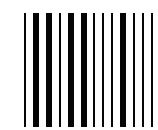


Instruction for use: TouStar® pen, your reusable insulin delivery device

Read
this
first



TouStar® is a reusable pen for the injection of U-300 insulin from Sanofi Group. **TouStar® pen can only be used for injection with Sanofi 1.5 mL (450 Units) Toujeo® dedicated cartridges that are sold separately. Only Toujeo® dedicated cartridges will attach correctly to a TouStar® pen.**

- ✗ **Never re-use needles.** If you do you might not get your dose as the needle could block.
- ✗ **Never share your pen and cartridge 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.
- ✗ **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.
- ✗ **Never use your pen if it is damaged or if you are not sure that it is working properly.**
- ✓ Always have a back-up method for delivering your insulin available (e.g. a spare dedicated Toujeo® cartridge and a spare TouStar® pen).
- ✓ Always perform a safety test (See STEP 4 below).

Learn to inject:

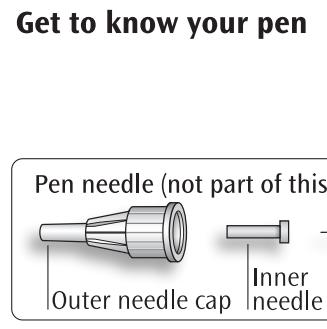
- Talk with your healthcare provider about how to inject, before using your pen.
- Ask for help if you have problems handling the pen, for example if you have problems with your sight.
- Read all of these instructions before using your pen. If you do not follow all of these instructions, you may get too much or too little insulin.
- Keep this leaflet for future reference.

Need help?

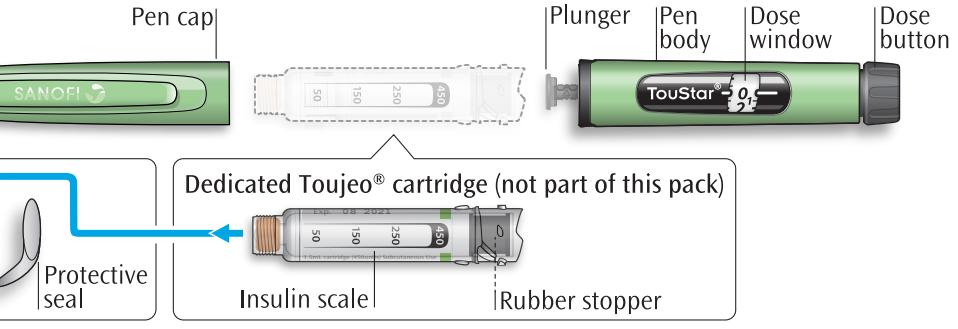
If you have any questions about your pen or about diabetes, ask your healthcare provider go to www.sanofi.in or email to medinfo.india@sanofi.com ptcindia@sanofi.com

Extra items you will need:

- a new dedicated Toujeo® cartridge (see STEP 1).
- a new sterile needle (see STEP 3).
- a puncture resistant container for used needles. (see STEP 7).



Get to know your pen



STEP 1: Use a new cartridge

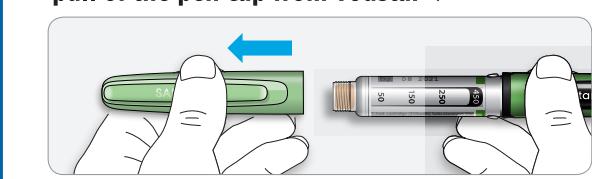
Follow Step 1 the first time you use TouStar® and when replacing your Toujeo® dedicated cartridge.

✓ TouStar® can only be used with Sanofi 1.5 mL (450 Units) Toujeo® dedicated cartridges. No other cartridges will attach correctly to a TouStar® pen.

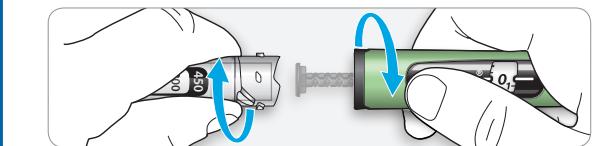
✗ Do not replace your dedicated Toujeo® cartridge unless it is empty, expired or broken. It can be used for multiple injections.

✓ Take a new dedicated Toujeo® cartridge out of the refrigerator at least 1 hour before you inject. Cold insulin is more painful to inject.

1A If you want to replace your insulin cartridge, pull off the pen cap from TouStar®.

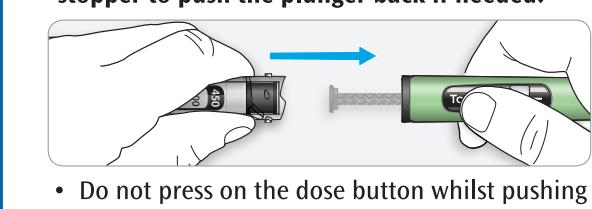


1B If you want to replace your insulin cartridge, unscrew the cartridge holder from the pen body. Dispose of the Toujeo® dedicated cartridge (cartridge and holder), as instructed by your healthcare provider or local authority.

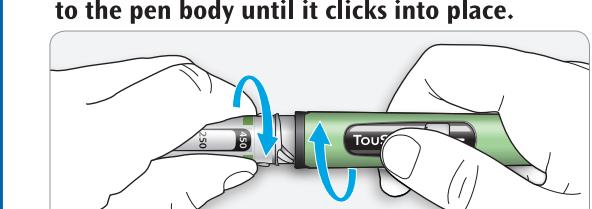


1C Check the label of your new dedicated Toujeo® cartridge for insulin type and expiry date.

1D Align the new dedicated Toujeo® cartridge straight with the pen body and use the cartridge's rubber stopper to push the plunger back if needed.



1E Screw the dedicated Toujeo® cartridge firmly on to the pen body until it clicks into place.



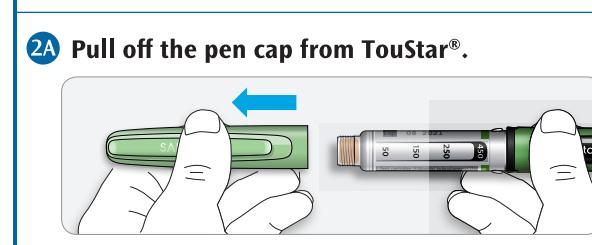
1F Check that the alignment marks on the dedicated Toujeo® cartridge and the pen body line up as shown.



• If the marks are not aligned, make sure you have the correct insulin, then unscrew the dedicated Toujeo® cartridge and try again.

STEP 2: Check your insulin

✓ Check insulin before every injection.



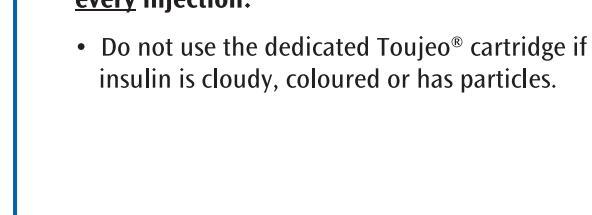
2B Check the label of your dedicated Toujeo® cartridge for insulin type and expiry date.

- Make sure you have the correct Toujeo® insulin cartridge.
- Do not use your insulin after the expiration date or after 42 days of use.
- Do not use a damaged or broken dedicated Toujeo® cartridge.



2C Check the appearance of your insulin before every injection:

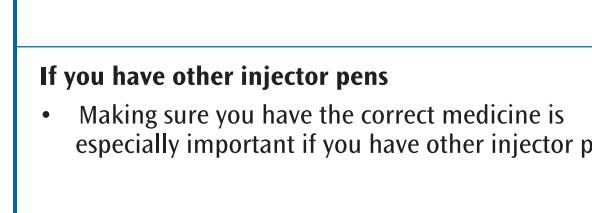
- Do not use the dedicated Toujeo® cartridge if the insulin is cloudy, coloured or has particles.



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



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



If you have other injector pens

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

• If the marks are not aligned, make sure you have the correct insulin, then unscrew the dedicated Toujeo® cartridge and try again.

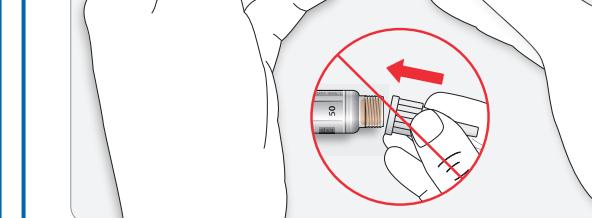
STEP 3: Attach a needle

✗ Do not re-use needles. Always use a new sterile needle for each injection. This helps stop blocked needles, contamination, and infection.

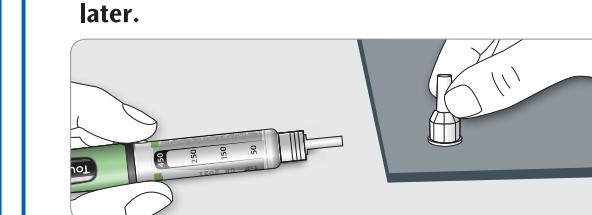
✓ Always use needles that are compatible with TouStar® pen, e.g. from Novo Nordisk (Novofine), Becton Dickinson (BD) and Ypsomed



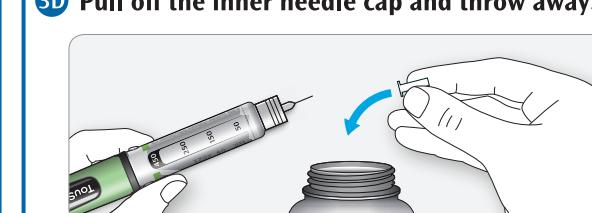
3B Keep the needle straight and screw it onto the pen until fixed. Do not over-tighten.



3C Pull off the outer needle cap. Keep this for later.



3D Pull off the inner needle cap and throw away.



If you have other injector pens

- Take care when handling needles to prevent needle injury and cross-infection.
- Special caution should be exercised if another person performs the injection.

STEP 4: Do a safety test

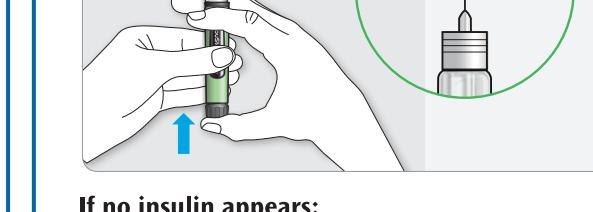
Always do a safety test after the attachment of a new dedicated Toujeo® cartridge and before each injection to:

- ✓ Check your pen and the needle to make sure they are working properly.
- ✓ Make sure that you get the correct dose.



4B Press the dose 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 7 and STEP 3),
 - check that the dedicated Toujeo® cartridge is properly attached and is not damaged.
 - then repeat the safety test (STEP 4).

5A Make sure a needle is attached and the dose is set to '0'.



Even numbers are shown in line with the dose pointer.

EXAMPLE 30 units selected

Odd numbers are shown as a line between even numbers.

EXAMPLE 15 units selected

6A Choose a place to inject as shown in the picture above ("Places to inject").



6B Push the needle into your skin as shown by your healthcare provider.

- Do not touch the dose button yet.

6C Place your thumb on the dose button. Then slowly press all the way in and hold.

- Do not press at an angle.

6D Keep the dose 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.

6E After holding and slowly counting to 5, release the dose button. Then remove the needle from your skin.

6F Put your pen cap back on.

- Each insulin cartridge can be used for multiple injections. Your TouStar® pen should be stored with the dedicated Toujeo® cartridge attached, ready for your next injection.
- Do not put the pen in the refrigerator.

6G Throw away the used needle in a puncture resistant container (or as instructed by your healthcare provider).

6H Consult instructions for use.

6I Keep away from direct sunlight.

6J Throw away the used needle in a puncture resistant container (or as instructed by your healthcare provider).

6K Storage temperature, for TouStar® pen without dedicated Toujeo® cartridge attached.

6L Storage temperature, for TouStar® pen with dedicated Toujeo® cartridge attached.

6M TouStar® homepage: www.sanofi.in/TouStar

6N Sanofi homepage: www.sanofi.in

6O MD registration number : Sh-Vadod-GJ/M/MD/001029

6P Manufactured and packed :

Sanofi Healthcare India Private Limited

Insulin Plant, Survey No. 354

Muppireddipalli (V), Manoharabad (M)-502236,

Medak (Dist), Telangana, India.

Marketed by: Sanofi India Limited

Sanofi House, CTS No. 117-B, L&T Business Park,

Saki Vihar Road, Powai, Mumbai 400072.

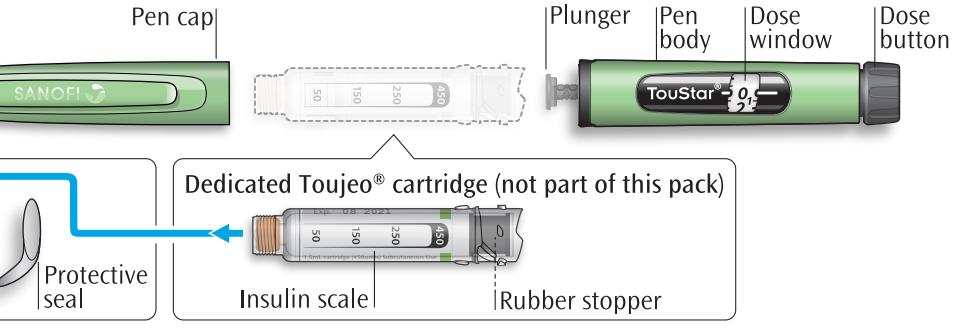
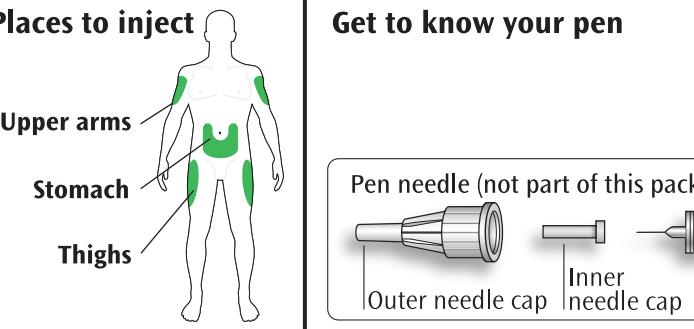
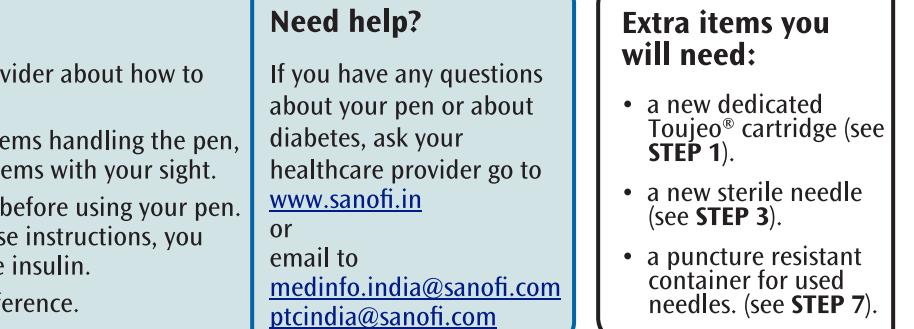
TouStar® meets the current dose accuracy and

functional requirements of the ISO 11608-1: 2014 with

Sanofi Group 1.5 mL (450 Units) dedicated Toujeo® cartridges (U-300).

TouStar® is a registered trademark of the Sanofi Group.

Date: March 2021



Use by

TouStar® pen has been designed to be used for up to 3 years after first use.

Record the date your pen was first used here:
dd / mm / yyyy

Do not use your TouStar® pen for more than 3 years. After 3 years contact your healthcare provider or pharmacist to get a new TouStar® pen.

Dispose of the pen safely as instructed by your healthcare provider or local authority.

How to store your pen

Keep your TouStar® pen and dedicated Toujeo® cartridges out of sight and reach of children. Your TouStar® pen should be stored with the dedicated Toujeo® cartridge attached.

- Do not store TouStar® pen with a needle attached.
- Store your pen with the pen cap on.
- Do not store TouStar® pen in the refrigerator.
- Do not freeze

If a dedicated Toujeo® cartridge is not attached, TouStar® pen can be stored up to 40°C [104°F].

Read the leaflet included with your Toujeo® insulin cartridge for complete cartridge storage information.

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 repair it. If you are not sure whether or not your TouStar® pen is broken or damaged, contact your healthcare provider or call Sanofi on Tel no. 022 2802000

Protect your pen from dust and dirt

- You can clean the outside of your pen by wiping it with a damp cloth. Do not soak, wash or lubricate your pen – this may damage it.

Consult instructions for use.

Keep away from direct sunlight.

Storage temperature, for TouStar® pen with dedicated Toujeo® cartridge attached.

15°C

798443 - LEAFLET TOUJEO PEN (INDIA)

Plant: MRP INSULIN
Packaging material code: 798443
Packaging material name: LEAFLET TOUJEO PEN (INDIA)
Second packaging material code:
VISTAlink folder number: 4151206
VISTAlink PDF version: 6

This document has been digitally signed by the following people within the VISTAlink system, following the sanofi group guidelines.

| Reason | Signed by | Date |
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| Market regulatory validation 2 | Asmita Nimkar (India Regulatory team) | 12/03/2021 11:14:42 |
| Plant final technical validation | Joanita Desouza (India PMTD team) | 12/03/2021 11:32:22 |
| Plant quality validation | Srikanth Reddy Machangari (MRP site quality team) | 12/03/2021 12:01:24 |
| Plant ready to print | Priyanka Nagvenkar (India PMTD team) | 05/04/2021 12:32:33 |