

PATIENT INFORMATION LEAFLET

SKYRIZI CONCENTRATE FOR SOLUTION FOR INFUSION 600mg/10mL

SKYRIZI SOLUTION FOR INJECTION IN PRE-FILLED CARTRIDGE WITH ON-BODY INJECTOR 360mg/2.4mL

(risankizumab)

Read all of this leaflet carefully before you start using this medicine. It includes important information on the safe and effective use of this medicine.

1. WHAT SKYRIZI IS USED FOR

SKYRIZI is used to treat:

- moderate to severe Crohn's disease in adults.

2. HOW SKYRIZI WORKS

SKYRIZI contains risankizumab. It works by stopping a protein in the body called IL-23, which causes inflammation.

Crohn's Disease

SKYRIZI reduces inflammation and can therefore help to reduce signs and symptoms of your disease such as abdominal pain, diarrhea, and tiredness, as well as improve healing of the bowel, which can help improve your quality of life.

3. WHAT SKYRIZI CONTAINS

Each 360 mg/2.4 mL prefilled cartridge contains 360 mg of the active ingredient, risankizumab, in 2.4 mL of solution. The other ingredients in the 360 mg/2.4 mL prefilled cartridge are sodium acetate trihydrate, acetic acid, trehalose dihydrate, polysorbate 20 and water for injection.

Each 600 mg/10 mL single-dose vial contains 600 mg of the active ingredient, risankizumab, in 10 mL of solution. The other ingredients in the 600 mg/mL single-use vial are sodium acetate trihydrate, acetic acid, trehalose dihydrate, polysorbate 20 and water for injection.

Information about certain ingredients in SKYRIZI

SKYRIZI 360 mg/2.4 mL and 600 mg/10 mL contain less than 1 mmol sodium (23 mg) per 150 mg dose, i.e., essentially 'sodium-free'.

4. DOSAGE FORM/APPEARANCE

SKYRIZI 360 mg/2.4 mL is a clear to slightly opalescent and colorless to yellow liquid in a prefilled cartridge with on-body injector. Each kit contains 1 prefilled cartridge and 1 on-body injector.

SKYRIZI 600 mg/10 mL is a clear to slightly opalescent and colorless to slightly yellow liquid in a single-use vial. Each carton contains 1 vial.

5. WHAT YOU NEED TO KNOW BEFORE YOU USE SKYRIZI

Do not take SKYRIZI if:

- you have had a serious allergic reaction to risankizumab or any of the other ingredients of SKYRIZI (listed in section 3). Symptoms of serious allergic reactions include: trouble breathing, feeling faint or dizzy, swelling of the face, lips, tongue, or throat, difficulty swallowing or severe itching of the skin, with a red rash or raised bumps.
- any of these symptoms occur during treatment with SKYRIZI, stop taking SKYRIZI and get emergency medical help right away.
- you have an infection, including active tuberculosis, which your doctor thinks is important

Talk to your doctor, pharmacist or nurse before and during use of SKYRIZI if:

- you currently have an infection or if you have an infection that keeps coming back.
- you have tuberculosis (TB).
- you have recently received or plan to receive an immunization (vaccine). You should not be given certain types of vaccines while using SKYRIZI.

Children and adolescents

SKYRIZI is not recommended for children and adolescents under 18 years of age with Crohn's disease. The safety and efficacy of SKYRIZI have not been established in this age group.

Taking other medicines with SKYRIZI

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines, or if you have recently had or are going to have a vaccination. You should not be given certain types of vaccines while using SKYRIZI.

Pregnancy and breastfeeding with SKYRIZI

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. This is because it is not known how this medicine will affect the baby.

If you are a woman of childbearing potential, you should use contraception while using SKYRIZI and for at least 20 weeks after your last dose of SKYRIZI.

Breastfeeding

If you are breastfeeding or are planning to breastfeed, talk to your doctor before using this medicine.

Driving and using machines with SKYRIZI

SKYRIZI is not likely to affect your driving and use of machines.

6. POSSIBLE SIDE EFFECTS WITH SKYRIZI

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Talk to your doctor or get medical help immediately if you have symptoms of serious infection such as:

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath, cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters

Your doctor will decide if you can keep using SKYRIZI.

Other side effects

Tell your doctor, pharmacist or nurse if you get any of the following side effects:

Very common: may affect more than 1 in 10 people

- upper respiratory infections with symptoms such as sore throat and stuffy nose

Common: may affect up to 1 in 10 people

- feeling tired
- fungal skin infection
- injection site reactions
- headache

Uncommon: may affect up to 1 in 100 people

- small raised red bumps on the skin

Not known: frequency cannot be estimated from the available data

- eczema
- rash
- hives (urticaria)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

7. HOW TO USE SKYRIZI

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure how to use this medicine.

SKYRIZI 360 mg/2.4 mL prefilled cartridge is injected under your skin (called ‘subcutaneous injection’).

You and your doctor, pharmacist or nurse will decide if you should inject SKYRIZI yourself. Do not inject yourself with this medicine unless you have been trained by your doctor, pharmacist or nurse. A caregiver may also give your injections after training.

Read the ‘Instructions for Use’ before injecting SKYRIZI yourself.

SKYRIZI 600 mg/10 mL single-use vial for intravenous infusion will be given by your doctor through a vein in the arm (intravenous infusion).

SKYRIZI 600 mg/10 mL should be prepared and given by a healthcare professional using aseptic technique.

How much SKYRIZI to use

Crohn’s Disease

You will begin treatment with SKYRIZI with a starting dose which will be given by your doctor through a drip in your arm (intravenous infusion).

Starting doses

	How much?	When?
Starting doses	600 mg	When your doctor tells you
	600 mg	4 weeks after 1 st dose
	600 mg	4 weeks after 2 nd dose

Afterwards, you will receive, or you will inject yourself SKYRIZI as an injection under your skin (subcutaneous injection) using a prefilled cartridge with on-body injector.

Maintenance doses

	How much?	When?
1 st maintenance dose	360 mg	4 weeks after the last starting dose (at Week 12)
Further doses	360 mg	Every 8 weeks, starting after the 1 st maintenance dose

If you use too much SKYRIZI

If you have used more SKYRIZI than you should or the dose has been given sooner than prescribed, talk to your doctor.

If you forget to use SKYRIZI

If you forget to use SKYRIZI, inject a dose as soon as you remember. Talk to your doctor if you are not sure what to do.

If you stop using SKYRIZI

Do not stop using SKYRIZI without talking to your doctor first. If you stop treatment, your symptoms may come back.

8. HOW TO STORE SKYRIZI

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

Do not use this medicine after the expiration date which is stated on the label and outer carton after ‘EXP’.

Store in a refrigerator at 2 °C – 8 °C. Do not freeze.

Keep in the original carton in order to protect from light.

SKYRIZI 360 mg/2.4 mL liquid should look clear to slightly opalescent and colorless to yellow.

SKYRIZI 600 mg/10 mL liquid should look clear to slightly opalescent and colorless to slightly yellow.

The liquid may contain tiny white or clear particles. Do not use if liquid is cloudy or contains flakes or large particles.

Ask your doctor, pharmacist or nurse how to throw away used pre-filled cartridge with on-body injector safely.

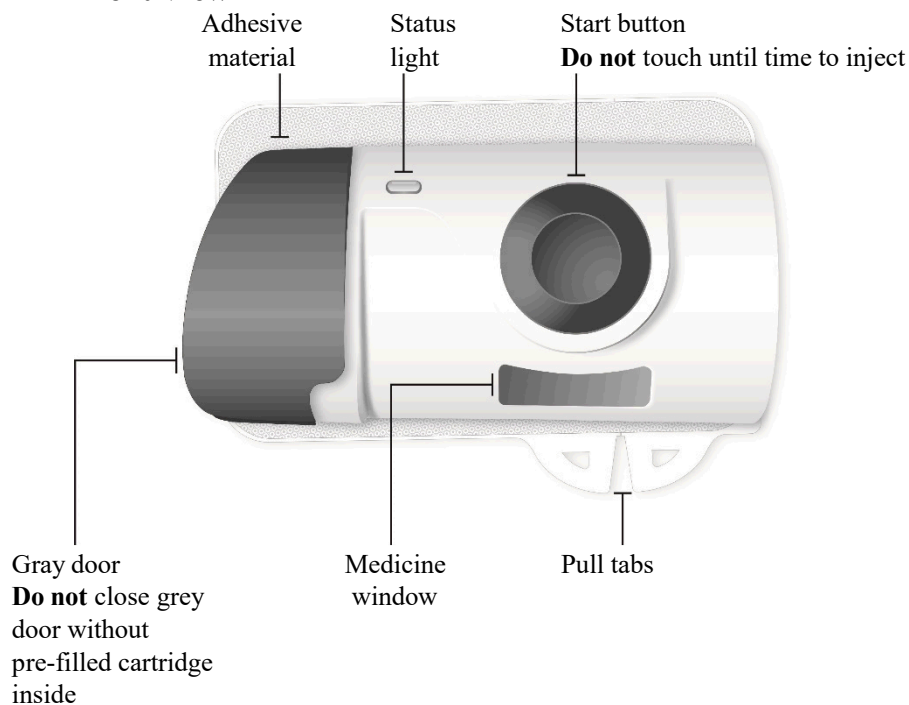
9. INSTRUCTIONS FOR USE

SKYRIZI 360 MG/2.4 ML PREFILLED CARTRIDGE WITH ON BODY INJECTOR

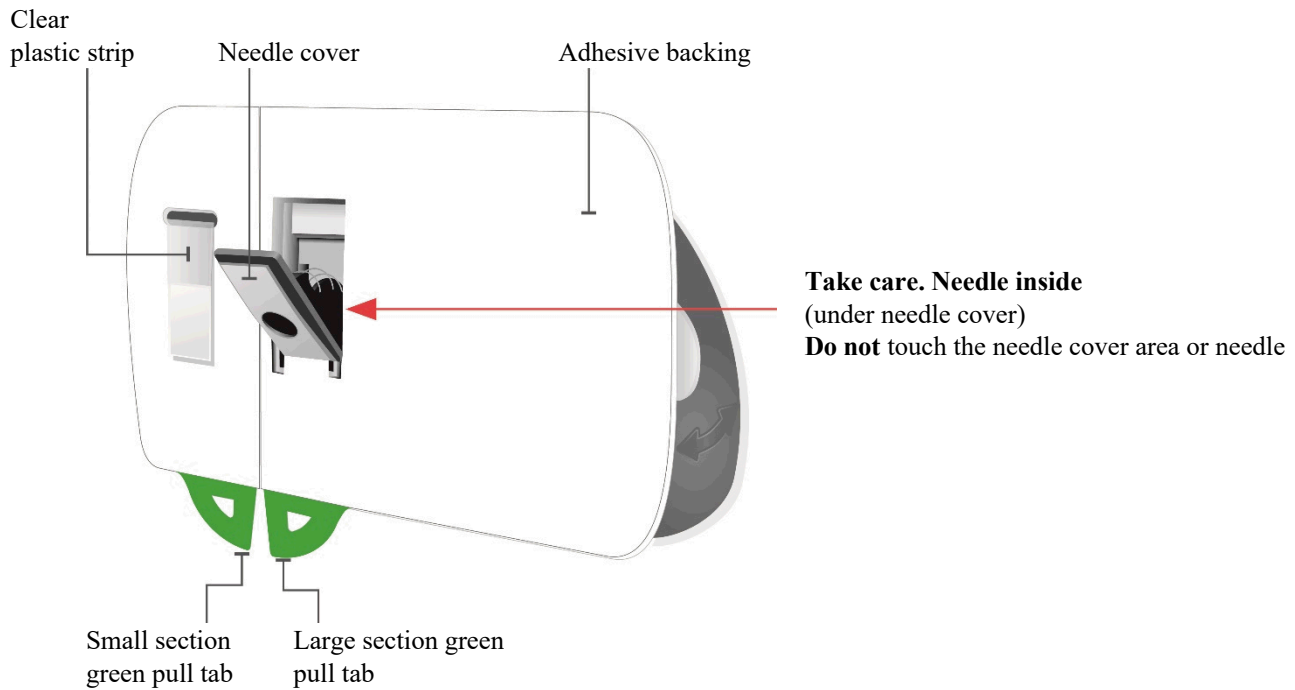
Please read complete instructions before using SKYRIZI

SKYRIZI on-body injector

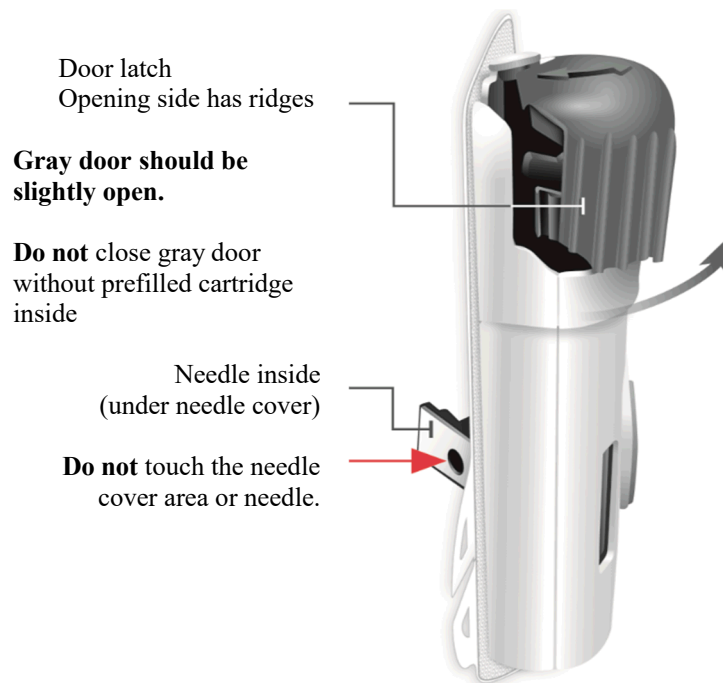
Front View



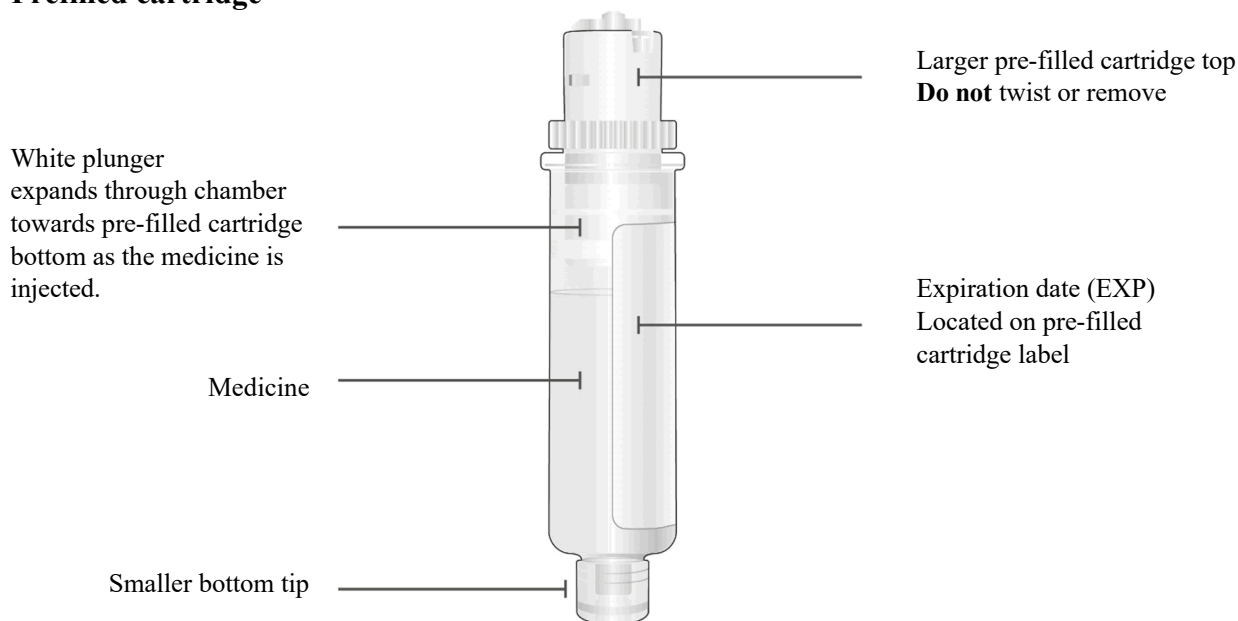
Back View



Side view



Prefilled cartridge



Important information to know before you inject SKYRIZI

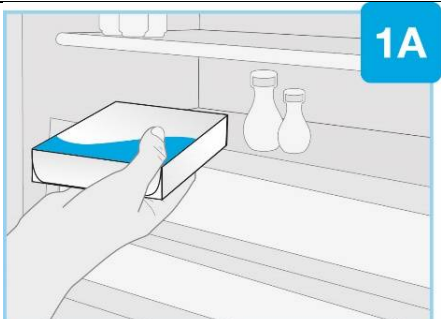
- You should receive training on how to inject SKYRIZI before giving an injection. Talk to your doctor, pharmacist or nurse if you need help
- Mark the dates on your calendar so you know when to inject SKYRIZI
- The single use on-body injector is designed for use with SKYRIZI prefilled cartridge only
- Keep SKYRIZI in the original carton to protect the medicine from light until it is time to use it
- Take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for at least **45 minutes up to 90 minutes** before injecting
- **Do not** let the on-body injector get wet with water or any other liquids
- **Do not** touch the start button until you place the on-body injector loaded with the cartridge onto your skin and are ready to inject
 - You can only press the start button **one** time
- Physical activity should be limited during the injection process. Moderate physical activities can be done, such as walking, reaching and bending
- **Do not** delay in injecting the medicine after loading the cleaned cartridge into the on-body injector. Waiting will dry out the medicine and the on-body injector will not work afterwards
- **Do not** inject if the liquid in the inspection window is cloudy or contains flakes or large particles. The liquid should look clear to yellow and may contain tiny white or clear particles
- **Do not** shake the carton, prefilled cartridge or on-body injector

Return this medicine to the pharmacy

- if the expiry date (EXP) has passed
- if the liquid has ever been frozen (even if thawed)
- if the cartridge or on-body injector has been dropped or damaged
- if the carton perforations are broken
- if the white paper tray cover is broken or missing

Follow the steps below each time you use SKYRIZI

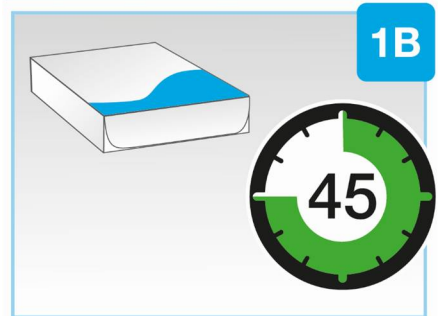
STEP 1 - Get ready



1A

Take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for at least **45 up to 90 minutes** before injecting.

- Check expiration date (EXP) on the carton. Do not use SKYRIZI if the expiration date (EXP) has passed.
- **Do not** remove the cartridge or on-body injector 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



1B

Sharps container



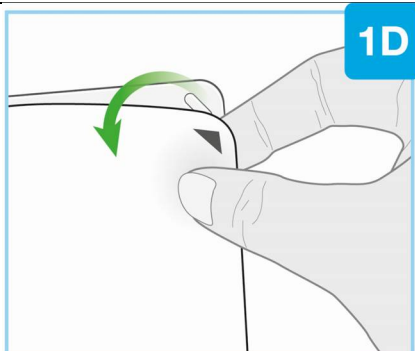
1C

Gather all supplies and wash your hands

Place the following items on a clean, flat surface

- plastic tray containing 1 On-Body Injector and 1 prefilled cartridge
- 2 alcohol pads (not included in the carton)
- 1 cotton ball or gauze pad (not included in the carton)
- special disposal container (not included in the carton)

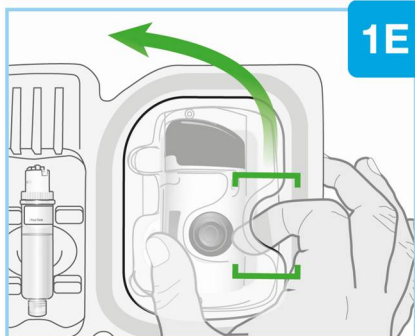
Wash and dry your hands.



1D

Remove the white paper tray seal

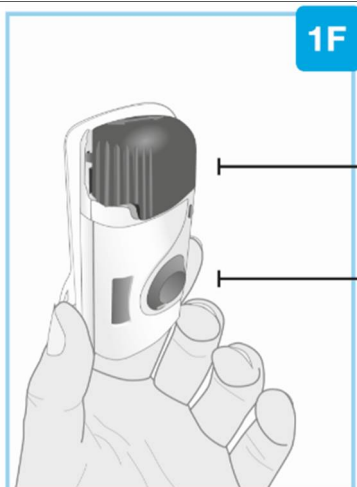
- Locate the black arrow
- Peel away the white paper tray seal from the plastic tray



1E

Lift the plastic cover

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



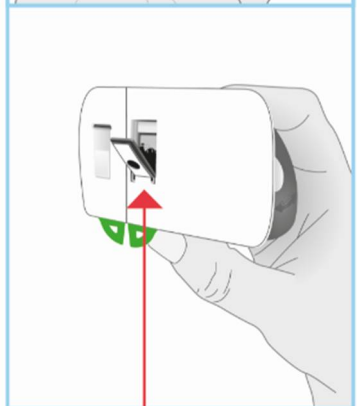
1F

Gray door

Start button

Inspect the on-body injector

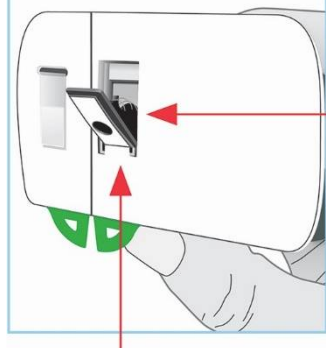
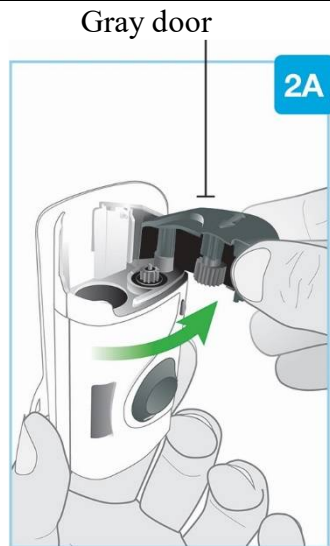
- Check that the on-body injector is intact and not damaged
- The gray door should be slightly open
- If the gray door does not open, press in firmly on the gray door ridges (left side of door) and swing open the door
- **Do not** close the gray door before the prefilled cartridge is loaded
- **Do not** use on-body injector if you drop it, discover missing pieces, or if it's damaged
- **Do not** touch the gray start button until it is time to inject. It can be pressed **one** time only
- **Do not** touch the needle cover area or needle



Needle inside
(under needle cover)

If the gray start button is pressed before placing it on your body, the on-body injector can no longer be used. If this happens, speak to your doctor, pharmacist, or nurse.

STEP 2 - Set up on-body injector



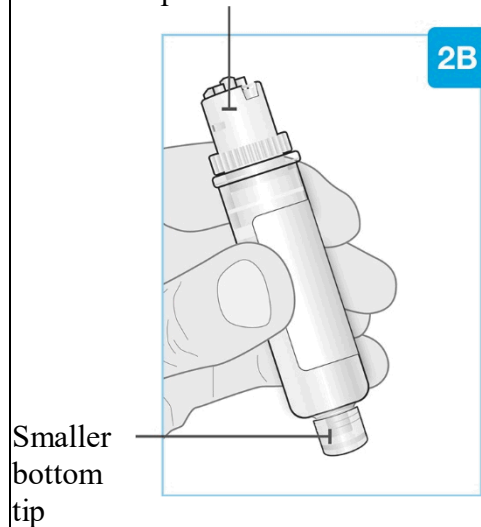
Needle cover

Fully open the gray door

- Avoid touching the needle cover area 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

Put the on-body injector aside.

Larger prefilled cartridge top



Inspect the prefilled cartridge

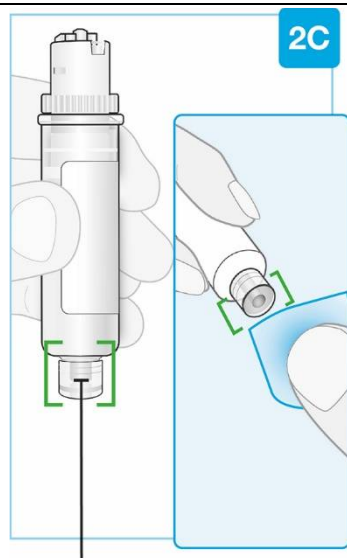
Carefully remove the prefilled cartridge from the plastic tray.

- **Do not** twist or remove cartridge top

Check the prefilled cartridge

- The liquid should look clear to yellow and may contain tiny white or clear particles. It is normal to see one or more bubbles
- **Do not** use if the liquid is cloudy, discolored, or contains flakes or large particles
- The prefilled cartridge parts and the clear plastic are not cracked or broken
- **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 center of smaller bottom tip

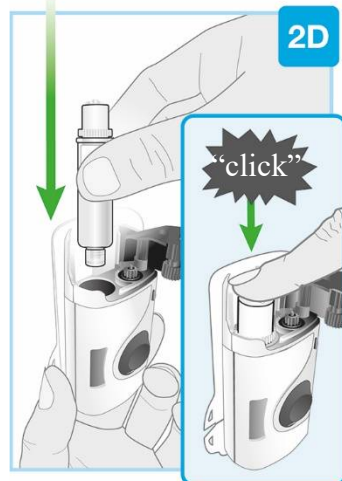
Smaller bottom tip

Clean the smaller bottom tip of the prefilled cartridge

Locate the smaller bottom tip of the prefilled cartridge

- Clean smaller bottom tip of the prefilled cartridge with an alcohol pad. Make sure to use the alcohol pad 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

Insert straight



Load the cleaned prefilled cartridge into the on-body injector

- **Do not** twist or remove the prefilled cartridge top
- Insert the smaller bottom tip of the prefilled cartridge into the on-body injector first
- Firmly push down on the prefilled cartridge top until you hear a "click"
- 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 to proceed to the next step without delay. Waiting will dry out the medicine.



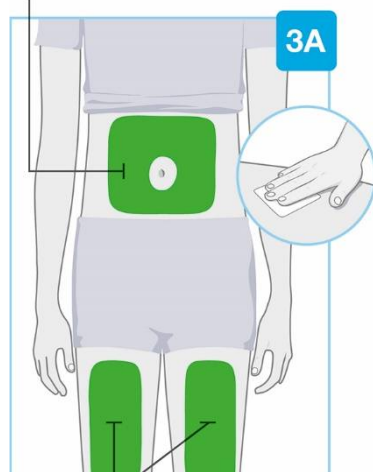
Close the gray door

Swing the gray door to the left, then squeeze firmly and listen for the gray door to "snap" shut

- The gray door should stay locked after loading the prefilled cartridge
- **Do not** close the gray door if the prefilled cartridge is not fully inserted or is missing
- Proceed without delay to the next step

STEP 3 - Prepare to inject

Areas to inject



Areas to inject

Choose and clean your injection site

Choose from these 3 areas to inject:

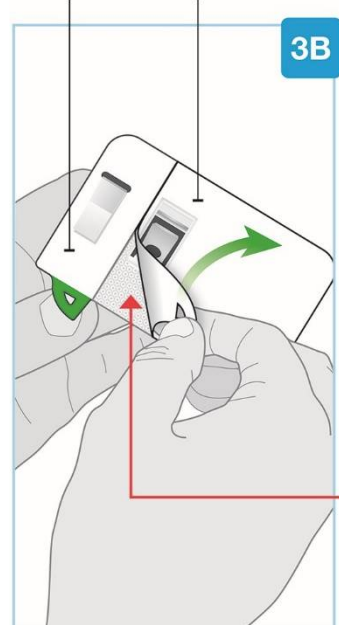
- front of left thigh
- front of right thigh
- your belly (abdomen) at least 5 cm from your belly button (navel)

Do not inject into areas of the skin that naturally fold or bulge because the on-body injector could fall off during wear.

Before the injection, wipe where you will inject in a circular motion with an alcohol pad.

- **Do not** touch or blow on the injection site after it is cleaned. Allow the skin to dry before placing the on-body injector on the skin
- **Do not** inject through clothes
- **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 site

Small section
Larger section



Needle inside
(under needle cover)

Peel both tabs to expose skin adhesive

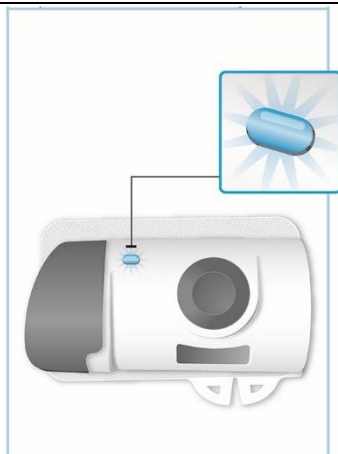
Turn the on-body injector over to find both green pull tabs

- Avoid touching the needle cover (needle inside)

Peel away the large section using the green pull tab to expose the skin adhesive

Peel away the small section using the green pull tab to expose the skin adhesive. This will remove the clear plastic strip, activating the on-body injector

- 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, speak to your doctor, pharmacist or nurse
- **Do not** press the gray start button yet
- **Do not** touch the needle cover or the needle



Activated injector

Status light flashing blue

- **Do not** pull the adhesive material off on-body injector or allow the sticky side to fold and stick to itself

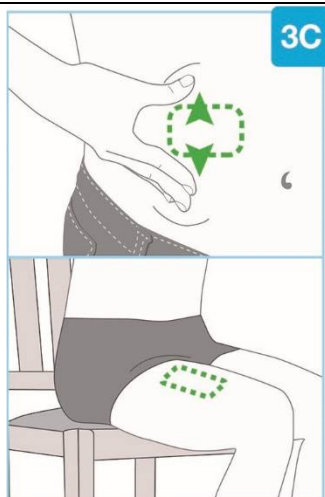
The SKYRIZI on-body injector must be placed on the skin and injection must be started within 30 minutes after removing the green pull tabs or it will not work. Make sure to proceed to next step without delay.



If the status light flashes red, the on-body injector is not working properly. Do not continue to use it.

Speak to your doctor, pharmacist or nurse for assistance.

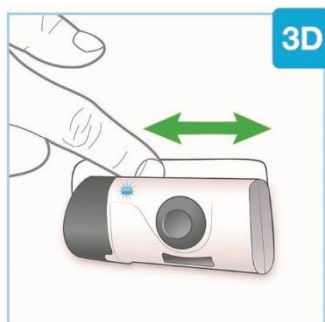
If on-body injector is attached to your body, carefully remove from your skin.



Prepare the on-body injector for placement

- For the belly (abdomen), move and hold the skin to create a firm, flat surface for injection at least 5 cm from your belly button (navel). Make sure to 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 place the on-body injector so that you can see the blue status light.

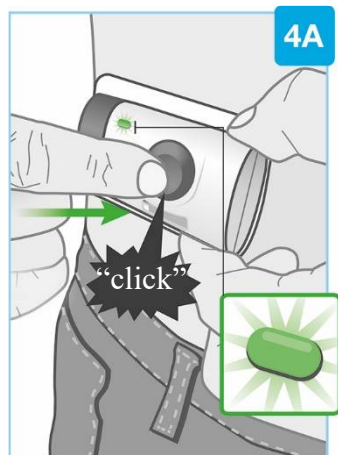


Place the on-body injector on your skin

- 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
- **Do not** move or adjust the on-body injector after it has been placed on your skin

Proceed without delay to the next step.

STEP 4 - Inject SKYRIZI

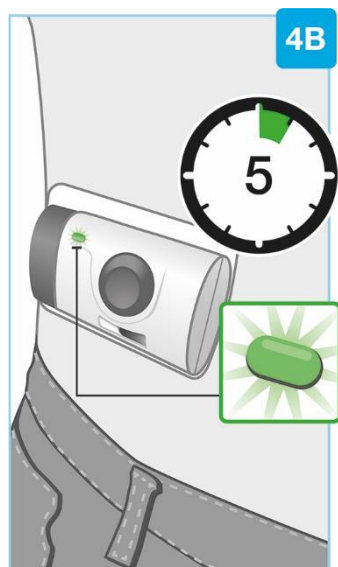


Start injection

Firmly press and release the gray start button

- You will hear a "click" and 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
- After starting the injection, you will hear pumping sounds as the on-body injector delivers the medicine

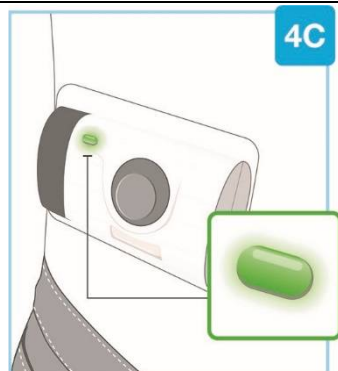
Do not continue to use the on-body injector if status light flashes red. Carefully remove from skin if the status light flashes red. If this happens, speak to your doctor, pharmacist or nurse.



Wait for the injection to finish

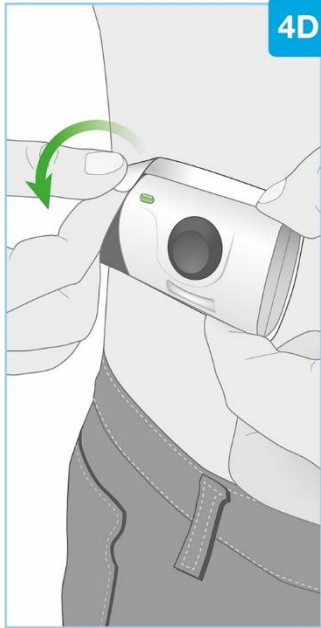
- It may take up to 5 minutes to complete the full dose of medicine. The on-body injector will automatically stop when the injection is finished
- During the injection, the status light will continue to flash green
- During the injection, you will hear pumping sounds as the on-body injector continues delivering the medicine
- During the injection, 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. Carefully remove it from the skin if the status light flashes red. If this happens, speak to your doctor, pharmacist or nurse.



Injection is complete when

- The on-body injector stops on its own
- You hear a beep and the status light changes to solid green. If the status light has changed to solid green, this means that the injection is complete

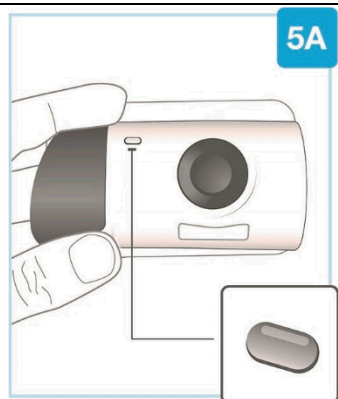


Remove the on-body injector

- **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
- 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 the next step.

STEP 5 - Finish

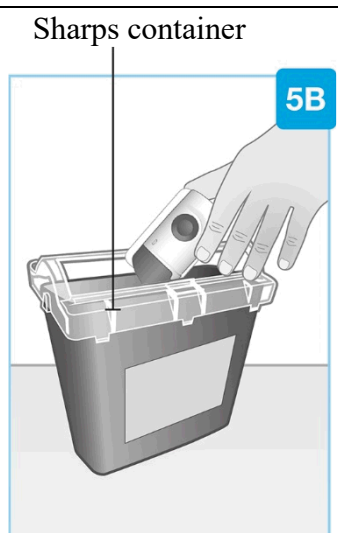


Check the on-body injector

Inspect the medicine window and status light.

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

- If the white plunger does not fill the window, speak to your doctor, pharmacist or nurse



Disposal

Throw away the used on-body injector in a special disposal container straight after use.

- The on-body injector contains batteries, electronics, and a needle.
- Leave the prefilled cartridge in the on-body injector.
- **Do not** throw away the used on-body injector in the household waste.
- Your doctor, pharmacist or nurse will tell you how to return the full special disposal container. There may be local guidelines for disposal.

Additional information

- On-body injector operating temperature range is 18°C to 28°C and relative humidity range 25% to 75%
- Altitude range is minus 400 meters to 3200 meters

Product Registrant:
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Date of Issue: DD MMM YYYY