Instructions for Use
SIMPONI® (SIM-po-nee) (golimumab)
SmartJect® autoinjector

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 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
Approved: May 2015
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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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Gather supplies

- 1 Alcohol swab
- 1 Cotton ball or gauze pad
- 1 Sharps container

Instructions for Use (continued)

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.

Your SmartJect® at-a-glance

4. Take out SmartJect®

Take SmartJect® out of the refrigerator and remove it from the carton. Place it 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.

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)

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
- able to withstand the weight of 16 ounces (453 grams) of water
- small enough to keep children away, and
- marked as a hazardous waste

1 Sharps container

1 Cotton ball or gauze pad

1 Alcohol swab

1 Hand

2. Inject SIMPONI® using SmartJect®

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.

1st click

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.

1st click

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.

1st click

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.

2nd click

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 JANSSSEN (800-526-7736).

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

2nd click

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.

3. After your injection

Check 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.

Choose injection site

SmartJect® at-a-glance

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.

Do not inject if the seal is broken.

2nd click

Dispose of your used SmartJect®

Put your used SmartJect® in an FDA-cleared sharps disposal container right away after use.

Do not throw away (dispose of) loose needles and syringes in your household trash.

Do not recycle your used sharps disposal container.

For more information, see “Helpful tips”.

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!

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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. Do not reuse your SIMPONI® prefilled syringe. If your healthcare provider decides 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 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.

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 syringes. Do not shake SIMPONI® prefilled syringes. 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

Before use

- Plunger
- Finger flange
- Body
- Needle cover
- Needle
- Viewing window

After use

- Plunger locks
- Safety guard activates
- Needle retracts into the body

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)

You will need these supplies:

1. Prepare for your injection

1. Remove needle cover

2. Inject SIMPONI® using the prefilled syringe

2. Position fingers and insert needle

Place your thumb, index and middle fingers directly under the flange as shown. Do not touch plunger or area above 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.

3. Release pressure from plunger

The safety guard will cover the needle and lock into place, removing the needle from your skin.

4. Dispose 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?”

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!

Check 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 in 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).

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 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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