for the replacement therapy of adrenal insufficiency. This acceptance is limited to use in infants and young children aged from birth to less than six years old, where the only options to get the right dose are to break up and crush hydrocortisone tablets, produce special solutions or to use hydrocortisone buccal tablets (that dissolve when held between the gum and the cheek) that are not licensed (approved) for treating adrenal insufficiency.



Why has SMC said this?

SMC looks at how well new medicines work compared with current treatments available in Scotland and in relation to how much they will cost to buy and administer (for example, if the medicine has to be given at a clinic or side effects have to be monitored).

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

To do this SMC consider the following:

- Clinical trial and economic evidence from the company that makes the medicine.
- 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.
- Information from patient groups about the potential impact of the medicine on patients and carers.

After careful consideration, applying extra flexibility because hydrocortisone granules is a medicine for a very rare condition, and after the company applied a confidential discount to the cost of the medicine, SMC was able to accept it as a possible treatment within NHSScotland.

What does SMC's decision mean for me?

If your healthcare professional thinks that hydrocortisone granules for use as described above is the right medicine for your child, they should be able to have the treatment on the NHS in Scotland. For further information see:

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

www.healthcareimprovementscotland.org/medicinesbooklet.aspx



More information

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

Addison's Disease Self-Help Group

 <https://www.addisons.org.uk>

Congenital Adrenal Hyperplasia Support Group (CAH Support Group)

 www.cah.org.uk

The Pituitary Foundation

 <https://www.pituitary.org.uk>

 0117 370 1320

You can find out more about hydrocortisone granules in the European public assessment report (EPAR) summary for the public by clicking on this [link](#) or searching for the medicine name on the European Medicines Agency (EMA) website.

 <http://www.ema.europa.eu>

Date advice published: 8 October 2018

SMC No: (SMC2088)