

INSTRUCTIONS FOR USE

Rx Only

SOLIQUA® 100/33 (So - lee - kwa)

(insulin glargine and lixisenatide injection) for subcutaneous use

Read these instructions carefully before using your SOLIQUA 100/33 pen.

Do not share your SOLIQUA 100/33 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.

SOLIQUA 100/33 is an injectable prescription medicine that contains 2 diabetes medicines, insulin glargine and lixisenatide in a SoloStar pen. The drug combination in this pen is only for the daily injection of 15 to 60 units of SOLIQUA 100/33. Each unit dialed contains 1 unit insulin glargine and 0.33 mcg lixisenatide.

Important information

- Check the label on the SOLIQUA 100/33 pen each time you give your injection to make sure you are using the correct medicine.
- **Do not** use your pen if it is damaged or if you are not sure that it is working correctly.
- Perform a safety test before each injection (see **“Step 3: Do a safety test”**).
- Always carry a spare pen and spare needles in case they are lost or stop working.
- **Do not reuse needles.** Always use a new sterile needle for each injection. This helps stop blocked needles, contamination, and infection. If you reuse needles, you might not get your dose (underdosing) or get too much (overdosing).
- **Do not** use SOLIQUA 100/33 in an insulin pump or inject SOLIQUA 100/33 into your vein (intravenously) or muscle (intramuscularly).
- **Do not** mix SOLIQUA 100/33 in any other type of insulin or liquid medicine prior to injection.
- Change (rotate) your injection sites within the area you chose with each dose. Do not use the same spot for each injection, to avoid skin thickening or pits at the injection site (lipodystrophy).

Learn to inject

- Talk with your healthcare provider about how to use the SOLIQUA 100/33 pen and how to inject correctly before using your pen.
- Ask for help if you have problems handling the pen, for example if you have vision problems.
- Read all of these instructions before using your pen. You may get too much or too little medicine if you do not follow the instructions correctly.

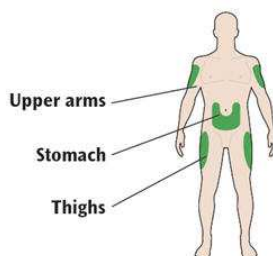
Need help?

If you have any questions about your pen or about diabetes, ask your healthcare provider, go to www.soliqua100-33.com or call sanofi-aventis at 1-800-633-1610.

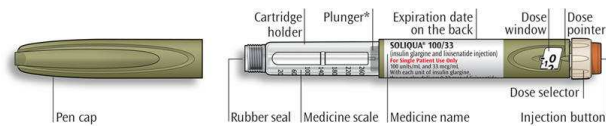
Supplies you will need:

- 1 SOLIQUA 100/33 pen
- 1 new sterile needle (see **Step 2 “Attach a new needle”**)
- 1 alcohol swab
- a puncture-resistant container for used needles and pens (see **“Throwing your pen away”** at the end of this Instructions for Use)

Places to inject



Get to know your pen



*You will not see the plunger until you have injected a few doses

Step 1: Check your pen

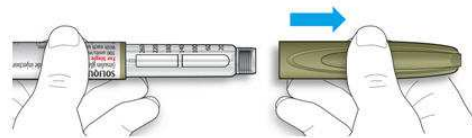
Take a new pen out of the refrigerator at least 1 hour before you inject. Cold medicine is more painful to inject.

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

- Make sure you have the correct medicine. This pen is colored light green with an orange injection button (see the **“Get to know your pen”** diagram).
- **Do not** use your pen after the expiration date on the pen label.

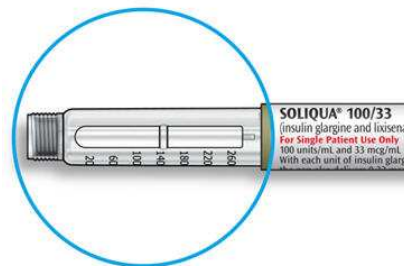


1B Pull off the pen cap.

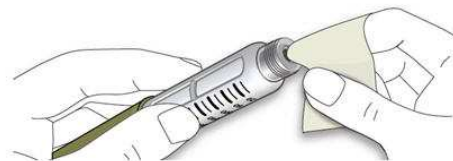


1C Check that the medicine is clear and colorless to almost colorless.

- **If you see small particles, return it to your pharmacy for a replacement.**



1D Wipe the rubber seal with an alcohol swab.



If you have other injector pens

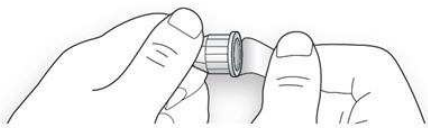
- Making sure you have the correct medicine is especially important if you have other injector pens.

Step 2: Attach a new needle

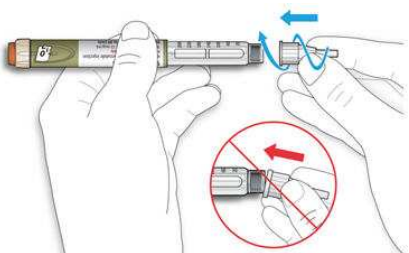
- **Do not** reuse needles. Always use a new sterile needle for each injection. This helps stop blocked needles, contamination and infection.

- Only use needles that are meant to be used with SOLIQUA 100/33. Needles are supplied separately. If you do not know what needles to use, ask your healthcare provider or pharmacist.

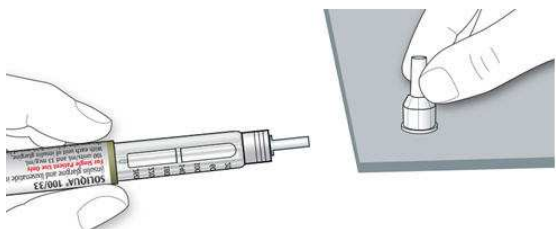
2A Take a new needle and peel off the protective seal.



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 it away.



Handling needles

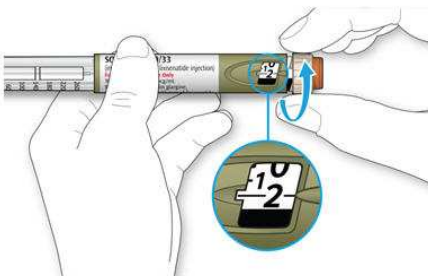
- Take care when handling needles to prevent needle-stick injury and cross-infection.

Step 3: Do a safety test

Perform a safety test before each injection to:

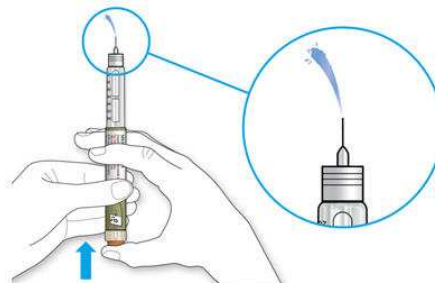
- Check your pen and the needle to make sure they are working properly.
- Make sure that you get the correct dose.

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 the medicine comes out of the needle tip, your pen is working correctly.



If no liquid appears:

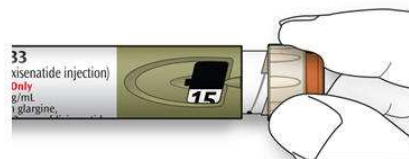
- You may need to repeat this step up to **3** times before seeing the medicine.
- If no medicine comes out after the third time, the needle may be blocked. If this happens:
 - change the needle (**see Step 6** to remove the needle and **Step 2** to attach a new needle),
 - then repeat the safety test (**see Step 3A**).
- **Do not** use your pen if still no medicine comes out of the needle tip. Use a new pen.
- **Do not** use a syringe to remove medicine from your pen.

If you see air bubbles

- You may see air bubbles in the medicine. 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.
- **Only use this pen to inject your daily dose from 15 to 60 units. Do not change your dose unless your healthcare provider has told you to change your dose.**
- **Do not** use this pen if you need a single daily dose that is more than 60 units.
- **Do not** use the pen if your single daily dose is less than 15 units, the black area in dose window as shown in the picture.



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.

- Do not dial your dose by counting the clicks, because you might dial the wrong dose. Always check the number in the dose window to make sure you dialed the correct 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.

How to read the dose window

- Each line in the dose window equals 1 unit of SOLIQUA 100/33.

- Even numbers are shown in line with the dose pointer, as shown in picture.



30 units selected

- Odd numbers are shown as a line between even numbers, as shown in picture.



29 units selected

Units of medicine in your pen

- This pen contains 300 units of SOLIQUA 100/33 and it is intended to be used for more than one dose.

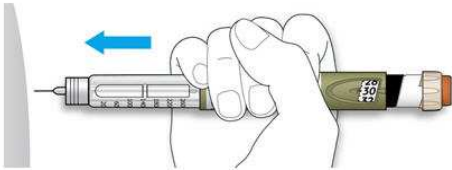
Step 5: Inject your dose

If you find it hard to press the injection button in, **do not** force it as this may break your pen. See the section after Step 5E below for help.

5A Choose a place to inject as shown in the picture labeled "Places to inject."

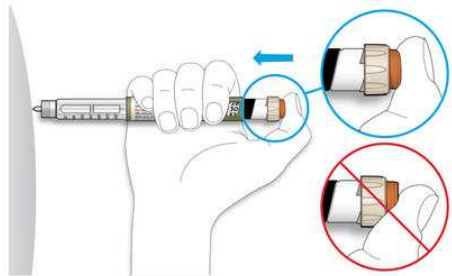
5B Push the needle into your skin as shown by your healthcare provider.

- Do not touch the injection button yet.



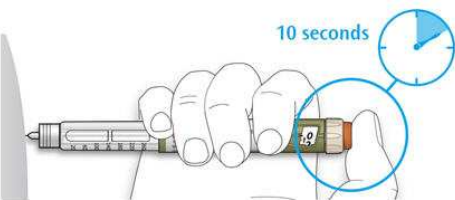
5C Place your thumb on the injection button. Then press all the way in and hold.

- Do not press injection button 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 injection button in:

- Change the needle (see Step 6 to remove the needle and Step 2 to attach a new needle) 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 medicine from your pen.

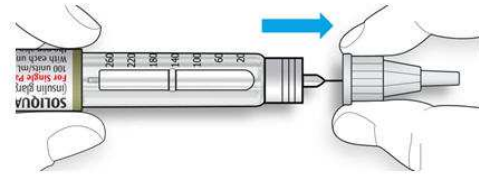
Step 6: Remove the needle

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

- Do not put the inner needle cap back on.

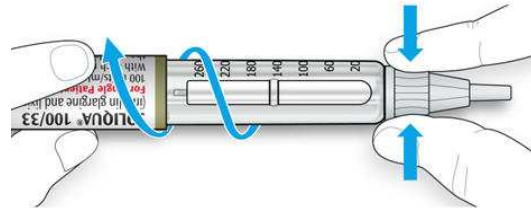
6A Grip the widest part of the outer needle cap. Keep the needle straight and guide it into the outer needle cap back. Then push firmly on.

- 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.

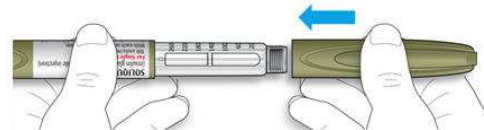


6C Throw away the used needle in a puncture-resistant container (see "Throwing your pen away" at the end of this Instructions for Use).



6D Put your pen cap back on.

- Do not put the pen back in the refrigerator.



Use by

- Only use your pen for up to **28 days** after its first use.

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. If you accidentally freeze your pen, throw it away.

After first use

- Keep your pen at room temperature, **below 77°F (25°C)**.
- Do not put your pen back in the refrigerator.
- Do not store your pen with the needle attached.
- Store the pen with your pen cap on.

Keep this pen out of the sight and reach of children.

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 the pen. This may damage it.

Throwing your pen away

- Put the used SOLIQUA 100/33 pen in a FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the SOLIQUA 100/33 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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