Important Information You Need to Know Before Injecting SARCLISA SC 1400 mg / 10 mL

- See Product Monograph for information on SARCLISA SC 1400 mg / 10 mL.
- The CirCLIQ OBDS contains one single-use 10 mL On-Body Injector and one Filling Base.
- The CirCLIQ OBDS is intended for abdominal subcutaneous injection of SARCLISA SC 1400 mg / 10 mL single dose by a healthcare professional in adult patients.
- SARCLISA SC 1400 mg / 10 mL is indicated for the treatment of adult patients with multiple myeloma. The SARCLISA SC 1400 mg / 10 mL 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 SC 1400 mg / 10 mL. 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 SC 1400 mg / 10 mL. **The injection should be completed as soon as possible once the vial is punctured. If the injection is not completed within 4 hours, discard the vial and the CirCLIQ OBDS.**
- ⚠ **Do not** attempt to reapply the 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 2°C–30°C.
- Use CirCLIQ OBDS where the temperature is 18°C–28°C.

Storing SARCLISA SC 1400 mg / 10 mL vial

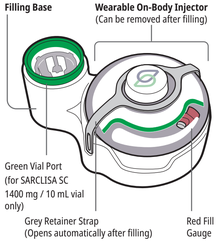
- See SARCLISA SC 1400 mg / 10 mL Product Monograph and vial carton for vial storage and handling information.

Parts of the CirCLIQ OBDS (Filling Base and Wearable On-Body Injector) and SARCLISA SC 1400 mg / 10 mL vial:

For single use only



Vial (not included in OBDS packaging)
See SARCLISA SC 1400 mg / 10 mL Product Monograph.



Part 1 Getting ready to inject SARCLISA SC 1400 mg / 10 mL

(vial packaged separately from OBDS)

1 Get and inspect vial and CirCLIQ OBDS

a. Take SARCLISA SC 1400 mg / 10 mL vial out of the refrigerator.
- **Do not** shake SARCLISA SC 1400 mg / 10 mL vial.

b. Check the vial label to make sure it is the correct medicine. The label should say "®SARCLISA® SC 1400 mg / 10 mL" and "Subcutaneous use only".



Vial cap should be green.
- **Do not** use SARCLISA SC 1400 mg / 10 mL vial if the expiration date has passed.
- The medicine in SARCLISA SC 1400 mg / 10 mL vial should be clear to slightly opalescent, colorless to slightly yellow, that may contain a few translucent to white particles.

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

d. Allow SARCLISA SC 1400 mg / 10 mL vial and CirCLIQ OBDS to come to room temperature for 20 minutes prior to use. This will minimize pain during the injection.

2 Gather supplies

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



1. Vial of SARCLISA SC 1400 mg / 10 mL (packaged separately)
2. CirCLIQ OBDS in packaging
3. Two alcohol wipes (not included in carton)
4. Single-use gloves (not included in carton)
5. Puncture-resistant 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 SC 1400 mg / 10 mL vial

a. Remove green cap from SARCLISA SC 1400 mg / 10 mL vial.



b. Wipe rubber at the top of SARCLISA SC 1400 mg / 10 mL 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 On-Body Injector from Filling Base.
- **Do not** remove the Grey Retainer Strap.

c. Discard plastic packaging.

5 Fill CirCLIQ On-Body Injector

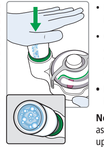
a. Confirm again the cap is removed from the SARCLISA SC 1400 mg / 10 mL vial.

b. Place SARCLISA SC 1400 mg / 10 mL vial top-first into Green Vial Port on the Filling Base.



⚠ **The injection should be completed as soon as possible once the vial is punctured. If the injection is not completed within 4 hours, discard the vial and the CirCLIQ OBDS.**

c. Firmly push SARCLISA SC 1400 mg / 10 mL vial down until a burst of bubbles quickly forms. This means filling has started.



- Leave on flat surface until filling is complete.
- Grey Retainer Strap will automatically open when SARCLISA SC 1400 mg / 10 mL vial is empty.
- **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.

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 5 cm around the belly button or in folded skin.

Note: The injection site should be rotated at least 2.5 cm 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** touch, fan, blow or let clothes touch the clean site.

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

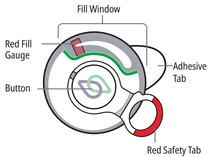
Continue to Part 4

Flip over these instructions for use.
If you have read and followed all of the instructions on this side, proceed to:
Part 4 "Preparing to inject SARCLISA SC 1400 mg / 10 mL" on the back side of this page.

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

Flip over for Parts 1-3

Get to know the CirCLIQ On-Body Injector



Underside of CirCLIQ On-Body Injector



Part 4 Preparing to inject SARCLISA SC 1400 mg / 10 mL

7 Remove the CirCLIQ On-Body Injector from Filling Base

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



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

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



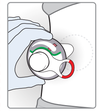
⚠ **Do not** touch the White Sticky Adhesive. The Needle is inside the center.

⚠ **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)

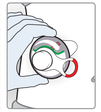
a. Position On-Body Injector where you can see the Fill Window. This allows a clear view of the Red Fill Gauge as it moves.



⚠ **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 SC 1400 mg / 10 mL

9 Remove Red Safety Tab and inject

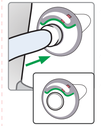
a. Hold the On-Body Injector with one hand. Use the other hand to pull the Red Safety Tab off to the side.



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 during injection.

10 Wait for injection to finish

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



- After a 1-2 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). 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 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 a puncture-resistant container or dispose according to local regulations. The On-Body Injector is a single-use device.

b. Dispose the Filling Base with attached SARCLISA SC 1400 mg / 10 mL vial in a medical disposal container in accordance with local guidance.

FAQs 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 Canada at 1-800-265-7927 for information.

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 SC 1400 mg / 10 mL.

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 Injector. Put the Injector in a puncture-resistant container. Call Sanofi Canada at 1-800-265-7927 for information.

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
	Manufacturer		Importer

Have Questions?

If you have questions, concerns, or are in need of assistance, please call Sanofi Canada: **1-800-265-7927**

Clinical Benefit:

The CirCLIQ OBDS provides hands-free administration of SARCLISA SC 1400 mg / 10 mL to the abdominal subcutaneous space which improves patient management by reducing the burden on the user.

The CirCLIQ OBDS is not made with natural rubber latex.

Imported / Distributed by:
sanofi-aventis Canada Inc.
1755 Steeles Avenue West
Toronto ON,
M2R 3T4

Manufactured By:
Enable Injections, Inc.
2863 E. Sharon Road
Cincinnati, OH 45241 USA

MANUFACTURED IN USA

Patent:
Enableinjections.com/patent

STERILE R

ISSUE DATE: SEPTEMBER 2026
10132312-C

INSTRUCTIONS FOR USE

CirCLIQ™ On-Body Delivery System for use with ®SARCLISA® SC (isatuximab) 1400 mg / 10 mL solution for subcutaneous injection Single-use CirCLIQ™ On-Body Delivery System

This Instructions for Use contains information on how to use the CirCLIQ On-Body Delivery System to inject SARCLISA SC 1400 mg / 10 mL solution for subcutaneous injection.



Read this Instructions for Use carefully before using the SARCLISA SC 1400 mg / 10 mL vial and CirCLIQ On-Body Delivery System (OBDS).