Instructions for Use
SIMPONI® (SIM-po-nee) (golimumab)
Injection, for subcutaneous use

This Instructions for Use contains information on how to inject SIMPONI® using the SmartJect® Autoinjector.

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.

Important Information
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.

Do not pinch the skin while injecting. Pinching the skin can cause failure of the device and injury, including needlestick injury.

Do not inject into the arm to avoid failure of the device or injury.

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 November 2023

Instructions for Use
SIMPONI® (SIM-po-nee) (golimumab)
Prefilled Syringe

Important
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 syringe 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 using 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.

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Horsham, PA 19044
US License No. 1864
Revised May 2018
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Important information
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.

Do not pinch the skin while injecting. Pinching the skin can cause failure of the device and injury, including needlestick injury.

Do not inject into the arm to avoid failure of the device or injury.

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

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 (dispose of) if not used within 30 days at room temperature.

Keep SIMPONI® in the original carton to protect from light before use.

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

This Instructions for Use contains information on how to prepare and inject SIMPONI® using SmartJect®. Before you use SIMPONI®, please read this Instructions for Use and the Instructions for Use that came with your SmartJect®.

1. Preparing to inject SIMPONI® using 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®
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 the security seal on the cap.
Do not inject if the seal is broken.

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 liquid in the arm
Do not inject into the arm to avoid failure of the device or injury.

Choose injection site
• 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. Avoid areas with scars or stretch marks.

2. Injecting SIMPONI® using SmartJect®

Remove cap
Twist the cap to break the security seal, then pull it straight off. Dispose of the cap after use.

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.

Do not pinch the skin while injecting. Pinching the skin can cause failure of the device and injury, including needlestick injury.

Position
Hold SmartJect® comfortably with one hand above the blue button and position it straight onto your skin, as shown.

Make sure the green safety sleeve is stable and as flat as possible against your skin. If the device is not stable during injection, you risk bending the needle.

Do not pinch your skin while positioning SmartJect® onto your skin.

Do not pinch the skin to avoid injury, including needlestick injury.

Push down
Push the open end of SmartJect® against your skin at a 90-degree angle. Apply enough pressure to slide the green safety sleeve up and to keep it inside the clear cover.

Only the wider part of the green safety sleeve stays outside of the clear cover.

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

The green safety sleeve protects prevent accidental injections.

Pushing the blue button before the safety sleeve is pressed down can lead to device failure.

Infect without pinching the skin.

Press button and wait
Keep holding SmartJect® against your skin. Use your other hand to press the raised part of the blue button to start your injection. Do not press the button until SmartJect® is pressed against your skin and the safety sleeve slides into the clear cover.

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.

Listen for 2nd ‘click’
Keep holding SmartJect® against your skin until you hear the 2nd ‘click’ (or for 15 seconds). It usually takes about 3-6 seconds, but may take up to 15 seconds for you to hear the second ‘click’ sound.

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

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

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).

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!

Helpful tips
If you are having difficulty injecting:
• Make sure the cap is removed.
• Make sure SmartJect® is pushed against your skin, so the green safety sleeve slides into the clear cover.
• Make sure you are pressing the raised part of button.
• If the button is hard to depress, do not press the button harder. Let go of the button, then lift 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.

Additional Disposal Information:
If you do not have an FDA-cleared sharps disposal container, you must 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
• up-right and stable during use
• leakage-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/medwatch/disposal
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.

1. Prepare for your injection

- Remove needle cover
- Inspect carton
- Choose injection site
- Clean injection site
- Inspect liquid
- Need help?

2. Inject SIMPONI® using the prefilled syringe

- Before use
- Plunger
- Safety guard
- Finger flange
- Body
- Viewing window
- Needle cover
- Do not remove until you are ready to inject SIMPONI® (See Step 2).

3. After your injection

- Dispose of your prefilled syringe
- Check injection site
- How should I dispose of the used prefilled syringe?

Important

SIMPONI® is a single-dose prefilled syringe prepared by healthcare providers for use in the treatment of moderate to severe plaque psoriasis and psoriatic arthritis. It is important to read this Instructions for Use before using your SIMPONI® prefilled syringe and each time you get a refill. There may be new information. If you have any questions, talk with your healthcare provider about your medical condition or your treatment.

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°F to 46°F (2°C 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.

Prefilled syringe parts

- You will need these supplies
- • 1 SIMPONI® prefilled syringe carton
- • 1 Adhesive bandage pad
- • 1 Cotton ball
- • 1 SIMPONI® prefilled syringe
- • 1 cotton ball or gauze pad
- • 1 Adhesive bandage
- • 1 Sharps container (See Step 3)

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1. Prepare for your injection

- Remove needle cover
- Hold your prefilled syringe by the body and pull needle cover straight off. 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

- Place thumb from the opposite hand on the plunger and press the plunger all the way down until it stops.
- Release pressure from plunger
- The safety guard will cover the needle and lock 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?”

Dispose of your 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!

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

You may also see one or more air bubbles.

Particles. You may also see tiny particles or clear particles. You may also see some of 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.

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- Do not shake SIMPONI® prefilled syringe.
- Keep SIMPONI® prefilled syringes in the original carton to protect from light before use.
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