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|--|---|
| | <p style="text-align: center;">Pen cap</p>  |
| | <p style="text-align: center;">Needle (example)</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>Outer needle cap</p>  </div> <div style="text-align: center;"> <p>Inner needle cap</p>  </div> <div style="text-align: center;"> <p>Needle</p>  </div> <div style="text-align: center;"> <p>Paper tab</p>  </div> </div> |
| <p>Supplies you will need:</p> <ul style="list-style-type: none"> • SOGROYA prefilled Pen • new injection needle. SOGROYA prefilled Pen is designed to be used with all Novo Nordisk disposable needles up to a length of 8 mm. • sharps disposal container. See Step 5 for information on how to throw away (dispose of) used needles and Pens. • alcohol pad • gauze pad |  |

How to use your SOGROYA Pen

5 steps you should follow for a SOGROYA injection:

Step 1: Prepare your SOGROYA Pen

Step 2: Check the SOGROYA flow with each new Pen

Step 3: Select your dose

Step 4: Inject your dose

Step 5: After your injection

For further information about your Pen see: [Frequently Asked Questions and Important information](#)

▲ Important information

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

❗ Additional information

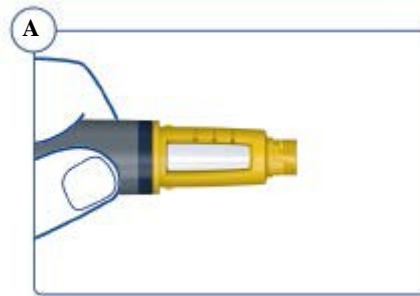
SOGROYA is a prefilled growth hormone Pen. It contains 10 mg of somapacitan-beco and delivers doses from 0.05 mg to 4.0 mg, in increments of 0.05 mg. **SOGROYA is for use under the skin only (subcutaneous) for injection 1 time each week.**

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

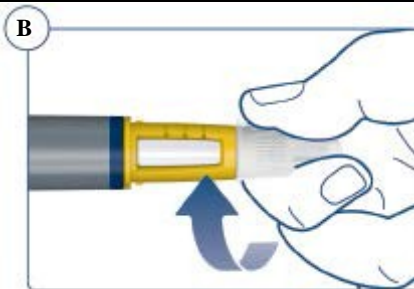
Do not use your Pen without proper training from your healthcare provider. Make sure that you are confident in giving an injection with the Pen before you start your treatment. If you are blind or have poor eyesight and cannot read the dose counter on the Pen, do not use this Pen without help. Get help from a person with good eyesight who is trained to use the Pen.

Step 1. Prepare your SOGROYA Pen

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



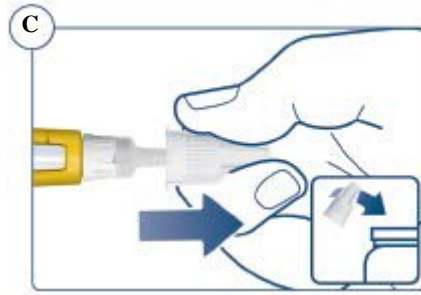
- When you are ready to give your injection, get a new disposable needle, and remove the paper tab.
- Push the needle straight onto the Pen. Turn the needle clockwise **until it is on tight** (See Figure B).




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

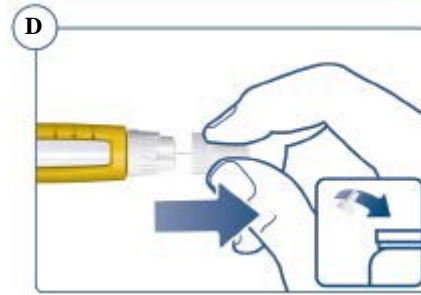
▲ Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of SOGROYA, and blocked needles leading to incorrect dosing.


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



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

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



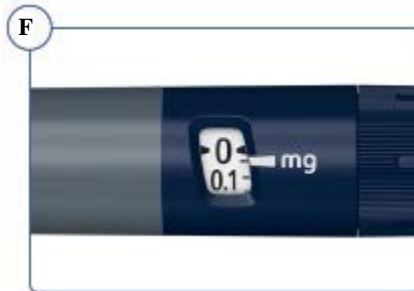
 **Never use a bent or damaged needle.**

Step 2. Check the SOGROYA flow with each new Pen

- i** If your Pen is already in use, go to Step 3.
- **Before using a new Pen**, check the SOGROYA flow to make sure the growth hormone can flow through the Pen and needle.
 - Turn the dose selector clockwise 1 marking on the dose counter to select 0.05 mg. You may hear a faint “click” when you turn the dose selector (See Figure E).



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



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



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

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:**

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

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



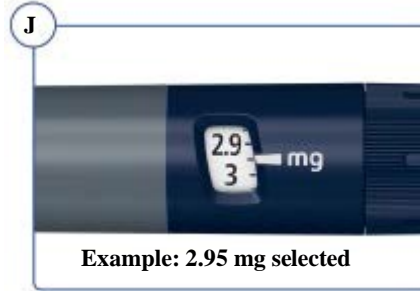
Step 3. Select your dose

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

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



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



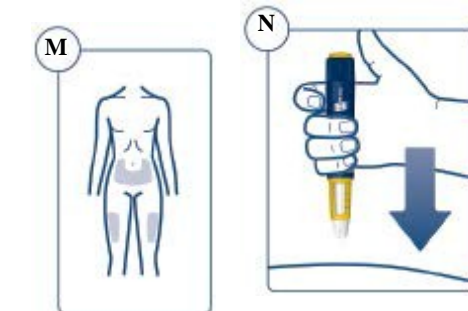
i If you select the wrong dose, you can turn the dose selector clockwise or counterclockwise to the correct dose (See Figure L).



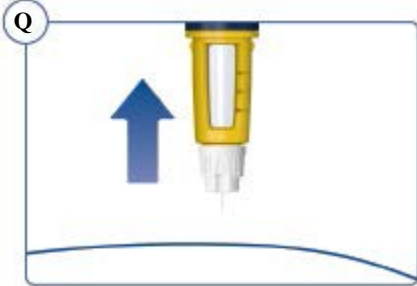

The Pen “clicks” sound and feel differently when the dose selector is turned clockwise, counterclockwise, or if you forcefully move it past the number of “mg” left in the Pen.



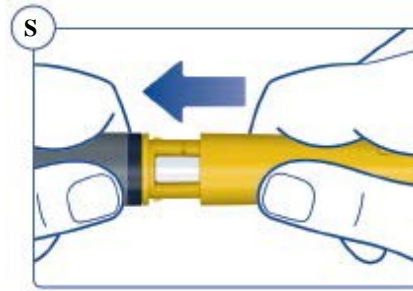
Step 4. Inject your dose

- Select the injection site.
- SOGROYA can be injected under the skin (subcutaneously) of your stomach area (abdomen) or upper legs (thighs) as instructed by your healthcare provider (See Figure M). **Change the injection site every week.**
- Wipe the injection site with an alcohol pad and let the area dry.
- Insert the needle into your skin as your healthcare provider has shown you (See Figure N).



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| <ul style="list-style-type: none"> Make sure you can see the dose counter. Do not cover it with your fingers. This could block the injection. | |
| <ul style="list-style-type: none"> Press and hold down the dose button until the dose counter shows “0” (See Figure O). The “0” must line up with the dose pointer. You may then hear or feel a “click”. Continue to hold down the dose button with the needle in your skin. <p>i If “0” does not appear in the dose counter after continuously pressing the dose button, your needle may be blocked or damaged. See Frequently Asked Questions.</p> |  |
| <ul style="list-style-type: none"> 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 P). |  |
| <ul style="list-style-type: none"> Carefully remove the needle from your skin (See Figure Q). If blood appears at the injection site, press lightly with a gauze pad. Do not rub the area. <p>i You may see a drop of SOGROYA at the needle tip after injecting. This is normal and does not affect your dose.</p> |  |
| <p>Step 5. After your injection</p> <ul style="list-style-type: none"> Carefully remove the needle from the Pen by turning the needle counterclockwise (See Figure R). Place the needle in an FDA-cleared sharps disposal container immediately to reduce the risk of a needle stick (See Figure R). <p>i Always throw away (dispose of) the needle after each injection.</p> <p>For further information about safe sharps disposal, see Frequently Asked Questions.</p> |  |

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



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

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

How should I store my SOGROYA Pen?

Before you use SOGROYA Pen for the first time:

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

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

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

Do not store SOGROYA Pen with the needle attached.

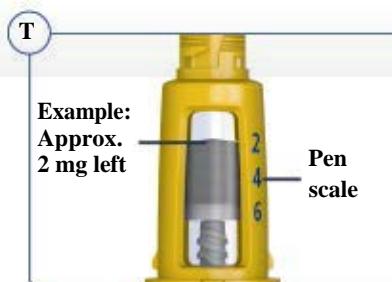
If needed, unused and in-use SOGROYA pens can be stored out of the refrigerator. SOGROYA pens can be stored at room temperature no warmer than 77°F (25°C) for up to 3 days (72 hours) and then returned to the refrigerator. Throw away (dispose of) SOGROYA if it has been stored above 77°F (25°C) for more than 3 days (72 hours) or in temperatures warmer than 86°F (30°C).

Always keep your SOGROYA Pen and needles out of reach of others, especially children.

Frequently Asked Questions

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

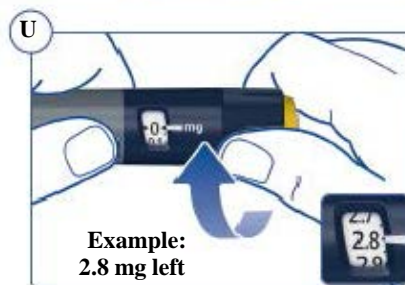
The Pen scale shows you approximately how much SOGROYA is left in your Pen (See Figure T).



To see how much SOGROYA is left in your Pen, use the dose counter:

Turn the dose selector clockwise until the dose counter stops. The dose pointer will line up with the number of “mg” left in the Pen. You can select a maximum dose of 4.0 mg. If the dose counter stops with the dose pointer lined up with “4”, at least 4.0 mg are left in your Pen.

If the dose counter stops with the dose pointer lined up with “2.8”, only 2.8 mg are left in your Pen (See Figure U).



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

It is not possible to select a larger dose on the dose counter than the number of “mg” left in your Pen. If you need more SOGROYA than you have left in your Pen, you can use a new Pen or split your dose between your current Pen and a new Pen. **Only split your dose if you have been trained or advised by your healthcare provider on how to do this.** You may find it helpful to use a calculator to plan the doses as instructed by your healthcare provider.

Be very careful to calculate your split dose correctly so that you do not give the wrong dose. If you are not sure how to split your dose using 2 Pens, then select and inject the dose you need with a new Pen.

What if no SOGROYA appears when I check the flow?

A. Your needle may be blocked or damaged, if no SOGROYA appears at the needle tip. Remove the needle as described in Step 5 and repeat Step 1 and Step 2.

B. Your Pen may be defective, if SOGROYA still does not appear after changing the needle. Do not use the Pen. Contact Novo Nordisk at 1-888-668-6444.

What if “0” does not appear after completing my injection?

The needle may be blocked or damaged, and **you have not received any SOGROYA**, even though the dose counter has moved from the dose that you have set. Remove the needle as described in Step 5 and repeat Step 1 to Step 4.

How should I take care of my Pen?

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

What if I drop my Pen?

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

How do I clean my Pen?

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

Frequently Asked Questions

How do I throw away (dispose of) used SOGROYA needles and Pens?

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

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

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should dispose of used needles and Pens. For more information about safe sharps disposal, and for specific information about safe sharps disposal in the state that you live in, go to the FDA's website at:

<http://www.fda.gov/safesharpsdisposal>.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.



Important information

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

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

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

Revised: 10/2021

Version: X

Instructions for Use

SOGROYA[®]

10 mg

(suh-GROY-uh)

(somapacitan-beco) injection

10 mg/1.5 mL (6.7 mg/mL)

1 time each week

