SOGROYA- somapacitan-beco injection, solution
Novo Nordisk

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use SOGROYA safely and effectively. See full prescribing information for SOGROYA.
SOGROYA® (somapacitan-beco) injection, for subcutaneous use
Initial U.S. Approval: 2020

RECENT MAJOR CHANGES

Indication and Usage (1)....2/2026
Dosage and Administration (2.1, 2.3)....2/2026
Warnings and Precautions (5.6, 5.10, 5.14) 2/2026
Warnings and Precautions (5.9)....7/2025

INDICATIONS AND USAGE

SOGROYA is a human growth hormone analog indicated for:
Pediatric Patients: Treatment of pediatric patients aged 2.5 years and older with:

- Growth failure due to inadequate secretion of endogenous growth hormone (GH). (1)
- Short stature born small for gestational age (SGA) and with no catch-up growth by 2 years of age. (1)
- Growth failure associated with Noonan syndrome (NS). (1)
- Idiopathic Short Stature (ISS). (1)

Adults: Replacement of endogenous growth hormone in adults with growth hormone deficiency (GHD). (1)

DOSAGE AND ADMINISTRATION

- SOGROYA treatment should be supervised by a healthcare provider who is experienced in the diagnosis and management of patients with growth hormone deficiency, pediatric patients born SGA, pediatric patients with NS, and pediatric patients with ISS. (2.1)
- SOGROYA should be administered by subcutaneous injection once weekly, any time of the day, in the upper arms, thigh, abdomen or buttocks with regular rotation of injection site to avoid lipohypertrophy/lipoatrophy. (2.1)
- See Full Prescribing Information for complete dosage, titration, and monitoring recommendations for pediatric and adult patients, including those aged 65 years and older, patients with hepatic impairment, and women receiving oral estrogen. (2.1, 2.2, 2.3, 2.4, 2.5)

For pediatric patients:

- GH deficiency: Initiate SOGROYA with a dosage of 0.16 mg/kg body weight once weekly for treatment-naïve patients and patients switching from daily growth hormone (somatropin). (2.3)
- SGA/NS/ISS: Initiate SOGROYA with a dosage of 0.24 mg/kg body weight once weekly for treatment-naïve patients and patients switching from daily growth hormone (somatropin). (2.3)
- Individualize dosage for each patient based on the growth response. (2.3)
- Patients switching from daily human growth hormone to once-weekly SOGROYA should choose the preferred day for the weekly dose and stop final dose of daily treatment the day before (or at least 8 hours before) taking the first dose of once-weekly somapacitan-beco. (2.3)

For adult patients with GHD:

- Initiate SOGROYA with a dosage of 1.5 mg once weekly for treatment naïve patients and patients switching from daily growth hormone. (2.4)
- Increase the weekly dosage every 2 to 4 weeks by approximately 0.5 mg to 1.5 mg until the desired response has been achieved. (2.4)
- Titrate the dosage based on clinical response and serum insulin-like growth factor-1 (IGF-1) concentrations. (2.4)
- The maximum recommended dosage for adult GHD is 8 mg once weekly. (2.4)

DOSAGE FORMS AND STRENGTHS

SOGROYA is a liquid solution available in a ready-to-use prefilled pen.
Injection: 5 mg/1.5 mL (3.3 mg/mL) or 10 mg/1.5 mL (6.7 mg/mL) or 15 mg/1.5 mL (10 mg/mL) in a single-patient-use prefilled pen. (3)

CONTRAINDICATIONS

- Acute critical illness (4)
- Active malignancy (4)
- Hypersensitivity to somapacitan-beco or excipients (4)
- Active proliferative or severe non-proliferative diabetic retinopathy (4)
- Closed epiphyses in children used for longitudinal growth promotion (4)
- Children with Prader-Willi syndrome who are severely obese or have severe respiratory impairment due to risk of sudden death (4)

WARNINGS AND PRECAUTIONS

- *Severe Hypersensitivity*: Serious hypersensitivity reactions, including anaphylactic reactions and angioedema, may occur. In the event of an allergic reaction, seek prompt medical attention. (5.2)
- *Increased Risk of Neoplasm*: Monitor patients with preexisting tumors for progression or recurrence. Increased risk of a second neoplasm in childhood cancer survivors treated with somatropin – in particular meningiomas in patients treated with radiation to the head for their first neoplasm. (5.3)
- *Glucose Intolerance and Diabetes Mellitus*: SOGROYA may decrease insulin sensitivity, particularly at higher doses. Monitor glucose levels periodically in all patients receiving SOGROYA, especially in patients with existing diabetes mellitus or at risk for its development. (5.4)
- *Intracranial Hypertension (IH)*: Perform fundoscopic examinations prior to initiation and periodically thereafter. If papilledema is identified prior to initiation, evaluate the etiology and treat the underlying cause before initiating. If papilledema occurs with SOGROYA, stop treatment. (5.5)
- *Fluid Retention*: Was observed and may be dose dependent. Reduce dose as necessary. (5.6)
- *Hypoadrenalism*: Monitor patients for reduced serum cortisol levels and/or need for glucocorticoid dose increases in those with known hypoadrenalism. (5.7)
- *Hypothyroidism*: Monitor thyroid function periodically as hypothyroidism may occur or worsen after initiation of SOGROYA. (5.8)
- *Slipped Capital Femoral Epiphysis in Pediatric Patients*: May develop. Evaluate children with the onset of a limp or persistent hip/knee pain. (5.9)
- *Progression of Preexisting Scoliosis in Pediatric Patients*: May develop. (5.10)
- *Pancreatitis*: Consider pancreatitis in patients with persistent severe abdominal pain. (5.11)
- *Lipohypertrophy/lipoatrophy*: May occur if SOGROYA is administered in the same location over a long period of time. Rotate injection sites on a regular basis. (5.12)

ADVERSE REACTIONS

- Common adverse reactions reported in pediatric patients treated with SOGROYA include: cough, diarrhea, ear infection, headache, injection site reaction, nasopharyngitis, pain in extremity, pyrexia, respiratory tract infection, and vomiting. (6.1)
- Adult patients with GHD: Adverse reactions reported in >2% of patients treated with SOGROYA are: back pain, arthralgia, dyspepsia, sleep disorder, dizziness, tonsillitis, peripheral edema, vomiting, adrenal insufficiency, hypertension, blood creatine phosphokinase increase, weight increase, anemia. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Novo Nordisk Inc. at 1-800-727-6500 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- *Replacement Glucocorticoid Treatment*: Patients treated with glucocorticoid for hypoadrenalism may require an increase in their maintenance or stress doses following initiation of SOGROYA. (7)
- *Cytochrome P450-Metabolized Drugs*: SOGROYA may alter the clearance. Monitor carefully if used with SOGROYA. (7)
- *Oral Estrogen*: Larger doses of SOGROYA may be required. (7)
- *Insulin and/or Other Antihyperglycemic Agents*: Dose adjustment of insulin or antihyperglycemic agent may be required. (5.4, 7)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 2/2026

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

SOGROYA is indicated for the treatment of pediatric patients aged 2.5 years and older with:

- Growth failure due to inadequate secretion of endogenous growth hormone (GH).
- Short stature born small for gestational age (SGA) and with no catch-up growth by 2 years of age.
- Growth failure associated with Noonan syndrome (NS).
- Idiopathic Short Stature (ISS).

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

2 DOSAGE AND ADMINISTRATION

2.1 Important Dosing and Administration Information

- SOGROYA treatment should be supervised by a healthcare provider who is experienced in the diagnosis and management of pediatric patients with growth failure due to GHD, pediatric patients born SGA, pediatric patients with NS, pediatric patients with ISS and/or adults with GHD *[see Indications and Usage (1)].*
- 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.
- Inspect visually for particulate matter and discoloration. SOGROYA should be a clear to slightly opalescent and colorless to slightly yellow solution. If the solution is cloudy or contains particulate matter do not use.
- Advise patients to read the PATIENT INFORMATION and INSTRUCTIONS FOR USE leaflets enclosed with the SOGROYA prefilled pen.
- SOGROYA is available in 3 single-patient-use prefilled pens with 3 different dosing ranges (**Table 1**).

Table 1. Strength and Dosing Range of SOGROYA Prefilled Pens

Strength	Dose increments (mg)	Dose Delivery Range (mg)
5 mg/1.5 mL (3.3 mg/mL)	0.025	0.025 to 2
10 mg/1.5 mL (6.7 mg/mL)	0.05	0.05 to 4
15 mg/1.5 mL (10 mg/mL)	0.1	0.1 to 8

2.2 Perform Fundoscopic Examination Prior to Initiation of SOGROYA

- 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 *[see Warnings and Precautions (5.5)].*

2.3 Recommended Dosage and Monitoring for Pediatric Patients

- GH Deficiency: Recommended dosage of SOGROYA is 0.16 mg/kg based on actual body weight once weekly for treatment-naïve patients and patients switching from daily growth hormone (somatropin).
- Small for Gestational Age (SGA), Noonan Syndrome (NS), and Idiopathic Short Stature (ISS): Recommended dosage of SOGROYA is 0.24 mg/kg based on actual body weight once weekly for treatment-naïve patients and patients switching from daily growth hormone (somatropin).
- Individualize dosage for each patient based on the growth response.
- When switching from daily human growth hormone to once-weekly SOGROYA, 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.
- When switching from a weekly human growth hormone to once-weekly SOGROYA, continue once weekly dosing schedule.
- Assess compliance and evaluate other causes of poor growth such as hypothyroidism, undernutrition, advanced bone age, and antibodies to recombinant human growth hormone if patients experience failure to increase height velocity, particularly during the first year of treatment.
- Patients who were treated with SOGROYA for GH deficiency in childhood and whose epiphyses are closed should be reevaluated before continuing SOGROYA.

2.4 Recommended Dosage, Titration, and Monitoring for Adults with GHD

- Initiate SOGROYA with a dosage of 1.5 mg once weekly for treatment naïve patients and patients switching from daily growth hormone (somatropin).
- Increase the weekly dosage every 2 to 4 weeks by approximately 0.5 mg to 1.5 mg until the desired response is achieved.
- Titrate the dosage based on clinical response and serum insulin-like growth factor-1 (IGF-1) concentrations. Draw IGF-1 samples 3 to 4 days after the prior dose.
- Decrease the dosage as necessary on the basis of adverse reactions and/or serum IGF-1 concentrations above the age- and sex-specific normal range.
- The maximum recommended dosage is 8 mg once weekly.

2.5 Recommended Dosage and Titration for Specific Populations

Patients Aged 65 Years and Older

Initiate SOGROYA with a dosage of 1 mg once weekly and use smaller dose increment increases when titrating the dosage *[see Use in Specific Populations (8.5)].* See above for monitoring recommendations and the maximum recommended dosage of SOGROYA *[see Dosage and Administration (2.4)].*

Patients with Hepatic Impairment

- SOGROYA is not recommended in adult and pediatric patients with severe hepatic impairment *[see Hepatic Impairment (8.6)]*.
- For adult patients with moderate hepatic impairment, initiate SOGROYA with a dosage of 1 mg once weekly and use smaller dose increment increases when titrating the dosage. See above for monitoring recommendations *[see Dosage and Administration (2.4), Pharmacokinetics (12.3)]*. The maximum recommended dosage is 4 mg once weekly.
- For pediatric patients with moderate hepatic impairment, SOGROYA is not recommended *[see Hepatic Impairment (8.6)]*.
- No dosage adjustment is recommended for adult and pediatric patients with mild hepatic impairment.

Women Receiving Oral Estrogen

Initiate SOGROYA with a dosage of 2 mg once weekly *[see Drug Interactions (7)].* See above for titration and monitoring recommendations and the maximum recommended dosage of SOGROYA *[see Dosage and Administration (2.4)].*

2.6 Missed Doses

- 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.

3 DOSAGE FORMS AND STRENGTHS

SOGROYA is a clear to slightly opalescent and colorless to slightly yellow solution available as follows:

- Injection: 5 mg/1.5 mL (3.3 mg/mL) in a single-patient-use prefilled pen (teal)
- Injection: 10 mg/1.5 mL (6.7 mg/mL) in a single-patient-use prefilled pen (yellow)
- Injection: 15 mg/1.5 mL (10 mg/mL) in a single-patient-use prefilled pen (red)

4 CONTRAINDICATIONS

SOGROYA is contraindicated in patients with:

- Acute critical illness after open-heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure because of the risk of increased mortality with use of pharmacologic doses of SOGROYA *[see Warnings*

and Precautions (5.1)].
- Hypersensitivity to SOGROYA or any of its excipients. Systemic hypersensitivity reactions have been reported postmarketing with somatropin *[see Warnings and Precautions (5.2)]*.
- Pediatric patients with closed epiphyses.
- Active malignancy *[see Warnings and Precautions (5.3)].*
- 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 *[see Warnings and Precautions (5.13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 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 and multiple accidental trauma, as well as patients with acute respiratory failure *[see Contraindications (4)]*. The safety of continuing SOGROYA treatment in patients receiving replacement doses for approved indications who concurrently develop these illnesses has not been established. SOGROYA is not indicated for the treatment of non-GH deficient adults.

5.2 Severe Hypersensitivity

Serious systemic hypersensitivity reactions including anaphylactic reactions and angioedema have been reported with postmarketing 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. SOGROYA is contraindicated in patients with known hypersensitivity to somatropin or any excipients in SOGROYA *[see Contraindications (4)].*

5.3 Increased Risk of Neoplasms

Active Malignancy

There is an increased risk of malignancy progression with somatropin treatment in patients with active malignancy *[see Contraindications (4)]*. Any preexisting malignancy should be inactive, and its treatment complete prior to instituting therapy with SOGROYA. Discontinue SOGROYA if there is evidence of recurrent activity.

Risk of Second Neoplasm in Pediatric Patients

In childhood cancer survivors who were treated with radiation to the brain/head for their first neoplasm and who developed subsequent growth hormone deficiency (GHD) and were treated with somatropin, an increased risk of second neoplasm has been reported. Intracranial tumors, in particular meningiomas, were the most common of these second neoplasms. Monitor all patients with a history of GHD secondary to an intracranial neoplasm while on somatropin therapy for progression or recurrence of the tumor.

New Malignancy During Treatment

Because children with certain rare genetic causes of short stature have an increased

risk of developing malignancies, thoroughly consider the risks and benefits of starting SOGROYA in these patients. If treatment with SOGROYA is initiated, carefully monitor these patients for development of neoplasms.

There is risk of malignant changes of preexisting nevi with somatropin treatment in patients. Monitor patients on SOGROYA therapy carefully for increased growth or potential malignant changes of preexisting nevi. Advise patients/caregivers to report marked changes in behavior, onset of headaches, vision disturbances, and/or changes in the appearance of preexisting nevi.

5.4 Glucose Intolerance and Diabetes Mellitus

Treatment with somatropin may decrease insulin sensitivity, particularly at higher doses. New onset type 2 diabetes mellitus has been reported in patients taking somatropin. Patients with undiagnosed pre-diabetes and diabetes mellitus may experience worsened glycemic control and become symptomatic. Monitor glucose levels periodically in all patients receiving SOGROYA, especially in those with risk factors for diabetes mellitus, such as obesity, Turner syndrome, or a family history of diabetes mellitus. Patients with preexisting type 1 or type 2 diabetes mellitus or pre-diabetes should be monitored closely. The doses of antidiabetic agents may require adjustment when SOGROYA is initiated.

5.5 Intracranial Hypertension

Intracranial hypertension with papilledema, visual changes, headache, nausea, and/or vomiting has been reported in patients treated with somatropin. Symptoms usually occurred within the first eight (8) weeks after the initiation of somatropin therapy. In all reported cases, intracranial hypertension-associated signs and symptoms rapidly resolved after cessation of therapy or a reduction of the somatropin dose.

Perform fundoscopic examination before initiating treatment with SOGROYA to exclude preexisting papilledema and periodically thereafter. If papilledema is identified prior to initiation, evaluate the etiology and treat the underlying cause before initiating SOGROYA. If papilledema is observed by fundoscopy during SOGROYA treatment, treatment should be stopped. If intracranial hypertension is confirmed, treatment with SOGROYA can be restarted at a lower dose after intracranial hypertension-associated signs and symptoms have resolved.

5.6 Fluid Retention

Fluid retention was observed 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.

5.7 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. In addition, patients treated with glucocorticoid replacement for previously diagnosed hypoadrenalism may require an increase in their maintenance or stress doses following initiation of SOGROYA treatment. Monitor patients with known hypoadrenalism for reduced serum cortisol levels and/or need for glucocorticoid dose increases *[see Drug Interactions (7)].*

5.8 Hypothyroidism

Undiagnosed/untreated hypothyroidism may prevent an optimal response to SOGROYA. In patients with GH deficiency, central (secondary) hypothyroidism may first become evident or worsen during treatment with somatropin therapy. Therefore, patients should have periodic thyroid function tests and thyroid hormone replacement therapy should be initiated or appropriately adjusted when indicated.

5.9 Slipped Capital Femoral Epiphysis in Pediatric Patients

Slipped capital femoral epiphysis may occur more frequently in patients undergoing rapid growth. Slipped capital femoral epiphysis may lead to osteonecrosis. Cases of slipped capital femoral epiphysis with or without osteonecrosis have been reported in pediatric patients with short stature receiving somatropin. Evaluate pediatric patients receiving SOGROYA with the onset of a limp or complaints of persistent hip or knee pain for slipped capital femoral epiphysis and osteonecrosis and manage accordingly.

5.10 Progression of Preexisting Scoliosis in Pediatric Patients

Somatropin, including SOGROYA, increases growth rate, and progression of preexisting scoliosis can occur in patients who experience rapid growth. Somatropin has not been shown to increase the occurrence of scoliosis. Monitor patients with a history of scoliosis for disease progression.

5.11 Pancreatitis

Cases of pancreatitis have been reported in patients receiving somatropin. The risk may be greater in pediatric patients compared with adults. Consider pancreatitis in patients who develop persistent severe abdominal pain.

5.12 Lipohypertrophy/Lipoatrophy

When SOGROYA is administered subcutaneously at the same site over a long period of time, tissue lipohypertrophy or lipoatrophy may result. Rotate injection sites when administering SOGROYA to reduce this risk *[see Dosage and Administration (2.1)].*

5.13 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.

5.14 Laboratory Tests

Serum levels of inorganic phosphorus and alkaline phosphatase have increased after somatropin therapy, including SOGROYA. Serum levels of parathyroid hormone may increase with somatropin treatment.

6 ADVERSE REACTIONS

The following clinically significant adverse drug reactions are described elsewhere in the labeling:

- Increased mortality in patients with acute critical illness *[see Warnings and Precautions (5.1)]*
- Severe hypersensitivity *[see Warnings and Precautions (5.2)]*
- Increased risk of neoplasms *[see Warnings and Precautions (5.3)]*
- Glucose intolerance and diabetes mellitus *[see Warnings and Precautions (5.4)]*
- Intracranial hypertension *[see Warnings and Precautions (5.5)]*
- Fluid retention *[see Warnings and Precautions (5.6)]*
- Hypoadrenalism *[see Warnings and Precautions (5.7)]*
- Hypothyroidism *[see Warnings and Precautions (5.8)]*
- Slipped capital femoral epiphysis in pediatric patients *[see Warnings and Precautions (5.9)]*
- Progression of preexisting scoliosis in pediatric patients *[see Warnings and Precautions (5.10)]*
- Pancreatitis *[see Warnings and Precautions (5.11)]*
- Lipohypertrophy/Lipoatrophy *[see Warnings and Precautions (5.12)]*
- Sudden death in pediatric patients with Prader-Willi syndrome *[see Warnings and Precautions (5.13)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Pediatric Patients with GHD

SOGROYA 0.16 mg/kg/week was studied in a 52-week randomized, open-label, active-controlled, parallel-group clinical study in 200 treatment-naïve, prepubertal pediatric patients with growth hormone deficiency *[see Clinical Studies (14.1)]*. **Table 2** shows common adverse reactions that occurred in ≥5% of patients treated with either SOGROYA or somatropin in this trial.

Table 2. Adverse Reactions Occurring ≥5% in SOGROYA or Somatropin-treated Pediatric Patients (52 Weeks of Treatment)

	Somatropin (N=68)	**SOGROYA (N=132)**
Adverse Reactions	**%**	**%**
Nasopharyngitis[a]	16.2	16.7
Headache	8.8	12.1
Pyrexia[b]	11.8	9.1
Pain in extremity[c]	2.9	9.8
Injection site reaction[d]	5.9	6.1
Diarrhea[e]	5.9	4.5
Nausea/vomiting[f]	5.9	4.5
Bronchitis	7.4	3

[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%)

Pediatric Patients Born Small for Gestational Age and with no Catch-up Growth by 2 Years of Age

SOGROYA 0.24 mg/kg/week was studied in a 52-week randomized, open-label, active-comparator, basket clinical study in GH treatment-naïve, pre-pubertal patients with short stature born small for gestational age (SGA), Noonan syndrome (NS) or idiopathic short stature (ISS) compared to somatropin *[see Clinical Studies (14.2)]*. **Table 3** shows the adverse reactions occurring at ≥10% in the SGA cohort with 141 pediatric patients.

Table 3. Adverse Reactions Occurring ≥10% in SOGROYA or Somatropin-Treated Pediatric Patients with SGA at Week 52

	Somatropin 0.035 mg/kg/day (N=37)	**Somatropin 0.067 mg/kg/day (N=35)**	**SOGROYA 0.24 mg/kg/week (N=69)**
Adverse Reactions	**%**	**%**	**%**
Nasopharyngitis[a]	38	29	26
Respiratory Tract Infection[b]	30	20	26
Pyrexia	16	17	19
Cough[c]	16	9	16
Ear Infection[d]	16	17	13
Diarrhea[e]	8	6	10
Vomiting[f]	11	11	10
Bronchitis	11	11	7

[a] Nasopharyngitis in the SOGROYA treatment group included nasopharyngitis (15.9%), pharyngitis (2.9%), rhinitis (2.9%), pharyngitis streptococcal (1.4%), sinusitis (1.4%), and viral rhinitis (1.4%).
[b] Respiratory tract infections in the SOGROYA treatment group included upper respiratory tract infection (20.3%), influenza (10.1%), metapneuomovirus infection (1.4%), mycoplasma infection (1.4%), pneumonia (1.4%), pneumonia bacterial (1.4%), pneumonia mycoplasmal (1.4%), respiratory syncytial virus infection (1.4%), and respiratory tract infection (1.4%).

[c] Cough in the SOGROYA treatment group included cough (15.9%).

[d] Ear infection in the SOGROYA treatment group included otitis media (7.2%), ear infection (2.9%), otitis externa (1.4%), and otitis media acute (1.4%).

[e] Diarrhea in the SOGROYA treatment group included diarrhea (4.3%), gastroenteritis (4.3%), and gastrointestinal viral infection (1.4%)

[f] Vomiting in the SOGROYA treatment group included vomiting (10.1%)

Description of Select Adverse Reactions

Adenoidal and tonsillar hypertrophy was reported in 1 (1%) subject with SGA in the first year of treatment with SOGROYA who received tonsillectomy and adenoidectomy. The adenoidal and tonsillar hypertrophy resolved after the procedure.

Pediatric Patients with Growth Failure Associated with Noonan Syndrome

SOGROYA 0.24 mg/kg/week was studied in a 52-week randomized, open-label, active-comparator, basket clinical study in GH treatment-naïve, pre-pubertal patients with NS compared to somatropin 0.05 mg/kg/day *[see Clinical Studies (14.3)]*. **Table 4** shows the adverse reactions occurring at ≥10% in the NS cohort with 77 pediatric patients.

Table 4. Adverse Reactions Occurring ≥10% in SOGROYA or Somatropin-Treated Pediatric Patients with NS at Week 52

	Somatropin 0.05 mg/kg/day (N=28)	**SOGROYA 0.24 mg/kg/week (N=49)**
Adverse Reactions	**%**	**%**
Respiratory Tract Infection[a]	29	43
Nasopharyngitis[b]	25	29
Diarrhea[c]	14	22
Ear Infection[d]	14	16
Cough[e]	14	14
Vomiting[f]	11	12
Pyrexia	25	10
Headache	7	10
Injection site reaction[g]	14	8
Abdominal Pain[h]	11	2
Wound	11	0

[a] Respiratory tract infection in the SOGROYA treatment group included upper respiratory tract infection (20.4%), influenza (10.2%), pneumonia (6.1%), influenza like illness (2%), respiratory syncytial virus infection (2%), respiratory tract infection (2%), respiratory tract infection viral (2%), upper respiratory tract infection bacterial (2%), and viral upper respiratory tract infection (2%).

[b] Nasopharyngitis in the SOGROYA treatment group included nasopharyngitis (24.5%), pharyngitis (4.1%), bacterial infection (2%), herpes pharyngitis (2%), pharyngitis streptococcal (2%), pharyngotonsillitis (2%), and rhinitis (2%).

[c] Diarrhea in the SOGROYA treatment group included gastroenteritis (14.3%), diarrhea (6.1%), gastroenteritis viral (2%), and parasitic gastroenteritis (2%).

[d] Ear infection in the SOGROYA treatment group included otitis media (8.2%), otitis externa (4.1%), ear infection (2%), otitis media acute (2%), and otitis media chronic (2%).

[e] Cough in the SOGROYA treatment group included cough (12.2%) and bacterial infection (2%).

[f] Vomiting in the SOGROYA treatment group included vomiting (8.2%) and gastritis (4.1%).

[g] Injection site reaction in the SOGROYA treatment group included injection site bruising (6.1%) and injection site hemorrhage (2%)

[h] Abdominal pain in the SOGROYA treatment group included abdominal distension (2%)

Pediatric Patients with Growth Failure Associated with Idiopathic Short Stature

SOGROYA 0.24 mg/kg/week was studied in a 52-week randomized, open-label, active-comparator, basket clinical study in GH treatment-naïve, pre-pubertal patients with ISS compared to somatropin 0.05 mg/kg/day *[see Clinical Studies (14.4)]*. **Table 5** shows the adverse reactions occurring at ≥10% in the ISS cohort with 87 pediatric patients.

Table 5. Adverse Reactions Occurring ≥10% in SOGROYA or Somatropin-Treated Pediatric Patients with ISS at Week 52

	Somatropin 0.05 mg/kg/day (N=28)	**SOGROYA 0.24 mg/kg/week (N=59)**
Adverse Reactions	**%**	**%**
Respiratory Tract Infection[a]	29	31
Nasopharyngitis[b]	21	22
Ear Infection[c]	7	12
Diarrhea[d]	25	10
Headache	11	10
Injection site reaction[e]	7	10
Cough[f]	11	5
Vomiting[g]	11	5

[a] Respiratory tract infection in the SOGROYA treatment group included influenza (16.9%), upper respiratory tract infection (6.8%), respiratory tract infection (3.4%),

pneumonia (1.7%), pneumonia bacterial (1.7%), respiratory tract infection viral (1.7%), and viral upper respiratory tract infection (1.7%).

[b] Nasopharyngitis in the SOGROYA treatment group included nasopharyngitis (15.3%), pharyngitis streptococcal (5.1%), pharyngitis (1.7%), rhinitis (1.7%), sinusitis (1.7%), and tracheitis (1.7%).

[c] Ear infection in the SOGROYA treatment group included otitis media (6.8%), ear infection (3.4%), and otitis media acute (1.7%).

[d] Diarrhea in the SOGROYA treatment group included gastroenteritis (3.4%), gastroenteritis viral (3.4%), diarrhea (1.7%), enterobiasis (1.7%), and parasitic gastroenteritis (1.7%).

[e] Injection site reaction in the SOGROYA treatment group included application site reaction (1.7%), injection site bruising (1.7%), injection site hematoma (1.7%), injection site hemorrhage (1.7%), injection site pruritis (1.7%), and injection site urticaria (1.7%).

[f] Cough in the SOGROYA treatment group included cough (5.1%).

[g] Vomiting in the SOGROYA treatment group included vomiting (5.1%).

Description of Select Adverse Reactions

Adenoidal and tonsillar hypertrophy was reported in 1 (2%) subject with ISS in the first year of treatment with SOGROYA who received tonsillectomy and adenoidectomy. The adenoidal and tonsillar hypertrophy resolved after the procedure.

Adult Patients with GHD

SOGROYA was studied in adult patients with GHD in a 35-week, placebo-controlled, double-blind trial with an active-control arm *[see Clinical Studies (14.5)]*. Adverse reactions occurring >2% with SOGROYA are presented in **Table 6**.

Table 6. Adverse Reactions Occurring >2% in Adults with GHD Treated with SOGROYA and More Frequently[#] than in Placebo-Treated Patients for 34 Weeks

	Placebo (N=61)	**SOGROYA (N=120)**
Adverse Reactions	**%**	**%**
Back pain	3.3	10
Arthralgia	1.6	6.7
Dyspepsia	3.3	5
Sleep disorder	1.6	4.2
Dizziness	1.6	4.2
Tonsillitis	1.6	3.3
Peripheral edema	1.6	3.3
Vomiting	1.6	3.3
Adrenal insufficiency	1.6	3.3
Hypertension	1.6	3.3
Blood creatine phosphokinase increase	0	3.3
Weight increased	0	3.3

Anemia	0	2.5

[#] Included adverse reactions reported with at least 1% greater incidence in SOGROYA group compared to the placebo group

More SOGROYA treated patients shifted from normal baseline levels to elevated phosphate and creatine phosphokinase levels at the end of the trial compared to the placebo group (17.5% vs 4.9% and 9.2% vs. 6.6%, respectively); these laboratory changes occurred intermittently, and were non-progressive.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of somatropins. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Musculoskeletal and connective tissue disorders – osteonecrosis in pediatric patients.

7 DRUG INTERACTIONS

Table 7 includes a list of drugs with clinically important drug interactions when administered concomitantly with SOGROYA and instructions for preventing or managing them.

Table 7. Clinically Important Drug Interactions with SOGROYA

Replacement Glucocorticoid Treatment	
Clinical Impact:	Microsomal enzyme 11β-hydroxysteroid dehydrogenase type 1 (11βHSD-1) is required for conversion of cortisone to its active metabolite, cortisol, in hepatic and adipose tissue. GH inhibits 11βHSD-1. Consequently, individuals with untreated GH deficiency have relative increases in 11βHSD-1 and serum cortisol. Initiation of SOGROYA may result in inhibition of 11βHSD-1 and reduced serum cortisol concentrations.
Intervention:	Patients treated with glucocorticoid replacement for hypoadrenalism may require an increase in their maintenance or stress doses following initiation of SOGROYA *[see Warnings and Precautions (5.7)].*
Examples:	Cortisone acetate and prednisone may be affected more than others because conversion of these drugs to their biologically active metabolites is dependent on the activity of 11βHSD-1.
Cytochrome P450-Metabolized Drugs	
Clinical Impact:	Limited published data indicate that GH treatment increases cytochrome P450 (CP450)-mediated antipyrine clearance. SOGROYA may alter the clearance of compounds known to be metabolized

	by CP450 liver enzymes.
Intervention:	Careful monitoring is advisable when SOGROYA is administered in combination with drugs metabolized by CP450 liver enzymes.
Oral Estrogen	
Clinical Impact:	Oral estrogens may reduce the serum IGF-1 response to SOGROYA.
Intervention:	Patients receiving oral estrogen replacement may require higher SOGROYA dosages *[see Dosage and Administration (2.5)]*.
Insulin and/or Other Hypoglycemic Agents	
Clinical Impact:	Treatment with SOGROYA may decrease insulin sensitivity, particularly at higher doses.
Intervention:	Patients with diabetes mellitus may require adjustment of their doses of insulin and/or other hypoglycemic agents *[see Warnings and Precautions (5.4)].*

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on the use of SOGROYA during pregnancy; however, published studies describing the use of short-acting recombinant growth hormone (rhGH) during pregnancy over several decades have not identified any drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. In animal reproduction studies, subcutaneously administered somapacitan-beco was not teratogenic in rats or rabbits during organogenesis at doses approximately 12 times the clinical exposure at the maximum recommended human dose (MRHD) of 8 mg/week. No adverse developmental outcomes were observed in a pre- and post-natal development study with administration of somapacitan-beco to pregnant rats from organogenesis through lactation at approximately 275 times the clinical exposure at the MRHD *(see Data)*.

The background risk of birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Animal Data

In an embryo-fetal development study in rats, somapacitan-beco was administered by subcutaneous injection at doses of 2, 6, and 18 mg/kg/day during the period of organogenesis from gestation day 6 to 17. Fetal viability and development were not affected at doses up to 6 mg/kg/day (31 times the MRHD, based on AUC). Transient, fetal skeletal variations (short/bent/thickened long bones) were observed at 18 mg/kg/day (261 times the MRHD, based on AUC).

In an embryo-fetal development study in rabbits, somapacitan-beco was administered by subcutaneous injection at doses of 1, 3, and 9 mg/kg every two days during the period of organogenesis from gestation day 6 to 18. Fetal viability and development were not adversely affected at somapacitan-beco dose of 1 mg/kg/every two days (12 times the MRHD, based on AUC). Reduced fetal growth was observed at doses ≥3 mg/kg/every two days (≥130 times the MRHD, based on C_{12h}).

In a pre- and post-natal development study in pregnant rats, somapacitan-beco was administered by subcutaneous injection at doses of 4, 9, and 18 mg/kg twice a week from gestation day 6 through lactation day 18. No adverse developmental effects were observed in the offspring at doses up to 9 mg/kg (275 times the MRHD, based on AUC). Increased incidence of renal pelvic dilatation was observed on post-natal day 21 at 18 mg/kg (630 times the MRHD, based on AUC), but was not observed in the adult F1 generation.

8.2 Lactation

Risk Summary

There is no information on the presence of somapacitan-beco in human milk, the effects on the breastfed infant, or the effects on milk production. Somapacitan-beco-related material was secreted into milk of lactating rats. When a substance is present in animal milk, it is likely that the substance will be present in human milk. Available published data describing administration of short-acting recombinant growth hormone (rhGH) to lactating women for 7 days reported that short-acting rhGH did not increase the normal breastmilk concentration of growth hormone and no adverse effects were reported in breastfed infants. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for SOGROYA and any potential adverse effects on the breastfed infant from SOGROYA or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of SOGROYA have been established in pediatric patients 2.5 years of age and older for the treatment of:

- Growth failure due to inadequate secretion of endogenous GH. The use of SOGROYA for this indication is supported by evidence from a 52-week randomized, multi-center, open-label, active-controlled, parallel-group phase 3 trial in 200 treatment-naïve, pediatric patients aged 2.5 to 11 years with GHD *[see Clinical Studies(14.1)]*. The safety profile from the pediatric trial was similar to that reported in adults *[see Adverse Reactions (6.1)]*.
- Short stature born SGA with no catch-up growth by 2 years of age. The use of SOGROYA for this indication is supported by evidence from a multi-center, randomized open-label, active-comparator, phase 3 basket study in 142 pediatric patients aged 2.6 to 10.7 years with short stature born SGA with no catch-up growth by 2 years of age *[see Clinical Studies (14.2)]*.
- Growth failure associated with NS. The use of SOGROYA for this indication is supported by evidence from a multi-center, randomized open-label, active-comparator, phase 3 basket study in 77 pediatric patients aged 2 to 11.1 years with growth failure associated with NS *[see Clinical Studies (14.3)].*
- ISS. The use of SOGROYA for this indication is supported by evidence from a multi-

center, randomized open-label, active-comparator, phase 3 basket study in 88 pediatric patients aged 2.8 to 10.8 years with ISS *[see Clinical Studies (14.4)].*

The safety and effectiveness of SOGROYA have not been established in pediatric patients less than 2.5 years of age for the treatment of growth failure due to inadequate secretion of endogenous GH, short stature born SGA with no catch-up growth, growth failure associated with NS, or with ISS.

Risks in pediatric patients associated with growth hormone use include:

- Sudden death in pediatric patients with Prader-Willi Syndrome. SOGROYA is not indicated for the treatment of pediatric patients with growth failure secondary to genetically confirmed Prader-Willi syndrome. *[see Warnings and Precautions (5.13)]*
- Increased risk of second neoplasm in pediatric cancer survivors treated with radiation to the brain and/or head *[see Warnings and Precautions (5.3)]*
- Slipped capital femoral epiphysis in pediatric patients *[see Warnings and Precautions (5.9)]*
- Progression of preexisting scoliosis in pediatric patients *[see Warnings and Precautions (5.10)]*
- Pancreatitis *[see Warnings and Precautions (5.11)]*

8.5 Geriatric Use

In clinical studies a total of 52 (15.6%) of the 333 SOGROYA-treated patients were 65 years or older and 3 (0.9%) were 75 years or older *[see Clinical Studies (14)]*. Subjects older than 65 years appeared to have higher exposure than younger subjects at the same dose level. Elderly patients may be more sensitive to the action of somapacitan-beco and therefore may be at increased risk for adverse reactions. Initiate SOGROYA with a dose of 1 mg once weekly and use smaller increments when increasing the dose *[see Dosage and Administration (2.5)].*

8.6 Hepatic Impairment

Adult patients: No dose adjustment of SOGROYA is required for patients with mild hepatic impairment. Higher somapacitan-beco exposure was observed in patients with moderate hepatic impairment. In patients with moderate hepatic impairment, initiate SOGROYA with a dose of 1 mg once weekly and use smaller increments when increasing the dose. The maximum dose should not exceed 4 mg once weekly. Somapacitan-beco was not studied in patients with severe hepatic impairment. Therefore, use of SOGROYA is not recommended in patients with severe hepatic impairment. *[see Dosage and Administration (2.5), Clinical Pharmacology (12.3)].*

Pediatric patients: Based on the hepatic impairment study in adults, no dose adjustment of SOGROYA is recommended for patients with mild hepatic impairment. Higher systemic exposure of SOGROYA is expected in pediatric patients with moderate and severe hepatic impairment; therefore, SOGROYA is not recommended in these pediatric patients *[see Dosage and Administration (2.5)]*.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

SOGROYA contains somapacitan-beco, which is not a controlled substance.

9.2 Abuse

Inappropriate use of SOGROYA may result in significant negative health consequences.

9.3 Dependence

SOGROYA is not associated with drug related withdrawal adverse reactions.

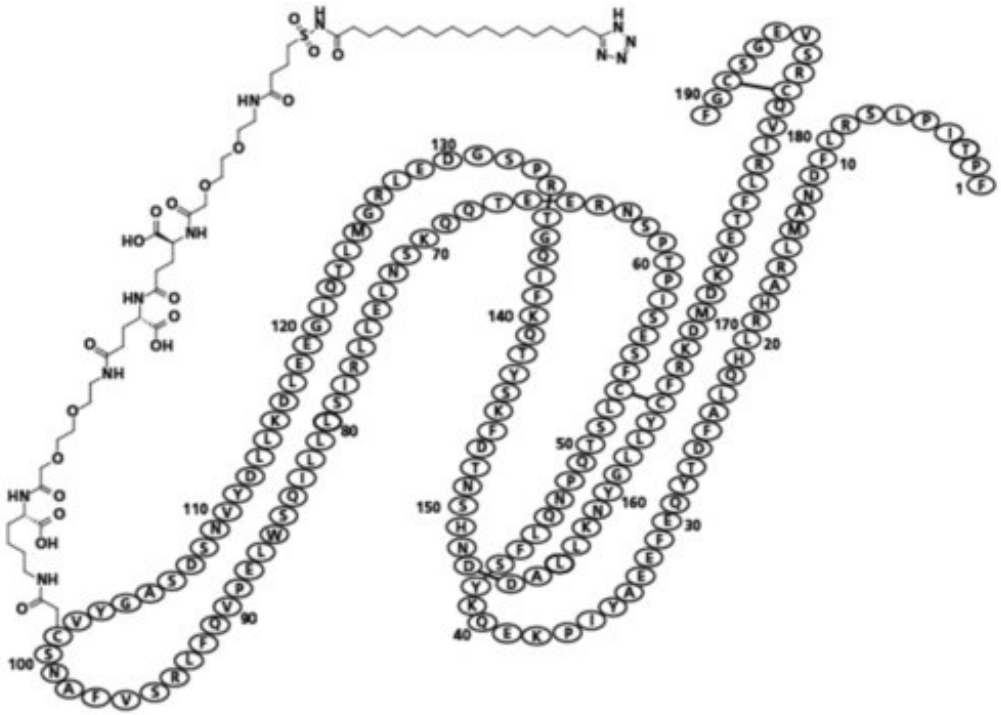
10 OVERDOSAGE

Acute overdosage could lead initially to hypoglycemia and subsequently to hyperglycemia. Overdose with SOGROYA is likely to cause fluid retention. Long-term overdosage could result in signs and symptoms of gigantism and/or acromegaly consistent with the known effects of excess endogenous growth hormone.

11 DESCRIPTION

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. Somapacitan-beco is produced in *Escherichia coli* by recombinant DNA technology. The molecular formula (including the albumin-binding moiety) is $C_{1038}H_{1609}N_{273}O_{319}S_9$ and the molecular weight is 23305.10 g/mol, of which the albumin-binding moiety is 1191.39 g/mol.

Structural Formula:



SOGROYA (somapacitan-beco) injection 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.

Each mL of SOGROYA 5 mg/1.5 mL prefilled pen contains 3.3 mg of somapacitan-beco, histidine (0.68 mg), mannitol (44 mg), phenol (4 mg), poloxamer 188 (1 mg), and Water for Injection, USP. The pH is approximately 6.8. Hydrochloric acid and sodium hydroxide may be added to adjust the pH.

Each mL of SOGROYA 10 mg/1.5 mL prefilled pen contains 6.7 mg of somapacitan-beco, histidine (0.68 mg), mannitol (44 mg), phenol (4 mg), poloxamer 188 (1 mg), and Water for Injection, USP. The pH is approximately 6.8. Hydrochloric acid and sodium hydroxide may be added to adjust the pH.

Each mL of SOGROYA 15 mg/1.5 mL prefilled pen contains 10 mg of somapacitan-beco, histidine (0.68 mg), mannitol (44 mg), phenol (4 mg), poloxamer 188 (1 mg), and Water for Injection, USP. The pH is approximately 6.8. Hydrochloric acid and sodium hydroxide may be added to adjust the pH.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Somapacitan-beco 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.

12.2 Pharmacodynamics

IGF-1 was measured to assess the pharmacodynamic (PD) properties of somapacitan-beco. Somapacitan-beco normalizes the mean IGF-1 standard deviation score (SDS) level from a baseline value below -2 to a value within the reference range (-2 to +2) in treatment-naïve adult patients with GHD *[see Clinical Studies (14)]*.

In adult patients with GHD (n=26), somapacitan-beco induces a less than dose proportional IGF-1 response at steady state. Maximum IGF-1 concentrations were observed within 2 to 4 days after dosing. Similar to the somapacitan-beco exposure time course, a steady state IGF-1 response was reached after 1 to 2 weekly doses with limited cumulative IGF-1 response.

In pediatric patients with GHD aged 2.5 to 11 years, somapacitan-beco produces a dose linear IGF-1 response, with a change of 0.02 mg/kg on average resulting in a change in IGF-1 standard deviation score (SDS) of 0.32. Approximately 97% of pediatric patients achieved an average IGF-1 SDS level within normal range after 52 weeks of treatment with once weekly SOGROYA in Study NCT03811535. IGF-1 SDS levels were -2.03 at baseline and the IGF-1 SDS level change from baseline was 2.36.

In pediatric patients born SGA aged 2.6 to 10.1 years, somapacitan-beco produces a dose linear IGF-1 response, with a change of 0.02 mg/kg/week on average resulting in a change in IGF-1 SDS of 0.24 in the dosing range of 0.16 mg to 0.24 mg/kg/week. IGF-1

SDS was normal at baseline and increased by 2.48 after 52 weeks of treatment with SOGROYA 0.24 mg/kg/week.

In pediatric patients with NS aged 2.6 to 11.1 years, IGF-1 SDS was normal at baseline and increased by 2.35 after 52 weeks of treatment with SOGROYA 0.24 mg/kg/week.

In pediatric patients with ISS aged 2.8 to 10.8 years, IGF-1 SDS was normal at baseline and increased by 2.44 after 52 weeks of treatment with SOGROYA 0.24 mg/kg/week.

12.3 Pharmacokinetics

Somapacitan-beco has pharmacokinetic properties compatible with once weekly administration. The reversible binding to endogenous albumin delays elimination of somapacitan and thereby prolongs the *in vivo* half-life and duration of action.

The pharmacokinetics (PK) of somapacitan-beco following subcutaneous administration have been investigated at clinically relevant doses (e.g., 0.01 to 0.32 mg/kg in healthy adults, 0.02 to 0.12 mg/kg in adults with GHD, 0.02 to 0.16 mg/kg in pediatric patients with GHD, 0.16 to 0.24 mg/kg in pediatric patient born SGA, 0.24 mg/kg in pediatric patient with NS, and 0.24 mg/kg in pediatric patient with ISS).

Overall, somapacitan-beco displays non-linear pharmacokinetics, however in the clinically relevant dose range of somapacitan-beco in adults with GHD, somapacitan-beco pharmacokinetics are approximately linear. After subcutaneous administration of 0.02 – 0.16 mg/kg/week somapacitan-beco in pediatric patients with GHD, a non-linear dose-exposure relationship with a greater than dose proportional increase in exposure was observed.

Absorption

In adults and pediatric patients, steady state exposure is achieved following 1 to 2 weeks of once weekly administration of subcutaneous somapacitan-beco.

In adults with GHD, a maximum concentration of somapacitan-beco is reached 4 to 24 hours post dose.

In pediatric patients with GHD, maximum somapacitan-beco concentrations occurred 8 to 25 hours after dosing at doses from 0.02 mg/kg/week to 0.16 mg/kg/week and increased with increasing dose level.

In pediatric patients born SGA, a maximum concentration of somapacitan-beco is reached 22 hours post dose at doses from 0.16 mg/kg/week to 0.24 mg/kg/week and increased with increasing dose level.

In pediatric patients with NS, a maximum concentration of somapacitan-beco is reached 23 hours post dose at 0.24 mg/kg/week.

In pediatric patients with ISS, a maximum concentration of somapacitan-beco is reached 23 hours post dose at 0.24 mg/kg/week.

Distribution

Somapacitan-beco is extensively bound (>99%) to plasma proteins.

Based on population PK analyses, the estimated volume of distribution (V/F) of somapacitan-beco in adult GHD patients is approximately 14.6 L, 1.7 L in pediatric patients with GHD, 2.97 L in pediatric patients born SGA, 3.23 L in pediatric patients with

NS, and 2.99 L in pediatric patients with ISS.

Elimination

The plasma elimination half-life of somapacitan-beco is approximately 2 to 3 days in adult patients with GHD. Following a dose of 0.16 mg/kg/week, the terminal half-life of somapacitan-beco was about 34 hours in pediatric patients with GHD.

Following a dose of 0.24 mg/kg/week, the mean terminal half-life of somapacitan-beco range from 36 to 37 hours in pediatric patients with SGA, NS, and ISS.

Somapacitan-beco was cleared within one week after treatment discontinuation.

Metabolism: Somapacitan-beco is metabolized via proteolytic cleavage of the linker sequence between the peptide backbone and albumin binder sidechain.

Excretion: The primary excretion routes of somapacitan-beco-related material are via the urine and feces. Approximately 81% of the dose is excreted in the urine and approximately 13% is excreted in the feces. No intact somapacitan-beco is excreted indicating full breakdown of somapacitan-beco prior to excretion.

Specific Populations

Body weight: Adults with GHD – The exposure of somapacitan-beco decreases with increasing body weight. However, the somapacitan-beco dose range of 0.1 to 8 mg/week provides adequate systemic exposure to reach target IGF-1 levels over the weight range of 34.5-150.5 kg evaluated in the clinical trials.

Pediatric patients with GHD: Based on pharmacokinetic analysis, gender and race do not have a clinically meaningful effect on the pharmacokinetics. The exposure of somapacitan-beco decreases with increasing body weight. However, the somapacitan-beco dose of 0.16 mg/kg/week provides adequate systemic exposure for pediatrics to reach target IGF-1 levels over the weight range of 9.9 to 61.8 kg evaluated in the clinical trials.

Geriatric patients: Adult patients greater than 65 years of age and geriatric patients have a higher exposure than younger subjects at the same somapacitan-beco dose *[see Dosage and Administration (2.5), Use in Specific Populations (8.5)]*.

Female patients receiving estrogen: Female patients and in particular female patients on oral estrogen, have lower exposure than males at the same somapacitan-beco dose *[see Dosage and Administration (2.5), Drug Interactions (7)]*.

Hepatic impairment: A somapacitan-beco dose of 0.08 mg/kg at steady state resulted in comparable somapacitan-beco exposure between patients with normal hepatic function and mild hepatic impairment (Child-Pugh A). However, higher exposure was observed in patients with moderate hepatic impairment (Child-Pugh B) (ratios to normal hepatic function were 4.69 and 3.52-fold increase for $AUC_{0\text{-}168h}$ and C_{max}, respectively). Lower somapacitan-beco stimulated IGF-1 levels were observed in patients with mild and moderate hepatic impairment (ratios to normal hepatic function were 0.85 and 0.75, respectively) *[see Dosage and Administration (2.5), Use in Specific Populations (8.6)]*.

Renal impairment: In general, somapacitan-beco exposure tended to increase with decreasing estimated glomerular filtration rate. A somapacitan-beco dose of 0.08 mg/kg at steady state resulted in higher exposures in patients with renal impairment, that was most pronounced for patients with severe renal impairment and patients requiring

hemodialysis ($AUC_{0\text{-}168h}$ ratios to normal renal function were 1.75 and 1.63, respectively). Higher IGF-1 $AUC_{0\text{-}168h}$ levels were also observed in patients with moderate and severe renal impairment and in patients requiring hemodialysis (ratios to normal renal function were 1.35, 1.40 and 1.24, respectively).

12.6 Immunogenicity

The observed incidence of anti-drug antibodies (ADA) is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of ADA in the studies described below with the incidence of ADA in other studies, include those of SOGROYA or other growth hormone analogs.

No anti-somapacitan-beco-antibodies were detected in the clinical trials in adult patients with GHD.

For pediatric patients with GHD, of the 132 subjects exposed to somapacitan-beco, 16 (12.1%) were ADA positive at any time during the 52-week main period of the trial following exposure to SOGROYA. Fourteen of the 16 subjects showed positive ADA only at one timepoint.

For pediatric patients born SGA, of the 69 subjects exposed to somapacitan-beco, 10 (14.5 %) were ADA positive at any time during the 52-week main period of the trial following exposure to SOGROYA. Three of the 10 subjects showed positive ADA at only one time point.

For pediatric patients with NS, of the 49 subjects exposed to somapacitan-beco, 2 (4.1 %) were ADA positive at any time during the 52-week main period of the trial following exposure to SOGROYA. One of the 2 subjects showed positive ADA at only one time point.

For pediatric patients with ISS, of the 59 subjects exposed to somapacitan-beco, 7 (11.9 %) were ADA positive at any time during the 52-week main period of the trial following exposure to SOGROYA. Three of the 7 subjects showed positive ADA at only one time point.

There was no identified clinically significant effect of ADA on pharmacokinetics, pharmacodynamics, safety, or effectiveness of SOGROYA over the treatment duration. No neutralizing antibodies to somapacitan-beco were detected across the studied pediatric patient populations.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term studies in animals with somapacitan-beco to evaluate carcinogenic potential have not been conducted.

Somapacitan-beco was not mutagenic or clastogenic in a standard battery of genotoxicity tests (bacterial mutagenicity (Ames), human lymphocyte chromosome aberration, rat bone marrow micronucleus).

In rat studies evaluating male and female fertility, somapacitan-beco was administered by subcutaneous injection at doses of 1, 2, and 4 mg/kg twice weekly. Males were dosed

from four weeks before pairing until termination and females were dosed beginning two weeks prior to mating through gestation day 7. No adverse effects were observed on male or female fertility in rats at doses up to 4 mg/kg (29 times the MRHD, based on AUC).

14 CLINICAL STUDIES

14.1 Pediatric Patients with Growth Hormone Deficiency (GHD)

A randomized, open-label, active-controlled, parallel-group phase 3 study was conducted in 200 treatment-naïve, pediatric patients with growth hormone deficiency (GHD) (NCT03811535). The primary efficacy endpoint was annualized height velocity at Week 52.

One hundred thirty-two patients (132) received 0.16 mg/kg/week SOGROYA, and 68 received 0.034 mg/kg/day daily somatropin. The patients ranged in age from 2.5 to 11 years with a mean of 6.4 years. Of these patients, 74.5% were male and 25.5% were female. Fifty-seven percent (57%) of patients were Caucasian, 37% of patients were Asian, 0.5% of patients were Black or African American, 5.0% were not reported, and 0.5% were categorized as “other.” The mean baseline height standard deviation score (SDS) of -2.99 (1.02) in SOGROYA group and -3.47 (1.52) in daily somatropin group.

Treatment with once-weekly SOGROYA for 52 weeks resulted in an annualized height velocity of 11.2 cm/year. Patients treated with daily somatropin achieved an annualized height velocity of 11.7 cm/year after 52 weeks of treatment. Refer to **Table 8**.

Table 8. Annualized Height Velocity at Week 52 in Pediatric Patients with GHD

	Once-Weekly SOGROYA (N=132)	**Daily somatropin (N=68)**	**Estimate of treatment difference (95% CI) (SOGROYA minus daily somatropin)**
Annualized Height Velocity (cm/year)	11.2	11.7	-0.5 [-1.1; 0.2]

The mean increase in height SDS over the 52-week period was 1.25 and 1.30 in the once-weekly SOGROYA and daily somatropin groups, respectively.

14.2 Pediatric Patients Born Small for Gestational Age (SGA)

A multi-center, randomized, open-label, active-comparator, phase 3 basket study was conducted in GH treatment-naïve, pre-pubertal pediatric patients with short stature in small for gestational age (SGA), Noonan syndrome (NS) or idiopathic short stature (ISS) (NCT05330325). The primary efficacy endpoint was annualized height velocity at Week 52.

One hundred forty-two pediatric patients with SGA were randomized to SOGROYA 0.24 mg/kg/week (n=70), daily somatropin 0.035 mg/kg/day (n=37), or daily somatropin

0.067 mg/kg/day (n=35). Dose 0.035 mg/kg/day of daily somatropin is less than maximum dose (0.067 mg/kg/day) approved for use in pediatric patients with SGA in the United States. Patients ranged in age from 2.6 to 10.7 years with a mean of 5.5 years. Of these patients, 49% were male and 51% were female. Fifty-nine percent of patients were Caucasian, 36% of patients were Asian, 1% of patients were Black or African American, and 4% were not reported. The mean baseline height SDS was -3, -3, and -3 in the SOGROYA, somatropin 0.035 mg/kg/day, and somatropin 0.067 mg/kg/day groups, respectively.

The annualized height velocity at Week 52 for SOGROYA and somatropin are presented in **Table 9**.

Table 9. Annualized Height Velocity at Week 52 in Pediatric Patients with SGA

	Once weekly SOGROYA 0.24 mg/kg/week (N=70)	**Daily somatropin 0.035 mg/kg/day (N=37)**	**Daily somatropin 0.067 mg/kg/day (N=35)**	**Estimated treatment difference (95% CI)***
Annualized Height Velocity (cm/year)	11	9.4	11.1	Once weekly SOGROYA 0.24 mg/kg/week vs. Daily somatropin 0.035 mg/kg/day: 1.6# [0.91; 2.23]
				Once weekly SOGROYA 0.24 mg/kg/week vs. Daily somatropin 0.067 mg/kg/day: -0.1# [-0.75; 0.60]

*Estimated treatment difference (Height Velocity of SOGROYA - Daily Somatropin)

#Height velocity at Week 52 is analyzed using an analysis of covariance model with treatment, gender, age group, region, baseline height SDS (<-3 or >=-3) and gender by age group by region interaction term as factors, and baseline height and baseline IGF-1 SDS as covariates. There were no missing values at Week 52, so no multiple imputation was done.

The mean increase in height SDS was 1.17, 0.85, and 1.21 following a 52-week treatment period with SOGROYA 0.24 mg/kg/week, daily somatropin 0.035 mg/kg/day, and daily somatropin 0.067 mg/kg/day, respectively.

14.3 Pediatric Patients with Noonan Syndrome (NS)

A multi-center, randomized, open-label, active-comparator, phase 3 basket study was conducted in GH treatment-naïve, pre-pubertal patients with short stature in small for gestational age (SGA), Noonan syndrome (NS) or idiopathic short stature (ISS) (NCT05330325). The primary efficacy endpoint was annualized height velocity at Week 52.

Seventy-seven NS patients were randomized to 0.24 mg/kg/week once weekly somapacitan-beco (n=49) or once daily somatropin at dose levels of 0.05 mg/kg/day (n=28). Dose 0.05 mg/kg/day of daily somatropin is less than maximum dose (0.066 mg/kg/day) approved for use in pediatric patients with NS in the United States. Patients ranged in age from 2 to 11.1 years with a mean of 6.2 years. Of these patients, 61% were male and 39% were female. Fifty-one percent of patients were Caucasian, 31% of patients were Asian, 5% of patients were Black or African American, and 12% were not reported, and 1% were reported as "multiple." The mean baseline height SDS was -2.7 and -2.6 in the SOGROYA and somatropin 0.05 mg/kg/day groups, respectively.

The annualized height velocity at Week 52 was similar for somapacitan-beco and somatropin (**Table 10**).

Table 10. Annualized Height Velocity at Week 52 in Pediatric Patients with NS

	Once weekly SOGROYA 0.24 mg/kg/week (N=49)	**Daily somatropin 0.050 mg/kg/day (N=28)**	**Estimated treatment difference (95% CI)* (SOGROYA vs. Daily somatropin)**
Annualized Height Velocity (cm/year)	10.4	9.2	1.2# [0.32; 2.03]

*Estimated treatment difference (Height Velocity of SOGROYA - Daily Somatropin)

#Height velocity at Week 52 is analyzed using an analysis of covariance model with treatment, gender, age group, region, baseline height SDS (<-3 or >=-3) and gender by age group by region interaction term as factors, and baseline height and baseline IGF-1 SDS as covariates. Missing values at Week 52 are imputed based on available landmark visit data using Multiple Imputations.

The mean increase in height SDS was 1.06 and 0.79 following a 52-week treatment period with SOGROYA 0.24 mg/kg/week and daily somatropin 0.050 mg/kg/day, respectively.

14.4 Pediatric Patients with Idiopathic Short Stature (ISS)

A multi-center randomized, open-label, active-comparator, phase 3 basket study was conducted in GH treatment-naïve, pre-pubertal patients with short stature in small for gestational age (SGA), Noonan syndrome (NS) or idiopathic short stature (ISS) (NCT05330325). The primary efficacy endpoint was annualized height velocity at Week 52.

Eighty-eight ISS patients were randomized to 0.24 mg/kg/week once weekly somapacitan-beco (n=60) or once daily somatropin at dose levels of 0.05 mg/kg/day (n=28). Dose 0.05 mg/kg/day of daily somatropin is less than maximum dose (0.067 mg/kg/day) approved for use in pediatric patients with ISS in the United States. Patients ranged in age from 2.8 to 10.8 years with a mean of 6.9 years. Of these patients, 41% were male and 59% were female. Sixty-four percent (%) of patients were Caucasian, 30% of patients were Asian, 1% of patients were Black or African American, 1% were American Indian or Alaskan Native, 2% were not reported, and 2% were reported as

“multiple.” The mean baseline height SDS was -2.8 and -2.9 in the SOGROYA and somatropin 0.05 mg/kg/day groups, respectively.

The annualized height velocity at Week 52 was similar for somapacitan-beco and somatropin (**Table 11**).

Table 11. Annualized Height Velocity at Week 52 in Pediatric Patients with ISS

	Once weekly SOGROYA 0.24 mg/kg/week (N=60)	**Daily somatropin 0.050 mg/kg/day (N=28)**	**Estimated treatment difference (95% CI)* (SOGROYA vs. Daily somatropin)**
Annualized Height Velocity (cm/year)	10.2	10.5	-0.3# [-1.00; 0.42]

*Estimated treatment difference (Height Velocity of SOGROYA - Daily Somatropin)

#Height velocity at Week 52 is analyzed using an analysis of covariance model with treatment, gender, age group, region, baseline height SDS (<-3 or >=-3) and gender by age group by region interaction term as factors, and baseline height and baseline IGF-1 SDS as covariates. Missing values at Week 52 are imputed based on available landmark visit data using Multiple Imputations.

The mean increase in height SDS was 0.98 and 1.09 following a 52-week treatment period with SOGROYA 0.24 mg/kg/week and daily somatropin 0.050 mg/kg/day, respectively.

14.5 Adults with Growth Hormone Deficiency (GHD)

In a 35-week, double-blind, placebo-controlled study, treatment-naïve adult patients with GHD were randomized (2:1:2) and exposed to once-weekly SOGROYA 10 mg/1.5mL (n=120) or placebo (n=60) or a daily somatropin product 10 mg/1.5mL (n=119) for a 34-week treatment period (NCT02229851).

In this study, patients were 51.7% female and had a mean age of 45.1 years. Most patients were 23 to 64 years old and most (69.7%) had adult onset GHD. The mean BMI was 27.4 kg/m^2. Overall, 66.7% were White, 28.7% were Asian and 2.3% were Black or African American; 4.5% identified as Hispanic or Latino ethnicity.

Treatment with SOGROYA demonstrated superiority compared to placebo in reduction in truncal fat percentage (%) as assessed by dual X-ray absorptiometry, with a change of -1.06% for SOGROYA and +0.47% for placebo after 34 weeks (see **Table 12**). Patients treated with daily somatropin achieved a change in truncal fat % of -2.23% after 34 weeks.

Table 12. Truncal Fat % Results for Weekly SOGROYA, Weekly Placebo and Daily Somatropin During the 34-week Pivotal Trial

Change from baseline at 34 weeks	**Weekly Placebo**	**Weekly SOGROYA**	**Daily Somatropin**

Number of subjects in FAS (N)	61	120	119
Truncal fat % (baseline)	36.9	39.11	38.10
Truncal fat %	0.47	-1.06	-2.23
Absolute Treatment Difference (%)* [95% Confidence Interval] p-value	-1.53 [-2.68; -0.38] 0.0090		

Abbreviations: FAS = Full analysis set, N = Number of subjects in FAS. Changes in truncal fat % from baseline to 34 weeks were analyzed using an analysis of covariance model with treatment, GHD onset type, sex, region, diabetes mellitus status and sex by region by diabetes mellitus interaction as factors and baseline as a covariate incorporating a multiple imputation technique where missing Week 34 values were imputed based on data from the placebo group.
*No formal statistical comparison between SOGROYA and daily somatropin was performed.

After 34 weeks SOGROYA normalized the mean IGF-1 SDS level in treatment-naïve adult patients with GHD with a IGF-1 SDS of -0.17 in SOGROYA-treated patients compared to -2.62 in placebo-treated patients (see **Table 13**). The mean IGF-1 SDS levels in daily somatropin-treated patients was -2.53 at baseline and -0.23 at 34 weeks.

Table 13. IGF-1 SDS for SOGROYA Compared to Placebo During the 34-week Pivotal Trial

	SOGROYA	**Placebo**
Number of subjects in FAS (N)	120	61
IGF-1 SDS values at baseline, mean	-2.54	-2.64
IGF-1 SDS value at Week 34, mean	-0.17	-2.62

Abbreviations: IGF-1 SDS: Insulin-like growth factor-1 standard deviation score, FAS = full analysis set, N = Number of patients in FAS. Baseline and end of main period (week 34) are observed means. Changes from baseline to the 35-week's measurements were analysed using a mixed-effect model for repeated measurements including treatment, GHD onset type, sex, region, diabetes mellitus and sex by region by diabetes mellitus interaction as factors and baseline as a covariate, all nested within week as a factor.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

SOGROYA (somapacitan-beco) injection is a clear to slightly opalescent and colorless to slightly yellow solution available as one 1.5 mL single-patient-use prefilled pen per carton:

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

SOGROYA 5 mg/1.5 mL, 10 mg/1.5 mL, and 15 mg/1.5 mL pens are compatible with FlexPro® PenMate®. The FlexPro PenMate is an accessory device that is dispensed separately with its enclosed Instructions for Use.

Storage and Handling

Before and during use: Store in a refrigerator at 2°C to 8°C (36°F to 46°F) with the cap on and in the original carton to protect from light. Do not freeze. Do not use SOGROYA if it has been frozen. Discard prefilled pen if kept above 30°C (86°F). Avoid direct or excessive heat. Avoid sunlight. Refer to storage conditions for SOGROYA (**Table 14**).

Write the date of first use in the space provided on the carton.

Always remove and safely discard the needle after each injection and store the SOGROYA prefilled pen without an injection needle attached. Always use a new needle for each injection to prevent contamination.

Table 14. Storage Conditions for SOGROYA

	Before first use (unopened)		**After first use (opened)**	
	Refrigerated 2°C to 8°C (36°F to 46°F)	**Room Temperature up to 25°C (77°F)**	**Refrigerated 2°C to 8°C (36°F to 46°F)**	**Room Temperature up to 25°C (77°F)**
SOGROYA	Until expiration date	Maximum 72 hours (3 days)*	up to 6 weeks	Maximum 72 hours (3 days)*

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

17 PATIENT COUNSELING INFORMATION

Advise patients and/or caregivers to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

- Advise patients and/or caregivers to administer SOGROYA once weekly.
- Hypersensitivity - Advise patients and/or caregivers that severe and/or serious systemic hypersensitivity reactions (anaphylaxis and angioedema) have been reported, and to seek prompt medical attention should an allergic reaction occur *[see Warnings and Precautions (5.2)]*.
- Neoplasms – Advise patients to report marked changes in skin pigmentation or changes in the appearance of preexisting nevi.
- Glucose Intolerance/ Diabetes Mellitus – Advise patients that new onset pre-/diabetes mellitus or exacerbation of preexisting diabetes mellitus can occur and monitoring of blood glucose during treatment with SOGROYA may be needed.
- Intracranial Hypertension - Advise patients to report to their healthcare provider any visual changes, headache, and nausea and/or vomiting.
- Fluid Retention - Advise patients that fluid retention during SOGROYA replacement therapy may frequently occur. Inform patients of the clinical manifestations of fluid

retention (e.g. edema, arthralgia, myalgia, nerve compression syndromes including carpal tunnel syndrome/paresthesia) and to report to their healthcare provider any of these signs or symptoms occur during treatment with SOGROYA.

- Hypoadrenalism - Advise patients who have or who are at risk for corticotropin deficiency that hypoadrenalism may develop and to report to their healthcare provider if they experience hyperpigmentation, extreme fatigue, dizziness, weakness, or weight loss.
- Hypothyroidism - Advise patients/caregivers that undiagnosed/untreated hypothyroidism may prevent an optimal response to SOGROYA. Advise patients/caregivers they may require periodic thyroid function tests.
- Pancreatitis - Advise patients that pancreatitis may develop and to report to their healthcare provider any new onset abdominal pain.
- Lipohypertrophy/ Lipoatrophy – Advise patients that lipohypertrophy or lipoatrophy can occur if SOGROYA is administered subcutaneously at the same site over a long period of time. Advise patients to rotate injection sites when administering SOGROYA to reduce this risk.

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SOGROYA® *and FlexPro® are registered trademarks of Novo Nordisk Health Care AG.*

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Patent Information: http://novonordisk-us.com/products/product-patents.html

For information about SOGROYA contact:

Novo Nordisk Inc.

800 Scudders Mill Road

Plainsboro, New Jersey 08536

1-888-668-6444

Manufactured by:

Novo Nordisk Inc.

800 Scudders Mill Road

Plainsboro, NJ 08536

U.S. License No. 1261

PATIENT INFORMATION

PATIENT INFORMATION

SOGROYA® (suh-GROY-uh)

(somapacitan-beco) injection, for subcutaneous use

What is SOGROYA?

- SOGROYA is a prescription medicine that contains human growth hormone, the same growth hormone made by the human body. SOGROYA is given by injection under the skin (subcutaneous).

- SOGROYA is used to treat children 2.5 years of age and older who:
  - are not growing because of low or no growth hormone.
  - are short (in stature) and were born small (small for gestational age-SGA) and have not caught up in growth by age 2 years.
  - are not growing and have Noonan syndrome.
  - have Idiopathic Short Stature (ISS).
- SOGROYA is used to treat adults who do not make enough growth hormone.

Do not use SOGROYA if:

- you have a critical illness caused by certain types of heart or stomach surgery, trauma or breathing (respiratory) problems.
- you have cancer or other tumors.
- you are allergic to somapacitan-beco or any of the ingredients in SOGROYA. See the end of this Patient Information leaflet for a complete list of ingredients in SOGROYA.
- your healthcare provider tells you that you have certain types of eye problems caused by diabetes (diabetic retinopathy).
- you are a child with closed bone growth plates.
- you are a child with Prader-Willi syndrome who is severely obese or has breathing problems including sleep apnea (briefly stop breathing during sleep).

Before taking SOGROYA, tell your healthcare provider about all of your medical conditions, including if you:

- have had heart or stomach surgery, trauma or serious breathing (respiratory) problems.
- have had cancer or any tumor.
- have diabetes.
- have adrenal gland problems.
- are taking replacement therapy with glucocorticoids.
- have thyroid gland problems.
- have liver problems.
- are a child with a history of worsening of curvature of the spine (scoliosis).
- are pregnant or plan to become pregnant. It is not known if SOGROYA will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if SOGROYA passes into your breast milk. You and your healthcare provider should decide if you will take SOGROYA while you breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SOGROYA may affect how other medicines work, and other medicines may affect how SOGROYA works.

How should I use SOGROYA?

- Read the detailed **Instructions for Use** that come with SOGROYA.
- SOGROYA comes in 3 strengths: 5 mg/1.5 mL (3.3 mg/mL) pen, 10 mg/1.5 mL (6.7 mg/mL) pen, and 15 mg/1.5 mL (10 mg/mL) pen. Your healthcare provider will prescribe the dose that is right for you.

- Your healthcare provider will show you how to inject SOGROYA.
- Use SOGROYA exactly as your healthcare provider tells you to.
- Use SOGROYA **1 time each week.**
- If you miss a dose of SOGROYA, the missed dose can be taken within **3** days (72 hours) after the scheduled dosing day. One-time weekly dosing for the next dose can be started again on the regularly scheduled dosing day.
- If more than 3 days (72 hours) have passed, skip the missed dose and take your next dose on the regularly scheduled dosing day.

    - SOGROYA pens are for use by 1 person only.
    - **Do not share your SOGROYA pens and needles with another person, even if the needle has been changed. You may give another person an infection or get an infection from them.**

What are the possible side effects of SOGROYA?
SOGROYA may cause serious side effects, including:

- high risk of death in people who have critical illnesses because of heart or stomach surgery, trauma, or serious breathing (respiratory) problems.
- increased risk of growth of cancer or a tumor that is already present and increased risk of the return of cancer or a tumor in people who were treated with radiation to the brain or head as children and who developed low growth hormone problems. Your or your child's healthcare provider will need to monitor you or your child for a return of cancer or a tumor. Contact the healthcare provider if you or your child start to have sudden changes in behavior, headaches, vision problems, or changes in moles, birthmarks, or the color of your or your child's skin.
- new or worsening high blood sugar (hyperglycemia) or diabetes. You or your child's blood sugar may need to be monitored during treatment with SOGROYA.
- increase in pressure in the skull (intracranial hypertension). If you or your child have headaches, eye problems, nausea or vomiting, contact the healthcare provider.
- serious allergic reactions. Get medical help right away if you or your child have the following symptoms:

    - swelling of your face, lips, mouth, or tongue
    - trouble breathing
    - wheezing
    - severe itching
    - skin rashes, redness, or swelling
    - dizziness or fainting
    - fast heartbeat or pounding in your chest
    - sweating

- your or your child's body holding too much fluid (fluid retention) such as swelling in the hands and feet, pain in your or your child's joints or muscles or nerve problems that cause pain, burning or tingling in the hands, arms, legs and feet. Tell your or your child's healthcare provider if you or your child have any of these signs or symptoms of fluid retention.
- decrease in a hormone called cortisol. The healthcare provider will do blood tests to check your or your child's cortisol levels. Tell your or your child's healthcare provider if you or your child has darkening of the skin, severe fatigue, dizziness, weakness, or weight loss.

- decrease in thyroid hormone levels. Decreased thyroid hormone levels may affect how well SOGROYA works. The healthcare provider will do blood tests to check your or your child's thyroid hormone levels.
- severe and constant abdominal pain. This could be a sign of pancreatitis. Tell your or your child's healthcare provider if you or your child has any new abdominal pain.
- loss of fat and tissue weakness in the area of skin you or your child inject. Talk to your or your child's healthcare provider about rotating the areas where you or your child inject SOGROYA.
- worsening of curvature of the spine in children (scoliosis).
- hip and knee pain or a limp in children (slipped capital femoral epiphysis). This may lead to a serious condition where bone tissue dies due to a lack of blood supply (osteonecrosis). Get medical help right away if you or your child develops a limp or has hip or knee pain.
- high risk of sudden death in children with Prader-Willi syndrome who are severely obese or have breathing problems, including sleep apnea. See "**Do not use SOGROYA if**".
- increase in phosphorus, alkaline phosphatase, and parathyroid hormone levels in your blood. Your or your child's healthcare provider will do blood tests to check this.

The most common side effects of SOGROYA in children include:

- cough
- common cold
- diarrhea
- ear infection
- headache
- fever
- pain in extremity
- reaction to injection
- respiratory tract infection
- vomiting

The most common side effects of SOGROYA in adults include:

- back pain
- joint pain
- indigestion
- sleep problems
- dizziness
- swelling of the tonsils (tonsillitis)
- swelling in the feet and hands (peripheral edema)
- vomiting
- low cortisol levels(adrenal insufficiency)
- high blood pressure
- increase in the level of an enzyme in your blood called creatine phosphokinase
- weight gain
- low red blood cells (anemia)

These are not all the possible side effects of SOGROYA.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
You may also report side effects to Novo Nordisk at 1-888-668-6444.

How should I store SOGROYA?

- **Before you use SOGROYA pens for the first time:**
- Store your new, unused SOGROYA pen in a refrigerator between 36ºF to 46ºF (2ºC to 8ºC).
- Store your new, unused SOGROYA pen with the cap on and keep it in the original carton.

- Do not freeze SOGROYA.
- Keep SOGROYA away from direct heat and light.
- Do not use SOGROYA that has been frozen or in temperatures warmer than 86ºF (30ºC).
- Do not use SOGROYA after the expiration date printed on the carton and the pen.

• **After you use SOGROYA pens and there is still medicine left:**

- Store remaining SOGROYA in the refrigerator between 36ºF to 46ºF (2ºC to 8ºC) and use within 6 weeks.
- Store your in-use SOGROYA pen with the cap on and keep it in the original carton.

• If needed, unused and in-use SOGROYA pens can be stored out of the refrigerator. SOGROYA pens can be stored at room temperature no warmer than 77ºF (25ºC) for up to 3 days (72 hours) and then returned to the refrigerator.

Keep SOGROYA and all medicines out of the reach of children.

General information about the safe and effective use of SOGROYA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use SOGROYA for a condition for which it was not prescribed. Do not give SOGROYA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about SOGROYA that is written for health professionals.

What are the ingredients in SOGROYA?

Active ingredient: somapacitan-beco

Inactive ingredients: histidine, mannitol, phenol, poloxamer 188, Water for Injection, and hydrochloric acid and sodium hydroxide (as needed)

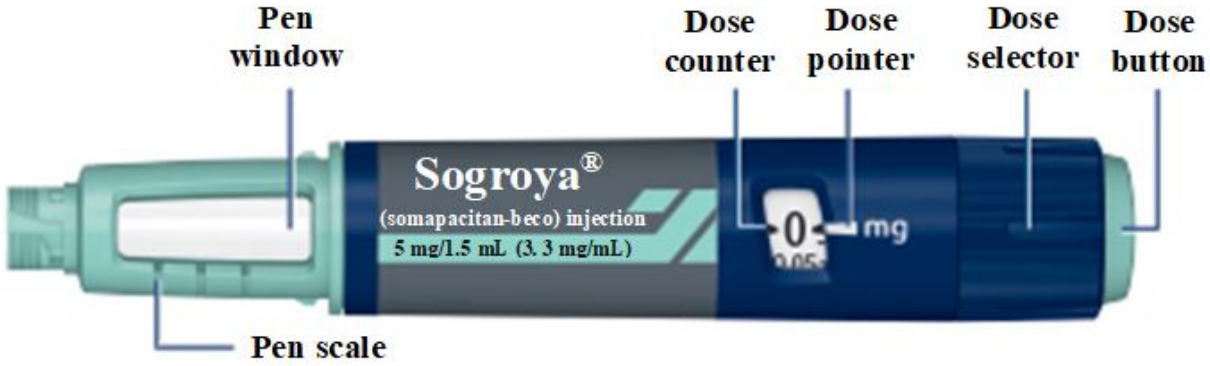
Manufactured by: Novo Nordisk Inc., Plainsboro, NJ 08536

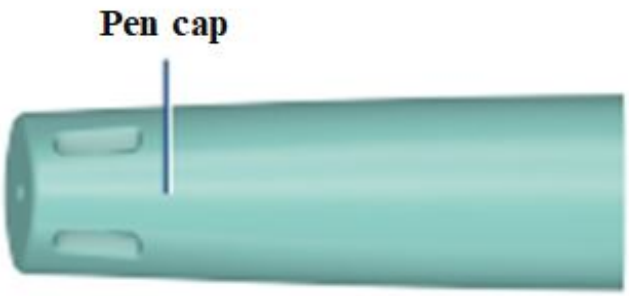
This Patient Information has been approved by the U.S. Food and Drug Administration.
Revised: 02/2026

Instructions for Use – 5 mg/1.5 mL (3.3 mg/mL)

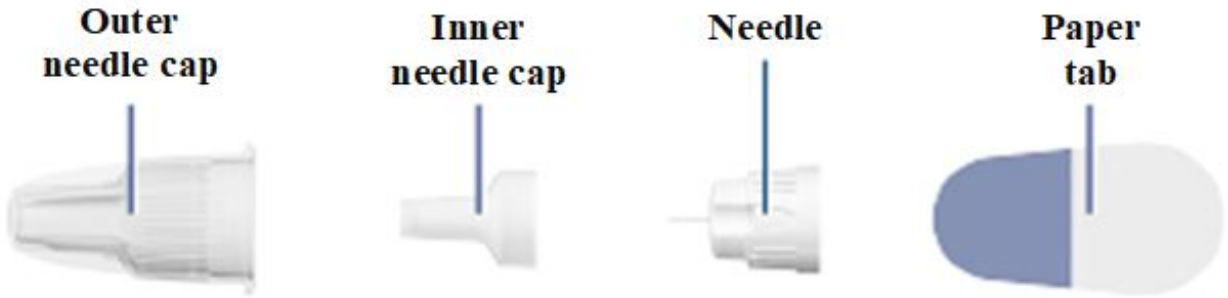
Instructions for Use
SOGROYA® 5 mg
(suh-GROY-uh)
(somapacitan-beco) injection
5 mg/1.5 mL (3.3 mg/mL)

SOGROYA Pen



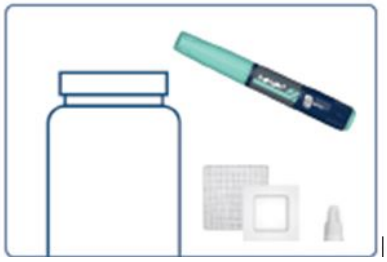


Needle (example)



Supplies you will need:

- SOGROYA prefilled Pen
- new injection needle. SOGROYA prefilled Pen is designed to be used with all Novo Nordisk disposable needles up to a length of 8 mm.
- sharps disposal container. See Step 5 for information on how to throw away (dispose of) used needles and Pens.
- alcohol pad
- gauze pad



How to use your SOGROYA Pen

5 steps you should follow for a SOGROYA injection:
Step 1: Prepare your SOGROYA Pen
Step 2: Check the SOGROYA flow with each new Pen
Step 3: Select your dose
Step 4: Inject your dose
Step 5: After your injection

For further information about your Pen see: Frequently Asked Questions and Important information

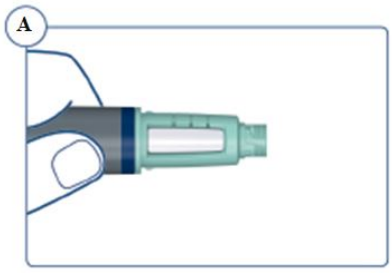
Important information
Pay special attention to these notes as they are important for safe use of the Pen.

Additional information

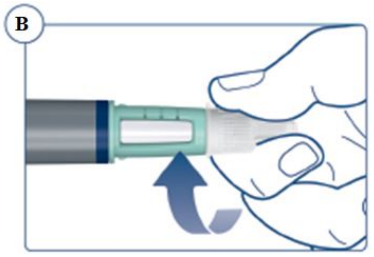
SOGROYA is a prefilled growth hormone Pen. It contains 5 mg of somapacitan-beco and delivers doses from 0.025 mg to 2.0 mg, in increments of 0.025 mg. **SOGROYA is for use under the skin only (subcutaneous) for injection 1 time each week.**
Do not share your SOGROYA Pen and needles with another person. You may give another person an infection or get an infection from them.
Do not use your Pen without proper training from your healthcare provider. Make sure that you are confident in giving an injection with the Pen before you start your treatment. If you are blind or have poor eyesight and cannot read the dose counter on the Pen, do not use this Pen without help. Get help from a person with good eyesight who is trained to use the Pen.

Step 1. Prepare your SOGROYA Pen

- Wash your hands with soap and water.
- **Check the name, strength, and colored label** on your Pen to make sure that it contains SOGROYA in the right strength.
- Pull off the Pen cap.
- Turn the Pen upside down 1 or 2 times to check that the SOGROYA in your Pen is clear to almost clear and colorless to slightly yellow (See Figure A). **If SOGROYA looks cloudy or you see particles, do not use the Pen.**



- When you are ready to give your injection, get a new disposable needle, and remove the paper tab.
- Push the needle straight onto the Pen. Turn the needle clockwise **until it is on tight** (See Figure B).

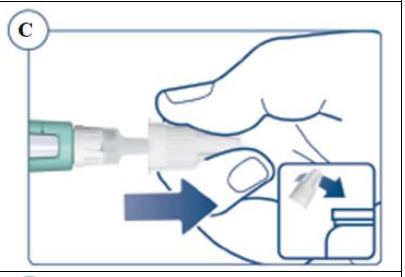


Make sure the right pen is used. Especially if you use more than one type of injection medicine. Using the wrong medicine could be harmful to your health.

Always use a new needle for each injection. This reduces the risk of

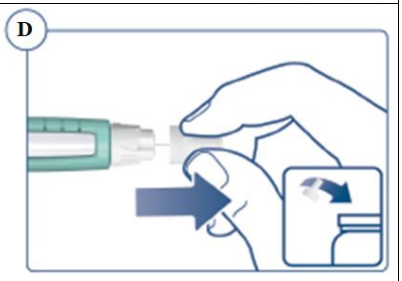
contamination, infection, leakage of SOGROYA, and blocked needles leading to incorrect dosing.

- Pull off the outer needle cap and throw it away (dispose of) (See Figure C).



- Pull off the inner needle cap and throw it away (dispose of) (See Figure D).

A drop of SOGROYA may appear at the needle tip. This is normal, but you must still check the SOGROYA flow with each new Pen (See Step 2).



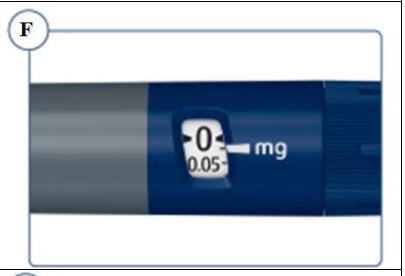
Never use a bent or damaged needle.

Step 2. Check the SOGROYA flow with each new Pen

If your Pen is already in use, go to Step 3.

- **Before using a new Pen**, check the SOGROYA flow to make sure the growth hormone can flow through the Pen and needle.
- Turn the dose selector clockwise 1 marking on the dose counter to select 0.025 mg. You may hear a faint “click” when you turn the dose selector (See Figure E).

- **1 marking on the dose counter equals 0.025 mg** (See Figure F).



- Hold the Pen with the needle pointing up. Press and hold in the dose button until the dose counter returns to “0”. **The “0” must line up with the dose pointer** (See Figure G).

- Check that a drop of SOGROYA appears at the needle tip (See Figure H).

If no SOGROYA appears, repeat Step 2 up to 6 times. If you still do not see a drop of SOGROYA, **change the needle:**

- Carefully remove the needle from the Pen by turning the needle counterclockwise. Place the needle in a sharps disposal container immediately (See Step 5).
- Repeat Step 2 again.

Do not use the Pen if a drop of SOGROYA still does not appear after changing the needle and repeating Step 2. Call Novo Nordisk at 1-888-668-6444 for help.

Step 3. Select your dose

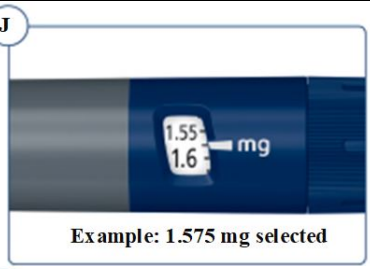
- To start, check that the dose pointer is set at "**0".**
- Turn the dose selector clockwise to select the dose you need (See Figure I). When you have selected your dose, you can go to Step 4.

If there is not enough SOGROYA left to select a full dose, see **Frequently Asked Questions**.

I

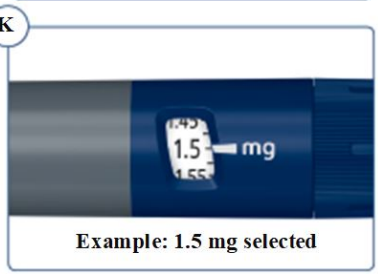
The dose counter shows the dose in "mg" (See Figure J and Figure K). Always use the dose counter to select the exact dose. **Do not use the "click" sounds you hear when you turn the dose selector to select your dose. Only the dose pointer on the dose counter will show the exact dose selected.**

J



Example: 1.575 mg selected

K



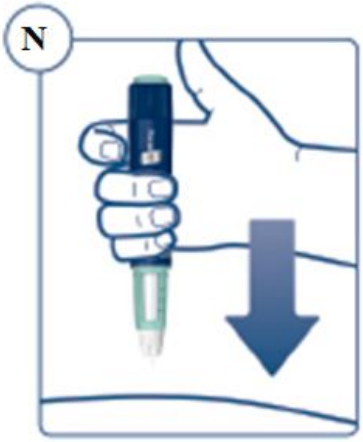
Example: 1.5 mg selected

If you select the wrong dose, you can turn the dose selector clockwise or counterclockwise to the correct dose (See Figure L).
The Pen "clicks" sound and feel differently when the dose selector is turned clockwise, counterclockwise, or if you forcefully move it past the number of "mg" left in the Pen.

L

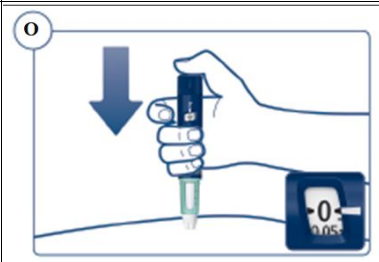
Step 4. Inject your dose

- Select the injection site.
- SOGROYA can be injected under the skin (subcutaneously) of your stomach area (abdomen) or upper legs (thighs) as instructed by your healthcare provider (See Figure M). **Change the injection site every week.**
- Wipe the injection site with an alcohol pad and let the area dry.
- Insert the needle into your skin as your healthcare provider has shown you (See Figure N).
- Make sure you can see the dose counter. **Do not cover it with your fingers.** This could block the injection.

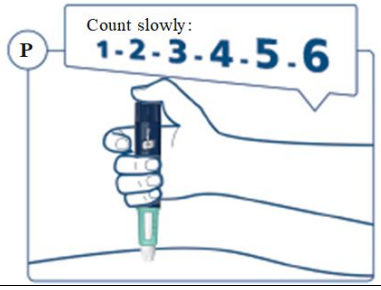


- Press and hold down the dose button until the dose counter shows “0” (See Figure O). **The “0” must line up with the dose pointer.** You may then hear or feel a “click”.
- **Continue to hold down the dose button with the needle in your skin.**

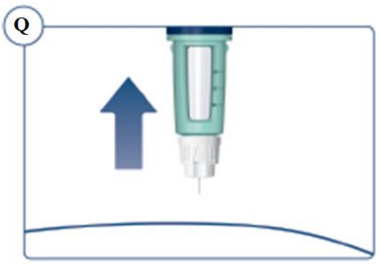
If “0” does not appear in the dose counter after continuously pressing the dose button, your needle may be blocked or damaged. See **Frequently Asked Questions**.



- **Keep holding down the dose button with the needle in your skin andslowly count to 6** to make sure that the full dose has been delivered (See Figure P).



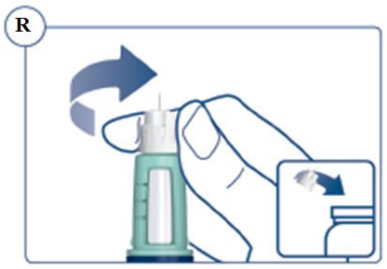
- Carefully remove the needle from your skin (See Figure Q). If blood appears at the injection site, press lightly with a gauze pad. Do not rub the area.



You may see a drop of SOGROYA at the needle tip after injecting. This is normal and does not affect your dose.

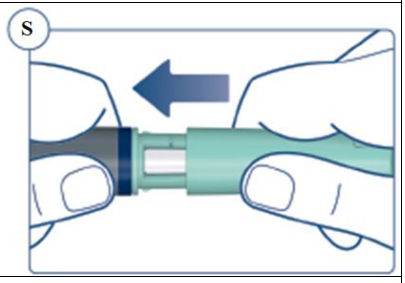
Step 5. After your injection

- Carefully remove the needle from the Pen by turning the needle counterclockwise (See Figure R).
- Place the needle in an FDA-cleared sharps disposal container immediately to reduce the risk of a needle stick (See Figure R).



Always throw away (dispose of) the needle after each injection.
For further information about safe sharps disposal, see **Frequently Asked Questions**.

- Put the Pen cap on your Pen after each use to protect SOGROYA from direct light (See Figure S).
  See "**How should I store my SOGROYA Pen?**".



Do not try to put the needle cap back on. You may stick yourself with the needle.

Always remove the needle from your Pen immediately after each injection. This reduces the risk of contamination, infection, leakage of SOGROYA, and blocked needles leading to incorrect dosing.

How should I store my SOGROYA Pen?

Before you use SOGROYA Pen for the first time:

- Store your new, unused SOGROYA Pen in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Store your new, unused SOGROYA Pen with the cap on and in the original carton.
- Do not freeze SOGROYA.
- When stored in the refrigerator, do not store the SOGROYA Pen directly next to the cooling element.
- Keep SOGROYA away from direct heat and light.
- Do not use SOGROYA if it has been frozen or in temperatures warmer than 86ºF (30°C).
- Do not use SOGROYA after the expiration date printed on the carton and the Pen.

After you use SOGROYA Pen and there is still medicine left:

- Store remaining SOGROYA in the refrigerator between 36°F to 46°F (2°C to 8°C) and use within 6 weeks.
- Store your in-use SOGROYA Pen with the cap on and keep it in the original carton.

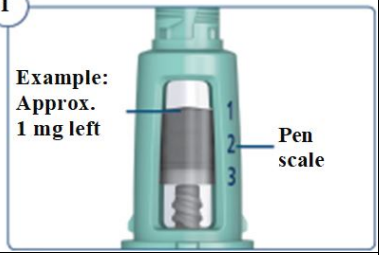
Do not store SOGROYA Pen with the needle attached.
If needed, unused and in-use SOGROYA pens can be stored out of the refrigerator. SOGROYA pens can be stored at room temperature no warmer than 77ºF (25ºC) for up to 3 days (72 hours) and then returned to the refrigerator. Throw away (dispose of) SOGROYA if it has been stored above 77°F (25°C) for more than 3 days (72 hours) **or** in temperatures warmer than 86°F (30°C).
Always keep your SOGROYA Pen and needles out of reach of others, especially children.

Frequently Asked Questions

How do I see how much SOGROYA is left in my Pen?

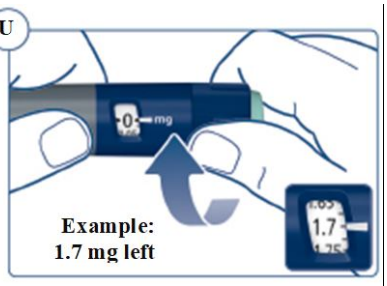
The Pen scale shows you approximately how much SOGROYA is left in your Pen (See Figure T).

T



To see how much SOGROYA is left in your Pen, use the dose counter:
Turn the dose selector clockwise until the dose counter stops. The dose pointer will line up with the number of “mg” left in the Pen. You can select a maximum dose of 2.0 mg. If the dose counter stops with the dose pointer lined up with “2”, at least 2.0 mg are left in your Pen.
If the dose counter stops with the dose pointer lined up with “1.7”, only 1.7 mg are left in your Pen (See Figure U).

U



What if I need a larger dose than what is left in my Pen?
It is not possible to select a larger dose on the dose counter than the number of “mg” left in your Pen. If you need more SOGROYA than you have left in your Pen, you can use a new Pen or split your dose between your current Pen and a new Pen. **Only split your dose if you have been trained or advised by your healthcare provider on how to do this.** You may find it helpful to use a calculator to plan the doses as instructed by your healthcare provider.
Be very careful to calculate your split dose correctly so that you do not give the wrong dose. If you are not sure how to split your dose using 2 Pens, then select and inject the dose you need with a new Pen.

What if no SOGROYA appears when I check the flow?
A. Your needle may be blocked or damaged, if no SOGROYA appears at the needle tip. Remove the needle as described in Step 5 and repeat Step 1 and Step 2.
B. Your Pen may be defective, if SOGROYA still does not appear after changing the needle. Do not use the Pen. Contact Novo Nordisk at 1-888-668-6444.

What if “0” does not appear after completing my injection?
The needle may be blocked or damaged, and **you have not received any SOGROYA**,even though the dose counter has moved from the dose that you have set. Remove the needle as described in Step 5 and repeat Step 1 to Step 4.

How should I take care of my Pen?
Be careful not to drop your Pen or knock it against hard surfaces. Do not expose your Pen to dust, dirt, liquid, or direct light. See “**How should I store SOGROYA?**” Do not try to refill your Pen, it is prefilled.

What if I drop my Pen?
If you drop your Pen or think that something is wrong with it, attach a new disposable needle and check the SOGROYA flow before you inject (See Step 1 and Step 2). Do not try to repair your Pen or pull it apart.

How do I clean my Pen?
Do not wash, soak, or lubricate your Pen. If necessary, clean it with mild detergent on a moistened cloth.

Frequently Asked Questions

How do I throw away (dispose of) used SOGROYAneedles and Pens?
Put your used needles and Pens in an FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and Pens in your household trash.** If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,

- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should dispose of used needles and Pens. For more information about safe sharps disposal, and for specific information about safe sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.
Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

Important information

- Caregivers must **be very careful when handling needles** to reduce the risk of needle sticks and infection.

PATENT Information: http://novonordisk-us.com/products/product-patents.html
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For further information contact:
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800 Scudders Mill Road
Plainsboro, NJ 08536, USA
1-888-668-6444
Sogroya.com
Manufactured by:
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Plainsboro, NJ 08536
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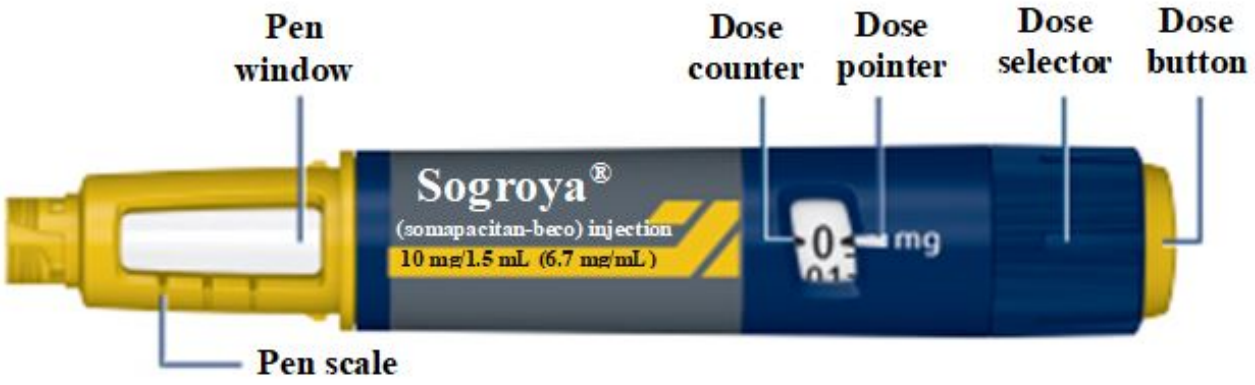
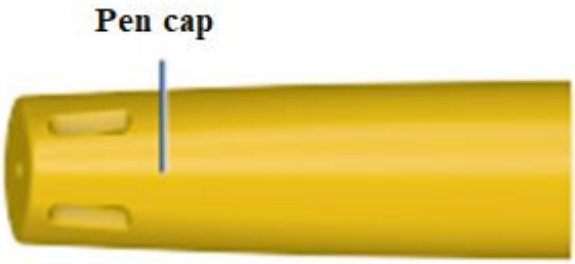
This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Issued: 10/2021
Version: 1

Instructions for Use – 10 mg/1.5 mL (6.7 mg/mL)

Instructions for Use
SOGROYA® 10 mg
(suh-GROY-uh)
(somapacitan-beco) injection
10 mg/1.5 mL (6.7 mg/mL)

SOGROYA Pen





Needle (example)

Supplies you will need:

- SOGROYA prefilled Pen
- new injection needle. SOGROYA prefilled Pen is designed to be used with all Novo Nordisk disposable needles up to a length of 8 mm.
- sharps disposal container. See Step 5 for information on how to throw away (dispose of) used needles and Pens.
- alcohol pad
- gauze pad

How to use your SOGROYA Pen
5 steps you should follow for a SOGROYA injection:
Step 1: Prepare your SOGROYA Pen

Step 2: Check the SOGROYA flow with each new Pen
Step 3: Select your dose
Step 4: Inject your dose
Step 5: After your injection

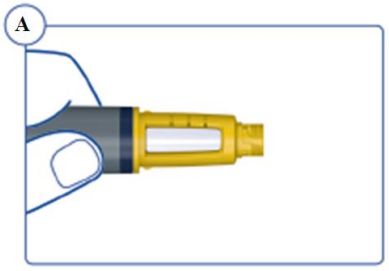
For further information about your Pen see: Frequently Asked Questions and Important information

Important information
Pay special attention to these notes as they are important for safe use of the Pen.

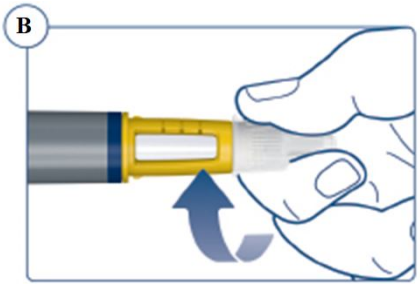
Additional information
SOGROYA is a prefilled growth hormone Pen. It contains 10 mg of somapacitan-beco and delivers doses from 0.05 mg to 4.0 mg, in increments of 0.05 mg. **SOGROYA is for use under the skin only (subcutaneous) for injection 1 time each week.**
Do not share your SOGROYA Pen and needles with another person. You may give another person an infection or get an infection from them.
Do not use your Pen without proper training from your healthcare provider. Make sure that you are confident in giving an injection with the Pen before you start your treatment. If you are blind or have poor eyesight and cannot read the dose counter on the Pen, do not use this Pen without help. Get help from a person with good eyesight who is trained to use the Pen.

Step 1. Prepare your SOGROYA Pen

- Wash your hands with soap and water.
- **Check the name, strength, and colored label** on your Pen to make sure that it contains SOGROYA in the right strength.
- Pull off the Pen cap.
- Turn the Pen upside down 1 or 2 times to check that the SOGROYA in your Pen is clear to almost clear and colorless to slightly yellow (See Figure A). **If SOGROYA looks cloudy or you see particles, do not use the Pen.**



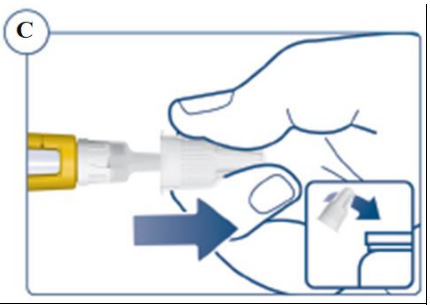
- When you are ready to give your injection, get a new disposable needle, and remove the paper tab.
- Push the needle straight onto the Pen. Turn the needle clockwise **until it is on tight** (See Figure B).



Make sure the right pen is used. Especially if you use more than one type of injection medicine. Using the wrong medicine could be harmful to your health.

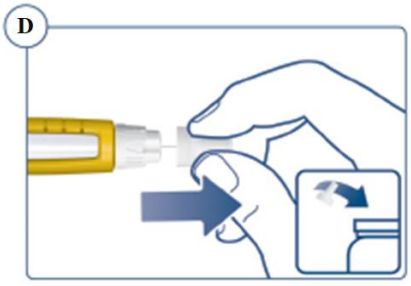
Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of SOGROYA, and blocked needles leading to incorrect dosing.

- Pull off the outer needle cap and throw it away (dispose of) (See Figure C).



- Pull off the inner needle cap and throw it away (dispose of) (See Figure D).

A drop of SOGROYA may appear at the needle tip. This is normal, but you must still check the SOGROYA flow with each new Pen (See Step 2).



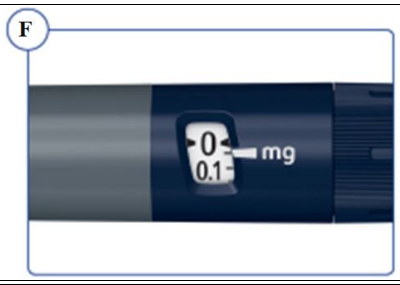
Never use a bent or damaged needle.

Step 2. Check the SOGROYA flow with each new Pen

If your Pen is already in use, go to Step 3.

- **Before using a new Pen**, check the SOGROYA flow to make sure the growth hormone can flow through the Pen and needle.
- Turn the dose selector clockwise 1 marking on the dose counter to select 0.05 mg. You may hear a faint “click” when you turn the dose selector (See Figure E).

- **1 marking on the dose counter equals 0.05 mg** (See Figure F).



- Hold the Pen with the needle pointing up. Press and hold in the dose button until the dose counter returns to “0”. **The “0” must line up with the dose pointer** (See Figure G).

- Check that a drop of SOGROYA appears at the needle tip (See Figure H).

If no SOGROYA appears, repeat Step 2 up to 6 times. If you still do not see a drop of SOGROYA, **change the needle:**

- Carefully remove the needle from the Pen by turning the needle counterclockwise. Place the needle in a sharps disposal container immediately (See Step 5).
- Repeat Step 2 again.

Do not use the Pen if a drop of SOGROYA still does not appear after changing the needle and repeating Step 2. Call Novo Nordisk at 1-888-668-6444 for help.

Step 3. Select your dose

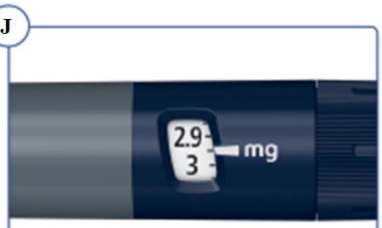
- To start, check that the dose pointer is set at "**0".**
- Turn the dose selector clockwise to select the dose you need (See Figure I). When you have selected your dose, you can go to Step 4.

If there is not enough SOGROYA left to select a full dose, see **Frequently Asked Questions**.

I

The dose counter shows the dose in "mg" (See Figure J and Figure K). Always use the dose counter to select the exact dose. **Do not use the "click" sounds you hear when you turn the dose selector to select your dose. Only the dose pointer on the dose counter will show the exact dose selected.**

J



Example: 2.95 mg selected

K

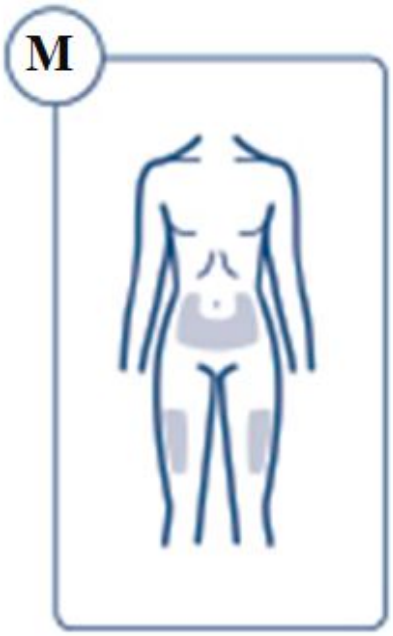
Example: 1.5 mg selected

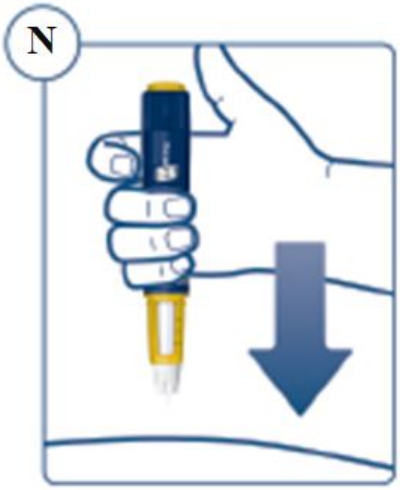
If you select the wrong dose, you can turn the dose selector clockwise or counterclockwise to the correct dose (See Figure L).
The Pen "clicks" sound and feel differently when the dose selector is turned clockwise, counterclockwise, or if you forcefully move it past the number of "mg" left in the Pen.

L

Step 4. Inject your dose

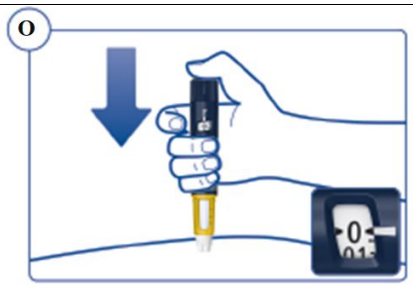
- Select the injection site.
- SOGROYA can be injected under the skin (subcutaneously) of your stomach area (abdomen) or upper legs (thighs) as instructed by your healthcare provider (See Figure M). **Change the injection site every week.**
- Wipe the injection site with an alcohol pad and let the area dry.
- Insert the needle into your skin as your healthcare provider has shown you (See Figure N).
- Make sure you can see the dose counter. **Do not cover it with your fingers.** This could block the injection.



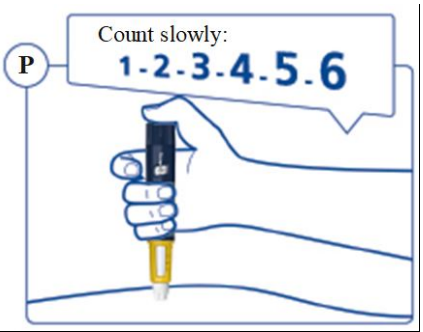


- Press and hold down the dose button until the dose counter shows “0” (See Figure O). **The “0” must line up with the dose pointer.** You may then hear or feel a “click”.
- **Continue to hold down the dose button with the needle in your skin.**

If “0” does not appear in the dose counter after continuously pressing the dose button, your needle may be blocked or damaged. See **Frequently Asked Questions**.

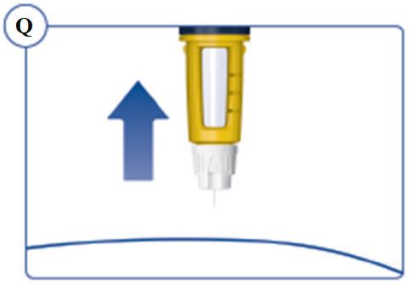


- **Keep holding down the dose button with the needle in your skinand slowly count to 6** to make sure that the full dose has been delivered (See Figure P).



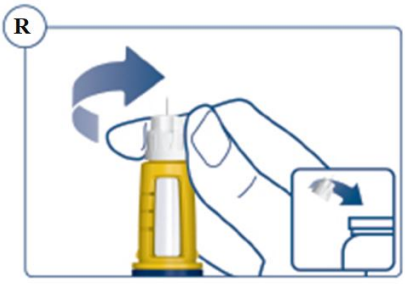
- Carefully remove the needle from your skin (See Figure Q). If blood appears at the injection site, press lightly with a gauze pad. Do not rub the area.

You may see a drop of SOGROYA at the needle tip after injecting. This is normal and does not affect your dose.



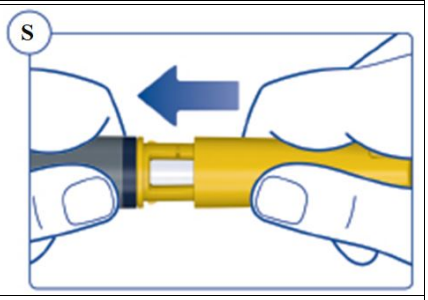
Step 5. After your injection

- Carefully remove the needle from the Pen by turning the needle counterclockwise (See Figure R).
- Place the needle in an FDA-cleared sharps disposal container immediately to reduce the risk of a needle stick (See Figure R).



Always throw away (dispose of) the needle after each injection.
For further information about safe sharps disposal, see **Frequently Asked Questions**.

- Put the Pen cap on your Pen after each use to protect SOGROYA from direct light (See Figure S).
  See "**How should I store my SOGROYA Pen?**".



Do not try to put the needle cap back on. You may stick yourself with the needle.

Always remove the needle from your Pen immediately after each injection. This reduces the risk of contamination, infection, leakage of SOGROYA, and blocked needles leading to incorrect dosing.

How should I store my SOGROYA Pen?

Before you use SOGROYA Pen for the first time:

- Store your new, unused SOGROYA Pen in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Store your new, unused SOGROYA Pen with the cap on and in the original carton.
- Do not freeze SOGROYA.
- When stored in the refrigerator, do not store the SOGROYA Pen directly next to the cooling element.
- Keep SOGROYA away from direct heat and light.
- Do not use SOGROYA if it has been frozen or in temperatures warmer than 86ºF (30°C).
- Do not use SOGROYA after the expiration date printed on the carton and the Pen.

After you use SOGROYA Pen and there is still medicine left:

- Store remaining SOGROYA in the refrigerator between 36°F to 46°F (2°C to 8°C) and use within 6 weeks.
- Store your in-use SOGROYA Pen with the cap on and keep it in the original carton.

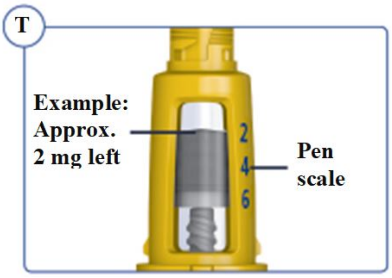
Do not store SOGROYA Pen with the needle attached.
If needed, unused and in-use SOGROYA pens can be stored out of the refrigerator. SOGROYA pens can be stored at room temperature no warmer than 77ºF (25ºC) for up to 3 days (72 hours) and then returned to the refrigerator. Throw away (dispose of) SOGROYA if it has been stored above 77°F (25°C) for more than 3 days (72 hours) **or** in temperatures warmer than 86°F (30°C).
Always keep your SOGROYA Pen and needles out of reach of others, especially children.

Frequently Asked Questions

How do I see how much SOGROYA is left in my Pen?

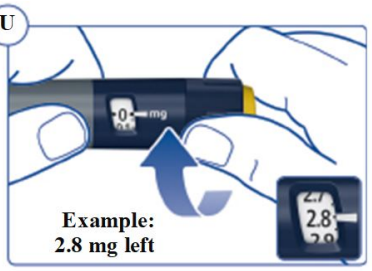
The Pen scale shows you approximately how much SOGROYA is left in your Pen (See Figure T).

T



To see how much SOGROYA is left in your Pen, use the dose counter:
Turn the dose selector clockwise until the dose counter stops. The dose pointer will line up with the number of "mg" left in the Pen. You can select a maximum dose of 4.0 mg. If the dose counter stops with the dose pointer lined up with "4", at least 4.0 mg are left in your Pen.
If the dose counter stops with the dose pointer lined up with "2.8", only 2.8 mg are left in your Pen (See Figure U).

U



What if I need a larger dose than what is left in my Pen?
It is not possible to select a larger dose on the dose counter than the number of "mg" left in your Pen. If you need more SOGROYA than you have left in your Pen, you can use a new Pen or split your dose between your current Pen and a new Pen. **Only split your dose if you have been trained or advised by your healthcare provider on how to do this.** You may find it helpful to use a calculator to plan the doses as instructed by your healthcare provider.
Be very careful to calculate your split dose correctly so that you do not give the wrong dose. If you are not sure how to split your dose using 2 Pens, then select and inject the dose you need with a new Pen.

What if no SOGROYA appears when I check the flow?
A. Your needle may be blocked or damaged, if no SOGROYA appears at the needle tip. Remove the needle as described in Step 5 and repeat Step 1 and Step 2.
B. Your Pen may be defective, if SOGROYA still does not appear after changing the needle. Do not use the Pen. Contact Novo Nordisk at 1-888-668-6444.

What if "0" does not appear after completing my injection?
The needle may be blocked or damaged, and **you have not received any SOGROYA**,even though the dose counter has moved from the dose that you have set. Remove the needle as described in Step 5 and repeat Step 1 to Step 4.

How should I take care of my Pen?
Be careful not to drop your Pen or knock it against hard surfaces. Do not expose your Pen to dust, dirt, liquid, or direct light. See "**How should I store SOGROYA?**" Do not try to refill your Pen, it is prefilled.

What if I drop my Pen?
If you drop your Pen or think that something is wrong with it, attach a new disposable needle and check the SOGROYA flow before you inject (See Step 1 and Step 2). Do not try to repair your Pen or pull it apart.

How do I clean my Pen?
Do not wash, soak, or lubricate your Pen. If necessary, clean it with mild detergent on a moistened cloth.

Frequently Asked Questions

How do I throw away (dispose of) used SOGROYAneedles and Pens?
Put your used needles and Pens in an FDA-cleared sharps disposal container right away

after use. **Do not throw away (dispose of) loose needles and Pens in your household trash.** If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should dispose of used needles and Pens. For more information about safe sharps disposal, and for specific information about safe sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.
Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

Important information

- Caregivers must **be very careful when handling needles** to reduce the risk of needle sticks and infection.

PATENT Information: http://novonordisk-us.com/products/product-patents.html
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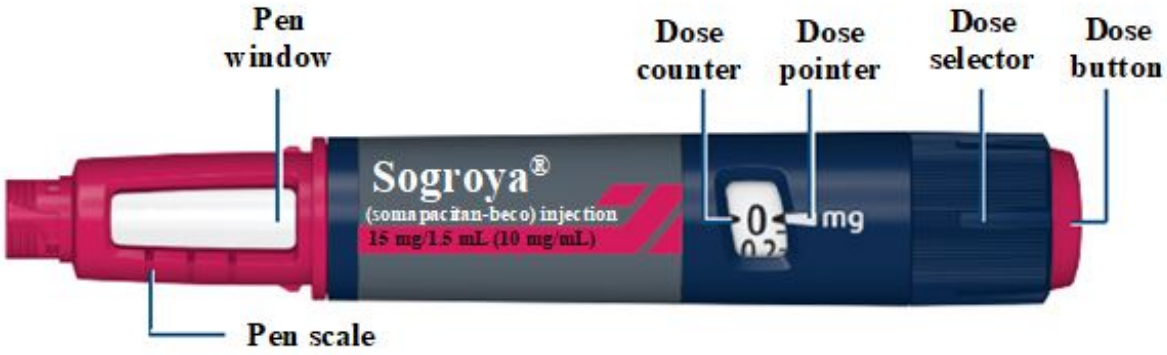
For further information contact:
Novo Nordisk Inc.
800 Scudders Mill Road
Plainsboro, NJ 08536, USA
1-888-668-6444
Sogroya.com
Manufactured by:
Novo Nordisk Inc.
Plainsboro, NJ 08536
U.S. License No. 1261
This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Revised: 10/2021
Version: 2

Instructions for Use – 15 mg/1.5 mL (10 mg/mL)

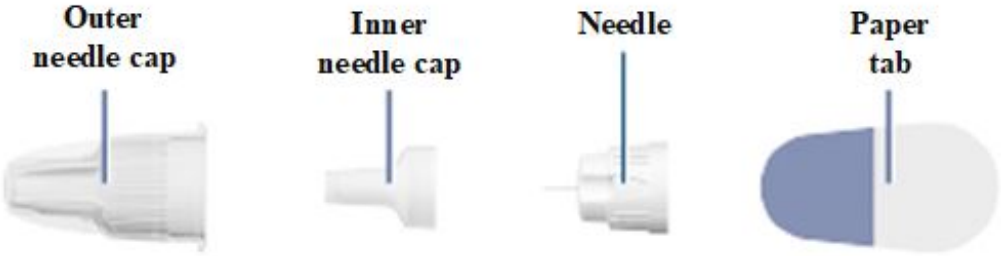
Instructions for Use
SOGROYA® 15 mg
(suh-GROY-uh)

(somapacitan-beco) injection
15 mg/1.5 mL (10 mg/mL)

SOGROYA pen



Needle (example)



Supplies you will need:

- SOGROYA prefilled Pen
- new injection needle. SOGROYA prefilled Pen is designed to be used with all Novo Nordisk disposable needles up to a length of 8 mm.
- sharps disposal container. See Step 5 for information on how to throw away (dispose of) used needles and Pens.
- alcohol pad
- gauze pad

How to use your SOGROYA Pen
5 steps you should follow for a SOGROYA injection:
Step 1: Prepare your SOGROYA Pen
Step 2: Check the SOGROYA flow with each new Pen
Step 3: Select your dose
Step 4: Inject your dose
Step 5: After your injection

For further information about your Pen see: Frequently Asked Questions and Important information

Important information

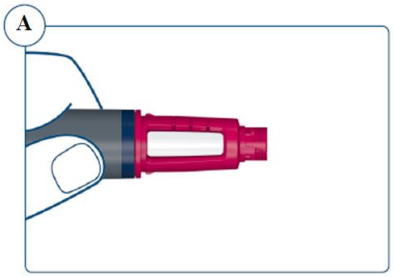
Pay special attention to these notes as they are important for safe use of the Pen.

Additional information

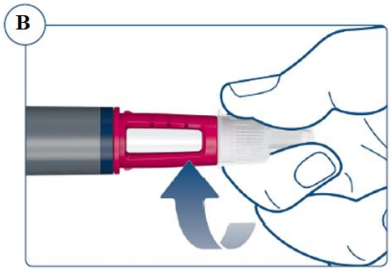
SOGROYA is a prefilled growth hormone Pen. It contains 15 mg of somapacitan-beco and delivers doses from 0.1 mg to 8.0 mg, in increments of 0.1 mg. **SOGROYA is for use under the skin only (subcutaneous) for injection 1 time each week.**
Do not share your SOGROYA Pen and needles with another person. You may give another person an infection or get an infection from them.
Do not use your Pen without proper training from your healthcare provider. Make sure that you are confident in giving an injection with the Pen before you start your treatment. If you are blind or have poor eyesight and cannot read the dose counter on the Pen, do not use this Pen without help. Get help from a person with good eyesight who is trained to use the Pen.

Step 1. Prepare your SOGROYA Pen

- Wash your hands with soap and water.
- **Check the name, strength, and colored label** on your Pen to make sure that it contains SOGROYA in the right strength.
- Pull off the Pen cap.
- Turn the Pen upside down 1 or 2 times to check that the SOGROYA in your Pen is clear to almost clear and colorless to slightly yellow (See Figure A). **If SOGROYA looks cloudy or you see particles, do not use the Pen.**



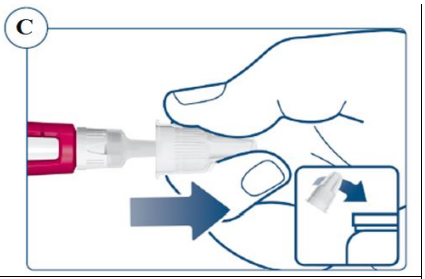
- When you are ready to give your injection, get a new disposable needle, and remove the paper tab.
- Push the needle straight onto the Pen. Turn the needle clockwise **until it is on tight** (See Figure B).



Make sure the right pen is used. Especially if you use more than one type of injection medicine. Using the wrong medicine could be harmful to your health.

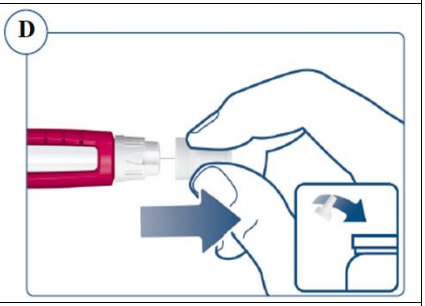
Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of SOGROYA, and blocked needles leading to incorrect dosing.

- Pull off the outer needle cap and throw it away (dispose of) (See Figure C).



- Pull off the inner needle cap and throw it away (dispose of) (See Figure D).

A drop of SOGROYA may appear at the needle tip. This is normal, but you must still check the SOGROYA flow with each new Pen (See Step 2).



Never use a bent or damaged needle.

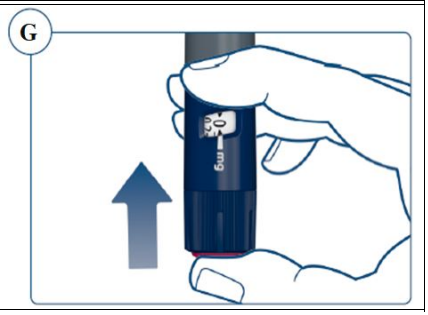
Step 2. Check the SOGROYA flow with each new Pen

If your Pen is already in use, go to Step 3.

- **Before using a new Pen**, check the SOGROYA flow to make sure the growth hormone can flow through the Pen and needle.
- Turn the dose selector clockwise 1 marking on the dose counter to select 0.1 mg. You may hear a faint “click” when you turn the dose selector (See Figure E).

- **1 marking on the dose counter equals 0.1 mg** (See Figure F).

- Hold the Pen with the needle pointing up. Press and hold in the dose button until the dose counter returns to “0”. **The “0” must line up with the dose pointer** (See Figure G).



- Check that a drop of SOGROYA appears at the needle tip (See Figure H).

If no SOGROYA appears, repeat Step 2 up to 6 times. If you still do not see a drop of SOGROYA, **change the needle:**

- Carefully remove the needle from the Pen by turning the needle counterclockwise. Place the needle in a sharps disposal container immediately (See Step 5).
- Repeat Step 2 again.

Do not use the Pen if a drop of SOGROYA still does not appear after changing the needle and repeating Step 2. Call Novo Nordisk at 1-888-668-6444 for help.

H

Step 3. Select your dose

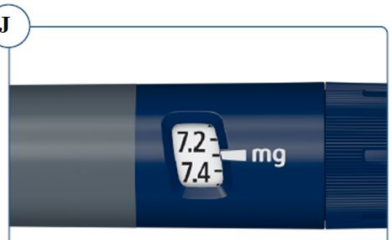
- To start, check that the dose pointer is set at "**0".**
- Turn the dose selector clockwise to select the dose you need (See Figure I). When you have selected your dose, you can go to Step 4.

If there is not enough SOGROYA left to select a full dose, see **Frequently Asked Questions**.

I

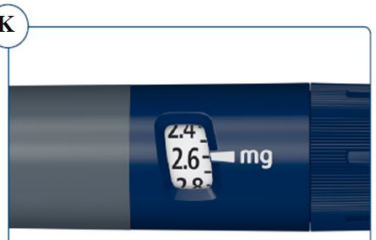
The dose counter shows the dose in "mg" (See Figure J and Figure K). Always use the dose counter to select the exact dose. **Do not use the "click" sounds you hear when you turn the dose selector to select your dose. Only the dose pointer on the dose counter will show the exact dose selected.**

J



Example: 7.3 mg selected

K



Example: 2.6 mg selected

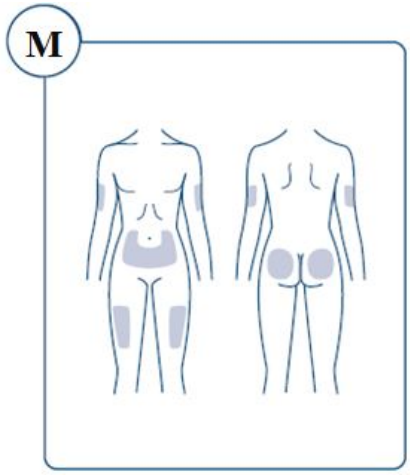
If you select the wrong dose, you can turn the dose selector clockwise or counterclockwise to the correct dose (See Figure L).
The Pen "clicks" sound and feel differently when the dose selector is turned clockwise, counterclockwise, or if you forcefully move it past the number of "mg" left in the Pen.

L

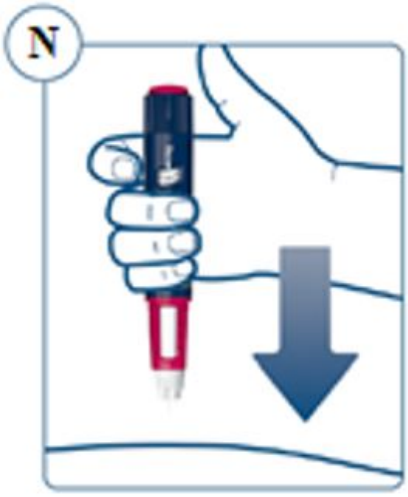
Step 4. Inject your dose

- Select the injection site.
- SOGROYA can be injected under the skin (subcutaneously) of your stomach area (abdomen), upper arms, upper legs (thighs) or buttocks as instructed by your healthcare provider (See Figure M). **Change the injection site every week.**
- Wipe the injection site with an alcohol pad and let the area dry.
- Insert the needle into your skin as your healthcare provider has shown you (See Figure N).
- Make sure you can see the dose counter. **Do not cover it with your fingers.** This could block the injection.

M



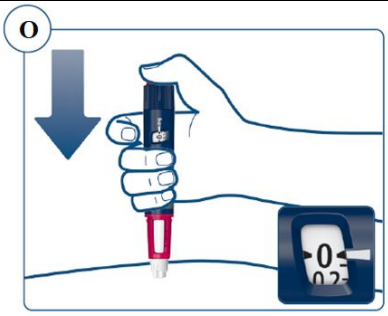
N



- Press and hold down the dose button until the dose counter shows “0” (See Figure O). **The “0” must line up with the dose pointer.** You may then hear or feel a “click”.
- **Continue to hold down the dose button with the needle in your skin.**

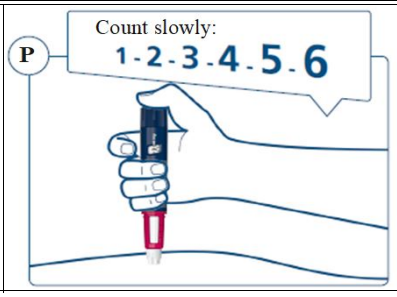
If “0” does not appear in the dose counter after continuously pressing the dose button, your needle may be blocked or damaged. See **Frequently Asked Questions**.

O

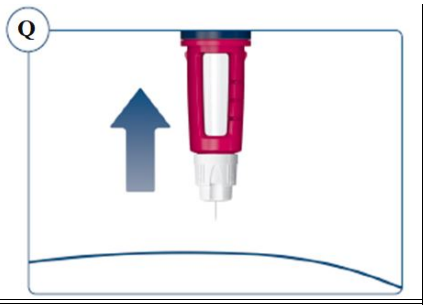


Keep holding down the dose button with the needle in your skinand slowly count to 6 to make sure that the full dose has been delivered (See Figure P).

P



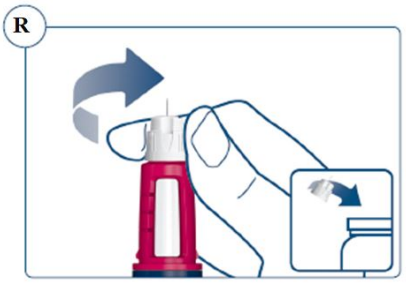
- Carefully remove the needle from your skin (See Figure Q). If blood appears at the injection site, press lightly with a gauze pad. Do not rub the area.



You may see a drop of SOGROYA at the needle tip after injecting. This is normal and does not affect your dose.

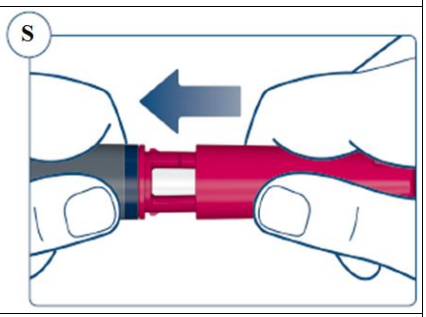
Step 5. After your injection

- Carefully remove the needle from the Pen by turning the needle counterclockwise (See Figure R).
- Place the needle in an FDA-cleared sharps disposal container immediately to reduce the risk of a needle stick (See Figure R).



Always throw away (dispose of) the needle after each injection.
For further information about safe sharps disposal, see **Frequently Asked Questions**.

- Put the Pen cap on your Pen after each use to protect SOGROYA from direct light (See Figure S).
  See "**How should I store my SOGROYA Pen?**".



Do not try to put the needle cap back on. You may stick yourself with the needle.

Always remove the needle from your Pen immediately after each injection. This reduces the risk of contamination, infection, leakage of SOGROYA, and blocked needles leading to incorrect dosing.

How should I store my SOGROYA Pen?

Before you use SOGROYA Pen for the first time:

- Store your new, unused SOGROYA Pen in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Store your new, unused SOGROYA Pen with the cap on and in the original carton.
- Do not freeze SOGROYA.
- When stored in the refrigerator, do not store the SOGROYA Pen directly next to the cooling element.
- Keep SOGROYA away from direct heat and light.
- Do not use SOGROYA if it has been frozen or in temperatures warmer than 86ºF (30°C).
- Do not use SOGROYA after the expiration date printed on the carton and the Pen.

After you use SOGROYA Pen and there is still medicine left:

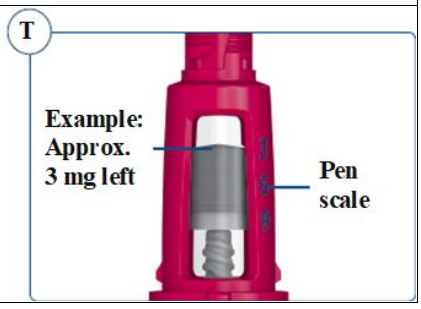
- Store remaining SOGROYA in the refrigerator between 36°F to 46°F (2°C to 8°C) and use within 6 weeks.
- Store your in-use SOGROYA Pen with the cap on and keep it in the original carton.

Do not store SOGROYA Pen with the needle attached.
If needed, unused and in-use SOGROYA pens can be stored out of the refrigerator. SOGROYA pens can be stored at room temperature no warmer than 77ºF (25ºC) for up to 3 days (72 hours) and then returned to the refrigerator. Throw away (dispose of) SOGROYA if it has been stored above 77°F (25°C) for more than 3 days (72 hours) **or** in temperatures warmer than 86°F (30°C).
Always keep your SOGROYA Pen and needles out of reach of others, especially children.

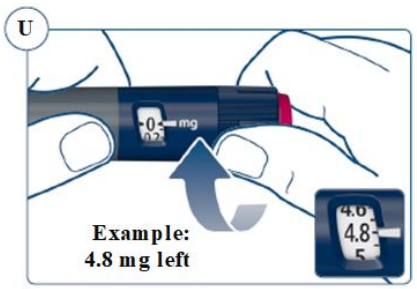
Frequently Asked Questions

How do I see how much SOGROYA is left in my Pen?

The Pen scale shows you approximately how much SOGROYA is left in your Pen (See Figure T).



To see how much SOGROYA is left in your Pen, use the dose counter:
Turn the dose selector clockwise until the dose counter stops. The dose pointer will line up with the number of "mg" left in the Pen. You can select a maximum dose of 8.0 mg. If the dose counter stops with the dose pointer lined up with "8", at least 8.0 mg are left in your Pen.
If the dose counter stops with the dose pointer lined up with "4.8", only 4.8 mg are left in your Pen (See Figure U).



What if I need a larger dose than what is left in my Pen?
It is not possible to select a larger dose on the dose counter than the number of "mg" left in your Pen. If you need more SOGROYA than you have left in your Pen, you can use a new Pen or split your dose between your current Pen and a new Pen. **Only split your dose if you have been trained or advised by your healthcare provider on how to do this.** You may find it helpful to use a calculator to plan the doses as instructed by your healthcare provider.
Be very careful to calculate your split dose correctly so that you do not give the wrong dose. If you are not sure how to split your dose using 2 Pens, then select and inject the dose you need with a new Pen.

What if no SOGROYA appears when I check the flow?
A. Your needle may be blocked or damaged, if no SOGROYA appears at the needle tip. Remove the needle as described in Step 5 and repeat Step 1 and Step 2.
B. Your Pen may be defective, if SOGROYA still does not appear after changing the needle. Do not use the Pen. Contact Novo Nordisk at 1-888-668-6444.

What if "0" does not appear after completing my injection?
The needle may be blocked or damaged, and **you have not received any SOGROYA**,even though the dose counter has moved from the dose that you have set. Remove the needle as described in Step 5 and repeat Step 1 to Step 4.

How should I take care of my Pen?
Be careful not to drop your Pen or knock it against hard surfaces. Do not expose your Pen to dust, dirt, liquid, or direct light. See "**How should I store SOGROYA?**" Do not try to refill your Pen, it is prefilled.

What if I drop my Pen?
If you drop your Pen or think that something is wrong with it, attach a new disposable needle and check the SOGROYA flow before you inject (See Step 1 and Step 2). Do not try to repair your Pen or pull it apart.

How do I clean my Pen?
Do not wash, soak, or lubricate your Pen. If necessary, clean it with mild detergent on a moistened cloth.

Frequently Asked Questions

How do I throw away (dispose of) used SOGROYAneedles and Pens?
Put your used needles and Pens in an FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and Pens in your household trash.** If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,

- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should dispose of used needles and Pens. For more information about safe sharps disposal, and for specific information about safe sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.
Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

Important information

- Caregivers must **be very careful when handling needles** to reduce the risk of needle sticks and infection.

www.sogroya.com

PATENT Information: http://novonordisk-us.com/products/product-patents.html

SOGROYA® is a registered trademark of Novo Nordisk Health Care AG.

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U.S. License No. 1261

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Issued: 4/2023
Version: 1

Instructions for Use – Norditropin® and Sogroya® with PenMate®

INSTRUCTIONS FOR USE
Norditropin® (nor-dee-tro-pin) **FlexPro®**
(somatropin)
injection
prefilled pen with PenMate®
and
Sogroya® (suh-GROY-uh)
(somapacitan-beco)
injection
prefilled pen with PenMate®

Read this Instructions for Use before you start using your Pen with PenMate.

- PenMate hides the needle when you inject your Norditropin growth hormone with Norditropin FlexPro 5 mg/1.5 mL, 10 mg/1.5 mL, and 15 mg/1.5 mL Pens **or** Sogroya growth hormone with Sogroya 5 mg/1.5 mL, 10 mg/1.5 mL, and 15 mg/1.5 mL Pens, so that you cannot see the needle.
- Use your PenMate only after you have been trained by a healthcare provider.
- People who are blind or have poor eyesight should only use the PenMate and Pen with help from a person with good eyesight who is trained to use the PenMate and Pen.
- The figures in this Instructions for Use show PenMate being used with a Norditropin FlexPro 5 mg/1.5 mL Pen and a NovoFine needle that is **8 mm** long. Even if you are using a Norditropin FlexPro 10 mg/1.5 mL or 15 mg/1.5 mL Pen or a Sogroya 5 mg/1.5 mL, 10 mg/1.5 mL, or 15 mg/1.5 mL Pen or a different needle that is **8 mm** long, the instructions are the same.
- **Do not** share your Norditropin FlexPro or Sogroya Pens and needles with another person. You may give another person an infection or get an infection from them.

Supplies you will need to use your Pen with PenMate:

- 1 PenMate. **See Figure A.**
- 1 Norditropin FlexPro Pen or Sogroya Pen. **See Figure B.** PenMate does not work with other injection devices.
- 1 disposable needle up to **8 mm** long**.See Figure C.** Needles are not included with your PenMate or Pen.
- 2 alcohol swabs. **See Figure C.**
- a sharps disposal container. **See Figure C.** See **"How should I dispose of my Pen and needles"** at the end of these instructions for information on how to throw away (dispose of) used Pens and needles.

PenMate:

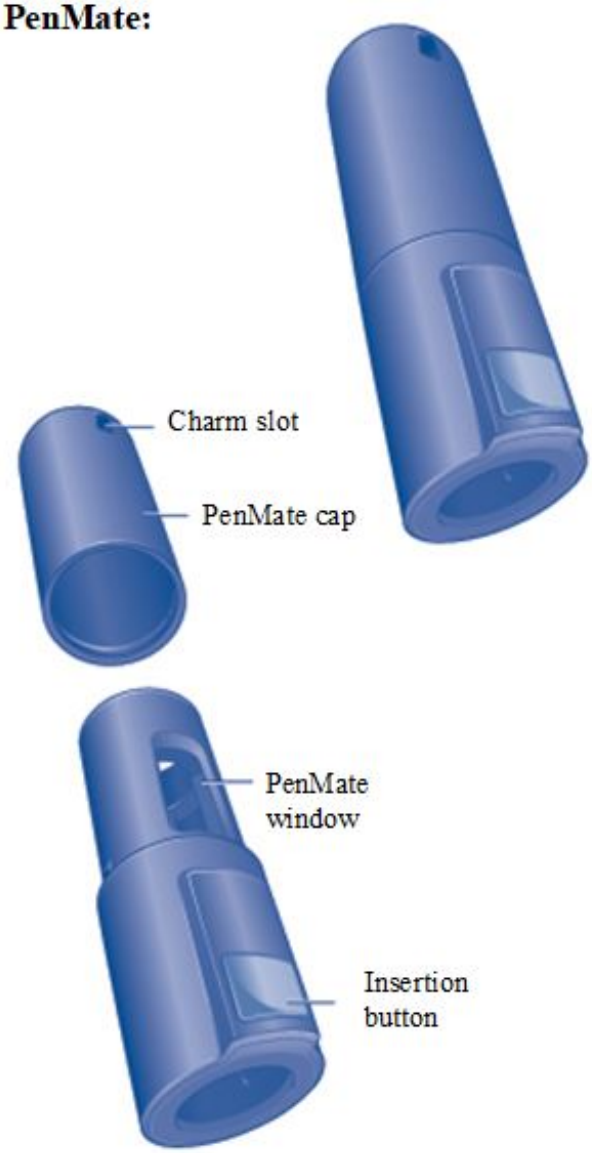


Figure A

Pen:
This pen represents Norditropin FlexPro 5 mg/1.5 mL, 10 mg/1.5 mL or 15 mg/1.5 mL Pen and Sogroya 5 mg/1.5 mL, 10 mg/1.5 mL, and 15 mg/1.5 mL Pen

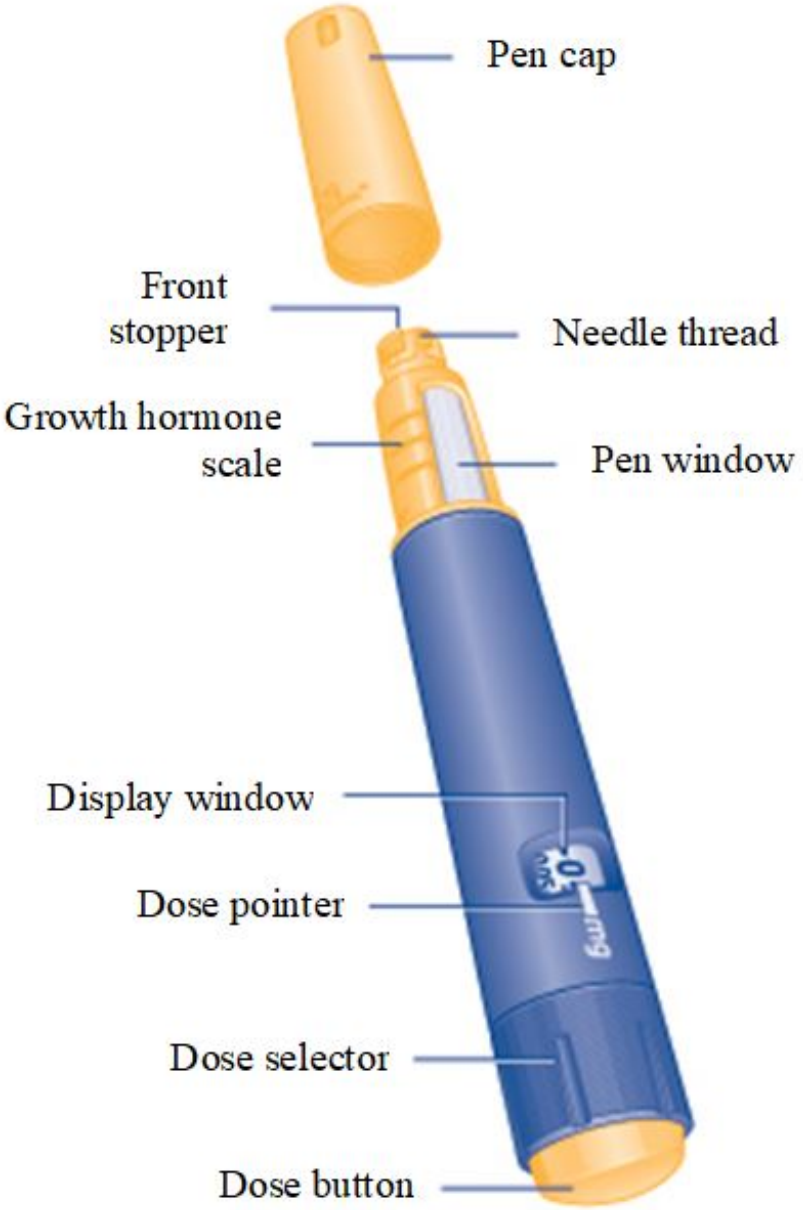


Figure B

Needle parts and supplies:

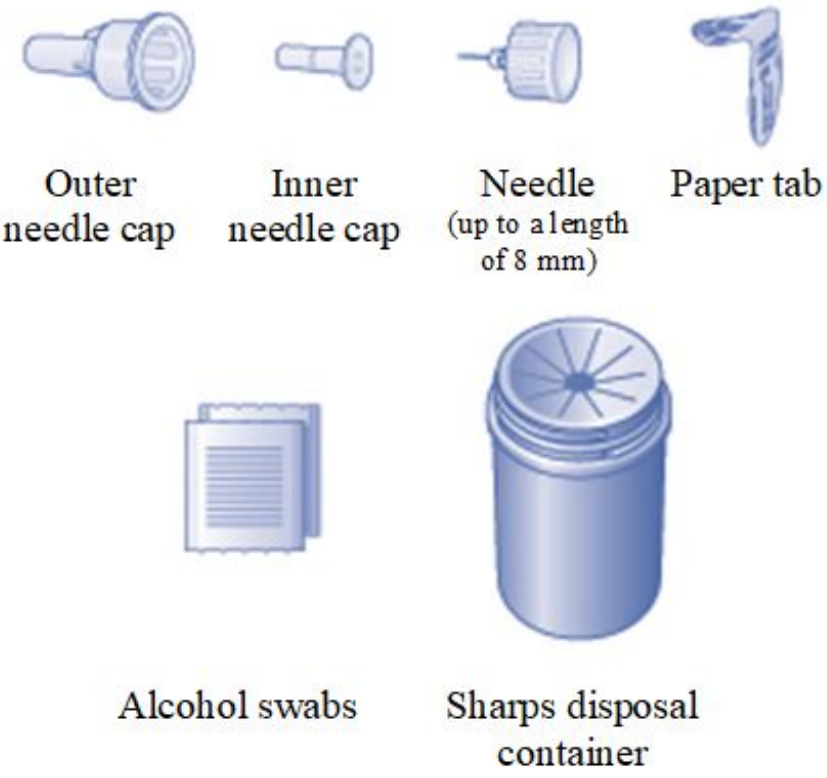

Outer needle cap
Inner needle cap
Needle (up to a length of 8 mm)
Paper tab
Alcohol swabs
Sharps disposal container

Figure C

Pen case:

Pen and needles are not included in the case.

Figure D

Step 1:PreparingyourPenwithPenMate:
Wash your hands with soap and water and dry them. Check the name and the colored label on your Pen to make sure it contains the growth hormone strength prescribed by your healthcare provider.

Pull off the PenMate cap.
See Figure E.

PenMate cap

Figure E

Pull off the Pen cap and throw it away. **See Figure F.**

You will not need the Pen cap with your PenMate.

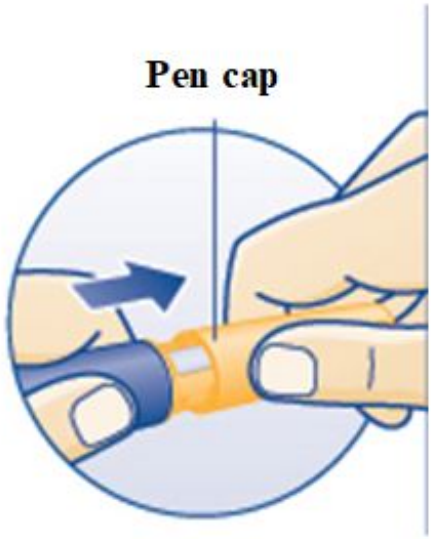


Figure F

Look in the Pen window. Check the liquid medicine in your Pen by turning it upside down 1 or 2 times.
See Figure G.

- **Norditropin FlexPro Pen**: the liquid in the Norditropin FlexPro Pen should be clear and colorless. **If the liquid looks cloudy or you see particles, do not use the Norditropin FlexPro Pen**.
- **Sogroya Pen**: the liquid in the Sogroya Pen should be clear to almost clear and colorless to slightly yellow. **If the liquid looks cloudy or you see particles, do not use the Sogroya Pen**.

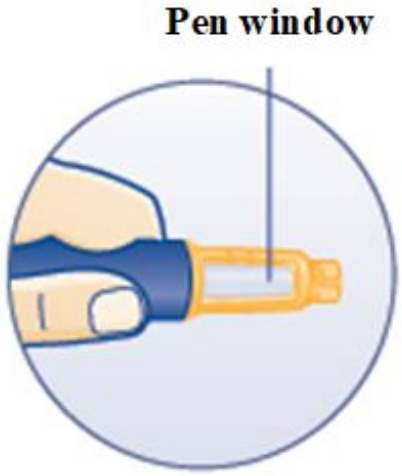


Figure G

Wipe the front stopper on the needle thread of the Pen with an alcohol swab.
See Figure H.

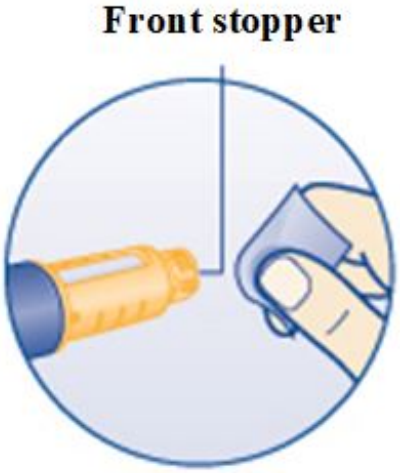


Figure H

Insert the Pen into the PenMate. Twist the Pen clockwise until you hear or feel a click.

See Figure I.

The Pen is correctly attached in your PenMate when the display window on the Pen lines up with the insertion button on your PenMate.

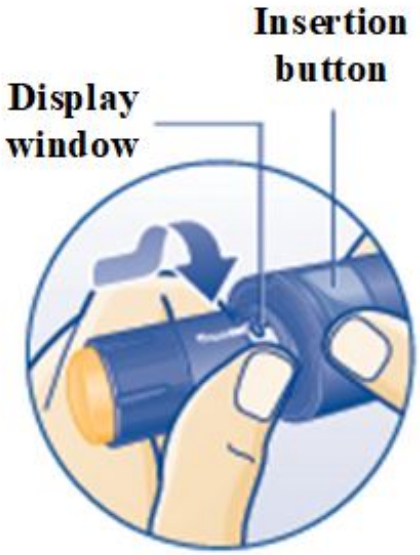
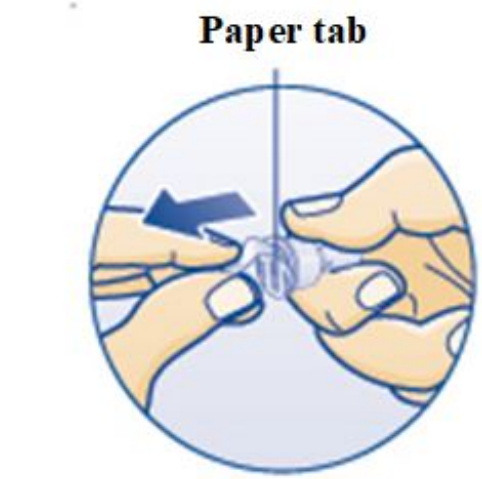
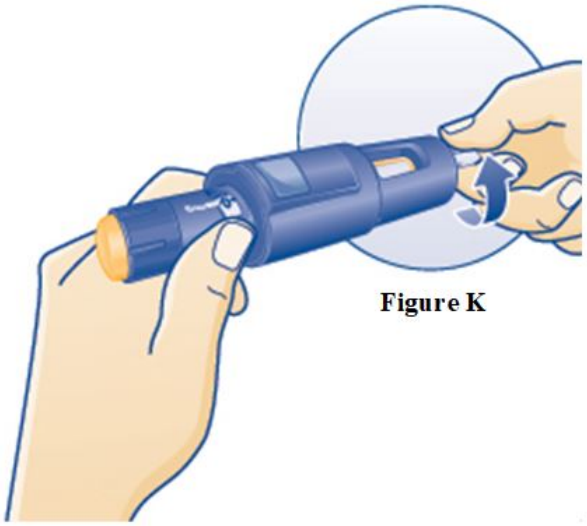
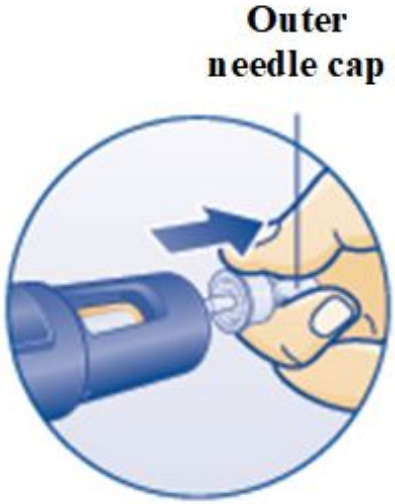


Figure I

Step 2. Attaching the needle to your Pen:

- **Do not** place a needle on your Pen until you are ready to give an injection.
- Always use a new needle for each injection.
- **Do not** use a bent or damaged needle.

Get a new disposable needle and tear off the paper tab. **See Figure J.**	 **Figure J**
Holding the Pen with 1 hand, firmly press the needle onto the needle thread of the Pen. Screw the needle in a clockwise direction until the needle will not turn anymore. **See Figure K.**	 **Figure K**
Pull off the outer needle cap and save it. **See Figure L.** You will need the outer needle cap after the injection so you can safely remove the needle from the Pen.	 **Figure L**

Pull off the inner needle cap and throw it away.
See Figure M.

A drop of liquid may appear at the needle tip. This is normal.

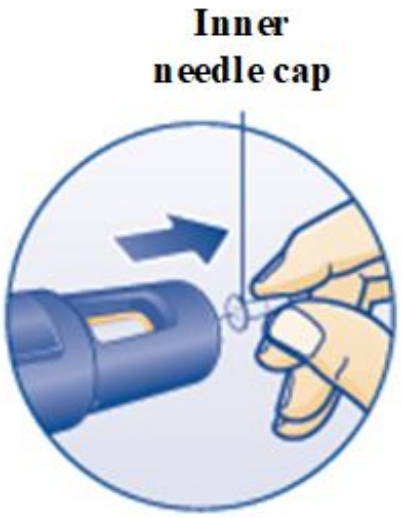


Figure M

Step 3. Priming a new Pen:
Checking the growth hormone flow in the Pen (priming) is not needed for a Pen you have used before.
If the Pen has already been primed, go to Step 4.

Before you use a new Pen you must prepare it for use. Hold the Pen with 1 hand and turn the dose selector clockwise 1 marking to select the **minimumdose.**
See Figure N.
You may hear or feel a click when you turn the dose selector.

Figure N

When you turn the dose selector 1 marking, you select the smallest amount of medicine for a dose.
See Figure O.

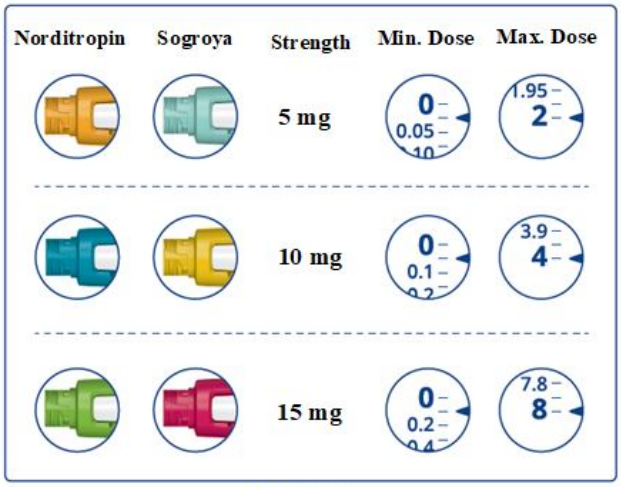


Figure O

This lowest dose will be used for your Norditropin or Sogroya flow check dose. Hold your Pen with PenMate with the needle pointing up. You may see air bubbles in the PenMate window. Gently tap the top of PenMate a few times to let any air bubbles rise to the top.
See Figure P.

Figure P

Press the dose button until the dose pointer lines up with the **"0"** in the display window on the Pen and a drop of liquid appears at the needle tip.
See Figure Q.

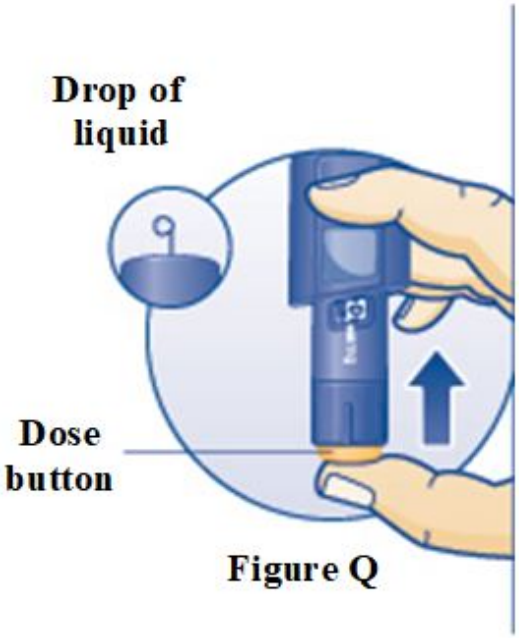


Figure Q

If no drop of liquid appears at the needle tip, repeat Step 3 again up to 6 times. If there is still no drop of liquid at the needle tip, **change the needle** and repeat Step 3 again.

If a drop of liquid still does not appear at the needle tip after repeating Step 3 and changing the needle, call Novo Nordisk at 1-888-668-6444 for help.

Step 4. Selecting the correct dose of Norditropin or Sogroya:

Use the dose selector on your Pen to make sure you have the exact dose selected. Your dose will be in a certain number of mg (milligrams).

To start, check that the dose pointer on the Pen is set at **"0".**

Select the dose you need by turning the dose selector clockwise. If you move past your dose, turn the dose selector counterclockwise until the right number of mg lines up with the dose pointer. **See Figure R.**

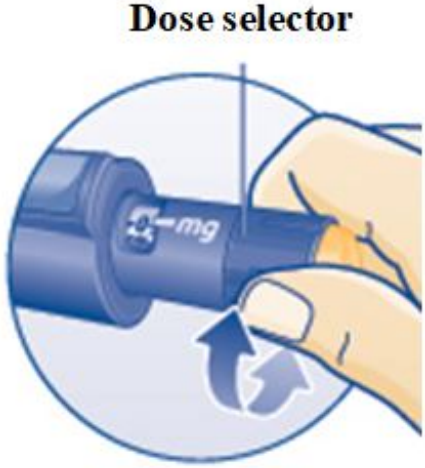


Figure R

To guide you, the dose selector click sound is different when turned clockwise (softer click) or counterclockwise (louder click). You will hear a click for every single unit dialed. When dialing counterclockwise, be careful not to press the dose button as liquid will come out.

You can use the growth hormone scale on the side of the Pen to see about how much growth hormone is left in the Pen. You can also use the dose selector to see exactly how much growth hormone is left in the Pen.

If the Pen contains less than 2 mg, 4 mg, or 8 mg (depending on whether you use a 5 mg/1.5 mL, 10 mg/1.5 mL, or 15 mg/1.5 mL Pen), turn the dose selector until it stops. The number that lines up with the dose pointer shows how many mg are left in the Pen. You cannot set a dose higher than the number of mg left in the Pen.

If there is not enough Norditropin or Sogroya left in the Pen for your full dose, use a new Norditropin FlexPro Pen or Sogroya Pen to inject the remaining amount of your dose or contact your healthcare provider.

Remember to subtract the dose already received. For example, if the dose is 0.7 mg and you can only set the dose selector to 0.35 mg, you should inject another 0.35 mg with a new Norditropin FlexPro Pen or Sogroya Pen.

Important:

- **Do not use the Pen clicks to count the number of mg you select. Only the display window and dose pointer will show the exact number.**
- **Do not use the growth hormone scale to measure how much liquid to inject. Only the display window and dose pointer will show the exact**

number.

Step 5. Selecting your injection site and injecting the dose of Norditropin or Sogroya:
Change your injection site every day. Select the injection site and wipe your skin with an alcohol swab as your healthcare provider showed you.

Norditropin or Sogroya can be injected under your skin (subcutaneously) of your buttocks, stomach area (abdomen), upper legs (thighs), upper arms, or as instructed by your healthcare provider.
See Figure S.

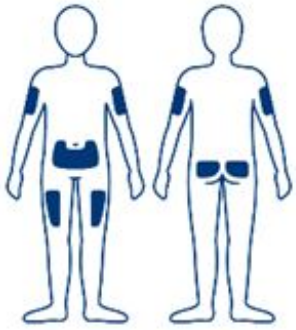


Figure S

Hold onto both the PenMate and your Pen without touching the insertion button on the PenMate **or** the dose button on the Pen.
Do not press the insertion button on the PenMate before you are ready to inject your dose. This lowers the risk of hurting yourself with the needle.

Hold the PenMate firmly with 1 hand and pull the Pen out with your other hand until you hear and feel a click. **See Figure T.**
The needle is now hidden in PenMate.

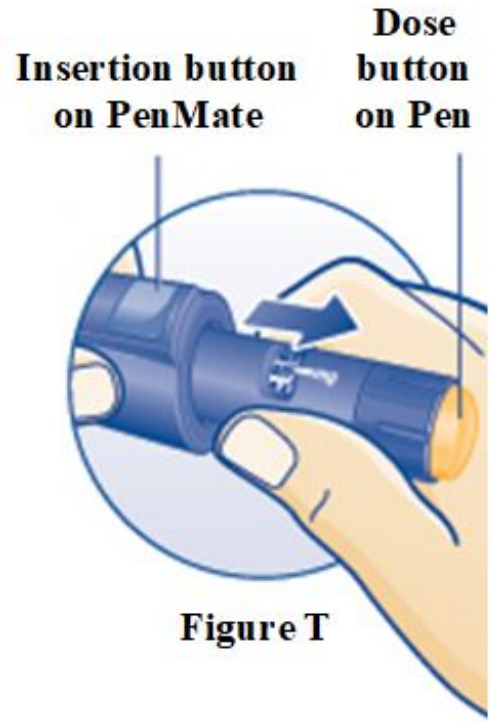


Figure T

Norditropin and Sogroya is for use under your skin only (subcutaneous). Hold the PenMate against your skin. Press the insertion button on the PenMate until you hear or feel a click.

When you hear or feel the click, the needle has been inserted automatically into your skin.
See Figure U.
You are now ready to inject your dose.

Figure U

Press the dose button on the Pen to inject your dose.Do not turn the dose button while you are pressing it. If you turn the dose button, you will not inject growth hormone.
Make sure you can see the display window. **Do not** cover it with your fingers.
Press and hold down the dose button on the Pen until the display window returns to "0".
The **"0"** must line up with the dose pointer. You may then hear or feel a firm click.

After the display window has returned to "0", leave the needle under your skin for at least 6 seconds to make sure you get your full dose.
See Figure V.
Let go of the dose button while you wait.
See Figure V.

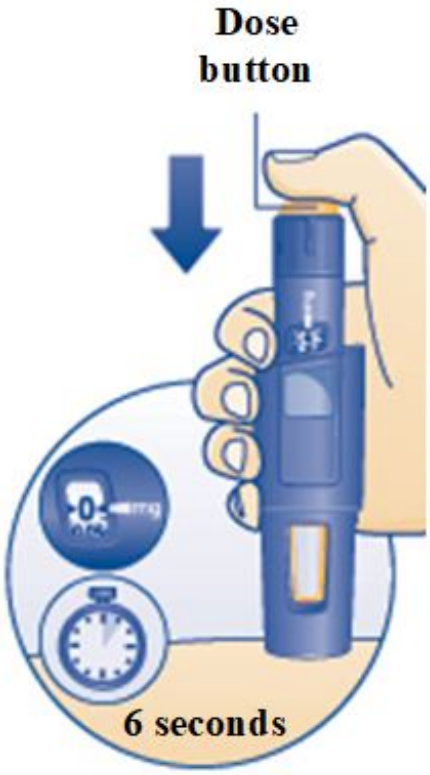


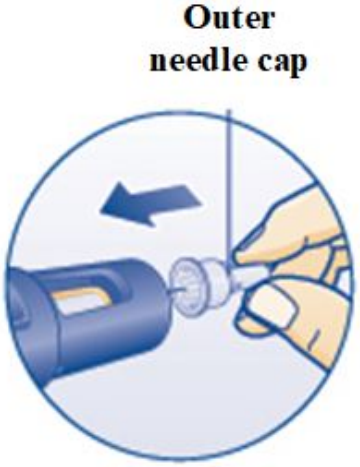
Figure V

If the dose button cannot be pushed in completely or "0" does not appear in the display window, you did not receive the full dose. Call Novo Nordisk at 1-888-668-6444 for help. You may need a new Pen.
Important:
Always press the dose button to inject the dose. Turning the dose selector will not inject the dose.
Do not touch the display window when you inject, as this can block the injection.

Carefully lift the Pen to remove the needle from the skin.
See Figure W.

Figure W

Step 6. What to do after your injection is completed:

Carefully put the outer needle cap back on the needle. Remove the needle from the Pen after each injection. **See Figure X.**	 **Figure X**
Unscrew the needle by turning it counterclockwise. Do not touch the needle. Hold the Pen with 1 hand and carefully remove the needle from the Pen with your other hand. **See Figure Y.** Throw away (dispose of) the needle. See **"How should I dispose of my Pen and needles?"** at the end of these instructions.	 **Figure Y**
Put the PenMate cap back on your PenMate after each use to protect the growth hormone from direct light. **See Figure Z.**	 **Figure Z**

Important safety information to remember:

- Be careful not to drop your PenMate and Pen or knock them against a hard surface. If this happens you will need to check the growth hormone flow.
- **Donot** try to put the inner needle cap back on the needle. You may stick yourself

with the needle. Be careful when handling used needles to avoid needle stick injuries.

- After each use always remove and throw away (dispose of) the needle from your Pen.
- **Do not** share your Pen or needles with other people.
- If your PenMate is damaged or lost, you can still use your Pen without your PenMate.
- Always keep your Pen and needles out of reach of others, especially children.

How should I replace an empty Pen?
PenMate is reusable and should not be thrown away (disposed of). Reuse your PenMate by replacing your Pen when it is empty.

When your Pen is empty, **twist thePen** counterclockwiseuntil you hear or feel a click.
See Figure AA.

Figure AA

Gently pull the Pen out of PenMate.
See Figure BB.
Before throwing away (disposing of) your empty Pen, make sure the needle has been removed. See **"How should I dispose of my Pen and needles?"** at the end of these instructions.

Figure BB

Insert the new Pen into your PenMate.
See Figure CC.

Figure CC

Twist the Pen clockwise until you hear or feel a click.
See Figure DD.
The Pen is correctly attached in your PenMate when the display window on the Pen lines up with the insertion button on your PenMate.

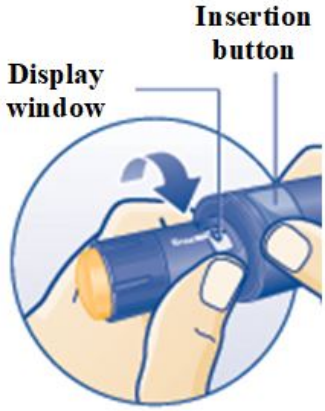


Figure DD

How should I store my PenMate and Pen?

- Do not expose your PenMate or Pen to dust, dirt, liquid, or direct light.
- Store your PenMate and Pen in their case. See **FigureD** at the beginning of these instructions.
- When your Pen is inserted in PenMate, store it as described in the Patient Information leaflet that comes with your Pen.

How should I care for and clean my Pen with PenMate?

- **Do not** try to refill your Pen. It is prefilled.
- **Do not** try to repair your PenMate or your Pen.
- Only clean your PenMate or Pen with a mild detergent on a moistened cloth.
- **Do not** wash, soak, or lubricate your PenMate or Pen. Do not use products containing bleaching agents, such as chlorine, iodine, or alcohol to clean your PenMate or Pen. These products may damage them.
- If there is liquid growth hormone on the outside of your PenMate or Pen, clean it with a mild detergent on a moistened cloth **before it dries up.**

How should I throw away (dispose of) my Pen and needles?

- Put your used needles and Pens in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and Pens in your household trash.**
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
    - made of a heavy-duty plastic,
    - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
    - upright and stable during use,
    - leak-resistant, and
    - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and Pens. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

Need help?

PenMate must only be used according to the instructions provided. The manufacturer cannot be held responsible for any problems with PenMate if these instructions have not been followed.

If you find that your PenMate or case is defective, make sure to have Novo Nordisk replace it. Call the number below to order a new PenMate or case and arrange return of the defective item for inspection.

For help or further information, write to:
Novo Nordisk Inc.
800 Scudders Mill Road
Plainsboro, NJ 08536, USA
Visit norditropin.com or sogroya.com
Or call: 1-888-668-6444
PATENT Information: http://novonordisk-us.com/products/product-patents.html

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Manufactured by:
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Novo Allé
DK-2880 Bagsvaerd
Denmark
This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Issued: 01/2025

PRINCIPAL DISPLAY PANEL – 5 mg

Sogroya® 5 mg pen NDC 0169-2035-11
(somapacitan-beco) injection List: 203511

5 mg / 1.5 mL (3.3 mg/mL) Prefilled Pen

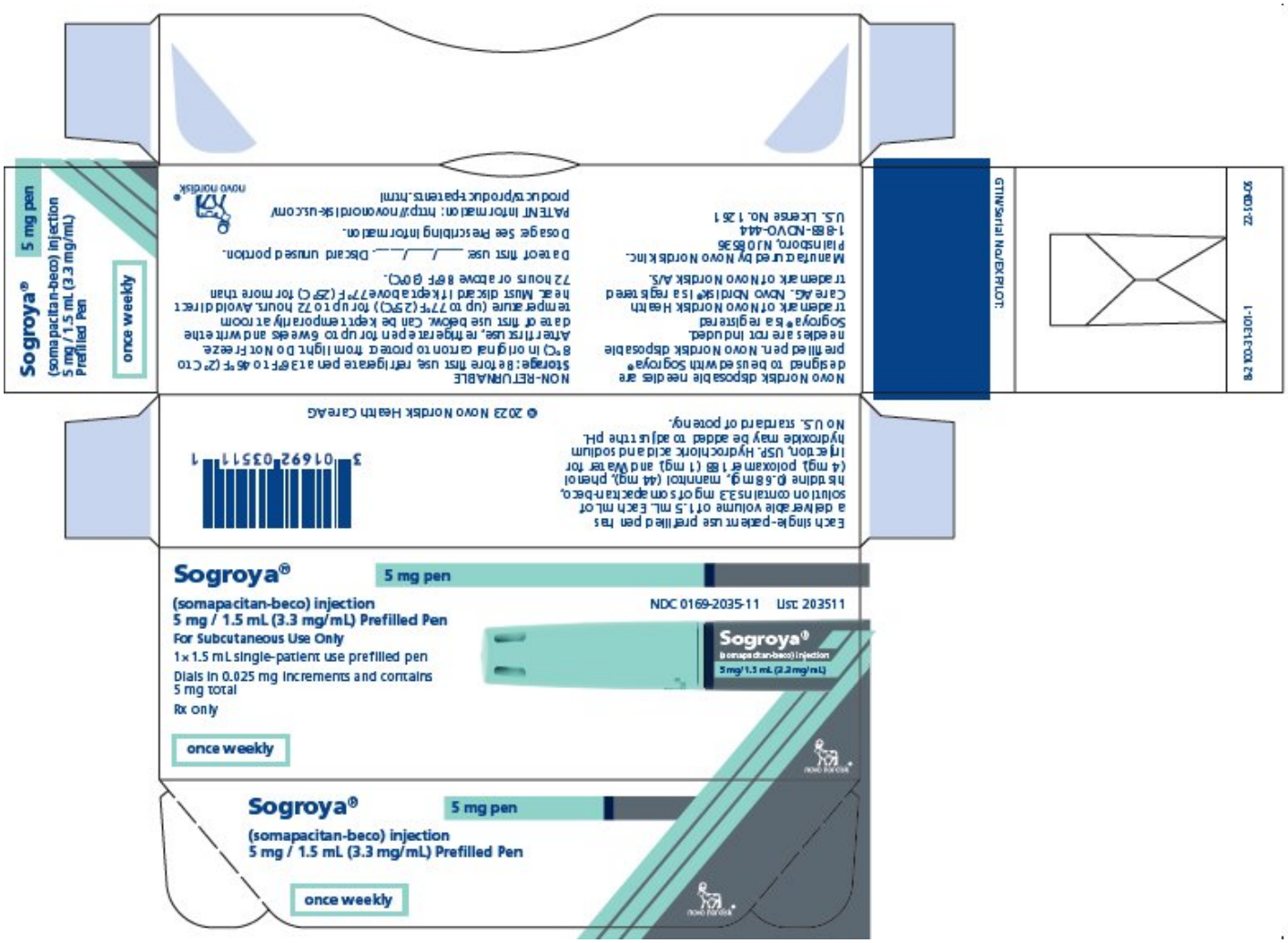
For subcutaneous Use Only

1x1.5 mL single-patient use prefilled pen

Dials in 0.025 mg increments and contains 5 mg total

Rx only

once weekly



PRINCIPAL DISPLAY PANEL – 10 mg

Sogroya® 10 mg pen NDC 0169-2030-11
(somapacitan-beco) injection List: 203011

10 mg / 1.5 mL (6.7 mg/mL) Prefilled Pen

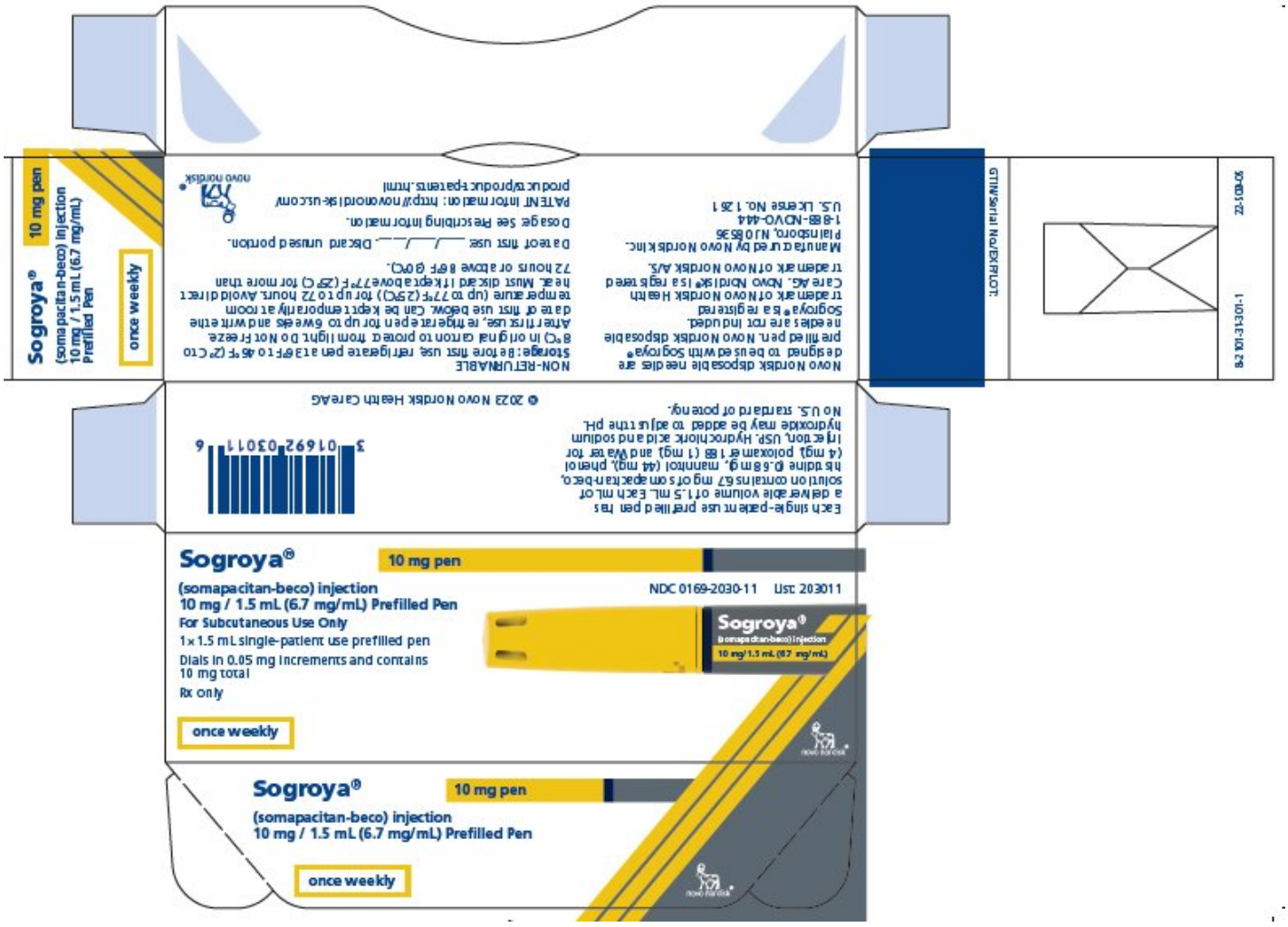
For subcutaneous Use Only

1x1.5 mL single-patient use prefilled pen

Dials in 0.05 mg increments and contains 10 mg total

Rx only

once weekly



PRINCIPAL DISPLAY PANEL – 15 mg

Sogroya® 15 mg pen NDC 0169-2037-11
(somapacitan-beco) injection List: 203711

15 mg / 1.5 mL (10 mg/mL) Prefilled Pen

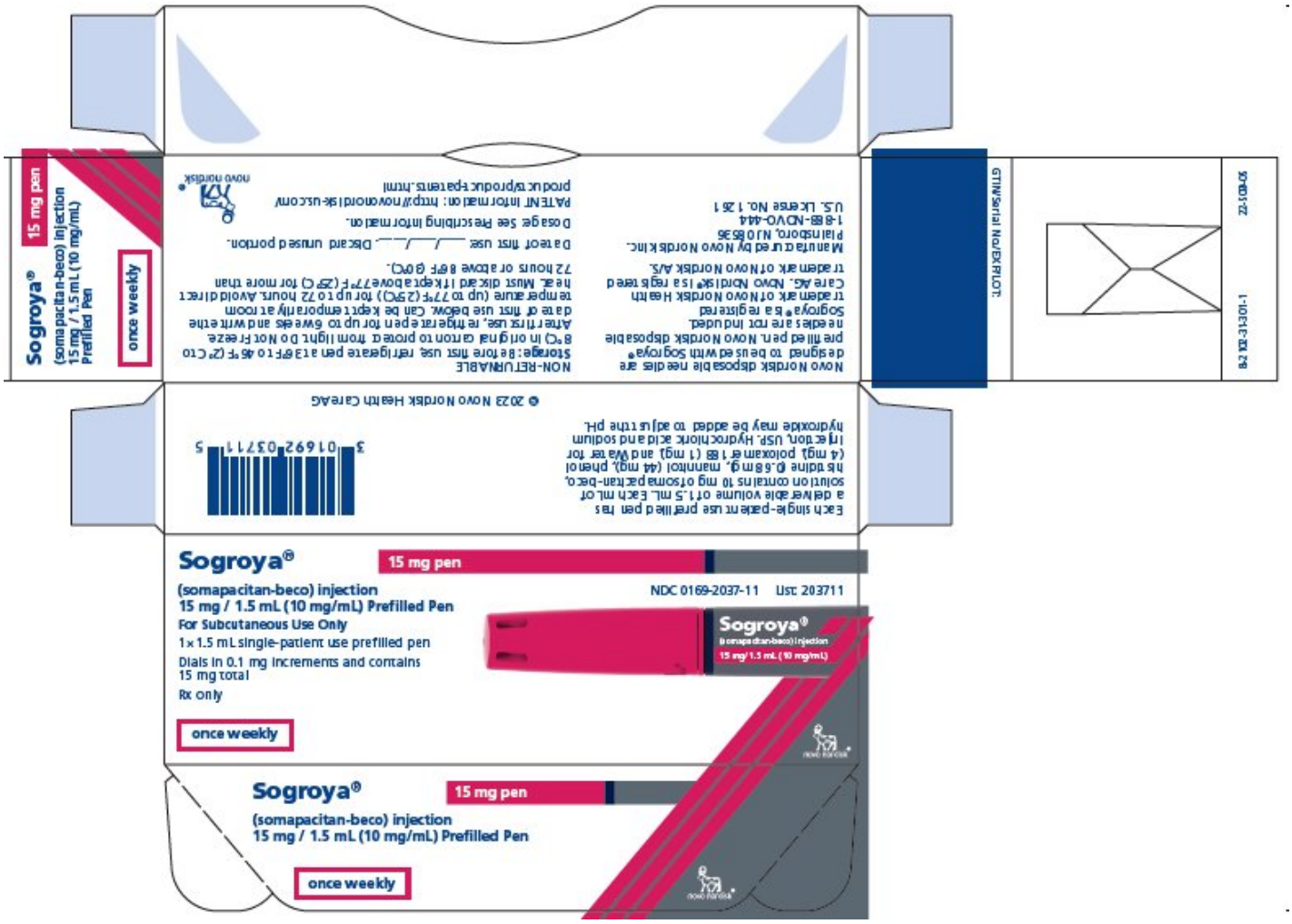
For subcutaneous Use Only

1x1.5 mL single-patient use prefilled pen

Dials in 0.1 mg increments and contains 15 mg total

Rx only

once weekly



SOGROYA

somapacitan-beco injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0169-2035
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SOMAPACITAN (UNII: 8FOJ430U94) (SOMAPACITAN - UNII:8FOJ430U94)	SOMAPACITAN	3.3 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
HISTIDINE (UNII: 4QD397987E)	0.68 mg in 1 mL
MANNITOL (UNII: 3OWL53L36A)	44 mg in 1 mL
PHENOL (UNII: 339NCG44TV)	4 mg in 1 mL

POLOXAMER 188 (UNII: LQA7B6G8JG)	1 mg in 1 mL
WATER (UNII: 059QF0KO0R)	

Other Ingredients		
Ingredient Kind	**Ingredient Name**	**Quantity**
May contain	**HYDROCHLORIC ACID** (UNII: QTT17582CB)	
May contain	**SODIUM HYDROXIDE** (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0169-2035-11	1 in 1 CARTON	05/01/2023	
1		1.5 mL in 1 SYRINGE, PLASTIC; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)		
2	NDC:0169-2035-90	1 in 1 CARTON	05/01/2023	
2		1.5 mL in 1 SYRINGE, PLASTIC; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761156	05/01/2023	

SOGROYA

somapacitan-beco injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0169-2030
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SOMAPACITAN (UNII: 8FOJ430U94) (SOMAPACITAN - UNII:8FOJ430U94)	SOMAPACITAN	6.7 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
HISTIDINE (UNII: 4QD397987E)	0.68 mg in 1 mL
MANNITOL (UNII: 3OWL53L36A)	44 mg in 1 mL
PHENOL (UNII: 339NCG44TV)	4 mg in 1 mL
POLOXAMER 188 (UNII: LQA7B6G8JG)	1 mg in 1 mL

WATER (UNII: 059QF0KO0R)	

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
May contain	**HYDROCHLORIC ACID** (UNII: QTT17582CB)	
May contain	**SODIUM HYDROXIDE** (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0169-2030-11	1 in 1 CARTON	05/01/2023	
1		1.5 mL in 1 SYRINGE, PLASTIC; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)		
2	NDC:0169-2030-90	1 in 1 CARTON	05/01/2023	
2		1.5 mL in 1 SYRINGE, PLASTIC; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761156	05/01/2023	

SOGROYA

somapacitan-beco injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0169-2037
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SOMAPACITAN (UNII: 8FOJ430U94) (SOMAPACITAN - UNII:8FOJ430U94)	SOMAPACITAN	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HISTIDINE (UNII: 4QD397987E)	0.68 mg in 1 mL
MANNITOL (UNII: 3OWL53L36A)	44 mg in 1 mL
PHENOL (UNII: 339NCG44TV)	4 mg in 1 mL
POLOXAMER 188 (UNII: LQA7B6G8JG)	1 mg in 1 mL
WATER (UNII: 059QF0KO0R)	

Other Ingredients		
Ingredient Kind	**Ingredient Name**	**Quantity**
May contain	**HYDROCHLORIC ACID** (UNII: QTT17582CB)	
May contain	**SODIUM HYDROXIDE** (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0169-2037-11	1 in 1 CARTON	05/01/2023	
1		1.5 mL in 1 SYRINGE, PLASTIC; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)		
2	NDC:0169-2037-90	1 in 1 CARTON	05/01/2023	
2		1.5 mL in 1 SYRINGE, PLASTIC; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761156	05/01/2023	

Labeler - Novo Nordisk (622920320)

Revised: 2/2026 Novo Nordisk