Sogroya® (somapacitan-beco) injection Product Specification Sheet

Trade Unit Product Information

Brand name	Sogroya® 5 mg/1.5 mL	Sogroya® 10 mg/1.5 mL	Sogroya® 15 mg/1.5 mL
Generic name	Somapacitan-beco	Somapacitan-beco	Somapacitan-beco
WAC price	$1317.90	$2635.80	$3953.70
Expiration date	Printed on carton and the pen	Printed on carton and the pen	Printed on carton and the pen
Package presentation	1 carton containing 1 prefilled Sogroya® pen	1 carton containing 1 prefilled Sogroya® pen	1 carton containing 1 prefilled Sogroya® pen
List number	203511	203011	203711
NDC	0169-2035-11	0169-2030-11	0169-2037-11
UPC	3 0169 203511 1	3 0169 203011 6	3 0169 203711 5
Bar code	3 01692 03511 1	3 01692 03011 6	3 01692 03711 5
Trade unit dimensions (inches L x W x H)	6 x 2.5 x 2.25	6 x 2.5 x 2.25	6 x 2.5 x 2.25
Trade unit weight (lb)	0.133	0.133	0.133
Storage Before and during use: Keep Sogroya® refrigerated: 36°F-46°F (2°C-8°C) with the cap on and in the original carton to protect from light until expiration date.	Before first use, Sogroya® can be stored at room temperature (up to 77°F/25°C) for up to 72 hours.* After first use, store at 36°F to 46°F (2°C to 8°C) for up to 6 weeks or at room temperature (up to 77°F/25°C) for up to 72 hours. Must discard if kept above 86°F (30°C).	Before first use, Sogroya® can be stored at room temperature (up to 77°F/25°C) for up to 72 hours.* After first use, store at 36°F to 46°F (2°C to 8°C) for up to 6 weeks or at room temperature (up to 77°F/25°C) for up to 72 hours. Must discard if kept above 86°F (30°C).	Before first use, Sogroya® can be stored at room temperature (up to 77°F/25°C) for up to 72 hours.* After first use, store at 36°F to 46°F (2°C to 8°C) for up to 6 weeks or at room temperature (up to 77°F/25°C) for up to 72 hours. Must discard if kept above 86°F (30°C).

*The total time allowed at room temperature (up to 77°F [25°C]) is 72 hours (3 days) regardless of whether the product is in-use *(opened) or before first use (unopened). Must discard if kept above 86°F (30°C).*

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)

Please see Important Safety Information on pages 2-3.
Please **click here** for Prescribing Information.

novo nordisk®

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

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

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

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- **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
- **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

Direct access to Sogroya® is available by contacting Novo Nordisk at 1-877-NOVO-777 (1-877-668-6777).

Please see additional Important Safety Information on page 2.
Please **click here** for Prescribing Information.

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

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