This Abbreviated Prescribing Information (API) reflects SmPC version as of July 2023
Were changes done to this API as a result of the SmPC change above?
YES ☒ NO ☐

Prepared and updated by Rare Disease Global Medical Affairs based on EU SmPC
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Abbreviated prescribing information

Sogroya® (somapacitan)

5 mg/1.5 mL, 10 mg/1.5 mL, and 15 mg/1.5 mL pre-filled pen, solution for injection

Consult Summary of Product Characteristics before prescribing.

Indications: Sogroya® is indicated for the replacement of endogenous growth hormone (GH) in children aged 3 years and above, and adolescents with growth failure due to growth hormone deficiency (paediatric GHD), and in adults with growth hormone deficiency (adult GHD).

Posology and method of administration

***Table 1: Dose recommendation**:*

Paediatric GHD	***Recommended starting dose***
Treatment-naïve paediatric patients and paediatric patients switching from other GH medicinal products	*0.16 mg/kg/week*
Adult GHD	***Recommended starting dose***
Naïve patients	
Adults (≥18 to <60 years)	*1.5 mg/week*
Women on oral oestrogen therapy (irrespective of age)	*2 mg/week*
Elderly (60 years or older)	*1 mg/week*
Patients switching from daily GH medicinal products	
Adults (≥18 to <60 years)	*2 mg/week*
Women on oral oestrogen therapy (irrespective of age)	*4 mg/week*
Elderly (60 years or older)	*1.5 mg/week*

Paediatric GHD

***Dose titration**:* Somapacitan dose may be individualised and adjusted based on growth velocity, adverse reactions, body weight and serum insulin-like growth factor I (IGF-I) concentrations. Average IGF-I standard deviation score (SDS) levels (drawn 4 days after dosing) can guide dose titration. Dose adjustments should be targeted to achieve average IGF-I SDS levels in the normal range, i.e. between -2 and +2 *(preferably close to 0 SDS)*. If the IGF-I (SDS) is > 2, it should be reassessed after a subsequent somapacitan administration. If the value remains > 2, reducing the dose by 0.04 mg/kg/week is recommended. More than one dose reduction may be required in some patients. In patients who have had the dose reduced but are not growing well, the dose may be gradually increased as tolerated up to a maximum dose of 0.16 mg/kg/week. Dose increments should not exceed 0.02 mg/kg per week.

Treatment should be discontinued in patients having achieved final height or near final height, i.e. an annualised height velocity < 2 cm/year and a bone age > 14 years in girls or > 16 years in boys which corresponds to the closure of the epiphyseal growth plates.

Once the epiphyses are fused, patients should be clinically re-evaluated for the need for growth hormone treatment. When GHD persists after growth completion, growth hormone treatment should be continued to achieve full somatic adult development including lean body mass and bone mineral accrual (for guidance on dosing see recommended dose for adults in table 1).

Adult GHD

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 adult GHD patients.

Paediatric and adult GHD

Switching from other growth hormone products: Patients switching from a weekly growth hormone to somapacitan are recommended to continue administration at their once weekly dosing day. Patients switching from daily human growth hormone to once-weekly somapacitan should choose the preferred day for the weekly dose and inject the final dose of daily treatment the day before (or at least 8 hours before) injecting the first dose of once-weekly somapacitan. Patients should follow the instructions for the dose presented in Table 1. ***Oral oestrogen therapy:*** Females on oral oestrogen-containing therapy may have reduced IGF-I levels and may require dose adjustment of growth hormone to achieve the treatment goal. In paediatric GHD doses above 0.16 mg/kg/week have not been studied and are not recommended. ***Missed dose:*** Patients who miss a dose are advised to inject once-weekly 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. ***Flexibility in dosing time:*** On occasions when injection at the scheduled dosing day is not possible, once-weekly somapacitan can be administered up to 2 days before or 3 days after the scheduled weekly dosing day as long as the time between two doses is at least 4 days (96 hours). Once-weekly dosing for the next dose could be resumed at the regularly scheduled dosing day.

Special populations

Elderly (60 years or older): Generally, lower doses of somapacitan may be necessary in older patients. ***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. In females using oral oestrogen, it should be considered to change the route of oestrogen administration (e.g. transdermal, vaginal). No adjustment of the starting dose is required for patients with ***Renal or Hepatic impairment, respectively***. 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.

Method of administration: Somapacitan is to be injected subcutaneously in the abdomen, thighs, buttocks or upper arms without dose adjustment once weekly at any time of the day. The injection site should be rotated every week. Sogroya® is delivered via colour-coded pre-filled pen. Sogroya® 5 mg/1.5 mL (3.3 mg/mL) pen (teal) delivers doses from 0.025 mg to 2 mg in increments of 0.025 mg (0.0075 mL), Sogroya® 10 mg/1.5 mL (6.7 mg/mL) pen (yellow) delivers doses from 0.05 mg to 4 mg in increments of 0.05 mg (0.0075 mL) and Sogroya® 15 mg/1.5 mL (10 mg/mL) pen (rubine red) delivers doses from 0.10 mg to 8 mg in increments of 0.1 mg (0.01 mL).

Contraindications

Hypersensitivity to the active substance or to any of the excipients. Somapacitan must not be used when there is any evidence of activity of a tumour. Intracranial tumours must be inactive and anti-tumour therapy must be completed prior to starting somapacitan therapy. Treatment should be discontinued if there is evidence of tumour growth. Somapacitan must not be used for longitudinal growth promotion in children with closed epiphyses. 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.

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 11βHSD-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. **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 patients treated with GH. In patients in complete remission from tumours or malignant disease, GH therapy has not been associated with an increased relapse rate. Patients who have achieved complete remission of malignant disease or who have been treated for benign tumours should be followed closely for relapse after commencement of GH therapy. GH treatment should be interrupted in case of any development or reoccurrence of malignant disease. An overall slight increase in second neoplasms has been observed in childhood cancer survivors treated with GH with the most frequent being intracranial tumours. The dominant risk factor for second 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 GH treatment should be discontinued. At present there is insufficient evidence to guide clinical decision making in patients with resolved intracranial hypertension. If growth GH is restarted, careful monitoring for symptoms of intracranial hypertension is necessary. **Thyroid function**: GH may unmask incipient hypothyroidism. Hypothyroidism interferes with the response to GH therapy, patients should have their thyroid function tested regularly, and should receive replacement therapy with thyroid hormone when indicated. **Use with oral oestrogen**: Female patients 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. If a female patient 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 female patient on somapacitan discontinues oral oestrogen therapy, the dose of somapacitan may need to be reduced to avoid excess of somapacitan and/or undesirable effects. **Skin and subcutaneous tissue disorders**: When somapacitan is administered at the same site over a long period of time, local changes in the subcutaneous tissue such as lipohypertrophy, lipoatrophy, and acquired lipodystrophy might occur. Rotate injection site to minimise the risk. **Antibodies**: Antibodies to somapacitan were not observed in adult GHD patients. Few paediatric GHD patients tested positive for somapacitan binding antibodies. None of these antibodies were neutralising and no impact on the clinical effects was observed. Testing for presence of anti-somapacitan antibodies should be carried out in patients who fails to respond to therapy. **Pancreatitis:** There have been few reports of pancreatitis during treatment with other growth hormone medicinal products. It should therefore be considered in somapacitan treated patients who develop unexplained abdominal pain.

Interaction with other medicinal products and other forms of interaction: 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. Antihyperglycaemic treatment including insulin may require dose adjustment in case of somapacitan co-administration since somapacitan may decrease insulin sensitivity.

Fertility, pregnancy, and lactation: There are no data from the use of somapacitan in pregnant women. Somapacitan is not recommended during pregnancy and in women of childbearing potential not using contraception. It is unknown whether somapacitan/metabolites are excreted in human milk. A risk to the breastfed child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue /abstain from Sogroya® therapy considering the benefit of breast-feeding for the child and the benefit of therapy for the woman. There is no clinical experience with somapacitan use and its potential effect on fertility.

Effects on ability to drive and use machines: Sogroya® has no or negligible influence on the ability to drive and use machines

Undesirable effects: The most frequently reported adverse drug reactions (ADRs) are (in decreasing order [paediatric GHD, adult GHD]) headache (12%, 12%), pain in extremity (9%, NA), hypothyroidism (5%, 2%), injection site reactions (5%, 1%), peripheral oedema (3%, 4%), arthralgia (2%, 7%), hyperglycaemia (2%, 1%), fatigue (2%, 6%) and adrenocortical insufficiency (1.5%, 3%). The adverse drug reactions from clinical trials in paediatric GHD include: *very common:* headache, *common:* Hypothyroidism, Adrenocortical insufficiency, Hyperglycaemia, Arthralgia, Pain in extremity, Peripheral oedema, Fatigue, Injection site reactions[#]. The adverse drug reactions from clinical trials in adult GHD include: *very common:* headache, *common:* Adrenocortical insufficiency, Hypothyroidism, Hyperglycaemia, Paraesthesia, Rash, Urticaria, Arthralgia, Myalgia, Muscle stiffness, Peripheral oedema, Fatigue, Asthenia, Injection site reactions. Uncommon: Carpal tunnel syndrome, Lipohypertrophy, Pruritus, Joint stiffness [#] The injection site reactions included injection site bruising (1.5%), injection site pain (1.5%), injection site haematoma (1.5%), and injection site swelling (0.8%)).

Overdose: There is limited clinical experience with overdose of somapacitan. Based on experience with daily GH treatment, short term overdose with low blood glucose levels initially, followed by high blood glucose levels can occur. Long-term overdosage could result in signs and symptoms consistent with the known effects of human growth hormone excess.

Storage and handling: Prior to use, the shelf life is 2 years stored in a refrigerator (2°C – 8°C). After first opening: 6 weeks in a refrigerator (2° - 8°C). 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. 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 freeze. Keep away from the refrigerator freezing element. Sogroya must not be used if it has been frozen. Sogroya pre-filled pen is designed to be used with disposable needles of a length between 4 mm and 8 mm and gauge between 30G and 32G. For instructions for use/handling please refer to package insert for full details.

Supply details: The available range of products may vary from country to country. Sogroya® is a registered trademark of Novo Nordisk Health Care AG, Switzerland. Please refer to local prescribing information for full details. **Legal category:** Prescription-only medicine (POM). **Marketing authorisation holder:** Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd Denmark.

Summary of Product Characteristics can be obtained from Novo Nordisk A/S.

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