

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

Sogroya 5 mg/1.5 mL solution for injection in pre-filled pen
Sogroya 10 mg/1.5 mL solution for injection in pre-filled pen

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sogroya 5 mg/1.5 mL solution for injection in pre-filled pen

One mL of solution contains 3.3 mg of somapacitan*
Each pre-filled pen contains 5 mg of somapacitan in 1.5 mL solution

Sogroya 10 mg/1.5 mL solution for injection in pre-filled pen

One mL of solution contains 6.7 mg of somapacitan*
Each pre-filled pen contains 10 mg of somapacitan in 1.5 mL solution

*Produced by recombinant DNA technology in *Escherichia coli* followed by attachment of an albumin binding moiety.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection (injection).
Clear to slightly opalescent, colourless to slightly yellow liquid, essentially free from visible particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Somapacitan should be initiated and monitored by physicians who are appropriately qualified and experienced in the diagnosis and management of adult patients with growth hormone deficiency (e.g. endocrinologists).

Posology

Starting dose

Table 1: Starting dose recommendation

AGHD population	Recommended starting dose
Naïve patients Adults (18-60 years) Women on oral oestrogen (irrespective of age) Elderly (≥ 60 years)	1.5 mg/week 2 mg/week 1 mg/week
Patients switching from daily GH medicinal products Adults (18-60 years) Women on oral oestrogen (irrespective of age) Elderly (≥ 60 years)	2 mg/week 4 mg/week 1.5 mg/week

Dose titration

The somapacitan dose must be individually adjusted for each patient. It is recommended to increase the dose gradually with 2-4 weeks intervals in steps from 0.5 mg to 1.5 mg based on the patients' clinical response and experience of adverse reactions up to a dose of 8 mg somapacitan per week. Serum insulin like growth factor-I (IGF-I) levels (drawn 3-4 days after dosing) can be used as guidance for the dose titration. The IGF-I standard deviation score (SDS) target should aim for the upper normal range not exceeding 2 SDS. IGF-I SDS levels in the target range are usually achieved within 8 weeks of dose titration. Longer dose titration may be necessary in some AGHD patients (see below and section 5.1).

Treatment evaluation

Using IGF-I SDS as a biomarker for dose titration, the aim is to reach IGF-I SDS levels within the age-adjusted upper reference range (IGF-I SDS upper reference range: 0 and +2) within 12 months of titration. If this target range cannot be achieved within this period, or the patient does not obtain the desired clinical response, other treatment options should be considered.

During somapacitan maintenance treatment, evaluation of efficacy and safety should be considered at approximately 6- to 12-month intervals and may be assessed by evaluating biochemistry (IGF-I-, glucose-, and lipid levels), body composition, and body mass index.

Missed dose

Patients who forget a dose are advised to inject somapacitan upon discovery as soon as possible, within 3 days after the missed dose, and then resume their usual once-weekly dosing schedule. If more than 3 days have passed, the dose should be skipped and the next dose should be administered on the regularly scheduled day. If two or more doses have been missed, the dose should be resumed on the regularly scheduled day.

Changing the dosing day

The day of weekly injection can be changed as long as the time between two doses is at least 4 days. After selecting a new dosing day, the once weekly dosing should be continued.

Special populations

Elderly (≥ 60 years of age)

Generally, lower doses of somapacitan may be necessary in older patients. For further information, see section 5.2.

Gender

Men show an increasing IGF-I sensitivity over time. This means that there is a risk that men are overtreated. Women, especially those on oral oestrogen, may require higher doses and a longer

titration period than men, see sections 5.1 and 5.2. In women using oral oestrogen, it should be considered to change the route of oestrogen administration (e.g. transdermal, vaginal) see section 4.4.

Renal impairment

No adjustment of the starting dose is required for patients with renal impairment. Patients with renal impairment may need lower doses of somapacitan but since the dose of somapacitan is individually adjusted according to the need of each patient, no further dose adjustment is required, see section 5.2.

Hepatic impairment

No adjustment of the starting dose is required for patients with hepatic impairment. Patients with moderate hepatic impairment may need higher doses of somapacitan but since the dose of somapacitan is individually adjusted according to the need of each patient, no further dose adjustment is required. No information regarding the use of somapacitan in patients with severe hepatic impairment is available. Caution should be exercised if treating these patients with somapacitan, see section 5.2.

Paediatric population

Safety and efficacy of somapacitan in children and adolescents below 18 years have not yet been established. No data are available.

Method of administration

Somapacitan is to be administered once-weekly at any time of the day.

Somapacitan is to be injected subcutaneously in the abdomen or in the thigh. The injection site can be changed without dose adjustment. The injection site should be rotated every week.

Sogroya 5 mg/1.5 mL solution for injection pre-filled pen

The Sogroya 5 mg/1.5 mL (3.3 mg/mL) pen delivers doses from 0.025 mg to 2 mg in increments of 0.025 mg (0.0075 mL).

Sogroya 10 mg/1.5 mL solution for injection in pre-filled pen

The Sogroya 10 mg/1.5 mL (6.7 mg/mL) pen delivers doses from 0.05 mg to 4 mg in increments of 0.05 mg (0.0075 mL).

For instructions of the medicinal product before administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Somapacitan must not be used when there is any evidence of activity of a tumour. Intracranial tumours must be inactive and antitumour therapy must be completed prior to starting somapacitan therapy. Treatment should be discontinued if there is evidence of tumour growth, see section 4.4.

Patients with acute critical illness suffering from complications following open heart surgery, abdominal surgery, multiple accidental trauma, acute respiratory failure or similar conditions must not be treated with somapacitan (regarding patients undergoing substitution therapy, see section 4.4).

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Adrenocortical insufficiency

Introduction of growth hormone treatment may result in inhibition of 11 β HSD-1 and reduced serum cortisol concentrations. In patients treated with growth hormone, previously undiagnosed central (secondary) hypoadrenalism may be unmasked and glucocorticoid replacement may be required. In addition, patients treated with glucocorticoid replacement for previously diagnosed hypoadrenalism may require an increase in their maintenance or stress doses following initiation of growth hormone treatment. It is necessary to monitor patients with known hypoadrenalism for reduced serum cortisol levels and/or for the need of increased doses of glucocorticoid, see section 4.5.

Glucose metabolism impairment

Treatment with growth hormone may decrease insulin sensitivity, particularly at higher doses in susceptible patients and consequently hyperglycaemia may occur in subjects with inadequate insulin secretory capacity. As a result, previously undiagnosed impaired glucose tolerance and overt diabetes mellitus may be unmasked during growth hormone treatment. Therefore, glucose levels should be monitored periodically in all patients treated with growth hormone, especially in those with risk factors for diabetes mellitus, such as obesity, or a family history of diabetes mellitus. Patients with pre-existing type 1 or type 2 diabetes mellitus or impaired glucose tolerance should be monitored closely during growth hormone therapy. The doses of antihyperglycaemic medicinal products may require adjustment when growth hormone therapy is instituted in these patients.

Neoplasms

There is no evidence for increased risk of new primary cancers in adults treated with growth hormone. In patients in complete remission from malignant diseases or who have been treated for benign tumours, growth hormone therapy has not been associated with an increased relapse rate. Patients who have achieved complete remission of malignant diseases or who have been treated for benign tumours should be followed closely for relapse after commencement of growth hormone therapy. Growth hormone treatment should be interrupted in case of any development or reoccurrence of malignant or benign tumour.

An overall slight increase in second neoplasms has been observed in childhood cancer survivors treated with growth hormone, with the most frequent being intracranial tumours. The dominant risk factor for secondary neoplasms seems to be prior exposure to radiation.

Benign intracranial hypertension

In the event of severe or recurrent headache, visual symptoms, nausea, and/or vomiting, a fundoscopy for papilloedema is recommended. If papilloedema is confirmed, a diagnosis of benign intracranial hypertension should be considered and if appropriate the growth hormone treatment should be discontinued. At present there is insufficient evidence to guide clinical decision making in patients with resolved intracranial hypertension. If growth hormone treatment is restarted, careful monitoring for symptoms of intracranial hypertension is necessary.

Thyroid function

Growth hormone increases the extrathyroidal conversion of T4 to T3 and may as such unmask incipient hypothyroidism. As hypothyroidism interferes with the response to growth hormone therapy, patients should have their thyroid function tested regularly and should receive replacement therapy with thyroid hormone when indicated, see sections 4.5 and 4.8.

Use with oral oestrogen

Oral oestrogen influences the IGF-I response to growth hormone including somapacitan. Women taking any form of oral oestrogen (hormone therapy or contraception) should consider changing the route of oestrogen administration (e.g. transdermal-, vaginal hormone products) or use

another form of contraception. If a woman on oral oestrogen is starting somapacitan therapy, higher starting doses and a longer titration period may be required (see section 4.2).

If a woman taking somapacitan begins oral oestrogen therapy, the dose of somapacitan may need to be increased to maintain the serum IGF-I levels within the normal age-appropriate range. Conversely, if a woman on somapacitan discontinues oral oestrogen therapy, the dose of somapacitan may need to be reduced to avoid excess of somapacitan and/or undesirable effects, see sections 4.2 and 4.5.

Lipohypertrophy

When somapacitan is administered at the same site over a long period of time, lipohypertrophy may occur. The injection site should be rotated to reduce the risk, see sections 4.2 and 4.8.

Antibodies

Although no antibodies were observed after treatment with somapacitan, antibodies could be expected as observed with other therapeutic proteins. Testing for presence of anti-somapacitan antibodies should be carried out in patients who fail to respond to therapy.

Acute critical illness

The effect of growth hormone on recovery was studied in two placebo controlled trials involving 522 critical ill adult patients suffering from complications following open heart surgery, abdominal surgery, multiple accidental trauma or acute respiratory failure. Mortality was higher in patients treated with 5.3 or 8 mg growth hormone daily compared to patients receiving placebo, 42% vs 19%. Based on this information, these types of patients should not be treated with somapacitan. As there is no information available on the safety of growth hormone substitution therapy in acutely critical ill patients, the benefits of continued treatment in this situation should be weighed against the potential risks involved.

Growth hormone deficiency in adults is a lifelong disease and needs to be treated accordingly, however, experience in patients older than 60 years and in patients with more than five years of treatment in adult growth hormone deficiency is still limited.

Paediatric population

Somapacitan should not be administered to patients below 18 years since safety and efficacy of somapacitan in children and adolescents below 18 years have not yet been established.

Sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. it is essentially sodium-free.

4.5 Interaction with other medicinal products and other forms of interaction

Cytochrome P450 metabolised drugs

Data from an interaction study performed in growth hormone deficient adults suggests that growth hormone administration may increase the clearance of compounds known to be metabolised by cytochrome P450 isoenzymes. The clearance of compounds metabolised by cytochrome P450 (e.g. sex steroids, corticosteroids, anticonvulsants and cyclosporine) may be especially increased resulting in lower plasma levels of these compounds. The clinical significance of this is unknown.

Glucocorticoids

Growth hormone decreases the conversion of cortisone to cortisol and may unmask previously undiscovered central hypoadrenalism or render low glucocorticoid replacement doses ineffective, see section 4.4.

Oral oestrogens

In women on oral oestrogen therapy, a higher dose of somapacitan may be required to achieve the treatment goal, see sections 4.2 and 4.4.

Antihyperglycaemic products

Antihyperglycaemic treatment including insulin may require dose adjustment in case of somapacitan co-administration since somapacitan may decrease insulin sensitivity, see sections 4.4 and 4.8.

Other

The metabolic effects of somapacitan can also be influenced by concomitant therapy with other hormones, e.g. testosterone and thyroid hormones, see section 4.4.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no data from the use of somapacitan in pregnant women.
Studies in animal have shown reproductive toxicity, see section 5.3.
Sogroya is not recommended during pregnancy and in women of childbearing potential not using contraception.

Breast-feeding

It is unknown whether somapacitan/metabolites are excreted in human milk.
Available pharmacodynamic/toxicological data in animals have shown excretion of somapacitan in milk, see section 5.3.
A risk to the breastfed newborns/infants cannot be excluded.
A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Sogroya therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility

There is no clinical experience with somapacitan use and its potential effect on fertility.
No adverse effects were observed on male and female fertility in rats, see section 5.3.

4.7 Effects on ability to drive and use machines

Sogroya has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of safety profile

The commonly reported and serious adverse reactions after treatment with somapacitan are headache (12%), peripheral oedema (4%) and adrenocortical insufficiency (3%).

Tabulated list of adverse reactions

The adverse reactions listed below are based on the compiled safety data from three completed phase 3 trials in patients with AGHD.

The adverse reactions are listed by MedDRA system organ class and frequency category defined as: Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$).

Table 2: Adverse reactions

MedDRA system organ class	Very common	Common	Uncommon
Endocrine disorders		Adrenocortical insufficiency Hypothyroidism	
Metabolism and nutrition disorders		Hyperglycaemia*	
Nervous system disorders	Headache	Paraesthesia	Carpal tunnel syndrome
Skin and subcutaneous tissue disorders		Rash* Urticaria*	Lipohypertrophy* Pruritus*
Musculoskeletal and connective tissue disorders		Arthralgia Myalgia Muscle stiffness*	Joint stiffness
General disorders and administration site conditions		Peripheral oedema Fatigue Asthenia Injection site reactions*	

*In general, these adverse reactions were non-serious, mild or moderate severity and transient

Description of selected adverse reactions

Peripheral oedema

Peripheral oedema was commonly observed (4%). Growth hormone deficient patients are characterised by extracellular volume deficit. When treatment with growth hormone products is initiated, this deficit is corrected. Fluid retention with peripheral oedema may occur. The symptoms are usually transient, dose dependent and may require transient dose reduction.

Adrenocortical insufficiency

Adrenocortical insufficiency was commonly observed (3%), see section 4.4.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in [Appendix V](#).

4.9 Overdose

Treatment with growth hormone can lead to an acute overdose with low blood glucose levels initially, followed by high blood glucose levels. These decreased glucose levels have been detected biochemically, but without clinical signs of hypoglycaemia.

Long-term overdosage could result in signs and symptoms consistent with the known effects of human growth hormone excess.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Pituitary and hypothalamic hormones and analogues, somatropin and somatropin agonists, ATC code: H01AC07.

Mechanism of action

Somapacitan is a long-acting recombinant human growth hormone derivative. It consists of 191 amino acids similar to endogenous human growth hormone, 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 a fatty acid moiety and a hydrophilic spacer attached to position 101 of the protein.

The mechanism of action of somapacitan is either directly via the GH-receptor and/or indirectly via IGF-I produced in tissues throughout the body, but predominantly by the liver.

When growth hormone deficiency is treated with somapacitan a normalisation of body composition (i.e., decreased body fat mass, increased lean body mass) and of metabolic action is achieved.

Pharmacodynamic effects

IGF-I

IGF-I is a generally accepted biomarker for efficacy in AGHD.

A dose-dependent IGF-I response is induced following somapacitan administration in AGHD patients.

A steady state pattern in IGF-I responses is reached after 1-2 weekly doses.

The IGF-I levels fluctuate during the week. The IGF-I response is maximal after 2 to 4 days.

Compared with daily GH treatment, the IGF-I profile of somapacitan differs, see Figure 1.

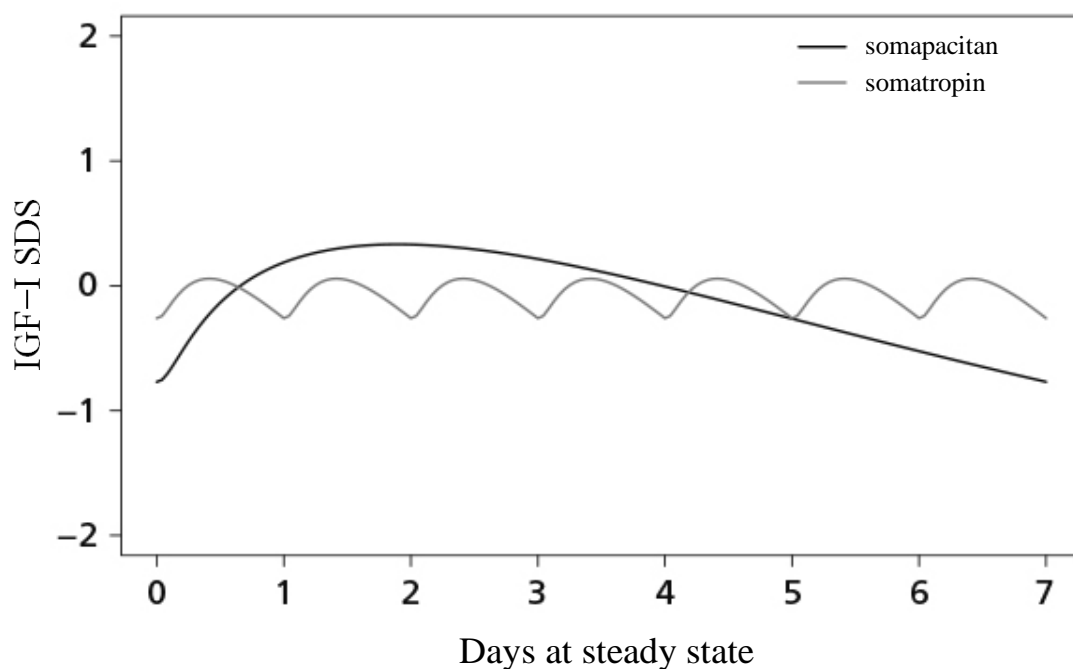


Figure 1: Model-derived IGF-I profiles during steady state of somapacitan and somatropin

Clinical efficacy and safety

In a 34-week placebo-controlled (double-blind) and active-controlled (open) trial, 301 treatment-naïve adult patients with GHD were randomised (2:1:2) and exposed to once-weekly somapacitan or to placebo or to daily somatropin for a 34-week treatment period (main phase of the trial). The patient population had a mean age of 45.1 years (range 23-77 years; 41 patients were 65 years or above), 51.7% were females, and 69.7% had adult onset GHD.

A total of 272 AGHD patients who completed the 34-week main phase continued in a 53-week open-label extension period. Subjects on placebo were switched to somapacitan and patients on somatropin were re-randomised (1:1) to either somapacitan or somatropin.

Observed clinical effects for the main endpoints in the main treatment phase (Table 3) and extension treatment phase (Table 4) are presented below.

Table 3: Results at 34 weeks

Change from baseline at 34 weeks ^a	somapacitan	somatropin	placebo	Difference somapacitan - placebo [95% CI] p-value	Difference somapacitan-somatropin [95% CI]
Number of subjects (N)	120	119	61		
Truncal fat % (Primary endpoint)	-1.06	-2.23	0.47	-1.53 [-2.68; -0.38] 0.0090 ^b	1.17 [0.23;2.11]
Visceral adipose tissue (cm ²)	-10	-9	3	-14 [-21; -7]	-1 [-7; 4]
Appendicular skeletal muscle mass (g)	558	462	-121	679 [340; 1,019]	96 [-182; 374]
Lean body mass (g)	1,394	1,345	250	1144 [459; 1,829]	49 [-513;610]
IGF-I SDS level	2.40	2.37	-0.01	2.40 [2.09; 2.72]	0.02 [-0.23;0.28]

Abbreviations: N = Number of subjects in full analysis set, CI = Confidence interval, DM=Diabetes mellitus. IGF-I SDS: Insulin-like growth factor-I standard deviation score.

^a Body composition parameters are based on dual-energy X-ray absorptiometry (DXA) scanning.

^b The primary analysis was a comparison of changes from baseline for somapacitan and placebo in truncal fat %. Changes in truncal fat % from baseline to the 34 week's measurements was analysed using an analysis of covariance model with treatment, GHD onset type, sex, region, DM and sex by region by DM 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.

Post-hoc subgroup analysis of changes from baseline in truncal fat percentage (%) compared to placebo at week 34 showed an estimated treatment difference (somapacitan-placebo) of -2.49% [-4.19; -0.79] in men, -0.80% [-2.99; 1.39] in women not on oral oestrogen, -1.44% [-3.97; 1.09] in women on oral oestrogen.

Table 4: Results at 87 weeks

Change from baseline at 87 weeks ^a	somapacitan/ somapacitan	somatropin/ somatropin	placebo/ somapacitan	somatropin/ somapacitan	Difference somapacitan/ somapacitan vs somatropin/somatropin [95% CI]
Number of subjects (N)	114	52	54	51	
Truncal fat %	-1.51	-2.67	-2.28	-1.35	1.15 [-0.10; 2.40]
Visceral adipose tissue (cm ²)	-6.64	-6.85	-10.21	-8.77	0.22 [-10; 10]
Appendicular skeletal muscle mass (g)	546.11	449.09	411.05	575.80	97.02 [-362; 556]
Lean body mass (g)	1,739.05	1,305.73	1,660.56	1,707.82	433.32 [-404; 1271]

^a Body composition parameters are based on DXA scanning.

Observed and simulated IGF-I SDS levels in the clinical study

In the main phase of the clinical study IGF-I SDS values of 0 and above were overall achieved in 53% of somapacitan-treated AGHD study patients after an 8-week dose titration period. This proportion was however lower in particular subgroups such as women on oral oestrogen (32%) and patients with childhood-onset (39%) (Table 5). *Post-hoc* simulation analyses indicated that the proportions of AGHD patients achieving IGF-I SDS levels above 0 are expected to be higher in case somapacitan dose titration beyond 8 weeks would be allowed. In this simulation analysis, it was assumed that somapacitan dose titration was well-tolerated in all patients until the IGF-I SDS target range or a somapacitan dose of 8 mg per week would be achieved.

Table 5 Proportions of somapacitan-treated AGHD patients with IGF-I SDS levels above 0

Subgroups	Men	Women not on oral oestrogen	Women on oral oestrogen	Childhood- onset AGHD	Adult- onset AGHD	All
Observed ^a	71%	46%	32%	39%	60%	53%
<i>Post-hoc</i> simulations	100%	96%	70%	84%	92%	90%

^a The trial was designed to titrate towards a IGF-I SDS level above -0.5

Maintenance dose

Maintenance dose varies from person to person and between male and female patients. The average somapacitan maintenance dose observed in the phase 3 clinical trials was 2.4 mg/week.

Paediatric population

The European Medicines Agency has waived the obligation to submit the results of studies with Sogroya in all subsets of the paediatric population in growth hormone deficiency (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

Somapacitan 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 of somapacitan following subcutaneous administration have been investigated at dose levels from 0.01 to 0.32 mg/kg in healthy adults, and in doses up to 0.12 mg/kg in adults with GHD.

Overall, somapacitan displays non-linear pharmacokinetics, but in the clinically relevant dose range of somapacitan in adults with GHD, somapacitan pharmacokinetics are approximately linear.

Absorption

In adult patients with GHD median t_{\max} ranged from 4 to 24 hours at doses from 0.02 mg/kg/week to 0.12 mg/kg/week.

Steady state exposure was achieved following 1-2 weekly administration.

Absolute bioavailability of somapacitan in humans has not been investigated.

Distribution

Somapacitan is extensively bound (>99%) to plasma proteins and is expected to be distributed like albumin. Based on population PK analyses, the estimated volume of distribution (V/F) was 14.6 L.

Elimination

The terminal half-life was estimated with geometric means ranging from approximately 2 to 3 days at steady state in AGHD patients (doses: 0.02 to 0.12 mg/kg).

Somapacitan will be present in circulation for approximately 2 weeks after the last dose. Little to no accumulation (mean accumulation ratio: 1-2) of somapacitan following multiple dosing has been observed in AGHD patients.

Biotransformation

Somapacitan is extensively metabolised by proteolytic degradation and cleavage of the linker sequence between the peptide and albumin binder.

Somapacitan was extensively metabolised before excretion and no intact somapacitan was found neither in urine, which was the main excretion route (81%), nor in faeces where 13% of somapacitan related material was found, indicating full biotransformation before excretion.

Special populations

Age

Subjects older than 60 years have higher exposure (29%) than younger subjects at the same somapacitan dose. A lower starting dose for subjects above 60 years is described in section 4.2.

Gender

Female subjects and in particular female subjects on oral oestrogen, have lower exposure (53% for females on oral oestrogen and 30 % for females not on oral oestrogen) than male subjects at the same somapacitan dose. A higher starting dose for females on oral oestrogen is described in section 4.2.

Race

There was no difference in somapacitan exposure and IGF-I response between Japanese and White subjects. Despite a higher exposure in Asian Non-Japanese compared to White at the same somapacitan dose, White, Japanese and Asian Non-Japanese needed the same doses to reach similar IGF-I levels. Therefore, there is no dose adjustment recommendation based on race.

Ethnicity

Ethnicity (Hispanic or Latino 4.5% (15 subjects received somapacitan)) was not investigated due to small sample size in the development programme.

Body weight

Despite a higher exposure in subjects with low body weight as compared to subjects with high body weight at the same somapacitan dose, subjects needed the same doses to reach similar IGF-I levels across the body weight range 35 kg to 150 kg. Therefore, there is no dose adjustment recommendation based on body weight.

Renal impairment

A somapacitan dose of 0.08 mg/kg at steady state resulted in higher exposures in subjects with renal impairment, most pronounced in subjects with severe renal impairment and in subjects requiring haemodialysis, where AUC_{0-168h} ratios to normal renal function were 1.75 and 1.63, respectively. In general, somapacitan exposure tended to increase with decreasing GFR.

Higher IGF-I AUC_{0-168h} levels were observed in subjects with moderate and severe renal impairment and subjects requiring haemodialysis, with ratios to normal renal function of 1.35, 1.40 and 1.24 respectively.

Due to the modest increase observed in IGF-I combined with the low recommended starting doses and the individual dose titration of somapacitan, there is no dose adjustment recommendation in patients with renal impairment.

Hepatic impairment

A somapacitan dose of 0.08 mg/kg at steady state resulted in higher exposure in subjects with moderate hepatic impairment with ratios to normal hepatic function of 4.69 for AUC_{0-168h} and 3.52 for C_{max} .

Lower somapacitan stimulated IGF-I levels were observed in subjects with mild and moderate hepatic impairment compared to subjects with normal hepatic function (ratio to normal was 0.85 for mild and 0.75 for moderate).

Due to the modest decrease observed in IGF-I combined with the individual dose titration of somapacitan, there is no dose adjustment recommendation in patients with hepatic impairment.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeat-dose toxicity, genotoxicity or pre- and postnatal development.

No carcinogenicity studies have been performed with somapacitan.

No adverse effects were observed on male and female fertility in rats at a dose resulting in exposure at least 13 and 15-times greater than the expected maximum clinical exposure at 8 mg/week for males and females, respectively. However, irregular female oestrus cycle was seen at all doses treated.

No evidence of foetal harm was identified when pregnant rats and rabbits were administered subcutaneous somapacitan during organogenesis at doses leading to exposures well above expected exposure at the maximum clinical dose of 8 mg/week (at least 18-fold). At high doses leading to exposure at least 130-fold above the expected maximum clinical exposure at 8 mg/week, short/bent/thickened long bones were found in pups from female rats receiving somapacitan. Such findings in rats are known to resolve after birth and should be regarded as minor malformations, not permanent abnormalities.

Foetal growth was reduced when pregnant rabbits were dosed with somapacitan subcutaneously at exposures at least 9-fold above the expected exposure at the maximum clinical dose of 8 mg/week.

In lactating rats, somapacitan related material was secreted into milk but to a lower level than observed in plasma (up to 50% of level in plasma).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Histidine
Mannitol
Poloxamer 188
Phenol
Water for injections
Hydrochloric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment).

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

2 years.

After first opening

6 weeks. Store in a refrigerator (2°C - 8°C).

Do not freeze. Keep away from the freezing element.

Keep Sogroya in the outer carton with the pen cap on to protect from light.

Before and after first opening

If refrigeration is not possible (e.g. during travelling), Sogroya may be kept temporarily at temperatures up to 30°C for up to a total of 72 hours (3 days). Return Sogroya to the refrigerator again after storage at this temperature. If stored out of refrigeration and then returned to refrigeration, the total combined time out of refrigeration should not exceed 3 days, monitor this carefully. The Sogroya pen should be discarded, if it has been kept up to 30°C for more than 72 hours (3 days) or for any period of time kept above 30°C.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C). Do not freeze. Keep away from the freezing element.

Keep Sogroya in the outer carton with the pen cap on to protect from light.

For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

The pre-filled pen consists of 1.5 mL solution in a glass cartridge (Type I colourless glass) with a plunger made of chlorobutyl rubber and a stopper made of bromobutyl/isoprene rubber sealed with an aluminium cap. The cartridge is contained in a multidose disposable pen made of polypropylene, polyacetal, polycarbonate and acrylonitrile butadiene styrene and in addition two metal springs. The cartridge is permanently sealed in a pen-injector.

Sogroya 5 mg/1.5 mL solution for injection in pre-filled pen

A colour-coded pre-filled pen with the dose button on the pen-injector coloured teal.

Sogroya 10 mg/1.5 mL solution for injection in pre-filled pen

A colour-coded pre-filled pen with the dose button on the pen-injector coloured yellow.

Pack sizes of 1 pre-filled pen and multipack of 5 (5 packs of 1) pre-filled pens. Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

The pen is for use by one person only.

Sogroya should not be used if the solution does not appear clear to slightly opalescent, colourless to slightly yellow and free from visible particles.

Sogroya must not be used if it has been frozen.

The cartridge must not be taken out of the pre-filled pen and refilled.

A needle must always be attached before use. Needles must not be re-used. The injection needle should be removed after each injection and the pen should be stored without a needle attached. This may prevent blocked needles, contamination, infection, leakage of solution and inaccurate dosing. In the event of blocked needles, patients must follow the instructions described in the instructions for use accompanying the package leaflet.

Needles are not included. Sogroya pre-filled pen-injector is designed to be used with disposable needles of a length between 4 mm and 8 mm and a gauge between 30G and 32G.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

8. MARKETING AUTHORISATION NUMBERS

EU/1/20/1501/001
EU/1/20/1501/002
EU/1/20/1501/003
EU/1/20/1501/004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31 March 2021

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu>.

ANNEX II

- A. MANUFACTURER OF THE BIOLOGICAL ACTIVE
SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR
BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY
AND USE**
- C. OTHER CONDITIONS AND REQUIREMENTS OF THE
MARKETING AUTHORISATION**
- D. CONDITIONS OR RESTRICTIONS WITH REGARD TO
THE SAFE AND EFFECTIVE USE OF THE MEDICINAL
PRODUCT**

**A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE
AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturer of the biological active substance

Novo Nordisk US Bio Production Inc.
9 Technology Drive
West Lebanon
New Hampshire
03784
United States

Name and address of the manufacturer responsible for batch release

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsvaerd
Denmark

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to restricted medical prescription (see Annex I: Summary of Product Characteristics, section 4.2).

**C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING
AUTHORISATION**

- Periodic safety update reports (PSURs)

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

The marketing authorisation holder (MAH) shall submit the first PSUR for this product within 6 months following authorisation.

**D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND
EFFECTIVE USE OF THE MEDICINAL PRODUCT**

- Risk management plan (RMP)

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**CARTON****1. NAME OF THE MEDICINAL PRODUCT**

Sogroya 5 mg/1.5 mL solution for injection in pre-filled pen
somapacitan

2. STATEMENT OF ACTIVE SUBSTANCE

One mL of solution contains 3.3 mg of somapacitan. Each pre-filled pen contains 5 mg of somapacitan in 1.5 mL solution

3. LIST OF EXCIPIENTS

Excipients: histidine, mannitol, poloxamer 188, phenol, water for injections, hydrochloric acid/sodium hydroxide (for pH adjustment). See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

solution for injection
1 pre-filled pen
1.5 mL

5. METHOD AND ROUTE OF ADMINISTRATION

subcutaneous use
once weekly
Needles are not included
Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children

7. OTHER SPECIAL WARNINGS, IF NECESSARY**8. EXPIRY DATE**

EXP
Discard the pen 6 weeks after first use. Open date: _____

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze. See the package leaflet for additional storage information
Keep in the outer carton with the pen cap on in order to protect from light

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

12. MARKETING AUTHORISATION NUMBER

EU/1/20/1501/003

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Sogroya 5 mg/1.5 mL

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**OUTER CARTON MULTIPACK (with blue box)****1. NAME OF THE MEDICINAL PRODUCT**

Sogroya 5 mg/1.5 mL solution for injection in pre-filled pen
somapacitan

2. STATEMENT OF ACTIVE SUBSTANCE

One mL of solution contains 3.3 mg of somapacitan. Each pre-filled pen contains 5 mg of somapacitan in 1.5 mL solution

3. LIST OF EXCIPIENTS

Excipients: histidine, mannitol, poloxamer 188, phenol, water for injections, hydrochloric acid/sodium hydroxide (for pH adjustment). See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

solution for injection

Multipack: 5 (5 packs of 1) pre-filled pens

5. METHOD AND ROUTE OF ADMINISTRATION

subcutaneous use

once weekly

Needles are not included

Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children

7. OTHER SPECIAL WARNINGS, IF NECESSARY**8. EXPIRY DATE**

EXP

Discard the pen 6 weeks after first use

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze. See the package leaflet for additional storage information

Keep in the outer carton with the pen cap on in order to protect from light

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

12. MARKETING AUTHORISATION NUMBERS

EU/1/20/1501/004

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Sogroya 5 mg/1.5 mL

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE INNER PACKAGING**CARTON IN MULTIPACK (without blue box)****1. NAME OF THE MEDICINAL PRODUCT**

Sogroya 5 mg/1.5 mL solution for injection in pre-filled pen
somapacitan

2. STATEMENT OF ACTIVE SUBSTANCE

One mL of solution contains 3.3 mg of somapacitan. Each pre-filled pen contains 5 mg of somapacitan in 1.5 mL solution

3. LIST OF EXCIPIENTS

Excipients: histidine, mannitol, poloxamer 188, phenol, water for injections, hydrochloric acid/sodium hydroxide (for pH adjustment). See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

solution for injection

1 pre-filled pen. Component of a multipack, can't be sold separately

5. METHOD AND ROUTE OF ADMINISTRATION

subcutaneous use

once weekly

Needles are not included

Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children

7. OTHER SPECIAL WARNINGS, IF NECESSARY**8. EXPIRY DATE**

EXP

Discard the pen 6 weeks after first use. Open date: _____

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze. See the package leaflet for additional storage information

Keep in the outer carton with the pen cap on in order to protect from light

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

12. MARKETING AUTHORISATION NUMBER

EU/1/20/1501/004 1 pack of 1 pen

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Sogroya 5 mg/1.5 mL

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS PRE-FILLED PEN LABEL
--

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE OF ADMINISTRATION

Sogroya 5 mg/1.5 mL injection
somapacitan
subcutaneous use

2. METHOD OF ADMINISTRATION

once weekly

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT
--

1.5 mL

6. OTHER

Novo Nordisk A/S

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**CARTON****1. NAME OF THE MEDICINAL PRODUCT**

Sogroya 10 mg/1.5 mL solution for injection in pre-filled pen
somapacitan

2. STATEMENT OF ACTIVE SUBSTANCE

One mL of solution contains 6.7 mg of somapacitan. Each pre-filled pen contains 10 mg of somapacitan in 1.5 mL solution

3. LIST OF EXCIPIENTS

Excipients: histidine, mannitol, poloxamer 188, phenol, water for injections, hydrochloric acid/sodium hydroxide (for pH adjustment). See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

solution for injection
1 pre-filled pen
1.5 mL

5. METHOD AND ROUTE OF ADMINISTRATION

subcutaneous use
once weekly
Needles are not included
Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children

7. OTHER SPECIAL WARNINGS, IF NECESSARY**8. EXPIRY DATE**

EXP
Discard the pen 6 weeks after first use. Open date: _____

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze. See the package leaflet for additional storage information
Keep in the outer carton with the pen cap on in order to protect from light

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

12. MARKETING AUTHORISATION NUMBER

EU/1/20/1501/001

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Sogroya 10 mg/1.5 mL

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**OUTER CARTON MULTIPACK (with blue box)****1. NAME OF THE MEDICINAL PRODUCT**

Sogroya 10 mg/1.5 mL solution for injection in pre-filled pen
somapacitan

2. STATEMENT OF ACTIVE SUBSTANCE

One mL of solution contains 6.7 mg of somapacitan. Each pre-filled pen contains 10 mg of somapacitan in 1.5 mL solution

3. LIST OF EXCIPIENTS

Excipients: histidine, mannitol, poloxamer 188, phenol, water for injections, hydrochloric acid/sodium hydroxide (for pH adjustment). See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

solution for injection

Multipack: 5 (5 packs of 1) pre-filled pens

5. METHOD AND ROUTE OF ADMINISTRATION

subcutaneous use

once weekly

Needles are not included

Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children

7. OTHER SPECIAL WARNINGS, IF NECESSARY**8. EXPIRY DATE**

EXP

Discard the pen 6 weeks after first use

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze. See the package leaflet for additional storage information

Keep in the outer carton with the pen cap on in order to protect from light

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

12. MARKETING AUTHORISATION NUMBERS

EU/1/20/1501/002

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Sogroya 10 mg/1.5 mL

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE INNER PACKAGING**CARTON IN MULTIPACK (without blue box)****1. NAME OF THE MEDICINAL PRODUCT**

Sogroya 10 mg/1.5 mL solution for injection in pre-filled pen
somapacitan

2. STATEMENT OF ACTIVE SUBSTANCE

One mL of solution contains 6.7 mg of somapacitan. Each pre-filled pen contains 10 mg of somapacitan in 1.5 mL solution

3. LIST OF EXCIPIENTS

Excipients: histidine, mannitol, poloxamer 188, phenol, water for injections, hydrochloric acid/sodium hydroxide (for pH adjustment). See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

solution for injection

1 pre-filled pen. Component of a multipack, can't be sold separately

5. METHOD AND ROUTE OF ADMINISTRATION

subcutaneous use

once weekly

Needles are not included

Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children

7. OTHER SPECIAL WARNINGS, IF NECESSARY**8. EXPIRY DATE**

EXP

Discard the pen 6 weeks after first use. Open date: _____

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze. See the package leaflet for additional storage information

Keep in the outer carton with the pen cap on in order to protect from light

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

12. MARKETING AUTHORISATION NUMBER

EU/1/20/1501/002 1 pack of 1 pen

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Sogroya 10 mg/1.5 mL

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS PRE-FILLED PEN LABEL
--

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE OF ADMINISTRATION

Sogroya 10 mg/1.5 mL injection
somapacitan
subcutaneous use

2. METHOD OF ADMINISTRATION

once weekly

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT
--

1.5 mL

6. OTHER

Novo Nordisk A/S

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Sogroya 5 mg/1.5 mL solution for injection in pre-filled pen somapacitan

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sogroya is and what it is used for
2. What you need to know before you use Sogroya
3. How to use Sogroya
4. Possible side effects
5. How to store Sogroya
6. Contents of the pack and other information

1. What Sogroya is and what it is used for

Sogroya contains the active substance somapacitan: a long acting version of the natural growth hormone produced by the body with a single amino acid substitution. Growth hormone regulates the composition of fat, muscle and bone in adults.

The active substance in Sogroya is made by 'recombinant DNA technology', meaning from cells that have received a gene (DNA) that makes them produce growth hormone. In Sogroya, a small side-chain has been attached to the growth hormone which links Sogroya to the protein (albumin) naturally found in the blood to slow down its removal from the body, allowing the medicine to be given less often.

Sogroya is used to treat adults who have growth hormone deficiency.

Your doctor will evaluate based on your response to Sogroya, if you should continue your treatment with Sogroya a year after starting with this medicine.

2. What you need to know before you use Sogroya

Do not use Sogroya if

- you are allergic to somapacitan or any of the other ingredients of this medicine (listed in section 6).
- you have a benign or malignant tumour which is growing. You must have completed your anti-tumour treatment before you start your Sogroya treatment. Sogroya must be stopped if the tumour grows.
- you have recently had open heart surgery or abdominal surgery or multiple accidental injury, severe breathing problems or similar condition.

If you are not sure talk to your doctor, pharmacist or nurse.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Sogroya if:

- you have ever had any kind of tumour
- you have high blood sugar (hyperglycaemia) as your blood sugar may need to be checked regularly and the dose of your diabetes medicine may need to be adjusted
- you have a replacement therapy with corticosteroids, because you have been told your body does not produce enough (adrenocortical insufficiency). Speak to your doctor, as your dose may need regular adjustment
- you have severe headaches, eyesight problems, nausea, or vomiting as these could be symptoms of increased pressure in the brain (benign intracranial hypertension) as your treatment may need to be stopped
- you have thyroid problems, your thyroid hormones need to be checked regularly and your dose of thyroid hormone may need to be adjusted
- you are a woman taking oral contraception or hormonal replacement therapy with oestrogen, your dose of somapacitan may need to be higher. If you stop using oral oestrogen, your dose of somapacitan may need to be reduced. Your doctor may recommend you to change the route of oestrogen administration (e.g transdermal, vaginal) or use another form of contraception.
- you are seriously ill (for example, complications following open heart surgery, abdominal surgery, accidental trauma, acute respiratory failure, or similar conditions). If you are about to have, or have had, a major operation, or go into hospital for the above reasons, tell your doctor and remind the other doctors you are seeing that you use growth hormone.

Thickening of skin

If you inject Sogroya at the same site for a long period, thickened skin may appear where you inject your medicine. Change the place of injection on your body from one week to the next.

Antibodies

You are not expected to get antibodies against somapacitan. Antibodies may occur as it happens with other growth hormone treatments. If your Sogroya treatment does not work, your doctor may test you for antibodies to somapacitan.

Children and adolescents

Do not use Sogroya in children and young people aged under 18 years. This is because it has not been fully studied how Sogroya works in this age group.

Other medicines and Sogroya

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. In particular, tell your doctor if you are taking or have recently taken any of the following medicines. This is because your doctor may have to adjust the doses of your medicines:

- Corticosteroids such as hydrocortisone, dexamethasone and prednisolone
- Oestrogen as part of oral contraception or hormonal replacement therapy with oestrogen
- Male sex hormones (androgen medicines) such as testosterone
- Gonadotropin medicines (gonad stimulating hormones such as luteinising hormone and follicle-stimulating hormone) which stimulate the production of sex hormones
- Insulin or other diabetes medicines
- Thyroid hormone medicines such as levothyroxine
- Medicines to treat epilepsy or fits (seizures) – such as carbamazepine
- Cyclosporine (immunosuppressive drug) – a medicine to suppress your immune system.

Pregnancy

- If you are able to get pregnant, you should not use Sogroya unless you are also using reliable contraception. This is because it is not known if it could harm your unborn child. If you become pregnant while you are using Sogroya, speak to your doctor immediately. If you wish to become pregnant, discuss it with your doctor, as you may need to stop using the medicine.

Breast-feeding

- It is not known whether Sogroya can pass into breast milk. Tell your doctor if you are breast-feeding or plan to do so. Your doctor will then help you decide whether to stop breast-feeding, or whether to stop taking Sogroya, considering the benefit of breast-feeding to the baby and the benefit of Sogroya to the mother.

Driving and using machines

Sogroya does not affect your ability to drive and use machines.

Sodium content

This medicine contains less than 1 mmol sodium (23 mg) per dose that is to say essentially 'sodium-free'.

3. How to use Sogroya

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Sogroya is given as an injection under the skin (subcutaneous injection) from a pen-injector. You can give the injection yourself. Your doctor or nurse will tell you the right dose and show you how to give the injection when you start treatment.

When to use Sogroya

- You should use Sogroya once a week on the same day each week if possible.
- You can give yourself the injection at any time of the day.

If necessary you can change the day of your weekly injection of Sogroya as long as it has been at least 4 days since you had your last injection of it. After selecting a new dosing day, continue giving yourself the injection on that day each week.

How much to use

The usual starting dose is 1.5 mg once a week if you are having growth hormone treatment for the first time. If you have been previously treated with daily growth hormone medicine (somatropin) the usual starting dose is 2 mg once a week.

If you are a woman taking oral oestrogen (contraception or hormonal replacement therapy) you may need a higher dose of somapacitan. If you are above 60 years, you may need a lower dose. See Table 1 below.

Your doctor may increase or decrease your dose step by step and regularly until you are on the right dose based on your individual needs and your experience of side effects.

- Do not use more than a maximum of 8 mg once a week.
- Do not change your dose unless your doctor has told you to.

Table 1 Starting dose recommendation

Adult growth hormone deficiency	Recommended starting dose
You have not received daily growth hormone medicine before You are between 18-60 years You are woman on oral oestrogen (contraception or hormonal therapy) regardless of age You are 60 years or above	1.5 mg/week 2 mg/week 1 mg/week
You have previously received daily growth hormone medicine You are between 18-60 years You are woman on oral oestrogen (contraception or hormonal therapy) regardless of age You are 60 years or above	2 mg/week 4 mg/week 1.5 mg/week

After you have reached your right dose, your doctor will evaluate your treatment every 6 to 12 months. You may need to have your body mass index checked and blood samples taken.

How Sogroya is used

Your doctor or nurse will show you how to inject Sogroya under your skin.

The best places to give the injection are:

- the front of your thighs
- the front of your waist (abdomen).

Change the place of injection on your body from one week to the next.

Detailed instructions on how to inject Sogroya, the instructions for use, are included at the end of this booklet.

If you use more Sogroya than you should

If you accidentally use more Sogroya than you should, talk to your doctor as your blood sugar levels may need to be checked.

If you forget to use Sogroya

If you forget to inject a dose:

- and it is 3 days or less after you should have used Sogroya, use it as soon as you remember. Then inject your next dose on your usual injection day.
- and it is more than 3 days since you should have used Sogroya, skip the missed dose. Then inject your next dose as usual on your next scheduled day.

Do not inject an extra dose or increase the dose to make up for a missed dose.

If you stop using Sogroya

Do not stop using Sogroya without talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common (may affect more than 1 in 10 people)

- Headache.

Common (may affect up to 1 in 10 people)

- The adrenal glands do not make enough steroid hormones (adrenocortical insufficiency)
- Decreased thyroid hormone (hypothyroidism)
- High blood sugar (hyperglycaemia)
- Feeling of 'pins and needles' mainly in fingers (paraesthesia)
- Rash
- Hives (urticaria)
- Joint pain (arthralgia), muscle pain (myalgia), muscle stiffness
- Swollen hands and feet due to a build-up of fluid under the skin (peripheral oedema)
- Feeling very tired or weak (fatigue or asthenia)
- Redness and pain in the area of injection (injection site reactions).

Uncommon (may affect up to 1 in 100 people)

- Thickening of skin where you inject your medicine (lipohypertrophy)
- Numb feeling and tingling in your hand(s) (carpal tunnel syndrome)
- Itching (pruritus)
- Joint stiffness.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sogroya

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pen label and carton after 'EXP'. The expiry date refers to the last day of that month.

Store in a refrigerator (2° - 8°C). Do not freeze. Keep away from the freezing element.

After first opening

Use within 6 weeks after first use. Store in a refrigerator (2° - 8°C).

Before and after first opening

If you cannot refrigerate (for example during travelling), Sogroya may be kept temporarily at temperatures up to 30°C for up to a total of 72 hours (3 days). Return Sogroya to the refrigerator again after storage at this temperature. If you store out of the refrigerator and then return to the refrigerator, the total combined time out of the refrigerator is 3 days, monitor this carefully. Discard the Sogroya pen, if you have kept it at 30°C for more than 72 hours, or for any period of time above 30°C.

Record the time outside the refrigerator: _____

Keep Sogroya in the outer carton with the pen cap on to protect from light.

Always remove the injection needle after each injection and store the pen without a needle attached.

Do not use this medicine if the solution is not clear and colourless or there are visible particles.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sogroya contains

- The active substance is somapacitan. One mL of solution contains 3.3 mg of somapacitan. Each pre-filled pen contains 5 mg of somapacitan in 1.5 mL solution.
- The other ingredients are: histidine, mannitol, poloxamer 188, phenol, water for injections, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment). See also section 2 'What you need to know before you use Sogroya' for information on sodium.

What Sogroya looks like and contents of the pack

Sogroya is a clear to slightly opalescent, colourless to slightly yellow liquid and free from visible particles for injection in a pre-filled pen.

Sogroya 5 mg/1.5 mL solution for injection in pre-filled pen with a teal dose button is available in the following pack sizes: a pack containing 1 pre-filled pen or a multipack containing 5 packs, each containing 1 pre-filled pen.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Novo Nordisk A/S

Novo Allé

DK-2880 Bagsværd

Denmark

This leaflet was last revised in

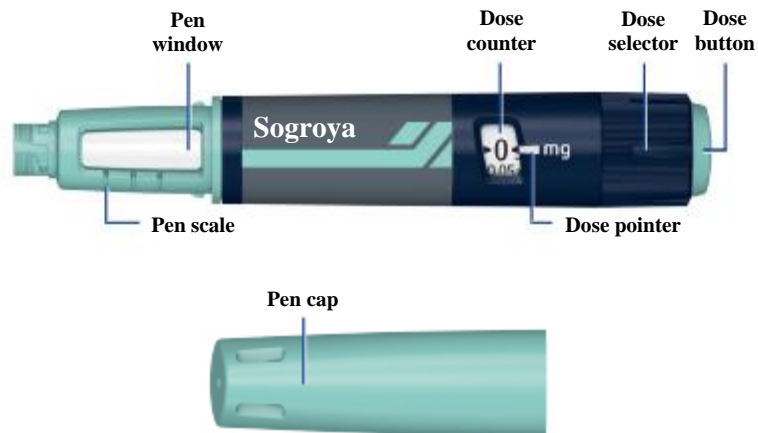
Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

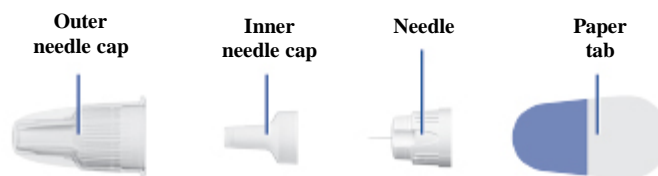
<http://www.ema.europa.eu>.

Instructions for use

Overview Sogroya 5 mg/1.5 mL pen



Needle (example)



How to use your Sogroya pen

5 Steps you should follow for a Sogroya injection:

Step 1. Prepare your Sogroya pen	43
Step 2. Check the flow with each new pen	44
Step 3. Select your dose	45
Step 4. Inject your dose	46
Step 5. After your injection	47

For further information about your pen, see sections: *Check how much Sogroya is left, How to care for your pen, Important information.*

Please read the package leaflet and these instructions carefully before using your Sogroya pre-filled pen.



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



Additional information

Sogroya contains 5 mg of somapacitan and it can be used to inject doses from 0.025 mg to 2 mg, in steps of 0.025 mg. Sogroya is for use under the skin only (subcutaneous). Needles are not included

and must be obtained separately. Sogroya pre-filled pen-injector is designed to be used with disposable needles of a length between 4 mm and 8 mm and a gauge between 30G and 32G.

Do not share your Sogroya pen and needles with another person. You may give another person an infection or get an infection from them.

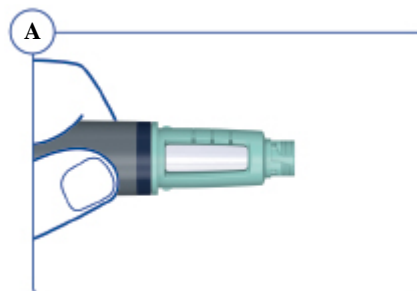
Do not use your pen without proper training from your doctor or nurse. Make sure that you are confident giving yourself an injection with the pen before you start your treatment. If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help. Get 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 coloured label** on your pen to make sure that it contains Sogroya and the appropriate strength.
- Pull off the pen cap.
- Turn the pen upside down once or twice to check that the Sogroya in your pen is **clear and colourless**. See figure A.
- **If Sogroya looks cloudy or particles are visible, do not use the pen.**



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



- When you are ready to inject, take a new disposable needle. Firstly, tear off the paper tab.
- Secondly, push the needle straight onto the pen. Turn the needle clockwise **until it is on tight**. See figure B.



- Pull off the outer needle cap and keep it for later. You will need it after the injection, to safely remove the needle from the pen. See figure C.



The needle is covered by two caps. You must remove both caps. If you forget to remove both caps you will not inject any medicine. See figure C and D.




- Pull off the inner needle cap and dispose of it. If you try to put it back on, you may accidentally stick yourself with the needle. See figure D.




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



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.

 Never use a bent or damaged needle.

Step 2. Check the flow with each new pen

 If your pen is already in use, proceed to Step 3.

- **Before using a new pen**, check the flow to make sure Sogroya can flow through the pen and needle.
- Turn the dose selector clockwise one tick mark to select 0.025 mg. You may hear a faint click. See figure E.



- **One tick mark equals 0.025 mg** in the dose counter. See figure F.



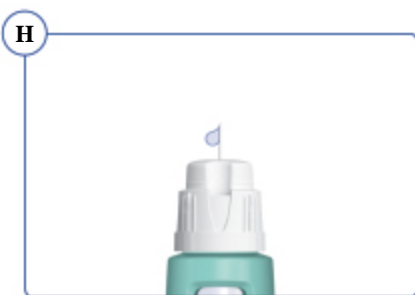
- Hold the pen with the needle pointing up. Press and hold in the dose button until the dose counter returns to '0'. **The '0' must line up with the dose pointer.** See figure G.




- 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, replace the needle once as described in Step 5 and repeat Step 1 and 2 again.



 If no Sogroya appears when you check the flow, your needle may be blocked or damaged. Do not use your pen if Sogroya still does not appear after changing the needle. Your pen may be defective.

Step 3. Select your dose

- To start, check that the dose counter is set at '0'.
- Turn the dose selector clockwise to select the dose you need. See figure I.

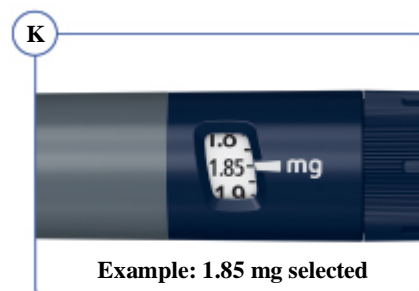
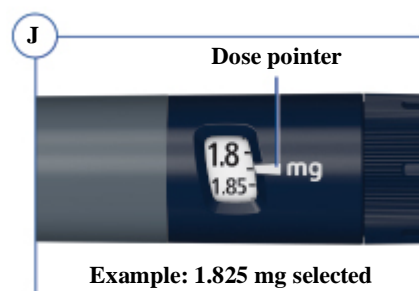
When you have selected your dose, you can proceed to Step 4.

i If there is not enough Sogroya left to select a full dose, see *Check how much Sogroya is left*.



i The dose counter shows the dose in mg. See figures J and K. Always use the **dose pointer to select the exact dose**.

Do not count the pen clicks. Do not use the pen scale (see Overview of Sogroya pen) to measure how much growth hormone to inject. Only the dose pointer will indicate the exact number of mg.



i 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 accidentally force it past the number of mg left.



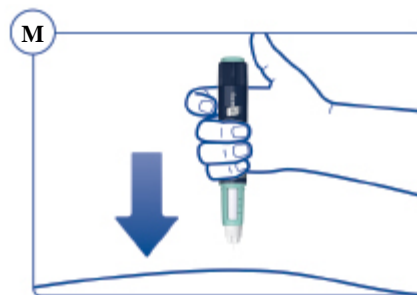
Step 4. Inject your dose

- Insert the needle into your skin as your doctor or nurse has shown you. See figure M.

Make sure you can see the dose counter. **Do not cover it with your fingers.** This could block the injection.



Remember to change the injection site every week.

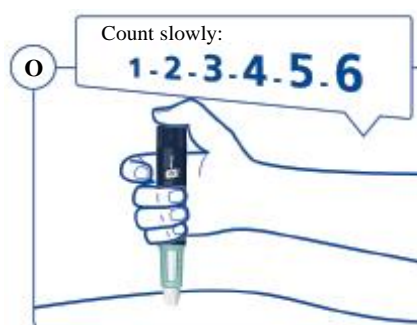


- Press and hold down the dose button until the dose counter shows '0' (See figure N). **The '0' must line up with the dose pointer.** You may then hear or feel a 'click'.

Continue to hold down the dose button with the needle in your skin.



- **Keep holding down the dose button with the needle in your skin and slowly count to 6** to make sure that the full dose has been delivered (see figure O).



If '0' does not appear in the dose counter after continuously pressing the dose button, the needle or pen may be blocked or damaged, and **you have not received any Sogroya** – even though the dose counter has moved from the original dose that you have set.

Remove the needle as described in Step 5 and repeat Steps 1 to 4.

- Carefully remove the needle from your skin. See figure P. If blood appears at the injection site, press lightly. Do not rub the area.

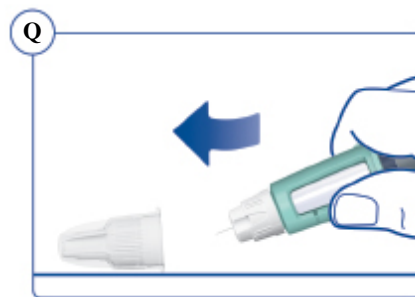


You may see a drop of Sogroya at the needle tip after injecting. This is normal and does not affect your dose.

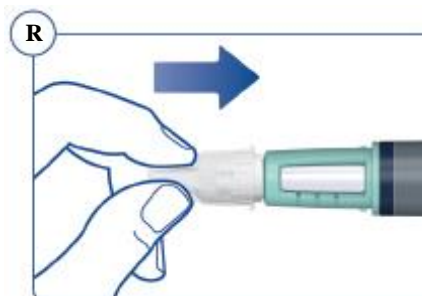


Step 5. After your injection

- Insert the needle tip into the outer needle cap on a flat surface without touching the needle or the outer needle cap. See figure Q.



- Once the needle is covered, carefully push the outer needle cap completely on. See figure R.



- Unscrew the needle and dispose of it carefully as instructed by your doctor, nurse, pharmacist or local authorities.
Always dispose of the needle after each injection.

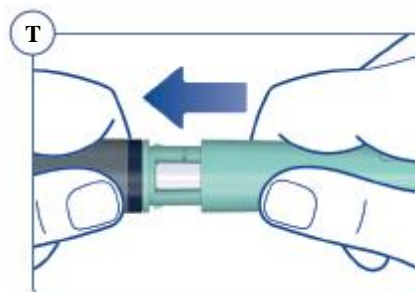
When the pen is empty, remove and dispose of the needle as above **and throw the pen away separately** as instructed by your doctor, nurse, pharmacist or local authorities.

The pen cap and the empty carton can be disposed of in your household waste.



- Put the pen cap on your pen after each use to protect Sogroya from direct light. See figure T.

To store your pen, see *How to store* in the *package leaflet*.



Do not try to put the inner needle cap back on.

You may stick yourself with the needle.

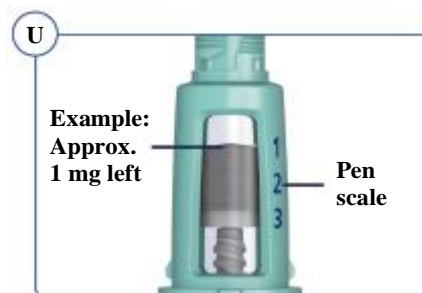


Always remove the needle from your pen immediately after each injection. This reduces the risk of contamination, infection, leakage of Sogroya, and blocked needles leading to incorrect dosing.

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Check how much Sogroya is left

The pen scale shows you approximately how much Sogroya is left in your pen. See figure U.



To see how much Sogroya is left, use the dose counter: Turn the dose selector clockwise until the dose counter stops. You can select a maximum dose of 2 mg. If it shows '2' at least 2 mg are left in your pen.

If the dose counter stops at '1.2', only 1.2 mg are left in your pen. See figure V.



What if I need a larger dose than what is left in my pen?

It is not possible to select a larger dose than the amount 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 if trained or advised by your doctor or nurse, you may split your dose.** Use a calculator to plan the doses as instructed by your doctor or nurse.

Be very careful to calculate correctly, otherwise it may lead to medication error. If you are not sure how to split your dose using two pens, then select and inject the dose you need with a new pen.

How to care for your pen

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.

Do not try to refill your pen, it is pre-filled and must be disposed of when empty.

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 flow before you inject, see Steps 1 and 2. If your pen has been dropped, check the cartridge, if the cartridge is cracked, do not use the pen.

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.
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Important information

- Caregivers must be very careful when handling needles – to reduce the risk of needle sticks and cross-infection.
- Always keep your pen and needles out of reach of others, especially children.
- **Do not use the pen** if it is damaged. Do not try to repair your pen or pull it apart.
- To store your pen, see *How to store* in the *package leaflet*.

Package leaflet: Information for the user

Sogroya 10 mg/1.5 mL solution for injection in pre-filled pen somapacitan

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sogroya is and what it is used for
2. What you need to know before you use Sogroya
3. How to use Sogroya
4. Possible side effects
5. How to store Sogroya
6. Contents of the pack and other information

1. What Sogroya is and what it is used for

Sogroya contains the active substance somapacitan: a long acting version of the natural growth hormone produced by the body with a single amino acid substitution. Growth hormone regulates the composition of fat, muscle and bone in adults.

The active substance in Sogroya is made by 'recombinant DNA technology', meaning from cells that have received a gene (DNA) that makes them produce growth hormone. In Sogroya, a small side-chain has been attached to the growth hormone which links Sogroya to the protein (albumin) naturally found in the blood to slow down its removal from the body, allowing the medicine to be given less often.

Sogroya is used to treat adults who have growth hormone deficiency.

Your doctor will evaluate based on your response to Sogroya, if you should continue your treatment with Sogroya a year after starting with this medicine.

2. What you need to know before you use Sogroya

Do not use Sogroya if

- you are allergic to somapacitan or any of the other ingredients of this medicine (listed in section 6).
- you have a benign or malignant tumour which is growing. You must have completed your anti-tumour treatment before you start your Sogroya treatment. Sogroya must be stopped if the tumour grows.
- you have recently had open heart surgery or abdominal surgery or multiple accidental injury, severe breathing problems or similar condition.

If you are not sure talk to your doctor, pharmacist or nurse.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Sogroya if:

- you have ever had any kind of tumour
- you have high blood sugar (hyperglycaemia) as your blood sugar may need to be checked regularly and the dose of your diabetes medicine may need to be adjusted
- you have a replacement therapy with corticosteroids, because you have been told your body does not produce enough (adrenocortical insufficiency). Speak to your doctor, as your dose may need regular adjustment
- you have severe headaches, eyesight problems, nausea, or vomiting as these could be symptoms of increased pressure in the brain (benign intracranial hypertension) as your treatment may need to be stopped
- you have thyroid problems, your thyroid hormones need to be checked regularly and your dose of thyroid hormone may need to be adjusted
- you are a woman taking oral contraception or hormonal replacement therapy with oestrogen, your dose of somapacitan may need to be higher. If you stop using oral oestrogen, your dose of somapacitan may need to be reduced. Your doctor may recommend you to change the route of oestrogen administration (e.g transdermal, vaginal) or use another form of contraception.
- you are seriously ill (for example, complications following open heart surgery, abdominal surgery, accidental trauma, acute respiratory failure, or similar conditions). If you are about to have, or have had, a major operation, or go into hospital for the above reasons, tell your doctor and remind the other doctors you are seeing that you use growth hormone.

Thickening of skin

If you inject Sogroya at the same site for a long period, thickened skin may appear where you inject your medicine. Change the place of injection on your body from one week to the next.

Antibodies

You are not expected to get antibodies against somapacitan. Antibodies may occur as it happens with other growth hormone treatments. If your Sogroya treatment does not work, your doctor may test you for antibodies to somapacitan.

Children and adolescents

Do not use Sogroya in children and young people aged under 18 years. This is because it has not been fully studied how Sogroya works in this age group.

Other medicines and Sogroya

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. In particular, tell your doctor if you are taking or have recently taken any of the following medicines. This is because your doctor may have to adjust the doses of your medicines:

- Corticosteroids such as hydrocortisone, dexamethasone and prednisolone
- Oestrogen as part of oral contraception or hormonal replacement therapy with oestrogen
- Male sex hormones (androgen medicines) such as testosterone
- Gonadotropin medicines (gonad stimulating hormones such as luteinising hormone and follicle-stimulating hormone) which stimulate the production of sex hormones
- Insulin or other diabetes medicines
- Thyroid hormone medicines such as levothyroxine
- Medicines to treat epilepsy or fits (seizures) – such as carbamazepine
- Cyclosporine (immunosuppressive drug) – a medicine to suppress your immune system.

Pregnancy

- If you are able to get pregnant, you should not use Sogroya unless you are also using reliable contraception. This is because it is not known if it could harm your unborn child. If you become pregnant while you are using Sogroya, speak to your doctor immediately. If you wish to become pregnant, discuss it with your doctor, as you may need to stop using the medicine.

Breast-feeding

- It is not known whether Sogroya can pass into breast milk. Tell your doctor if you are breast-feeding or plan to do so. Your doctor will then help you decide whether to stop breast-feeding, or whether to stop taking Sogroya, considering the benefit of breast-feeding to the baby and the benefit of Sogroya to the mother.

Driving and using machines

Sogroya does not affect your ability to drive and use machines.

Sodium content

This medicine contains less than 1 mmol sodium (23 mg) per dose that is to say essentially 'sodium-free'.

3. How to use Sogroya

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Sogroya is given as an injection under the skin (subcutaneous injection) from a pen injector. You can give the injection yourself. Your doctor or nurse will tell you the right dose and show you how to give the injection when you start treatment.

When to use Sogroya

- You should use Sogroya once a week on the same day each week if possible.
- You can give yourself the injection at any time of the day.

If necessary you can change the day of your weekly injection of Sogroya as long as it has been at least 4 days since you had your last injection of it. After selecting a new dosing day, continue giving yourself the injection on that day each week.

How much to use

The usual starting dose is 1.5 mg once a week if you are having growth hormone treatment for the first time. If you have been previously treated with daily growth hormone medicine (somatropin) the usual starting dose is 2 mg once a week.

If you are a woman taking oral oestrogen (contraception or hormonal replacement therapy) you may need a higher dose of somapacitan. If you are above 60 years, you may need a lower dose. See Table 1 below.

Your doctor may increase or decrease your dose step by step and regularly until you are on the right dose based on your individual needs and your experience of side effects.

- Do not use more than a maximum of 8 mg once a week.
- Do not change your dose unless your doctor has told you to.

Table 1 Starting dose recommendation

Adult growth hormone deficiency	Recommended starting dose
You have not received daily growth hormone medicine before You are between 18-60 years You are woman on oral oestrogen (contraception or hormonal therapy) regardless of age You are 60 years or above	1.5 mg/week 2 mg/week 1 mg/week
You have previously received daily growth hormone medicine You are between 18-60 years You are woman on oral oestrogen (contraception or hormonal therapy) regardless of age You are 60 years or above	2 mg/week 4 mg/week 1.5 mg/week

After you have reached your right dose, your doctor will evaluate your treatment every 6 to 12 months. You may need to have your body mass index checked and blood samples taken.

How Sogroya is used

Your doctor or nurse will show you how to inject Sogroya under your skin.

The best places to give the injection are:

- the front of your thighs
- the front of your waist (abdomen).

Change the place of injection on your body from one week to the next.

Detailed instructions on how to inject Sogroya, the instructions for use, are included at the end of this booklet.

If you use more Sogroya than you should

If you accidentally use more Sogroya than you should, talk to your doctor as your blood sugar levels may need to be checked.

If you forget to use Sogroya

If you forget to inject a dose:

- and it is 3 days or less after you should have used Sogroya, use it as soon as you remember. Then inject your next dose on your usual injection day.
- and it is more than 3 days since you should have used Sogroya, skip the missed dose. Then inject your next dose as usual on your next scheduled day.

Do not inject an extra dose or increase the dose to make up for a missed dose.

If you stop using Sogroya

Do not stop using Sogroya without talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common (may affect more than 1 in 10 people)

- Headache.

Common (may affect up to 1 in 10 people)

- The adrenal glands do not make enough steroid hormones (adrenocortical insufficiency)
- Decreased thyroid hormone (hypothyroidism)
- High blood sugar (hyperglycaemia)
- Feeling of 'pins and needles' mainly in fingers (paraesthesia)
- Rash
- Hives (urticaria)
- Joint pain (arthralgia), muscle pain (myalgia), muscle stiffness
- Swollen hands and feet due to a build-up of fluid under the skin (peripheral oedema)
- Feeling very tired or weak (fatigue or asthenia)
- Redness and pain in the area of injection (injection site reactions).

Uncommon (may affect up to 1 in 100 people)

- Thickening of skin where you inject your medicine (lipohypertrophy)
- Numb feeling and tingling in your hand(s) (carpal tunnel syndrome)
- Itching (pruritus)
- Joint stiffness.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sogroya

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pen label and carton after 'EXP'. The expiry date refers to the last day of that month.

Store in a refrigerator (2° - 8°C). Do not freeze. Keep away from the freezing element.

After first opening

Use within 6 weeks after first use. Store in a refrigerator (2° - 8°C).

Before and after first opening

If you cannot refrigerate (for example during travelling), Sogroya may be kept temporarily at temperatures up to 30°C for up to a total of 72 hours (3 days). Return Sogroya to the refrigerator again after storage at this temperature. If you store out of the refrigerator and then return to the refrigerator, the total combined time out of the refrigerator is 3 days, monitor this carefully. Discard the Sogroya pen, if you have kept it at 30°C for more than 72 hours, or for any period of time above 30°C.

Record the time outside the refrigerator: _____

Keep Sogroya in the outer carton with the pen cap on to protect from light.

Always remove the injection needle after each injection and store the pen without a needle attached.

Do not use this medicine if the solution is not clear and colourless or there are visible particles.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sogroya contains

- The active substance is somapacitan. One mL of solution contains 6.7 mg of somapacitan. Each pre-filled pen contains 10 mg of somapacitan in 1.5 mL solution.
- The other ingredients are: histidine, mannitol, poloxamer 188, phenol, water for injections, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment). See also section 2 ‘What you need to know before you use Sogroya’ for information on sodium.

What Sogroya looks like and contents of the pack

Sogroya is a clear to slightly opalescent, colourless to slightly yellow liquid and free from visible particles for injection in a pre-filled pen.

Sogroya 10 mg/1.5 mL solution for injection in pre-filled pen with a yellow dose button is available in the following pack sizes: a pack containing 1 pre-filled pen or a multipack containing 5 packs, each containing 1 pre-filled pen.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Novo Nordisk A/S

Novo Allé

DK-2880 Bagsværd

Denmark

This leaflet was last revised in

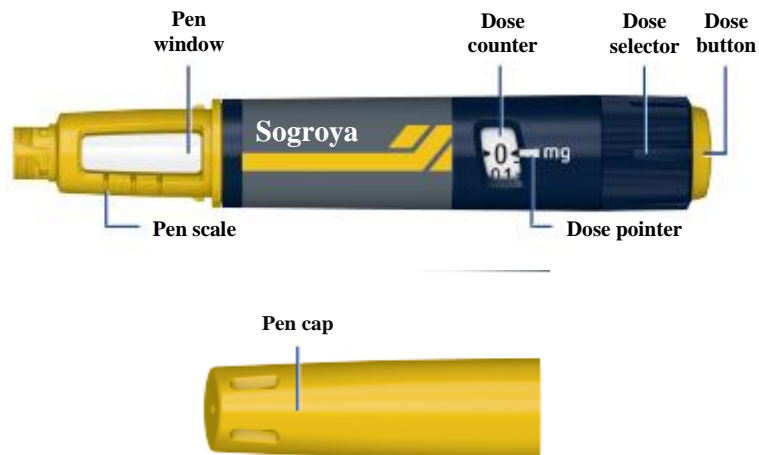
Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

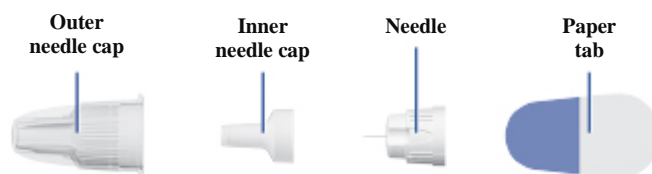
<http://www.ema.europa.eu>.

Instructions for use

Overview Sogroya 10 mg/1.5 mL pen



Needle (example)



How to use your Sogroya pen

5 Steps you should follow for a Sogroya injection:

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For further information about your pen, see sections: *Check how much Sogroya is left, How to care for your pen, Important information.*

Please read the package leaflet and these instructions carefully before using your Sogroya pre-filled pen.



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



Additional information

Sogroya contains 10 mg of somapacitan and it can be used to inject doses from 0.05 mg to 4 mg, in steps of 0.05 mg. Sogroya is for use under the skin only (subcutaneous). Needles are not included

and must be obtained separately. Sogroya pre-filled pen-injector is designed to be used with disposable needles of a length between 4 mm and 8 mm and a gauge between 30G and 32G.

Do not share your Sogroya pen and needles with another person. You may give another person an infection or get an infection from them.

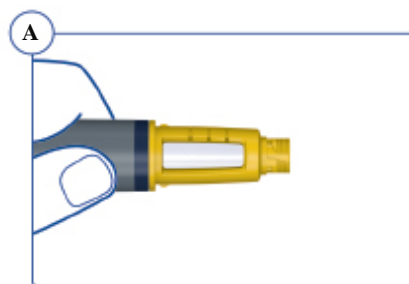
Do not use your pen without proper training from your doctor or nurse. Make sure that you are confident giving yourself an injection with the pen before you start your treatment. If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help. Get 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 coloured label** on your pen to make sure that it contains Sogroya and the appropriate strength.
- Pull off the pen cap.
- Turn the pen upside down once or twice to check that the Sogroya in your pen is **clear and colourless**. See figure A.
- **If Sogroya looks cloudy or particles are visible, do not use the pen.**



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



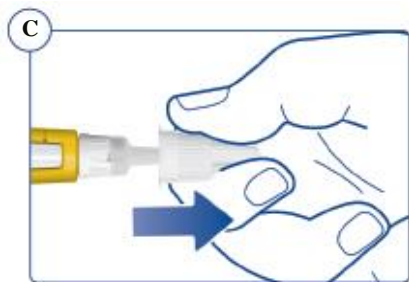
- When you are ready to inject, take a new disposable needle. Firstly, tear off the paper tab.
- Secondly, push the needle straight onto the pen. Turn the needle clockwise **until it is on tight**. See figure B.



- Pull off the outer needle cap and keep it for later. You will need it after the injection, to safely remove the needle from the pen. See figure C.



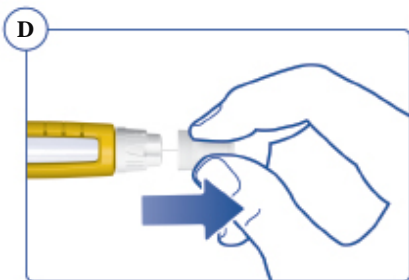
The needle is covered by two caps. You must remove both caps. If you forget to remove both caps you will not inject any medicine. See figure C and D.




- Pull off the inner needle cap and dispose of it. If you try to put it back on, you may accidentally stick yourself with the needle. See figure D.




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



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.

 Never use a bent or damaged needle.

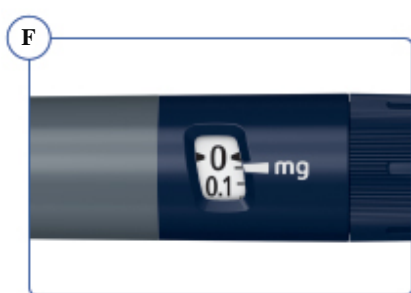
Step 2. Check the flow with each new pen

 If your pen is already in use, proceed to Step 3.

- **Before using a new pen**, check the flow to make sure Sogroya can flow through the pen and needle.
- Turn the dose selector clockwise one tick mark to select 0.05 mg. You may hear a faint click. See figure E.




- **One tick mark equals 0.05 mg** in the dose counter. See figure F.



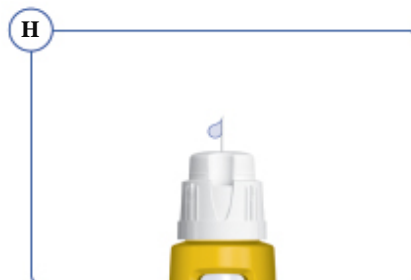
- Hold the pen with the needle pointing up. Press and hold in the dose button until the dose counter returns to '0'. **The '0' must line up with the dose pointer.** See figure G.




- 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, replace the needle once as described in Step 5 and repeat Step 1 and 2 again.



 If no Sogroya appears when you check the flow, your needle may be blocked or damaged. Do not use your pen if Sogroya still does not appear after changing the needle. Your pen may be defective.

Step 3. Select your dose

- To start, check that the dose counter is set at '0'.
- Turn the dose selector clockwise to select the dose you need. See figure I.

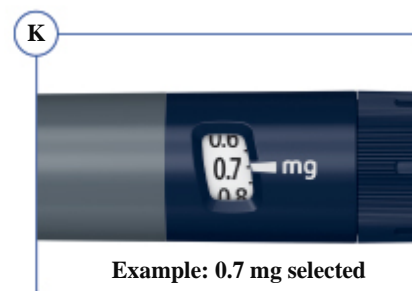
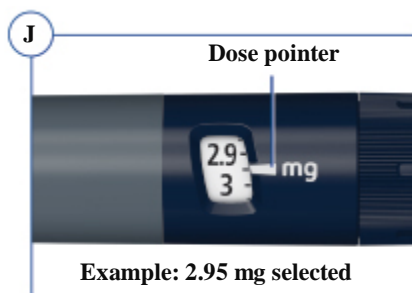
When you have selected your dose, you can proceed to Step 4.

i If there is not enough Sogroya left to select a full dose, see *Check how much Sogroya is left*.



i The dose counter shows the dose in mg. See figures J and K. Always use the **dose pointer to select the exact dose**.

Do not count the pen clicks. Do not use the pen scale (see Overview of Sogroya pen) to measure how much growth hormone to inject. Only the dose pointer will indicate the exact number of mg.



i 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 accidentally force it past the number of mg left.



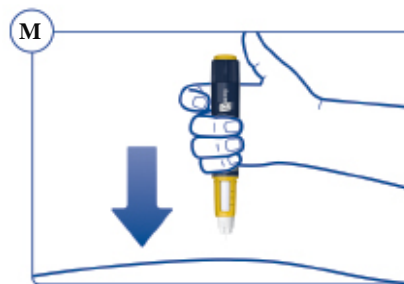
Step 4. Inject your dose

- Insert the needle into your skin as your doctor or nurse has shown you. See figure M.

Make sure you can see the dose counter. **Do not cover it with your fingers.** This could block the injection.



Remember to change the injection site every week.

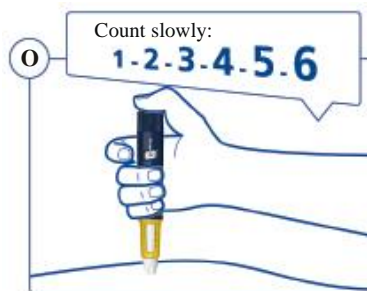


- Press and hold down the dose button until the dose counter shows '0' (See figure N). **The '0' must line up with the dose pointer.** You may then hear or feel a 'click'.

Continue to hold down the dose button with the needle in your skin.



- **Keep holding down the dose button with the needle in your skin and slowly count to 6** to make sure that the full dose has been delivered (see figure O).



If '0' does not appear in the dose counter after continuously pressing the dose button, the needle or pen may be blocked or damaged, and **you have not received any Sogroya** – even though the dose counter has moved from the original dose that you have set.

Remove the needle as described in Step 5 and repeat Steps 1 to 4.

- Carefully remove the needle from your skin. See figure P. If blood appears at the injection site, press lightly. Do not rub the area.

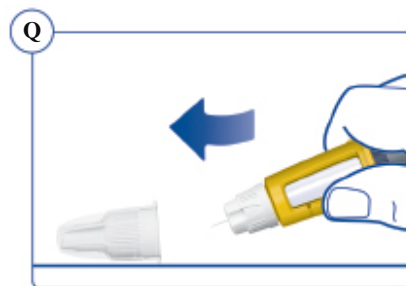


You may see a drop of Sogroya at the needle tip after injecting. This is normal and does not affect your dose.



Step 5. After your injection

- Insert the needle tip into the outer needle cap on a flat surface without touching the needle or the outer needle cap. See figure Q.



- Once the needle is covered, carefully push the outer needle cap completely on. See figure R.



- Unscrew the needle and dispose of it carefully as instructed by your doctor, nurse, pharmacist or local authorities.
Always dispose of the needle after each injection.

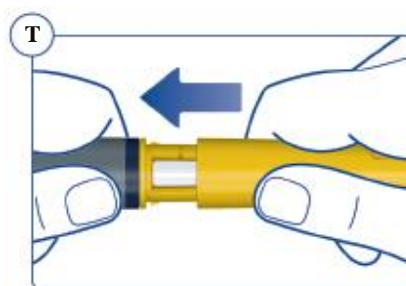
When the pen is empty, remove and dispose of the needle as above **and throw the pen away separately** as instructed by your doctor, nurse, pharmacist or local authorities.

The pen cap and the empty carton can be disposed of in your household waste.



- Put the pen cap on your pen after each use to protect Sogroya from direct light. See figure T.

To store your pen, see *How to store* in the *package leaflet*.



Do not try to put the inner needle cap back on.

You may stick yourself with the needle.

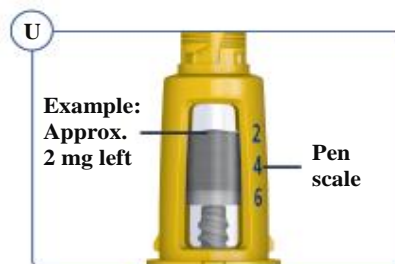


Always remove the needle from your pen immediately after each injection. This reduces the risk of contamination, infection, leakage of Sogroya, and blocked needles leading to incorrect dosing.

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Check how much Sogroya is left

The pen scale shows you approximately how much Sogroya is left in your pen. See figure U.



To see how much Sogroya is left, use the dose counter: Turn the dose selector clockwise until the dose counter stops. You can select a maximum dose of 4 mg. If it shows '4' at least 4 mg are left in your pen.

If the dose counter stops at '2.8', only 2.8 mg are left in your pen. See figure V.



What if I need a larger dose than what is left in my pen?

It is not possible to select a larger dose than the amount 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 if trained or advised by your doctor or nurse, you may split your dose.** Use a calculator to plan the doses as instructed by your doctor or nurse.

Be very careful to calculate correctly, otherwise it may lead to medication error. If you are not sure how to split your dose using two pens, then select and inject the dose you need with a new pen.

How to care for your pen

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.

Do not try to refill your pen, it is pre-filled and must be disposed of when empty.

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 flow before you inject, see Steps 1 and 2. If your pen has been dropped, check the cartridge, if the cartridge is cracked, do not use the pen.

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.
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Important information

- Caregivers must be very careful when handling needles – to reduce the risk of needle sticks and cross-infection.
- Always keep your pen and needles out of reach of others, especially children.
- **Do not use the pen** if it is damaged. Do not try to repair your pen or pull it apart.
- To store your pen, see *How to store* in the *package leaflet*.