

## What are the ingredients in TOUJEO?

- Active ingredient: insulin glargine
- Inactive ingredients: zinc, m-cresol, glycerol and water for injection  
Hydrochloric acid and sodium hydroxide may be added to adjust the pH.

5 Manufactured By: sanofi-aventis U.S., LLC, Bridgewater, NJ 08807

This Patient Information has been approved by the U.S. Food and Drug Administration

Approved: February 2015

Revised September 2015

[BACK TO TOP](#)

# Instructions for Use

10 TOUJEO® SoloStar® (Too-Jay-o)  
(insulin glargine injection)  
1.5 mL disposable prefilled pen

Read this first

Do not share your TOUJEO SoloStar pen with other people, even if the needle has been changed. You

15 may give other people a serious infection, or get a serious infection from them.

TOUJEO contains 300 units/mL insulin glargine

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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.

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20 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.

## 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.
- 25 • Always carry a spare pen and spare needles in case they got lost or stop working.

## Learn to inject

- Talk with your healthcare provider about how to inject, before using your pen.
- Ask for help if you have problems handling the pen, for example if you have problems with your sight.
- 30 • 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.

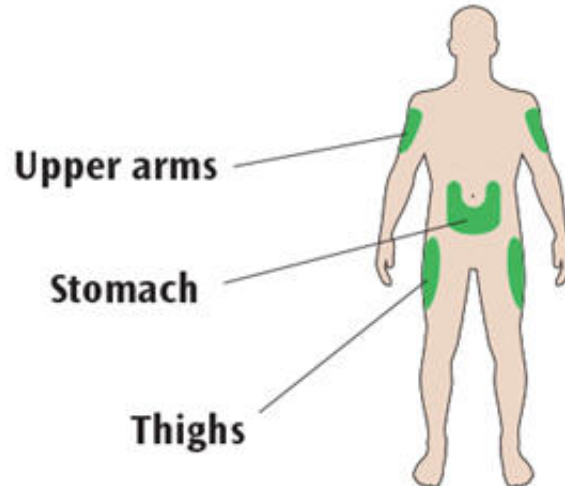
## Need help?

If you have any questions about your pen or about diabetes, ask your healthcare provider, go to [www.Toujeo.com](http://www.Toujeo.com) or call sanofi-aventis on 1-800-633-1610.

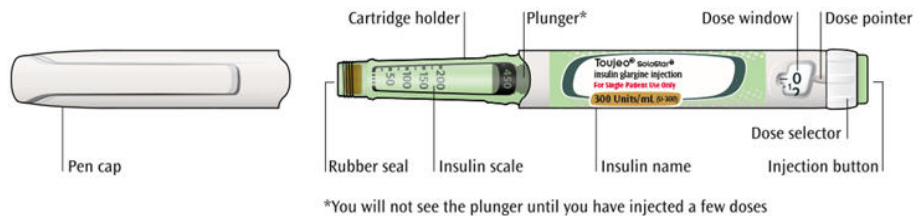
Extra items you will need:

- a new sterile needle (see [Step 2](#)).
- an alcohol swab.
- a puncture resistant container for used needles and pens.

## 5 Places to inject



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.

### 10 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.

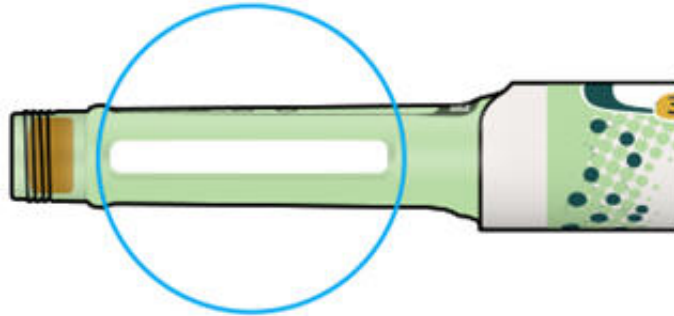


1B Pull off the pen cap.

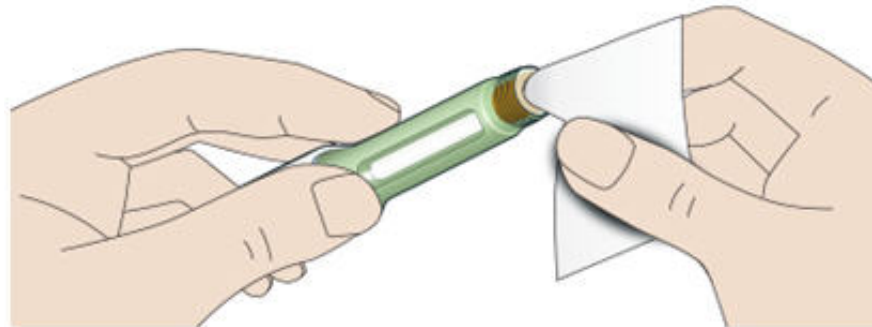


1C Check that the insulin is clear.

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



1D Wipe the rubber seal with an alcohol swab.



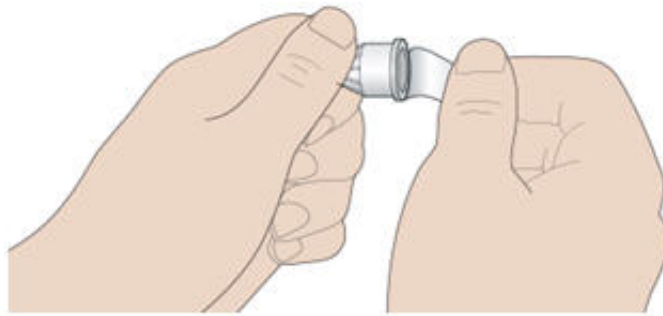
If you have other injector pens

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

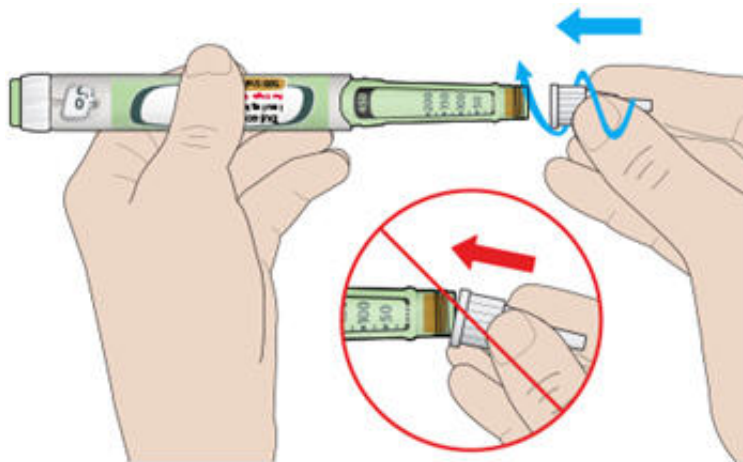
Step 2: Attach a new needle

- Do not reuse needles. Always use a new sterile needle for each injection. This helps stop blocked needles, contamination and infection.
- Always use needles<sup>2</sup> from BD (such as BD Ultra-Fine®), Ypsomed (such as Clickfine®) or Owen Mumford (such as Unifine® Pentips®).

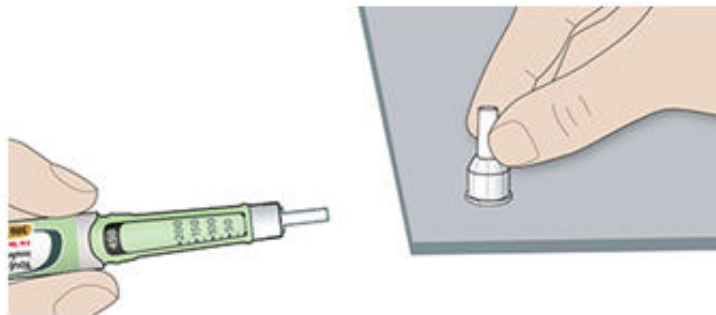
2A Take a new needle and peel off the protective seal.



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

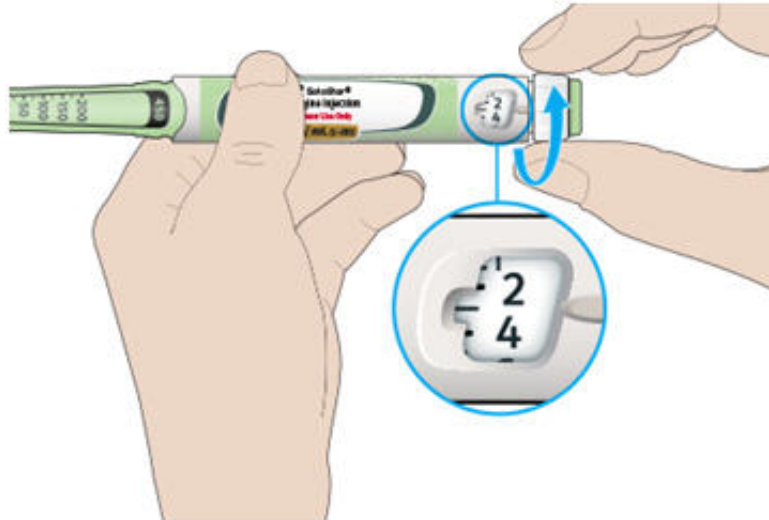
- 5 • Take care when handling needles to prevent needle injury and cross-infection.

### Step 3: Do a safety test

Always do a safety test before each injection to:

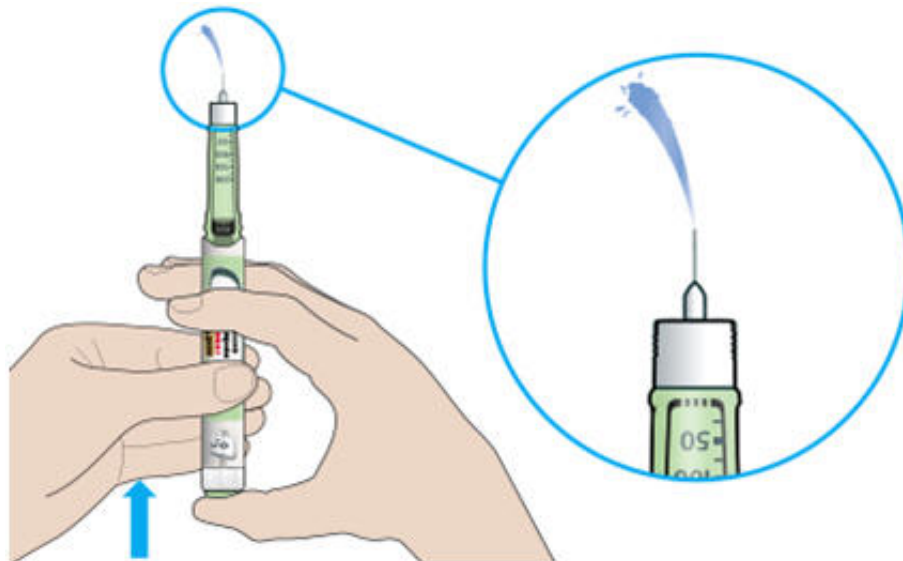
- check your pen and the needle to make sure they are working properly.
- make sure that you get the correct insulin dose.

- 5 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.
- 10 • 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 ([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

- 5
- 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.

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



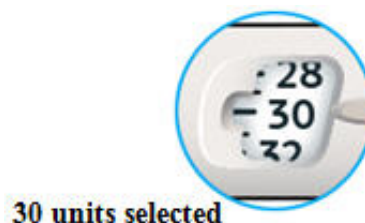
4B Turn the dose selector until the dose pointer lines up with your dose.

- 10
- 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.



How to read the dose window

- 15
- Even numbers are shown in line with the dose pointer:



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 in steps of 1 unit. 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.

5

### 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 above.

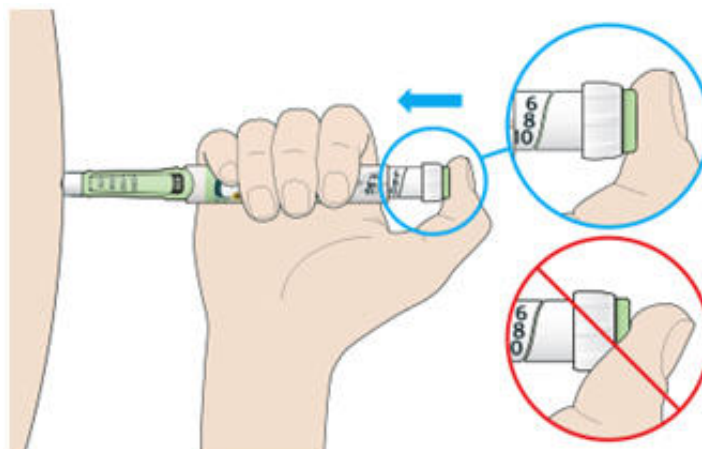
10 5B Push the needle into your skin as shown by your healthcare provider.

- Do not touch the injection button yet.



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

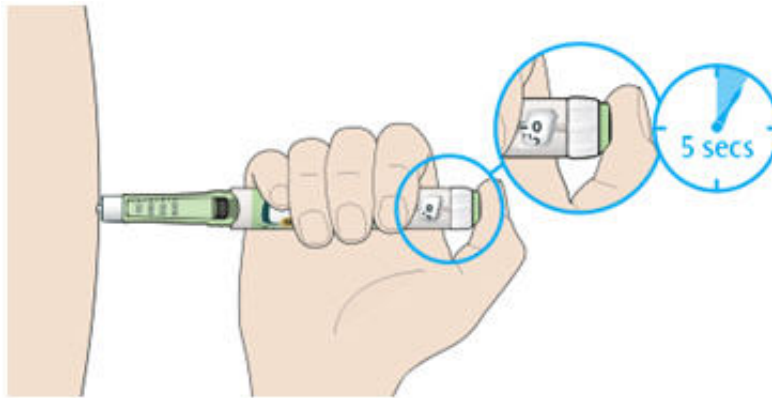
- Do not press at an angle. Your thumb could block the dose selector from turning.





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.

5 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.

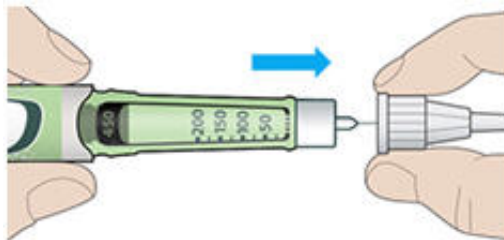
Step 6: Remove the needle

- 10
- 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.

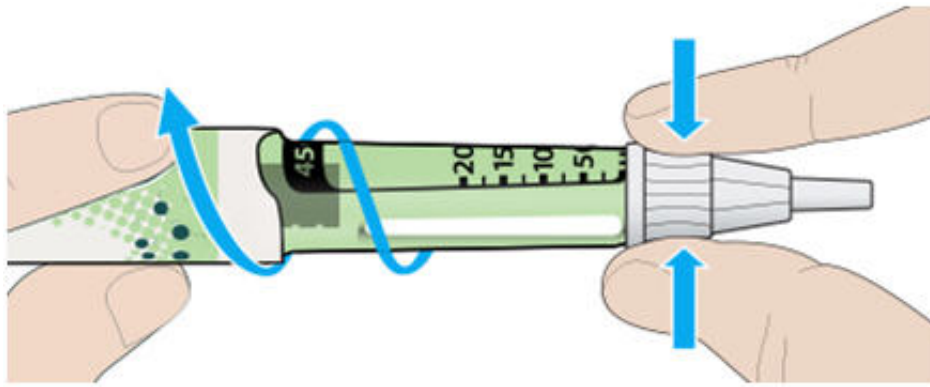
- 15
- The needle can puncture the cap if it is recapped at an angle.



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.



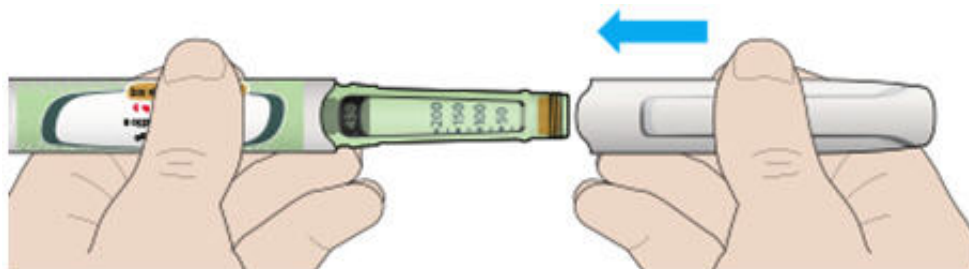


6C Throw away the used needle in a puncture resistant container (see "[Throwing your pen away](#)" at the end of this Instructions for Use).



6D Put the pen cap back on.

- Do not put the pen back in the refrigerator.



## 5 Use by

- Only use your pen for up to 42 days after its first use.

## How to store your pen

### Before first use

- Keep new pens in the refrigerator between 36°F to 46°F (2°C to 8°C).
- 10 • Do not freeze.

### After first use

- Keep your pen at room temperature below 86°F (30°C)

- 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.

## How to care for your pen

### 5 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

- 10
- 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  
15 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,
  - 20 ◦ 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  
25 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>

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

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Bridgewater, NJ 08807  
A SANOFI COMPANY

Date of Revision: September 2015

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[BACK TO TOP](#)