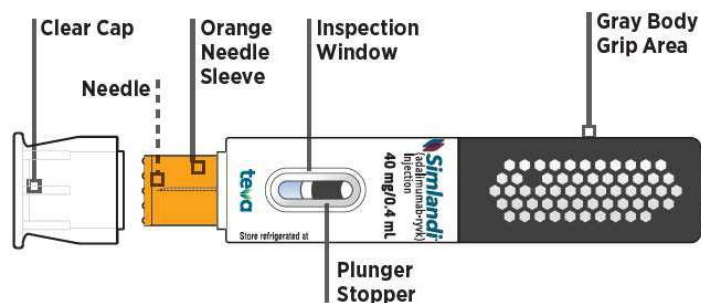


INSTRUCTIONS FOR USE

**SIMLANDI® (sim-LAN-dee)
(adalimumab-ryvk)
injection, for subcutaneous use
40 mg/0.4 mL
Single-Dose Autoinjector**

Before Injecting: Your healthcare provider should show you how to use SIMLANDI before you use it for the first time. Call your healthcare provider or **1-888-483-8279** if you have any questions.

SIMLANDI Autoinjector Parts



Important Information You Need to Know Before Injecting SIMLANDI

Do not use the Autoinjector and call your healthcare provider or pharmacist if:

- Liquid is cloudy, discolored, or has flakes or particles in it
- Expiration date has passed
- Liquid has been frozen (even if thawed) or left in direct sunlight
- The Autoinjector has been dropped or crushed

Keep the Clear Cap on until right before your injection.

How should I store SIMLANDI?

- Store SIMLANDI in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Store SIMLANDI in the original carton until use to protect it from light.
- **Do not freeze**
- Refrigerated SIMLANDI may be used until the expiration date printed on the SIMLANDI carton, dose tray or Autoinjector.
- If needed, for example when you are traveling, you may also store SIMLANDI at room temperature up to 77°F (25°C) for up to **30** days.
- Throw away SIMLANDI if it has been kept at room temperature and not used within **30** days.
- Record the date you first remove SIMLANDI from the refrigerator in the spaces provided on the carton and dose tray.
- Do not store SIMLANDI in extreme heat or cold.
- Do not drop or crush SIMLANDI. The prefilled syringe is glass.

Keep SIMLANDI, injection supplies, and all other medicines out of reach of children.

Read Instructions on All Pages Before Using the SIMLANDI Autoinjector

Step 1

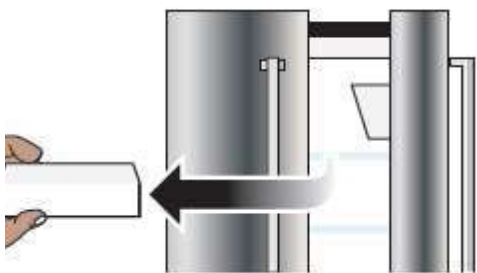


Figure A



Figure B

Take SIMLANDI out of the refrigerator (see **Figure A**).

Leave SIMLANDI at room temperature for **15 to 30 minutes** before injecting (see **Figure B**).

- **Do not** remove the Clear Cap while allowing SIMLANDI to reach room temperature.
- **Do not** warm SIMLANDI in any other way. For example, **do not** warm it in a microwave or in hot water.
- **Do not** use the Autoinjector if liquid has been frozen (even if thawed).

Step 2

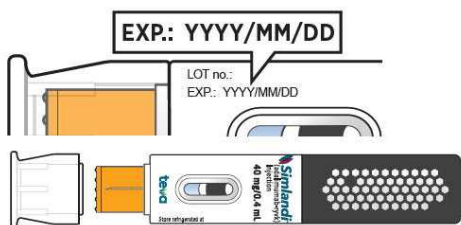


Figure C

Check expiration date on the Autoinjector label (see **Figure C**). **Do not** use the Autoinjector if expiration date has passed.

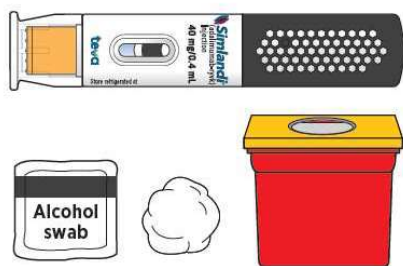


Figure D

Place the following on a clean, flat surface (see **Figure D**):

- 1 single-dose Autoinjector and alcohol swab
- 1 cotton ball or gauze pad (not included)
- Puncture-resistant sharps disposal container (not included). See Step 9 at the end of this Instructions for Use for instructions on how to throw away (dispose of) your SIMLANDI Autoinjector



Figure E

Wash and dry your hands (see **Figure E**).

Step 3

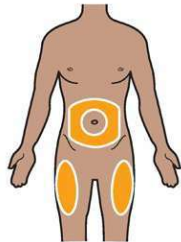


Figure F

Choose an injection site (see **Figure F**):

- On the front of your thighs **or**
- Your abdomen (belly) at least 2 inches from your navel (belly button)
- Different from your last injection site

Wipe the injection site in a circular motion with the alcohol swab (see **Figure G**). **Do not** inject through clothes



Figure G

- **Do not** inject into skin that is sore, bruised, red, hard, scarred, has stretch marks, or areas with psoriasis plaques

Step 4

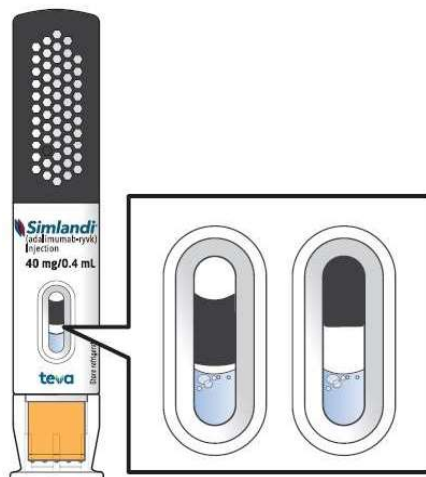


Figure H

Hold the Autoinjector with the Gray Body Grip Area facing up.

Check the window (see **Figure H**).

- It is normal to see a different plunger stopper position, from about halfway down to higher up in the inspection window
- It is normal to see 1 or more bubbles in the window
- Make sure the liquid is clear and colorless
- **Do not** use the Autoinjector if the liquid is cloudy, discolored, or has flakes or particles in it
- **Do not** use the Autoinjector if it has been dropped or crushed

Step 5



Figure I

Pull the Clear Cap straight off of the Autoinjector (see **Figure I**).

Throw the Clear Cap away.

- It is normal to see a few drops of liquid come out of the needle
- Never put the clear cap back on. It may damage the needle.

Turn the Autoinjector so that the orange needle sleeve points toward the injection site.

Step 6

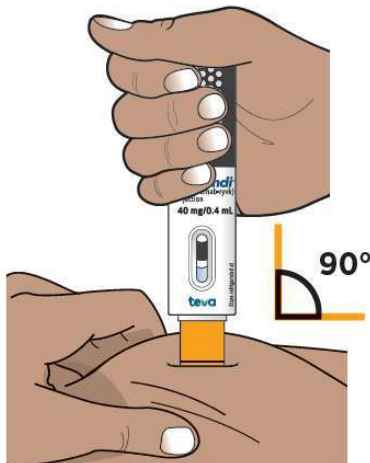


Figure J

Squeeze the skin at your injection site to make a raised area and hold it firmly until the injection is complete.

Place the orange needle sleeve straight (**90° angle**) against the injection site (see **Figure J**).

Hold the Autoinjector so that you can see the window.

Step 7

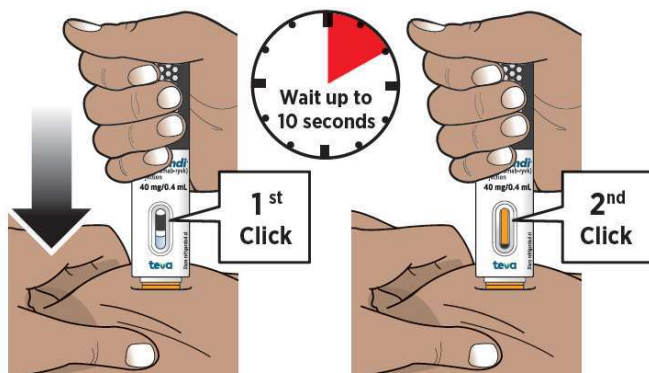


Figure K

Figure L

It is important that you firmly push the Autoinjector down all the way against the injection site.

Keep pushing the Autoinjector down during the injection (see **Figure K**).

- The first “click” will signal the start of the injection (see **Figure K**). It may take up to 10 seconds after the first ‘click’ to complete.
- Injection is complete when the orange indicator has stopped moving and you hear a second ‘click’ (see **Figure L**). Do not lift up or let go of the pressure from the injection site, until you

have confirmed the injection is complete.

Step 8

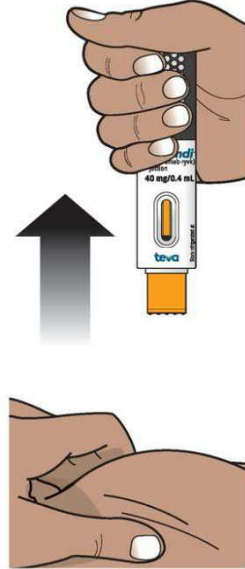


Figure M

When the injection is completed, slowly pull the Autoinjector from the skin. The orange needle sleeve will cover the needle tip (see **Figure M**).

- A small amount of liquid on the injection site is normal

If there are more than a few drops of liquid on the injection site, call **1-888-483-8279** for help.

After completing the injection, place a cotton ball or gauze pad on the skin of the injection site.

- **Do not** rub
- Slight bleeding at the injection site is normal

Step 9



Figure N

- Put your used Autoinjectors in a FDA-cleared sharps disposal container right away after use (see **figure N**). **Do not throw away (dispose of) the Autoinjector in the household trash.**
- If you do not have a 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. There may be state or local laws about how you should throw away used needles and syringes. 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>.

- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

The Clear Cap, alcohol swab, cotton ball or gauze pad, dose tray, and packaging may be placed in your household trash.

Questions About Using the SIMLANDI Autoinjector

What if I have not received in person training from a healthcare provider?

- Call your healthcare provider or visit www.SIMLANDI.com if you need help

How do I know when the injection is complete?

- The orange indicator has stopped moving and you hear a second 'click'. This takes up to **10** seconds.

What should I do if there are more than a few drops of liquid on the injection site?

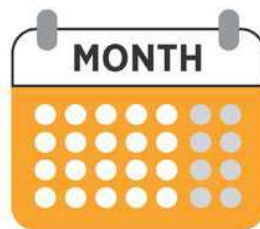
- Call **1-888-483-8279** for help

What if I do not have an FDA-cleared sharps disposal container or proper household container?

- If you do not have a 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 and 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.

Always keep the Autoinjector and the sharps disposal container out of reach of children.

Keep a record of the dates and locations of your injections. To help remember when to take SIMLANDI, mark your calendar ahead of time.



Manufactured By: **Alvotech USA Inc.**, Leesburg, VA 20175

U.S. License No. 2225

Product of Iceland

Marketed By: **Teva Pharmaceuticals**, Parsippany, NJ 07054

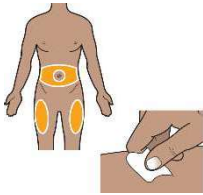
This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Revised: 11/2025

Simlandi® (adalimumab-ryvk) Injection 40 mg/0.4 mL Single-Dose Autoinjector QUICK GUIDE

Before Injecting: Your healthcare provider should show you how to use Simlandi before you use it for the first time. Call your healthcare provider or 1-888-483-8279 if you need help. Please read the Instructions for Use completely so that you understand how to properly use this device before injecting. Store autoinjector in refrigerator between 36°F to 46°F (2°C to 8°C) and keep in carton to protect from light.

Step 1 Choose and clean injection site (front of your thighs or abdomen at least 2 inches from your navel). Choose a different site each time you give yourself an injection.



Step 2 Remove clear needle cap.



Step 3 Pinch skin and position autoinjector over injection site (90° angle).



Step 4 Give injection. Press and hold down to start injection (first click will signal start of the injection).



Step 5 Keep pushing the autoinjector down against the injection site (until second click).

Viewing window is all orange when injection is complete.



Hold down against skin up to 10 seconds