

SOLIQUA® SoloSTAR®

HOW TO INJECT SOLIQUA®

READ THE INSTRUCTIONS FOR USE
PAMPHLET CAREFULLY BEFORE USING
YOUR SOLIQUA® SOLOSTAR® PEN.



SOLIQUA®, a fixed ratio combination of insulin glargine and lixisenatide, once daily injection, is indicated in combination with metformin as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus inadequately controlled on:

- basal insulin (<60 units daily) alone or in combination with metformin
- a glucagon-like peptide-1 receptor agonist (GLP-1 RA) in combination with metformin

Please refer to the Patient Information leaflet for information regarding serious warning and precautions, side effects, drug interactions and dosing.

BEFORE YOU START

Welcome to SOLIQUA®. Before you start the injection process, there are a few things you'll need to know.



IMPORTANT INFORMATION

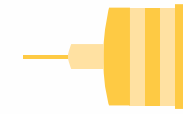
Just a few safety instructions before you inject:

- Check the label on the SOLIQUA® SoloSTAR® pen before each 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 below)
- 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® in an insulin pump or inject SOLIQUA® into your vein (intravenously) or muscle (intramuscularly).
- **Do not** mix SOLIQUA® 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).
- Talk to your healthcare professional about how to properly use SOLIQUA® before you use it for the first time
- Use SOLIQUA® exactly as prescribed by your doctor
- **Do not** share SOLIQUA® with anyone else, even if you change the needle. You may give another person an infection or get an infection from them

WHAT YOU'LL NEED



1 SOLIQUA®
SoloSTAR® pen



1 new sterile needle



1 alcohol swab



A puncture-resistant
container for used
needles and pens

LEARN TO INJECT

- Talk with your healthcare professional about how to use the SOLIQUA® SoloSTAR® 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.



Tip: Take a new pen out of the fridge at least 1 hour before you inject. Cold medicine can be painful to inject.



INJECTION STEPS

Now that you have the materials you need, it's time to inject. Find a comfortable place and follow the steps below.

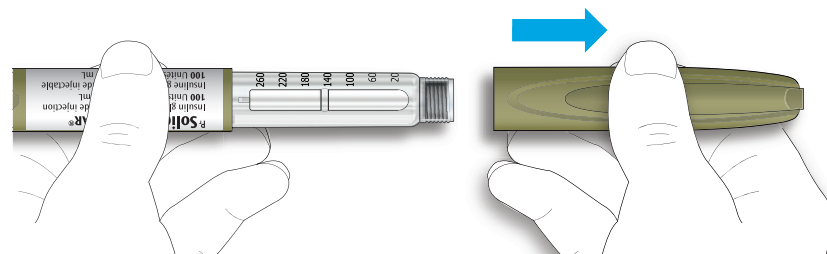
STEP 1: CHECK YOUR PEN

1A CHECK THE NAME AND EXPIRATION DATE ON THE LABEL OF YOUR PEN

- Check the label on your SOLIQUA® SoloSTAR® to make sure you have the correct medicine.
- This pen is olive coloured with a brown injection button
- **DO NOT** use your pen after the expiration date

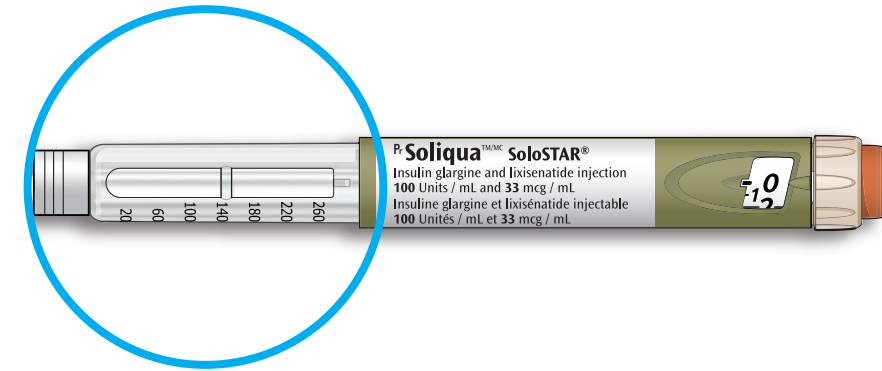
1B REMOVE THE PEN CAP

If you see small particles, do not use this pen. Contact your healthcare professional.
Do not use SOLIQUA® if liquid inside the pen is discolored, cloudy, contains particles, or if there are any signs of leakage.

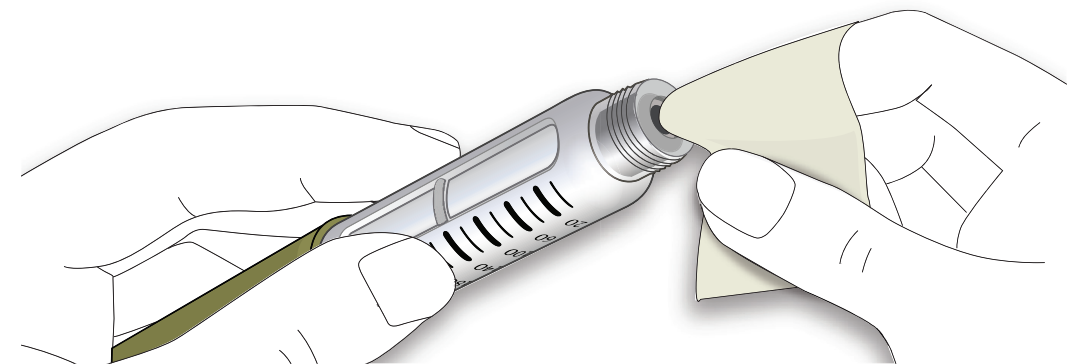


1C MAKE SURE THAT THE MEDICINE IS CLEAR AND ALMOST COLOURLESS

Always look through the pen window before each injection. The liquid inside the pen should be clear, colourless, water-like and free of particle.



1D WIPE THE RUBBER SEAL WITH AN ALCOHOL SWAB



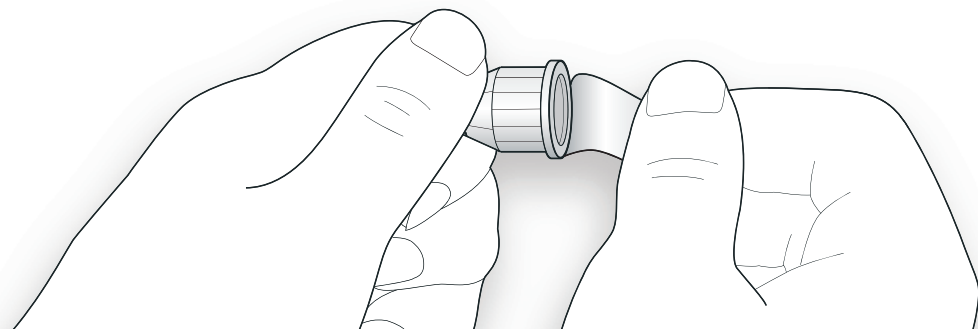
Tip: If you have other injector pens, double check to make sure you have the correct medicine.

STEP 2: ATTACH A NEW NEEDLE

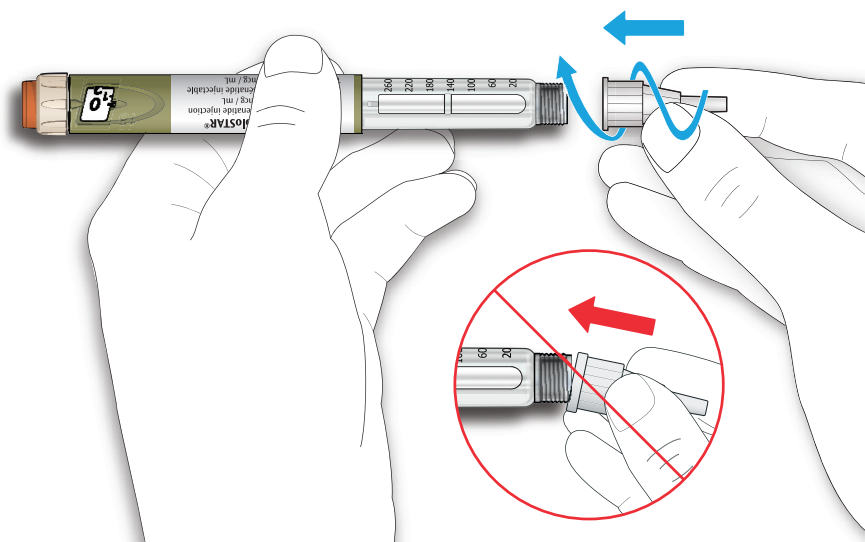
Do not reuse needles. Always use a new sterile needle for each injection. This helps stop blocked needles, contamination and infection.

- Only use needles that are meant to be used with SOLIQUA® SoloSTAR® pen. Needles are supplied separately. If you do not know what needles to use, ask your healthcare professional or pharmacist.

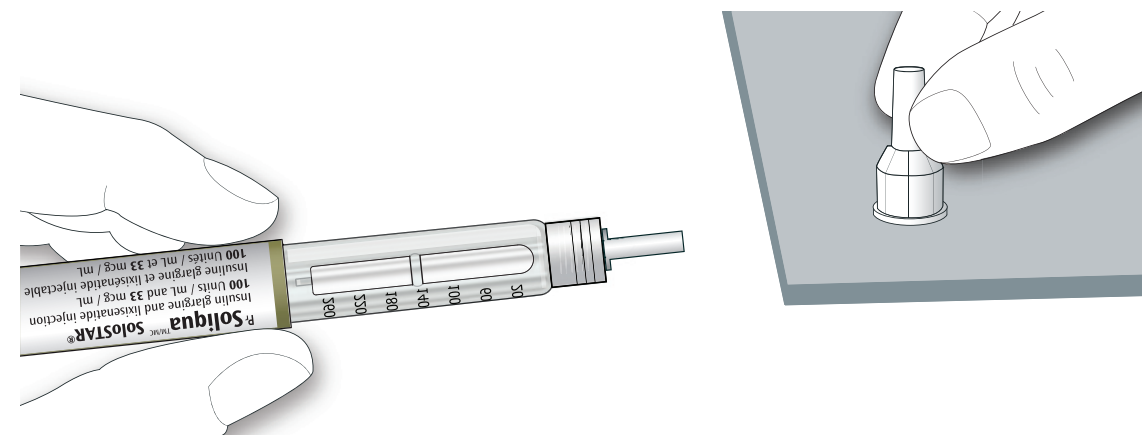
2A TAKE A NEW NEEDLE AND PEEL OFF THE PROTECTIVE SEAL



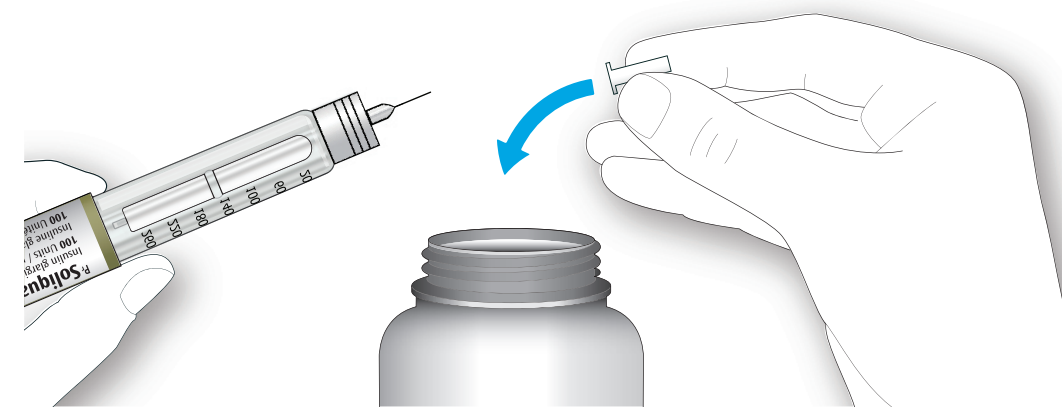
2B KEEP THE NEEDLE STRAIGHT AND SCREW IT ONTO THE PEN UNTIL FIXED. DO NOT OVER-TIGHTEN



2C PULL OFF THE OUTER NEEDLE CAP. KEEP THIS FOR LATER



2D PULL OFF THE INNER NEEDLE CAP AND THROW IT AWAY



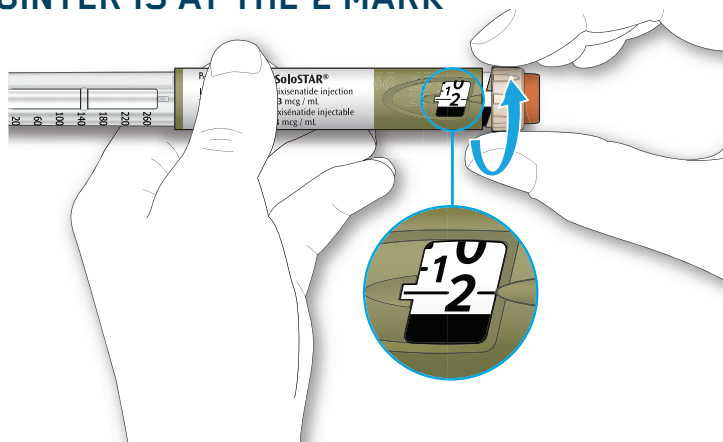
Handling needles
Take care when handling needles to prevent injury and cross-infection.

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



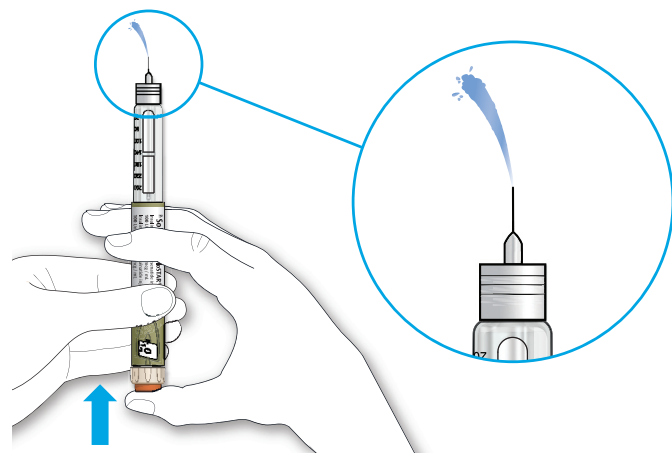
3B PRESS THE INJECTION BUTTON ALL THE WAY IN

If 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 try, the needle may be blocked.

If this happens:

- Go to **step 6** and change the needle
- Go back to **step 3** and repeat the safety test



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.

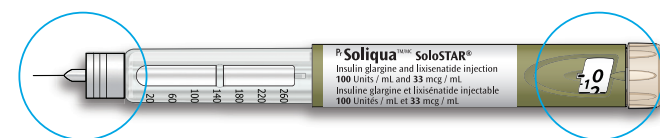
If you see air bubbles

- 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.

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, don't worry, you can dial it back down.
- If there aren't 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.

• **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® and it is intended to be used for more than one dose.

SOLIQUA
insulin glargine & lixisenatide injection

STEP 5: INJECTING YOUR DOSE

5A CHOOSE A PLACE TO INJECT AS SHOWN HERE

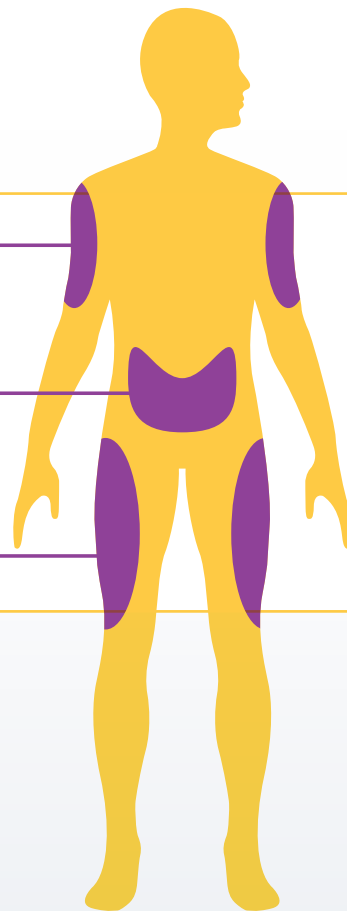
The SOLIQUA® pen may be injected in the thigh, belly, or upper arm.

Do not use the same spot for each injection, to avoid skin thickening or pits at the injection site.

UPPER ARMS

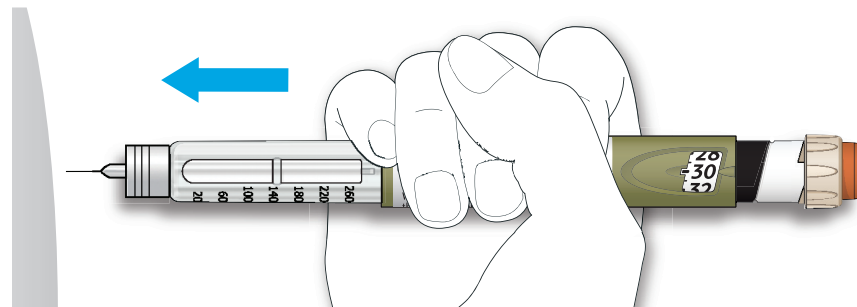
STOMACH

THIGHS



5B PUSH THE NEEDLE INTO YOUR SKIN AS DEMONSTRATED BY YOUR HEALTHCARE PROFESSIONAL

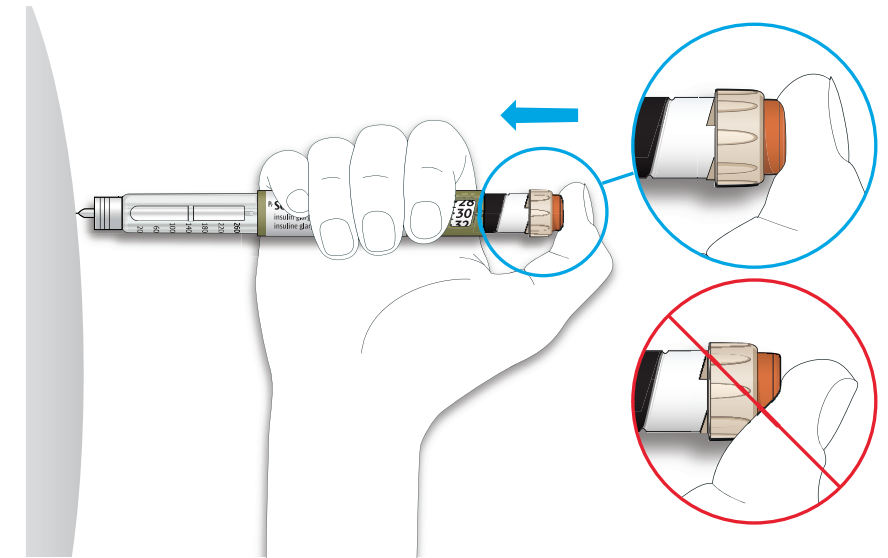
Do not touch the injection button yet.



5C PLACE YOUR THUMB ON THE INJECTION BUTTON. THEN PRESS ALL THE WAY IN AND HOLD

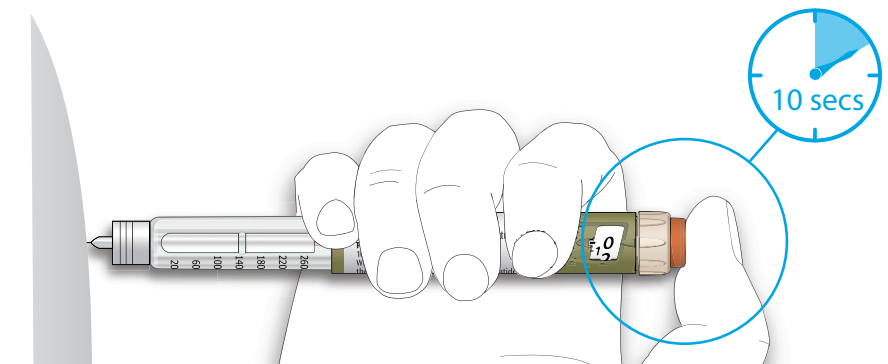
If you find it hard to press the injection button in, do not force it as this may break your pen.

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:

- Go to step 6 and change the needle then go back to step 3 to do a safety test
- If you still find it hard to press in, get a new pen.
- **Do not** use a syringe to remove medicine from your pen.

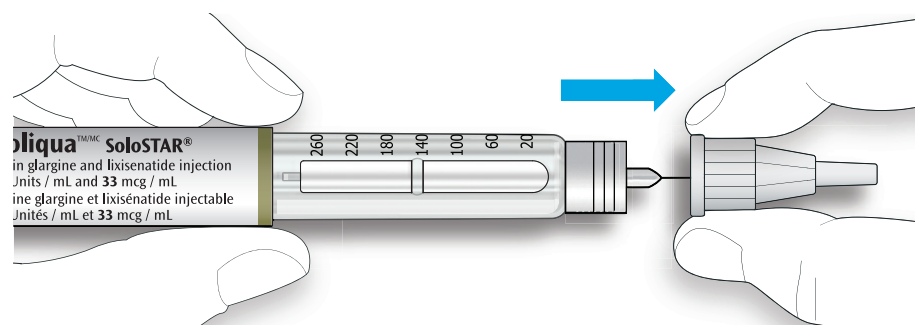
STEP 6: REMOVE THE NEEDLE

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

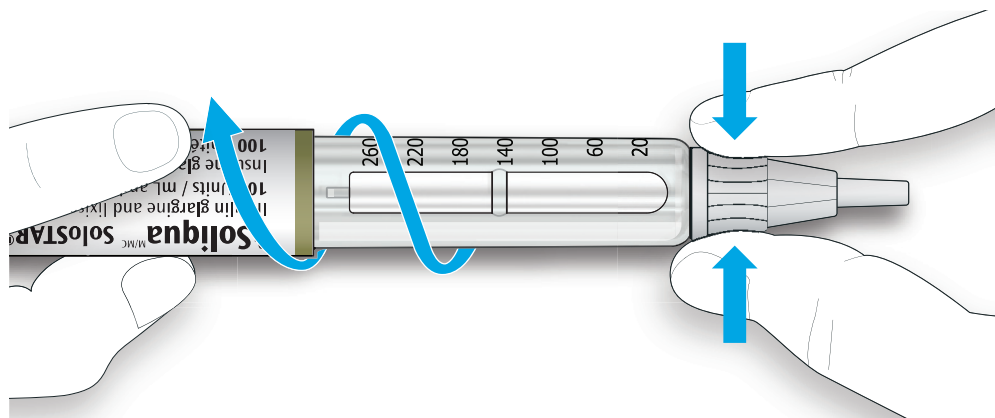
The needle can puncture the cap if it is recapped at an angle.



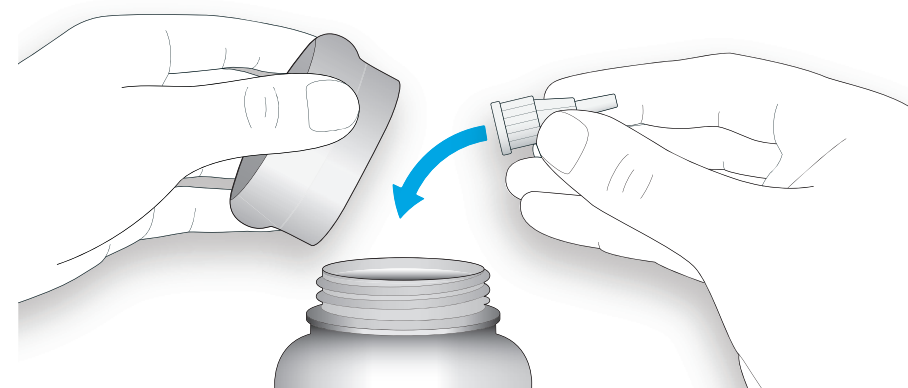
6B GRIP AND SQUEEZE THE WIDEST PART OF THE OUTER NEEDLE CAP

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.

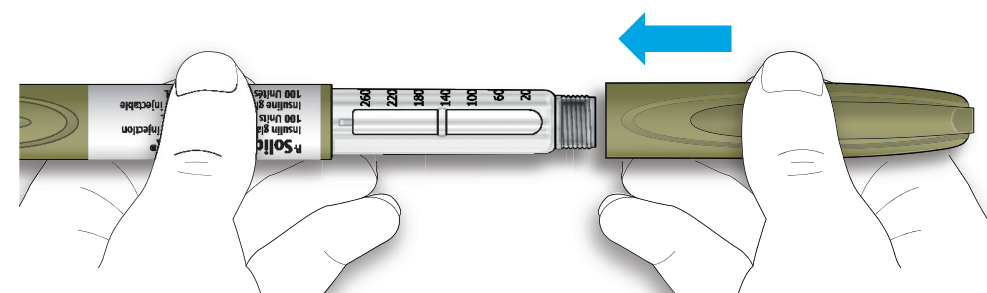


6C THROW AWAY THE USED NEEDLE IN A PUNCTURE-RESISTANT CONTAINER (SEE “THROWING YOUR PEN AWAY” AT THE END OF THESE INSTRUCTIONS FOR USE).



6D PUT YOUR PEN CAP BACK ON

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



Do not put the pen back in the refrigerator after you've used it. Continue on to the next section to learn how to store your pen.

HOW TO STORE YOUR PEN

BEFORE FIRST USE

- Keep new pens in the refrigerator between **2°C to 8°C**.
- **Do not** freeze. If you accidentally freeze your pen, throw it away.
- Keep the pen in the original package to protect from light
- Discard the pen if heated

AFTER FIRST USE

- Keep your pen at room temperature, up to 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.
- Replace the pen cap after use to protect from light.
- Discard the pen 28 days after first use or if heated or frozen.

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.

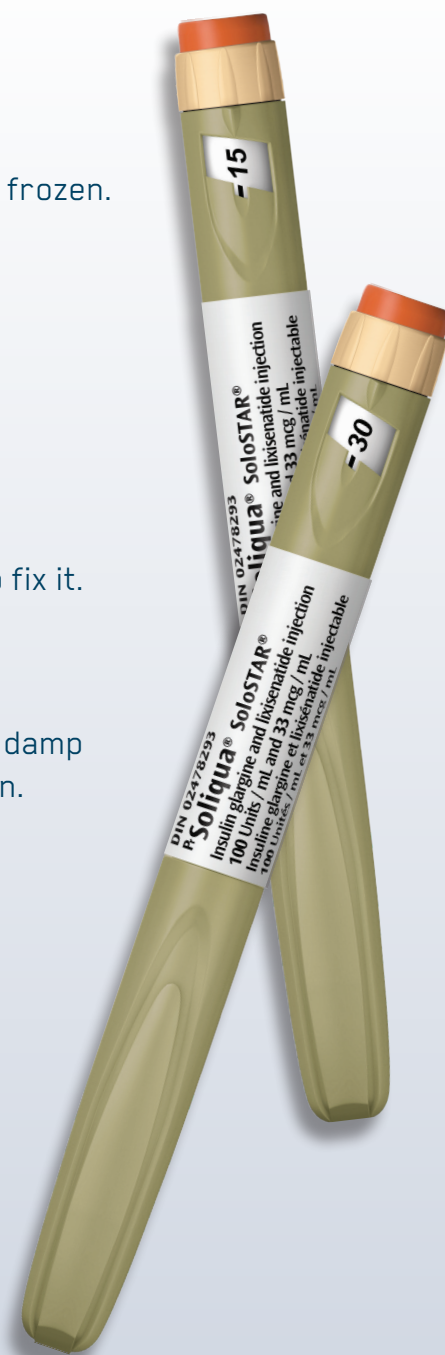
THROWING YOUR PEN AWAY

Replace the pen cap before disposing of your SOLIQUA® SoloSTAR® pen.

- Put the used SOLIQUA® SoloSTAR® pen in a sharps container right away after use. Do not dispose of the SOLIQUA® SoloSTAR® pen in your household trash.
- If you do not have a sharps 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
 - properly labelled to warn of hazardous waste inside the container

Such containers should be sealed and disposed of properly.

If you have any questions about SOLIQUA® or about diabetes, ask your healthcare professional or call sanofi-aventis Canada Inc. at **1-888-852-6887**.



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