Package leaflet: Information for the user
Sogroya® 15 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

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 sidechain 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 growth failure in children and adolescents aged 3 years and above if they have no or very low production of growth hormone (growth hormone deficiency) and 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 or the child in your care are allergic to somapacitan or any of the other ingredients of this medicine (listed in section 6).
- if you or the child in your care 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.

- if you or the child in your care have recently had open heart surgery or abdominal surgery or multiple accidental injury, severe breathing problems or similar condition.
- for children and adolescents who have stopped growing because of closure of the growth plates (closed epiphyses) meaning that you or the child in your care have been told by your doctor that your bones have stopped growing.

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 or the child in your care have ever had any kind of tumour
- you or the child in your care 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 or the child in your care 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 or the child in your care 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 or the child in your care 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 female taking oral contraception or hormonal replacement therapy with oestrogen, your dose of Sogroya® 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 or the child in your care 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
- you or the child in your care develop a severe stomach ache during treatment with Sogroya® as this could be a symptom of inflammation of the pancreas seen in treatments with other growth hormone products.

Skin changes at the injection site
The injection site of Sogroya® should be rotated to prevent changes to the fatty tissue under the skin, such as skin thickening, skin shrinking or lumps under the skin. Change the place of injection on your body from one week to the next.

Antibodies
You are not expected to get antibodies against somapacitan. However, only very rarely your child may get antibodies. If your Sogroya® treatment does not work, your doctor may test you for antibodies to somapacitan.

Other medicines and Sogroya®
Tell your doctor or pharmacist if you or the child in your care are using, have recently used or might use any other medicines.
In particular, tell your doctor if you or the child in your care 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 folliclestimulating 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 breastfeeding 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 pre-filled pen. 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 or the child in your care start treatment.

When to use Sogroya®
- You or the child in your care 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 you or the child in your care are changing from another weekly growth hormone therapy to Sogroya®, you are advised to continue injecting on the same week day.
If you or the child in your care are changing from daily growth hormone therapy to Sogroya® choose the preferred day for the weekly dose and inject the last dose of daily treatment the day before (or at least 8 hours before) inejcting the first dose of Sogroya®.
Changing from another type or brand of growth hormone should be done by your doctor.

If it is not possible for you or the child in your care to inject Sogroya® on your usual week day, you can inject Sogroya® up to 2 days before or 3 days after your scheduled dosing day. The next dose you can inject as usual the following week.

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 long you will need treatment for

You may need Sogroya® for as long as your body does not produce enough growth hormone

- If you or the child in your care are using Sogroya® for growth failure you will continue using Sogroya® until you stop growing
- If you or the child in your care still lack growth hormone after you stop growing, you may need to continue using Sogroya® into adulthood

Do not stop using Sogroya® without discussing this with your doctor first.

How much to use

Children and adolescents

The dose for children and adolescents depends on the body weight.
The recommended dose of Sogroya® is 0.16 mg per kg body weight given once a week.

Adults

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 Dose recommendation

Adult growth hormone deficiency	**Recommended starting dose**
You have not received daily growth hormone medicine before	
You are ≥18 to <60 years	1.5 mg/week
You are woman on oral oestrogen therapy regardless of age	2 mg/week
You are 60 years or above	1 mg/week
You have previously received daily growth hormone medicine	
You are ≥18 to <60 years	2 mg/week
You are woman on oral oestrogen therapy regardless of age	4 mg/week
You are 60 years or above	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)
- the buttocks
- the upper arms.

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 or the child in your care 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 or the child in your care 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.

Side effects seen in children and adolescents Very common (may affect more than 1 in 10 people)
- Headache.

Common (may affect up to 1 in 10 people)
- Swollen hands and feet due to a build-up of fluid under the skin (peripheral oedema)
- The adrenal glands do not make enough steroid hormones (adrenocortical insufficiency).
- Decreased thyroid hormone (hypothyroidism)
- Redness and pain in the area of injection (injection site reactions)
- Joint pain (arthralgia)
- Pain in arms or legs (pain in extremity)
- High blood sugar (hyperglycaemia)
- Feeling very tired (fatigue).

Side effects seen in adults
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

Great Britain
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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°C - 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°C - 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 does not appear clear to slightly opalescent, colourless to slightly yellow and free from 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 10 mg of somapacitan. Each pre-filled pen contains 15 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.

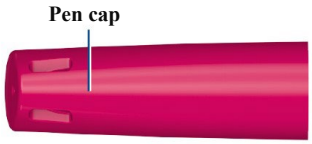
Sogroya® 15 mg/1.5 mL solution for injection in pre-filled pen with a rubine red dose button is available in the following pack sizes: a pack containing 1 pre-filled pen or a multipack containing 5 packs, each containing 1 pre-filled pen.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

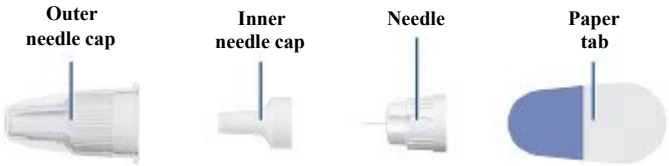
Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

This leaflet was last revised in 05/2023

Instructions for use
Overview Sogroya® 15 mg/1.5 mL



Needle (example)



How to use your Sogroya® pen

5 Steps you should follow for a Sogroya® injection:

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 15 mg of somapacitan and it can be used to inject doses from 0.10 mg to 8 mg, in steps of 0.1 mg. Sogroya® is for use under the skin only (subcutaneous). Needles are not included and must be obtained separately. Sogroya® pre-filled pen is designed to be used with disposable needles of a length between 4 mm and 8 mm and a gauge between 30G and 32G.

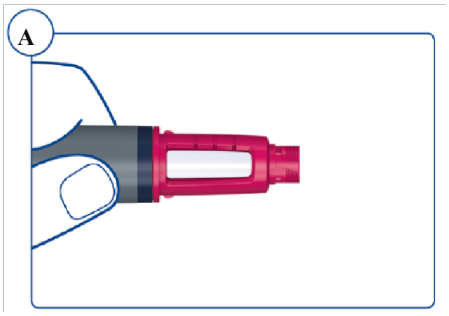
Do not share your Sogroya® pen and needles with another person. You may give another person an infection or get an infection from them.

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.

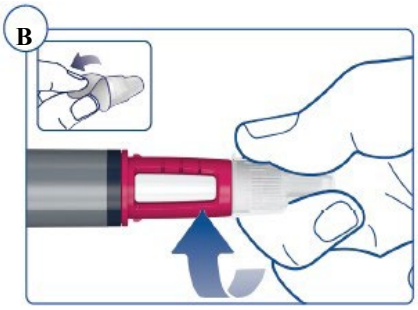
Step 1. Prepare your Sogroya® pen

- 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 to slightly opalescent or colourless to slightly yellow.** See figure A.
- **If Sogroya® contains visible particles, 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.

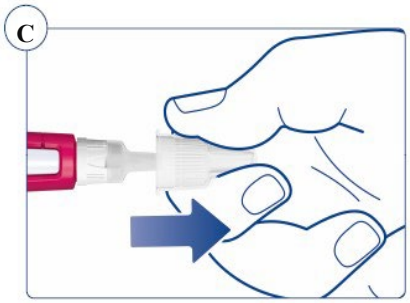


- When you are ready to inject, take a new disposable needle. Firstly, tear off the paper tab.
- Secondly, push the needle straight onto the pen. Turn the needle clockwise **until it is on tight.** See figure B.



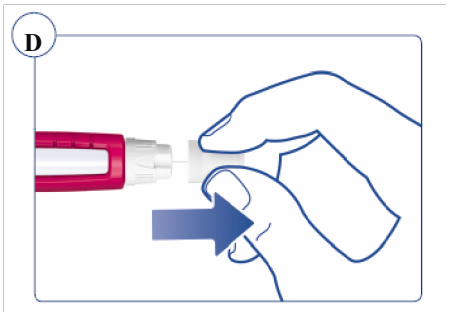
- Pull off the outer needle cap and keep it for later. You will need it after the injection, to safely remove the needle from the pen. See figure C.

ⓘ 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.



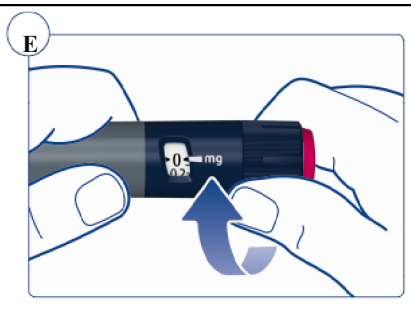
⚠ **Always use a new needle for each injection.** This reduces the risk of contamination, infection, leakage of Sogroya®, and blocked needles leading to incorrect dosing.

⚠ 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 0.10 mg. You may hear a faint click. See figure E.



- **One tick mark equals 0.10 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.

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.

H

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.

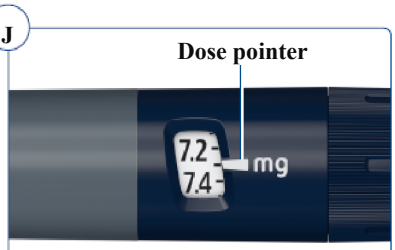
If there is not enough Sogroya® left to select a full dose, see *Check how much Sogroya® is left.*

I

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

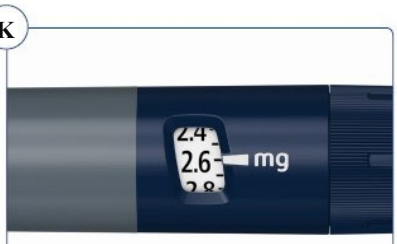
Do not count the pen clicks. Do not use the pen scale (see Overview of Sogroya® pen) to measure how much growth hormone to inject. Only the dose pointer will indicate the exact number of mg.

J



Example: 7.3 mg selected

K



Example: 2.6 mg selected

If you select the wrong dose, you can turn the dose selector clockwise or counterclockwise to the correct dose. See figure L.

The pen clicks sound and feel differently when the dose selector is turned clockwise, counterclockwise, or if you accidentally force it past the number of mg left.

L

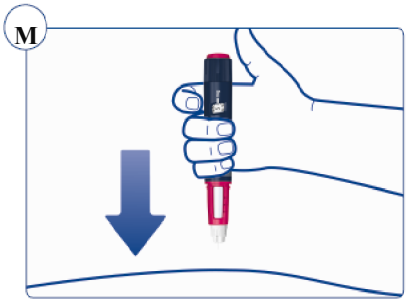
Step 4. Inject your dose

- 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.

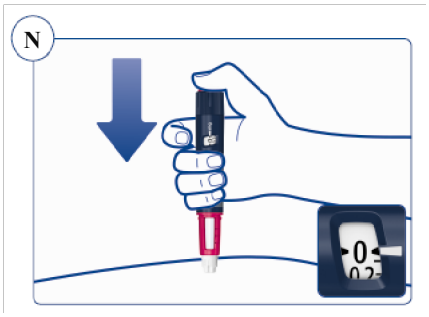
Remember to change the injection site every week.

M

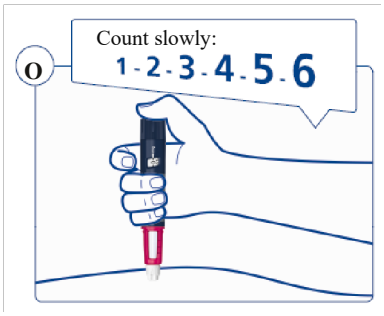


- Press and hold down the dose button until the dose counter shows ‘0’ (See figure N). **The ‘0’ must line up with the dose pointer.** You may then hear or feel a ‘click’.

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



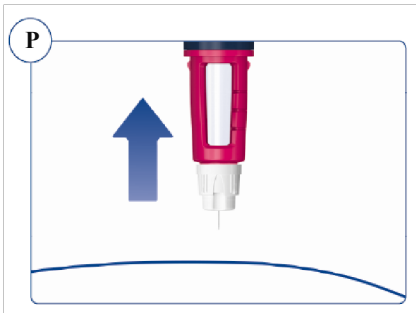
- **Keep holding down the dose button with the needle in your skin and slowly count to 6** to make sure that the full dose has been delivered (see figure O).



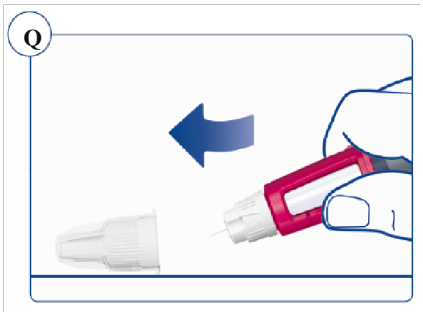
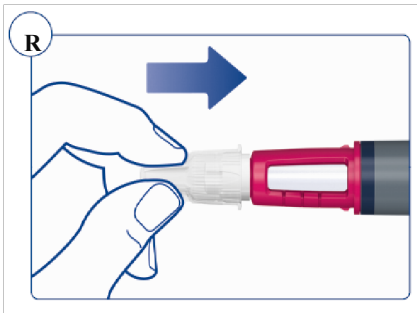
⚠ If ‘0’ does not appear in the dose counter after continuously pressing the dose button, the needle or pen may be blocked or damaged, and **you have not received any Sogroya®** – even though the dose counter has moved from the original dose that you have set. Remove the needle as described in Step 5 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.



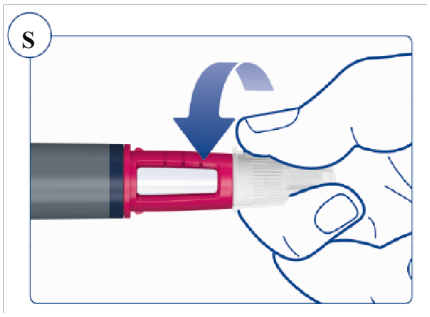
Step 5. After your injection

• 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.

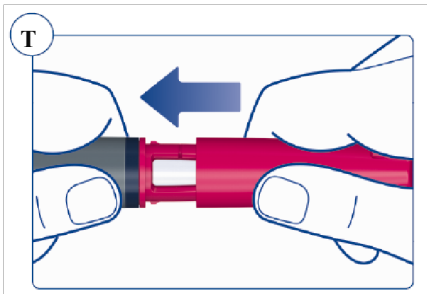
  When the pen is empty, remove and dispose of the needle as above **and throw the pen away separately** as instructed by your doctor, nurse, pharmacist or local authorities.

  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 this *booklet.*

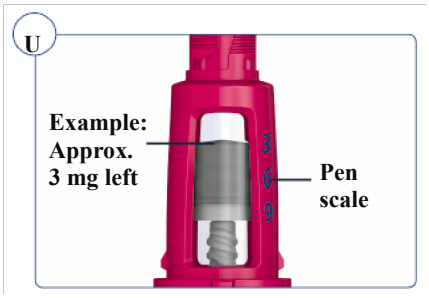


⚠ **Do not try to put the inner needle cap back on.** You may stick yourself with the needle.

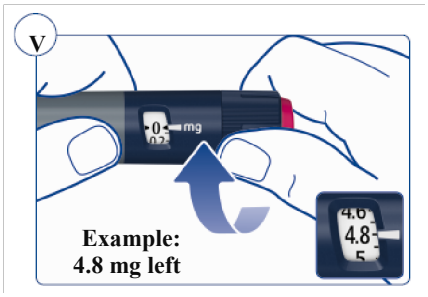
⚠ Always remove the needle from your pen immediately after each injection. This reduces the risk of contamination, infection, leakage of Sogroya®, and blocked needles leading to incorrect dosing.

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 8 mg. If it shows '8' at least 8 mg are left in your pen.
If the dose counter stops at '4.8', only 4.8 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 yourcurrent 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. It may be cleaned with mild detergent on a moistened cloth.

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 this *booklet.*