Instructions for Use
SKYRIZI® (sky-RIZZ-ee) On-Body Injector
risankizumab-rzaa

injection, for subcutaneous use only
On-Body Injector and 180 mg/1.2 mL Prefilled Cartridge,
On-Body Injector and 360 mg/2.4 mL Prefilled Cartridge

Read this Instructions for Use before you start using SKYRIZI and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

Refer to the Medication Guide for SKYRIZI product information. Call your healthcare provider, call (866) SKYRIZI or (866) 759-7494 or go to SKYRIZI.com if you need help.

Important information you need to know before injecting SKYRIZI

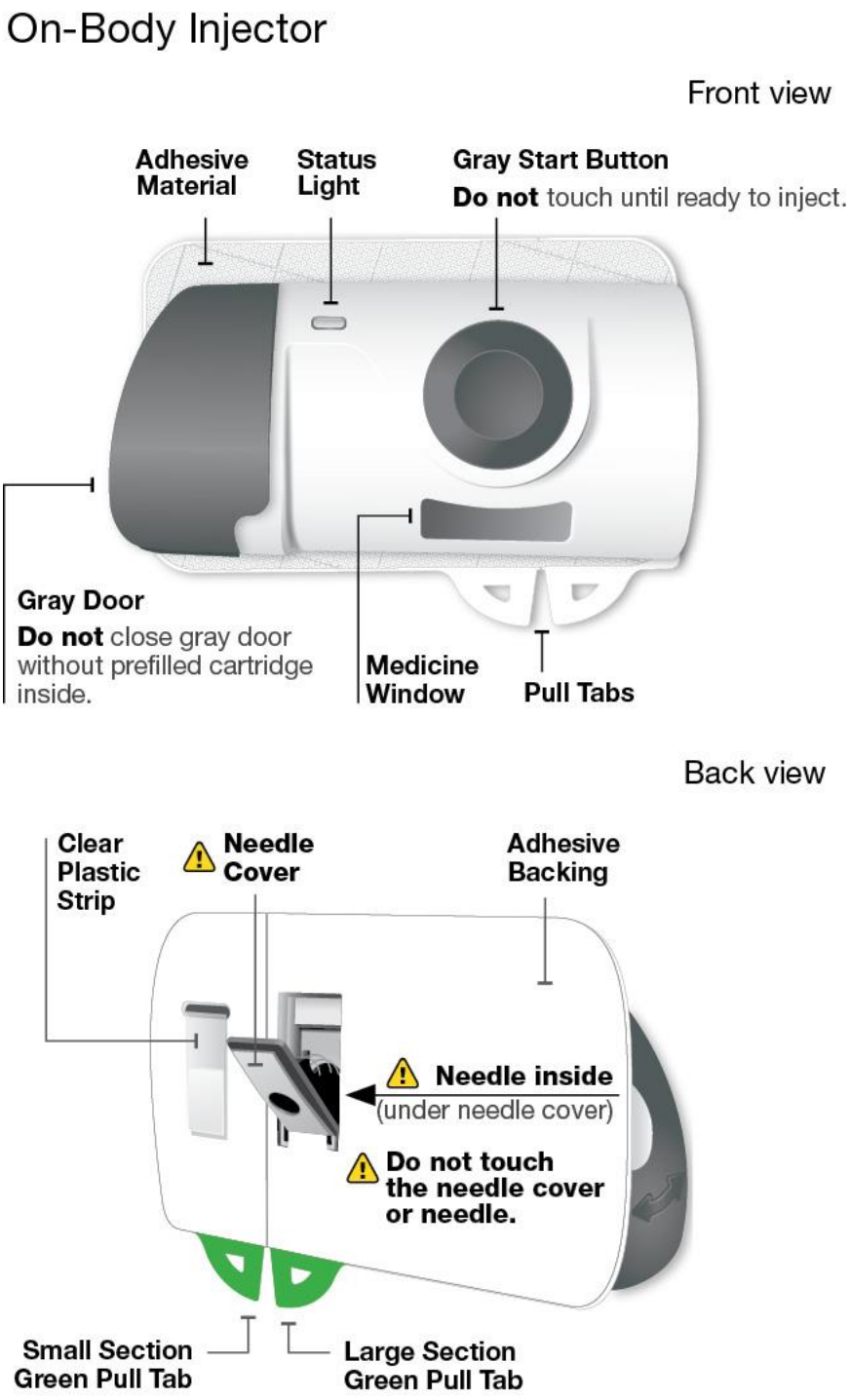
- Receive training on how to inject SKYRIZI before giving an injection.
- **Do not** shake the SKYRIZI carton, On-Body Injector or prefilled cartridge.
- **Do not** remove the On-Body Injector or prefilled cartridge from the carton until you are ready to inject.
- **Do not** wait more than 5 minutes to start the injection after loading the cleaned prefilled cartridge into the On-Body Injector. Waiting will dry out the medicine and the On-Body Injector will not work afterwards.
- **Do not** touch the start button until you place the On-Body Injector loaded with the prefilled cartridge onto your skin and are ready to inject.
    - You can only press the start button 1-time.
- **Do not** use On-Body Injector or prefilled cartridge if either has been dropped or damaged.
- **Do not** reuse On-Body Injector or prefilled cartridge. The On-Body Injector and prefilled cartridge are for 1-time (single-dose) use only.
- **Do not** let the On-Body Injector get wet with water or any other liquids.
- This single-dose On-Body Injector is designed for use with SKYRIZI prefilled cartridge only.
- Physical activity should be limited during the injection process. Moderate physical activities can be done, such as walking, reaching and bending.
- **Do not** use SKYRIZI if the expiration date (EXP:) has passed.
- **Do not** use the prefilled cartridge if the liquid is **discolored**, **cloudy** or contains **flakes** or **large particles**. The liquid should look clear to yellow and may contain tiny white or clear particles.
- The On-Body Injector and the prefilled cartridge are not made with natural rubber latex.
- Keep SKYRIZI and all medicines out of the reach of children.

Storage and preparation for use

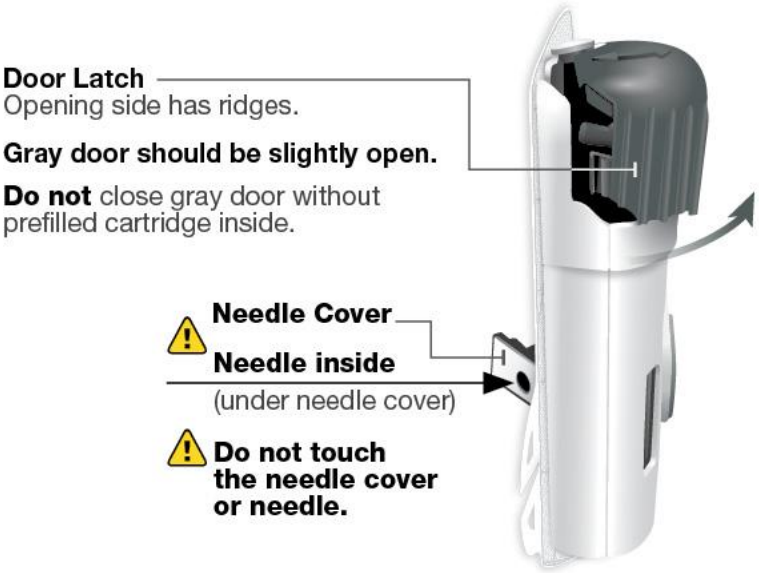
- Keep SKYRIZI in the original carton to protect from light and physical damage until time to use.
- Store SKYRIZI in your refrigerator between 36°F to 46°F (2°C to 8°C).
- When ready to use, take the carton out of the refrigerator and leave it at room temperature for at least 45 minutes for up to 90 minutes to allow SKYRIZI to warm.
    - The On-Body Injector will not work if left at **room temperature** for less than **45 minutes**.
- **Do not** leave out in direct sunlight.
- **Do not** remove the On-body Injector or prefilled cartridge from the carton while allowing SKYRIZI to reach room temperature.
- **Do not** warm SKYRIZI in any other way. For example, **do not** warm it in a microwave or in hot water.
- **Do not** use if liquid has been frozen (even if thawed).
- **Do not** use SKYRIZI if carton perforations are broken. Return product to the pharmacy.

- **Do not** use the On-Body Injector and prefilled cartridge if the white paper tray seal is missing or damaged. Return the carton to the pharmacy.

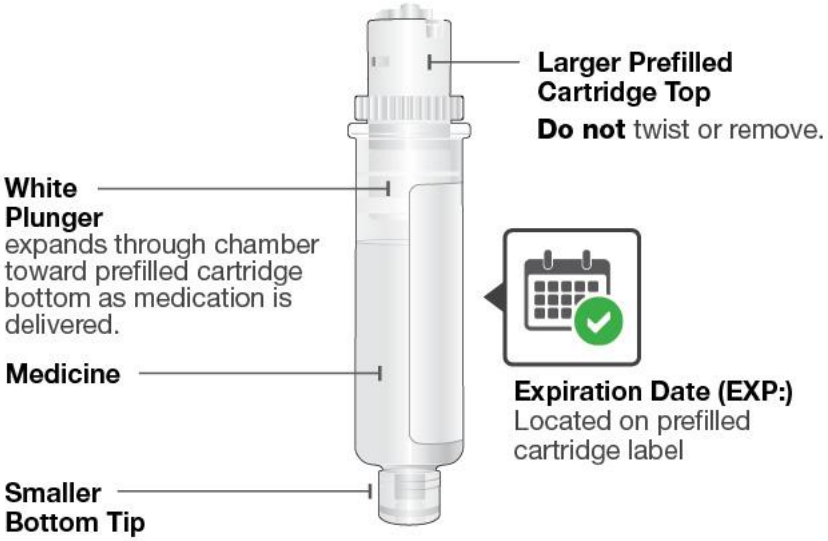
Get to know your SKYRIZI On-Body Injector and prefilled cartridge



Side view



Prefilled Cartridge



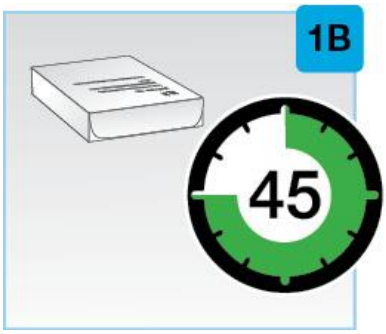
Please read complete Instructions for Use before using SKYRIZI. Call your healthcare provider or (866) SKYRIZI or (866) 759-7494 or go to www.SKYRIZI.com if you need help or if you do not know how to proceed.

Step 1 Get ready

Before using SKYRIZI, you should receive training on how to inject SKYRIZI.

Check expiration date

- Remove the carton from the refrigerator.
- Check expiration date (EXP:) on the carton.
- **Do not** use SKYRIZI if the expiration date (EXP:) has passed.



Wait at least 45 minutes

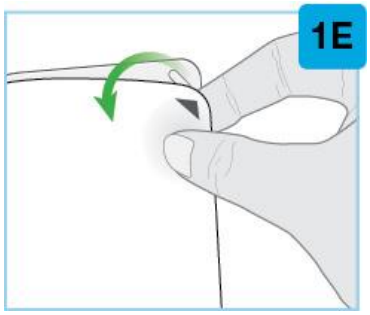
- Leave unopened carton at room temperature to warm.
- Keep out of direct sunlight.
- Wait at least 45 minutes up to a maximum of 90 minutes to allow SKYRIZI to warm.
    - The On-Body Injector will not work if left at **room temperature** for less than **45 minutes**.
- **Do not** warm SKYRIZI in any other way (for example, **do not** warm it in a microwave or in hot water).

Open the carton and remove the plastic tray

- Lift up the flap on the side of the carton.
- Take out the plastic tray.

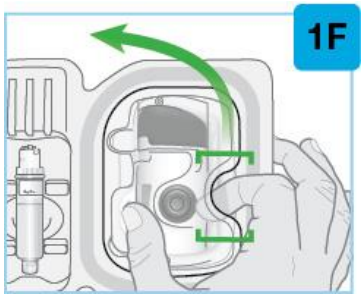
Gather all supplies and wash hands

- Place the following on a clean surface:
    - plastic tray containing the On-Body Injector and prefilled cartridge (included)
    - 2 alcohol wipes (not included)
    - cotton ball or gauze pad (not included)
    - sharps disposal container (not included) (see “Disposing of SKYRIZI”)
- Wash and dry your hands.



Remove the white paper tray seal

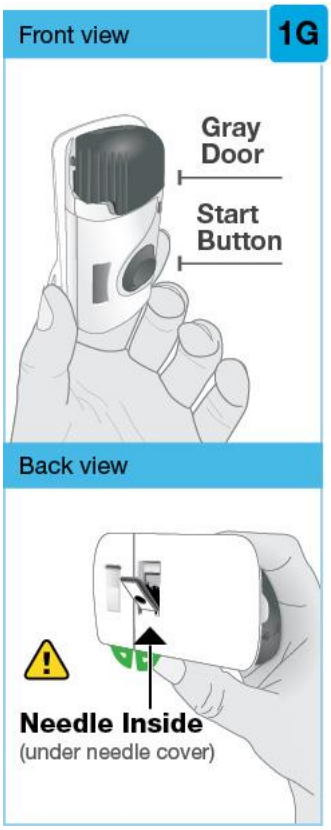
- Locate the black arrow.
- Peel away the white paper tray seal from the plastic tray.
- **Do not** use the On-Body Injector and prefilled cartridge if the white paper tray seal is missing or damaged and return the carton to the pharmacy.



Lift the plastic cover

- Locate the rounded opening on the top cover.
- Insert your pointer finger in the opening and place your thumb on the opposite side.
- Lift the cover to remove and set aside.

⚠ **Do not** touch the gray start button until it is time to inject. It can be pressed 1-time only.



Inspect the On-Body Injector

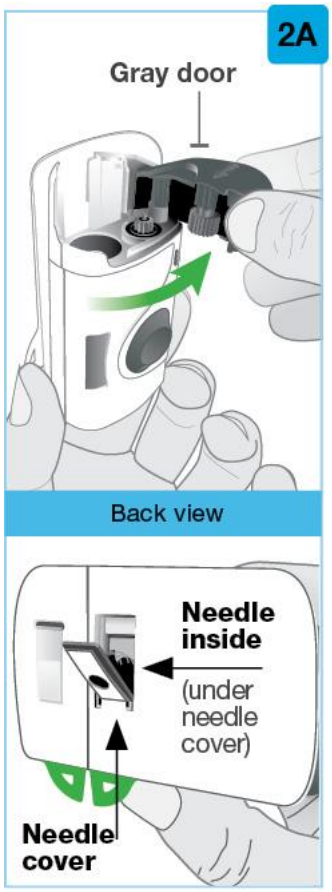
- **Carefully remove the On-Body Injector from the plastic tray by holding it on the sides.**
- Check that the On-Body Injector is intact and undamaged.
- **Do not** close the gray door before the prefilled cartridge is loaded.
- The gray door should be slightly open.
- If the gray door is not open, press in firmly on the gray door ridges (left side of door) and swing open the door.
- **Do not** use On-Body Injector if you drop it, discover missing pieces, or it is damaged.
- **Do not** let the On-Body Injector get wet with water or any other liquids.

⚠ **Do not** touch the gray start button until it is time to inject. It can be pressed 1-time only.

If the gray start button is pressed before placing it on your body, the On-Body Injector can no longer be used. Call (866) SKYRIZI or (866) 759-7494.

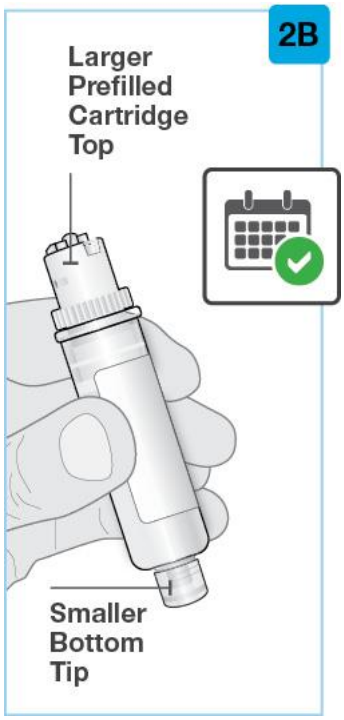
- **Do not** touch the needle cover or the needle.
- Proceed to "**Set up On-Body Injector**".

Step 2 Set up On-Body Injector



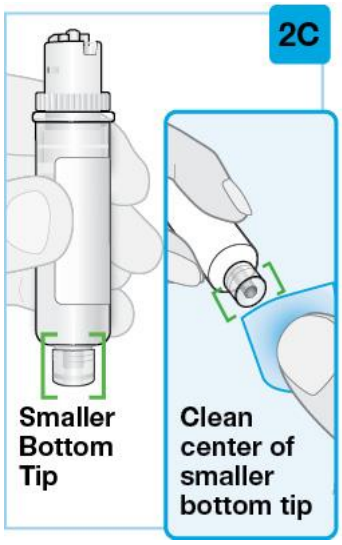
Fully open the gray door

- ⚠ Avoid touching the needle cover or the needle on the back of the On-Body Injector. The needle is behind the needle cover.
- Swing the gray door all the way to the right to open it.
- If the gray door does not open, press in firmly on the gray door ridges (left side of door) and swing open the door.
- **Do not** close the gray door before the prefilled cartridge is loaded.
- **Do not** touch the needle cover or needle.
- ⚠ **Do not** touch the gray start button until it is time to inject. It can be pressed 1-time only.
- Put the On-Body Injector aside.



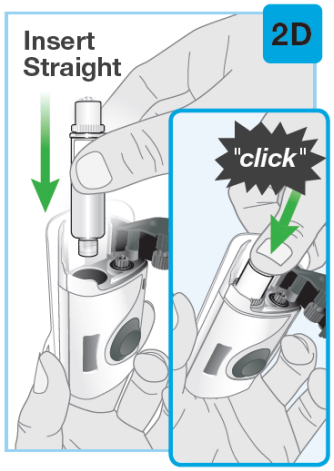
Inspect the prefilled cartridge

- **Do not** twist or remove the larger prefilled cartridge top.
- Carefully remove the prefilled cartridge from the plastic tray.
- Check the prefilled cartridge to make sure:
  - The expiration date (EXP:) has not passed.
  - The liquid should look clear to yellow and may contain tiny white or clear particles. It is normal to see one or more bubbles.
  - The prefilled cartridge parts appear intact, and the clear plastic is not cracked or broken.
- **Do not** use if the expiration date (EXP:) has passed.
- **Do not** use if the liquid is cloudy, discolored, or contains flakes or large particles.
- **Do not** use if the liquid has been frozen (even if thawed).
- **Do not** use the prefilled cartridge if you drop it, discover missing pieces, or it is damaged.



Clean the smaller bottom tip of the prefilled cartridge

- Locate the smaller bottom tip of the prefilled cartridge.
- Clean the smaller bottom tip of the prefilled cartridge with an alcohol wipe. Make sure to use the alcohol wipe to clean the center of the smaller bottom tip of the prefilled cartridge.
- **Do not** touch the smaller bottom tip of the prefilled cartridge after cleaning.



Load the cleaned prefilled cartridge into the On-Body Injector

- **Do not** twist or remove the larger prefilled cartridge top.

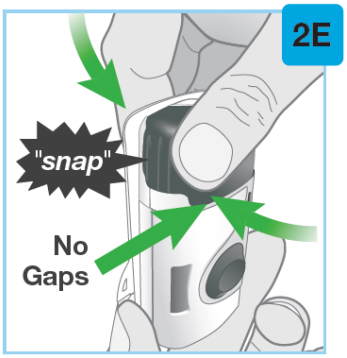
⚠ **Do not** touch the gray start button until it is time to inject. It can be pressed 1-time only.

- Securely holding the sides of the On-Body Injector, insert the smaller bottom tip of the prefilled cartridge into the On-Body Injector first.

⚠ Firmly push down on the larger prefilled cartridge top until you hear a “click”. It is now fully inserted.

- After loading the prefilled cartridge, you may see a few drops of medicine on the back of the On-Body Injector. This is normal.

⚠ **Make sure that you start the injection within 5 minutes after inserting the prefilled cartridge into the On-Body Injector. Waiting will dry out the medicine and the On-Body Injector will not work afterwards.**



Confirm cartridge is inserted and close the gray door

- **Do not** close the gray door if the prefilled cartridge is not fully inserted or is missing. Confirm steps in 2D are complete before proceeding.

⚠ Swing the gray door to the left, then squeeze firmly and listen for the gray door to "snap" shut. No gaps should exist between the door and the On-Body Injector.

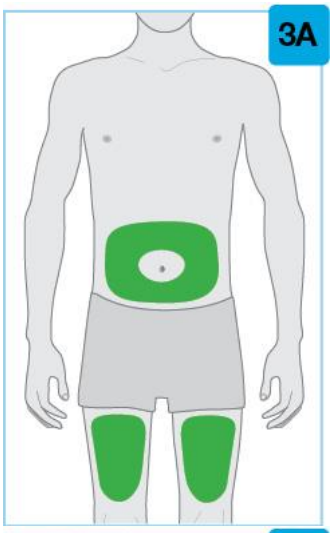
- The gray door should stay locked after loading the prefilled cartridge.

⚠ **Do not** touch the gray start button until it is time to inject. It can be pressed 1-time only.

- Proceed without delay to “**Prepare to inject**”.

Step 3 Prepare to inject

Keep electronic devices including cell phones at least 12 inches (30 cm) from On-Body Injector until injection is complete



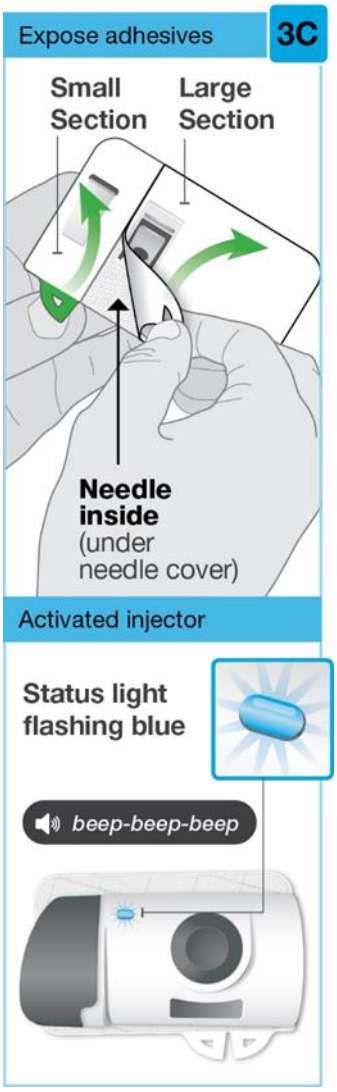
Pick your injection area

Locate a firm and flat area on your bare skin. Make sure the area is clear of clothing:

- Your abdomen (belly) at least 2 inches from your navel (belly button).
- The front of your left thigh or your right thigh.
- **Do not** inject into areas of the skin that naturally fold or bulge because the On-Body Injector could fall off during wear.
- **Do not** inject into skin that is sore, bruised, red, hard, scarred, or has stretch marks, moles or excessive hair. You can trim the excessive hair from the injection area.

Clean the injection area

- Clean injection area with an alcohol wipe.
- Allow the injection area to completely dry.
- **Do not** touch cleaned injection area before placing the On-Body Injector on the skin.



Peel both tabs to expose adhesive

- Turn the On-Body Injector over to find both green pull tabs.

⚠ Avoid touching the needle cover or the needle (needle inside).

- Peel away the large section using the green pull tab to expose the adhesive.
- Peel away the small section using the green pull tab to expose the adhesive. **This will remove the clear plastic strip, activating the On-Body Injector**.
- **Do not** pull the adhesive material off the On-Body Injector or allow the sticky side to fold and stick to itself.
- Check the status light when the On-Body Injector beeps.
- The status light will flash blue when the On-Body Injector is activated.
- If the status light does not flash blue, call (866) SKYRIZI or (866) 759-7494.

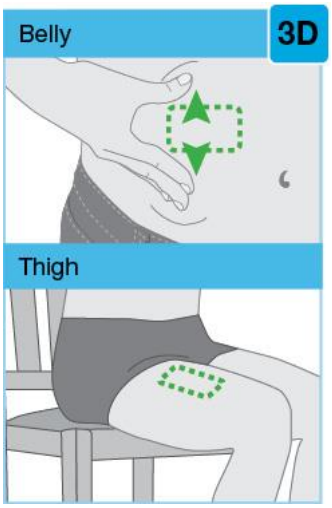
⚠ **Do not** press the gray start button yet.

- **Do not** touch the needle cover or the needle.

If the status light flashes red, and beeps are heard, the On-Body Injector is not working properly. Do not continue to use it.

Call (866) SKYRIZI or (866) 759-7494 for assistance.
If On-Body Injector is attached to body, carefully remove from skin.

beep-beep-beep-beep-beep



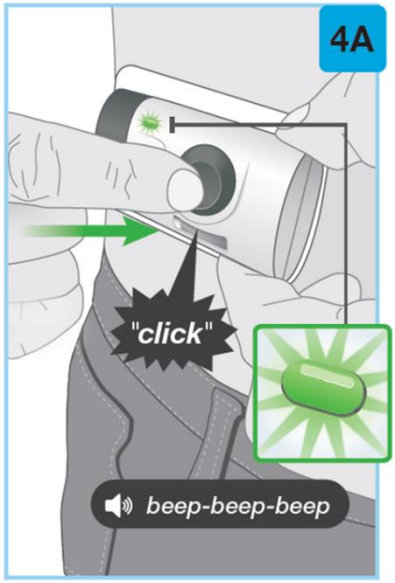
Prepare the On-Body Injector for placement

- For the abdomen (belly), move and hold the skin to create a firm, flat surface for injection at least 2 inches from your navel (belly button). Make sure to adjust your posture (sit up straight) to avoid skin folds and bulges.
- You do not need to pull the skin flat for the front of left thigh or right thigh.
- Make sure to position the On-Body Injector so that you can see the blue status light.

Place the On-Body Injector on your skin

- When the blue light flashes, the On-Body Injector is ready. Place the On-Body Injector onto the cleaned skin with the status light visible.
- **Do not** place the On-Body Injector on clothes. Only place on bare skin.
- Run your finger around the adhesive material to secure it. Make sure all of the adhesive is attached to your skin.
- **Do not** move or adjust the On-Body Injector after it has been placed on your skin.
- When the On-Body Injector is on your skin, proceed to Inject medicine

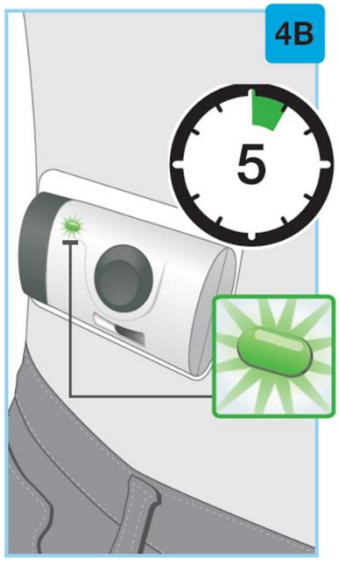
Step 4 Inject medicine



Start injection

Do not touch the gray start button until you place the On-Body Injector loaded with the prefilled cartridge onto your skin and are ready to inject. You can only press the start button 1 time.

- Firmly press the gray start button until you hear a click. Then release the gray start button.
- You may feel a needle pinch.
- Check the status light when the On-Body Injector beeps.
- After starting the injection, the status light will continuously flash green.
- You will hear pumping sounds as the On-Body Injector delivers the medicine.
- **Do not** continue to use the On-Body Injector if status light flashes red and beeps. Carefully remove from skin if the status light flashes red. Call (866) SKYRIZI or (866) 759-7494.

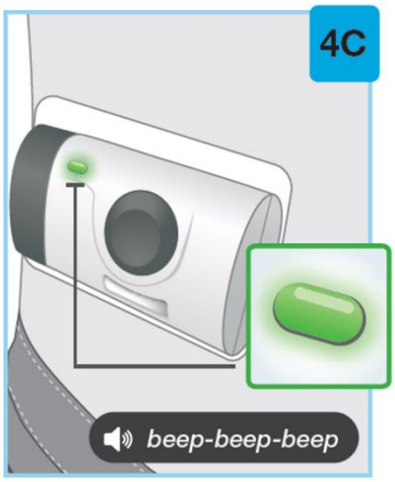


Wait for the injection to finish

- It may take up to 5 minutes to complete full dose of medicine. The On-Body Injector will automatically stop when the injection is finished.

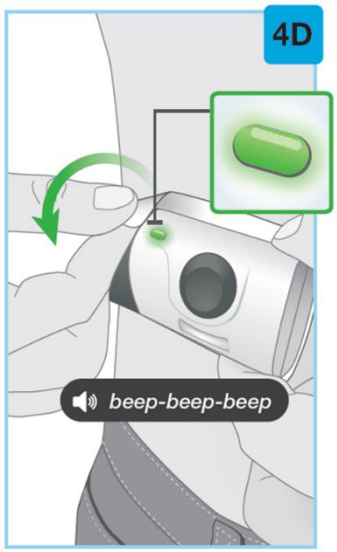
  During the injection:

  - the status light will continue to flash green.
  - you will hear pumping sounds as the On-Body Injector continues delivering the medicine.
  - moderate physical activities can be done, such as walking, reaching and bending.
- **Do not** continue to use the On-Body Injector if the status light flashes red and beeps. Carefully remove it from the skin if the status light flashes red and beeps. Call (866) SKYRIZI or (866) 759-7494.



Injection is finished

- The On-Body Injector will stop on its own.
- After the injection is finished, you will hear beeps and the status light will change to solid green. Check the status light. If it has changed to solid green, this means that the injection is finished.
- When the injection is finished and the status light is solid green, proceed to the next step.



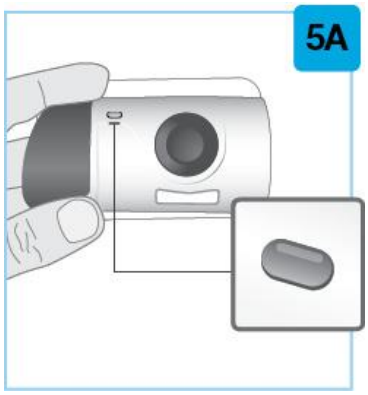
Remove the On-Body Injector

- **Do not** remove the On-Body Injector if the status light is still flashing green and the injection is not finished.
- **Do not** put your fingers on the back side of the On-Body Injector when removing it from your skin.
- When the injection is done, grab the corner of the adhesive to carefully peel the On-Body Injector from the skin.

⚠ Avoid touching the needle cover or needle on the back of the On-Body Injector.

- After removing the On-Body Injector, you will hear several beeps and the status light will turn off.
- The needle cover will cover the needle when the On-Body Injector is removed from the skin.
- It is normal to see a few small drops of liquid on your skin after removing the On-Body Injector. If you see more than a few small drops of liquid left on your skin, call (866) SKYRIZI or (866) 759-7494.
- Press a cotton ball or gauze pad over the injection site on your skin and hold for 10 seconds.
- **Do not** rub the injection site.
- Slight bleeding at the injection site is normal.
- Proceed to “**Confirm and dispose**”.

Step 5 Confirm and dispose



Check the On-Body Injector

- Inspect the medicine window and status light.
- Check to see that the used white plunger fills the medicine window and the solid green light turns off, letting you know that all the medicine has been injected.

⚠ If the used white plunger does not fill the window, call (866) SKYRIZI or (866) 759-7494**.**

Put the used On-Body Injector in an FDA-cleared sharps disposal container right away after use

- Leave the prefilled cartridge in the On-Body Injector.
- **Do not** throw away (dispose of) the used On-Body Injector in your household trash.
- For more information, see "**Disposing of SKYRIZI**" section.

Symbol Key

	Caution	Be aware or follow closely
	Flashing blue light	On / Ready
	Flashing green light	Injection has started
	Solid green light	Injection has finished
	No light	Off / Finished
	Flashing red light	**Do not** continue to use the On-Body Injector. It is not working properly. Call (866) SKYRIZI or (866) 759-7494 for more information.

Please read complete Instructions for Use before using SKYRIZI. Call your healthcare provider or (866) SKYRIZI or (866) 759-7494 or go to www.SKYRIZI.com if you need help or if you do not know how to proceed.

Commonly asked questions

Q. What if I cannot open the On-Body Injector door to insert the prefilled cartridge?
A. To open the On-Body Injector door, press in firmly on the left side of the door to release the door latch. If you are still unable to open the door, call (866) SKYRIZI or (866) 759-7494.

Q. What if I push the gray start button before I place the On-Body Injector on my skin?
A. The gray start button may be pressed just 1 time only. If the gray start button is pressed before placing it on your body, it can no longer be used. Call (866) SKYRIZI or (866) 759-7494.

Q. What if the On-Body Injector does not beep and the blue status light does not flash when I remove the green pull tabs?
A. Peeling off the small green pull tab will remove the clear plastic strip, activating the On-Body Injector. If all of the adhesive backing has been removed and the On-Body Injector still does not turn on, call (866) SKYRIZI or (866) 759-7494.

Q. What if I push the start button as instructed after placing the On-Body Injector on the skin and the light remains blue?

A. Firmly press the gray start button again. If the status light remains blue or flashes red, remove the On-Body Injector by carefully peeling it away from your skin. **Do not** re-apply the On-Body Injector. Call (866) SKYRIZI or (866) 759-7494.

Q. What if the status light flashes red and beeps while wearing the On-Body Injector?

A. If the status light continuously flashes red and beeps, **do not** use the On-Body Injector. If it is attached to your body, carefully remove it. Call (866) SKYRIZI or (866) 759-7494.

Q. What should I do if the On-Body Injector comes off my body during the injection?

A. The loaded On-Body Injector can no longer be used. **Do not** re-apply it to your body. Call (866) SKYRIZI or (866) 759-7494.

Q. How do I know when the injection is complete?

A. The injection is complete when the On-Body Injector beeps, the white plunger has completely filled the medicine window, and the status light turns from flashing green to solid green.

Q. What should I do if there are more than a few drops of liquid on the injection area?

A. Call (866) SKYRIZI or (866) 759-7494 for help.

Q. What should I do with the used On-Body Injector after my injection?

A. Throw away (dispose of) used On-Body Injector in a FDA-cleared sharps disposal container and not your household trash. You can receive a sharps container for SKYRIZI disposal at no additional cost by going to www.SKYRIZI.com or by calling (866) SKYRIZI or (866) 759-7494.

Q. What if I have not received in-person training from a healthcare professional?

A. Call your healthcare provider or (866) SKYRIZI or (866) 759-7494 if you need help. **Receive** training on how to inject **SKYRIZI** before giving injections.

Disposing of SKYRIZI

- Put SKYRIZI in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) SKYRIZI in your household trash.
- If you do not have an 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 in the state that you live in, go to the FDA's website at: www.fda.gov/safesharpsdisposal.

Do not recycle your used sharps disposal container.

Additional information

- Type BF applied part.
-

On-Body Injector sterilized using ethylene oxide.
- Altitude range is -1,312 feet to 10,499 feet (-400 meters to 3,200 meters).

Electromagnetic Compatibility (EMC) of the On-Body Injector

The On-Body Injector is intended for home use or use in a professional healthcare environment and complies with ISO 11608-1:2014 and IEC 60601-1-2:2014.

Care should be taken to use the On-Body Injector within the following specific limits and environments to avoid adversely impacting the performance (missed or incomplete SKYRIZI dose).

- Keep electronic devices including cell phones at least 12 inches (30 cm) from the On-Body Injector until injection is complete. The potential impact of electronic interference is unknown when the On-Body Injector is operated within 12 inches (30 cm).
- Do not expose the On-Body Injector to Magnetic Resonance (MR) Environment (e.g., MRI).
- If it is used adjacent to other electrical equipment, observe the On-Body Injector and other equipment to ensure it is operating normally.

Emissions

Emissions test name	Test levels
Radiated Radio frequency electromagnetic fields	Per CISPR 11, class B

Electromagnetic Immunity

Test Name	Test Levels
Electrostatic discharge (ESD)	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radio frequency electromagnetic field	10 V/m 80 MHz – 2.7 GHz
Power frequency 50 Hz magnetic field	30 A/m

The enclosure port immunity to RF wireless communications equipment complies with IEC 60601-1-2:2014.

Glossary of symbols

Symbol	Description of Symbol
	Keep dry
	Sterilized using ethylene oxide
	Do not re-use
	Do not use if package is damaged and consult instructions for use
	Date of manufacture
	Batch code
	Catalogue number
	Serial number
	Refer to instruction manual / booklet
	Type BF Applied Part
	MR Unsafe

Manufactured by:
AbbVie Inc., North Chicago, IL 60064, U.S.A.
US License Number 1889
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This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Revised: 3/2026
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