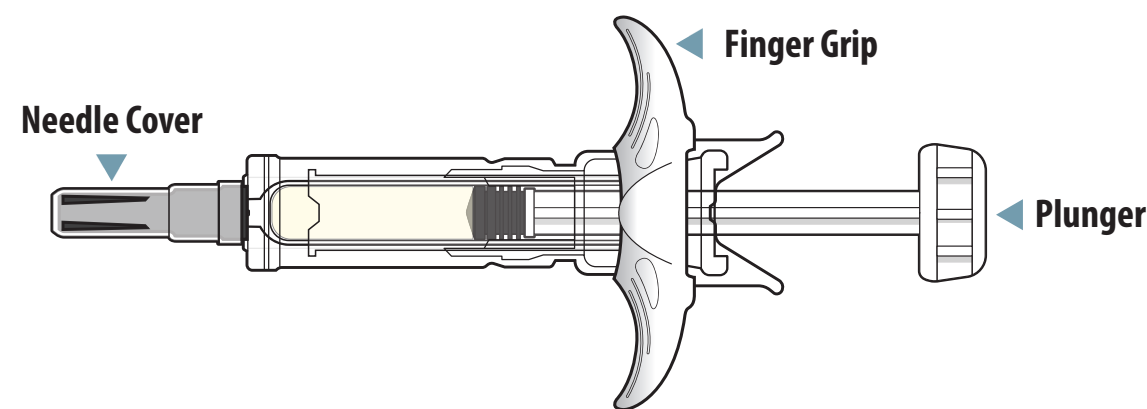


This "INSTRUCTIONS FOR USE" contains information on how to inject <sup>Pr</sup>Simlandi™.

## <sup>Pr</sup>Simlandi™ Single-Use Prefilled Syringe



## Important Information You Need to Know Before Injecting <sup>Pr</sup>Simlandi™

### Important Information:

- For subcutaneous injection only.
- **Do not** use the syringe 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 prefilled syringe has been dropped or crushed
- Keep the needle cover on until right before injection. Keep <sup>Pr</sup>Simlandi™ out of reach of children.
- See the Storage Information section at the end of these instructions for how to store <sup>Pr</sup>Simlandi™.
- Read these instructions for use before using the <sup>Pr</sup>Simlandi™ single-use prefilled syringe.

### Before Use:

Your healthcare provider should show you how to use <sup>Pr</sup>Simlandi™ before you use it for the first time. Call your healthcare provider or 1 866-399-9091 #2 if you need help.

### Current Adalimumab Syringe Users (e.g., Humira®):

Even if you have used the Humira® (adalimumab) syringe in the past, or other syringes on the market, please read the instructions completely so that you understand how to properly use this device before attempting to inject.

### Questions about using the <sup>Pr</sup>Simlandi™ Single-Use prefilled Syringe?

If you have any questions contact your healthcare provider, pharmacist or call 1 866-399-9091 #2 for help.

## Preparing to Inject <sup>Pr</sup>Simlandi™

### STEP 1 Take Syringe Out of Refrigerator and Warm to Room Temperature for 15-30 Minutes

- 1.1 Take <sup>Pr</sup>Simlandi™ out of the refrigerator (see Figure A).
- 1.2 Leave <sup>Pr</sup>Simlandi™ at room temperature for 15 to 30 minutes before injecting (see Figure B).

- **Do not** remove the gray needle cover while allowing <sup>Pr</sup>Simlandi™ to reach room temperature.
- **Do not** warm <sup>Pr</sup>Simlandi™ in any other way. For example, **do not** warm it in a microwave or in hot water.
- **Do not** use the prefilled syringe if liquid has been frozen (even if thawed).

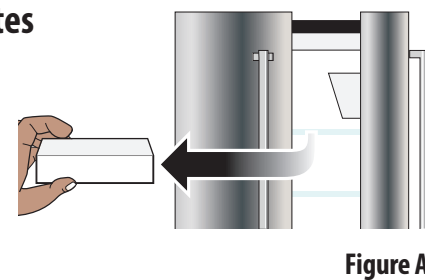


Figure A



Figure B

### STEP 2 Check Expiration Date and Liquid Drug

- 2.1 Check expiration date on the prefilled syringe label (see Figure C).
  - **Do not** use the prefilled syringe if expiration date has passed.
- 2.2 Check the liquid drug in the syringe to ensure it is clear and colorless (Figure C).
  - **Do not** use the syringe and call your healthcare provider or pharmacist if: Liquid is cloudy, discolored, or has flakes or particles in it.

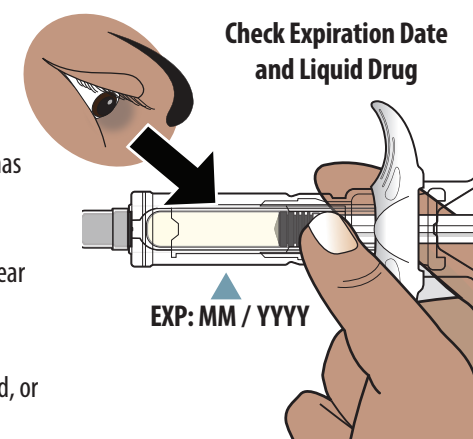


Figure C

### STEP 3 Gather Supplies and Wash Hands

- 3.1 Place the following on a clean, flat surface (see Figure D):
  - 1 single-use prefilled syringe and alcohol swab
  - 1 cotton ball or gauze pad (not included)
  - Puncture-resistant sharps disposal container (not included). See Step 9.
- 3.2 Wash and dry your hands (see Figure E).

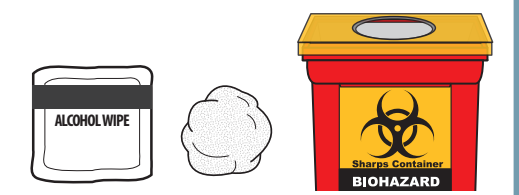


Figure D

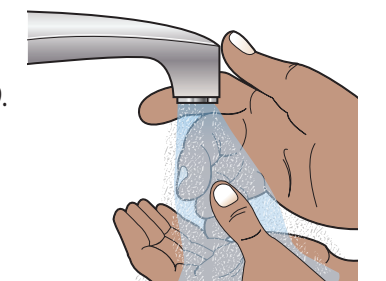


Figure E

## Injecting <sup>Pr</sup>Simlandi™

### STEP 4 Choose and Clean Injection Site

- 4.1 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 (at least one inch from last injection site).
- 4.2 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.

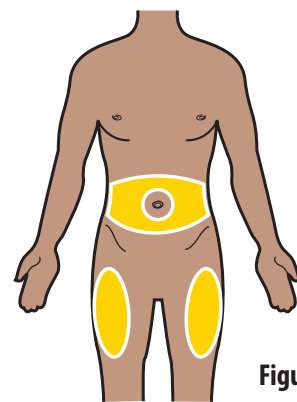


Figure F



Figure G

### STEP 5 Remove Needle Cover

- 5.1 Hold the prefilled syringe in one hand (see Figure H).
- 5.2 Gently pull the needle covers straight off with the other hand (see Figure H).
  - Throw the needle cover away.
  - **Do not** recap.
  - **Do not** touch the needle with your fingers or let the needle touch anything.
  - You may see a drop of liquid at the end of the needle. This is normal.

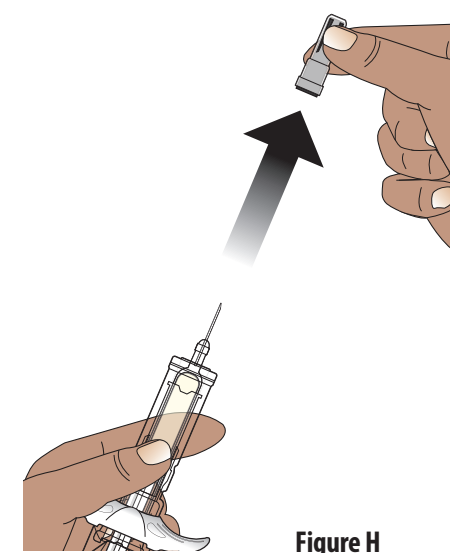


Figure H

### STEP 6 Grasp the Syringe and Pinch the Skin

- 6.1 Hold the body of the prefilled syringe in one hand between the thumb and index fingers, like a pencil (see Figure I). Do not pull back on the plunger at any time.
- 6.2 Gently squeeze (pinch) the area of cleaned skin at your injection site with your other hand (see Figure J). Hold the skin firmly.

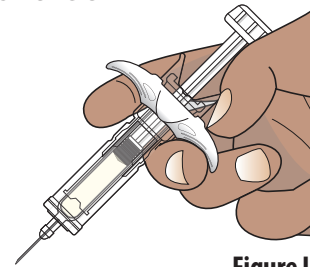


Figure I

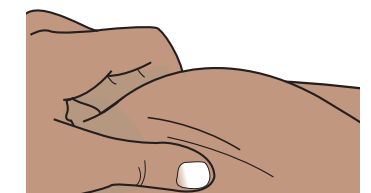


Figure J

### STEP 7 Inject the Drug

- 7.1 Insert the needle into the pinched skin at about a 45-degree angle using a quick, dart-like motion (see Figure K).
- 7.2 Slowly push the plunger all the way in until all of the liquid is injected, and the prefilled syringe is empty (see Figure L).

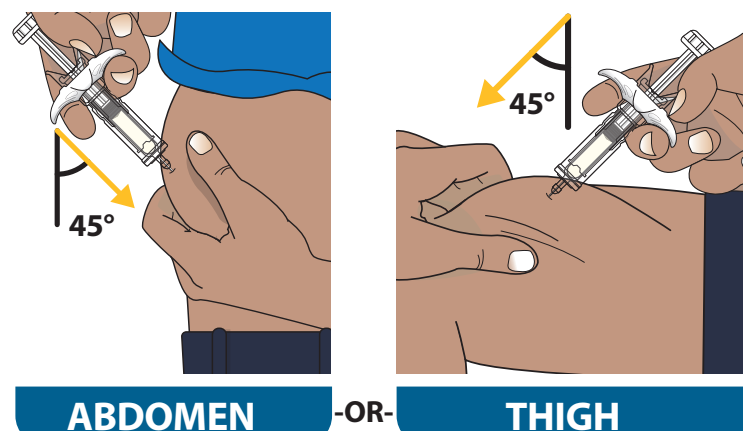
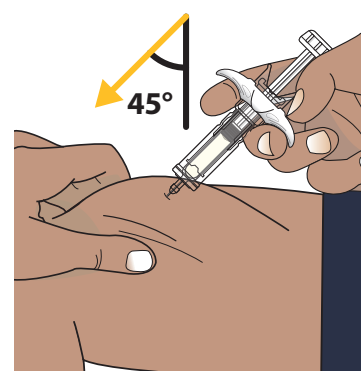


Figure K



THIGH

Figure L

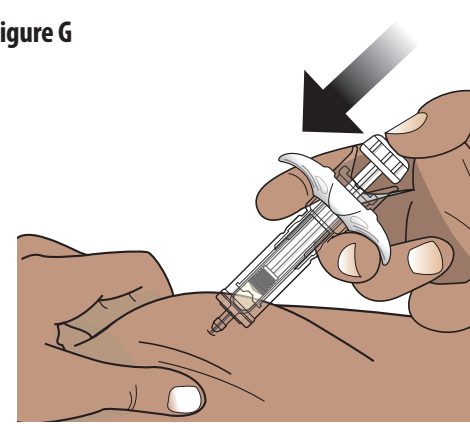


Figure M

### STEP 8 Allow Prefilled Syringe To Retract Needle from Skin

- 8.1 Slowly lift your finger from the plunger. The plunger will move up with your finger and retract the needle from the site, into the needle guard (see Figure M).
  - The needle will not be retracted unless all the liquid is injected. Speak to your doctor, pharmacist or nurse if you think you have not given a full dose.
  - It is normal to see a spring around the plunger rod after the needle is retracted.
- 8.2 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.

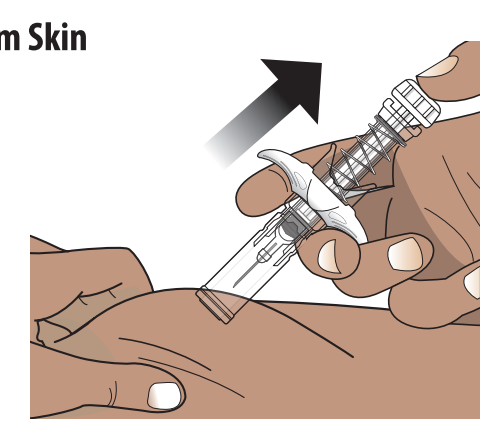


Figure N

## Disposing of <sup>Pr</sup>Simlandi™

### STEP 9 Dispose Used Syringe into a biohazard safe container

- 9.1 Put your used needles, syringes, and sharps in a biohazard safe container right away after use (see Figure N).
  - **Do not** throw away (dispose of) loose needles and syringes in the household trash.
- 9.2 The needle cover, 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.

## Storing <sup>Pr</sup>Simlandi™

- Store <sup>Pr</sup>Simlandi™ in the refrigerator between 2°C to 8°C (36°F to 46°F). Store <sup>Pr</sup>Simlandi™ in the original carton until use to protect it from light.
  - **Do not** freeze <sup>Pr</sup>Simlandi™. **Do not** use <sup>Pr</sup>Simlandi™ if frozen, even if it has been thawed.
  - Refrigerated <sup>Pr</sup>Simlandi™ may be used until the expiration date printed on the <sup>Pr</sup>Simlandi™ carton, dose tray or prefilled syringe. **Do not** use <sup>Pr</sup>Simlandi™ after the expiration date.
- If needed, for example when you are traveling, you may also store <sup>Pr</sup>Simlandi™ at room temperature up to 77°F (25°C) for up to 14 days. Store <sup>Pr</sup>Simlandi™ in the original carton until use to protect it from light.
  - Throw away <sup>Pr</sup>Simlandi™ if it has been kept at room temperature and not been used within 14 days.
  - Record the date you first remove <sup>Pr</sup>Simlandi™ from the refrigerator in the spaces provided on the carton and dose tray.
- **Do not** store <sup>Pr</sup>Simlandi™ in extreme heat or cold.
- **Do not** use a prefilled syringe if the liquid is cloudy, discolored, or has flakes or particles in it.
- **Do not** drop or crush <sup>Pr</sup>Simlandi™. The prefilled syringe is glass.
- Keep <sup>Pr</sup>Simlandi™, injection supplies, and all other medicines out of the reach of children.