# INSTRUCTIONS FOR USE

**SKYRIZI**® (sky-RIZZ-ee) Pen (risankizumab-rzaa) injection, for subcutaneous use

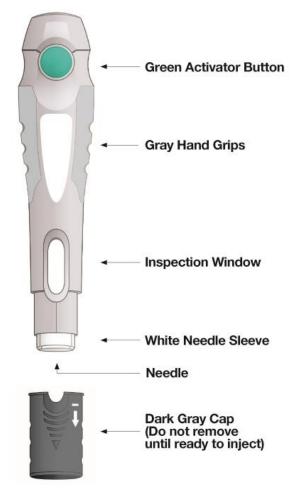
### **Read Before First Use**

Refer to the **Medication Guide** for product information.

Read this Instructions for Use before using SKYRIZI Pen (risankizumab-rzaa) injection.

Before using SKYRIZI, you should receive training from your healthcare provider on how to inject SKYRIZI.

## SKYRIZI Single-Dose Pen

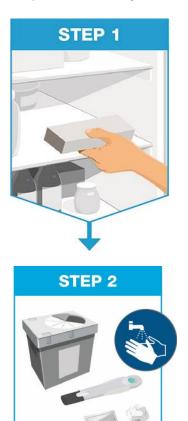


## Important Information

- Store SKYRIZI in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Keep SKYRIZI in the original carton to protect from light until you are ready to use.
- Before injecting, take the SKYRIZI carton out of the refrigerator. Leave the carton at room temperature and out of direct sunlight for 30 to 90 minutes.

- The liquid in the inspection window should look clear to yellow and may contain tiny white or clear particles.
- Do not use SKYRIZI if the liquid is discolored, cloudy or contains flakes or large particles.
- Do not use SKYRIZI if the expiration date (EXP) has passed.
- Do not use SKYRIZI if the liquid has been frozen, even if it has been thawed.
- Do not shake SKYRIZI.
- Do not use if the SKYRIZI Pen has been dropped or damaged.
- Do not use SKYRIZI if carton perforations are broken. Return product to pharmacy.
- **Do not** remove the dark gray cap until right before injection.
- SKYRIZI is not made with natural rubber latex.

## Prepare SKYRIZI injection



**Take** the SKYRIZI carton out of the refrigerator. **Leave** the carton at room temperature and out of direct sunlight for **30 to 90 minutes** before injecting.

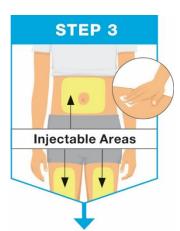
- **Do not** remove the Pen from the carton while allowing SKYRIZI to reach room temperature.
- **Do not** warm SKYRIZI in any other way. For example, **do not** warm it in a microwave or in hot water.
- **Do not** use the Pen if the liquid has been frozen, even if it has been thawed.

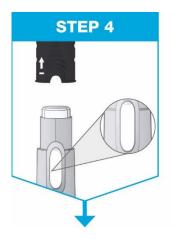
**Check** expiration date **(EXP). Do not** use the Pen if expiration date has passed.

**Place** the following on a clean, flat surface:

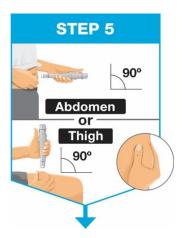
- 1 single-dose SKYRIZI Pen (included)
- 1 alcohol swab (not included)
- 1 cotton ball or gauze pad (not included)
- FDA-cleared sharps disposal container (not included). See "Used SKYRIZI Prefilled Pen Disposal" for information on how to throw away (dispose of) used Pens.

Wash and dry your hands.





## **Give SKYRIZI injection**



**Choose** an injection site:

- on the front of your thighs or
- your abdomen (belly) at least 2 inches from your navel (belly button)

**Wipe** the injection site in a circular motion with the alcohol swab and let it dry.

- **Do not** touch or blow on the injection site after it is cleaned. Allow the skin to dry before injecting.
- Do not inject through clothes.
- **Do not** inject into skin that is sore, bruised, red, hard, scarred, has stretch marks, or areas with psoriasis.

Hold the Pen with the dark gray cap pointing up.

- Pull the dark gray cap straight off.
- Throw the dark gray cap away.

Check the liquid through the inspection window.

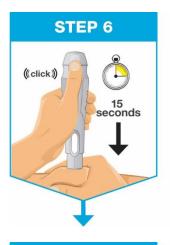
- It is normal to see 1 or more bubbles in the liquid.
- The liquid should look clear to yellow and may contain tiny white or clear particles.
- Do not use if the liquid is discolored, cloudy or contains flakes or large particles.

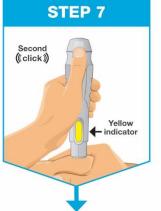
Hold the Pen with your fingers on the gray hand grips.

**Turn** the Pen so that the white needle sleeve points toward the injection site and you can see the green activator button.

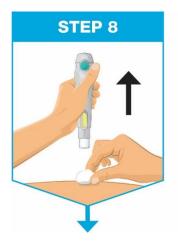
**Pinch** the skin at your injection site to make a raised area and hold it firmly.

**Place** the white needle sleeve straight (90-degree angle) against the raised injection site.





After SKYRIZI injection



**Hold** the Pen so that you can see the green activator button and inspection window.

**Push and keep pressing** the Pen **down** against the raised injection site.

• The Pen will activate only if the white needle sleeve is pressed down against the injection site before pressing the green activator button.

**Press** the green activator button and hold the Pen for **15** seconds.

• The first loud "click" means the start of the injection.

**Keep pressing** the Pen **down** against the injection site.

The injection is **complete** when:

- the Pen has made a second "click" or
- the yellow indicator has filled the inspection window

This takes up to 15 seconds.

When the injection is complete, slowly pull the Pen straight out from the skin.

The white needle sleeve will cover the needle tip and make another "click."

After completing the injection, place a cotton ball or gauze pad on the skin at the injection site.

- Do not rub the injection site.
- Slight bleeding at the injection site is normal.



Throw away (dispose of) the used Pen in a FDAcleared sharps disposal container right away after use.

- **Do not** dispose of used Pens in your household trash unless your community guidelines permit this.
- Do not recycle your sharps disposal container.

The dark gray cap, alcohol swab, cotton ball or gauze pad, and packaging may be placed in your household trash.

For more information, see "Used SKYRIZI Prefilled Pen Disposal".

## **Important Information**

- Store SKYRIZI in the **refrigerator** at 36°F to 46°F (2°C to 8°C).
- Keep SKYRIZI in the original carton to protect from light until you are ready to use.
- Before injecting, take the SKYRIZI carton out of the refrigerator. Leave the carton at room temperature and out of direct sunlight for 30 to 90 minutes.
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- Do not use SKYRIZI if the expiration date (EXP) has passed.
- Do not use SKYRIZI if the liquid has been frozen, even if it has been thawed.
- **Do not** shake SKYRIZI.
- Do not use if the SKYRIZI Pen has been dropped or damaged.
- Do not use SKYRIZI if carton perforations are broken. Return product to pharmacy.
- Do not remove the dark gray cap until right before injection.
- SKYRIZI is not made with natural rubber latex.

#### Keep the SKYRIZI Pen and sharps disposal container out of the reach of children.

Call your healthcare provider or (866) SKYRIZI or (866) 759-7494 if you need help or do not know how to proceed.

#### **Questions About Using the SKYRIZI Pen**

- Q. What if I need help on how to inject SKYRIZI?
- A. Call your healthcare provider or (866) SKYRIZI or (866) 759-7494 if you need help.
- Q. I have removed the dark gray cap and pressed the green activator button. Why isn't my injection starting?
- **A.** The green activator button will not start the injection unless the white needle sleeve is pressed firmly against the injection site.

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

- **A.** The injection is complete if the Pen makes a second "click" or the yellow indicator fills the inspection window. This takes up to **15** seconds.
- Q. What should I do if there are more than a few drops of liquid on the injection site?
- A. Call (866) SKYRIZI or (866) 759-7494 for help.

#### Q. What should I do with the used Pen after my injection?

A. Dispose of the used Pen in a sharps disposal container right after use. Do not dispose of the used Pen in your household trash. You can sign up to receive sharps containers for SKYRIZI Pen disposal at no additional cost by going to www.SKYRIZI.com or calling (866) SKYRIZI or (866) 759-7494.

Call (866) SKYRIZI or (866) 759-7494 or go to www.SKYRIZI.com for help with your injection.



To help remember when to inject, mark your calendar with the date you give your SKYRIZI injection.

## Keep the SKYRIZI Pen and sharps disposal container out of the reach of children.

Call your healthcare provider or (866) SKYRIZI or (866) 759-7494 if you need help or have questions about the use of SKYRIZI.

#### **Used SKYRIZI Prefilled Pen Disposal**

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 Pens.

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: <u>www.fda.gov/safesharpsdisposal</u>.

Do not recycle your used sharps disposal container.

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

Revised: 6/2024