21 May 2026
EMADOC-1700519818-3170422
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Sogroya

somapacitan

On 21 May 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Sogroya. The marketing authorisation holder for this medicinal product is Novo Nordisk A/S.

The CHMP adopted two new indications as follows:

> Sogroya is indicated for treatment of growth failure in children and adolescents in the following indications:
>
> - Growth disturbance (current height SDS < -2.5 and parental adjusted height SDS < -1) in short children born small for gestational age (SGA), with a birth weight and/or length below -2 SD, who failed to show catch-up growth (HV SDS < 0 during the last year) by 4 years of age or later,
> - Noonan syndrome (NS).

For information, the full indications for Sogroya will now be:[2]

> Paediatric patients
>
> Sogroya is indicated for treatment of growth failure in children and adolescents in the following indications:
>
> - The replacement of endogenous hormone (GH), aged 3 years and above due to growth hormone deficiency (paediatric GHD),
> - **Growth disturbance (current height SDS < -2.5 and parental adjusted height SDS < -1) in short children born small for gestational age (SGA), with a birth weight and/or length below -2 SD, who failed to show catch-up growth (HV SDS < 0 during the last year) by 4 years of age or later,**

[1] Summary of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

[2] New text in bold.

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- **Noonan syndrome (NS).**

  Adult patients

  Sogroya is indicated for the replacement of endogenous growth hormone (GH) in adults with growth hormone deficiency (adult GHD).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.