Frequently Asked Questions

Indications and Usage

Sogroya® (somapacitan-beco) injection 5 mg, 10 mg, or 15 mg is indicated for the:

- treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (GH)
- replacement of endogenous GH in adults with growth hormone deficiency (GHD)

Important Safety Information

Contraindications

Sogroya® is contraindicated in patients with:

- acute critical illness after open-heart surgery, abdominal surgery, multiple accidental trauma, or acute respiratory failure because of the risk of increased mortality with use of Sogroya®
- hypersensitivity to Sogroya® or any of its excipients. Systemic hypersensitivity reactions have been reported postmarketing with Sogroya®
- pediatric patients with closed epiphyses
- active malignancy
- active proliferative or severe non-proliferative diabetic retinopathy
- pediatric patients with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment due to risk of sudden death

Frequently Asked Questions

Q. What is Sogroya®?

A. Sogroya® (somapacitan-beco) is a human growth hormone (hGH) analog with a single substitution in the amino acid backbone (L101C) to which an albumin-binding moiety has been attached. The albumin-binding moiety (side-chain) consists of an albumin binder and a hydrophilic spacer attached to position 101 of the protein. The protein part consists of 191 amino acids. Sogroya® is produced in *Escherichia coli* by recombinant DNA technology. The molecular weight is 23305.10 g/mol, of which the albumin-binding moiety is 1191.39 g/mol. Sogroya® is supplied as a sterile, clear to slightly opalescent and colorless to slightly yellow solution for subcutaneous use in a single-patient-use prefilled pen with a deliverable volume of 1.5 mL.[1]

Q. What is Sogroya® indicated for?

A. Sogroya® is indicated for the treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (GH) and for the replacement of endogenous GH in adults with growth hormone deficiency (GHD).

Q. What is pediatric growth hormone deficiency?

A. Pediatric GHD is a rare disorder characterized by inadequate secretion of GH from the anterior pituitary gland.[2] GHD may be isolated or combined with other pituitary hormonal deficits; congenital; acquired; or idiopathic.[2,3] GHD is one of the causes of short stature, and when diagnosed, can be treated with GH therapy.[2,4] GHD in children may also be associated with delayed bone age and delayed onset of puberty.[3]

Q. What is adult growth hormone deficiency?

A. Adult GHD is a rare disorder characterized by decreased secretion of GH from the anterior pituitary gland that is different than the normal age-associated reduction in GH signaling. Onset can be either of childhood or adult onset. Common causes could be organic structural defects or damage to the pituitary by trauma, surgery and/or radiation therapy.[4] GHD may be isolated or combined with other pituitary hormonal deficits; congenital; acquired; or idiopathic.[2-4] Adult GHD is characterized by reduced lean body mass, increased fat mass, decreased bone mineral density, and increased insulin resistance.[4] Adults with GHD may receive GH therapy to reverse the metabolic effects of GHD.[4]

Q. What is the mechanism of action of Sogroya®?

A. Sogroya® binds to a dimeric GH receptor in the cell membrane of target cells resulting in intracellular signal transduction and a host of pharmacodynamic effects. Some of these pharmacodynamic effects are primarily mediated by insulin-like growth factor 1 (IGF-1) produced in the liver, while others are primarily a consequence of the direct effects of somapacitan-beco.[1]

Q. When did Sogroya® receive FDA approval?

A. Sogroya® was approved by the Food and Drug Administration (FDA) in 2020 for the replacement of endogenous GH in adults with GHD.[5] Sogroya® was approved by the FDA in April 2023 for the treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (GH).[1]

Frequently Asked Questions

Q. What are the ingredients in Sogroya®?

A. Sogroya® is a sterile, clear to slightly opalescent and colorless to slightly yellow solution containing the active ingredient somapacitan-beco and the following excipients: histidine, mannitol, phenol, poloxamer 188, hydrochloric acid/sodium hydroxide (as needed), and water.[1]

Q. What are the most frequently reported adverse reactions that occur in patients treated with Sogroya®?

A. The most common adverse reactions in pediatric patients with GHD treated with Sogroya (reported in ≥5% of patients) were nasopharyngitis, headache, pyrexia, pain in extremity, and injection site reaction. The most common adverse reactions in adult patients with GHD treated with Sogroya (reported in >2% of patients and more frequent than placebo) were back pain, arthralgia, dyspepsia, sleep disorder, dizziness, tonsillitis, peripheral edema, vomiting, adrenal insufficiency, hypertension, blood creatine phosphokinase increase, weight increase, and anemia.[1]

Q. Who should not use Sogroya®?

A. Sogroya® is contraindicated in patients with[1]:

- Acute critical illness after open-heart surgery, abdominal surgery, multiple accidental trauma, or acute respiratory failure because of the risk of increased mortality with use of Sogroya®
- Hypersensitivity to Sogroya® or any of its excipients. Systemic hypersensitivity reactions have been reported postmarketing with Sogroya®
- Pediatric patients with closed epiphyses
- Active malignancy
- Active proliferative or severe non-proliferative diabetic retinopathy
- Pediatric patients with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment due to risk of sudden death

Q. Who manufactures Sogroya®?

A. Sogroya® is manufactured by Novo Nordisk Inc.

Q. How is Sogroya® supplied?

A. Sogroya® injection is a clear to slightly opalescent and colorless to slightly yellow solution available as a single-patient-use prefilled pen per carton[1]:

- 5 mg/1.5 mL (3.3 mg/mL) (teal) pen; NDC 0169-2035-11
- 10 mg/1.5 mL (6.7 mg/mL) (yellow) pen; NDC 0169-2030-11
- 15 mg/1.5 mL (10 mg/mL) (red) pen; NDC 0169-2037-11

Please see Important Safety Information on pages 1, 5 and 6.
Please **click here** for Prescribing Information.

Frequently Asked Questions

Q. How is Sogroya® administered?

A. Administer Sogroya® by subcutaneous injection, once weekly, any time of the day, in the upper arms, thigh, abdomen, or buttocks with weekly rotation of injection site. Instructions for delivering the dosage are provided in the Patient Information and Instructions for Use leaflets enclosed with the Sogroya® prefilled pen.[1]

Q. What if a dose of Sogroya® is missed?

A. If the dose is missed, Sogroya® can be taken within 3 days after the scheduled dosing day. Once-weekly dosing for the next dose could be resumed at the regularly scheduled dosing day. If more than 3 days have passed since the missed dose, skip the dose and administer the next dose on the regularly scheduled dosing day.[1]

Q. How are Sogroya® pens obtained?

A. Sogroya® pens can be accessed and acquired through specialty pharmacy distributors.

Q. How is Sogroya® stored?

A. New, unused Sogroya® pens are stored in a refrigerator at 36°F to 46°F (2°C to 8°C). New, unused pens should be stored with the cap on and in the original carton. Do not freeze. Avoid direct heat and light. If Sogroya® has been frozen or stored in temperatures warmer than 86°F (30°C), do not use. Do not use Sogroya® after the expiration date printed on the carton and the pen.[1]

While in use, Sogroya® pens may be stored in the refrigerator at 36°F to 46°F (2°C to 8°C) and used within 6 weeks. In-use Sogroya® pens should be stored with the cap on and in the original carton.[1]

If needed, new and in-use Sogroya® pens can be stored at room temperature no warmer than 77°F (25°C) for up to 3 days (72 hours) and then returned to the refrigerator.[1]

Q. Where can I get more information about Sogroya®?

A. More information about Sogroya® is available at **www.sogroya.com**.

Important Safety Information (cont'd)

Warnings and Precautions

- **Increased Mortality in Patients with Acute Critical Illness:** Increased mortality has been reported after treatment with somatropin in patients with acute critical illness due to complications following open-heart surgery, abdominal surgery, multiple accidental trauma, and in patients with acute respiratory failure
- **Severe Hypersensitivity:** Serious systemic hypersensitivity reactions including anaphylactic reactions and angioedema have been reported postmarketing with use of somatropin. Inform patients and/or caregivers that such reactions are possible, and that prompt medical attention should be sought if an allergic reaction occurs
- **Increased Risk of Neoplasms:** There is an increased risk of malignancy progression with somatropin in patients with active malignancy. Any preexisting malignancy should be inactive, and its treatment complete prior to instituting Sogroya®. In childhood cancer survivors treated with radiation to the brain/head for their first neoplasm who developed subsequent GHD and were treated with somatropin, an increased risk of a second neoplasm has been reported. Monitor patients with a history of GHD secondary to an intracranial neoplasm for progression or recurrence of the tumor. Children with certain rare genetic causes of short stature have an increased risk of developing malignancies and should be carefully monitored for development of neoplasms. Monitor patients for increased growth or potential malignant changes of preexisting nevi. Advise patients/caregivers to report changes in the appearance of preexisting nevi
- **Glucose Intolerance and Diabetes Mellitus:** Treatment with somatropin may decrease insulin sensitivity, particularly at higher doses. New onset type 2 diabetes has been reported. Monitor glucose levels in all patients, especially in those with existing diabetes mellitus or with risk factors for diabetes mellitus, such as obesity, Turner syndrome or a family history of diabetes mellitus. The doses of antidiabetic agents may require adjustment when Sogroya® is initiated
- **Intracranial Hypertension:** Has been reported usually within 8 weeks of treatment initiation. Perform fundoscopic examination prior to initiation of treatment and periodically thereafter. If papilledema is identified, evaluate the etiology, and treat the underlying cause before initiating Sogroya®. If papilledema is observed, stop treatment. If intracranial hypertension is confirmed, Sogroya® can be restarted at a lower dose after intracranial hypertension signs and symptoms have resolved
- **Fluid retention:** May occur during Sogroya® therapy. Clinical manifestations of fluid retention (e.g. edema and nerve compression syndromes including carpal tunnel syndrome/paresthesia) are usually transient and dose dependent
- **Hypoadrenalism:** Patients receiving somatropin therapy who have or are at risk for corticotropin deficiency may be at risk for reduced serum cortisol levels and/or unmasking of central (secondary) hypoadrenalism. Patients treated with glucocorticoid replacement for previously diagnosed hypoadrenalism may require an increase in their maintenance or stress doses following initiation of Sogroya®. Monitor patients with known hypoadrenalism for reduced serum cortisol levels and/or need for glucocorticoid dose increases
- **Hypothyroidism:** Undiagnosed/untreated hypothyroidism may prevent an optimal response to Sogroya®. Monitor thyroid function periodically as hypothyroidism may occur or worsen after initiation of Sogroya®
- **Slipped Capital Femoral Epiphysis in Pediatric Patients:** Slipped capital femoral epiphysis may occur more frequently in patients undergoing rapid growth. Evaluate pediatric patients with the onset of a limp or complaints of persistent hip or knee pain

novo nordisk®

Please see additional Important Safety Information on pages 1 and 6.
Please **click here** for Prescribing Information.

SOGROYA® somapacitan-beco injection 5mg | 10mg | 15mg

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- **Progression of Preexisting Scoliosis in Pediatric Patients:** Monitor patients with a history of scoliosis for disease progression
- **Pancreatitis:** Cases of pancreatitis have been reported in patients receiving somatropin. The risk may be greater in pediatric patients compared to adults. Consider pancreatitis in patients with persistent severe abdominal pain
- **Lipohypertrophy/Lipoatrophy:** May occur if Sogroya® is administered at the same site over a long period of time. Rotate injection sites to reduce this risk
- **Sudden death in Pediatric Patients with Prader-Willi Syndrome:** There have been reports of fatalities after initiating therapy with somatropin in pediatric patients with Prader-Willi syndrome who had one or more of the following risk factors: severe obesity, history of upper airway obstruction or sleep apnea, or unidentified respiratory infection. Male patients with one or more of these factors may be at greater risk than females. Sogroya® is not indicated for the treatment of pediatric patients who have growth failure due to genetically confirmed Prader-Willi syndrome
- **Laboratory Tests:** Serum levels of inorganic phosphorus and alkaline phosphatase may increase after Sogroya® therapy. Serum levels of parathyroid hormone may increase with somatropin treatment

Adverse Reactions

- **Pediatric patients with GHD:** Adverse reactions reported in ≥5% of patients are nasopharyngitis, headache, pyrexia, pain in extremity, and injection site reaction
- **Adult patients with GHD:** Adverse reactions reported in >2% of patients are back pain, arthralgia, dyspepsia, sleep disorder, dizziness, tonsillitis, peripheral edema, vomiting, adrenal insufficiency, hypertension, blood creatine phosphokinase increase, weight increase, and anemia

Drug Interactions

- **Glucocorticoids:** Patients treated with glucocorticoid for hypoadrenalism may require an increase in their maintenance or stress doses following initiation of Sogroya®
- **Cytochrome P450-Metabolized Drugs:** Sogroya® may alter the clearance. Monitor carefully if used with Sogroya®
- **Oral Estrogen:** Patients receiving oral estrogen replacement may require higher Sogroya® dosages
- **Insulin and/or Other Antihyperglycemic Agents:** Dose adjustment of insulin and/or antihyperglycemic agent may be required for patients with diabetes mellitus

References

1. Sogroya. Prescribing information. Novo Nordisk Inc; 2023. **2.** Dattani MT, Malhotra M. A review of growth hormone deficiency. *Paediatr Child Health.* 2019;29(7):285-292. **3.** Webb EA, Dattani MT. Diagnosis of growth hormone deficiency. *Endocr Dev.* 2010;18:55-66. doi:10.1159/000316127. **4.** Yuen KCJ, Biller BMK, Radovick S, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for Management of Growth Hormone Deficiency in Adults and Patients Transitioning From Pediatric to Adult Care. *Endocr Pract.* 2019;25(11):1191-1232. doi:10.4158/GL-2019-0405. **5.** Yuen KCJ, Miller BS, Boguszewski CL, et al. Usefulness and potential pitfalls of long-acting growth hormone analogs. *Front Endocrinol (Lausanne).* 2021;12:637209. doi:10.3389/fendo.2021.637209.

Please see Important Safety Information on pages 5 and 6.
Please **click here** for Prescribing Information.

Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, New Jersey 08536 U.S.A.

SOGROYA® somapacitan-beco injection 5mg | 10mg | 15mg