

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.

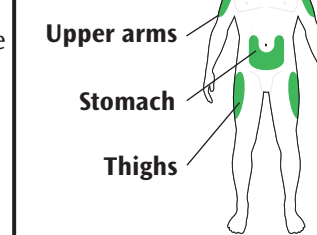
Need help?

If you have any questions about your pen or about diabetes, ask your healthcare provider, or contact us via <http://www.sanofi.in> or www.sanofi.in/TouStar or call Sanofi on Tel. No.: + (91-22) 28032000 or email to medinfo.india@sanofi.com or ptcindia@sanofi.com

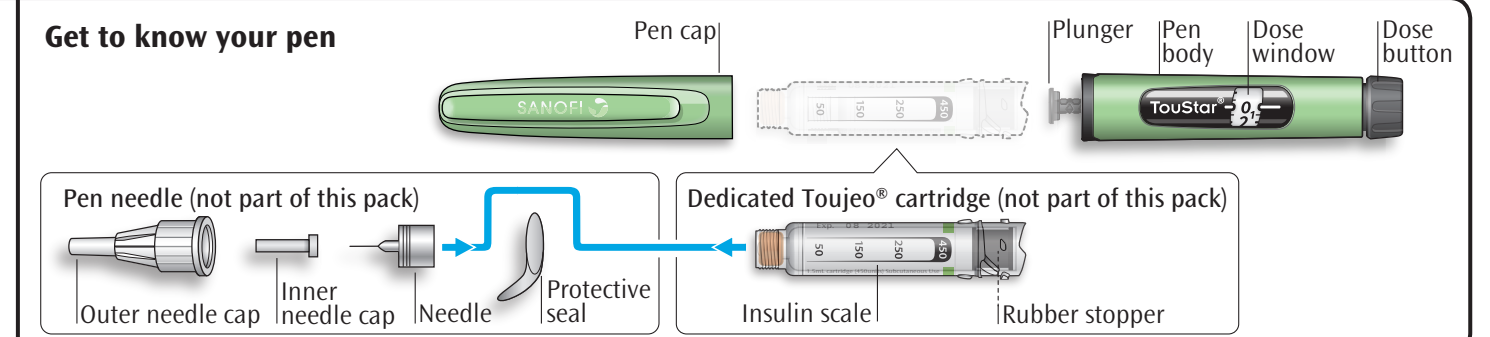
Extra items you will need:

- 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).

Places to inject



Get to know your pen

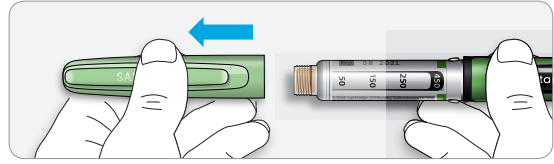


STEP 1: Use a new cartridge

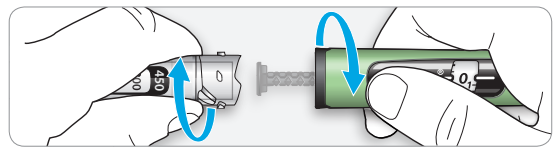
Follow Step 1 the first time you use TouStar® and when replacing your Toujeo® dedicated cartridge.

- ✓ 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®.

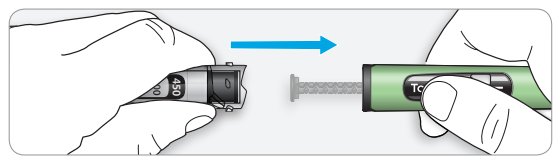


1B If you want to replace your insulin cartridge, unscrew the cartridge holder from the pen body. Dispose of the Toujeo® dedicated cartridge (cartridge and holder), as instructed by your healthcare provider or local authority.

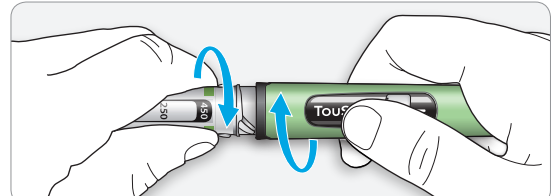


1C Check the label of your new dedicated Toujeo® cartridge for insulin type and expiry date.

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.

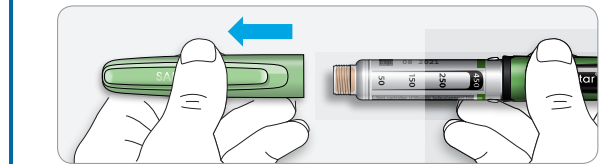


- If the marks are not aligned, make sure you have the correct insulin, then unscrew the dedicated Toujeo® cartridge and try again.

STEP 2: Check your insulin

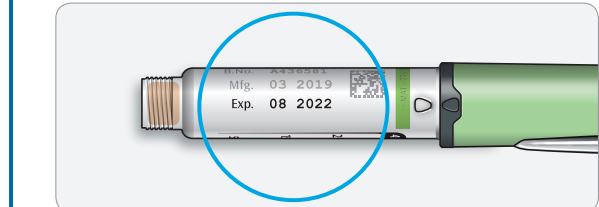
✓ Check insulin before every injection.

2A Pull off the pen cap from TouStar®.



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 inner needle cap and throw away.



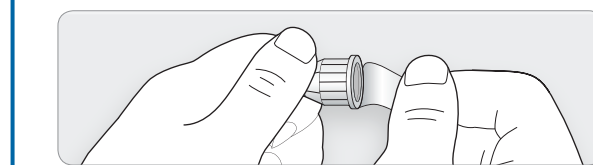
If you have other injector pens

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

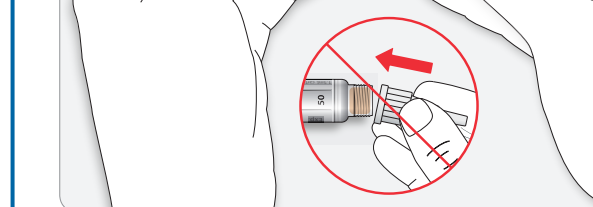
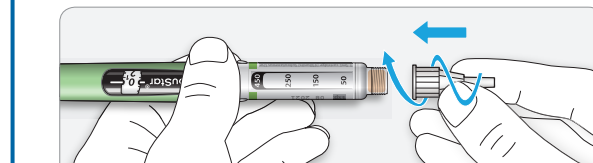
STEP 3: Attach a needle

- ✗ 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

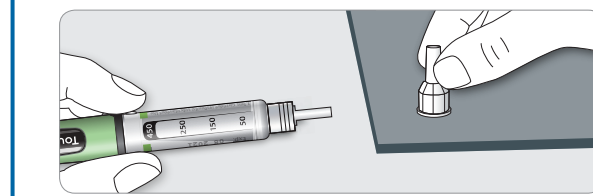
3A Take a new needle and peel off the protective seal.



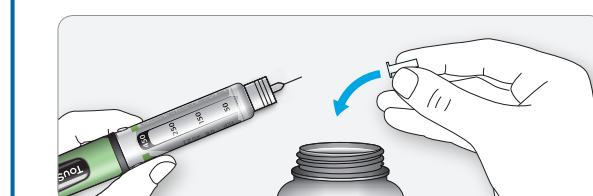
3B Keep the needle straight and screw it onto the pen until fixed. Do not over-tighten.



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



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



Handling needles

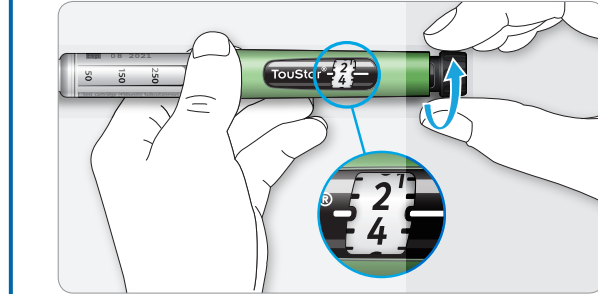
- Take care when handling needles to prevent needle injury and cross-infection.
- Special caution should be exercised if another person performs the injection.

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:

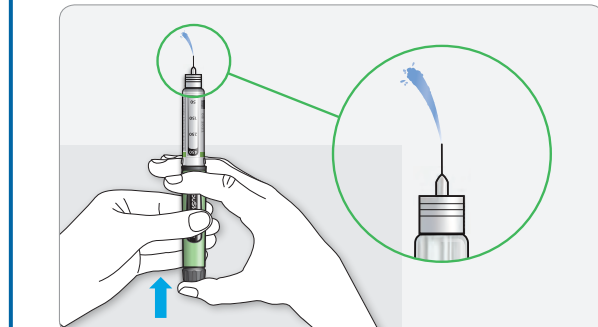
- ✓ Check your pen and the needle to make sure they are working properly.
- ✓ Make sure that you get the correct dose.

4A Select 3 units by turning the dose button until the dose pointer lines up with the 3 unit line marker (halfway between the number 2 & 4 numerals).



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).

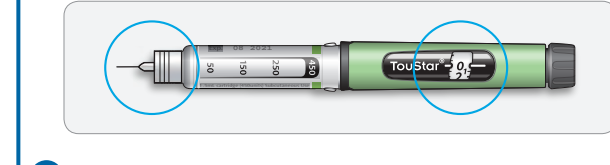
If you see air bubbles

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

STEP 5: Select the dose

- ✗ Do not select a dose AND press the dose button without a needle attached. This may damage your pen.

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



5B Turn the dose button until the dose pointer lines up with your dose.



Even numbers are shown in line with the dose pointer.



Odd numbers are shown as a line between even numbers.



- If you turned past your dose, you can turn back down.
- If there are not enough units left in your pen for your dose, the dose button will stop at the number of units left.
- If you cannot select your full prescribed dose, you can either:
 - inject what is left (STEP 6-7), then replace the cartridge with a new one (STEP 1) and complete your dose (STEP 2-7).
 - or discard what is left and use a new cartridge for your full dose (STEP 1-7).

Units of insulin in your pen

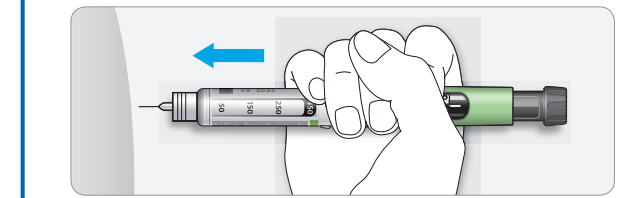
- Each cartridge contains a total of 450 units. You can select doses from 1 to 80 units in steps of 1 unit. Each dedicated Toujeo® cartridge can be used for multiple injections until it is empty or expired. You can see roughly how many units of insulin are left by looking at where the rubber stopper is on the insulin scale.

STEP 6: Inject the dose

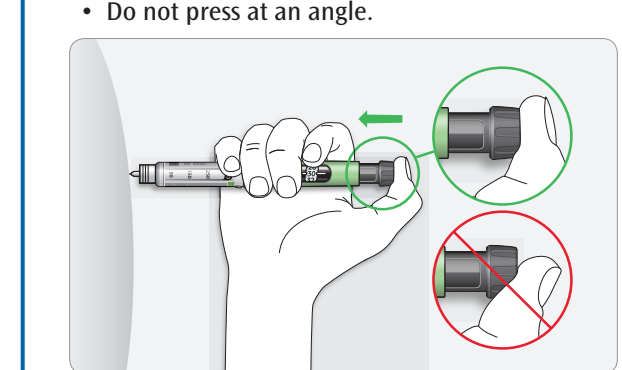
- ✗ If you find it hard to press the dose button in, do not force it as this may break your pen. See the section below for help.

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

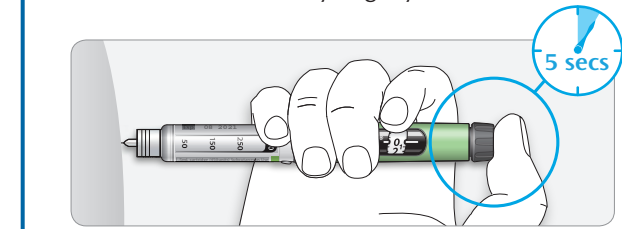
6B Push the needle into your skin as shown by your healthcare provider.



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



6D Keep the dose button held in, and when you see "0" in the dose window, slowly count to 5.



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

If you find it hard to press the dose button in:

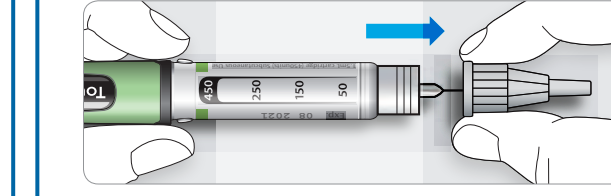
- Change the needle (see STEP 7 and STEP 3) then do a safety test (see STEP 4).
- If you still find it hard to press in, change the cartridge or do not use the pen.
- Do not use a syringe to remove insulin from your pen.

STEP 7: Remove the needle

- ✓ Take care when handling needles to prevent needle injury and cross-infection.
- ✗ Do not put the inner needle cap back on.
- ✗ Do not store TouStar® pen in the refrigerator.

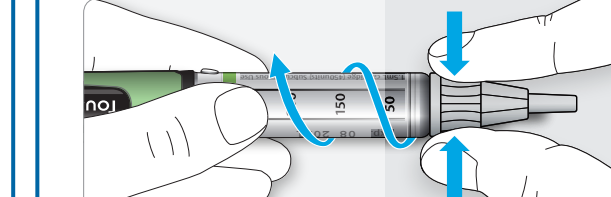
7A Grip the widest part of the outer needle cap. Keep the needle straight and guide it into the outer needle cap. Then push firmly on.

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

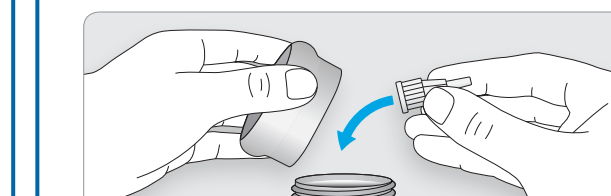


7B Grip and squeeze the widest part of the outer needle cap. Turn your pen several times with your other hand to remove the needle.

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

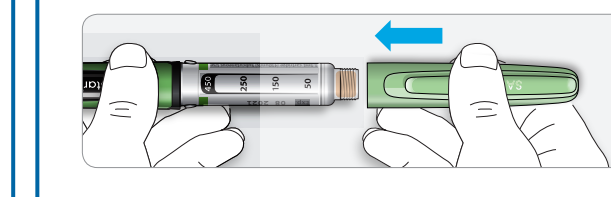


7C Throw away the used needle in a puncture resistant container (or as instructed by your healthcare provider).



7D 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.



Use by

TouStar® has been designed to be used for 3 years after first use or until expiry date, whichever is earlier.



Do not use your TouStar® pen for more than 3 years after first use or until expiry date, whichever is earlier. 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 contact us via medinfo.india@sanofi.com, or call Sanofi on Tel No.: + (91-22) 28032000

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.
- Storage temperature, for TouStar® pen without dedicated Toujeo® cartridge attached: 40°C
- Keep away from direct sunlight.
- Storage temperature, for TouStar® pen with dedicated Toujeo® cartridge attached: 30°C
- LOT Batch code
- 15°C

TouStar Homepage: www.sanofi.in/TouStar
Sanofi Homepage: www.sanofi.in

Mfg. Lic. No.: MFG/MD/2022/00695
Manufactured and Packed at:
Sanofi Healthcare India Private Limited
Insulin Plant, Survey No. 354
Muppidreddipalli (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, Maharashtra, India.
TouStar® meets the current dose accuracy and functional requirements of the ISO 11608-1 with Sanofi Group 1.5 mL (450 Units) dedicated Toujeo® cartridges (U-300).
TouStar® is a registered trademark of the Sanofi Group. Source: Adapted from AllStar® CDDM V7 dated 05 March 2020.

Revision date: July 2023



Artwork Approval
History Reference
No.: Vista Folder # 4261248

REGULATORY

PACKAGING

QUALITY



SANOFI INDIA LIMITED - GDA
Corporate Office: Sanofi, 11th Floor, No. 100,
Preeti, 1st Stage, Vennalahalli, Bengaluru - 560022, India.
Tel: (91) 802 962222 Fax: (91) 802 962222

Artwork Number : IMF-01208723-2it
Version Number : 5
Edition Number : 2
Product : TouStar Pen
Artwork Type : Leaflet
Dimensions(mm) : 711 x 343 mm
Market/Country : India
PM GMID Code : 893300
Technical Drawing : NA
Manufacturing site : Insulin Plant- MRP
Style \ Folds : 178 x 58 mm
Minimum font size : 10 Pts
Pharma Code No. : 12087
EAN bar Code No : NA

Artwork Operator : PN
Date : 26.07.23
Colours
1 CMYK

Braille : NA
Non-Varnished area : NA
Outline : NA