

TEGSEDI (Teg-SED-ee)

(inotersen) injection
for subcutaneous use

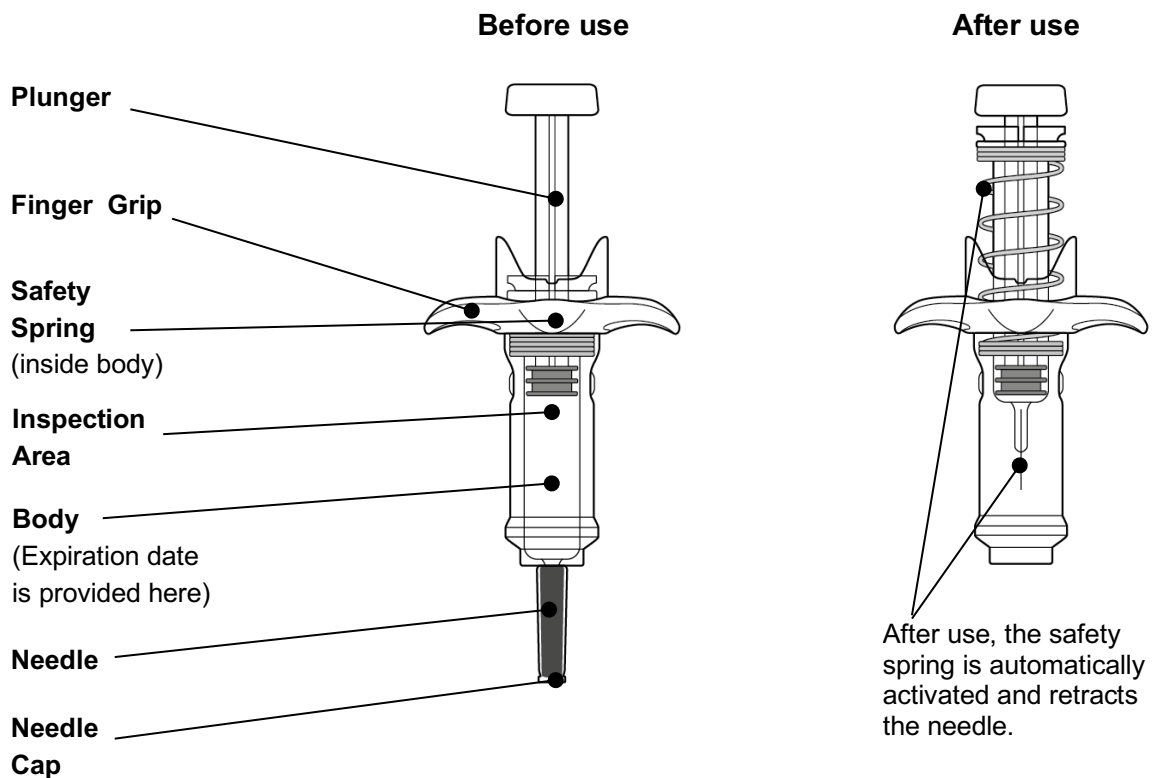
Instructions For Use

Introduction

Before using your TEGSEDI prefilled syringe, your healthcare provider should show you or your caregiver how to use it the right way. If you or your caregiver have any questions, ask your healthcare provider.

Read this Instructions for Use before you start using your TEGSEDI prefilled syringe and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Guide to parts



Important information

- Store TEGSEDI in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original container.
- **Do not** freeze.
- TEGSEDI prefilled syringes can also be kept at room temperature that is no higher than 86°F (30°C) in the original container for up to 6 weeks.
- **Do not** let TEGSEDI reach temperatures above 86°F (30°C).
- If you do not use TEGSEDI kept at room temperature within the 6 weeks, throw it away.
- Protect from light.
- **Keep TEGSEDI and all medicines out of reach of children.**

Each TEGSEDI prefilled syringe contains 1 dose of TEGSEDI and is for 1-time use only.

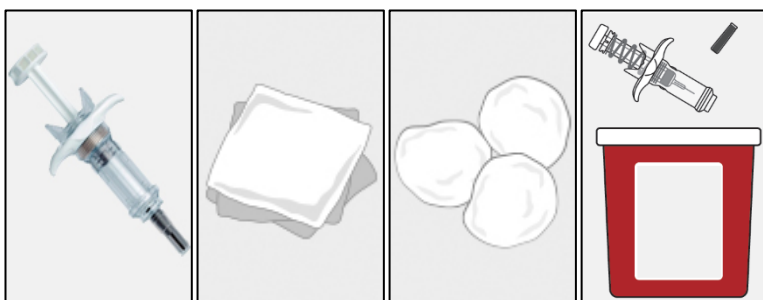
Warnings

- **Do not** remove needle cap until you have reached **Step 6** of the **Injection** phase of these instructions and are ready to inject TEGSEDI
- **Do not** share your syringe with another person or re-use your syringe
- **Do not** use if dropped onto a hard surface or damaged
- **Do not** shake or freeze the prefilled syringe
- **Do not** use if the expiration date on the side of the syringe body has passed

If any of the above happens, throw away the prefilled syringe in a puncture-resistant (sharps) container and use a new prefilled syringe.

Preparation

Step 1. Gather supplies



- 1 TEGSEDI prefilled syringe from the refrigerator
- 1 Alcohol wipe (not supplied)
- 1 Gauze pad or cotton ball (not supplied)
- 1 Puncture-resistant (sharps) container (not supplied)

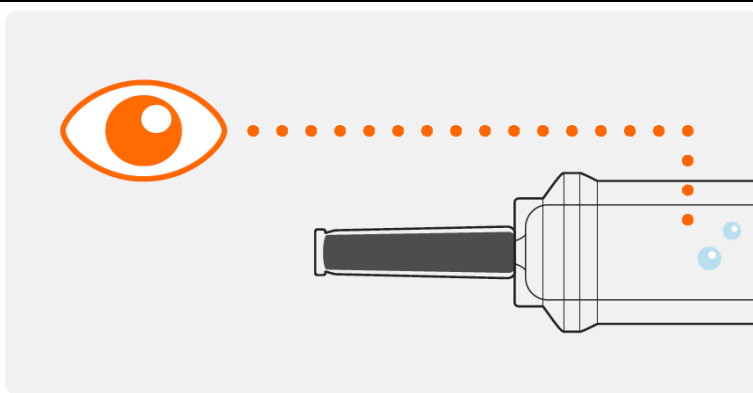
Do not perform the injection without all the supplies listed.

Step 2. Prepare to use your TEGSEDI prefilled syringe

- Remove the TEGSEDI tray from the carton and check the expiration date. **Do not** use if the expiration date has passed.
- Let TEGSEDI warm up at room temperature 68°F to 77°F (20°C to 25°C) for 30 minutes before giving the injection.
 - **Do not** warm the syringe in any other way. For example, do not warm in a microwave or hot water, or near other heat sources.
- Remove the syringe from the tray by holding onto the syringe body.
 - **Do not** move the plunger
 - **Do not** remove the syringe from the tray by holding onto the needle cap or plunger.

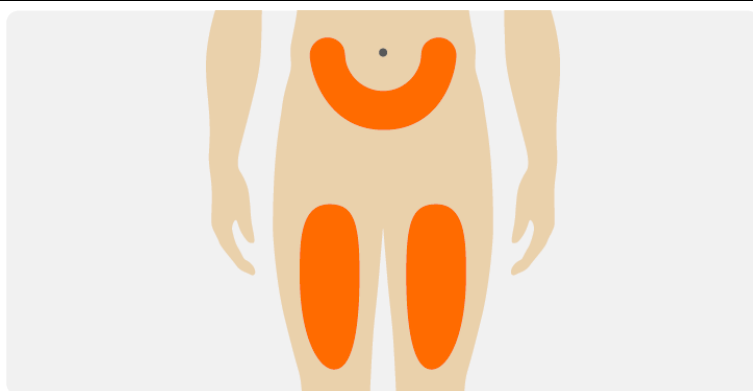


Step 3. Check medicine in the syringe



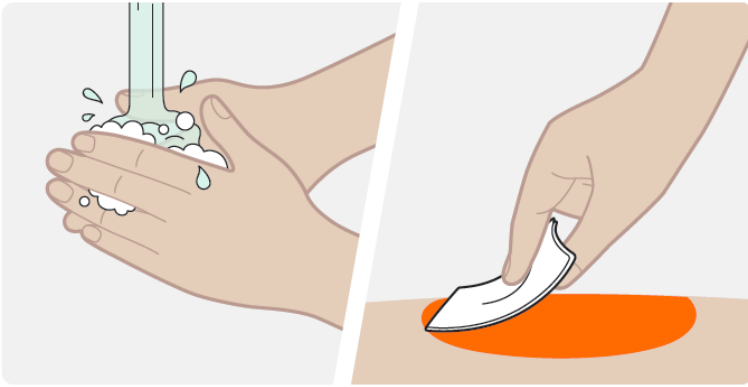
- Look in the inspection area to check that the TEGSEDI solution is clear and colorless or pale yellow in color. It is normal to see air bubbles in the solution. You do not need to do anything about it.
- **Do not** use if the solution looks cloudy, discolored, or has particles. Throw the prefilled syringe away in a puncture resistant (sharps) container, and use a new prefilled syringe.

Step 4. Choose the injection site



- Choose an injection site on your abdomen or the front of your thigh.
- **Do not** inject into the same site each time.
- **Do not** inject into the 2 inch area around the belly-button (naval).
- **Do not** inject where skin is bruised, tender, red, or hard.
- **Do not** inject into areas of the skin with scars or tattoos.
- **Do not** inject through clothing.

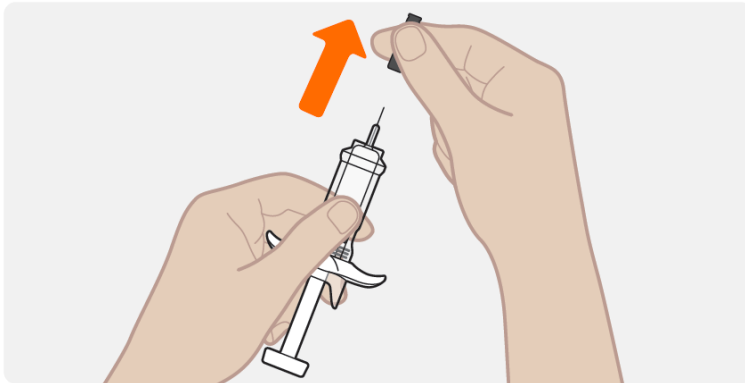
Step 5. Clean the injection site



- Wash your hands with soap and water.
- Clean the injection site with an alcohol wipe in a circular motion. Let the skin air dry.
- **Do not** touch the area again before injecting.

Injection

Step 6. Remove the needle cap



- Hold the syringe by the body, with the needle facing away from you.
- Remove needle cap by pulling it straight off. Do not twist it off.
- You may see a drop of liquid at the end of the needle. This is normal.
- Keep your hands away from the plunger to avoid pushing the plunger before you are ready to inject.

Do not remove the needle cap until right before you inject.

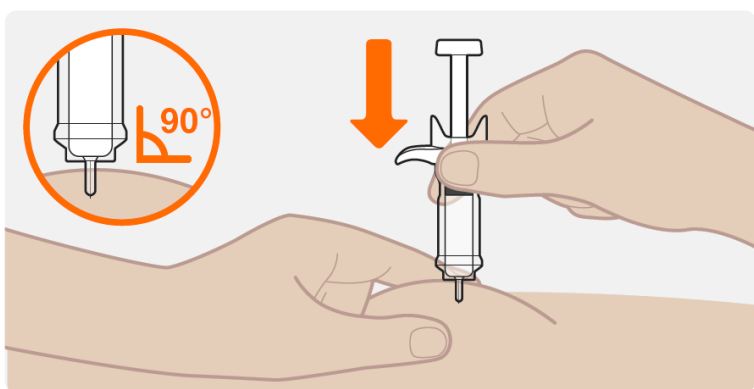
Do not pull the cap off while holding the syringe by the plunger. Always hold by the body of the syringe.

Do not let the needle touch any surface.

Do not remove any air bubbles from the syringe.

Do not put the needle cap back onto the syringe.

Step 7. Insert the needle

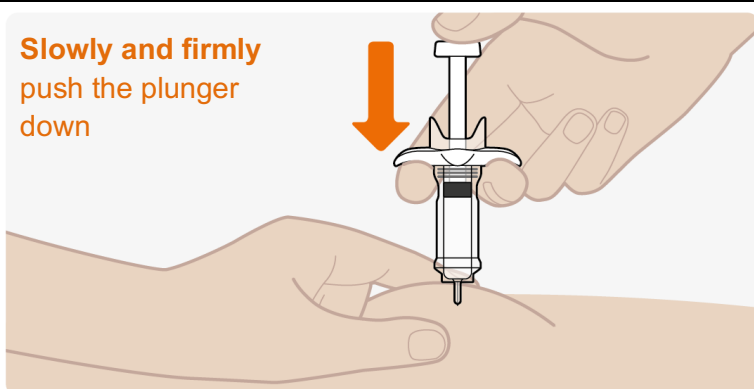


- Hold the syringe in 1 hand.
- Hold the skin around the injection site as your healthcare provider has instructed you. You should either gently pinch the skin at the injection site or give the injection without pinching the skin.
- Slowly insert the entire needle into the chosen injection site at a 90° angle until fully inserted.

Do not hold the syringe by the plunger or push against the plunger to insert the needle.

Step 8. Start the injection

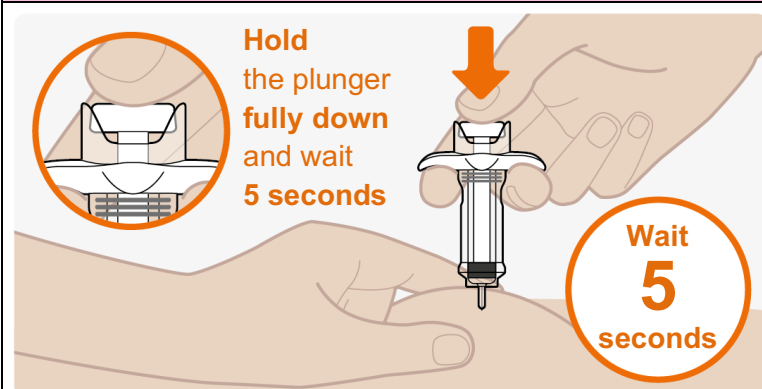
Slowly and firmly
push the plunger
down



- Slowly and firmly push the plunger all the way down until the medicine is injected. Make sure the needle stays fully inserted in the injection site while you are injecting the medicine.
- It is important to fully push the plunger all the way down.
- Your syringe may make a click sound as you push the plunger down. This is normal. This **does not** mean that the injection is finished.
- The plunger can feel stiffer towards the end of the injection. You may need to press a little harder on the plunger to make sure you have pushed it as far as it will go.

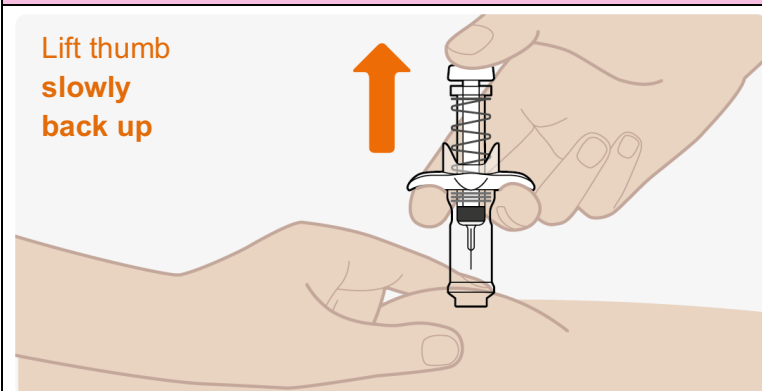
Do not let go of the plunger.

Step 9. Push the plunger down



- Push firmly on the plunger at the end of the injection. Hold the plunger fully down and wait for **5 seconds**. If you let go of the plunger too quickly, you may lose some of the medicine.
- The plunger will start to lift automatically which means that the plunger has been pushed fully down.
- Press down again if the plunger does not start to lift automatically.

Step 10. Complete the injection



- Slowly lift up on the plunger and let the safety spring push the plunger up automatically.
- The needle should now be retracted safely inside the syringe, and the safety mechanism spring visible on the outside of the plunger.
- When the plunger comes to a stop, your injection is complete.
- If the plunger does not rise up automatically when you release the pressure, it means the safety spring did not activate and you should push the plunger again but harder.
- Throw away the cap and syringe into the puncture-resistant (sharps) container right away (See section - "Dispose of the used syringe").

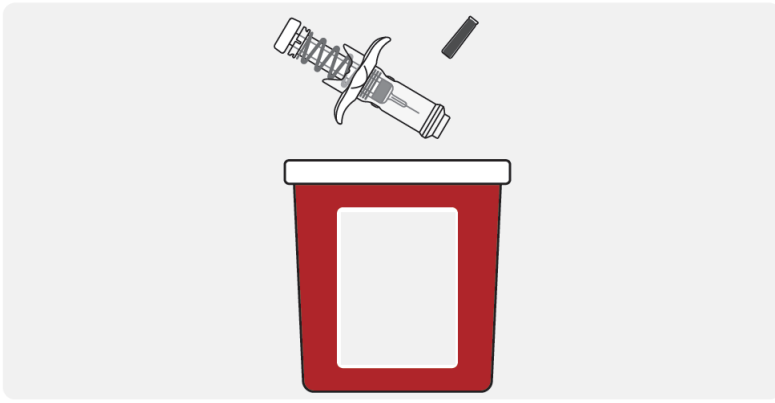
Do not pull the plunger up by hand. Lift the whole syringe straight up.

Do not try to replace the cap on the retracted needle.

Do not rub the injection site.

Disposal and care

Dispose of the used syringe



- Put the used TEGSEDI prefilled syringe in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) the TEGSEDI prefilled syringe in your household trash.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of 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 labelled 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 throw away used needles and syringes. For more information about 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>

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

Issued:10/2018