

Instructions for Use **Rx Only**
ADMELOG® SoloStar® (ad-mah-log)
 (insulin lispro injection) for subcutaneous use
 3 mL single-patient-use prefilled pen (100 Units/mL, U-100)

Read this first

Do not share your ADMELOG SoloStar pen 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.

People who are blind or have vision problems should not use ADMELOG SoloStar prefilled pen without help from a person trained to use ADMELOG SoloStar prefilled pen.

ADMELOG SoloStar is a disposable prefilled pen used to inject ADMELOG. Each ADMELOG SoloStar has 300 units of insulin which can be used for multiple injections. You can select doses from 1 to 80 units in steps of 1 unit. The pen plunger moves with each dose. The plunger will only move to the end of the cartridge when 300 units of insulin have been given.

Important information

- **Do not** use your pen if it is damaged or if you are not sure that it is working properly.
- **Do not** use a syringe to remove insulin from your pen.
- **Do not reuse needles.** If you do, you might get the wrong dose of ADMELOG and/or increase the chance of getting an infection.
- Always perform a safety test (see **Step 3**).
- Always carry a spare pen and spare needles in case they got lost or stop working.
- Change (rotate) your injection sites within the area you choose for each dose (see **"Places to inject"**).

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.

Need help?

If you have any questions about your pen or about diabetes, ask your healthcare provider, or go to www.Admelog.com or call sanofi-aventis at 1-800-633-1610.

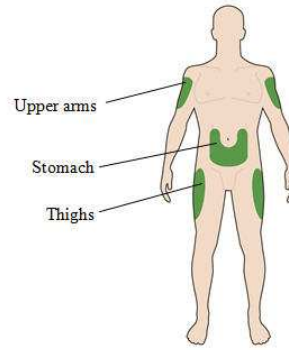
Extra items you will need:

- a new sterile needle (see **Step 2**).
- an alcohol swab.
- a puncture-resistant container for used needles and pens. (See **"Throwing your pen away"**).

Places to inject

- Inject your insulin exactly as your healthcare provider has shown you.
- Inject your insulin under the skin (subcutaneously) of your upper legs (thighs), upper arms, or stomach area (abdomen).
- Change (rotate) your injection sites within the area you choose for each dose to reduce your risk of getting lipodystrophy (pits in skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the injection sites.
- **Do not** inject where the skin has pits, is thickened, or has lumps.

- **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.



Get to know your pen



Step 1: Check your pen

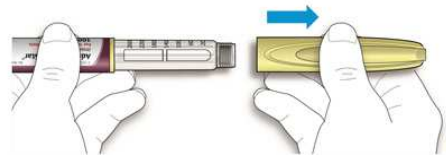
Take a new pen out of the refrigerator at least 1 hour before you inject. Cold insulin is more painful to inject.

1A Check the name and expiration date on the label of your pen.

- Make sure you have the correct insulin.
- **Do not** use your pen after the expiration date.

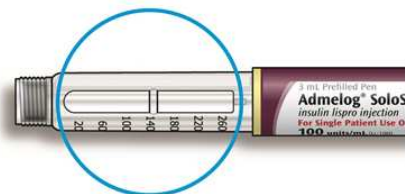


1B Pull off the pen cap.

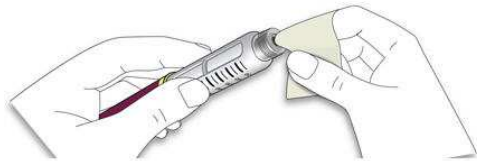


1C Check that the insulin is clear.

- **Do not** use the pen if the insulin looks cloudy, colored or contains particles.



1D Wipe the rubber seal with an alcohol swab.



If you have other injector pens:

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

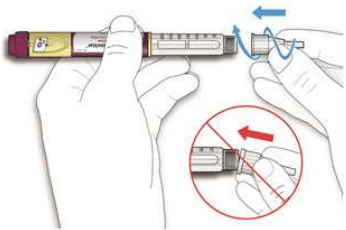
Step 2: Attach a new needle

- **Do not reuse needles.** Always use a new sterile needle for each injection. This helps stop blocked needles, contamination, and infection.
- Only use needles¹ that are compatible for use with ADMELOG SoloStar, e.g. needles from BD (such as BD Ultra-Fine[®]), Ypsomed (such as Clickfine[®]), Owen Mumford (such as Unifine[®] Pentips[®]).

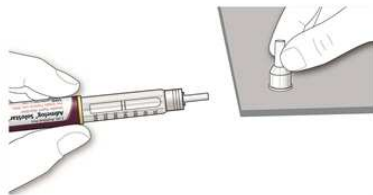
2A Take a new needle and peel off the protective seal.



2B Keep the needle straight and screw it onto the pen until fixed. Do not over-tighten.



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



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



Handling needles:

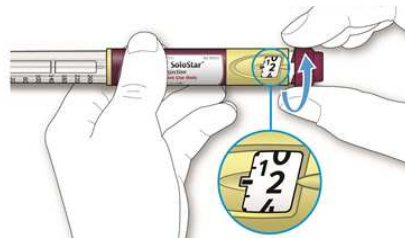
- Take care when handling needles to prevent needle-stick injury and cross-infection.

Step 3: Do a safety test

Always do a safety test before each injection to:

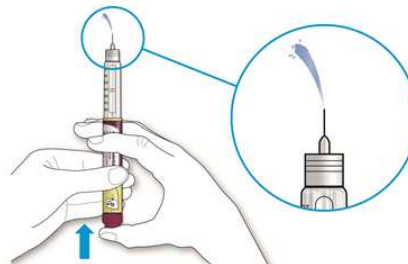
- Check your pen and the needle to make sure they are working properly.
- Make sure that you get the correct insulin dose.

3A Select 2 units by turning the dose selector until the dose pointer is at the 2 mark.



3B Press the injection 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 6** and **Step 2**),
 - then repeat the safety test (**Step 3**).
- **Do not** use your pen if there is still no insulin coming out of the needle tip. Use a new pen.
- **Do not** use a syringe to remove insulin from your pen.

If you see air bubbles:

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

Step 4: Select the dose

Do not select a dose or press the injection button without a needle attached. This may damage your pen.

4A Make sure a needle is attached and the dose is set to '0'.



4B Turn the dose selector until the dose pointer lines up with your dose.

- If you turn past your dose, you can turn back down.
- If there are not enough units left in your pen for your dose, the dose selector will stop at the number of units left.

- If you cannot select your full prescribed dose, use a new pen or inject the remaining units and use a new pen to complete your dose.



How to read the dose window

Even numbers are shown in line with dose pointer.



20 units selected

Odd numbers are shown as a line between even numbers.



21 units selected

Units of insulin in your pen:

- Your pen contains a total of **300** units of insulin. You can select doses from **1** to **80** units in steps of **1** unit. Each pen contains more than 1 dose.
- You can see roughly how many units of insulin are left by looking at where the plunger is on the insulin scale.

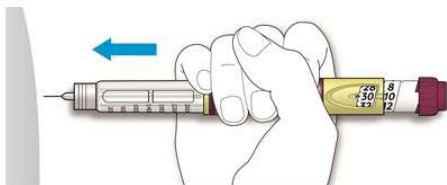
Step 5: Inject your dose

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

5A Choose a place to inject as shown in the picture above.

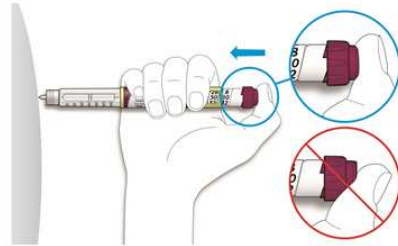
5B Push the needle into your skin as shown by your healthcare provider.

- Do not touch the injection button yet.



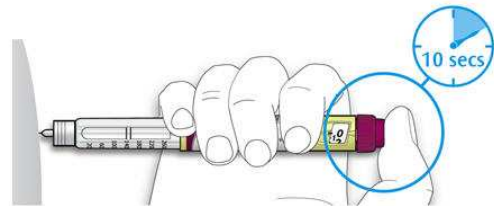
5C Place your thumb on the injection button. Then press all the way in and hold.

- **Do not** press at an angle. Your thumb could block the dose selector from turning.



5D Keep the injection 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.



5E After holding and slowly counting to 10, release the injection button. Then remove the needle from your skin.

If you find it hard to press the button in:

- Change the needle (see **Step 6** and **Step 2**) then do a safety test (see **Step 3**).
- If you still find it hard to press in, get a new pen.
- **Do not** use a syringe to remove insulin from your pen.

Step 6: Remove the needle

- Take care when handling needles to prevent needle-stick injury and cross-infection.
- **Do not** put the inner needle cap back on.

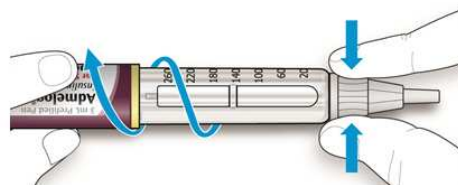
6A Grip the widest part of the outer needle cap. Keep the needle straight and guide it into the outer needle cap. Then push firmly on.

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



6B 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.

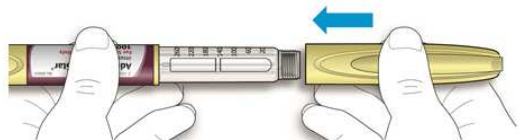


6C Throw away the used needle in a puncture-resistant container (see “Throwing your pen away” at the end of this Instructions for Use).



6D Put your pen cap back on.

- Do not put the pen back in the refrigerator.



How to store your pen

Before first use

- Keep new pens in the refrigerator between **36°F to 46°F (2°C to 8°C)**.
- **Do not freeze. Do not** use ADMELOG if it has been frozen.

After first use

- Keep your pen at room temperature **below 86°F (30°C)**.
- Keep your pen away from heat or light.
- Store your pen with the pen cap on.
- **Do not** put your pen back in the refrigerator.
- **Do not** store your pen with the needle attached.
- **Keep out of the reach of children.**
- Only use your pen for **up to 28 days** after its first use. Throw away the ADMELOG SoloStar pen you are using after 28 days, even if it still has insulin left in it.

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 fix it. Use a new one.

Protect your pen from dust and dirt

- You can clean the outside of your pen by wiping it with a damp cloth (water only). **Do not** soak, wash or lubricate your pen. This may damage it.

Throwing your pen away

- Put the used ADMELOG SoloStar pen in a FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the ADMELOG SoloStar pen in your household trash.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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