

# READ THIS ENTIRE SHEET BEFORE USING THE SINGLE DOSE SMARTJECT™ AUTOINJECTOR.

## The single dose SmartJect™ autoinjector

If your doctor decides that you or a caregiver may be able to give your injections of SIMPONI™ (golimumab) at home, you should receive training on the right way to prepare and inject SIMPONI™. Do not try to inject SIMPONI™ yourself until you have been shown the right way to give the injections by your doctor or nurse. Call your doctor if you or your caregiver has any questions about the right way to inject SIMPONI™.

### Important things to note about your single dose SmartJect™ autoinjector:

#### • Do not:

- Shake the SmartJect™ autoinjector at any time.
- Remove the SmartJect™ autoinjector cap until you get to that step.
- You must continue to hold the SmartJect™ autoinjector firmly against the skin until you hear 2 clicks. The first click is a loud click. Do not be alarmed. This click indicates the start of the injection, and it is important that you do not lift or move the SmartJect™ autoinjector at this time. If you pull the SmartJect™ autoinjector away from the skin before your injection is complete, you may not get your full dose of medicine. The second click indicates the end of the injection. Do not lift the SmartJect™ autoinjector from the skin until after you have heard both clicks.
- The SmartJect™ autoinjector will not work unless the safety sleeve is fully depressed against the skin.
- **These instructions are not meant to replace the *Instructions for Use* that come with your single dose SmartJect™ autoinjector. When it is time to take your medication, please thoroughly read the *Instructions for Use* and the *Medication Guide* enclosed in the carton before use.**

## STEP 1: GATHER AND INSPECT THE SUPPLIES FOR YOUR INJECTION



1 alcohol swab



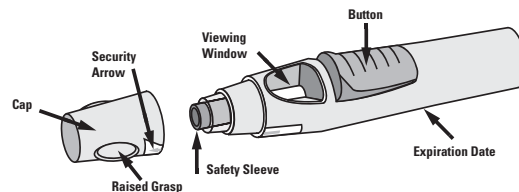
1 cotton ball  
or gauze



1 SIMPONI™ single dose  
SmartJect™ autoinjector



sharps container for  
autoinjector disposal

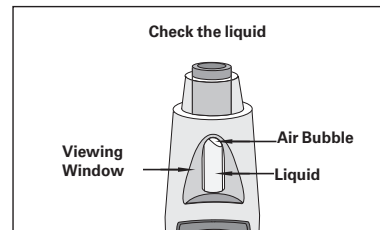


**1. Check Expiration Date on SmartJect™ autoinjector label:** If it has passed, do not use the SmartJect™ autoinjector. Call your doctor or pharmacist, or call 1-800-457-6399 for help.

**2. Check Security Seal on SmartJect™ autoinjector:** If it is broken, do not use the SmartJect™ autoinjector.

**3. Wait 30 minutes:** To ensure proper injection, allow the SmartJect™ autoinjector to sit at room temperature outside the carton for 30 minutes and out of reach of children. Do not warm the SmartJect™ autoinjector in any other way.

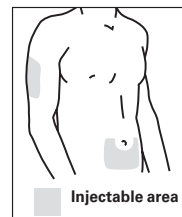
**4. Check the liquid through the viewing window of the SmartJect™ autoinjector:** Make sure that the liquid is clear and colorless to slightly yellow in color. You may see a small amount of tiny particles that are white, or that you can see through. **Do not inject the liquid if it is cloudy or discolored, or has large particles in it.** You may also notice an air bubble. This is normal.



## STEP 2: CHOOSE AND PREPARE THE INJECTION SITE

**1. Choose the injection site:** The recommended injection site is the front of your middle thighs. You can also use the lower part of the abdomen below the navel/belly button, except for the two-inch area directly around the navel. If a caregiver is giving you the injection, the outer area of the upper arms may also be used. Do not inject into areas where the skin is tender, bruised, red, scaly, or hard. Avoid areas with scars or stretch marks.

**2. Prepare the injection site:** Wash your hands well with soap and warm water. Wipe the injection site with an alcohol swab. Do not touch this area again before giving the injection. Allow the skin to dry before injecting. Do not fan or blow on the clean area.



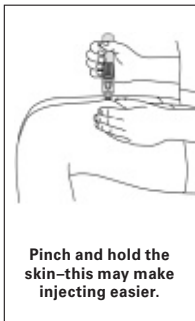
# READ THIS ENTIRE SHEET BEFORE USING THE SINGLE DOSE SMARTJECT™ AUTOINJECTOR.

## STEP 3: INJECTING SIMPONI™ USING THE SINGLE DOSE SMARTJECT™ AUTOINJECTOR

### 1. Remove the Cap - Do not remove the cap until you are ready to inject

**SIMPONI™** Inject SIMPONI™ within 5 minutes after the cap has been removed. When you are ready to inject, twist the cap slightly to break the security seal. Pull the cap off and throw it in the trash right away. **DO NOT** replace the cap, as it could damage the needle.

### 2. Hold the SmartJect™ autoinjector comfortably in your hand. Do not press the button.



**3. Push the open end of the SmartJect™ autoinjector firmly against your skin at a 90-degree angle.** Use your free hand to pinch and hold the skin at the injection site. This can help you create a firmer, more stable surface for your injection, and may make injecting easier. You will not be able to push the button unless the SmartJect™ autoinjector is pressed **firmly** against your skin.

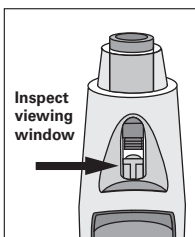
**4. Press the button to inject - You will hear a loud click—don't be alarmed. This click indicates the injection has begun. Do not pull the SmartJect™ autoinjector away from your skin.** If you pull the SmartJect™ autoinjector away from the skin, you might not get your full dose of medicine. You will also feel a needle prick at this time.

### 5. Wait for Second Click - Continue to hold the single dose SmartJect™ autoinjector firmly against your skin until you hear the second click.

This usually takes about 3 to 6 seconds, but may take up to 15 seconds. The second click means your injection is complete and the needle has pulled back into the SmartJect™ autoinjector. Lift the SmartJect™ autoinjector from the injection site after the second click.

Note – If you have hearing problems, count for 15 seconds from the time you press the button and then lift the SmartJect™ autoinjector from the injection site.

## STEP 4: AFTER THE INJECTION



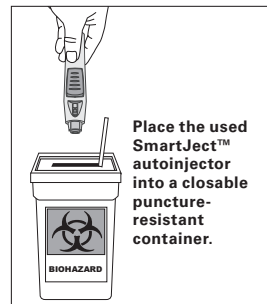
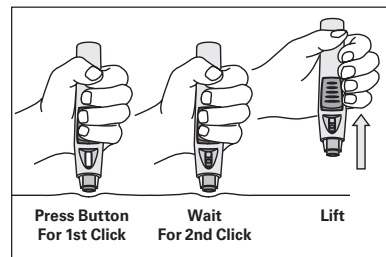
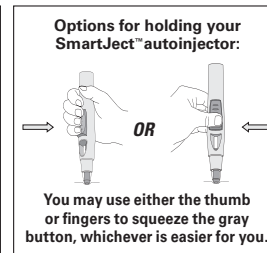
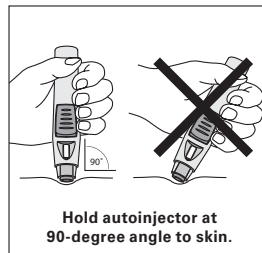
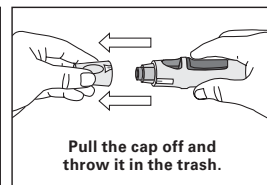
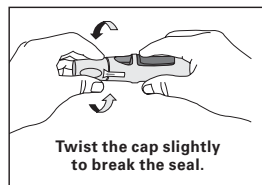
**1. Check the viewing window** - Make sure that the yellow indicator is visible. This shows you that the SmartJect™ autoinjector has worked properly. If you do not see the yellow indicator in the viewing window, call 1-800-457-6399 for help.

**2. Dispose of the single dose SmartJect™ autoinjector** - Place the used SmartJect™ autoinjector into a closable puncture-resistant container. Do not throw away your used SmartJect™ autoinjector in household trash. Do not recycle.

**3. Use Cotton Ball or Gauze** - After the injection there may be a small amount of blood or liquid at the injection site, which is normal. You can press a cotton ball or gauze over the injection site for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if needed.

For injection assistance, please call SimponiOne™ Nursing Support Line at 877-MY SIMPONI (877-697-4676) or for more information visit [www.simpONI.com](http://www.simpONI.com).

**Please read the accompanying Medication Guide, and discuss any questions you may have with your doctor.**



## Medication Guide

### MEDICATION GUIDE SIMPONI™ (SIM-po-nee) (golimumab)

Read the Medication Guide that comes with SIMPONI before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment. It is important to remain under your doctor's care while using SIMPONI.

#### 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 tuberculosis (TB), and 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 before starting SIMPONI.
- Your doctor should monitor you closely for signs and symptoms of TB during treatment with SIMPONI.

You should not start taking 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
  - diarrhea or stomach pain
  - burning when you urinate or urinate more often than normal
  - feel very tired
- are being treated for an infection
- get a lot of infections or have infections that keep coming back
- have diabetes, HIV, or a weak immune system. People with these conditions have a higher chance for infections.
- have TB, or have been in close contact with someone with TB
- 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. Ask your doctor, if you do not know if you have lived in an area where these infections are common.
- have or have had hepatitis B
- use the medicine Orenzia (abatacept), Kineret (anakinra), or Rituxan (rituximab)

**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 make worse any infection that you have.

#### Cancer

- There have been cases of unusual cancers in children and teenage patients taking TNF-blocking agents.
- For children and adults taking TNF-blocker medicines, including SIMPONI, the chances of getting lymphoma or other cancers may increase.
- 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.

#### 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 methotrexate
- to treat active ankylosing spondylitis (AS)

You may continue to use other medicines that help treat your condition while taking SIMPONI, such as non-steroidal anti-inflammatory drugs (NSAIDs) and prescription steroids, as recommended by your doctor.

#### What should I tell my doctor before starting treatment with SIMPONI?

SIMPONI may not be right for you. Before starting SIMPONI, tell your doctor about all your medical conditions, including if you:

- have an infection (see “**What is the most important information I should know about SIMPONI?**”).
- have or have had lymphoma 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.
- have recently received or are scheduled to receive a vaccine. People taking SIMPONI should not receive live vaccines. People taking SIMPONI can receive non-live vaccines.
- are allergic to rubber or latex. The needle cover on the prefilled syringe and SmartJect autoinjector contains dry natural rubber.
- are pregnant or planning to become pregnant. It is not known if SIMPONI will harm your unborn baby.
- are breastfeeding. You and your doctor should decide if you will take SIMPONI or breastfeed. You should not do both without talking to your doctor first.

**Tell your doctor about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially, tell your doctor if you use:

- ORENCIA (abatacept), KINERET (anakinra), or RITUXAN (rituximab). You should not take SIMPONI while you are also taking ORENCIA or KINERET. Your doctor may not want to give you SIMPONI if you have received RITUXAN recently.
- Another TNF-blocker medicine. You should not take SIMPONI while you are also taking REMICADE (infliximab), HUMIRA (adalimumab), ENBREL (etanercept), or CIMZIA (certolizumab pegol).

Ask your doctor if you are not sure if your medicine is one listed above.

Keep a list of all your medications with you to show your doctor and pharmacist each time you get a new medicine.

#### How should I use SIMPONI?

- SIMPONI is given as an injection under the skin (subcutaneous injection or SC).
- SIMPONI should be injected one time each month.
- If your doctor 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. Do not try to inject SIMPONI yourself until you have been shown the right way to give the injections by your doctor or nurse.
- Use SIMPONI exactly as prescribed by your doctor.
- SIMPONI comes in a prefilled syringe or SmartJect autoinjector. Your doctor will prescribe the type that is best for you.
- See the detailed **Patient Instructions for Use** at the end of this Medication Guide for instructions about the right way to prepare and give your SIMPONI injections at home.
- Do not miss any doses of SIMPONI. If you forget to use

SIMPONI, inject your dose as soon as you remember. Then, take your next dose at your regular scheduled time. In case you are not sure when to inject SIMPONI, call your doctor or pharmacist.

### What are the possible side effects with SIMPONI?

SIMPONI can cause serious side effects, including:

See “What is the most important information I should know about SIMPONI?”

### Serious Infections

#### Hepatitis B infection in people who carry the virus in their blood.

• 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 may do blood tests before you start treatment with SIMPONI and while you are using SIMPONI. Tell your doctor if you have any of the following symptoms of a possible hepatitis B infection:

- feel very tired
- skin or eyes look yellow
- little or no appetite
- vomiting
- muscle aches
- dark urine
- clay-colored bowel movements
- fevers
- chills
- stomach discomfort
- skin rash

#### Heart failure, including new heart failure or worsening of heart failure that you already have.

New or worse heart failure can happen in people who use TNF-blocker medicines like SIMPONI.

- If you have heart failure, your condition should be watched closely while you take SIMPONI.
- Call your doctor right away if you get new or worsening symptoms of heart failure while taking SIMPONI (such as shortness of breath or swelling of your lower legs or feet).

### Nervous System Problems

Rarely, people using TNF-blocker medicine have nervous system problems such as multiple sclerosis.

- Tell your doctor right away if you get any of these symptoms:
  - vision changes
  - weakness in your arms or legs
  - numbness or tingling in any part of your body

### 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:

- feel very tired
- skin or eyes look yellow
- poor appetite or vomiting
- pain on the right side of your stomach (abdomen)

### Blood Problems

Low blood counts have been seen with other TNF blockers. 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.

### Common side effects with SIMPONI include:

- upper respiratory tract infection
- nausea
- abnormal liver tests
- redness at the site of injection
- high blood pressure
- bronchitis
- dizziness
- sinus infection (sinusitis)
- flu
- runny nose
- fever
- cold sores
- numbness or tingling

Other side effects with SIMPONI include:

- **Immune System Problems.** Rarely, people using TNF-blocker

medicines have developed symptoms that are like the symptoms of lupus. Tell your doctor if you have any of these symptoms:

- a rash on your cheeks or other parts of the body
- sensitivity to the sun
- new joint or muscle pains
- becoming very tired
- chest pain or shortness of breath
- swelling of the feet, ankles, and/or legs
- **Psoriasis.** Some people using SIMPONI had new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red scaly patches or raised bumps that are filled with pus. Your doctor may decide to stop your treatment with SIMPONI.
- **Allergic Reactions.** Allergic reactions can happen in people who use TNF-blocker medicines. Call your doctor right away if you have any of these symptoms of an allergic reaction:
  - hives
  - swollen face
  - breathing trouble
  - chest pain

These are not all of the side effects with SIMPONI. Tell your doctor about any side effect that bothers you or does not go away. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

### How do I store SIMPONI?

- Refrigerate SIMPONI at 36°F to 46°F (2°C to 8°C).
- Do not freeze SIMPONI.
- Keep SIMPONI in the carton to protect it from light when not being used.
- Do not shake SIMPONI.

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

### General Information about SIMPONI

- Medicines are sometimes prescribed for purposes other than those listed in the 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 condition that you have. It may harm them.
- 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](http://www.simponi.com) or call 1-800-457-6399.

### What are the ingredients in SIMPONI?

Active ingredient: golimumab.

Inactive ingredients: L-histidine, L-histidine monohydrochloride monohydrate, sorbitol, polysorbate 80, and water for injection.

SIMPONI does not contain preservatives.

### Manufactured by:

Centocor Ortho Biotech Inc.  
Horsham, PA 19044  
US License No. 1821

Revised: 11/2009  
25GL09421

This Medication Guide has been approved by the U.S. Food and Drug Administration.



**Simpsoni**<sup>™</sup>  
golimumab