

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 before using the SIMPONI SmartJect autoinjector so you inject the right way. Call your doctor if you or your caregiver has any questions about the right way to inject SIMPONI.

Read this information before you start

Important things to know about your SmartJect autoinjector

When you are ready to inject SIMPONI, position the autoinjector straight onto your skin (90 degrees), then push firmly. **Do not press the button until you have pushed the autoinjector firmly against your skin, allowing the green safety sleeve to slide into the clear cover.**

The green safety sleeve (see Figure A) helps prevent accidental injections. The sleeve must slide into the clear cover before you will be able to press the button.

When the button is pressed you will hear a loud first 'click' sound. **Do not lift the autoinjector away from your skin. Hold and wait for the second 'click'.** It is very important to practice injecting SIMPONI with your doctor or nurse so you become comfortable with this 'click' sound.

Keep holding the autoinjector firmly against your skin until you hear a second 'click' sound (may take 3-15 seconds), then lift the autoinjector. The injection is complete when you hear the second 'click'. If you lift the autoinjector before hearing the second 'click', you may not get the full dose of medicine.

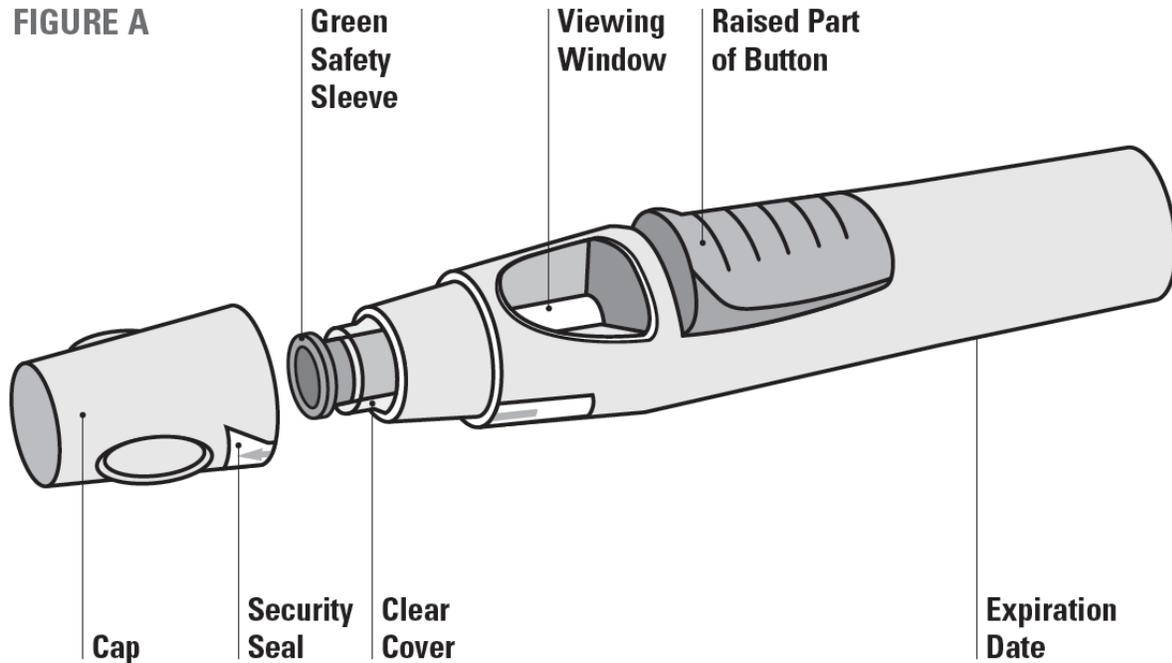
Important things to remember

- **Do not** remove the cap until you get to Step 3.1.
- **Do not** press the button until you get to Step 3.3.
- **Do not** shake the SmartJect autoinjector at any time.

Read all instructions below before using SmartJect autoinjector

Figure A below shows what the SmartJect autoinjector looks like.

FIGURE A



STEP 1. Gather and inspect the supplies for your injection

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

- 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 disposal container for throwing away the used SmartJect autoinjector. See Step 4.2 for disposal instructions.

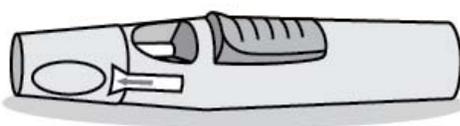
FIGURE B



1 alcohol swab



1 cotton ball or gauze



1 SIMPONI single use SmartJect autoinjector



Sharps container for autoinjector disposal

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

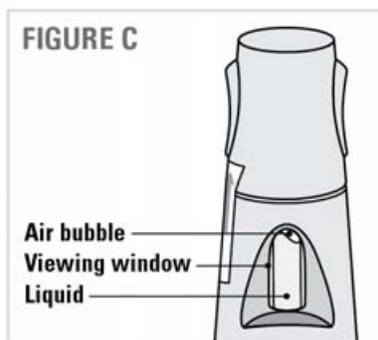
- To ensure proper injection, allow the autoinjector to sit at room temperature outside the carton for 30 minutes and out of the reach of children.
- **Do not** warm the SmartJect autoinjector in any other way (for example, **do not** warm it in a microwave or in hot water).



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

1.4 Check the liquid in the SmartJect autoinjector

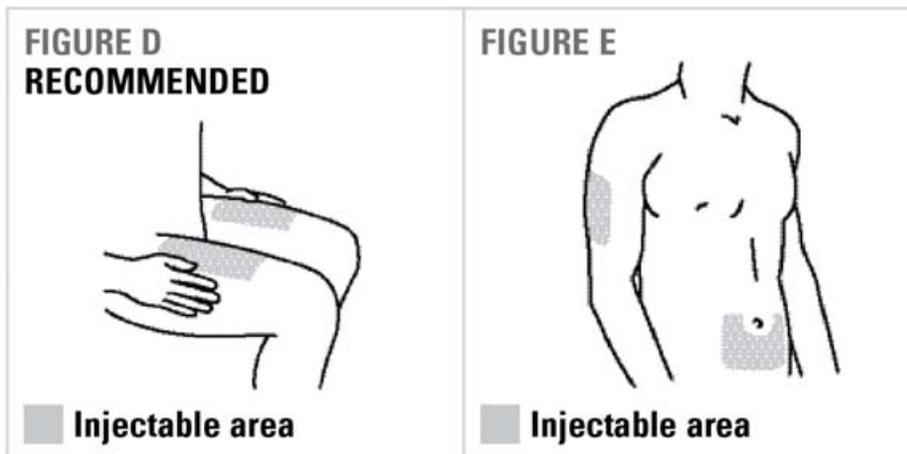
- Look through the viewing window of the SmartJect autoinjector. See Figure C.
- Make sure that the liquid in the prefilled syringe is clear and colorless to slightly yellow in color. You may see a small amount of tiny particles that are white, or that you can see through.
- **Do not** inject the liquid 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.



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.
- 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.



- If more than one injection is needed for a dose of SIMPONI, each injection should be given at different sites on the body.
- Choose a different injection area each time you give your injection. See Figures D and E.
- **Do not** inject into areas where the skin is tender, bruised, red, scaly, or hard. Avoid areas with scars or stretch marks.

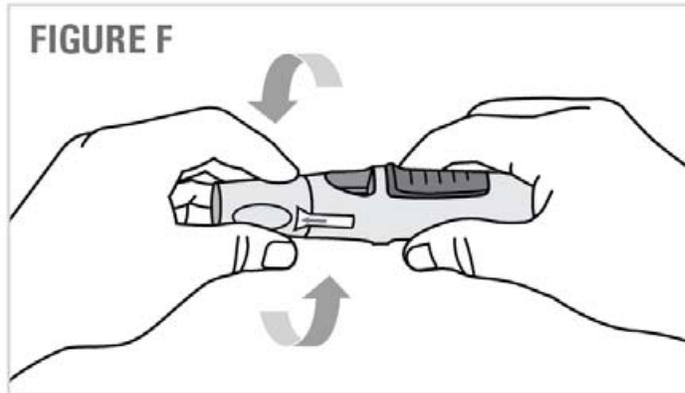
2.2 Prepare the injection site

- 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.

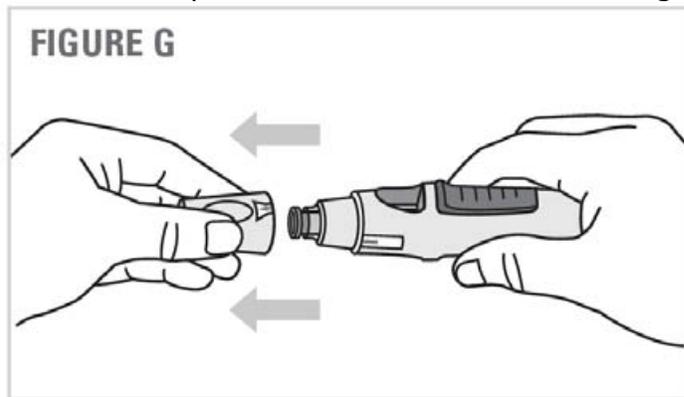
STEP 3. Inject SIMPONI using the single dose SmartJect autoinjector

3.1 Remove 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.



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



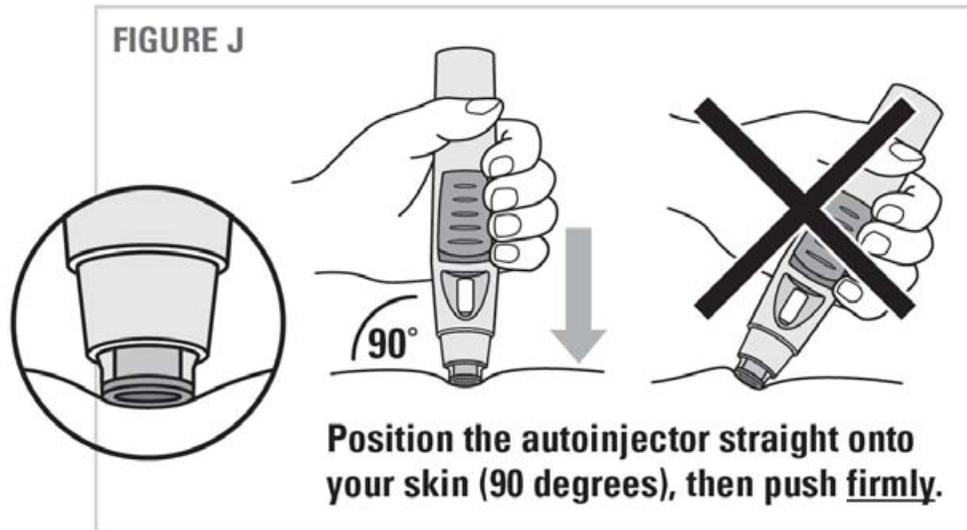
- **Do not** put the cap back on because it may damage the needle inside the SmartJect autoinjector.
- **Do not** use your SmartJect autoinjector if it is dropped without the cap in place.

3.2 Push autoinjector firmly against 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. See Figure H.



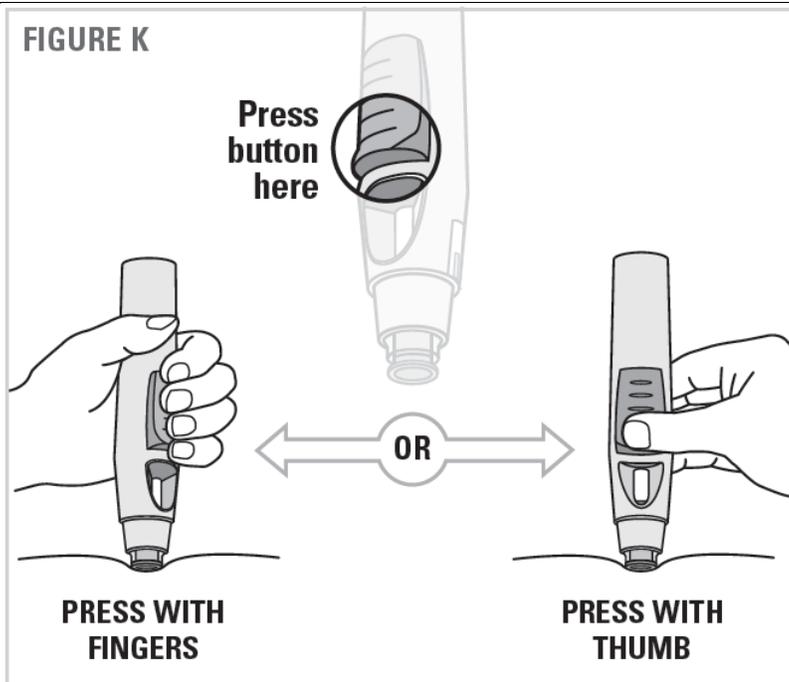
- If you prefer, you may pinch the skin to create a firmer surface for your injection.
See Figure I.
- Position the **open end** of the SmartJect autoinjector **straight onto your skin** (90 degrees) and **push firmly** until the green safety sleeve slides into the clear cover. See Figure J.



3.3 Press button to inject. Hold and wait!

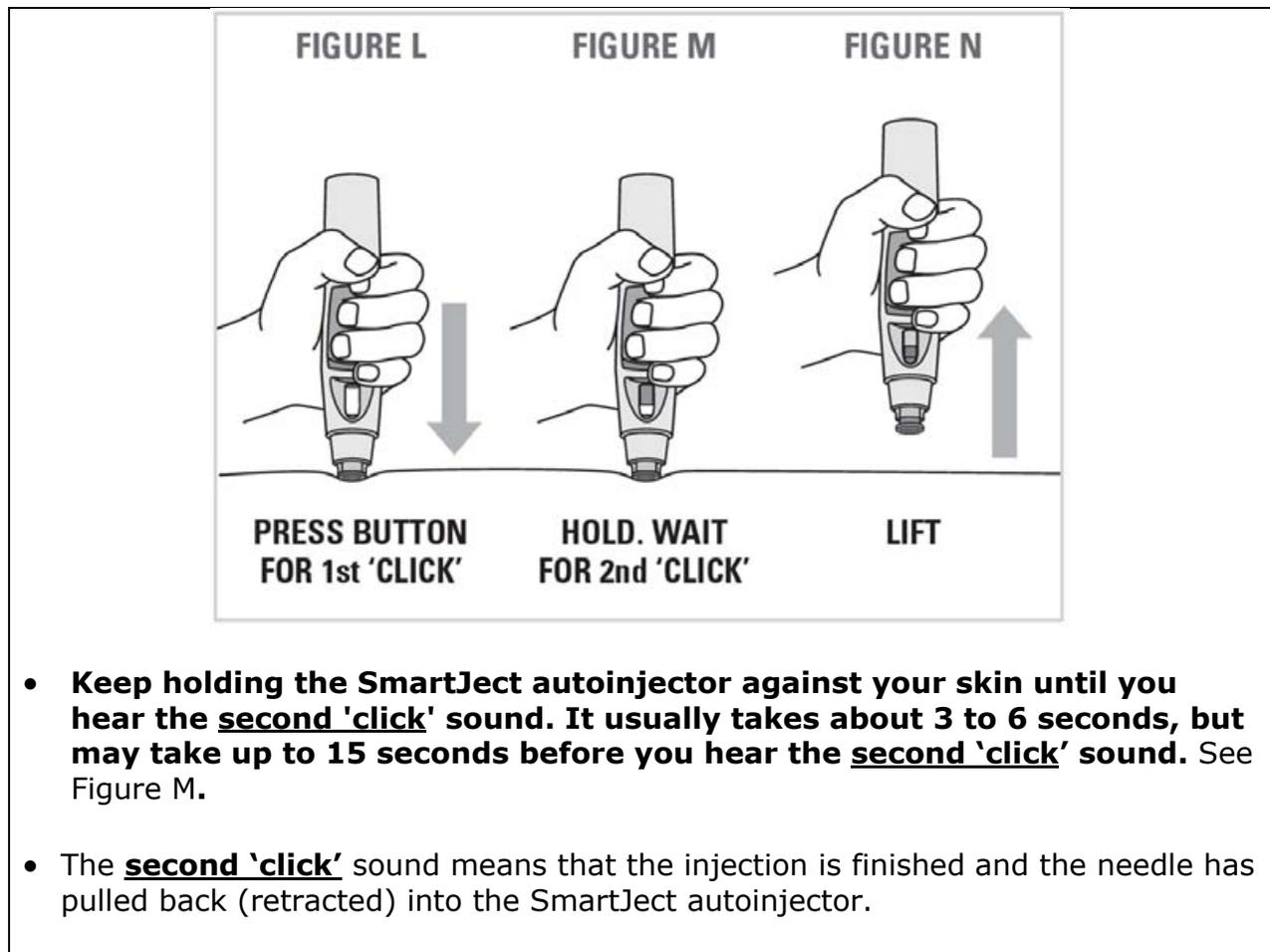
- **Continue to hold the SmartJect autoinjector firmly against the skin, and press the raised part of the button with your fingers or thumb.**
See Figure K.

NOTE: You will not be able to press the button unless the autoinjector is pushed firmly against your skin and the green safety sleeve slides into the clear cover.



- 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 first 'click' sound, do not be alarmed.** This is normal. This 'click' means that the needle has been inserted and the injection has started. You may or may not feel a needle prick at this time. See Figure L.
- **Do not lift the SmartJect autoinjector away from your skin until you hear the second loud 'click'.** If you lift the autoinjector before the second 'click', you may not get your full dose of medicine. See Figure M.

3.4 Wait for second 'click' (3-15 seconds)

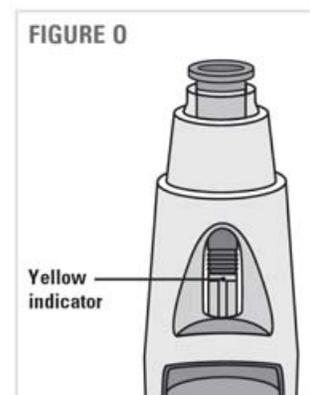


- Lift the SmartJect autoinjector from the injection site. See Figure N.
- If you have a problem hearing the 'clicks', count for 15 seconds from the time you pressed the button and then lift the SmartJect autoinjector from the injection site.

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.
- The yellow indicator will fill about half of the viewing window. This is normal.
- 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 Dispose 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.



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.
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Need more help with your injection?

Quick Reminders

Do not press the button until you are ready to inject SIMPONI.

Position the autoinjector straight onto your skin (90 degrees), then push firmly.

Press the raised part of the button to start the injection and listen for the **first 'click'**. **Do not** lift the SmartJect autoinjector away from your skin yet.

Keep holding the autoinjector firmly against your skin until you hear the **second 'click'**, or you can count to 15 after pressing the button.

Lift and check the viewing window to confirm that you see the yellow indicator.

If you're having difficulty injecting:

- Make sure you removed and disposed of the cap.
- Make sure you **do not** press the button while positioning and pushing the autoinjector firmly against your skin.
- Try pushing the autoinjector against your skin more firmly.
- Try using two hands to inject. Use your other hand to steady the autoinjector.
- Make sure you press the raised part of the button. See Figure K.
- Try pressing the button with a little more force.
- Make sure your injection site is flat. If you are using the "pinching technique," try pinching less skin.
- Try a different injection site. See Figures D and E.

For additional questions or assistance, or to share your feedback, call 1-800-JANSSEN (1-800-526-7736).

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

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