

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PRÉPARATIONS) – 1996

This medicine is dispensed with a doctor's prescription only

Skyrizi® 360 mg
Solution for injection in a pre-filled cartridge

The active ingredient and its concentration:
Each pre-filled cartridge contains 360 mg of risankizumab in 2.4 mL solution (150 mg/1 mL).

For the list of inactive and allergenic ingredients, please see section 6 "Further Information" in this leaflet.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Skyrizi is indicated for the treatment of patients 16 years and older with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy, or if such therapies are not advisable.

Therapeutic group:

Immunosuppressive agents, interleukin inhibitors.

Skyrizi works by blocking a protein in the body called "IL-23", which causes inflammation. Crohn's disease is an inflammatory disease of the digestive tract. If you have active Crohn's disease you will first be given other medicines. If these medicines do not work well enough, you will be given Skyrizi to treat your Crohn's disease. Skyrizi reduces the inflammation and can therefore help to reduce the signs and symptoms of your disease.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to risankizumab or to any of the additional ingredients contained in this medicine (listed in section 6).
- You have an infection, including active tuberculosis, which your doctor thinks is important

Special Warnings Regarding Use of the Medicine

Before treatment and during the use of Skyrizi, inform the doctor 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 immunisation (vaccine). You should not be given certain types of vaccines while using Skyrizi.

Allergic reactions

Tell your doctor or seek medical help immediately if you notice any signs of an allergic reaction while using Skyrizi, such as:

- Difficulty breathing or swallowing
- Swelling of the face, lips, tongue or throat
- Severe itching of the skin, with a red rash or raised bumps

Children and adolescents

Skyrizi is not intended for children and adolescents under 16 years of age. There are no data available regarding the safety and efficacy of skyrizi for children and adolescents under 16 years of age.

Drug-Drug Interactions

If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are going to have a vaccination. This medicine should not be given certain types of vaccines while using Skyrizi. If you are not sure, talk to your doctor, pharmacist or nurse before and during the use of Skyrizi.

Pregnancy, breastfeeding and fertility

If you are a woman of childbearing age, you should use contraception while using this medicine, and for at least 21 weeks after your last dose of Skyrizi.

There is no adequate information regarding the use of Skyrizi in pregnancy; therefore, as a precautionary measure, it is recommended to avoid the use of the medicine during pregnancy.

It is not known whether Skyrizi is excreted into human milk. If you are breastfeeding or are planning to breastfeed, talk to your doctor before using this medicine.

Driving and using machines

Skyrizi is not likely to affect or has a negligible effect on your driving and use of machines.

Skyrizi contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per cartridge, that is to say essentially "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen of the medicine.

This medicine is given as an injection under your skin (called a 'subcutaneous injection'). The dosage and treatment regimen will be determined by the doctor only. Generally, the usual dosage is:

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

Starting doses

How much?	When?
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 Skyrizi 360 mg as an injection under your skin.

Maintenance doses

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

You and your doctor, pharmacist or nurse will decide if you should inject this medicine 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 injection after they have been trained.

Do not exceed the recommended dose.

Read section 7 "Instructions for use" at the end of this leaflet before injecting Skyrizi yourself.

If you accidentally have injected a higher dosage

If you accidentally inject more Skyrizi than you should or the dose has been given sooner than prescribed or if a child accidentally swallowed the medicine, refer immediately to the doctor or proceed to a hospital emergency room and bring the outer carton with you.

If you forget to inject Skyrizi

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

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.

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.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Skyrizi may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Serious side effects

Talk to your doctor or get medical help immediately if you have symptoms of a 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 continue using Skyrizi.

Other side effects

Tell your doctor if you get any of the following side effects:

- **Very common side effects (effects that occur in more than 1 in 10 users):**
- Upper respiratory infections with symptoms such as sore throat and stuffy nose

Common side effects (effects that occur in 1-10 out of 100 users):

- Feeling tired
- Fungal skin infection
- Injection site reactions (such as redness or pain)
- Itching
- Headache

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):

- Small raised red bumps on the skin

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects due to Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the pre-filled cartridge label and outer carton. The expiry date refers to the last day of that month.

- **Storage conditions:** Store in a refrigerator (2°C-8°C). Do not freeze.
- Keep the pre-filled cartridge in the original carton in order to protect from light.
- Do not use this medicine if the liquid is cloudy or contains flakes or large particles.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What Skyrizi contains

In addition to the active ingredient, the medicine also contains: Trehalose dihydrate, sodium acetate trihydrate, polysorbate 20, acetic acid glacial and water for injection.

What the medicine looks like and contents of the pack

Skyrizi is a clear and colourless to yellow liquid in a pre-filled cartridge. The liquid may contain tiny white or clear particles.

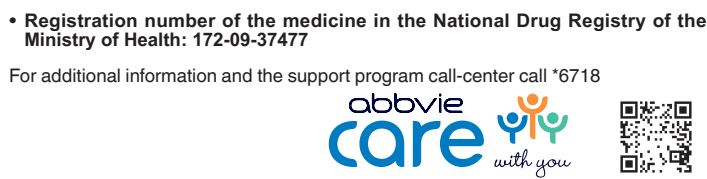
Each pack contains 1 pre-filled cartridge and 1 on-body injector.

- **License holder and its address:** AbbVie Biopharmaceuticals Ltd., 4 Haharash, Hod Hasharon, Israel.
- **Manufacturer name and its address:** AbbVie Inc., 1N Waukegan Road, North Chicago, IL 60064, USA

This leaflet was checked and approved by the Ministry of Health in February 2023.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 172-09-37477

For additional information and the support program call-center call *6718

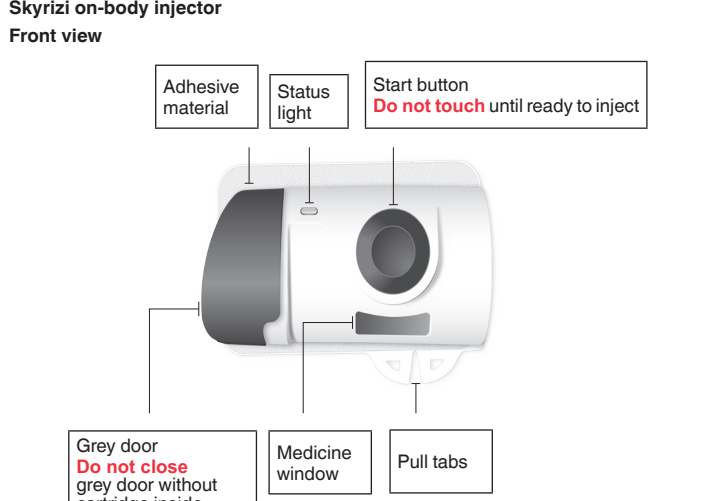


7. INSTRUCTIONS FOR USE

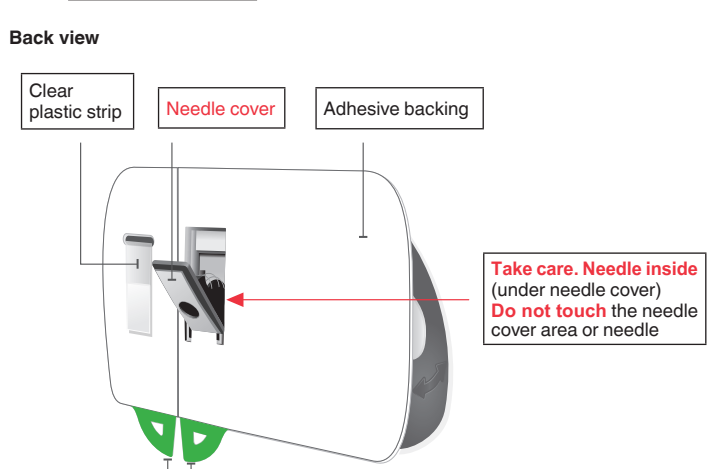
Please read all of section 7 before using Skyrizi

Skyrizi on-body injector

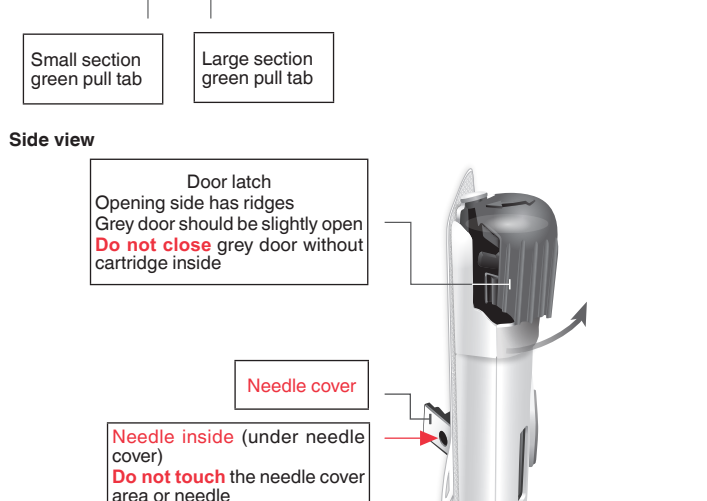
Front view



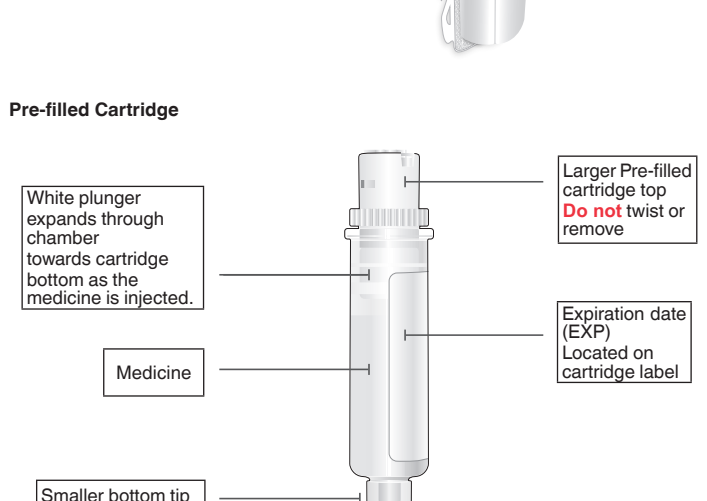
Back view



Side view



Pre-filled Cartridge



Important information to know before you inject Skyrizi

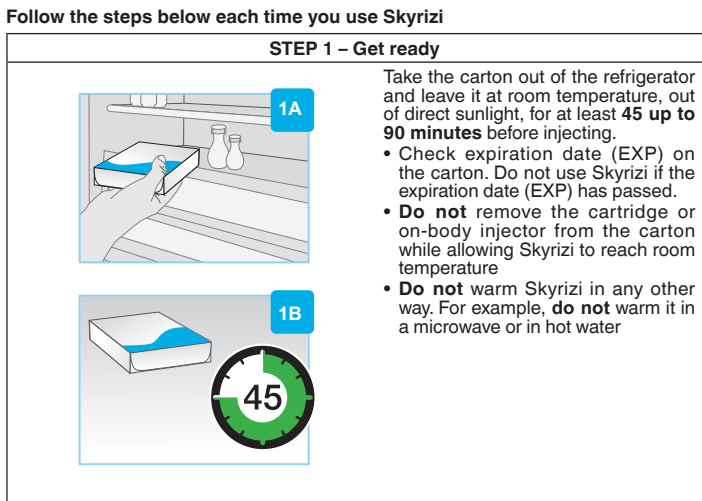
- Store in a refrigerator (2°C-8°C). Do not freeze.
- Keep the cartridge in the original carton in order to protect from light.
- You should receive training on how to inject Skyrizi before giving an injection. Talk to your doctor, pharmacist or nurse if you need help
- Mark the dates on your calendar so you know when to inject Skyrizi
- The single use on-body injector is designed for use with Skyrizi 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 up to 90 minutes before injecting
- Do not use the medicine after the expiry date (exp. date) that appears on the pre-filled cartridge label and outer carton.
- **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, cartridge or on-body injector
- If you have any questions on the use of the cartridge or on-body injector, speak to your doctor, pharmacist or nurse for assistance

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**
- 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



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 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.

Remove the white paper tray seal

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

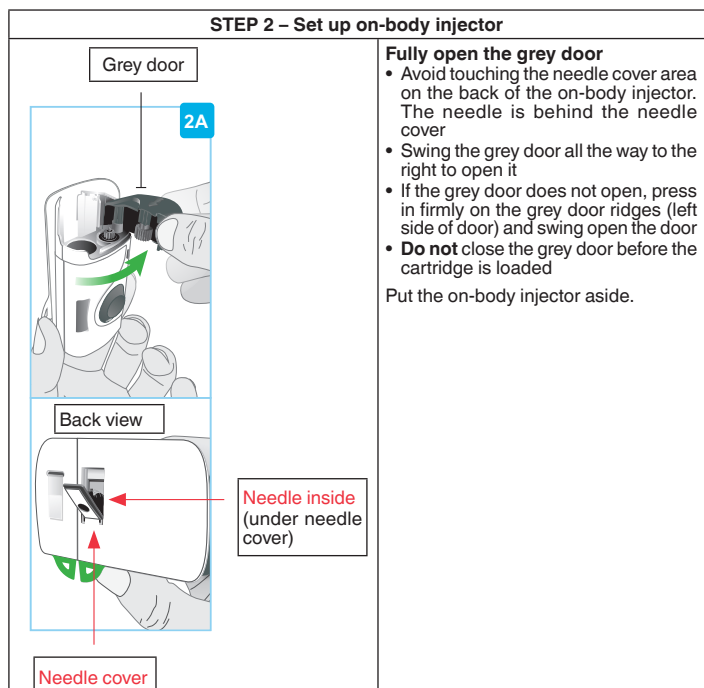
Lift the plastic cover

- 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

Inspect the on-body injector

- Check that the on-body injector is intact and not damaged
- The grey door should be slightly open
- If the grey door does not open, press in firmly on the grey door ridges (left side of door) and swing open the door
- **Do not** close the grey door before the 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 grey start button until it is time to inject. It can be pressed one time only
- **Do not** touch the needle cover area or needle

If the grey 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.



Fully open the grey door

- Avoid touching the needle cover area on the back of the on-body injector. The needle is behind the needle cover
- Swing the grey door all the way to the right to open it
- If the grey door does not open, press in firmly on the grey door ridges (left side of door) and swing open the door
- **Do not** close the grey door before the cartridge is loaded

Put the on-body injector aside.

Inspect the cartridge
Carefully remove the cartridge from the plastic tray.

- **Do not** twist or remove cartridge top
- Check the 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, discoloured, or contains flakes or large particles
- The 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 cartridge if you drop it, discover missing pieces, or it is damaged.

Clean the smaller bottom tip of the cartridge
Locate the smaller bottom tip of the cartridge

- Clean smaller bottom tip of the cartridge with an alcohol pad. Make sure to use the alcohol pad to clean the centre of the smaller bottom tip of the cartridge
- **Do not** touch the smaller bottom tip of the cartridge after cleaning

Load the cleaned cartridge into the on-body injector

- **Do not** twist or remove the cartridge top
- Insert the smaller bottom tip of the cartridge into the on-body injector first
- Firmly push down on the cartridge top until you hear a "click"
- After loading the 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 grey door
Swing the grey door to the left, then squeeze firmly and listen for the grey door to "snap" shut

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

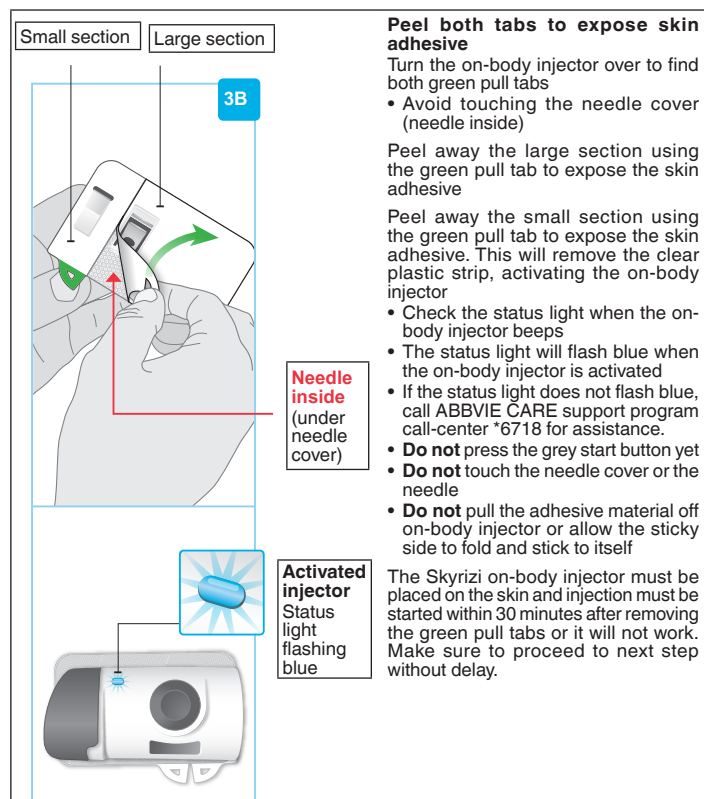
Choose and clean your injection site
Choose from these 3 areas to inject:

- 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



Peel both tabs to expose skin adhesive
Turn the on-body injector over to find both green pull tabs to expose the skin adhesive.

- 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, call ABBVIE CARE support program call-center *6718 for assistance.
- **Do not** press the grey start button yet
- **Do not** touch the needle cover or the needle
- **Do not** pull the adhesive material off on-body injector or allow the sticky side to fold and stick to itself

If the status light flashes red, the on-body injector is not working properly. Do not continue to use it.
Call ABBVIE CARE support program call-center *6718 for assistance.
If the on-body injector is attached to your body, carefully remove it 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 grey 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, Call ABBVIE CARE support program call-center *6718.

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, Call ABBVIE CARE support program call-center *6718.

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, 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, Call ABBVIE CARE support program call-center *6718.

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 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.

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 metres to 3,200 metres

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