

**Patient Instructions for Use
SIMPONI[®] (SIM-po-nee)
(golimumab)
SmartJect[®] autoinjector**

If your doctor decides that you or a caregiver may be able to give your injections of SIMPONI at home, you should receive training on the right way to prepare and inject SIMPONI. **Do not** try to inject SIMPONI yourself until you have been shown the right way to give the injections by your doctor or nurse.

It is important to read, understand, and follow these instructions so that you inject SIMPONI the right way. Call your doctor if you or your caregiver has any questions about the right way to inject SIMPONI.

Important information about your SmartJect autoinjector:

- **When the button on the SmartJect autoinjector is pressed to give the dose of SIMPONI you will hear a loud 'click' sound.** It is very important that you practice injecting SIMPONI with your doctor or nurse so that you are not startled by this click when you start giving the injections to yourself at home.
- If you pull the SmartJect autoinjector away from the skin before the injection is completed, you may not get your full dose of medicine and may lose some of the medicine. The injection will be completed when you hear a second click.

Do not:

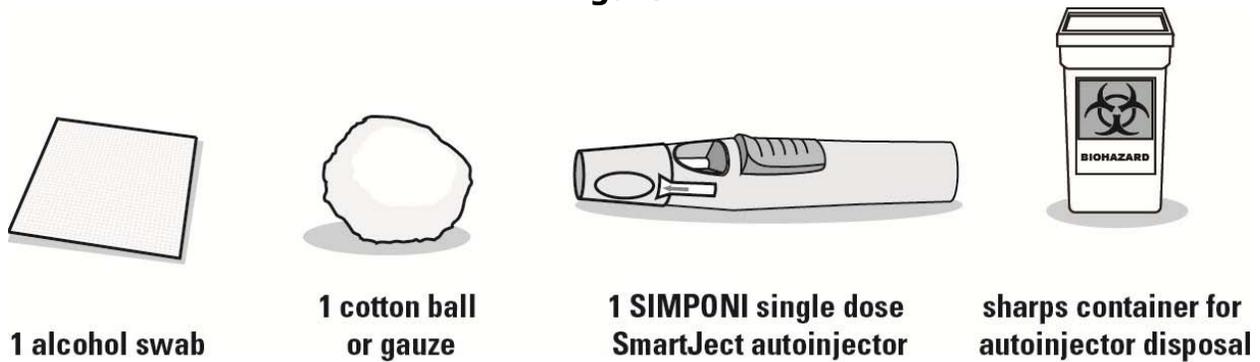
- shake the SmartJect autoinjector at any time
- remove the SmartJect autoinjector cap until you get to that step

Step 1: Gather and inspect the supplies for your injection

You will need these supplies for an injection of SIMPONI. See Figure A.

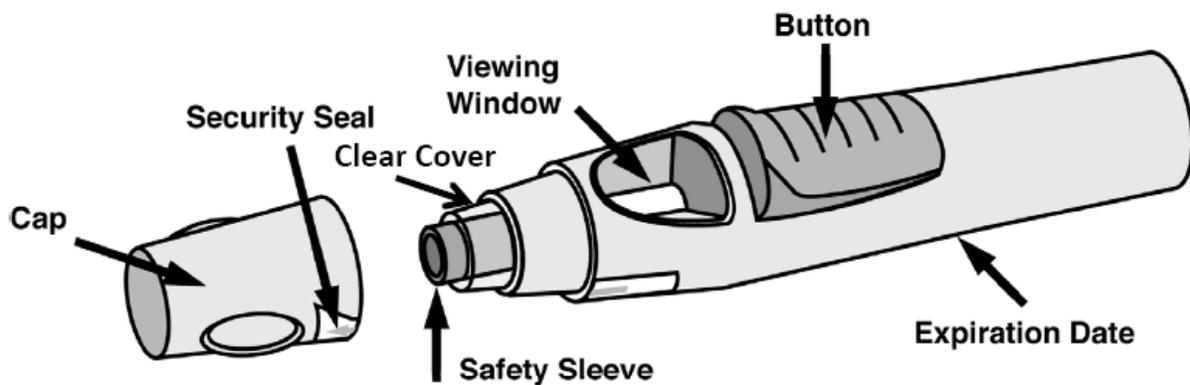
- 1 alcohol swab
- 1 cotton ball or gauze
- 1 SIMPONI prefilled SmartJect autoinjector from the refrigerator (stored at 36°F to 46°F (2°C to 8°C))
- 1 sharps container for throwing away the used autoinjector. See "**4.2 Disposal of the used SmartJect autoinjector**" at the end of these instructions.

Figure A



The figure below shows what the SmartJect autoinjector looks like. See Figure B.

Figure B



1.1 Check Expiration Date

- Check the expiration date ("EXP") on the SmartJect autoinjector.
- You can also check the expiration date printed on the back panel of the SIMPONI carton, to the left of the SIMPONI logo.
- If the expiration date has passed, **do not** use the SmartJect autoinjector. Call your doctor or pharmacist, or call 1-800-JANSSEN (1-800-526-7736) for help.

1.2 Check Security Seal

- Check the security seal around the cap of the SmartJect autoinjector. If the security seal is broken, **do not** use the SmartJect autoinjector.

1.3 Wait 30 minutes

- To ensure proper injection, allow the autoinjector to sit at room temperature outside the carton for 30 minutes and out of the reach of children.



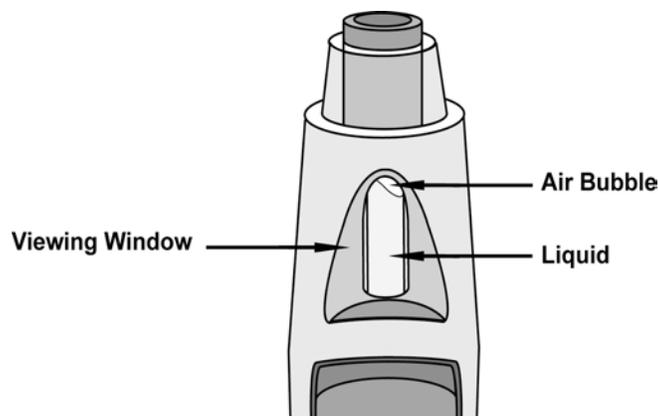
Do not warm the SmartJect autoinjector in any other way (for example, **do not** warm it in a microwave or in hot water).

Do not remove the SmartJect autoinjector cap while allowing it to reach room temperature.

1.4 Check the Liquid in the SmartJect autoinjector

- Look through the viewing window of the SmartJect autoinjector. See Figure C. Make sure that the liquid in the prefilled syringe is clear and colorless to slightly yellow in color. You may see a small amount of tiny particles that are white, or that you can see through. **Do not** inject the liquid if it is cloudy or discolored, or has large particles in it.
- You may also notice an air bubble. This is normal. See Figure C.

Figure C

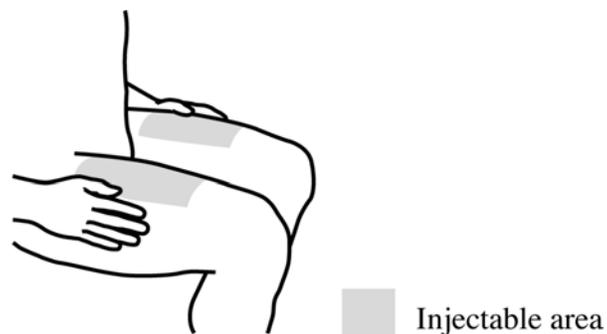


Step 2: Choose and prepare the injection site

2.1 Choose the Injection Site

- The recommended injection site is the front of your middle thighs. See Figure D.

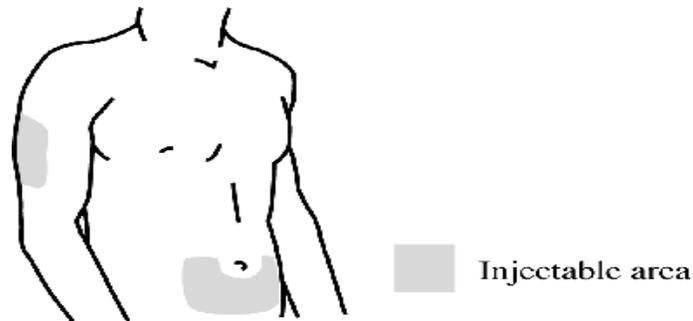
Figure D



- You can also use the lower part of the abdomen below the navel (belly button), except for the two-inch area directly around the navel. See Figure E.

- If a caregiver is giving you the injection, the outer area of the upper arms may also be used. See Figure E.

Figure E



- **Do not** inject into areas where the skin is tender, bruised, red, scaly, or hard. Avoid areas with scars or stretch marks.

2.2 Prepare the Injection Site

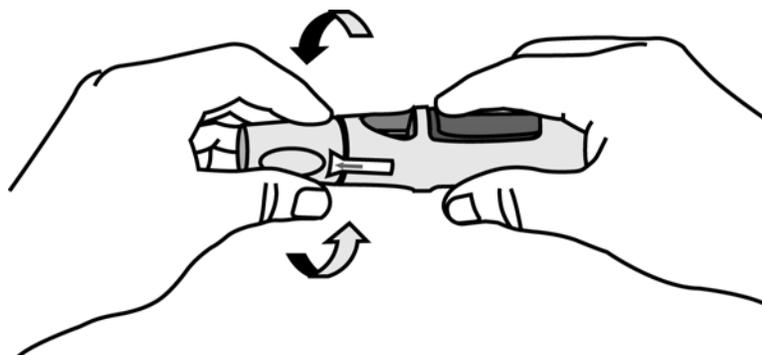
- Wash your hands well with soap and warm water.
- Wipe the injection site with an alcohol swab.
- **Do not** touch this area again before giving the injection. Allow the skin to dry before injecting.
- **Do not** fan or blow on the clean area.

Step 3: Injecting SIMPONI using the single dose SmartJect autoinjector

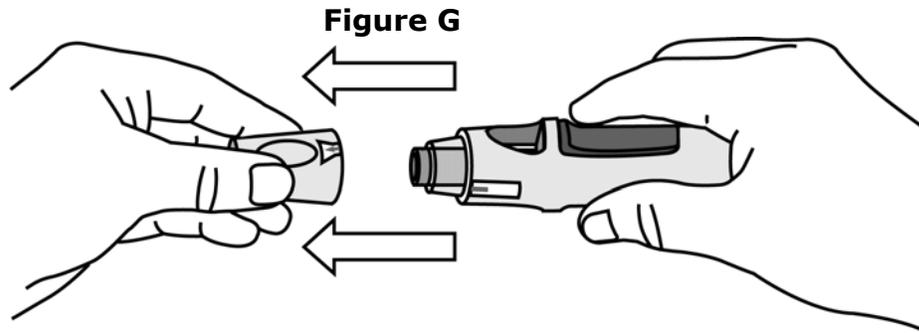
3.1 Remove the Cap

- **Do not** remove the cap until you are ready to inject SIMPONI. Inject SIMPONI within 5 minutes after the cap has been removed.
- When you are ready to inject, twist the cap slightly to break the security seal. See Figure F.

Figure F



- Pull the cap off and throw it in the trash right away. See Figure G.



- **Do not** put the cap back on because it may damage the needle inside the SmartJect autoinjector.
- **Do not** use your SmartJect autoinjector if it is dropped without the cap in place.

3.2 Push the open end of the SmartJect autoinjector firmly against the skin.

- Hold the SmartJect autoinjector comfortably in your hand. **Do not** press the button at this time.
- Choose from 2 injection methods.
 - You should inject the medicine without pinching the skin (Figure H).
 - If you prefer, you may pinch the skin to create a firmer surface for your injection (Figure I).
- Push the open end of the SmartJect autoinjector firmly against the skin at a **90-degree angle** until the safety sleeve slides fully into the clear cover. See Figure J.

Figure H
Injection without pinching

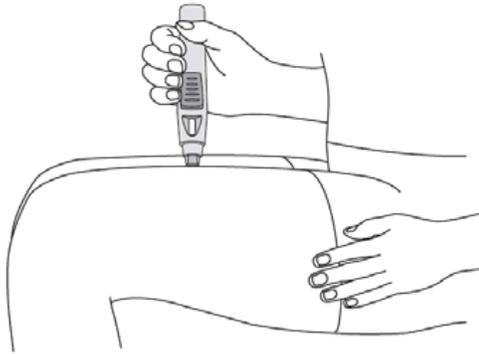


Figure I
Injection with pinching

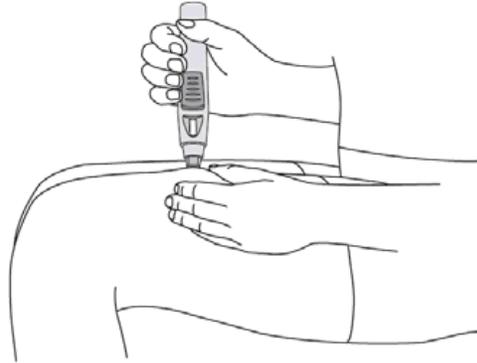
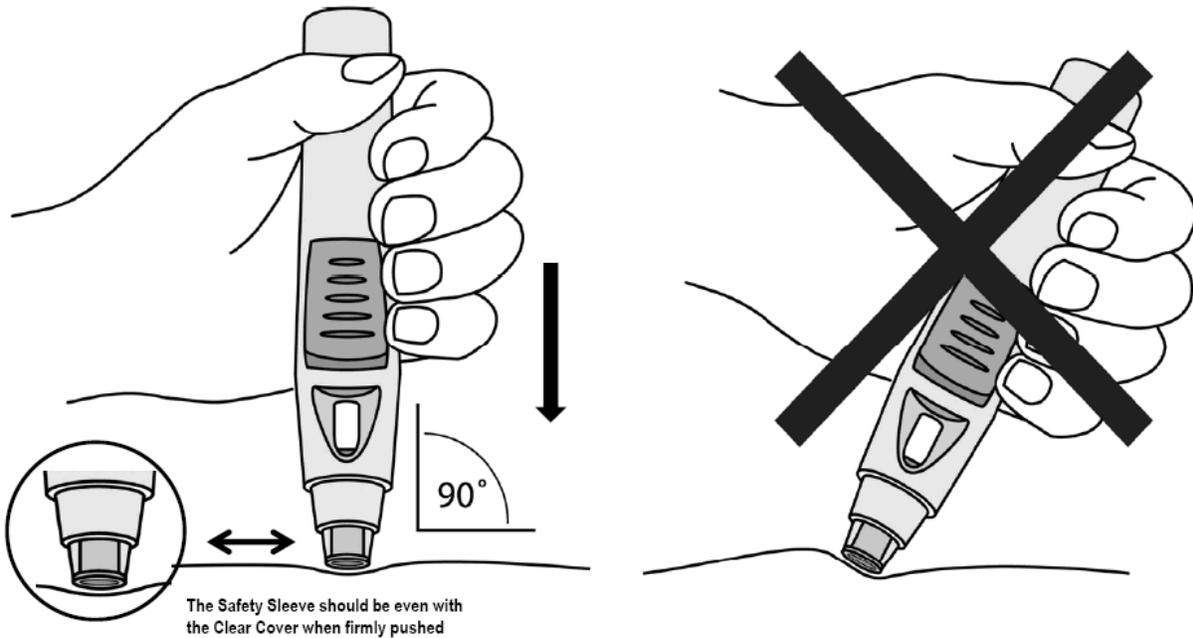


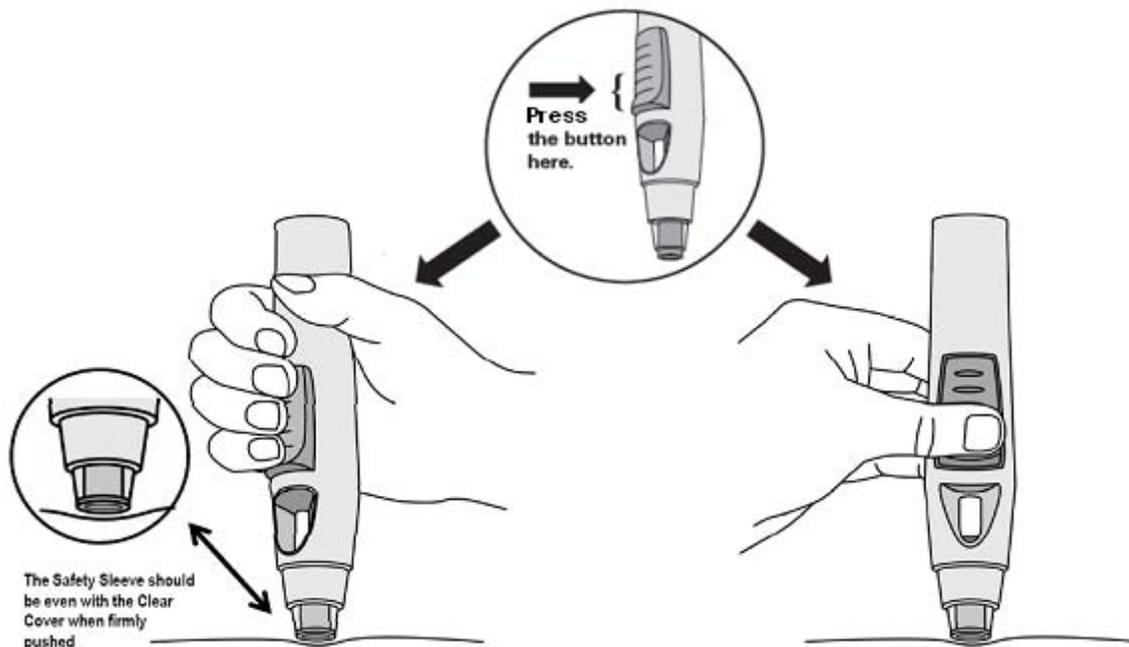
Figure J



3.3 Press button to inject

- **Continue to hold the SmartJect autoinjector firmly against the skin, and press the front raised part of the button with your fingers or thumb. See Figure K.** You will not be able to press the button unless the SmartJect autoinjector is pushed firmly against your skin and the safety sleeve slides into the clear cover.

Figure K



- After the button is pressed, it will stay pressed in so you **do not** need to keep pressure on it.

- **You will hear a loud 'click' sound – don't be alarmed.** This 'click' indicates that the needle has been inserted and the injection has started. You may or may not feel a needle prick at this time. **Do not pull the SmartJect autoinjector away from your skin. If you pull the SmartJect autoinjector away from the skin, you may not get your full dose of medicine. See Figure L.**
- **Do not** lift the SmartJect autoinjector yet.

3.4 Wait for Second "Click"

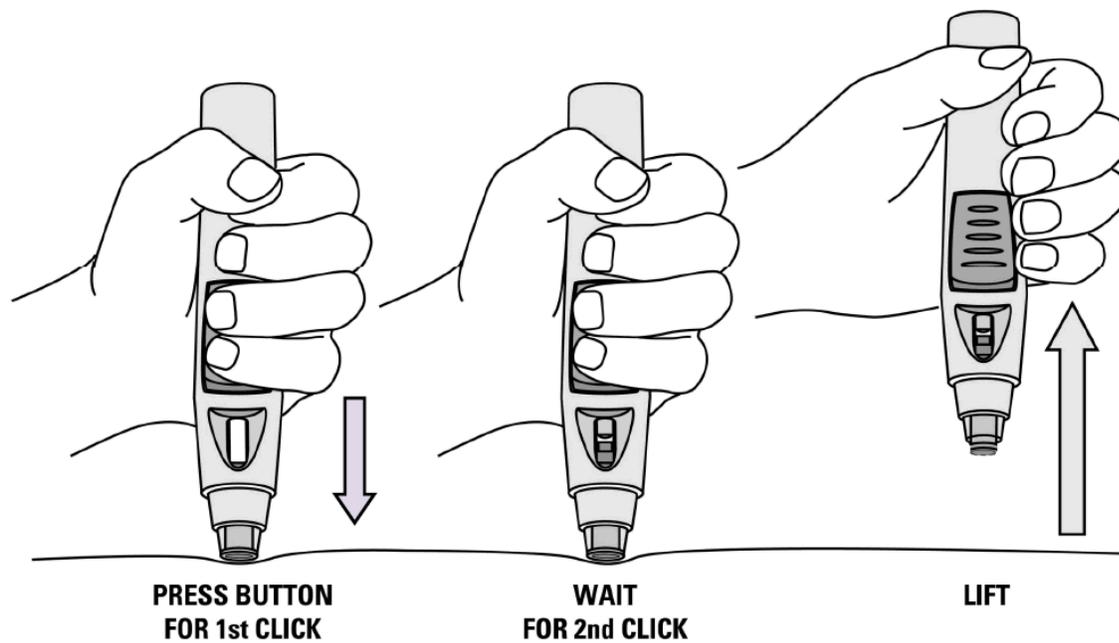
Keep holding the SmartJect autoinjector against your skin until you hear the second 'click' sound. It usually takes about 3 to 6 seconds, but may take up to 15 seconds for you to hear the second 'click' sound. See Figure M.

- The second 'click' sound means that the injection is finished and the needle has pulled back (retracted) into the SmartJect autoinjector.
- Lift the SmartJect autoinjector from the injection site. See Figure N.
- If you have hearing problems, count for 15 seconds from the time you pressed the button and then lift the SmartJect autoinjector from the injection site.

Figure L

Figure M

Figure N

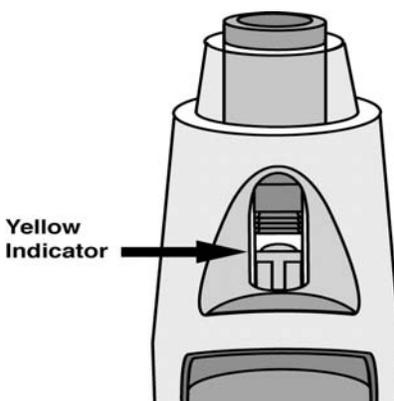


Step 4: After the injection

4.1 Check the Viewing Window

- After you finish injecting, check the viewing window to see the yellow indicator. See Figure O. This means the SmartJect autoinjector has worked the right way.

Figure O



- If you do not think you received your injection, check the yellow indicator again to confirm that the dose was delivered.
- If you do not see the yellow indicator in the viewing window, call 1-800-JANSSEN (1-800-526-7736) for help. **Do not** administer a second dose without speaking to your doctor.

4.2 Disposal of the used SmartJect autoinjector

- Put your used SmartJect autoinjector in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) the SmartJect autoinjector in your household trash. See Figure P.**
- 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.

Figure P



4.3 Use Cotton Ball or Gauze

- There may be a small amount of blood or liquid at the injection site, which is normal.
- You can press a cotton ball or gauze over the injection site for 10 seconds. **Do not** rub the injection site.
- You may cover the injection site with a small adhesive bandage, if needed.

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

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