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.
Manufactured by:
Janssen Biotech, Inc.
Horsham, PA 19044
US License No. 1864
Revised March 2023
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Do not try to inject SIMPONI® until you have been shown the right way to give the injections by your doctor or nurse.

Prepare for your injection

1. Remove cap
   - Twist the cap to break the security seal; then pull it straight off. Do not take off the cap until you are ready to inject (See Step 2).

2. Injection site
   - Do not inject into sites that are tender, bruised, red, scaly or hard.
   - Do not inject into areas with scars or stretch marks.
   - Do not inject into skin that is less than 2 inches (5 centimeters) thick.
   - Do not inject if the liquid is cloudy or discolored, or has large particles.
   - Do not inject if the cap is dropped.
   - Do not pinch your skin.
   - Do not inject if SmartJect® is dropped.
   - Do not put the cap back on, this may damage the cap.

3. After your injection
   - Check the expiration date. If needed, cover injection site with a cotton ball or gauze pad and allow it to dry.
   - Do not remove the cap yet.
   - Do not remove the cap until you are ready to inject (See Step 2).

Inject SmartJect®

Take out SmartJect®
- Take 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®
- Inspect SmartJect® before using SIMPONI®.
- Do not use SIMPONI® if the expiration date has passed. Call your doctor or pharmacist for a refill.
- Do not inject the liquid if it is cloudy or discolored, or has large particles.
- Do not inject if the cap is dropped.

Select from the following areas for your injection:
- Front of thighs
- Lower abdomen (do not use the 2-inch area around your navel (belly button))
- Do not inject into the arms
- 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.

Check liquid in the SmartJect®
- Check the expiration date on the back of SmartJect®.
- Do not inject if the liquid is cloudy or discolored, or has large particles.

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.

For more information, see “Helpful tips”.

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 button.
- Try pressing the button a little harder.
- Try a different injection site.

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, without sharps being able to come out
- upright and stable during use
- leak-resistant
- 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: www.fda.gov/safesharpsdisposal

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JANSSEN

This page contains important instructions for Use. It is important to read the instructions before using SIMPONI®. If you do not understand this information or have questions, call 800-JANSSEN (800-526-7736) or your doctor.

SIMPONI® (Pronunciation: SIM-poh-nee) (Golimumab) 200 mg/mL

Do not inject if the liquid is cloudy or discolored, or has large particles.

Do not inject if the cap is dropped.

Do not remove the cap until you are ready to inject (See Step 2).

Your SmartJect® at-a-glance

Cap
- Do not remove the cap until you are ready to inject (See Step 2).
- Do not try to inject SIMPONI®

Security seal (on side of cap)
- Green safety sleeve
- Clear cover
- Thin hidden needle

Viewing window
- Raised part of button
- Press here only when SmartJect® is pushed firmly against your skin and you are ready to inject (See Step 2).

Expiration date (on back)

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

- **Before use**
  - Plunger
  - Do not hold or pull plunger at any time.
  - Safety guard
  - Finger flange
  - Body
  - Hold syringe body below finger flange.
  - Viewing window
  - Needle cover
  - Do not remove until you are ready to inject SIMPONI® (See Step 2).

- **After use**
  - Needle retracts into the body
  - Plunger locks
  - Safety guard activates

**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 syringes in the original carton to protect from light before use.
- Keep SIMPONI® prefilled syringes and all medicines out of the reach of children.

**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

**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!

**Inspect liquid**

- Do not inject the liquid if the liquid is cloudy or discolored, or has large particles. Call your healthcare provider or pharmacist for a refill.

**Discard syringe and container**

- Do not attempt to inject. Do not try to inject yourself until you are ready to inject.
- Do not inject SIMPONI® using the prefilled syringe if the expiration date has passed.
- Do not inject SIMPONI® after 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.

**Instructions for Use**

**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.**

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 you use your SIMPONI® prefilled syringe and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or your treatment.

**1. Prepare for your injection**

- 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 navel (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 800-JANSSEN (800-526-7736).

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

- 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 the 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 least 45° 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 pressure from plunger
  - The safety guard will cover the needle and lock it into place, removing the needle from your skin.

- Release pressure from plunger
  - 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?”

- 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.

- You will need these supplies
  - 1 SIMPONI® prefilled syringe
  - Not provided in the SIMPONI® prefilled syringe carton:
    - 1 Alcohol swab
    - 1 Cotton ball or gauze pad
    - 1 Adhesive bandage
    - 1 Sharps container
  - (See Step 3)

**3. After your injection**

- 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 the 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 least 45° angle to the skin.
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- Release pressure from plunger
  - 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?”

- 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!

- After your injection
  - There may be a small amount of blood or liquid at the injection site.
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  - Do not rub the injection site.
  - If needed, cover injection site with a bandage. Your injection is now complete!

- 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 800-JANSSEN (800-526-7736).

- Dispose of your SIMPONI® prefilled syringe.
  - Do not attempt to inject. Do not try to inject yourself until you are ready to inject.
  - Do not inject SIMPONI® using the prefilled syringe if the expiration date has passed.
  - Do not inject SIMPONI® after 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.

- 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.

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    - 1 Sharps container
  - (See Step 3)