

INSTRUCTIONS FOR USE

SIMPONI® (SIM-po-nee) (golimumab) SmartJect® injector

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 injector 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 injector

When you are ready to inject SIMPONI, position the injector straight onto your skin (90 degrees), then push against the skin without pinching the skin. **Do not press the button until you have pushed the injector 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 injector 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.

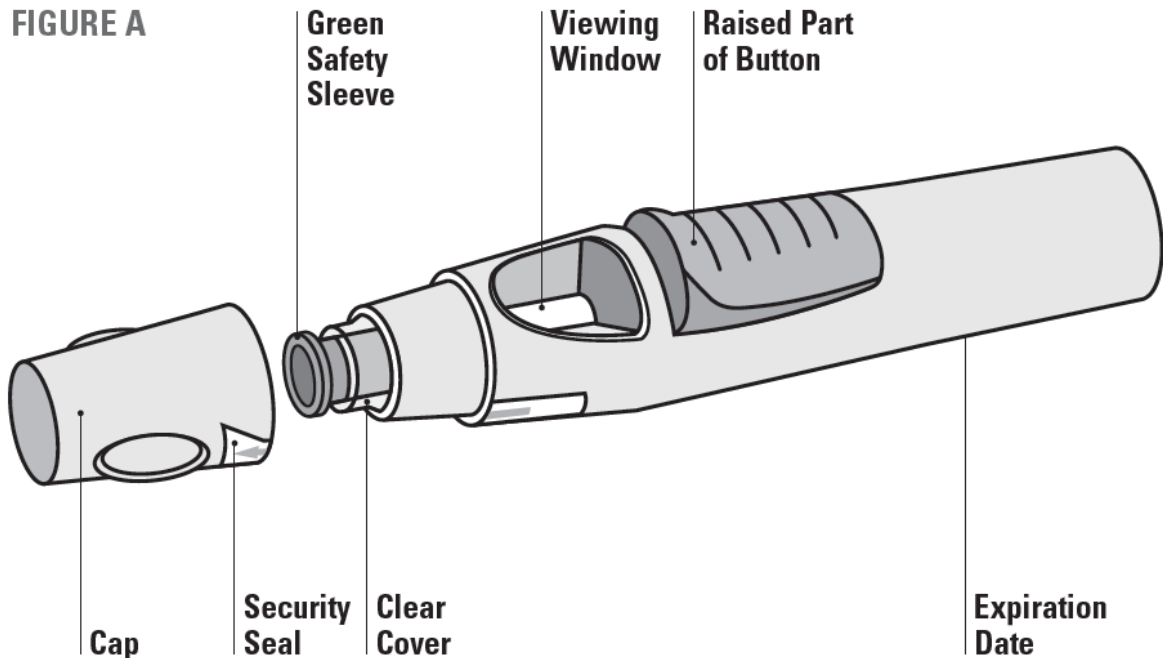
Keep holding the injector against your skin until you hear a second 'click' sound (may take 3-15 seconds), then lift the injector. The injection is complete when you hear the second 'click'. If you lift the injector before hearing the **second 'click'**, you may not get the full dose of medicine.

Important things to remember

- **Do NOT** remove the SmartJect injector cap until you get to Step 3.1.
- **Do NOT** put the SmartJect injector cap back on if removed to avoid bending the needle.
- **Do NOT** press the button until you get to Step 3.3.
- **Do NOT** shake the SmartJect injector at any time.

Read all instructions below before using SmartJect injector

Figure A below shows what the SmartJect injector looks like.

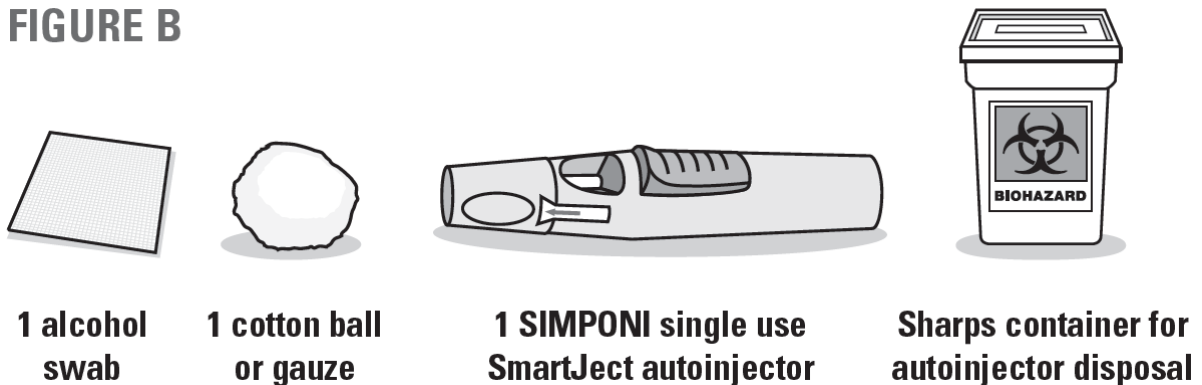


STEP 1. Gather and inspect the supplies for your injection

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 injector from the refrigerator (stored at 2°C to 8°C).
- 1 sharps disposal container for throwing away the used SmartJect injector. See Step 4.2 for disposal instructions.

FIGURE B



1.1 Check expiration date

- Check the expiration date (“EXP”) on the SmartJect injector.
- 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 injector.

1.2 Check security seal

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

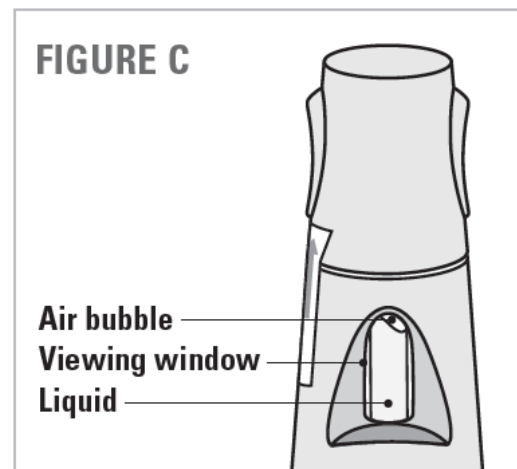
1.3 Wait 30 minutes

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



1.4 Check the liquid in the SmartJect injector

- Look through the viewing window of the SmartJect injector. See Figure C.
- Make sure that the liquid in the window is clear and colourless to slightly yellow in colour. 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 discoloured, or has large particles in it.
- You may also notice an air bubble. This is normal. See Figure C.



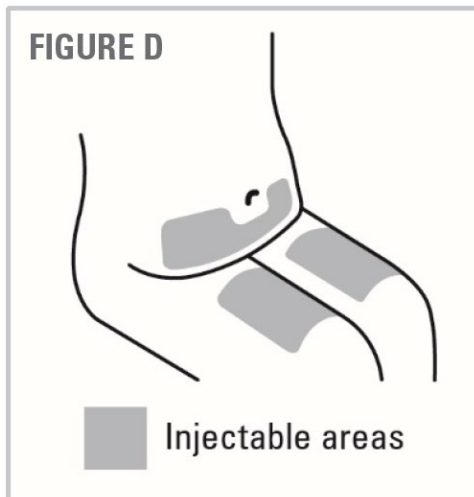
STEP 2. Choose and prepare the injection site

2.1 Choose the injection site

Select from the following areas for your injection:

- Front of your middle thighs. See Figure D.
- Lower part of the abdomen below the navel (belly button), except for the 5 cm area directly around the navel. See Figure D.
- Do **NOT** inject into the arm
- If more than one injection is needed for a dose of SIMPONI, each injection should be given at different injection sites on the body.

- Choose a different injection site each time you give your injection. See Figure D.
- **Do NOT** inject into areas where the skin is tender, bruised, red, scaly, or hard. Avoid areas with scars or stretch marks.



! **Do NOT** inject into the arm to avoid failure of the device and/or unintentional injury.

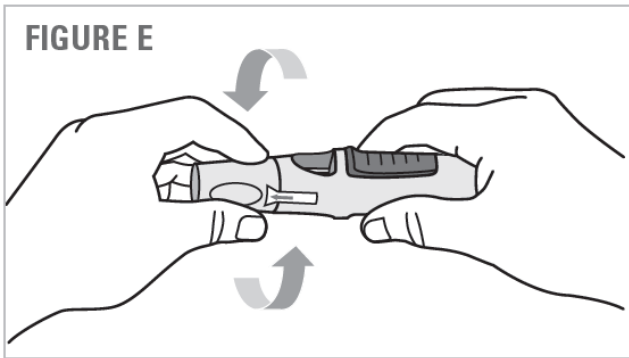
2.2 Wash hands and clean the injection site

- 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.

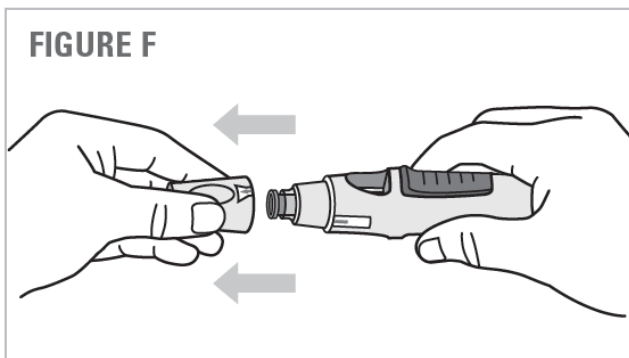
STEP 3. Inject SIMPONI using the single dose SmartJect injector

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 E.



- Pull the cap off and throw it in the rubbish right away. See Figure F.

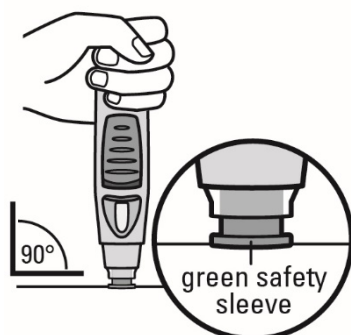


- **Do NOT** put the cap back on because it may damage the needle inside the SmartJect injector.
- **Do not** use your SmartJect injector if it is dropped without the cap in place.

3.2 Push SmartJect against the skin without pinching the skin

- Hold the SmartJect injector comfortably with one hand **above the blue button**.
- Make sure the green safety sleeve is stable and is as flat as possible against your skin. If the device is not stable during the injection, you risk bending the needle. See Figure G.

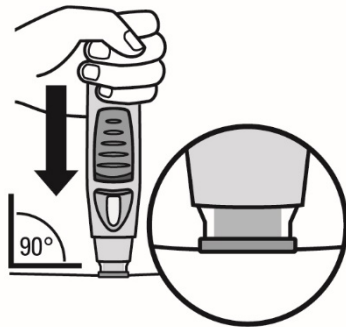
FIGURE G



- **Do NOT** pinch the skin to avoid unintentional needlestick injury.
- **Do NOT** touch or press the blue button while positioning the SmartJect onto your skin.

- Push the open end of the SmartJect against the skin at a 90-degree angle. Apply enough pressure to slide the green safety sleeve up and to maintain it inside the clear cover. Only the wider portion of the green safety sleeve remains outside of the clear cover. See Figure H.

FIGURE H



- **Do not** press the button until **after** the safety sleeve slides into the clear cover. Pushing the blue button before the safety sleeve is depressed can lead to device failure.
- Inject without pinching the skin.

3.3 Press button to inject. Hold and wait!

- Continue to hold the SmartJect injector against the skin. Use your other hand to press the front raised part of the button to start your injection. See Figure I and J.

NOTE: Do NOT press the button unless the SmartJect injector is pressed against your skin and the green safety sleeve slides into the clear cover.

FIGURE I

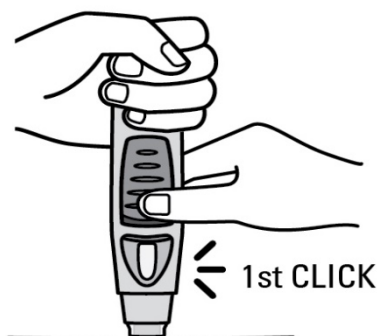
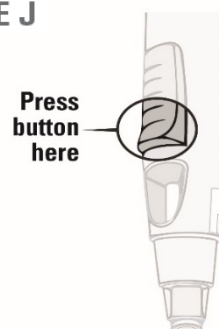


FIGURE J



- Once the button is pressed, it will remain pressed in so you do not need to keep pressure on it.
- Tip: If the button seems hard to depress, do not press the button harder. Let go of the button, then lift the SmartJect injector and start again. Ensure no pressure is on the

button until the green safety sleeve is fully depressed against the skin, then press the button.

- **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.
- **Do NOT lift the SmartJect injector away from your skin until you hear the second loud 'click'.** If you lift the injector before the second 'click', you may not get your full dose of medicine.

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

- It usually takes about 3 to 6 seconds, but may take up to 15 seconds for you to hear the second 'click' sound.
- Keep holding the SmartJect injector against your skin until you hear the second 'click' sound indicating that the injection has finished and the needle has retracted into the SmartJect injector. See Figure K.

FIGURE K

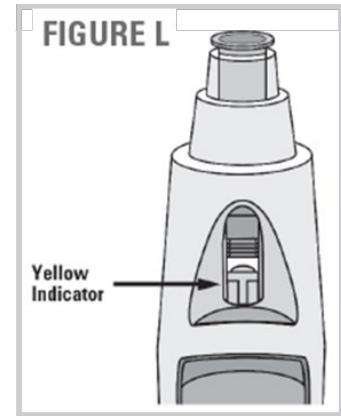


- Lift the SmartJect injector from the injection site.
- Note: If you do not hear the second 'click', wait 15 seconds from the time you first press the button and then lift the SmartJect injector from the injection site.

STEP 4. After the injection

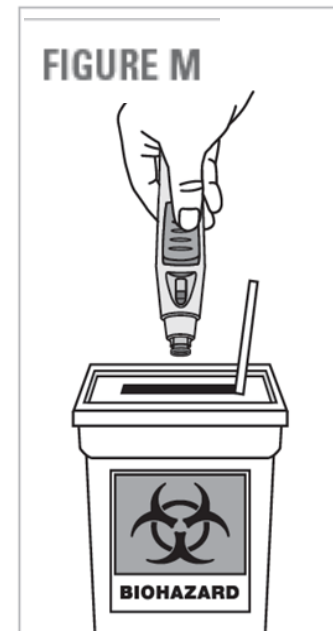
4.1 Check the viewing window

- After you finish injecting, check the viewing window to see the yellow indicator. See Figure L. This means the SmartJect injector 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 1800 666 845 for help. **Do not** administer a second dose without speaking to your doctor.



4.2 Dispose of the used SmartJect injector

- Put your used SmartJect injector in a sharps disposal container right away after use. **Do not throw away (dispose of) the SmartJect injector in your household rubbish.** See Figure M.
- If you do not have a sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tightfitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and properly labelled to warn of hazardous waste inside the container.
- **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.

Need more help with your injection?

Quick Reminders

Do NOT touch or press the blue button while positioning the SmartJect injector onto your skin.

Position the injector straight onto your skin (90 degrees), then **push against the skin without pinching the skin**. Apply enough pressure to slide the green safety sleeve up and to maintain it inside the clear cover.

Press the raised part of the button using your other hand to start the injection and listen for the **first 'click'**.

Do NOT lift the SmartJect injector away from your skin yet.

Keep holding the injector against your skin until you hear the **second 'click'**, or you can wait 15 seconds 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 your injection site is flat.
- Make sure you **do NOT** press the button while positioning and pushing the injector against your skin.
- Do NOT press the button unless the SmartJect injector is pressed against your skin and the safety sleeve slides into the clear cover.
- Hold the SmartJect injector comfortably with one hand **above the blue button**. Use your other hand to press the front raised part of the button to start your injection.
- Make sure you press the raised part of the button. See Figure J and K.
- Do NOT press the button harder. Let go of the button, then lift the SmartJect and start again. Ensure no pressure is on the button until the green safety sleeve is fully depressed against the skin, then press the button.
- Try a different injection site. See Figure D.

The Janssen Immunology Patient Support Program is available to patients prescribed SIMPONI.

Call 1800 666 845

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