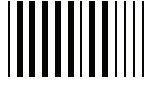


Instruction for use: AllStar®, your reusable insulin delivery device

Read
this
first



AllStar® is a reusable pen for the injection of insulin. AllStar® can only be used with Sanofi 3 ml (300 units) insulin cartridges (U-100) from Sanofi Group.

- ✗ 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.
- ✗ Never use your pen if it is damaged or if you are not sure that it is working properly.
- ✓ AllStar is for use by adult patients, caregivers and health care professionals (HCP). Patients and caregivers must be assessed by their HCP on their ability to use the pen safely
- ✓ If you use different types of insulin, you should use a different colour or different type of pen for each insulin.
- ✓ Always have a back-up method for delivering your insulin available (e.g. a spare insulin cartridge and a spare AllStar®).
- ✓ 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.

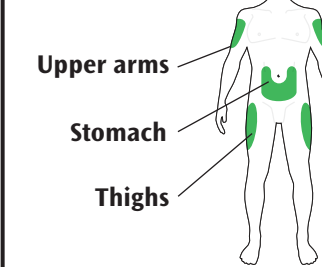
Need help?

If you have any questions about your pen or about diabetes, ask your healthcare provider, go to <http://www.sanofi.in> or www.sanofi.in/AllStar or call Sanofi on Tel. no.: + (91-22) 28032000 or email to medinfo.india@sanofi.com or ptcindia@sanofi.com. Any serious incident that has occurred in relation to the device should be reported to Sanofi and your local health authority.

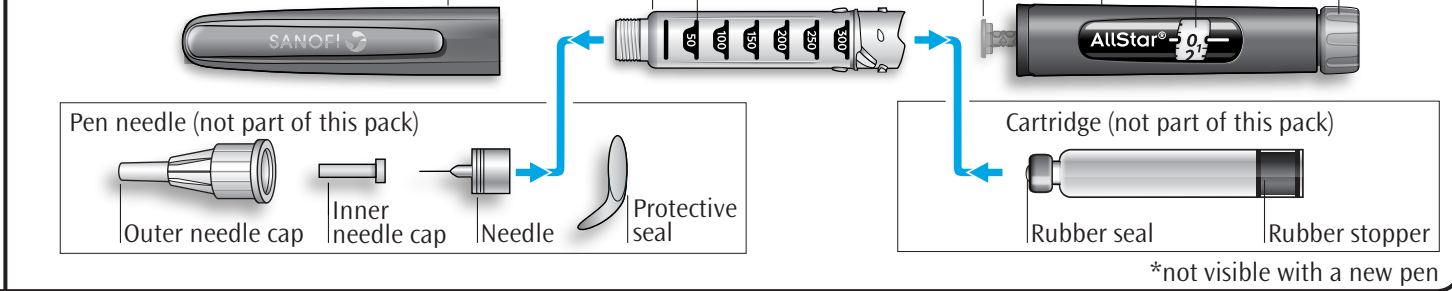
Extra items you will need:

- a new insulin cartridge (see STEP 1).
- an alcohol swab
- 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

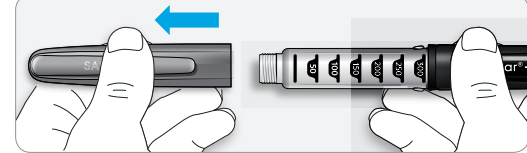


STEP 1: Insert a new cartridge

Follow STEP 1 the first time you use AllStar® and when replacing an insulin cartridge.

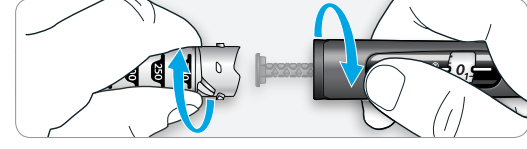
- ✗ Do not replace the insulin cartridge unless it is empty, expired or broken. It can be used for multiple injections.
- ✓ Take a new cartridge out of the refrigerator at least 1 hour before you inject. Cold insulin is more painful to inject.

1A Pull off the pen cap from AllStar®.



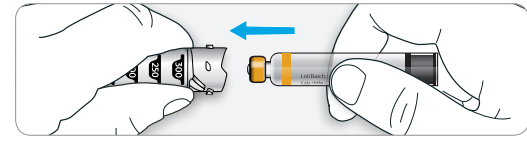
1B Unscrew the cartridge holder from the pen body.

- If there is an insulin cartridge that needs to be replaced, remove it from the cartridge holder and discard it.



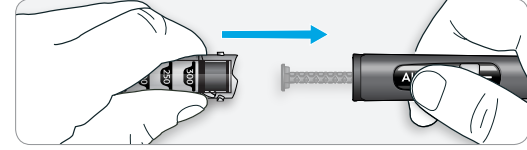
1C Check the label of your new insulin cartridge for insulin type and expiry date.

1D Insert the new cartridge, narrow end first, into the cartridge holder.

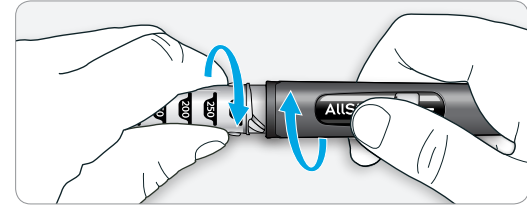


1E Align the insulin cartridge holder straight with the pen body. Use the cartridge's rubber stopper to push the plunger back.

- Do not press on the dose button whilst pushing back the plunger.



1F Screw the cartridge holder firmly back on to the pen body until it clicks into place.



1G Check that the alignment marks on the cartridge holder and the pen body line up as shown.

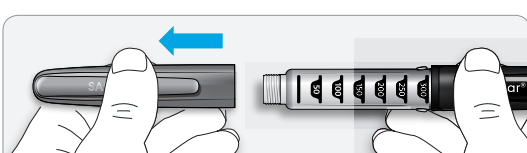


- If the features are not aligned, unscrew the cartridge holder and try again.

STEP 2: Check your insulin

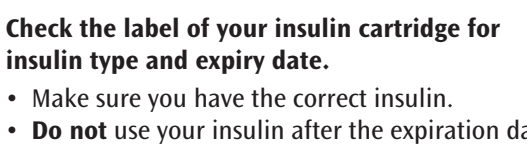
- ✓ Check insulin before every injection.

2A Pull off the pen cap from AllStar®.

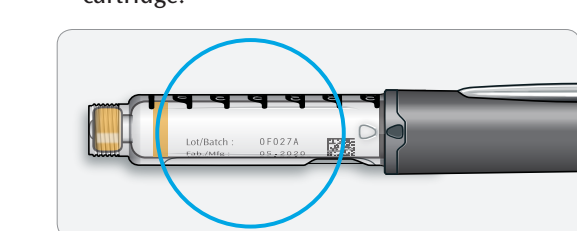


2B Check the label of your insulin cartridge for insulin type and expiry date.

- Make sure you have the correct insulin.
- Do not use your insulin after the expiration date or after 28 days of use.
- Do not use a damaged or broken insulin cartridge.



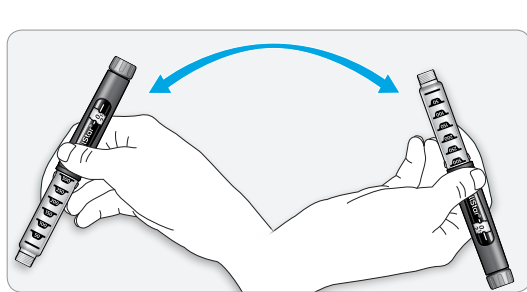
2C Check the appearance of your insulin before every injection:



- For **clear insulins** (Lantus®, Apidra®)
 - Do not use the cartridge if the insulin is cloudy, coloured or has particles.

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

- For **clear insulins** (Lantus®, Apidra®)
 - Do not use the cartridge if the insulin is cloudy, coloured or has particles.



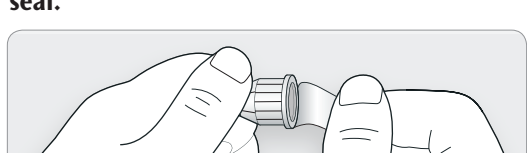
If you have other injector pens

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

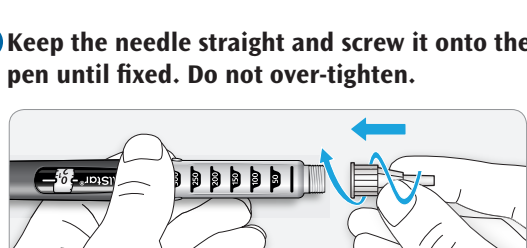
STEP 3: Attach a needle

- ✗ 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 AllStar®, e.g. from Becton Dickinson and Owen Mumford.

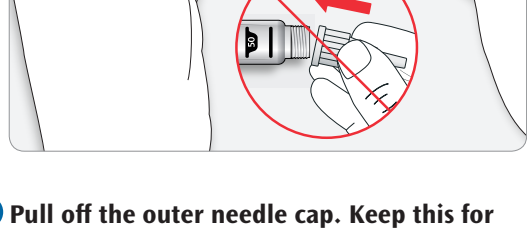
3A Take a new needle and peel off the protective seal.



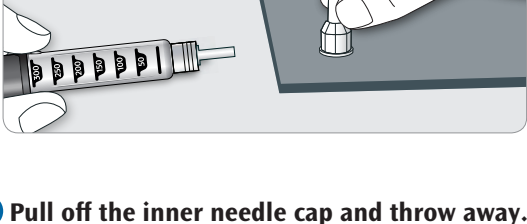
3B Keep the needle straight and screw it onto the pen until fixed. Do not over-tighten.



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 insertion of a new insulin cartridge and before each injection to:

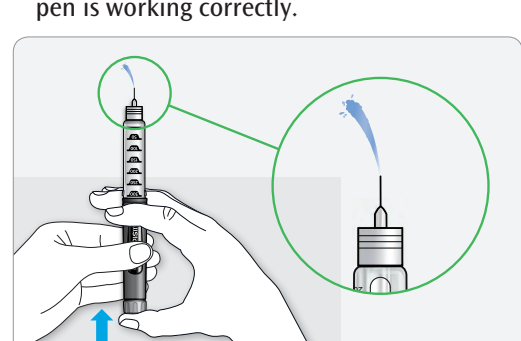
- ✓ Check your pen and the needle to make sure they are working properly.
- ✓ Make sure that you get the correct dose.

4A Select 2 units by turning the dose button until the dose pointer lines up with the number 2.



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 cartridge is properly inserted (see STEP 1), not damaged and not empty.
 - 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.

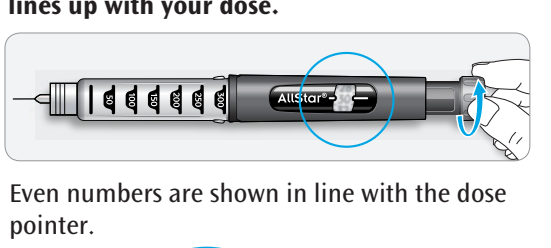
STEP 5: Select the dose

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

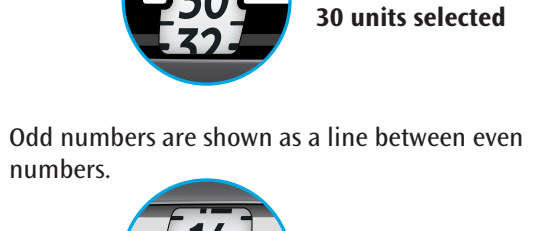
5A Make sure a needle is attached and the dose is set to '0'.



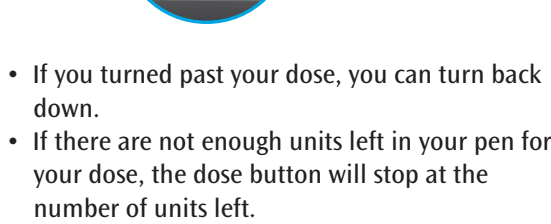
5B Turn the dose button until the dose pointer lines up with your dose.



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:
 - (i) inject what is left (STEP 6-7), then replace the cartridge with a new one (STEP 1) and complete your dose (STEP 2-7);
 - (ii) 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 300 units. You can select doses from 1 to 80 units in steps of 1 unit. Each insulin 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

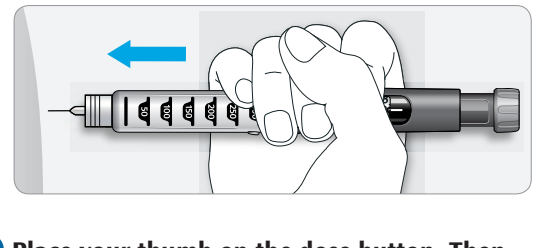
- ✗ If you find it hard to press the dose button in, do not force it as this may break your pen. See the section below for help.

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

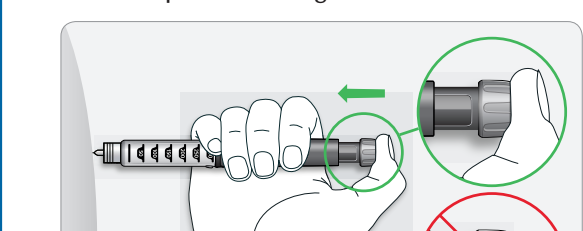
- Clean the area of skin to be injected (e.g. with rubbing alcohol/spirit)

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

- Do not touch the dose button yet.

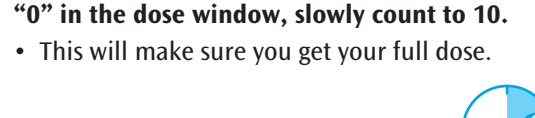


6C Place your thumb on the dose button. Then slowly press all the way in and hold.



6D Keep the dose button held in, and when you see "0" in the dose window, slowly count to 10.

- This will make sure you get your full dose.



6E After holding and slowly counting to 10, 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.

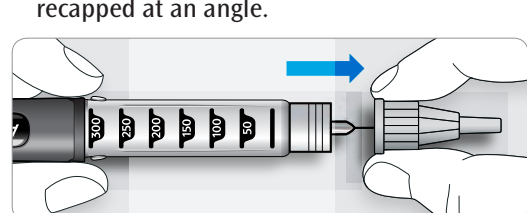
STEP 7: Remove the needle

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

- ✗ Do not put the inner needle cap back on.
- ✗ Do not store AllStar® in the refrigerator.

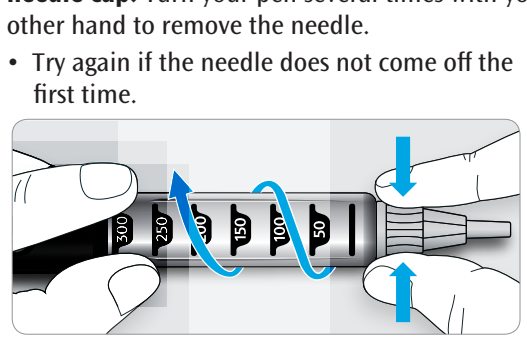
7A Grip the widest part of the outer needle cap. Keep the needle straight and guide it into the outer needle cap. Then push firmly on.

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

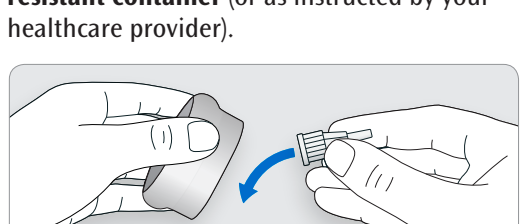


7B Grip and squeeze the widest part of the outer needle cap. Turn your pen several times with your other hand to remove the needle.

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

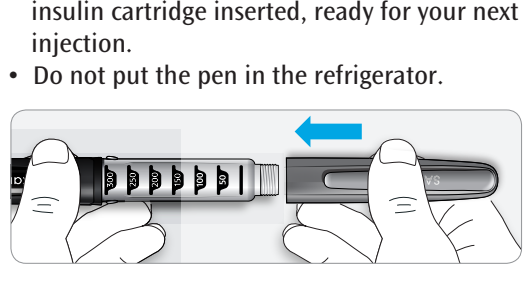


7C Throw away the used needle in a puncture resistant container (or as instructed by your healthcare provider).



7D Put your pen cap back on.

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



Use by

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

Record the date your pen was first used here:

dd	mm	yyyy
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Do not use your AllStar® pen for more than 3 years or after expiry date.

Contact your healthcare provider or pharmacist to get a new AllStar®. Dispose of the pen safely as instructed by your healthcare provider or local authority and according to your local waste regulation.

How to store your pen

Keep your AllStar® and insulin cartridges out of sight and reach of children. Your AllStar® should be stored with the insulin cartridge inserted.

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

Depending on the insulin inserted, keep AllStar® at room temperature either below 25°C [77°F] or 30°C [86°F].

Please check the insulin leaflet for instructions on how to store AllStar® with an insulin cartridge inserted in the pen.

Without a cartridge, AllStar® can be stored between 5°C [41°F] and 30°C [86°F].

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 AllStar® 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.
- Keep away from direct sunlight

- Storage temperature for AllStar® without an insulin cartridge inserted.

- Please check the insulin leaflet for instructions on how to store AllStar® with an insulin cartridge inserted in the pen.

- Medical Device

- AllStar Homepage: www.sanofi.in/AllStar
- Sanofi Homepage: www.sanofi.in

- Mfg. Lic. No.: MFG/MD/2023/001100

- Legal Manufacturer and CE Mark owner: Sanofi-Aventis Deutschland GmbH, Industriepark Hoechst, D-65926 Frankfurt am Main, Germany.

- Manufactured by: Shaily Engineering Plastics Limited, Survey Number 363 At & PO Rania, Taluka Savli, Vadodara, Gujarat (India) - 391780

- Marketed By: Sanofi India Limited, Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai-400072, Maharashtra, India.

- AllStar® meets the current dose accuracy and functional requirements of the ISO 11608-1 with Sanofi Group 3 ml (300 units) insulin cartridges (U-100)

- AllStar® is a registered trademark of the Sanofi Group.

- Source: AllStar® CDM Version 8.2 dated 30th November 2023. Updated: May 2024

SIL-01220724-11 [B010000164]

SANOFI

Artwork Approval History Reference No.: Vista Folder # 4237845

REGULATORY

PACKAGING

QUALITY

Design Unit

SANOFI INDIA LIMITED - GDA
Sanofi India Limited, Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai-400072, Maharashtra, India.
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Version Number : 3

Edition Number : 1

Product : Allstar

Artwork Type : Leaflet

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Market/Country : India [Domestic]

PM GMID Code : B010000164

Technical Drawing : NA

Machine : NA

Style 1 Folds : 178 x 58 mm

Minimum font size : 9 Pts

Pharma Code No. : 12207

EAN bar Code No : NA

Artwork Operator: PN

Date : 20.08.24

Colours

1 CMYK

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Non-Varnished area : NA

Outline: NA