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Withdrawal of application to change the marketing authorisation for Ngenla (somatrogon)

Pfizer Europe MA EEIG withdrew its application for the use of Ngenla in the treatment of adults with growth hormone deficiency.

The company withdrew the application on 20 December 2024.

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 has been authorised in the EU since February 2022. It contains the active substance somatrogon and is available as an injection in pre-filled pens to be given under the skin.

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

What change had the company applied for?

The company applied to extend the use of Ngenla to adults with growth hormone deficiency.

How does Ngenla work?

People with growth hormone deficiency lack the natural growth hormone. This hormone is important for growth during childhood and adolescence. It also affects how the body handles proteins, fat and carbohydrates and is therefore also important in adults.

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. 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Ngenla is expected to work in adults with growth hormone deficiency in the same way as it does in children and adolescents.

What did the company present to support its application?

The company presented data from a main study involving 202 adults with growth hormone deficiency who received either Ngenla or placebo (a dummy treatment) for 26 weeks. The main measure of effectiveness was a change in patients' trunk fat mass (the amount of fat located in the trunk region of the body, which includes the chest, abdomen and back). This was assessed using an imaging method called dual-energy X-ray absorptiometry (DXA), which measures body composition, including fat mass, lean mass and bone density.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the initial information from the company and had prepared questions for the company. The company had not responded to the questions at the time of the withdrawal.

What did the Agency recommend at that time?

Based on the review of the information, at the time of the withdrawal, the Agency's provisional opinion was that Ngenla could not have been authorised for the treatment of adults with growth hormone deficiency.

The results of the main study failed to show that Ngenla is more effective than placebo at reducing patients' trunk fat mass. Other measures of effectiveness also failed to demonstrate beneficial effects of Ngenla over placebo in adults with growth hormone deficiency.

Therefore, at the time of the withdrawal, the Agency's opinion was that the effectiveness of Ngenla in adults with growth hormone deficiency had not been proven.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that the withdrawal at this time is to allow the conduct of additional analyses related to the use of Ngenla in the target population.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Ngenla.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.

What is happening with Ngenla for the treatment of children and adolescents with growth hormone deficiency?

There are no consequences on the use of Ngenla in its authorised uses.