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Ngenla (*somatrogon*)

An overview of Ngenla and why it is authorised in the EU

What is Ngenla and what is it used for?

Ngenla is a medicine used to treat children and adolescents who are not growing at the normal rate as a result of growth hormone deficiency (lack of natural growth hormone). It is given to patients from 3 years of age.

Ngenla contains the active substance somatrogon.

How is Ngenla used?

Ngenla can only be obtained with a prescription and treatment should be started and monitored by a doctor experienced in the management of children and adolescents with growth hormone deficiency.

Ngenla is available as an injection in pre-filled pens of different strengths, to be given under the skin once a week. The recommended dose is 0.66 mg per kilogram of body weight each week, adjusted by the doctor if necessary. For patients over 45 kg who require doses higher than 30 mg the dose is given as two injections. Patients or their caregivers can inject the dose themselves after appropriate training.

For more information about using Ngenla, see the package leaflet or contact your doctor or pharmacist.

How does Ngenla work?

In healthy patients, growth hormone is released by the pituitary gland (a gland at the base of the brain). It is important for growth during childhood and adolescence. Growth hormone also affects how the body handles proteins, fat and carbohydrates. The active substance in Ngenla, somatrogon, is a version of natural human growth hormone which has been modified by combining it with part of another human hormone called chorionic gonadotropin in a so-called recombinant hormone. Because only a part of this other hormone is used, it does not have an effect on the body, but the combination lets somatrogon remain active in the body for a longer period of time than natural growth hormone so injections do not need to be given every day.

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What benefits of Ngenla have been shown in studies?

Ngenla once a week has been shown to be at least as effective as daily somatropin (a medicine with the same structure as natural growth hormone) in promoting growth. In a main study in 224 pre-pubertal patients with growth hormone deficiency the average rate of growth over a year was 10.1 cm in those given Ngenla and 9.8 cm in those given somatropin. Other measures of growth, such as bone maturation, were also comparable between children from both groups.

What are the risks associated with Ngenla?

The most common side effects with Ngenla (which may affect more than 1 in 10 people) are reactions at the site of injection, headache, and fever. For the full list of side effects of Ngenla, see the package leaflet.

Ngenla must not be used if the patient has an active tumour or an acute life-threatening illness. It must also not be used for promoting growth in children with closed epiphyses (when the large bones have finished growing). For the full list of restrictions, see the package leaflet.

Why is Ngenla authorised in the EU?

Ngenla injected once per week was shown to be at least as effective as somatropin given by injection once per day. The safety profile of Ngenla was also comparable with somatropin, although injection site reactions were more common in patients treated with Ngenla. Longer-term effects will continue to be monitored after marketing. The majority of patients preferred once-weekly treatment compared with daily injections.

The European Medicines Agency therefore decided that the benefits of Ngenla are greater than its risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Ngenla are continuously monitored. Side effects reported with Ngenla are carefully evaluated and any necessary action taken to protect patients.

Other information about Ngenla

Ngenla received a marketing authorisation valid throughout the EU on 14 February 2022.

Further information on Ngenla can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ngenla

This overview was last updated in 02-2022.