swissmedic

Summary report on authorisation dated 22 October 2025

Sogroya® (active substance: somapacitan)

Authorisation in Switzerland: 26 April 2024

Solution for injection in pre-filled pen for the treatment of growth disorders

About the medicinal product

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

Patients with a growth hormone deficiency often suffer from growth disorders that impair their quality of life. Conventional treatments require daily injections, potentially affecting adherence to treatment. The medicinal product Sogroya is injected under the skin once a week. This replaces the body's natural requirement for growth hormones and supports the growth of children with a proven deficiency.

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 required for growth in children and adolescents.

Until recently, a growth disorder caused by a proven growth hormone deficiency could only be treated by the daily injection of the missing growth hormone.

The active substance in Sogroya, somapacitan, differs from the natural growth hormone by a single amino acid to which an albumin-binding unit has been attached. In the body, the reversible binding of somapacitan to albumin delays its breakdown and prolongs its elimination, resulting in a longer duration of action compared to natural human growth hormone. This means that somapacitan only needs to be administered once a week.

Administration

Sogroya is a prescription-only medicine.

Sogroya is available as a solution for injection in a pre-filled pen. Each pre-filled pen contains several doses.

The recommended dose is 0.08 to 0.16 mg per kilogram body weight once a week at any time of the day.

The solution is injected under the skin. The injection should be administered into the abdominal wall, thighs, buttocks or upper arms, and the injection site should be rotated every week.

Sogroya should be prescribed by a specialist, and the treatment should be initiated and monitored by a doctor with experience in the treatment of growth hormone deficiency.

Efficacy

The efficacy of Sogroya was investigated in a 52-week study in n=200 treatment-naïve children with growth hormone deficiency, who were aged between 2.5 and 10 years (girls) or 11 years (boys) at the time of enrolment in the study. In this study, the once-weekly administration of somapacitan was compared with the once-daily administration of somatropin (conventional standard treatment).

There were no differences in growth rate in the two groups after 12 months. Other indicators of growth, including bone maturation, were also comparable in children in the two groups.

Precautions, undesirable effects, & risks

Sogroya must not be used in those who are hypersensitive to the active substance or any of the excipients. The most common undesirable effects of Sogroya in the clinical trials were headache (12%), hypothyroidism (5%) and injection site reactions (5%).

Sogroya 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 undesirable 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 Sogroya administered once weekly was as effective as the conventional therapy with daily injections of a growth hormone product.

Taking all the risks and precautions into account, and based on the available data, the benefits of Sogroya outweigh the risks. Swissmedic has therefore authorised the medicinal product Sogroya, containing the active substance somapacitan, for the treatment of growth disorders due to a proven growth hormone deficiency in children aged 3 years and older in Switzerland.

Further information on the medicinal product

Sogroya must be stored in a refrigerator (2-8°C).

Information for healthcare professionals: Information for healthcare professionals Sogroya®

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

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 Summary report on authorisation.

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.