For your pediatric patients with GHD aged 2.5 years and older

UNLEASH THEIR POTENTIAL

with **once-weekly Sogroya®**

From Novo Nordisk—the makers of the
#1 prescribed growth hormone treatment[2,a]

[a]Norditropin® (somatropin) injection is the #1 prescribed growth hormone product based on IQVIA XPO PlanTrak monthly through December 2022.
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

novo nordisk®

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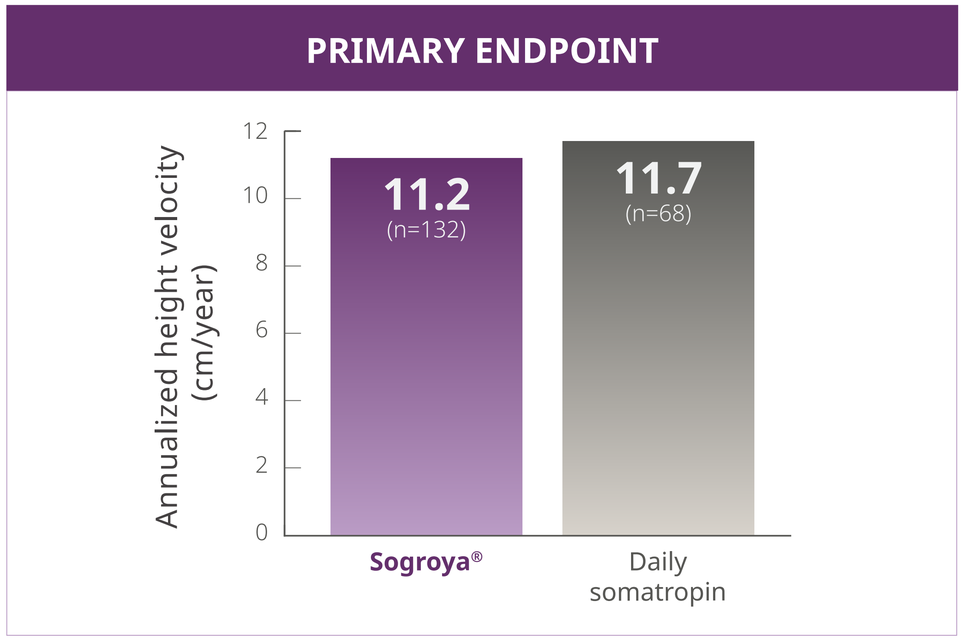
ONCE-WEEKLY
SOGROYA®
somapacitan-beco
injection 5mg | 10mg | 15mg

After 1 year, Sogroya® demonstrated results similar to daily somatropin[1]



ETD=–0.5 cm/year (95% CI, –1.1 to 0.2).

Visit Sogroyapro.com for full safety and efficacy results.

REAL4 is a multicenter, open-label, active-controlled, parallel-group phase 3 trial. A total of 200 treatment-naïve children aged 2.5 to 11 years with a confirmed diagnosis of GHD were randomized 2:1 to receive Sogroya® 0.16 mg/kg/week (n=132) or daily somatropin 0.034 mg/kg/day (n=68). The primary endpoint was annualized height velocity at Week 52.

CI=confidence interval; ETD=estimated treatment difference; GHD=growth hormone deficiency.

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

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Proven safety profile

Adverse reactions occurring ≥5% in Sogroya®- or somatropin-treated pediatric patients (52 weeks)[1]

Adverse Reactions	Sogroya® (n=132) %	Daily somatropin (n=68) %
Nasopharyngitis[a]	**16.7**	16.2
Headache	**12.1**	8.8
Pyrexia[b]	**9.1**	11.8
Pain in extremity[c]	**9.8**	2.9

Adverse Reactions	Sogroya® (n=132) %	Daily somatropin (n=68) %
Injection-site reaction[d]	**6.1**	5.9
Diarrhea[e]	**4.5**	5.9
Nausea/vomiting[f]	**4.5**	5.9
Bronchitis	**3**	7.4

[a]Nasopharyngitis in the Sogroya® treatment group included nasopharyngitis (11.4%), rhinitis (3.8%), pharyngitis streptococcal (0.8%), acute sinusitis (0.8%), nasal congestion (0.8%), pharyngitis (0.8%), and sinusitis (0.8%).

[b]Pyrexia in the Sogroya® treatment group included pyrexia (8.3%) and hyperthermia (0.8%).

[c]Pain in extremity in the Sogroya® treatment group included pain in extremity (9.1%) and growing pains (0.8%).

[d]Injection-site reaction in the Sogroya® treatment group included injection-site bruising (1.5%), injection-site pain (1.5%), injection-site hematoma (1.5%), injection-site reaction (0.8%), and injection-site swelling (0.8%).

[e]Diarrhea in the Sogroya® treatment group included diarrhea (2.3%), gastroenteritis viral (1.5%), and gastrointestinal viral infection (0.8%).

[f]Nausea/vomiting in the Sogroya® treatment group included vomiting (4.5%) and nausea (1.5%).

Important Safety Information

Warnings & Precautions

- **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

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

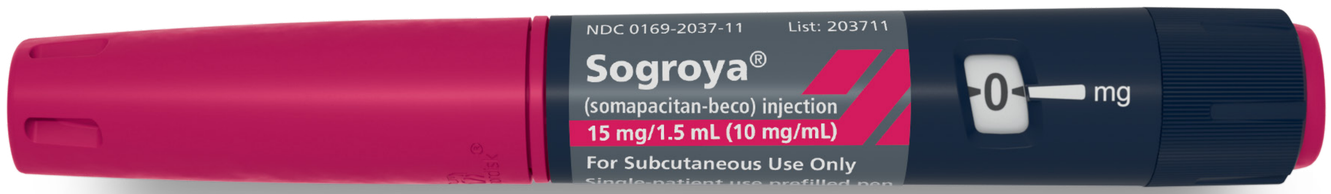
UP TO **6x MORE** INJECTION-FREE DAYS

NO MIXING REQUIRED

Prefilled, premixed, preloaded[1]

PRECISE DOSING

Over 100 dosing increments available across all pens[1]



FAMILIAR

Based on the FlexPro® you know with more than 10 years of patient experience[2]

10 YEARS

PORTABLE

Stable at room temperature (up to 77 °F) for up to 3 days (72 hours)[1,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® pen 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 in temperature warmer than 86 °F. Keep Sogroya® away from direct heat and light.[1]

GHD=growth hormone deficiency; HCP=healthcare provider.

Important Safety Information

Warnings & Precautions

- **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

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

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

5 mg/1.5 mL

Max dose: 2 mg/injection
Dosing increment: 0.025 mg

10 mg/1.5 mL

Max dose: 4 mg/injection
Dosing increment: 0.05 mg

15 mg/1.5 mL

Max dose: 8 mg/injection
Dosing increment: 0.1 mg

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

- 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 therapy with Sogroya®
- Administer Sogroya® by SQ injection, once weekly, any time of the day, in the upper arms, thighs, abdomen, or buttocks with weekly rotation of injection site
- Individualize dosage for each patient based on the growth response

GH=growth hormone; SQ=subcutaneous.

Important Safety Information

Warnings & Precautions

- **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

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NovoCare® support—there for your patients along their treatment journey

From benefit verification to insurance appeals, NovoCare® is here to help

Patient assistance programs to fit your patients' needs

Professional resources

- Assistance through the prior authorization, appeals, and reauthorization process
- Interim care support
- Field reimbursement managers
- QuickCheck™ benefit verification
- Territory case manager

Patient resources

- Patient Assistance Program (PAP) for eligible patients[a]
- Sogroya® savings card offer
- JumpStart™ program to avoid delay in therapy initiation
- In-person or virtual device training
- Patient Starter Kit with an injection-site buddy and sharps disposal container

[a]Eligible uninsured and underinsured patients may receive therapy at no cost until insurance or financial circumstances improve, including patients whose appeals for therapy approval have been denied. Eligibility and restrictions apply.

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Unleash what's possible with once-weekly Sogroya®

See the difference Sogroya® can make for your patients.
Visit Sogroyapro.com to learn more and access professional and patient support resources.

GHD=growth hormone deficiency.

Important Safety Information

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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