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EPAR summary for the public

NutropinAq

somatropin

This is a summary of the European public assessment report (EPAR) for NutropinAq. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for NutropinAq.

What is NutropinAq?

NutropinAq is a solution for injection in a cartridge. Each cartridge contains 10 mg of the active substance somatropin.

What is NutropinAq used for?

NutropinAq is used to treat the following groups of children:

- children who fail to grow because of a lack of growth hormone;
- girls from 2 years old who are short because of Turner syndrome (a rare genetic disorder affecting girls), confirmed by chromosome analysis (DNA testing);
- children (before puberty) who fail to grow because of long-lasting kidney disease, up to the time when they receive a kidney transplant.

NutropinAq is also used to treat adults with a deficiency (low levels) of growth hormone. The deficiency can have started in adulthood or childhood, and needs to be confirmed by testing before treatment.

The medicine can only be obtained with a prescription.

How is NutropinAq used?

NutropinAq treatment should be started and supervised by a doctor who has experience in the management of patients with growth disorders.

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The medicine is given once a day by injection under the skin, using the injection pen specially designed for the NutropinAq cartridge. The patient or their carer can inject NutropinAq after training by a doctor or a nurse. They should use a different injection site each day. The doctor calculates the dose for each patient individually depending on the patient's condition. The dose may need to be adjusted over time, depending on the patient's response, age and body weight.

How does NutropinAq work?

Growth hormone is a substance secreted by a gland located at the base of the brain called the pituitary gland. It promotes growth during childhood and adolescence, and also affects the way the body handles proteins, fat and carbohydrates. The active substance in NutropinAq, somatropin, is identical to human growth hormone. It is produced by a method known as 'recombinant DNA technology': the hormone is made by bacteria into which a gene (DNA) has been introduced that makes them able to produce somatropin. NutropinAq replaces the natural hormone.

How has NutropinAq been studied?

NutropinAq has been studied in children with growth failure caused by a lack of growth hormone (230 patients), Turner syndrome (117 patients) or kidney disease (195 patients). NutropinAq has also been studied in 171 adults with growth hormone deficiency. NutropinAq was compared with a placebo (a dummy treatment) or with a group of untreated patients, except in the studies of children with a lack of growth hormone where there was no comparison with any other group. The main measures in the studies in children were the speed of growth during the study and the height at the end of the study. The main measures in the adult study were lean body mass and the decrease in total body fat.

What benefit has NutropinAq shown during the studies?

NutropinAq produced better growth in children than would have been expected without treatment. In adults, NutropinAq increased lean body mass and reduced total body fat.

What is the risk associated with NutropinAq?

In adults, the most common side effects with NutropinAq (seen in more than 1 patient in 10) are myalgia (muscle pain), arthralgia (joint pain) and oedema (swelling). In children, these side effects are seen in between 1 and 10 patients in 100. Other side effects seen at this lower frequency are reactions at the injection site, headache, hypertonia (muscle tension), hypothyroidism (under-activity of the thyroid gland), impaired glucose tolerance, asthenia (weakness) and development of antibodies (proteins that are produced in response to NutropinAq). The most serious side effects reported were the development of neoplasms (tumours) and intracranial hypertension (increased pressure inside the skull). For the full list of all side effects reported with NutropinAq, see the package leaflet.

NutropinAq must not be used in people who are hypersensitive (allergic) to somatropin or any of the other ingredients. NutropinAq must not be used when the patient has an active tumour or a life-threatening illness. NutropinAq must not be used for growth promotion in children with closed epiphyses (when the large bones have finished growing). For the full list of restrictions, see the package leaflet.

Somatropin may interfere with the body's use of insulin. Blood sugar levels will need to be checked during treatment, and treatment with insulin may sometimes need to be started or adjusted.

Why has NutropinAq been approved?

The CHMP concluded that NutropinAq's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about NutropinAq

The European Commission granted a marketing authorisation valid throughout the European Union for NutropinAq on on 16 February 2001.

The full EPAR for NutropinAq 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 NutropinAq, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2013.