

## **Package leaflet: Information for the patient**

**Skyrizi 180 mg solution for injection in cartridge**

**Skyrizi 360 mg solution for injection in cartridge**

risankizumab

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

1. What Skyrizi is and what it is used for
2. What you need to know before you use Skyrizi
3. How to use Skyrizi
4. Possible side effects
5. How to store Skyrizi
6. Contents of the pack and other information
7. Instructions for use

#### **1. What Skyrizi is and what it is used for**

Skyrizi contains the active substance risankizumab.

Skyrizi is used to treat patients 16 years and older with moderate to severe Crohn's disease and adults with moderate to severe ulcerative colitis.

#### **How Skyrizi works**

This medicine works by stopping a protein in the body called 'IL-23', which causes inflammation.

##### Crohn's disease

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.

##### Ulcerative colitis

Ulcerative colitis is an inflammatory disease of the large bowel. If you have active ulcerative colitis you will first be given other medicines. If these medicines do not work well enough or if you cannot take these medicines, you will be given Skyrizi to treat your ulcerative colitis.

Skyrizi reduces the inflammation and can therefore help to reduce the signs and symptoms of your disease.

#### **2. What you need to know before you use Skyrizi**

##### **Do not use Skyrizi**

- if you are allergic to risankizumab or any of the other ingredients of this medicine (listed in section 6).

- if you have an infection, including active tuberculosis, which your doctor thinks is important.

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before and during the use of Skyrizi

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

It is important to keep a record of the batch number of your Skyrizi.

Every time you get a new pack of Skyrizi, note down the date and the batch number (which is on the packaging after “Lot”) and keep this information in a safe place.

### **Serious allergic reactions**

Skyrizi can cause serious side effects, including serious allergic reactions (‘anaphylaxis’).

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

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- low blood pressure, which can cause dizziness or light-headedness
- severe itching of the skin, with a red rash or raised bumps

### **Children and adolescents**

Skyrizi is not recommended for children and adolescents under 16 years of age. This is because Skyrizi has not been studied in this age group.

### **Other medicines and Skyrizi**

Tell your doctor, pharmacist or nurse

- if you are using, have recently used or might use any other medicines.
- if you have recently had or are going to have a vaccination. You 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, contraception and breast-feeding**

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 who can become pregnant, you should use contraception while using this medicine and for at least 21 weeks after your last dose of Skyrizi.

If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine.

### **Driving and using machines**

Skyrizi is not likely to affect 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 to use Skyrizi**

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

This medicine is given as an injection under your skin (called a ‘subcutaneous injection’).

### How much Skyrizi to use

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?
Crohn’s disease	600 mg	When your doctor tells you
	600 mg	4 weeks after 1 <sup>st</sup> dose
	600 mg	4 weeks after 2 <sup>nd</sup> dose

	How much?	When?
Ulcerative colitis	1 200 mg	When your doctor tells you
	1 200 mg	4 weeks after 1 <sup>st</sup> dose
	1 200 mg	4 weeks after 2 <sup>nd</sup> dose

Afterwards, you will receive Skyrizi as an injection under your skin.

#### Maintenance doses

	How much?		When?
Crohn’s disease	1 <sup>st</sup> 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 <sup>st</sup> maintenance dose

	How much?		When?
Ulcerative colitis	1 <sup>st</sup> maintenance dose	180 mg or 360 mg	4 weeks after the last starting dose (at week 12)
	Further doses	180 mg or 360 mg	Every 8 weeks, starting after the 1 <sup>st</sup> 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.

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

#### If you use more Skyrizi than you should

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.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

## 4. Possible side effects

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

### **Serious side effects**

Allergic reactions – these may need urgent treatment. Tell your doctor or get emergency medical help straight away if you notice any of the following signs:

Serious allergic reactions ('anaphylaxis') are rare in people taking Skyrizi (may affect up to 1 in a 1 000 people). Signs include:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- low blood pressure, which can cause dizziness or light-headedness

Talk to your doctor or get medical help immediately if you have the following symptoms.

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 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 (such as redness or pain)
- itching
- headache
- rash
- eczema

**Uncommon:** may affect up to 1 in 100 people

- small raised red bumps on the skin
- 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. You can also report side effects directly via the national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

### **United Kingdom**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

## **5. How to store Skyrizi**

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

Do not use this medicine after the expiry date which is stated on the cartridge label and outer carton after 'EXP'.

Store in a refrigerator (2°C - 8°C). Do not freeze.

If needed, you may also store the cartridge out of the refrigerator (up to a maximum of 25°C) for up to 24 hours.

Keep the 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. Contents of the pack and other information**

### **What Skyrizi contains**

The active substance is risankizumab.

Skyrizi 180 mg solution for injection in cartridge

- Each cartridge contains 180 mg of risankizumab in 1.2 mL solution.
- The other ingredients are sodium acetate trihydrate, acetic acid, trehalose dihydrate, polysorbate 20 and water for injections.

Skyrizi 360 mg solution for injection in cartridge

- Each cartridge contains 360 mg of risankizumab in 2.4 mL solution (150 mg/mL).
- The other ingredients are sodium acetate trihydrate, acetic acid, trehalose dihydrate, polysorbate 20 and water for injections.

### **What Skyrizi looks like and contents of the pack**

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

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

### **Marketing Authorisation Holder**

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### **Manufacturer**

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Knollstrasse  
67061 Ludwigshafen  
Germany

**This leaflet was last revised in 11/2024**

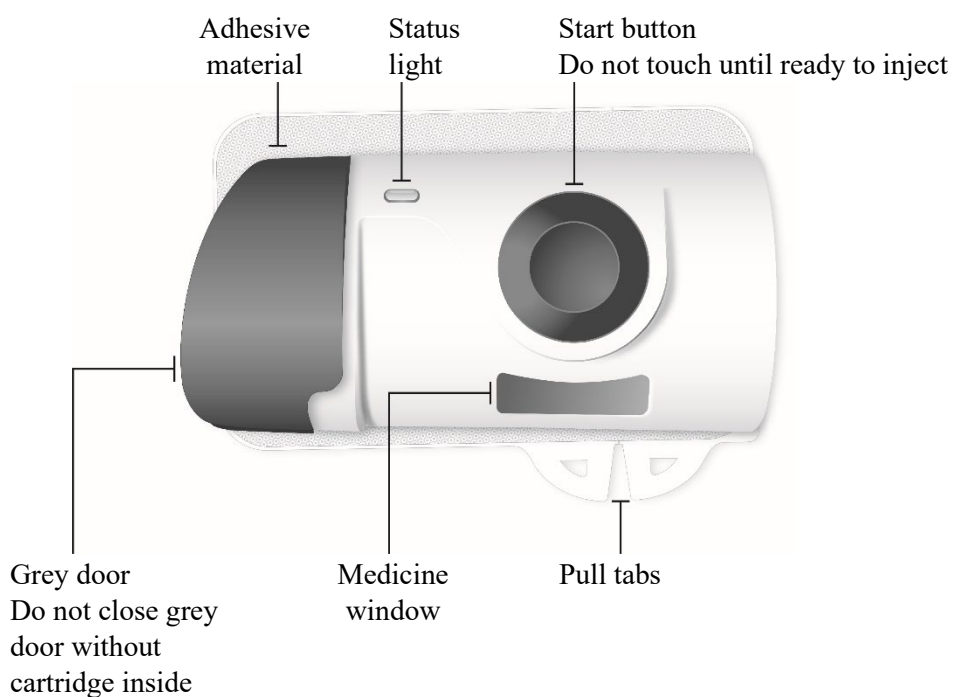
To listen to or request a copy of this leaflet in Braille, large print or audio, please contact the Marketing Authorisation Holder.

## **7. Instructions for use**

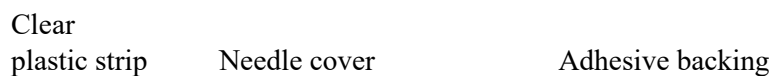
**Please read all of section 7 before using Skyrizi**

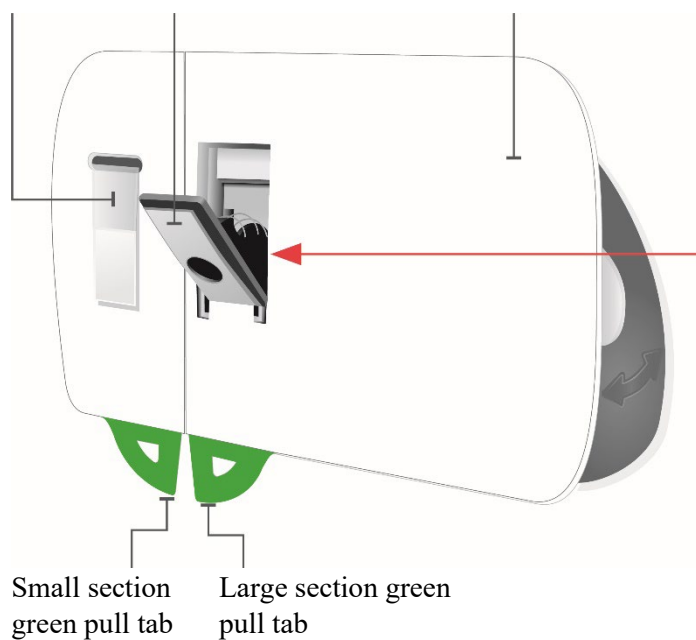
### **Skyrizi on-body injector**

#### **Front view**



#### **Back view**



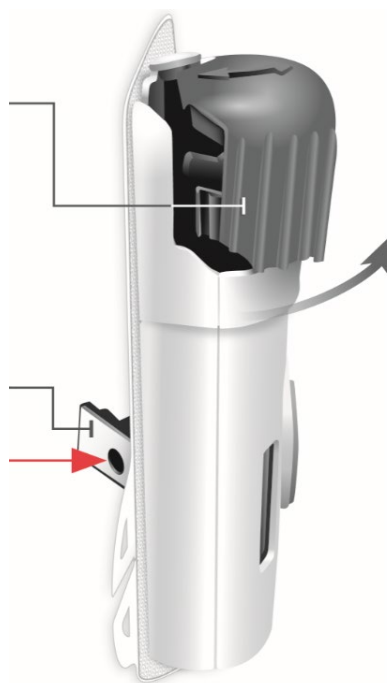


### Side view

Door latch  
Opening side has ridges  
Grey door should be slightly open  
Do not close grey door without cartridge inside

Needle cover

Needle inside (under needle cover)  
Do not touch the needle cover area or needle

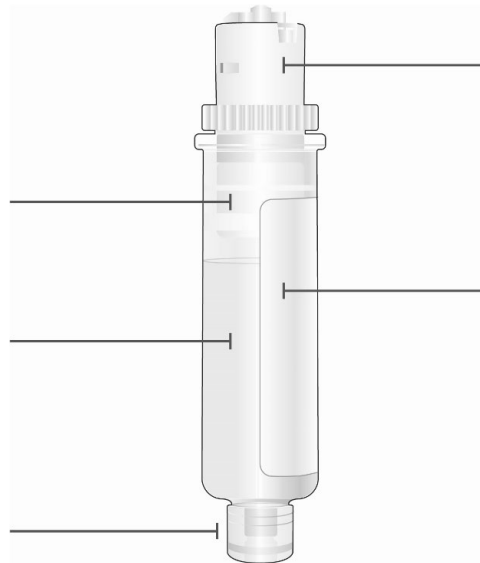


## Cartridge

White plunger  
expands through chamber  
towards cartridge  
bottom as the medicine is  
injected.

Medicine

Smaller bottom tip



Larger cartridge top  
Do not twist or remove

Expiration date (EXP)  
Located on cartridge label

### 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** 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, 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

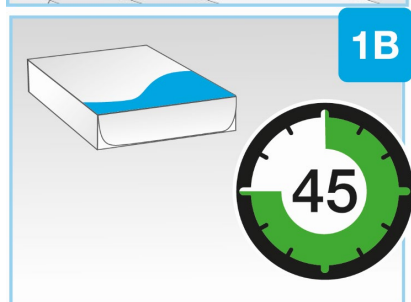
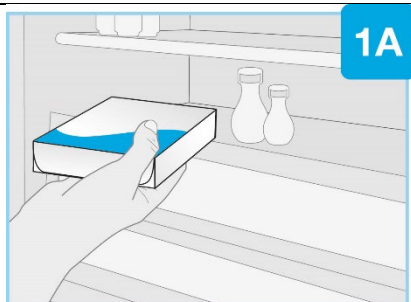
### Return this medicine to the pharmacy

- 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 Skeyrizi

### 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 Skeyrizi if the expiration date (EXP) has passed.
- **Do not** remove the cartridge or on-body injector from the carton while allowing Skeyrizi to reach room temperature
- **Do not** warm Skeyrizi in any other way. For example, **do not** warm it in a microwave or in hot water

#### Special disposal container

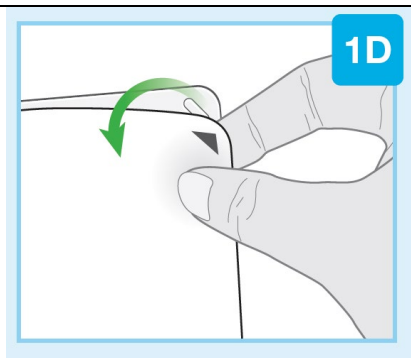


#### Gather all supplies and wash your hands

Place the following items on a clean, flat surface

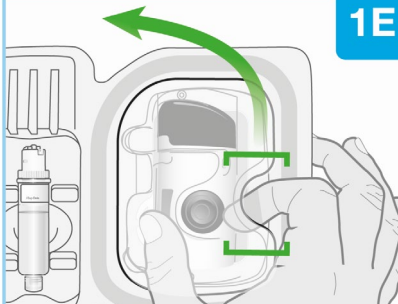
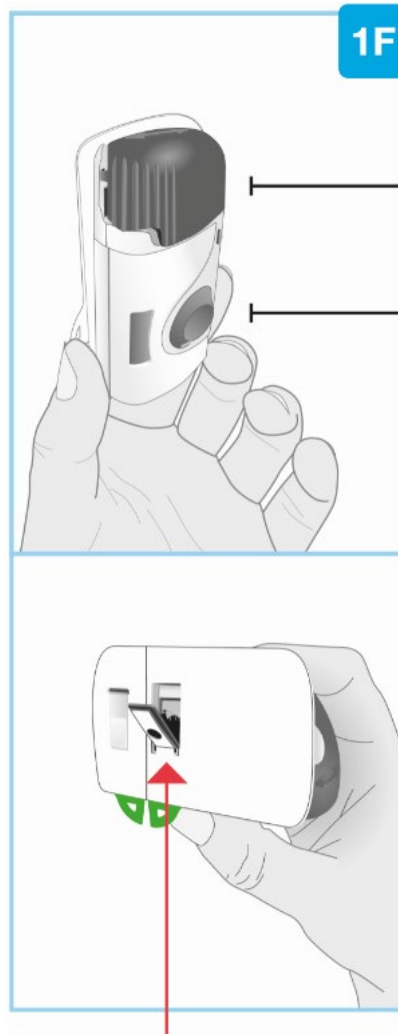
- plastic tray containing 1 on-body injector and 1 cartridge
- 2 alcohol pads (not included in the carton)
- 1 cotton ball or gauze pad (not included in the carton)
- special disposal container (not included in the carton)

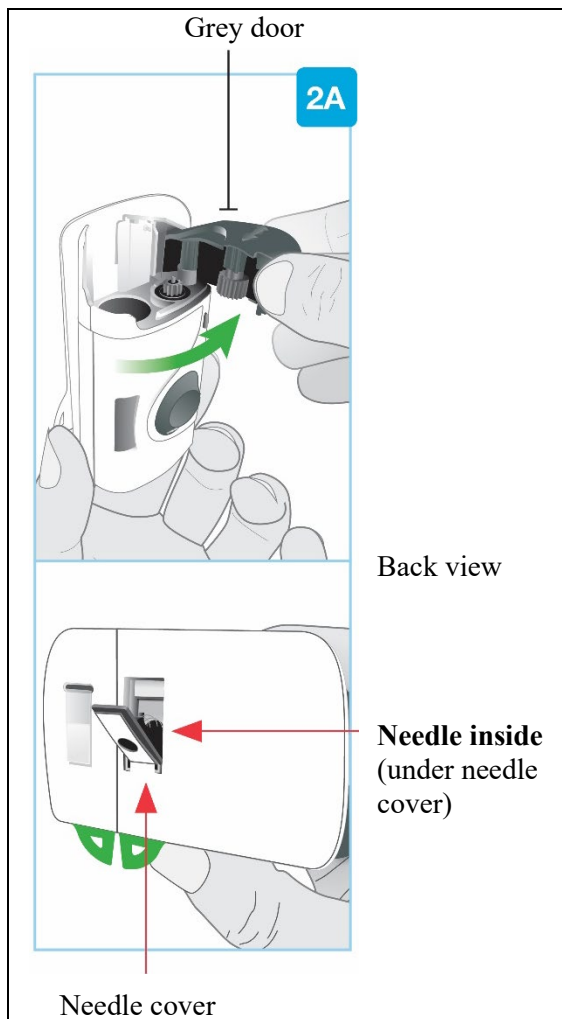
Wash and dry your hands.



#### Remove the white paper tray seal

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

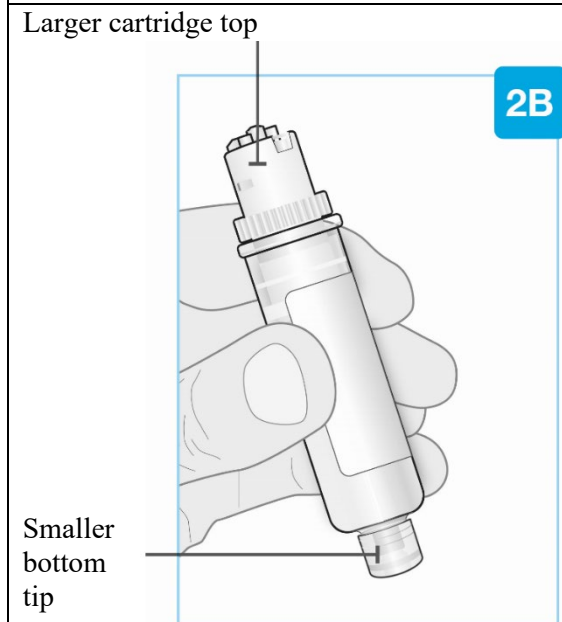
 <p><b>1E</b></p>	<p><b>Lift the plastic cover</b></p> <ul style="list-style-type: none"> <li>• Locate the rounded opening on the top cover</li> <li>• Insert your index finger in the opening and place your thumb on the opposite side</li> <li>• Lift the cover to remove and set it aside</li> </ul>
 <p><b>1F</b></p> <p>Grey door</p> <p>Start button</p> <p><b>Needle inside</b> (under needle cover)</p>	<p><b>Inspect the on-body injector</b></p> <ul style="list-style-type: none"> <li>• Check that the on-body injector is intact and not damaged</li> <li>• The grey door should be slightly open</li> <li>• If the grey door does not open, press in firmly on the grey door ridges (left side of door) and swing open the door</li> <li>• <b>Do not</b> close the grey door before the cartridge is loaded</li> <li>• <b>Do not</b> use on-body injector if you drop it, discover missing pieces, or if it's damaged</li> <li>• <b>Do not</b> touch the grey start button until it is time to inject. It can be pressed one time only</li> <li>• <b>Do not</b> touch the needle cover area or needle</li> </ul> <p>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.</p> <p><b>STEP 2 - Set up on-body injector</b></p>



### 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.



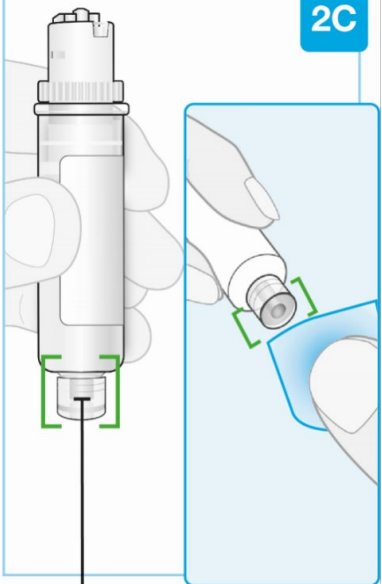
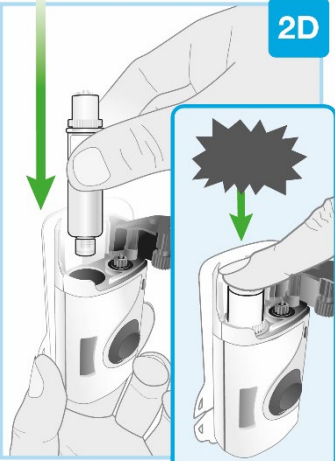

### Inspect the cartridge

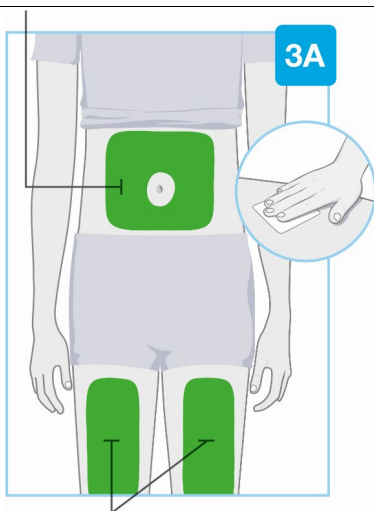
Carefully remove the cartridge from the plastic tray.

- **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.

 <p>Smaller bottom tip</p> <p>Clean centre of smaller bottom tip</p>	<p><b>Clean the smaller bottom tip of the cartridge</b> Locate the smaller bottom tip of the cartridge</p> <ul style="list-style-type: none"> <li>• 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</li> <li>• <b>Do not</b> touch the smaller bottom tip of the cartridge after cleaning</li> </ul>
<p>Insert straight</p> <p>“click”</p> 	<p><b>Load the cleaned cartridge into the on-body injector</b></p> <ul style="list-style-type: none"> <li>• <b>Do not</b> twist or remove the cartridge top</li> <li>• Insert the smaller bottom tip of the cartridge into the on-body injector first</li> <li>• Firmly push down on the cartridge top until you hear a “click”</li> <li>• After loading the cartridge, you may see a few drops of medicine on the back of the on-body injector. This is normal</li> </ul> <p>Make sure to proceed to the next step without delay. Waiting will dry out the medicine.</p>
 <p>“snap”</p>	<p><b>Close the grey door</b> Swing the grey door to the left, then squeeze firmly and listen for the grey door to “snap” shut</p> <ul style="list-style-type: none"> <li>• The grey door should stay locked after loading the cartridge</li> <li>• <b>Do not</b> close the grey door if the cartridge is not fully inserted or is missing</li> <li>• Proceed without delay to the next step</li> </ul>
<p><b>STEP 3 - Prepare to inject</b></p>	
<p>Areas to inject</p>	<p><b>Choose and clean your injection site</b> Choose from these 3 areas to inject:</p> <ul style="list-style-type: none"> <li>• front of left thigh</li> <li>• front of right thigh</li> </ul>



Areas to inject

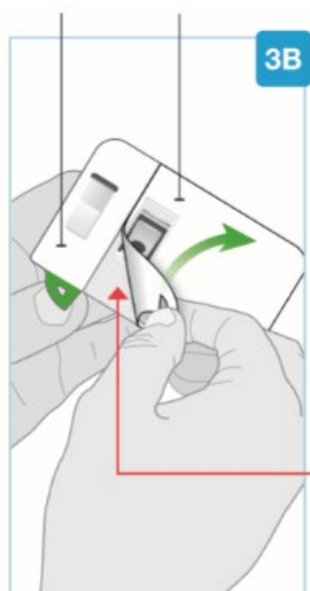
- your belly (abdomen) at least 5 cm from your belly button (navel)

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

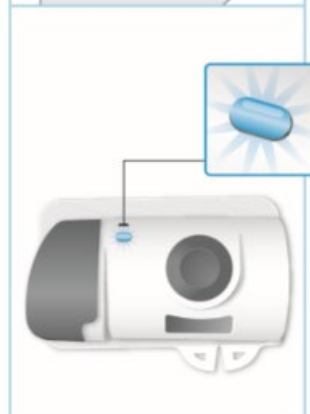
Before the injection, wipe where you will inject in a circular motion with an alcohol pad.

- **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 Large section



**Needle inside**  
(under needle cover)



**Activated injector**  
Status light flashing blue

### 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

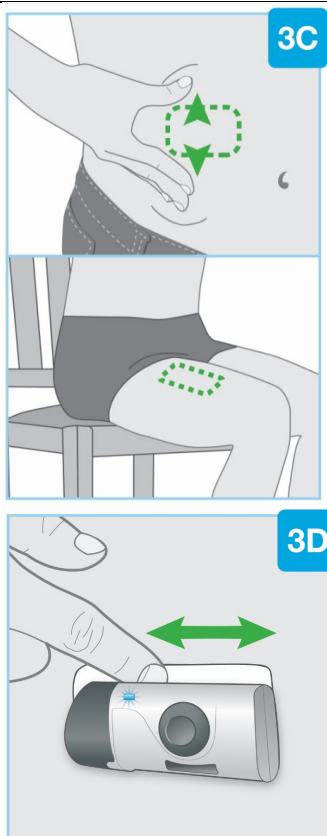
- Check the status light when the on-body injector beeps
- The status light will flash blue when the on-body injector is activated
- If the status light does not flash blue, speak to your doctor, pharmacist or nurse
- **Do not** press the grey start button yet
- **Do not** touch the needle cover or the needle
- **Do not** pull the adhesive material off on-body injector or allow the sticky side to fold and stick to itself

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 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.

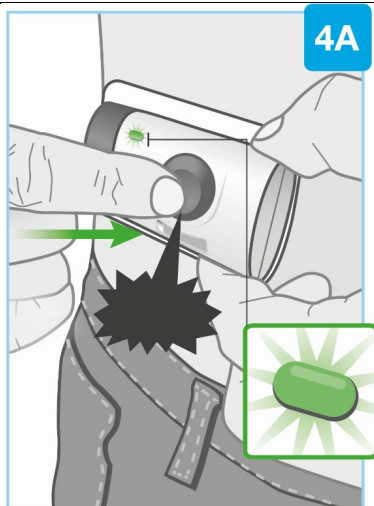
Make sure to place the on-body injector so that you can see the blue status light.

### 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 Sskyrizi



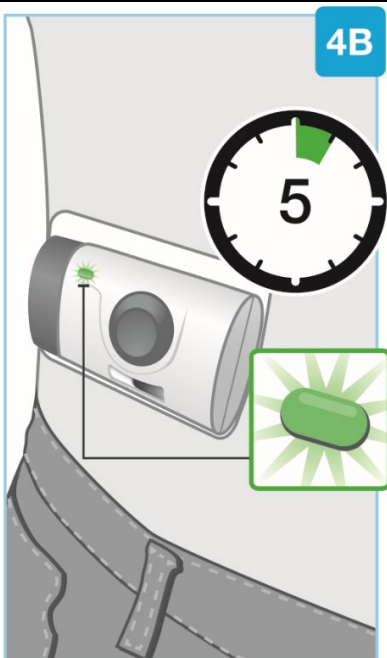
“click”

##### 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

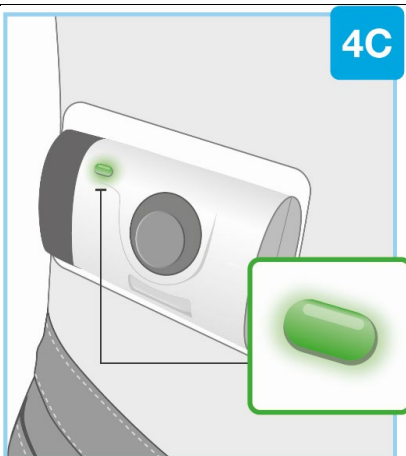
**Do not** continue to use the on-body injector if status light flashes red. Carefully remove from skin if the status light flashes red. If this happens, speak to your doctor, pharmacist or nurse.



##### 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.

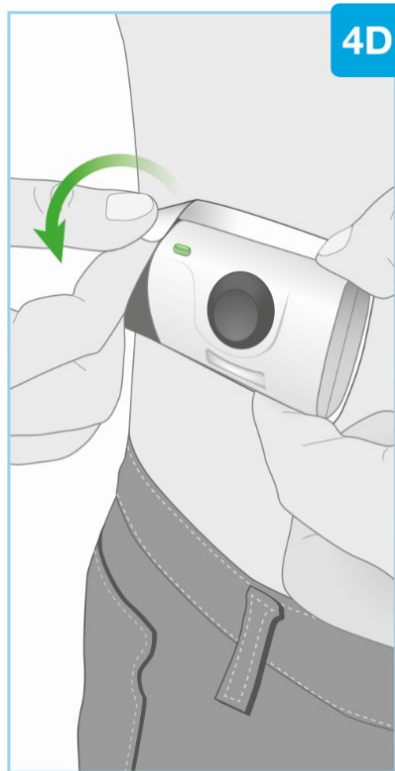
**Do not** continue to use the on-body injector if the status light flashes red. Carefully remove it from the skin if the status light flashes red. If this happens, speak to your doctor, pharmacist or nurse.



##### 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



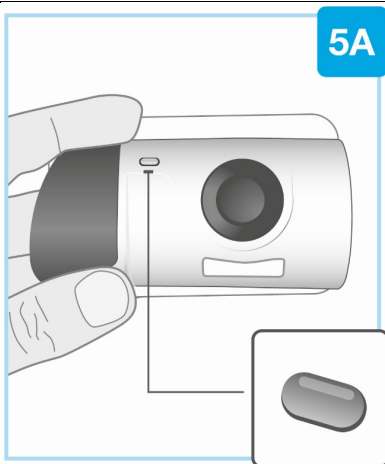


#### Remove the on-body injector

- **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



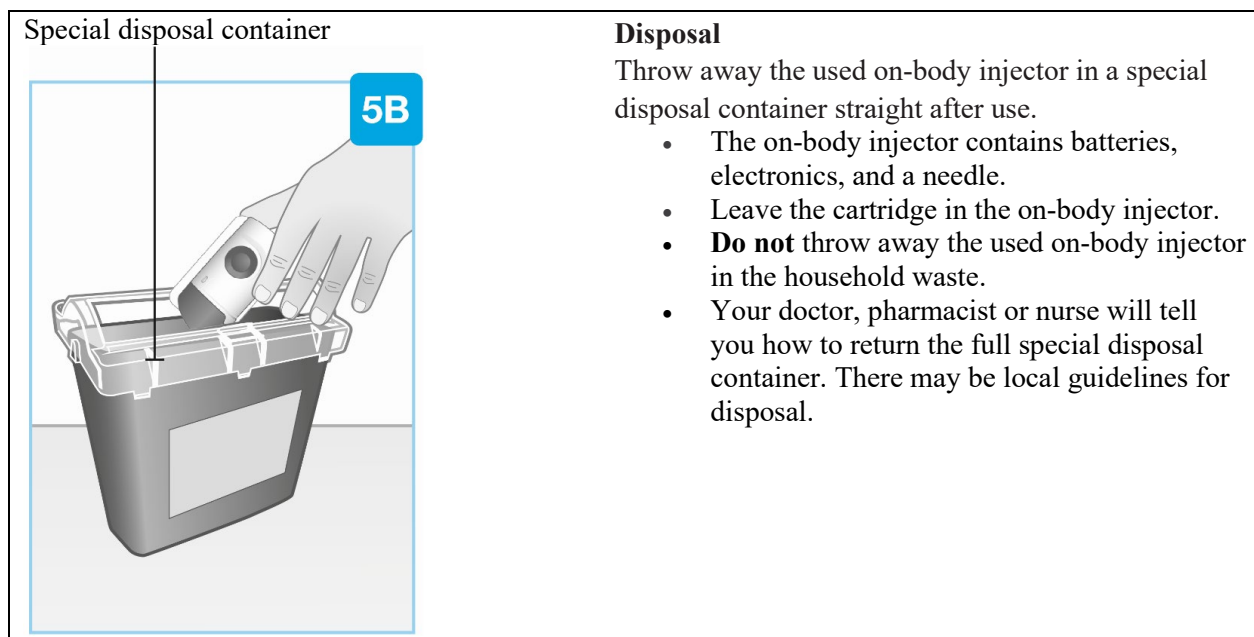
#### Check the on-body injector

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




















**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 used on the white paper tray seal and on-body injector**

Symbol	Description
	Keep Dry
	Do not use if package is damaged and consult instructions for use.
	Single sterile barrier system
	Medical Device
	Do not reuse
	Manufacturer
	Date of Manufacture
	Serial Number
	Lot Number
	Reference Number
	Refer to instruction Manual/Booklet
	CE Mark
	Sterilised using ethylene oxide
	Type BF Applied Part
	Authorised representative in European Community/European Union