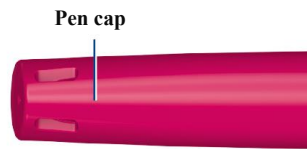
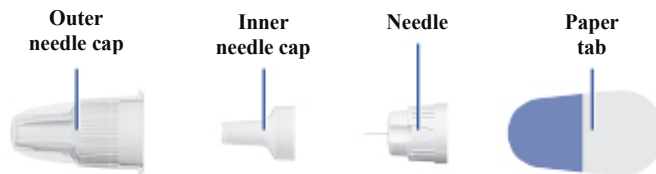


8. INSTRUCTIONS FOR USE – 15 MG/1.5 ML



Needle (example)




How to use your Sogroya[®] pen

Five steps you should follow for a Sogroya[®] 15 mg/1.5 mL injection:

| | |
|--|-------------------|
| Step 1. Prepare your once weekly Sogroya[®] pen | 2 |
| Step 2. Check the flow with each new pen | 3 |
| Step 3. Select your dose | 4 |
| Step 4. Inject your dose | 4 |
| Step 5. After your injection | 5 |
| Check how much Sogroya[®] 15 mg/1.5 mL is left | 6 |
| Frequently Asked Questions | 7 |

For further information about your pen, see sections: [Check how much Sogroya[®] 15 mg/1.5 mL is left](#), [Frequently asked questions](#), [Important information](#).

Please read the Consumer Medicine Information 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[®] 15 mg/1.5 mL is a pre-filled growth hormone pen. It contains 15 mg of Sogroya[®] and delivers doses from 0.1 mg to 8 mg, in increments of 0.1 mg. Sogroya[®] is for use under the skin only (subcutaneous). Sogroya[®] pre-filled pen is designed to be used with NovoFine[®] disposable needles up to a length of 8 mm.


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

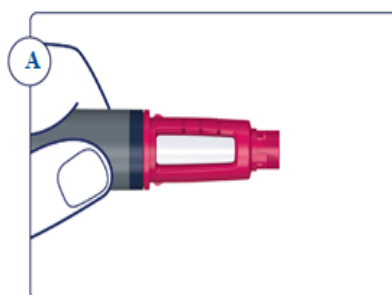
Do not use your pen without proper training from your doctor or nurse. Make sure that you are confident in making an injection with the pen before you start your treatment.

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 once weekly 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[®] in the right 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, 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.

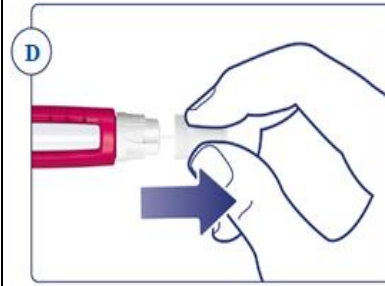


- Pull off the outer needle cap and keep it for later. You will need it after the injection, to safely remove the needle from the pen. See figure C.

 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.



- 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.



- **i** 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

- **i** 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 0.1 mg** in the dose counter. See figure E.



- 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 F.
- Check that a drop of Sogroya® appears at the needle tip. See figure F.



- **i** If no Sogroya® appears, repeat Step 2 up to 6 times.

If you still do not see a drop of Sogroya®, **change the needle** once as described in Step 5 and repeat Step 1 and 2 again.

Do not use the pen if a drop of Sogroya® still does not appear after repeating step 2.

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 G.

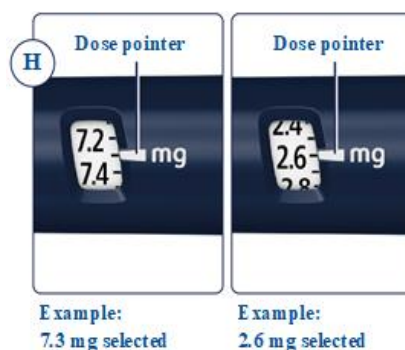
When you have selected your dose, you can proceed to Step 4.

- ⓘ **If there is not enough Sogroya® left** to select a full dose, see [Frequently asked questions](#).



- ⓘ The dose counter shows the dose in mg. See figures H. Always use the **dose pointer** to select the exact dose.

Do not count the pen clicks. Do not use the pen scale.



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

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.

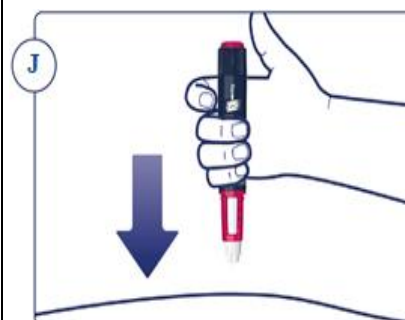


Step 4. Inject your dose

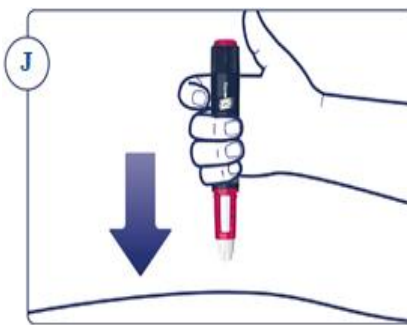
- Insert the needle into your skin as your doctor or nurse has shown you. See figure J.

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’.** Keep pressing the dose button with the needle in your skin and slowly count to 6. See figure K.
- The ‘0’ must line up with the dose pointer. You may then hear or feel a ‘click’.



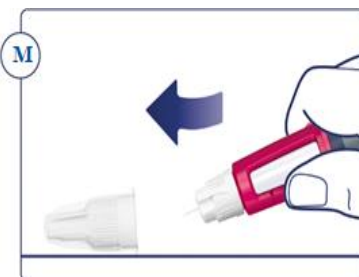
⚠ If “0” does not appear in the dose counter after continuously pressing the dose button, the needle or pen may be blocked or damaged, see [Frequently asked questions](#).

- Carefully remove the needle from your skin. See figure L. If blood appears at the injection site, press lightly. Do not rub the area.
- i** You may see a drop of Sogroya® at the needle tip after injecting. This is normal and does not affect your dose.

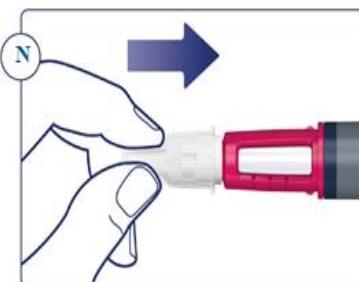


Step 5. After your injection

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



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



- Unscrew the needle and dispose of it carefully as instructed by your doctor, nurse, or pharmacist. See Figure O.

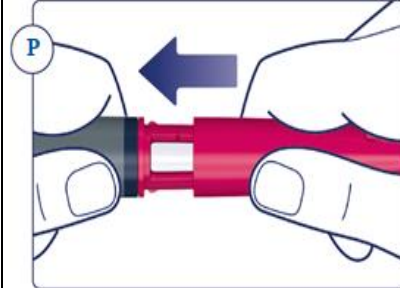
Always dispose of the needle after each injection.

When the pen is empty, throw it away **without** a needle on as instructed by your doctor, nurse, or pharmacist.



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

To store your pen, see *Looking after your medicine* under 5. *What should I know while using Sogroya®?* in the [Consumer Medicine Information](#).



⚠ 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® 15 mg/1.5 mL is left

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



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 R.



Frequently Asked Questions

| | |
|--|---|
| What if I need a larger dose than what is left in my pen? | <p>It is not possible to select a larger dose than the amount of mg left in your pen.</p> <p>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.</p> <p>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.</p> |
| What if no Sogroya[®] appears when I check the flow? | <p>A. Your needle may be blocked or damaged, if no Sogroya[®] appears at the needle tip. Remove the needle as described in Step 5 and repeat Steps 1 and 2.</p> <p>B. Your pen may be defective, if Sogroya[®] still does not appear after changing the needle. Do not use the pen.</p> |
| What if “0” does not appear after completing my injection? | <p>In this case 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.</p> <p>Remove the needle as described in Step 5 and repeat Steps 1 to 4.</p> |
| How should I take care of my pen? | <p>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.</p> <p>If there is Sogroya[®] left in the pen, store the pen as directed in Looking after your medicine under 5. <i>What should I know while using Sogroya[®]?</i> in the Consumer Medicine Information.</p> <p>Do not try to refill your pen, it is pre-filled and must be disposed of when empty.</p> |
| What if I drop my pen? | <p>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.</p> |
| How do I clean my pen? | <p>Do not wash, soak, or lubricate your pen. If necessary, clean it with mild detergent on a moistened cloth.</p> |



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 *Looking after your medicine* under 5. *What should I know while using Sogroya[®]?* in the [Consumer Medicine Information](#).