

Instructions for Use

TOUJEO® SoloStar® (Too-Jay-o)
(insulin glargine injection)
1.5 mL single-patient-use prefilled pen

Rx Only

Read this first

Do not share your TOUJEO SoloStar pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

TOUJEO contains 300 units/mL insulin glargine

- **Do not re-use needles.** If you do you might not get your dose (underdosing) or get too much (overdosing) as the needle could block.
- **Do not use a syringe to remove insulin from your pen.** If you do you will get too much insulin. The scale on most syringes is made for non-concentrated insulin only.
- The dose selector of your TOUJEO SoloStar pen dials by **1 unit**.

People who are blind or have vision problems should not use the TOUJEO SoloStar pen without help from a person trained to use the TOUJEO SoloStar pen.

Important information

- **Do not** use your pen if it is damaged or if you are not sure that it is working properly.
- Always perform a safety test (see **Step 3**).
- Always carry a spare pen and spare needles in case they are lost or stop working.
- Change (rotate) your injection sites within the area you choose for each dose (see **"Places to inject"**).

Learn to inject

- Talk with your healthcare provider about how to inject, before using your pen.
- Read all of these instructions before using your pen. If you do not follow all of these instructions, you may get too much or too little insulin.

Need help?

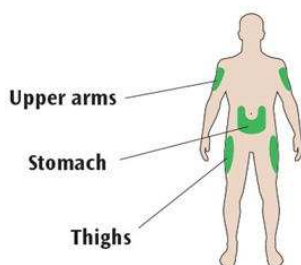
If you have any questions about your pen or about diabetes, ask your healthcare provider, go to www.Toujeo.com or call sanofi-aventis at 1-800-633-1610.

Extra items you will need:

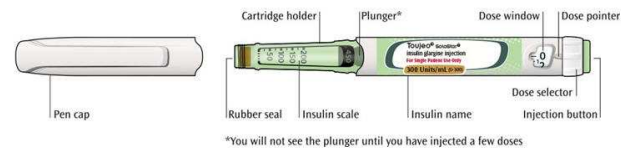
- a new sterile needle (not included with the pen) (see **Step 2**).
- an alcohol swab.
- a puncture-resistant container for used needles and pens (see **"Throwing your pen away"**).

Places to inject

- Inject your insulin exactly as your healthcare provider has shown you.
- Inject your insulin under the skin (subcutaneously) of your upper legs (thighs), upper arms, or stomach area (abdomen).
- Change (rotate) your injection sites within the area you choose for each dose to reduce your risk of getting pits or thickening of the skin (lipodystrophy) and lumps in the skin (localized cutaneous amyloidosis) at the injection sites.
- **Do not** inject where the skin has pits, is thickened, or has lumps.
- **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.



Get to know your pen



Step 1: Check your pen

Take a new pen out of the refrigerator at least **1 hour** before you inject. Cold insulin is more painful to inject.

1A Check the name and expiration date on the label of your pen.

- **Make sure you have the correct insulin.**



- **Do not** use your pen after the expiration date printed on the label.

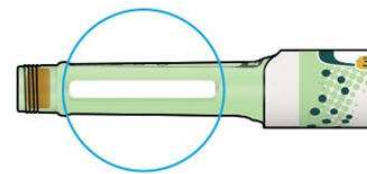


1B Pull off the pen cap.

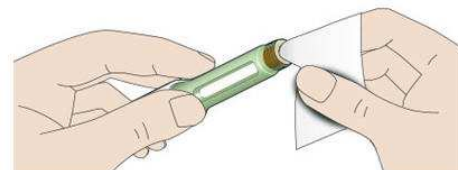


1C Check that the insulin is clear.

- **Do not** use the pen if the insulin looks cloudy, colored or contains particles.



1D Wipe the rubber seal with an alcohol swab.



If you have other injector pens

- Making sure you have the correct medicine is especially important if you have other injector pens.

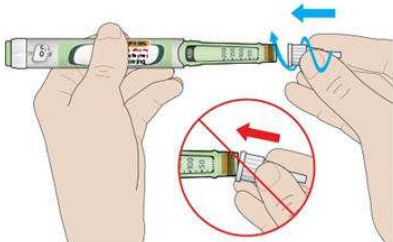
Step 2: Attach a new needle

- **Do not** re-use needles. Always use a new sterile needle for each injection. This helps stop blocked needles, contamination and infection.
- Always use needles* from BD (such as BD Ultra-Fine®), Ypsomed (such as Clickfine®), or Owen Mumford (such as Unifine® Pentips®).

2A Take a new needle and peel off the protective seal.



2B Keep the needle straight and screw it onto the pen until fixed. Do not over-tighten.



2C Pull off the outer needle cap. Keep this for later.



2D Pull off the inner needle cap and throw away.



Handling needles

- Be careful when you are handling needles to help prevent accidental needle-stick injury. You may give other people a serious infection, or get a serious infection from them.

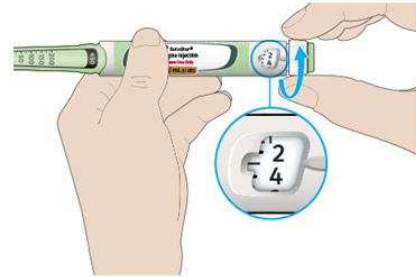
Step 3: Do a safety test

Always do a safety test before each injection to:

- check your pen and the needle to make sure they are working properly.
- make sure that you get the correct insulin dose.

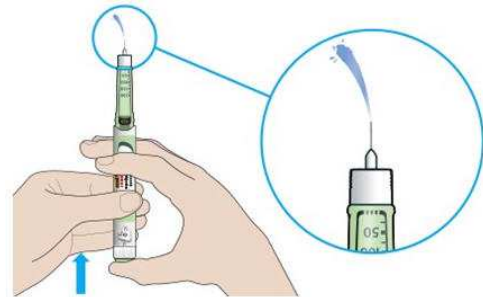
If the pen is new, you must perform safety tests before you use the pen for the first time until you see insulin coming out of the needle tip. If you see insulin coming out of the needle tip, the pen is ready to use. If you do not see insulin coming out before taking your dose, you could get an underdose or no insulin at all. This could cause high blood sugar.

3A Select 3 units by turning the dose selector until the dose pointer is at the mark between 2 and 4.



3B Press the injection button all the way in.

- When insulin comes out of the needle tip, your pen is working correctly.



If no insulin appears:

- You may need to repeat this step up to 3 times before seeing insulin.
- If no insulin comes out after the third time, the needle may be blocked. If this happens:
 - change the needle (see Step 6 and Step 2),
 - then repeat the safety test (see Step 3).
- **Do not** use your pen if there is still no insulin coming out of the needle tip. Use a new pen.
- **Do not** use a syringe to remove insulin from your pen.

If you see air bubbles

- You may see air bubbles in the insulin. This is normal, they will not harm you.

Step 4: Select the dose

- **Do not** select a dose or press the injection button without a needle attached. This may damage your pen.
- TOUJEO SoloStar is made to deliver the number of insulin units that your healthcare provider prescribed. You **do not need to do any dose calculations**.
- The dose selector of your TOUJEO SoloStar pen dials by 1 unit.

4A Make sure a needle is attached and the dose is set to '0'.



4B Turn the dose selector until the dose pointer lines up with your dose.

- Set the dose by turning the dose selector to a line in the dose window. Each line equals 1 unit.
- The dose selector clicks as you turn it.
- Always check the number in the dose window to make sure you dialed the correct dose.
- **Do not** dial your dose by counting the clicks. You may dial the wrong dose. This may lead to you getting too much insulin or not enough insulin.
- If you turn past your dose, you can turn back down.

- If there are not enough units left in your pen for your dose, the dose selector will stop at the number of units left.
- If you cannot select your full prescribed dose, split the dose into 2 injections or use a new pen. If you use a new pen, perform a safety test (see **Step 3**).



How to read the dose window

The dose selector dials by 1 unit.
Even numbers are shown in line with the dose pointer:



30 units selected

Odd numbers are shown as a line between even numbers:



29 units selected

Units of insulin in your pen

- Your pen contains a total of **450** units of insulin. You can select doses from **1** to **80** units. Each pen contains more than 1 dose.
- You can see roughly how many units of insulin are left by looking at where the plunger is on the insulin scale.

Step 5: Inject your dose

If you find it hard to press the injection button in, **do not** force it as this may break your pen. See the section below for help.

5A Choose a place to inject as shown in the picture labeled "Places to inject."

- The site you choose for the injection should be clean and dry.
- If your skin is dirty, clean it as instructed by your healthcare provider.

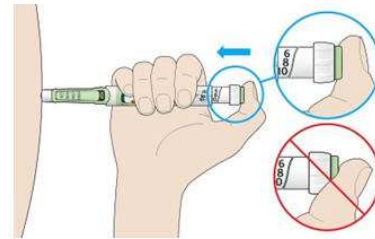
5B Push the needle into your skin as shown by your healthcare provider.

- **Do not** touch the injection button yet.



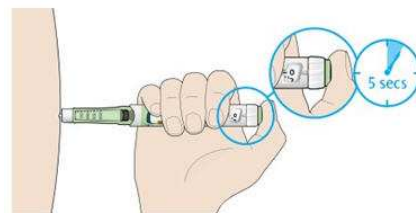
5C Place your thumb on the injection button. Then press all the way in and hold.

- **Do not** press at an angle. Your thumb could block the dose selector from turning.



5D Keep the injection button held in and when you see "0" in the dose window, slowly count to 5.

- This will make sure you get your full dose.



5E After holding and slowly counting to 5, release the injection button. Then remove the needle from your skin.

If you find it hard to press the button in:

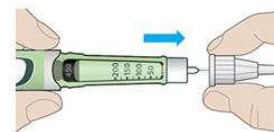
- Change the needle (see **Step 6** and **Step 2**) then do a safety test (see **Step 3**).
- If you still find it hard to press in, get a new pen.
- **Do not** use a syringe to remove insulin from your pen.

Step 6: Remove the needle

- Take care when handling needles to prevent needle injury and cross-infection.
- **Do not** put the inner needle cap back on.

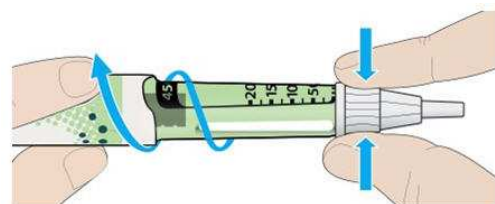
6A Grip the widest part of the outer needle cap. Keep the needle straight and guide it into the outer needle cap. Then push firmly on.

- The needle can puncture the cap if it is recapped at an angle.



6B Grip and squeeze the widest part of the outer needle cap. Turn your pen several times with your other hand to remove the needle.

- Try again if the needle does not come off the first time.

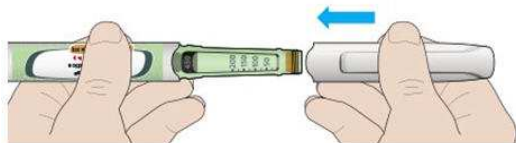


6C Throw away the used needle in a puncture-resistant container (see “Throwing your pen away” at the end of this Instructions for Use).



6D Put the pen cap back on.

- **Do not** put the pen back in the refrigerator.



Use by

- Only use your pen for up to **56 days** after its first use.

How to store your pen

Before first use

- Keep new pens in the refrigerator between **36°F and 46°F (2°C and 8°C)**.
- **Do not** freeze. Throw away your pen if it has been frozen (See “Throwing your pen away”).

After first use

- Keep your pen at room **temperature below 86°F (30°C)**.
- Protect your pen from direct heat and light.
- **Do not** put your pen back in the refrigerator.
- **Do not** store your pen with the needle attached.
- Store your pen with the pen cap on.
- Keep TOUJEO SoloStar pens and needles out of the reach of children.

How to care for your pen

Handle your pen with care

- **Do not** drop your pen or knock it against hard surfaces.
- If you think that your pen may be damaged, **do not** try to fix it. Use a new one.

Protect your pen from dust and dirt

- You can clean the outside of your pen by wiping it with a damp cloth (water only). **Do not** soak, wash or lubricate your pen. This may damage it.

Throwing your pen away

- Put the used TOUJEO SoloStar pen in a FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the TOUJEO SoloStar pen 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 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 throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about 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.

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

Revised: November 2019

sanofi-aventis U.S. LLC
Bridgewater, NJ 08807
A SANOFI COMPANY

©2019 sanofi-aventis U.S. LLC

* The brands listed are the registered trademarks of their respective owners and are not trademarks of sanofi-aventis U.S. LLC.

GLR-IFU-SL-NOV19