**Important**

If your doctor decides that you or a caregiver may be able to give your SIMPONI® injections at home, you should receive training on the right way to prepare and inject SIMPONI® using SmartJect®. Do not try to inject SIMPONI® yourself until you have been shown the right way to give the injections by your doctor or nurse. Please read this Instructions for Use before using SIMPONI® SMARTJect® and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

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

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Janssen Biotech, Inc.
Horsham, PA 19044
US License No. 1864
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Instructions for Use

1. Prepare for your injection

Take out SmartJect®
Take the SmartJect® out of the refrigerator and remove it from the carton. Place on a flat surface out of reach of children. SmartJect® should sit at room temperature for at least 30 minutes to ensure proper injection. Do not warm any other way. Do not remove the cap yet.

Inspect SmartJect®
Check the expiration date (‘EXP’) on the back of SmartJect®. Do not use SIMPONI® SmartJect® if the expiration date has passed. Call your doctor or pharmacist for a refill.

Check liquid in the SmartJect®
After 30 minutes, check the liquid in the viewing window. It should be clear to slightly yellow and may contain tiny white or clear particles. It is also normal to see a small air bubble. Do not inject if the liquid is cloudy or discolored, or has large particles.

Choose injection site
Select from the following areas for your injection:
1. Front of thighs (recommended)
2. Lower abdomen (do not use the 2-inch area around your navel (belly button))
3. Back of upper arms (if a caregiver is giving you the injection).

Choose a different site within your preferred area for each injection. Do not inject into skin that is tender, bruised, red, scaly or hard. Do not inject into areas with scars or stretch marks.

Gather supplies
While SmartJect® sits at room temperature for 30 minutes, gather your supplies:
- 1 Alcohol swab
- 1 Cotton ball or gauze pad
- 1 Sharps container
(See Step 3)

Check the security seal on SmartJect® if the expiration date is broken.

2. Inject SIMPONI® using SmartJect®

Remove cap
Twist the cap to break the security seal, then pull it straight off. Dispose of the cap right away. It is important to inject within 5 minutes of removing the cap.

Do not put the cap back on, this may damage the hidden needle. Do not inject if SmartJect® is dropped without the cap on.

Position
Hold SmartJect® comfortably and position it straight onto your skin, as shown. Make sure the green safety sleeve is flat against your skin and that your injection site is as flat as possible.

Do not touch or press the button while positioning the SmartJect® onto your skin.
Do not inject if SmartJect® is dropped without the cap on.

Push firmly
Push SmartJect® firmly against your skin so the green safety sleeve slides into the clear cover.

Do not touch or press the button while positioning SmartJect® against your skin.

The green safety sleeve helps prevent accidental injections. You will not be able to press the button to start your injection until SmartJect® is pushed firmly enough against your skin for the green safety sleeve to slide into the clear cover.

Press button and wait
Keep holding SmartJect® firmly against your skin. Use your other hand to press the raised part of the button to start your injection. You will hear a loud 1st ‘click’ as you press the button. This is normal, the medication is just beginning to be delivered. You may or may not feel a needle prick.

Do not lift SmartJect® up yet! This may result in loss of medication. After 1 press of the button, you do not need to keep pressure on the button.

Wait for the 2nd ‘click’ which means your injection is complete.

Listen for 2nd ‘click’
Keep holding SmartJect® firmly against your skin until you hear the 2nd ‘click’ (3–15 seconds).

The 2nd ‘click’ means the injection is complete and you can lift SmartJect® from your skin.

If you have trouble hearing the ‘clicks’, count to 15 after pressing the button, then lift the SmartJect® off your skin.

Check the viewing window
After lifting SmartJect® from your skin, look for the yellow indicator in the viewing window to confirm SmartJect® worked properly. The yellow indicator will fill about half of the viewing window. If you do not see the yellow indicator, call 800-JANSSEN (800-526-7736).

Do not administer a second dose without speaking to your doctor.

Check injection site
There may be a small amount of blood or liquid at the injection site. Hold pressure over your skin with a cotton ball or gauze pad until any bleeding stops.
Do not rub the injection site.
Do not recycle used sharps disposal container.

If needed, cover injection site with a Bandage. Your injection is now complete!

Helpful tips
If you are having difficulty injecting:
- Make sure the cap is removed.
- Make sure SmartJect® is pushed firmly against your skin.
- Make sure you are pressing the raised part of the button.
- Try pressing the button a little harder.
- Try a different injection site.

If you are pinching the skin to inject:
Use 1 hand to both position SmartJect® against the skin and press the button.

Additional disposal information:
If you do not have an 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
- Made of a heavy-duty plastic
- Leak-resistant lid, without tight-fitting, puncture-resistant lid without sharps being able to come out
- Weighted and stable during use
- Leak-resistant
- Properly labeled to warn of hazardous waste inside the container
When your 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: www.fda.gov/safety/sharpsdisposal

Important
If your doctor decides that you or a caregiver may be able to give your SIMPONI® injections at home, you should receive training on the right way to prepare and inject SIMPONI® using SmartJect®.
Do not try to inject SIMPONI® yourself until you have been shown the right way to give the injections by your doctor or nurse. Please read this instructions for Use before using SIMPONI® SmartJect® and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

Keep SIMPONI® and all medicines out of the reach of children.

Storing SmartJect®
Store in refrigerator (on back) if not used within 30 days. If not used within 30 days at room temperature, up to 77°F (25°C) for one period of time up to 30 days. Do not return to the refrigerator. Throw away (dispose of) if not used within 30 days at room temperature.
Do not freeze SmartJect®.
Do not shake SmartJect®.
Keep SIMPONI® in the original carton to protect from light before use.

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**Instructions for Use**

**1. Prepare for your injection**

- **Inspect carton**
  - Remove your SIMPONI® prefilled syringe carton from the refrigerator.
  - Remove the prefilled syringe from the carton and let it sit on a flat surface at room temperature for at least 30 minutes before use.
  - Do not warm the prefilled syringe any other way.
  - Check the expiration date (‘EXP’) on the back panel of the carton and on the prefilled syringe (through the viewing window).
  - Do not use your prefilled syringe if the expiration date has passed.
  - Do not inject SIMPONI® if the perforations on the carton are broken. Call your healthcare provider or pharmacist for a refill.

- **Choose injection site**
  - Select from the following areas for your injection:
    - **Front of thighs** (recommended)
    - Lower stomach area (lower abdomen), except for a 2-inch area right around your naval (belly button)
    - Back of upper arms (only if someone else is giving you the injection)
  - Choose a different site within your preferred area for each injection.
  - Do not inject into skin that is tender, bruised, red, hard, thick or scaly.
  - Do not inject into areas with scars or stretch marks.

- **Clean injection site**
  - Wash your hands well with soap and warm water.
  - Wipe your chosen injection site with an alcohol swab and allow it to dry.
  - Do not touch, fan or blow on the injection site after you have cleaned it.

- **Need help?**
  - Call your doctor to talk about any questions you may have.
  - For additional assistance or to share your feedback call JANSSEN (800-526-7736).

**2. Inject SIMPONI® using the prefilled syringe**

- **Remove needle cover**
  - Hold your prefilled syringe by the body and pull needle cover straight out. It is normal to see a drop of liquid.
  - Inject SIMPONI® within 5 minutes of removing the needle cover.
  - Do not put needle cover back on, as this may damage the needle or cause a needle stick injury.
  - Do not touch needle or let it touch any surface.
  - Do not use a SIMPONI® prefilled syringe if it is dropped. Call your healthcare provider or pharmacist for a refill.

- **Position fingers and insert needle**
  - Place your thumb, index and middle fingers directly under the finger flange, as shown.
  - Do not touch plunger or area above finger flange as this may cause the needle safety device to activate.
  - Use your other hand to pinch skin at the injection site. Position syringe at about a 45 degree angle to the skin.
  - It is important to pinch enough skin to inject under the skin and not into the muscle.
  - Insert needle with a quick, dart-like motion.

- **Release pinch and reposition hand**
  - Use your free hand to grasp the body of the prefilled syringe.

- **Release pressure from plunger**
  - The safety guard will cover the needle and look into place, removing the needle from your skin.

- **Dispense of your prefilled syringe**
  - Put your used SIMPONI® prefilled syringe in an FDA-cleared sharps disposal container right away after use.
  - Do not throw away (dispose of) your SIMPONI® prefilled syringe in your household trash.
  - Do not recycle your used sharps disposal container.

- **For more information, see “How should I dispose of the used prefilled syringe?”**

**3. After your injection**

- **Check injection site**
  - There may be a small amount of blood or liquid at the injection site.
  - Hold pressure over your skin with a cotton ball or gauze pad until any bleeding stops.
  - Do not rub the injection site.
  - If needed, cover injection site with a bandage. Your injection is now complete!

- **How should I dispose of the used prefilled syringe?**
  - If you do not have an 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
  - 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: www.fda.gov/safesharpsdisposal

**Use before using your SIMPONI® prefilled syringe.**

- **Step 3) after one dose, even if you have been shown the right way to give the injections by your healthcare provider.**

- **Your caregiver may be able to give your injections of SIMPONI®.**

- **SIMPONI® comes as a single-dose prefilled syringe containing one 50 mg or one 100 mg dose.**

- **Each SIMPONI® prefilled syringe can only be used one time.**

- **Throw away (dispose of) the used prefilled syringe (See Step 3) after one dose, even if there is medicine left in it.**

- **Do not reuse your SIMPONI® prefilled syringe.**

- **If your healthcare provider 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® using the prefilled syringes before attempting to inject. Do not try to inject yourself until you have been shown the right way to give the injections by your healthcare provider.**

- **Read this Instructions for Use before before using your SIMPONI® prefilled syringe and each time you get a refill. There may be new information.**

- **This Instructions for Use does not take the place of talking with your healthcare provider about your medical condition or your treatment.**

- **Normal to see a drop of liquid at the injection site. This is normal.**

- **One or more air bubbles. This is normal.**

- **Yellow and may contain large particles. Call your pharmacist for a refill.**

- **Before use**
  - Do not hold or pull plunger at any time.

- **After use**
  - Plunger locks.
  - Safety guard activates.

**Important**

- **SIMPONI®**
  - Prefilled syringe parts
  - IMPORTANT
  - The SIMPONI® prefilled syringe is intended for injection under the skin, not into the muscle or vein. After injection, the needle will retract into the body of the device and lock into place.

- **Storage information**
  - Store SIMPONI® in the refrigerator at 36° to 46°F (2° to 8°C).
  - If needed, store SIMPONI® at room temperature, up to 77°F (25°C) for one period of time up to 30 days. Do not return it to the refrigerator. Throw away if not used within 30 days at room temperature.
  - Do not freeze SIMPONI® prefilled syringe.
  - Do not shake SIMPONI® prefilled syringe.
  - Keep SIMPONI® prefilled syringe in the original carton to protect from light before use.
  - Keep SIMPONI® prefilled syringe and all medicines out of the reach of children.

- **In case of accidental injection**
  - Do not attempt to inject. Do not return it to the refrigerator. Throw away if not used within 30 days at room temperature.
  - Do not inject into skin that is tender, bruised, red, hard, thick or scaly.
  - Do not inject into areas with scars or stretch marks.

- **Choosing a site**
  - Front of thighs (recommended)
  - Lower stomach area (lower abdomen), except for a 2-inch area right around your naval (belly button)
  - Back of upper arms (only if someone else is giving you the injection)

- **SIMPONI® prefilled syringe parts**
  - Before use
    - Plunger
    - Safety guard
    - Finger flange
    - Body
    - Needle cover
    - Needle guard
  - After use
    - Needle retracts into the body
  - Important parts
    - Viewing window
    - Finger flange
    - Needle guard
    - Safety guard
    - Body

- **Choosing a site**
  - Front of thighs (recommended)
  - Lower stomach area (lower abdomen), except for a 2-inch area right around your naval (belly button)
  - Back of upper arms (only if someone else is giving you the injection)