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.

- X Never re-use needles. If you do you might not get your dose as the needle could block.
- X 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
- ✓ 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
- ✓ 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.

Extra items you will need:

If you have any questions about

your pen or about diabetes, ask

your healthcare provider, or

www.sanofi.in/AllStar or call

Sanofi on Tel. no.: +(91-22)

medinfo.india@sanofi.com

STEP 5: Select the dose

X Do not select a dose AND press the dose button

5A Make sure a needle is attached and the dose is

5B Turn the dose button until the dose pointer

Even numbers are shown in line with the dose

Odd numbers are shown as a line between even

• If you turned past your dose, you can turn back

· If there are not enough units left in your pen for

your dose, the dose button will stop at the

If you cannot select your full prescribed dose,

(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).

30 units selected

15 units selected

lines up with your dose.

numbers.

without a needle attached. This may damage your

http://www.sanofi.in or

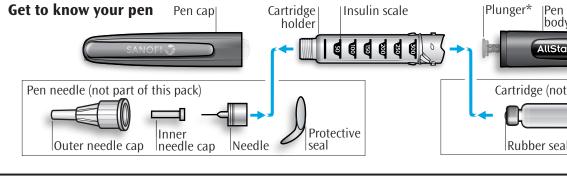
28032000 or email to

ptcindia@sanofi.com

contact us via

- 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).





window button Cartridge (not part of this pack) Rubber stopper *not visible with a new pen

STEP 1: Insert a new cartridge

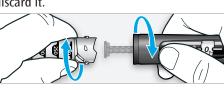
Follow STEP 1 the first time you use AllStar® and when replacing an insulin cartridge.

- X Do not replace the insulin cartridge unless it is empty, expired or broken. It can be used for
- Take a new cartridge out of the refrigerator at least 1 hour before you inject. Cold insulin is more
- 1A Pull off the pen cap from AllStar®

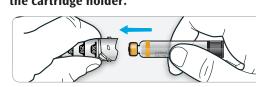


(IB) Unscrew the cartridge holder from the pen body. If there is an insulin cartridge that needs to be

replaced, remove it from the cartridge holder and

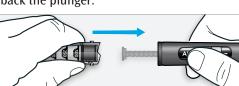


- 10 Check the label of your new insulin cartridge for insulin type and expiry date.
- **1D** Insert the new cartridge, narrow end first, into the cartridge holder

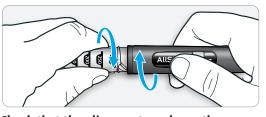


1 Align the insulin cartridge holder straight with the pen body. Use the cartridge's rubber stopper to push the plunger back.

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



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



16 Check that the alignment marks on the cartridge holder and the pen body line up as



cartridge holder and try again.

If the features are not aligned, unscrew the

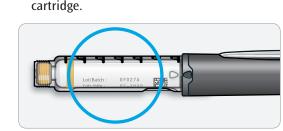
STEP 2: Check your insulin

- Check insulin before every injection.
 - e.g. from Becton Dickinson and Owen Mumford.
- **2A** Pull off the pen cap from AllStar®.



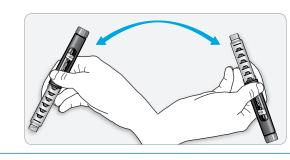
2B Check the label of your insulin cartridge for insulin type and expiry date.

- 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.



Check the appearance of your insulin before every injection:

- For <u>clear insulins</u> (Lantus[®], Apidra[®] or Insuman® Rapid):
- Do not use the cartridge if the insulin is cloudy, coloured or has particles. For <u>suspension insulins</u> (Insuman® Comb):
- Turn the pen up and down at least 10 times to mix the insulin. Turn the pen gently to avoid foaming in the cartridge. After mixing, check your insulin. Insulin
- suspensions must have an even milky-white appearance.



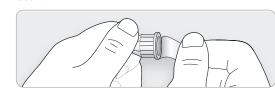
If you have other injector pens

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

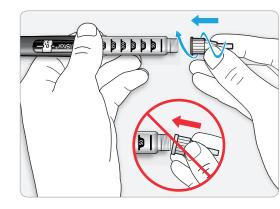
STEP 3: Attach a needle

- **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®

3A Take a new needle and peel off the protective



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



30 Pull off the outer needle cap. Keep this for



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.

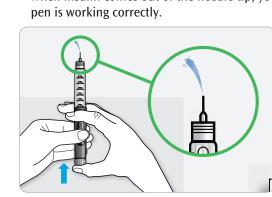
STEP 4: Do a safety test

- 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
- If no insulin comes out after the third time, the
- change the needle (see STEP 7 and STEP 3),

- before seeing insulin.
- needle may be blocked. If this happens:
- 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.

Units of insulin in your pen

number of units left.

you can either:

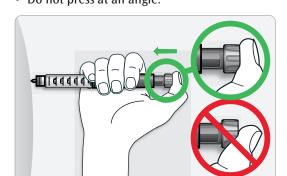
• Each cartridge contains a total of 300 units. You can select doses from 1 to 80 units in steps of 1 unit. Each insulin cartridge can be used for multiple injections until it is empty or expired. You can see roughly how many units of insulin are left by looking at where the rubber stopper is on the 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").
- rubbing alcohol/spirit) B Push the needle into your skin as shown by your
- 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.



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:

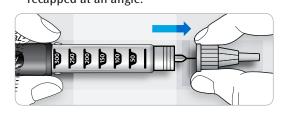
- safety test (see **STEP 4**).
- If you still find it hard to press in, change the cartridge or do not use the pen.

STEP 7: Remove the needle

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

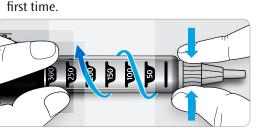
7A Grip the widest part of the outer needle cap. Keep the needle straight and guide it into the outer needle cap. Then push firmly on.

• 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

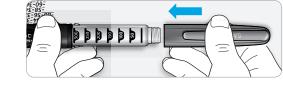


70 Throw away the used needle in a puncture resistant container (or as instructed by your healthcare provider).



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

Do not use your AllStar® 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 AllStar®. Dispose of the pen safely as instructed by your healthcare provider or local

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

- Store your pen with the pen cap on. • **Do not** store AllStar® in the refrigerator.
- Depending on the insulin inserted, keep AllStar® at

room temperature either below 25°C[77°F] or 30°C[86°F

Without a cartridge, AllStar® can be stored upto 30°C

How to care for your pen

Handle your pen with care

- If you think that your pen may be damaged, **do not** try to repair it. If you are not sure whether or not
- healthcare provider or contact us via medinfo.india@sanofi.com or call Sanofi on Tel no.

+(91-22) 28032000

 You can clean the outside of your pen by wiping it with a damp cloth. **Do not** soak, wash or lubricate

direct sunlight Storage temperature for Allstar® without an

cartridge inserted in the pen. **LOT** Batch code

Mfg. Lic. No.: MFG/MD/2022/000695 Legal Manufacturer and CE Mark owner:
Sanofi-Aventis Deutschland C

Manufactured and Packed at: Sanofi Healthcare India Private Limited CTS No. 117-B, L&T Business Park, Śaki Vihar Road, Powai, Mumbai-400072, Maharashtra, India. AllStar® meets the current dose accuracy and

Source: AllStar® CCDM Version 7 dated 05 March 2020. Revision date: Apr 2023

SANOFI **Artwork Approval** (REGULATORY

(QUALITY

Artwork Number : IMF-01200223-4tt Version Number : 5 Edition Number : 4

Minimum font size: 10 Pts

EAN bar Code No : NA

: 05.04.23 Colours

No.: Vista Folder # 4237845 PACKAGING

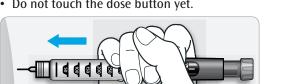
Artwork Type : Leaflet Dimensions(mm) : 711 x 343 mm Market/Country : India [Domestic] PM GMID Code : 880084

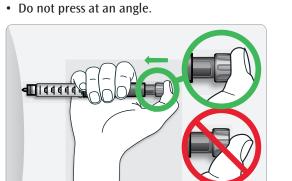
Non-Varnished area: NA

Artwork Operater: PN 1 CMYK

Outline: NA

- Clean the area of skin to be injected (e.g. with
- healthcare provider.







Change the needle (see **STEP 7** and **STEP 3**) then do a

after first use or until expiry date, whichever is



- cartridge inserted. • **Do not** store AllStar® with a needle attached.
- Do not freeze.

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

• Do not drop your pen or knock it against hard

your AllStar® is broken or damaged, contact your

Protect your pen from dust and dirt

your pen – this may damage it. Consult instructions Keep away from

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

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

Sanofi-Aventis Deutschland GmbH. Industriepark Hoechst, D-65926 Frankfurt am Main, Germany. Insulin Plant, Survey No. 354, Muppireddipalli (V), 0123 Manoharabad (M)-502236, Medak (Dist.), Telangana, India. Marketed By: Sanofi India Limited, Sanofi House,

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.

Technical Drawing: NA Manufacturing site: Insulin Plant- MRP Design Unit Style \ Folds : 178 x 58 mm