



INSTRUCTIONS FOR USE

Injection, for subcutaneous use

PrSimlandi™ adalimumab injection

40mg / 0.4mL Single-Use Pen

Before Injecting

Your healthcare provider should show you how to use PrSimlandi™ before you use it for the first time.

Call your healthcare provider or 1 866-399-9091 #2 if you need help.

If you have used an adalimumab Pen (for example Humira) in the past, or other Pens that are similar to Humira, this Pen works differently from other Pens. Please read these Instructions for Use completely so that you understand how to properly use this device before injecting.

Important Information

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

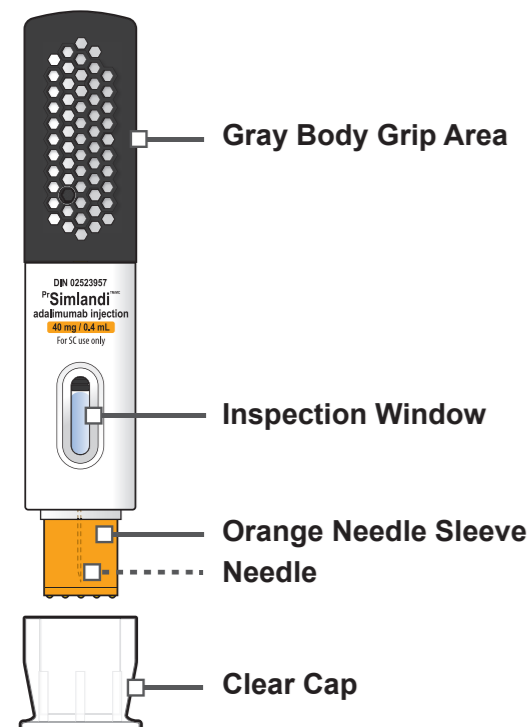
- Liquid is cloudy, discolored, or has flakes or particles in it
- Expiration date has passed
- Pen has been left in direct sunlight
- The Pen has been dropped or crushed

Keep the Clear Cap on until right before injection. Keep PrSimlandi™ out of reach of children.

Read Instructions on all pages before using the PrSimlandi™ Pen.

See the Storage Information section at the end of these instructions for how to store PrSimlandi™.

PrSimlandi™ Pen Parts



How should I store PrSimlandi™?

Store PrSimlandi™ in the original carton in the refrigerator between 36°F to 46°F (2°C to 8°C).

If needed, for example when you are traveling, you may also store PrSimlandi™ at room temperature up to 77°F (25°C) for up to **14 days**.

See the "Storage Information" section at the end of these instructions for more details.

Step 1 Take PrSimlandi™ Out of Refrigerator and Leave at Room Temperature for 15 to 30 Minutes Before Injecting

Step 1a. Take PrSimlandi™ out of the refrigerator (see Figure A).

Step 1b. Leave PrSimlandi™ at room temperature for 15 to 30 minutes before injecting (see Figure B).

Do not remove the Clear Cap while allowing PrSimlandi™ to reach room temperature.

Do not warm PrSimlandi™ in any other way. For example, **do not** warm it in a microwave or in hot water.

Do not use the Pen if liquid has been frozen (even if thawed).

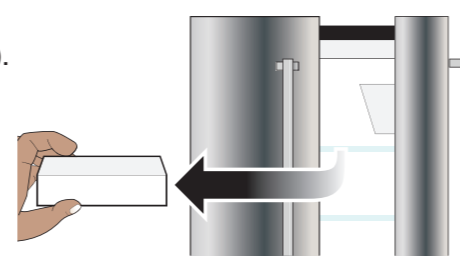


Figure A



Figure B

Step 2 Check Expiration Date, Gather Supplies and Wash Hands

Step 2a. Check expiration date on the PrSimlandi™ Pen label (see Figure C). **Do not** use the PrSimlandi™ Pen if expiration date has passed.

Step 2b. Place the following on a clean, flat surface (see Figure D):

- 1 single-use PrSimlandi™ Pen 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 on how to throw away (dispose of) your PrSimlandi™ Pen.

Step 2c. Wash and dry your hands (see Figure E).

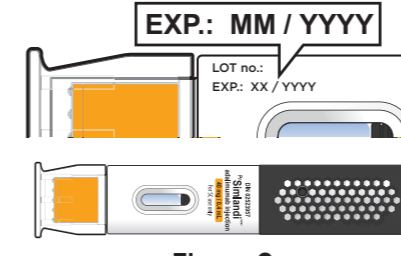


Figure C

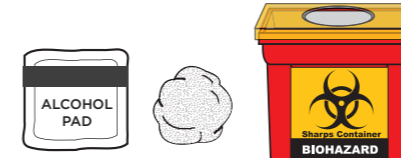


Figure D

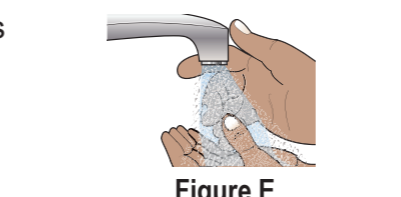


Figure E

Step 3 Choose and Clean Injection Site

Step 3a. 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)
- At least one inch from your last injection site

Step 3b. Wipe the injection site in a circular motion with the alcohol swab (see Figure G).

Do not inject through clothes.

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

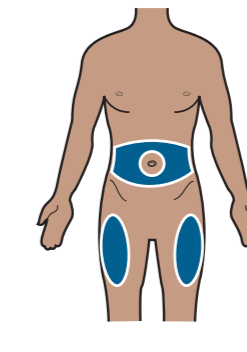


Figure F

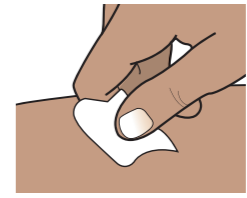


Figure G

Step 4 Check Medicine in Inspection Window

Step 4a. Hold the PrSimlandi™ Pen with the Gray Body Grip Area facing up. Check the inspection window. (see Figure H).

- It is normal to see 1 or more bubbles in the window.
- Make sure the liquid is clear and colorless.

Do not use the PrSimlandi™ Pen if the liquid is cloudy or has particles.

Do not use the PrSimlandi™ Pen if it has been dropped or crushed.

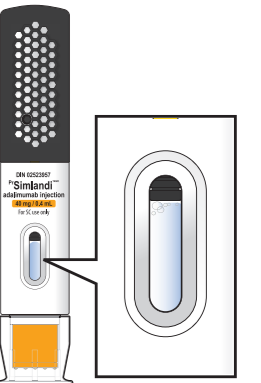


Figure H

Step 5 Remove Clear Cap

Step 5a. Pull the Clear Cap straight off (see Figure I).

It is normal to see a few drops of liquid come out of the needle.

Step 5b. Throw the Clear Cap away.

Do not put the Clear Cap back on the Pen. This may damage the needle. The Pen is ready to use after the Clear Cap has been removed.

Step 5c. Turn the PrSimlandi™ Pen so that the Orange Needle Sleeve points toward the injection site.

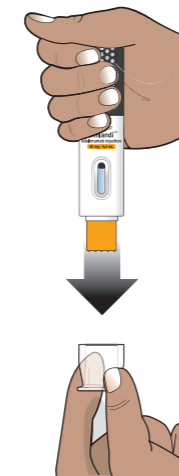


Figure I

Step 6 Pinch Skin and Position PrSimlandi™ Pen Over Injection Site

Step 6a. Squeeze the skin at your injection site to make a raised area and hold it firmly.

Step 6b. Place the orange needle sleeve straight (90° angle) against the injection site (see Figure J).

Hold the Pen so that you can see the inspection window.

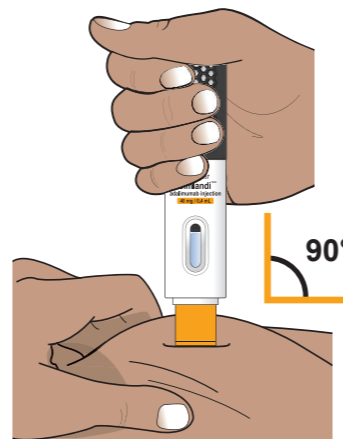


Figure J

Step 7 Give Injection

Step 7a. Push and keep pushing the Pen down against the injection site (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.
- Keep pushing the Pen down against the injection site.
- The injection is complete when the orange indicator has stopped moving and you may 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.

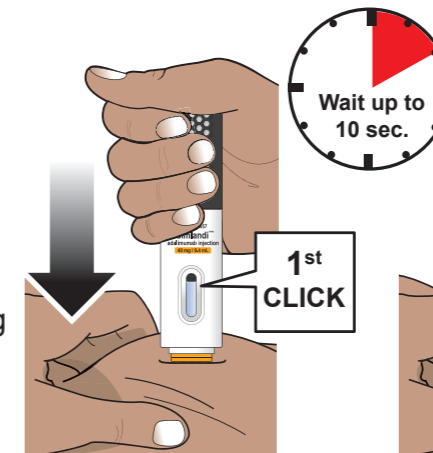


Figure K

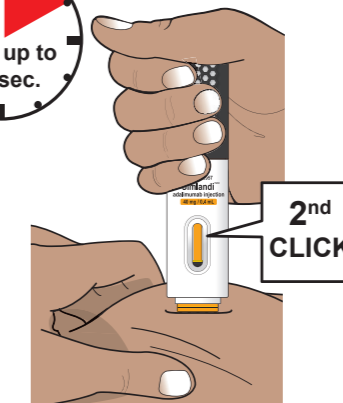


Figure L

Step 8 Remove PrSimlandi™ Pen from Skin and Care

Step 8a. When the injection is completed, slowly pull the PrSimlandi™ pen from the skin. The orange needle sleeve will cover the needle tip (see Figure M).

If there are more than a few drops of liquid on the injection site, call 1 866-399-9091 #2 for help.

Step 8b. 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.

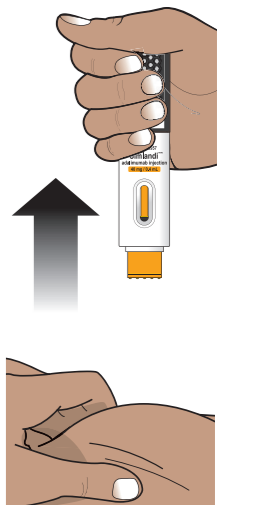


Figure M

Step 9 How Should I Dispose of the Used PrSimlandi™ Pen?

Step 9a. Put your used needles, Pens, and sharps in a biohazard safe container right away after use (see Figure N).

Do not throw away (dispose of) the Pen in the household trash.

Step 9b. The Clear Cap, alcohol swab, cotton ball or gauze pad, and packaging may be placed in your household trash.



Figure N

Additional Disposal Information

You may use a household container that is:

- made of a heavy-duty plastic,
- 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.

- **Do not** dispose of your used sharps disposal container in your household trash.
- **Do not** recycle your used sharps disposal container.

Storage Information

Store PrSimlandi™ in the original carton in the refrigerator between 36°F to 46°F (2°C to 8°C).

Store PrSimlandi™ in the original carton until use to protect it from light.

- **Do not** freeze PrSimlandi™. **Do not** use PrSimlandi™ if frozen, even if it has been thawed.
- Refrigerated PrSimlandi™ may be used until the expiration date printed on the PrSimlandi™ carton, dose tray or Pen. **Do not** use PrSimlandi™ after the expiration date.

If needed, for example when you are traveling, you may also store PrSimlandi™ at room temperature up to 77°F (25°C) for up to **14 days**. Store PrSimlandi™ in the original carton until use to protect it from light.

- Throw away PrSimlandi™ if it has been kept at room temperature and not been used within **14 days**.
- Record the date you first remove PrSimlandi™ from the refrigerator in the spaces provided on the carton and dose tray.
- **Do not** store PrSimlandi™ in extreme heat or cold.
- **Do not** use a Pen if the liquid is cloudy, discolored, or has flakes or particles in it.
- **Do not** drop or crush PrSimlandi™.
- Keep PrSimlandi™, injection supplies, and all other medicines out of the reach of children.