Once-weekly Sogroya®

Pediatric Dosing Guide

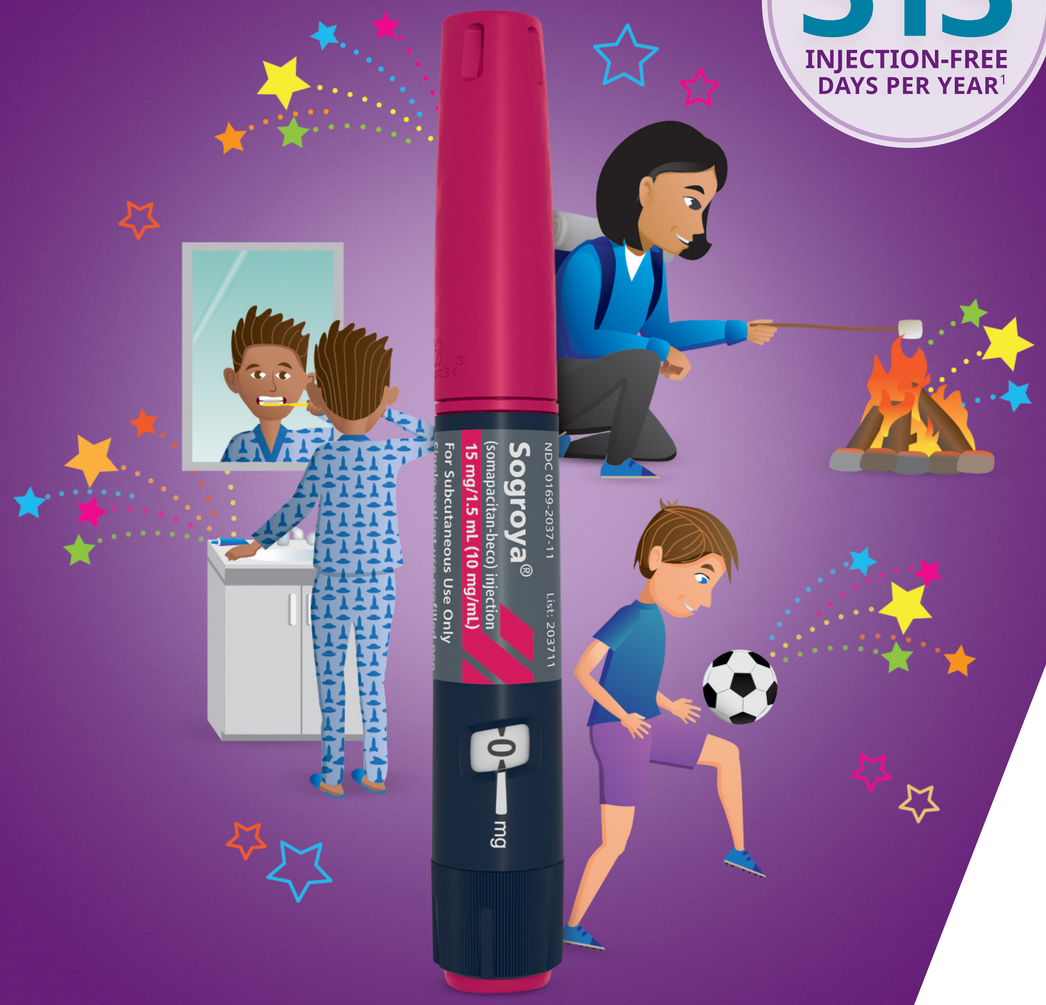
For treatment-naïve patients or those switching to once-weekly dosing

313
INJECTION-FREE DAYS PER YEAR[1]

For your pediatric patients with GHD aged 2.5 years and older

UNLEASH THEIR POTENTIAL

with **once-weekly Sogroya®**



Dosing that fits into your **PATIENTS' LIVES**

GHD=growth hormone deficiency.

Indication 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)

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

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Please see additional Important Safety Information throughout.
Please click here for Prescribing Information.

Imagine the possibilities

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

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Pediatric Dosing Guide

Start or switch with straightforward dosing[1]

Recommended dosage: **0.16 mg/kg** based on actual body weight per week for treatment-naïve patients and those switching from daily GH[1]

Switching patients:

From daily GH
- Choose the preferred day for the weekly dose. Take the final dose of daily treatment on the day before (or at least 8 hours before) the first dose of Sogroya®

From once-weekly GH
- Continue once-weekly dosing schedule with Sogroya®

What if your patient misses a dose?[1]

- 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

- Perform fundoscopic examination before initiating treatment with Sogroya® to exclude preexisting papilledema. If papilledema is identified, evaluate the etiology and treat the underlying cause before initiating treatment with Sogroya®
- Sogroya® should be administered by subcutaneous injection once weekly, any time of the day, in the upper arms, thigh, abdomen, or buttocks with weekly rotation of injection site
- Patients who were treated with Sogroya® for GH deficiency in childhood and whose epiphyses are closed should be reevaluated before continuing Sogroya®

GH=growth hormone.

Important Safety Information

Contraindications

Sogroya® is contraindicated in patients with:
- 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 & 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

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Individualized dosing: Dial in the right amount of Sogroya®

Dial the dose in precise dosing increments

with the Sogroya® pen[1]

- Individualize dosage for each patient based on the growth response

The Sogroya® pen comes in 3 dosing strengths[1]

5 mg/ 1.5 mL

Delivers doses from 0.025 mg up to 2 mg

10 mg/ 1.5 mL

Delivers doses from 0.05 mg up to 4 mg

15 mg/ 1.5 mL

Delivers doses from 0.1 mg up to 8 mg

Important Safety Information

Warnings & Precautions

- **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
- **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

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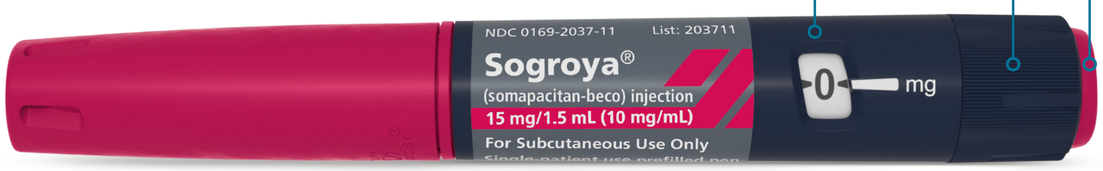
Pediatric Dosing Guide

The Sogroya® pen—easy to learn to use,[a] based on the FlexPro® you know[2]

- Dose counter lets patients view the dose prescribed
- Dose selector allows patients to choose the dose they need
- Dose button for patients to administer medication



Know the 3 *P*'s of the Sogroya® pen

PREMIXED: No reconstitution required

PRELOADED: No separate cartridges

PORTABLE: Stable at room temperature (up to 77 °F) for up to 3 days (72 hours)[b]

[a]Based on a human factors study of the safety and usability of the Norditropin® FlexPro® 30 mg pen in 94 participants (children ages 10-17 with growth-related disorders, adults with GHD, HCPs, and caregivers). Users performed injections using a foam cushion and then completed a device-specific questionnaire. Participants rated the device a 6.7 out of 7 (on a scale of 1 to 7, where 1 means "strongly disagree" and 7 means "strongly agree") for the statement, "FlexPro® was easy to learn to use." The FlexPro® used in this human factors study is similar to the Sogroya® pen.[2]

[b]The pen should be refrigerated (36 °F-46 °F). The pen can be taken in and out of a refrigerator as needed. The pen must be discarded 6 weeks after first use, or if it has been frozen, or if kept above 86 °F. See Prescribing Information for full storage and handling instructions.[1]

GHD=growth hormone deficiency; HCP=healthcare professional.

Important Safety Information

Warnings & Precautions

- **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

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.** Data on file. Novo Nordisk Inc.; Plainsboro, NJ.

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