Your SmartJect® at-a-glance

1. Prepare for your injection

- **Cap**: Do not remove the cap until you are ready to inject (See Step 2).
- **Security seal (on side of cap)**: Remove the cap right away.
- **Green safety sleeve**: Do not touch or press the green safety sleeve slides against your skin so the thin hidden needle is dropped onto your skin.
- **Clear cover**: Do not remove the cover until after injection.

**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)**

**Needle 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 SmartJect®

- **Remove cap**: Twist the cap to break the security seal; then pull it straight off. Dispose of the cap right away.
- **Position**: Hold SmartJect® comfortably and position it straight onto your skin, as shown.
- **Push firmly**: Push SmartJect® firmly against your skin so the green safety sleeve slides 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 ‘1 st 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 2 nd ‘click’**: The 2nd ‘click’ means the injection is complete and you can lift SmartJect® from 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.
- **Inspect SmartJect®**: Check the expiration date (‘EXP’) on the back of SmartJect®.
- **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.
- **Check the security seal on the cap**: Do not inject if the seal is broken.
- **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 30 minutes to ensure proper injection.
- **Do not warm SmartJect®**: Do not shake SmartJect®. Keep SIMPONI® and all medicines out of the refrigerator. Keep SIMPONI® in the refrigerator 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:
  - **Front of thighs (recommended)**
  - **Lower abdomen (do not use the 2-inch area around your navel [belly button])**
  - **Back of upper arms (if a caregiver is giving you the injection)**
- **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.**

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

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

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 your state that you live in, go to the FDA’s website: www.fda.gov/safesharpsdisposal

3. After your injection

- **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.**
- **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!

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.

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MEDICATION GUIDE
SIMPONI® (SIM-po-nee) (golimumab) injection, for subcutaneous use

What is the most important information I should know about SIMPONI?
SIMPONI is a medicine that affects your immune system. SIMPONI can lower the ability of your immune system to fight infections. Some people have serious infections while taking SIMPONI, including including tuberculosis (TB), infections caused by bacteria, fungi, or viruses that spread throughout their body. Some people have died from these serious infections.

• Your doctor should test you for TB and hepatitis B before starting SIMPONI.
• Your doctor should monitor you closely for signs and symptoms of TB during treatment with SIMPONI.
• You should not start SIMPONI if you have any kind of infection unless your doctor says it is okay.

Before starting SIMPONI, tell your doctor if you:
• think you have an infection or have symptoms of an infection such as:
  • fever, sweat, or chills
  • muscle aches
  • cough
  • shortness of breath
  • blood in phlegm
  • weight loss
  • warm, red, or painful skin or sores on your body
• are being treated for an infection.
• get a lot of infections or have infections that keep coming back.
• have, or have had hepatitis B.
• use the medicine ORENCIA (abatacept), KINERET (anakinra), ACTEMRA (tocilizumab), or XELZA (tiotixen).

After starting SIMPONI, call your doctor right away if you have any symptoms of an infection. SIMPONI can make you more likely to get infections or may make worse any infection that you have.

What is SIMPONI?
SIMPONI is a prescription medicine called a Tumor Necrosis Factor (TNF) blocker. SIMPONI is used in adults:
• with the medicine methotrexate to treat moderately to severely active rheumatoid arthritis (RA) to treat active psoriatic arthritis (PsA) alone or with other medicines, or
• to treat active ankylosing spondylitis (AS)
• with moderately to severely active ulcerative colitis (UC) when certain other UC medicines have not worked well enough or cannot be used (if it is necessary to continue taking steroids)
• to begin helping some of your symptoms.
• in people who respond to SIMPONI, to get their UC under control (induce remission) and keep UC under control (sustain remission).
• to begin to improve the way the lining of your large intestine looks to your doctor during colonoscopy.

What can I do if I have an infection?
You may continue to use other medicines that help treat your infection. Your doctor may prescribe antimicrobial drugs, such as non-steroidal anti-inflammatory drugs (NSAIDs) and prescription steroids, as recommended by your doctor.

Tell your doctor:
• if you are pregnant or planning to become pregnant. It is not known if SIMPONI will harm your unborn baby.

What is the most important information I should know about SIMPONI before starting treatment with SIMPONI?
SIMPONI may not be right for you. See “What is the most important information I should know about SIMPONI?” before starting SIMPONI, tell your doctor about all your medical conditions, including if you:
• have an infection.
• have or have had hepatitis B or any other type of cancer.
• have or had heart failure.
• have or have had a condition that affects your nervous system, such as multiple sclerosis or Guillain-Barré syndrome.
• have recently received or are scheduled to receive a vaccine. People taking SIMPONI should not receive live vaccines or treatment with a weakened bacteria (such as BCG for tuberculosis) in people taking SIMPONI can receive non-live vaccines.

What should I tell my doctor before starting treatment with SIMPONI?
SIMPONI may not be right for you. See “What is the most important information I should know about SIMPONI?” before starting SIMPONI, tell your doctor about all your medical conditions, including if you:
• have or have had tuberculosis (TB) or any other type of infection.
• have or have had hepatitis B.
• live, have lived, or traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, blastomycosis). These infections may happen or become more severe if you use SIMPONI.
• are being treated for an infection.
• are breastfeeding or plan to breastfeed. You and your doctor should decide if you will take SIMPONI or breastfeed.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially, tell your doctor if you:
• take ORENCIA (abatacept) or KINERET (anakinra). You should not take SIMPONI while you are taking ORENCIA (abatacept) or KINERET (anakinra).
• take other TNF-blocker medicines, including REMICADE (infliximab), HUMIRA (adalimumab), ENBREL (etanercept), or ADACTIL (adalimumab). You should not take these medicines if you are using SIMPONI. Tell your doctor if you have any of the following symptoms of a possible Hepatitis B infection:
  • fever
  • dark urine
  • skin or eyes look yellow
  • loss of appetite
  • vomiting
  • muscle aches

Heart failure, including new heart failure or worsening of heart failure that you already have, can happen in people who use TNF-blocker medicines including SIMPONI. If you develop new or worsening heart failure with SIMPONI, you may need to be treated in a hospital, and it may result in death.

• If you have heart failure before starting SIMPONI, your condition should be watched closely during treatment with SIMPONI.
• Do not use SIMPONI if you have new or worsening symptoms of heart failure during treatment with SIMPONI (such as shortness of breath or swelling of your lower legs or feet, or sudden weight gain).

Nonsystemic Problem: Rarely, people using TNF-blocker medicines, including SIMPONI, have nervous system problems such as multiple sclerosis or Guillain-Barré syndrome. Tell your doctor right away if you get any of these symptoms:
• vision changes
• numbness or tingling in any part of your body
• weakness in your arms or legs

Immune System Problems. Rarely, people using TNF-blocker medicines have developed symptoms of some lymphoma types. Tell your doctor if you have any of these symptoms:
• a rash on your cheeks or a butterfly-shaped rash on your body
• sensitivity to the sun
• new joint or muscle pains

Liver Problems. Liver problems can happen in people who use TNF-blocker medicines, including SIMPONI. These problems can lead to liver failure and death. Call your doctor right away if you have any of these symptoms:
• feeling tired
• poor appetite or vomiting pain on the right side of your stomach (abdomen)

Blood Problems. Low blood counts have been seen with TNF-blockers, including SIMPONI. Your body may not make enough blood cells that help fight infections or help stop bleeding. Symptoms include fever, bruising or bleeding easily, or looking pale. Your doctor will check your blood counts before and during treatment with SIMPONI.

What are the possible side effects of SIMPONI?

Cancer
• For children and adults taking TNF-blocker medicines, including SIMPONI, the chances of getting cancer may increase.
• There have been cases of unusual cancers in children and teenage patients taking TNF-blocking agents.
• People with inflammatory diseases including rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis, especially those with very active disease, may be more likely to get lymphoma.

Liver
• A child or adolescent taking SIMPONI may have a low grade fever that does not go away. If your temperature stays above 100.4 °F (38 °C) for 6 months after starting SIMPONI, talk to your doctor.

Hepatitis B infection in people who carry the virus in their bodies
• If you are a carrier of the hepatitis B virus (a virus that affects the liver), the virus can become active while you use SIMPONI. Your doctor should do blood tests before you begin treatment with SIMPONI and several times while you are using SIMPONI. Tell your doctor if you have any of the following symptoms of a possible Hepatitis B infection:
  • feeling tired
  • dark urine
  • skin or eyes look yellow
  • lost appetite
  • vomiting
  • muscle aches

Drug Administration.

What are the possible side effects of SIMPONI?

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SIMPONI for a condition for which it was not prescribed. Do not give SIMPONI to other people, even if they have the same symptoms that you have. Use of SIMPONI by people who do not need it could be harmful.

This Medication Guide summarizes the most important information about SIMPONI. If you would like more information, talk to your doctor. You can ask your doctor or pharmacist for information about SIMPONI that is written for health professionals. For more information go to www.simponi.com or call 1-800-JANSSEN (1-800-526-7736).

What are the ingredients in SIMPONI?
Active ingredient: golimumab.
Inactive Ingredients: hyaluronidase, L-histidine monohydrochloride monohydrate, polysorbate 80, sorbitol, and water for injection. SIMPONI does not contain preservatives.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: May 2018

A low grade fever