swissmedic

Public Summary SwissPAR dated 10 February 2023

Ngenla® (active substance: somatrogon)

First authorisation in Switzerland: 9 September 2022

Injection with pre-filled pen for the treatment of growth disorders

About the medicinal product

The medicinal product Ngenla, containing the active substance somatrogon, is used for growth disorders due to a proven growth hormone deficiency in children and adolescents aged 3 years and older.

Mode of action

In healthy individuals, the pituitary gland (a gland at the base of the brain) releases hormones including a growth hormone known as somatropin. This hormone is important for growth in children and adolescents. The growth hormone also affects how the body handles proteins, fats and carbohydrates.

To treat a growth disorder caused by a proven growth hormone deficiency, the missing growth hormone must be injected daily together with the currently available medicinal products (standard therapy).

Somatrogon (the active substance in Ngenla) is a combination of human growth hormone and another human hormone known as chorionic gonadotropin. By altering the molecule in this way, somatrogon remains active in the body longer than natural growth hormone and therefore only needs to be administered once a week.

Indication

Ngenla, containing the active substance somatrogon, is a prescription-only medicine and is available as an injection in pre-filled pens (disposable syringes) in the dosage strengths 24 mg/1.2. mL and 60 mg/1.2 mL. Each pre-filled pen contains several doses. The recommended dose is 0.66 mg/kg body weight once a week. The solution is injected under the skin.

The treatment should be initiated and monitored by a doctor experienced in treating children and adolescents with growth hormone deficiency.

Efficacy

The efficacy of Ngenla was investigated in a multi-year study in 224 children with growth hormone deficiency, who were aged between 2.5 years and 10 years (girls) or 11 years (boys) at the time of enrolment in the study. The patients were given either Ngenla once a week or the standard therapy (growth hormone) daily. There were no differences in growth rate in the two groups after 6 and 12 months, respectively. Other indicators of growth including bone maturation were also comparable in children in the two groups. The efficacy of Ngenla in this indication and dosage was therefore demonstrated.

Precautions, undesirable effects & risks

Ngenla must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects are reactions at the injection site (43%), headache (19%) and hypersensitivity reactions such as allergic conjunctivitis or fever (19%).

Ngenla should no longer be used after the epiphyses have closed (i.e. when the large bones have finished growing) as it is no longer effective.

All precautions, risks and other possible side effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

The study showed that Ngenla administered once weekly was as effective as standard therapy with daily injections of the currently available growth hormone products. The safety profile of Ngenla was also comparable with those of growth hormone products that have already been authorised. Reactions at the injection site occurred more frequently in the Ngenla group.

Taking all the risks and precautions into account, and based on the available data, the benefits of Ngenla outweigh the risks. Swissmedic has therefore authorised the medicinal product Ngenla, containing the active substance somatrogon, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Ngenla®

Information for patients (package leaflet): Information for patients Ngenla®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.