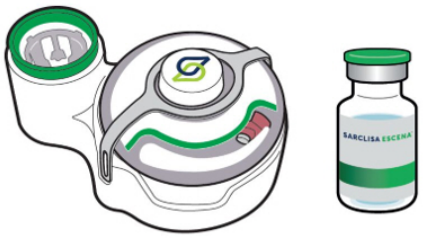
**Healthcare Provider**
**INSTRUCTIONS FOR USE**
**CirCLIQ™ On-Body Delivery System**
**for use with SARCLISA ESCENA™**
**[sar-cli-sa es-SEEN-ah]**
**(isatuximab-irfc)**
**injection, for subcutaneous use**
**Single-use CirCLIQ™ On-Body Delivery System**
**Rx only**

This Instructions for Use contains information on how to use the CirCLIQ On-Body Delivery System to inject SARCLISA ESCENA.




**Read this Instructions for Use carefully before using the SARCLISA ESCENA vial and CirCLIQ On-Body Delivery System (OBDS).**

**Important Information You Need to Know Before Injecting SARCLISA ESCENA.**

- See United States Prescribing Information (USPI) for information on SARCLISA ESCENA.
- The CirCLIQ OBDS contains one 10 mL single-use On-Body Injector and one Filling Base. Device must be filled prior to use.
- The CirCLIQ OBDS is intended for abdominal subcutaneous injection of SARCLISA ESCENA single dose by a healthcare provider in adult patients.
- SARCLISA ESCENA is indicated for the treatment of adult patients with multiple myeloma. The SARCLISA ESCENA vial is not included in the CirCLIQ OBDS packaging.
- For abdominal subcutaneous injection only. Administer directly into fatty layer under skin.
- Only use the CirCLIQ OBDS with SARCLISA ESCENA. The CirCLIQ OBDS should not be used with any other medicines.
- **Do not** use the CirCLIQ OBDS if the expiration date has passed or its packaging was previously opened.
- **Do not** use the CirCLIQ OBDS components if they have been dropped on a hard surface because they could be damaged. Start again with a new CirCLIQ OBDS.

⚠ **Do not** use the CirCLIQ OBDS if the wearer has an acrylic allergy. The CirCLIQ On-Body Injector adhesive contains acrylic.

⚠ Use the CirCLIQ On-Body Injector as soon as possible after filling it with SARCLISA ESCENA.

**The injection should be completed within 4 hours once the vial is punctured.**

⚠ **Do not** attempt to reapply CirCLIQ On-Body Injector once attached to the abdomen.

**Storing CirCLIQ OBDS**

⚠ Keep CirCLIQ OBDS away from children of 3 years and younger. Contains small parts.

- Store and transport CirCLIQ OBDS in its unopened plastic packaging inside of the original carton.
- Store CirCLIQ OBDS in a clean, dry area away from heat and sunlight at 36°F to 86°F (2°C to 30°C).
- Use CirCLIQ OBDS where the temperature is 64°F to 82°F (18°C to 28°C).

**Storing SARCLISA ESCENA vial**

- Store SARCLISA ESCENA vial in a refrigerator at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light until 20 minutes prior to use. **Do not** freeze. **Do not** shake.
- Unpunctured vials may be stored at ambient temperature 64°F to 82°F (18°C to 28°C) for a single period of up to 24 hours. Once the vial has been taken out of the refrigerator, it must not be returned to the refrigerator.

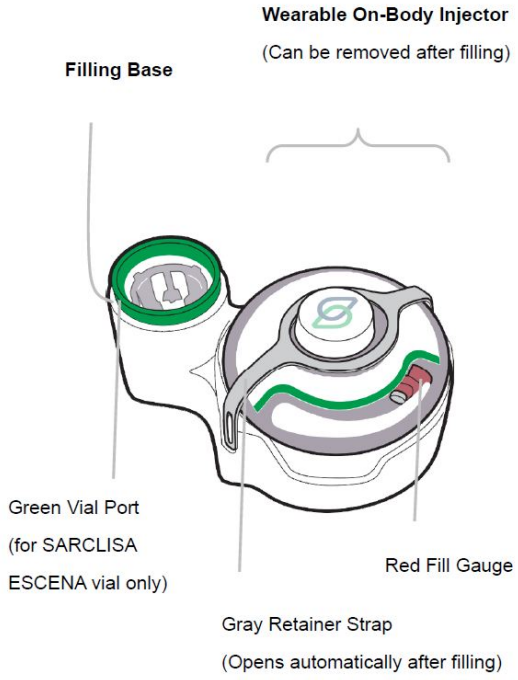
**Parts of the CirCLIQ OBDS (Filling Base and Wearable On-Body Injector) and SARCLISA ESCENA vial:**

For single use only




**Vial** (not included in OBDS packaging)

See SARCLISA ESCENA USPI for information on SARCLISA ESCENA.




**Part 1 – Getting ready to inject SARCLISA ESCENA (vial packaged separately from OBDS)**

**1 Get and inspect vial and CirCLIQ OBDS**

a) Take SARCLISA ESCENA vial out of the refrigerator.

- **Do not** shake SARCLISA ESCENA vial.

b) Allow the vial and OBDS to come to ambient temperature 64°F to 82°F (18°C to 28°C) for 20 minutes prior to use.

c) Check SARCLISA ESCENA vial label to make sure it is the correct medication. The label should say : "SARCLISA ESCENA for subcutaneous use". Vial cap should be green.



- **Do not** use SARCLISA ESCENA vial if the expiration date has passed.
- The medicine in SARCLISA ESCENA vial should be clear to slightly opalescent, colorless to slightly yellow. The solution may contain a few translucent to white particles.

d) Check CirCLIQ OBDS.

- **Do not** use CirCLIQ OBDS if the expiration date has passed or its packaging was previously opened.

**2 Gather supplies**



a) Place the following on a flat clean surface:
1) Vial filled with 1,400 mg dose of SARCLISA ESCENA (packaged separately)
2) CirCLIQ OBDS in packaging
3) Two alcohol wipes (not included in carton)
4) Single-use gloves (not included in carton)
5) FDA-cleared sharps container (not included in carton)
6) Medical disposal container (not included in carton)

**Part 2 – Fill CirCLIQ On-Body Injector**

**3 Remove cap and clean SARCLISA ESCENA vial**

a) Remove green cap from SARCLISA ESCENA vial.



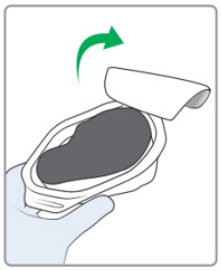
b) Wipe rubber at the top of SARCLISA ESCENA vial with an alcohol wipe and allow to air dry.



**4 Unpack CirCLIQ OBDS**

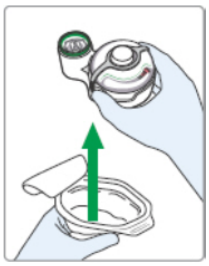
a) Peel away white seal from package.

- **Do not** use if sealed plastic packaging was already opened or damaged because CirCLIQ OBDS may be contaminated. Use a new one.



b) Remove CirCLIQ OBDS from plastic packaging and place on a clean, flat surface.

- **Do not** remove the On-Body Injector from Filling Base.
- **Do not** remove the Gray Retainer Strap.



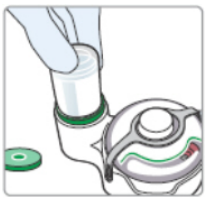
c) Discard plastic packaging.

**5 Fill CirCLIQ On-Body Injector**

a) Confirm again the cap is removed from the SARCLISA ESCENA vial.

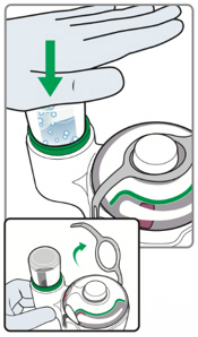
b) Place SARCLISA ESCENA vial top-first into Green Vial Port on the Filling Base.

**⚠ The injection should be completed within 4 hours once the vial is punctured.**



c) Firmly push SARCLISA ESCENA vial down until a burst of bubbles quickly forms. This means filling has started.

- Leave on flat surface until filling is complete.
- **Do not** lift or tilt device while it is filling.
- **Note**: The Red Fill Gauge will move as the device fills. Filling may take up to 2 minutes.
- Gray Retainer Strap will automatically open when SARCLISA ESCENA vial is empty.



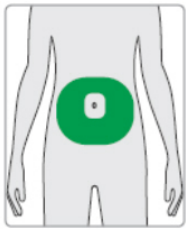
**Part 3 – Preparing the injection site**

**6 Clean the injection site on abdomen**

a) Choose a flat injection site on bare skin around abdomen.

⚠ Avoid injecting within 2 inches (5 cm) around the belly button or in folded skin.

- **Note:** The injection site should be changed (rotated) at least 1 inch (2.5 cm) from previous injection site - with every injection to avoid accumulation of fatty tissue.



b) Clean injection site with an alcohol wipe. Then allow the skin to completely air dry; this should take about 30 seconds.

⚠ **Do not** apply the On-Body Injector on areas where belts, waistbands, or tight clothing may rub against, disturb, or dislodge the On-Body Injector.

⚠ **Do not** inject into areas where the skin is injured, tender, red, hot, has scars, or is excessively hairy. If hair on injection site might prevent secure adhesive attachment, carefully trim hair to clear a patch of skin large enough for the On-Body Injector.

**Continue to Part 4**

**Flip over these instructions for use.**

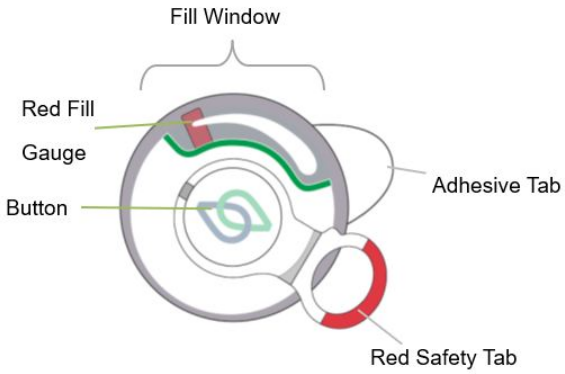
If you have read and followed all of the instructions for use on this side, proceed to:

**Part 4 "Preparing to inject SARCLISA ESCENA** on the back side of this page.

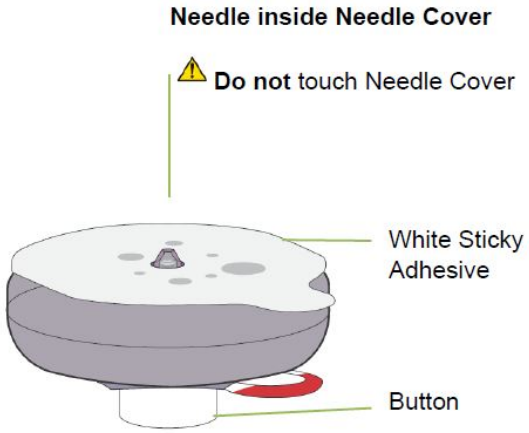
STOP **Confirm Parts 1 to 3 are completed.**

**Flip over for Parts 1 to 3.**

**Get to know the CirCLIQ On-Body Injector**




**Underside of CirCLIQ On-Body Injector**

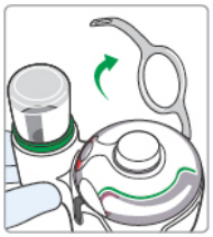



**Part 4 – Preparing to inject SARCLISA ESCENA**

**7 Remove the CirCLIQ On-Body Injector from Filling Base**

a) Confirm the Gray Retainer Strap has opened on its own and has risen away from Filling Base.

- **Do not** use force to open the Gray Retainer Strap.

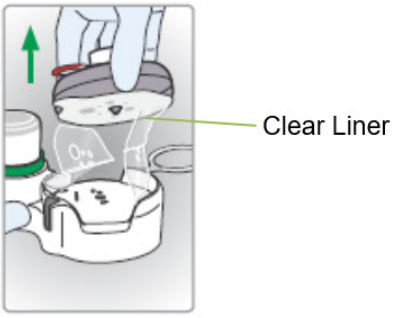


b) Hold the sides of the On-Body Injector and pull it straight up from the Filling Base to expose the White Sticky Adhesive underneath.

⚠ **Do not** touch the White Sticky Adhesive. The Needle is inside the center.

⚠ **Do not** remove Red Safety Tab until the On-Body Injector is attached to body and you are ready to inject. The Red Safety Tab prevents accidental Needle sticks.

- **Note:** The Clear Liner will remain attached to Filling Base.

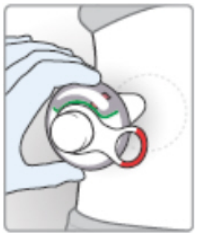



**8 Apply the CirCLIQ On-Body Injector to abdomen (injection site)**

a) Position the On-Body Injector where you can see the Fill Window. This allows a clear view of the Red Fill Gauge as it moves.

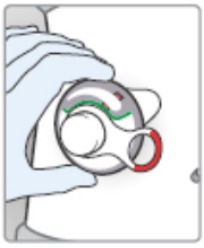
⚠ **Do not** move the On-Body Injector once attached to the abdomen.

- **Note:** The On-Body Injector will continue to work properly no matter which way the Fill Window is facing.



b) Once on the skin, press the On-Body Injector firmly onto injection site to attach adhesive to abdomen.

- **Do not** remove the Red Safety Tab until ready to inject. The Red Safety Tab prevents the start of the injection.



## Part 5 – Injecting SARCLISA ESCENA

**9 Remove Red Safety Tab and inject**

a) Hold the On-Body Injector with one hand. Use the other hand to pull the Red Safety Tab off to the side.

- **Note:** The injection cannot start until the Red Safety Tab is removed.



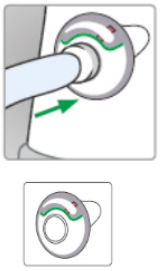
b) Push Button in firmly.

- The Button will stay in place when you let go.
- The Button pushes the Needle into the skin. This starts the injection.

⚠ **Do not** bump or knock On-Body Injector or Button during the injection.

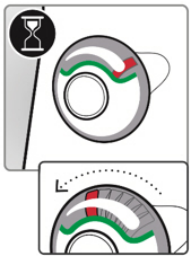
⚠ Keep injection site dry during injection.

⚠ The patient should **not** sleep or bathe during injection.



**10 Wait for injection to finish**

a) Leave the On-Body Injector on body until the Button pops out.

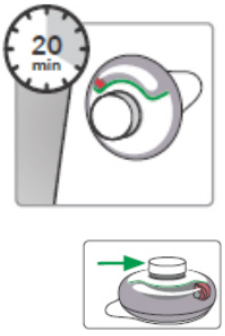


- After a 1 to 2 minute delay, the Red Fill Gauge will begin to move toward the other end of the Fill Window.

⚠ **Do not** remove the On-Body Injector before the Button pops out. The Needle may be exposed. Sticking yourself with an exposed Needle may result in infection.

b) Check the Button to see if it has popped out. This means the injection is complete.

- **Note:** The injection could take up to 20 minutes. If the Button has not popped out after 20 minutes, allow the injection to complete (wait for the Button to pop out up to 60 minutes, if not, refer to FAQ).



**Part 6 – Removing and disposing of the CirCLIQ On-Body Injector and Filling Base**

**11 Remove the CirCLIQ On-Body Injector**

a) Confirm again that the Button on the On-Body Injector has popped out. This means the Needle has retracted and is locked inside the On-Body Injector.



b) Slowly peel off the On-Body Injector with the Adhesive Tab.
- Lift the Adhesive Tab.
- Hold the Adhesive Tab against the On-Body Injector and slowly peel away from skin.



**12 Dispose of the CirCLIQ On-Body Injector and Filling Base**

a) Put the On-Body Injector in an FDA-cleared sharps disposal container. The On-Body Injector is a single-use device.

b) Dispose the Filling Base with attached SARCLISA ESCENA vial in an approved medical disposal container in accordance with local guidelines.

**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.

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: http://www.fda.gov/safesharpsdisposal.

**FAQ**

**How long should delivery take after the Button is pressed?**

The injection typically takes up to 20 minutes but may be slower based on local absorption of medication. If the Button has not popped out after 60 minutes, slowly remove the On-Body Injector from skin. Do not touch the Needle or any medicine that may be on the Injector. Call Sanofi at 1-800-633-1610 for help or assistance.

**Can the injection be paused if necessary?**

Yes, holding down the Button will stop the flow of medicine. Delivery will resume when the Button is released.

**What activities can the patient perform during injection?**

The patient may move around and perform light or non-strenuous routine activities during injection. Refer also to Part 5 – Injecting SARCLISA ESCENA.

**What if the On-Body Injector falls off?**

If the On-Body Injector falls off the body, pick it up carefully. **Do not** touch the Needle or any medicine that may be on the On-Body Injector. Put the On-Body Injector in an FDA-cleared sharps disposal container. Call Sanofi at 1-800-633-1610 for help or assistance.

**Symbol Table**

| Symbol | Meaning | Symbol | Meaning |
|---|---|---|---|
| | Consult instructions for use | | Country and date of manufacture |
| UDI | Unique device identifier | LOT | Batch code |
| | Keep dry | | Use-by date |
| | Temperature limitation | REF | Catalogue or model number |
| | Non-pyrogenic | | Do not re-use |
| STERILE R | Sterilized using irradiation | | Do not resterilize |
| | Do not use if package is damaged | | Caution: Read all warnings and precautions in instructions for use |
| ℞ Only | Requires prescription in the United States | | |

**Have Questions?**

If you have questions, concerns, or are in need of assistance, please call Sanofi: 1-800-633-1610.

The CirCLIQ OBDS is not made with natural rubber latex.

Manufactured for:
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Morristown, NJ 07960 USA
A SANOFI COMPANY
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Manufactured by:
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