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EPAR summary for the public

Alkindi

hydrocortisone

This is a summary of the European public assessment report (EPAR) for Alkindi. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Alkindi.

For practical information about using Alkindi, patients should read the package leaflet or contact their doctor or pharmacist.

What is Alkindi and what is it used for?

Alkindi is a medicine for children (from birth to up to 18 years of age) whose adrenal glands cannot make enough of a hormone called cortisol.

Cortisol is needed to control many body processes (including inflammation and the control of sugar and mineral levels) and is sometimes referred to as the 'stress hormone' because it helps the body respond to stress. A lack of the hormone causes several symptoms, including weight loss, muscle weakness, tiredness and low blood pressure.

Alkindi is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance (in this case Hydrocortisone Tablets Auden Mckenzie), but Alkindi is available in a different form (granules instead of tablets) and has been developed for children only.

Alkindi contains the active substance hydrocortisone.

How is Alkindi used?

Alkindi is available as capsules containing granules. The capsules are opened and the granules are placed in the child's mouth. The child should then be given water or milk to swallow the granules. The granules can also be sprinkled on a spoonful of soft food and given to the child immediately.

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The dose is chosen to be lowest possible that controls the child's symptoms. For further information, see the package leaflet.

The medicine can only be obtained with a prescription.

How does Alkindi work?

The active substance in Alkindi, hydrocortisone, is the same as cortisol, the main steroid hormone released by the body's adrenal gland. Hydrocortisone replaces the natural cortisol that is missing in children whose adrenal glands do not produce enough of the hormone, thereby helping to relieve their symptoms.

What benefits of Alkindi have been shown in studies?

Studies on the benefits and risks of the active substance have already been carried out with the reference medicine and do not need to be repeated for Alkindi.

As for every medicine, the company provided studies on the quality of Alkindi. The company also carried out studies to show that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the risks associated with Alkindi?

No side effects were reported in studies with Alkindi, but some side effects have been reported with other hydrocortisone medicines. These include changes in behaviour, nausea, inflammation in the lining of the stomach and changes in blood potassium levels and excess acid in the blood. For the full list of side effects see the package leaflet.

Alkindi must not be used in patients with hypersensitivity (allergy) to the active substance or to any of the ingredients of Alkindi. It must also not be used in children with difficulty swallowing or in premature babies who haven't started feeding by mouth.

Why is Alkindi approved?

Alkindi produces similar levels of hydrocortisone in the blood to a reference medicine already authorised in the EU. Alkindi is also available in a form suitable for children and it is easier to give a precise dose with Alkindi than with other treatments which require crushing tablets and weighing up the right dose.

The European Medicines Agency concluded that the benefits of Alkindi are greater than its risks and recommended that it be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Alkindi?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Alkindi have been included in the summary of product characteristics and the package leaflet.

Other information about Alkindi

The European Commission granted a marketing authorisation valid throughout the European Union for Alkindi on 9 February 2018.

The full EPAR for Alkindi can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Alkindi, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2018.