

APIDRA[®] SOLOSTAR[®]

Instruction Leaflet

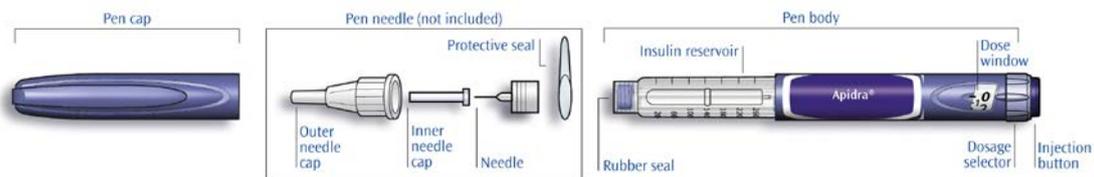
SoloSTAR[®] is a prefilled pen for the injection of insulin. Your health professional has decided that SoloSTAR is appropriate for you, based on your ability to handle SoloSTAR. Talk with your health professional about proper injection technique before using SoloSTAR.

Read these instructions carefully before using your SoloSTAR. If you are not able to use SoloSTAR or to follow all the instructions completely on your own, you must use SoloSTAR only if you have help from a person who is able to follow the instructions completely. Hold the pen as shown in this leaflet. To ensure that you read the dose correctly, hold the pen horizontally, with the needle on the left and the dosage selector to the right as shown in the illustrations below.

Each SoloSTAR contains in total 300 units of insulin. You can set doses from 1 to 80 units in steps of 1 unit. Each pen contains multiple doses.

Keep this leaflet for future reference.

If you have any questions about SoloSTAR or about diabetes, ask your health professional or call sanofi-aventis at 1-888-852-6887.



Important information for use of SoloSTAR:

- To avoid transmission of disease do not share injection pens, cartridges, needles or syringes. This injection pen is for single patient use. Do not share it with anyone including other family members, even if the needle on the injection pen is changed. Do not use on multiple patients.
- Always attach a new needle before each use. Needles are available in different lengths and gauges. Only use needles that have been approved for use with SoloSTAR. Contact your health professional for further information.
- Do not select a dose and/or press the injection button without a needle attached
- Always perform the safety test before each injection (see Step 3).
- If your injection is given by another person, special caution must be taken by this person to avoid accidental needle injury and transmission of infection.
- Never use SoloSTAR if it is damaged or if you are not sure that it is working properly.
- Always have a spare SoloSTAR in case your SoloSTAR is lost or damaged.

Step 1. Check the insulin

- A. Check the label on your SoloSTAR to make sure you have the correct insulin. The Apidra[®] SoloSTAR is blue. It has a dark blue injection button with a raised ring on the top.
- B. Take off the pen cap.
- C. Check the appearance of your insulin. Apidra is a clear insulin. Do not use this SoloSTAR if the insulin is cloudy, colored or has particles.

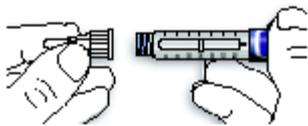
Step 2. Attach the needle

Always use a new sterile needle for each injection. This helps prevent contamination, and potential needle blocks.

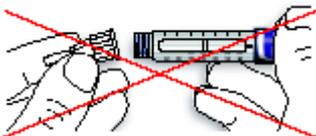
Before use of needle, carefully read the “Instructions for Use” accompanying the needles.

Please note: The needles shown are for illustrative purposes only.

- A. Wipe the rubber seal with alcohol.
- B. Remove the protective seal from a new needle.
- C. Line up the needle with the pen, and keep it straight as you attach it (screw or push on, depending on the needle type).



- If the needle is not kept straight while you attach it, it can damage the rubber seal and cause leakage, or break the needle.

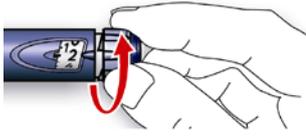


Step 3. Perform a safety test

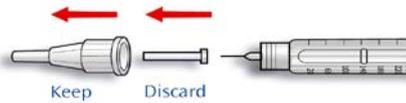
Always perform the safety test before each injection. This ensures that you get an accurate dose by:

- ensuring that pen and needle work properly
- removing air bubbles

A. Select a dose of 2 units by turning the dosage selector clockwise.



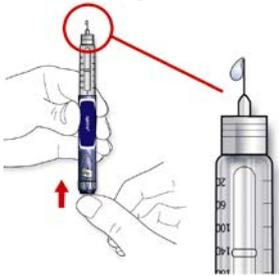
B. Take off the outer needle cap and keep it to remove the used needle after injection. Take off the inner needle cap and discard it.



C. Hold the pen with the needle pointing upwards.

D. Tap the insulin reservoir so that any air bubbles rise up towards the needle.

E. Press the injection button all the way in. Check if insulin comes out of the needle tip.



You may have to perform the safety test several times before insulin is seen.

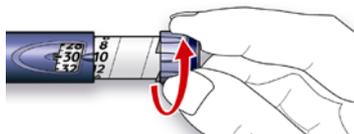
- If no insulin comes out, check for air bubbles and repeat the safety test two more times to remove them.
- If still no insulin comes out, the needle may be blocked. Change the needle and try again.
- If no insulin comes out after changing the needle, your SoloSTAR may be damaged. Do not use this SoloSTAR.

Step 4. Select the dose

You can set the dose in steps of 1 unit, from a minimum of 1 unit to a maximum of 80 units. If you need a dose greater than 80 units, you should give it as two or more injections.

A. Check that the dose window shows “0” following the safety test.

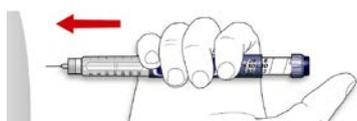
B. Select your required dose turning the dosage selector clockwise (in the example below, the selected dose is 30 units). If you turn past your dose, you can turn back down. (counter-clockwise)



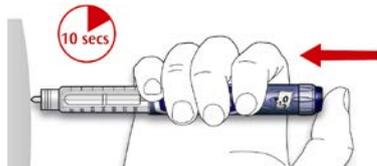
- Do not push the injection button while turning, as insulin will come out.
- You cannot turn the dosage selector past the number of units left in the pen. Do not force the dosage selector to turn. In this case, either you can inject what is remaining in the pen and complete your dose with a new SoloSTAR or use a new SoloSTAR for your full dose.

Step 5. Inject the dose

- Clean the area of skin to be injected (e.g. with rubbing alcohol).
- Use the injection method as instructed by your health professional.
- Insert the needle into the skin.



- Deliver the dose by pressing the injection button in all the way. The number in the dose window will progressively return to “0” as you inject.
- Keep the injection button pressed all the way in. Slowly count to 10 before you withdraw the needle from the skin. This ensures that the full dose will be delivered.



The pen plunger moves with each dose. The plunger will reach the end of the cartridge when the total of 300 units of insulin has been used.

Step 6. Remove and discard the needle

Always remove the needle after each injection and store SoloSTAR without a needle attached. This helps prevent:

- Contamination and/or infection
 - Entry of air into the insulin reservoir and leakage of insulin, which can cause inaccurate dosing.
- Put the outer needle cap back on the needle, and use it to unscrew the needle from the pen. To reduce the risk of accidental needle injury, never replace the inner needle cap.
- If your injection is given by another person, or if you are giving an injection to another person, special caution must be taken by this person when removing and disposing of the needle. Follow recommended safety measures for removal and disposal of needles (e.g. contact your health professional) in order to reduce the risk of accidental needle injury and transmission of infectious diseases.

- B. Dispose of the needle safely. Used needles should be placed in sharps containers (such as biohazard containers), hard plastic containers (such as detergent bottles), or metal containers (such as an empty coffee can). Such containers should be sealed and disposed of properly.
- C. Always put the pen cap back on the pen, then store the pen until your next injection.

Storage Instructions

Please also check the reverse side of this leaflet for instructions on how to store SoloSTAR.

Keep SoloSTAR out of the reach and sight of children.

Keep your SoloSTAR in cool storage (2°C – 8°C) until first use. Do not allow it to freeze. Do not put it next to the freezer compartment of your refrigerator, or next to a freezer pack.

If your SoloSTAR is in cool storage, take it out 1 to 2 hours before you inject to allow it to warm up. Cold insulin is more painful to inject.

Once you take your SoloSTAR out of cool storage, for use or as a spare, you can use it for up to 28 days. During this time it should be kept at room temperature (15 – 25°C) and must not be stored in the refrigerator. If there is any remaining insulin after 28 days, discard it.

Do not use SoloSTAR after the expiration date printed on the label of the pen or if it is cloudy, colored or if you see particles.

Protect SoloSTAR from light.

Discard your used SoloSTAR as required by your local authorities.

Maintenance

Protect your SoloSTAR from dust and dirt.

You can clean the outside of your SoloSTAR by wiping it with a damp cloth.

Do not soak, wash or lubricate the pen as this may damage it.

Your SoloSTAR is designed to work accurately and safely. It should be handled with care. Avoid situations where SoloSTAR might be damaged. If you are concerned that your SoloSTAR may be damaged, use a new one.

Manufacturer:

Sanofi-aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany

Importer/Distributor:

Sanofi-aventis Canada Inc. Laval (Quebec) Canada H7V 0A3

Call toll free 1-888-852-6887.

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