RA-2, and RA-3) versus patients treated with the MTX alone. There was no clear evidence of improved ACR response with the higher SIMPONI dose group (100 mg) compared to the lower SIMPONI dose group (50 mg). In Studies RA-2 and RA-3, the SIMPONI monotherapy groups were not statistically different from the MTX monotherapy groups in ACR responses. Table 2 shows the proportion of patients with the ACR response for the SIMPONI 50 mg and control groups in Studies RA-1, RA-2, and RA-3. In the subset of patients who received SIMPONI in combination with MTX in Study RA-1, the proportion of patients achieving ACR 20, 50 and 70 responses at Week 14 were 40%, 18%, and 13%, respectively, in the SIMPONI 50 mg + MTX group (N = 103) compared with 17%, 6%, and 2%, respectively, in the placebo + MTX group (N = 107). Table 3 shows the percent improvement in the components of the ACR response criteria for the SIMPONI 50 mg + MTX and MTX groups in Study RA-2. The percent of patients achieving ACR 20 responses by visit for Study RA-2 is shown in Figure 1. ACR 20 responses were observed in 38% of patients in the SIMPONI 50 mg + MTX group at the first assessment (Week 4) after the initial SIMPONI administration.

Table 2. Studies RA-1, RA-2, and RA-3 Proportion of Patients with an ACR Response[a]

	Study RA-1 Active RA previously treated with one or more doses of TNF-blockers		**Study RA-2 Active RA, despite MTX**		**Study RA-3 Active RA, MTX Naïve**	
	Placebo ± DMARDs[b]	SIMPONI 50 mg ± DMARDs[b]	Background MTX	SIMPONI 50 mg + Background MTX	MTX	SIMPONI 50 mg + MTX
N[c]	155	153	133	89	160	159
ACR 20						
Week 14	18%	35%	33%	55%	NA	NA
Week 24	17%	34%	28%	60%	49%	62%
ACR 50						
Week 14	6%	16%	10%	35%	NA	NA
Week 24	5%	18%	14%	37%	29%	40%
ACR 70						
Week 14	2%	10%	4%	13%	NA	NA
Week 24	3%	12%	5%	20%	16%	24%[d]

a Approximately 78% and 58% of the patients received concomitant low dose corticosteroids (equivalent to ≤ 10 mg of prednisone a day) and NSAIDs, respectively, during the 3 pooled RA trials.
b DMARDs in Study RA-1 included MTX, HCQ, and/or SSZ (about 68%, 8%, and 5% of patients received MTX, HCQ,and SSZ, respectively).
c N reflects randomized patients.
d Not significantly different from MTX monotherapy.
NA Not applicable, as data was not collected at Week 14 in Study RA-3.

Table 3. Study RA-2 — Median Percent Improvement from Baseline in the Individual ACR Components at Weeks 14[a]

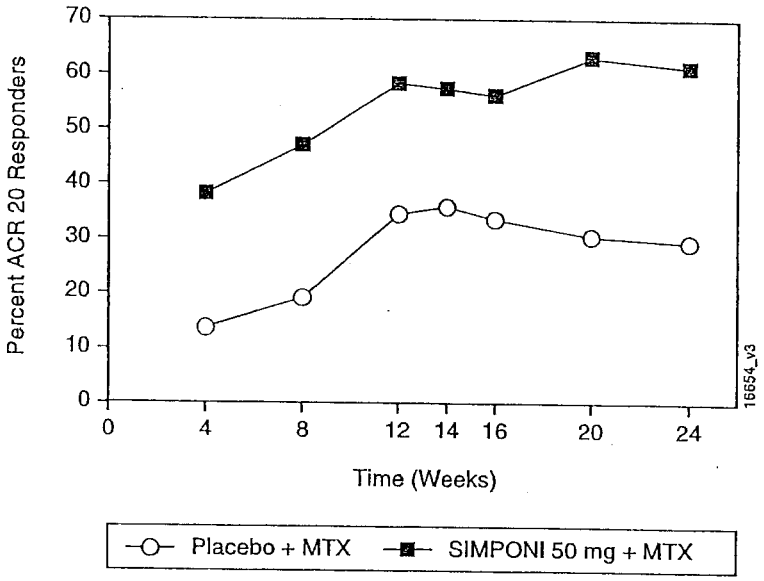
	Background MTX	SIMPONI 50 mg + Background MTX
N[b]	133	89
Number of swollen joints (0-66)		
Baseline	12	13
Week 14	38%	62%
Number of tender joints (0-68)		
Baseline	21	26
Week 14	30%	60%
Patient's assessment of pain (0-10)		
Baseline	5.7	6.1
Week 14	18%	55%
Patient's global assessment of disease activity (0-10)		
Baseline	5.3	6.0
Week 14	15%	45%
Physician's global assessment of disease activity (0-10)		
Baseline	5.7	6.1
Week 14	35%	55%
HAQ score (0-3)		
Baseline	1.25	1.38
Week 14	10%	29%
CRP (mg/dl)		
Baseline	0.8	1.0
Week 14	2%	44%

Note: Baseline values are medians.

a In Study RA-2, about 70% and 85% of patients received concomitant low dose corticosteroids (equivalent to ≤ 10 mg of prednisone a day) and/or NSAIDs during the trials, respectively.

b N reflects randomized patients; actual number of patients evaluable for each endpoint may vary.

Figure 1. Study RA- 2 — Percent of Patients Achieving ACR 20 Response by Visit: Randomized Patients*



* The same patients may not have responded at each timepoint.

Physical Function Response in Patients with RA

In Studies RA-1 and RA-2, the SIMPONI 50 mg groups demonstrated a greater improvement compared to the control groups in the change in mean Health Assessment Questionnaire Disability Index (HAQ-DI) score from baseline to Week 24: 0.25 vs. 0.05 in RA-1, 0.47 vs. 0.13 in RA-2, respectively. Also in Studies RA-1 and RA-2, the SIMPONI 50 mg groups compared to the control groups had a greater proportion of HAQ responders (change from baseline > 0.22) at Week 24: 44% vs. 28%, 65% vs. 35%, respectively.

14.2 Psoriatic Arthritis

The safety and efficacy of SIMPONI were evaluated in a multi-center, randomized, double-blind, placebo-controlled trial in 405 adult patients with moderately to severely active PsA (≥ 3 swollen joints and ≥ 3 tender joints) despite NSAID or DMARD therapy (Study PsA). Patients in this study had a diagnosis of PsA for at least 6 months with a qualifying psoriatic skin lesion of at least 2 cm in diameter. Previous treatment with a biologic TNF-blocker was not allowed. Patients were randomly assigned to placebo (n = 113), SIMPONI 50 mg (n = 146), or SIMPONI 100 mg (n = 146) given subcutaneously every 4 weeks. Patients were allowed to receive stable doses of concomitant MTX (≤ 25 mg/week), low dose oral corticosteroids (equivalent to ≤ 10 mg of prednisone a day), and/or NSAIDs during the trial. The use of other DMARDs including SSZ, HCQ, cytotoxic agents, or other biologics was prohibited. The primary endpoint was the percentage of patients achieving ACR 20 response at Week 14. Placebo-controlled efficacy data were collected and analyzed through Week 24.

Patients with each subtype of PsA were enrolled, including polyarticular arthritis with no rheumatoid nodules (43%), asymmetric peripheral arthritis (30%), distal interphalangeal (DIP) joint arthritis (15%), spondylitis with peripheral arthritis (11%), and arthritis mutilans (1%). The median duration of

PsA disease was 5.1 years, 78% of patients received at least one DMARD in the past, and approximately 48% of patients received MTX, and 16% received low dose oral steroids.

Clinical Response in Patients with PsA

SIMPONI ± MTX, compared with placebo ± MTX, resulted in significant improvement in signs and symptoms as demonstrated by the proportion of patients with an ACR 20 response at Week 14 in Study PsA (see Table 4). There was no clear evidence of improved ACR response with the higher SIMPONI dose group (100 mg) compared to the lower SIMPONI dose group (50 mg). ACR responses observed in the SIMPONI-treated groups were similar in patients receiving and not receiving concomitant MTX. Similar ACR 20 responses at Week 14 were observed in patients with different PsA subtypes. However, the number of patients with arthritis mutilans was too small to allow meaningful assessment. SIMPONI 50 mg treatment also resulted in significantly greater improvement compared with placebo for each ACR component in Study PsA (Table 5). Treatment with SIMPONI resulted in improvement in enthesitis and skin manifestations in patients with PsA. However, the safety and efficacy of SIMPONI in the treatment of patients with plaque psoriasis has not been established.

The percent of patients achieving ACR 20 responses by visit for Study PsA is shown in Figure 2. ACR 20 responses were observed in 31% of patients in the SIMPONI 50 mg + MTX group at the first assessment (Week 4) after the initial SIMPONI administration.

Table 4. Study PsA - Proportion of Patients with ACR Responses

	Placebo ± MTX[a]	**SIMPONI 50 mg ± MTX[a]**
N[b]	113	146
ACR 20		
Week 14	**9 %**	**51 %**
Week 24	12 %	52 %
ACR 50		
Week 14	2 %	30 %
Week 24	4 %	32 %
ACR 70		
Week 14	1 %	12 %
Week 24	1 %	19 %

a In Study PsA, about 48%, 16%, and 72% of the patients received stable doses of MTX (≤ 25 mg/day), low dose corticosteroids (equivalent to ≤ 10 mg of prednisone a day), and NSAIDs, respectively.
b N reflects randomized patients.
Bold text indicates primary endpoint

Table 5. Study PsA - Percent Improvement in ACR Components at Week 14

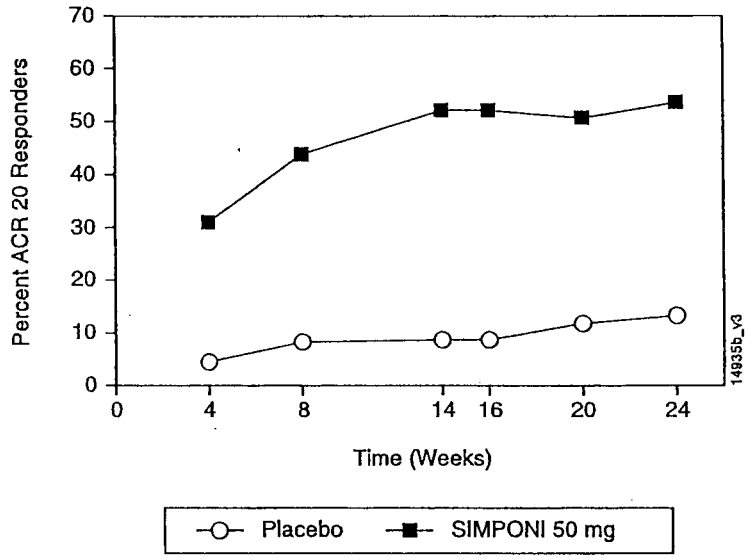
	Placebo± MTX[a]	SIMPONI 50 mg ± MTX[a]
N[b]	113	146
Number of swollen joints (0-66)		
Baseline	10.0	11.0
Week 14	8 %	60 %
Number of tender joints (0-68)		
Baseline	18.0	19.0
Week 14	0 %	54 %
Patient's assessment of pain (0-10)		
Baseline	5.4	5.8
Week 14	-1 %	48 %
Patient's global assessment of disease activity (0-10)		
Baseline	5.2	5.2
Week 14	2 %	49 %
Physician's global assessment of disease activity (0-10)		
Baseline	5.2	5.4
Week 14	7 %	59 %
HAQ score (0-10)		
Baseline	1.0	1.0
Week 14	0 %	28 %
CRP (mg/dL) (0-10)		
Baseline	0.6	0.6
Week 14	0 %	40 %

Note: Baseline are median values

a In Study PsA, about 48%, 16%, and 78% of the patients received stable doses of MTX (≤ 25 mg/day), low dose corticosteroids (equivalent to ≤ 10 mg of prednisone a day), and NSAIDs, respectively.

b N reflects randomized patients; actual number of patients evaluable for each endpoint may vary by timepoint

Figure 2. Study PsA – Percent of ACR 20 PsA Responders by Visit: Randomized Patients*



* The same patients may not have responded at each timepoint.

Physical Function Response in Patients with PsA
In Study PsA, SIMPONI 50 mg demonstrated a greater improvement compared to placebo in the change in mean Health Assessment Questionnaire Disability Index (HAQ-DI) score from baseline to Week 24 (0.33 and -0.01, respectively). In addition, the SIMPONI 50 mg group compared to the placebo group had a greater proportion of HAQ responders ($\geq$ 0.3 change from baseline) at Week 24: 43% vs. 22%, respectively.

14.3 Ankylosing Spondylitis

The safety and efficacy of SIMPONI were evaluated in a multi-center, randomized, double-blind, placebo-controlled trial in 356 adult patients with active ankylosing spondylitis according to modified New York criteria for at least 3 months (Study AS). Patients had symptoms of active disease [defined as a Bath AS Disease Activity Index (BASDAI) $\geq$ 4 and VAS for total back pain of $\geq$ 4, on scales of 0 to 10 cm] despite current or previous NSAID therapy. Patients were excluded if they were previously treated with a biologic TNF-blocker or if they had complete ankylosis of the spine. Patients were randomly assigned to placebo (n = 78), SIMPONI 50 mg (n = 138), or SIMPONI 100 mg (n = 140) administered subcutaneously every 4 weeks. Patients were allowed to continue stable doses of concomitant MTX, sulfasalazine (SSZ), hydroxychloroquine (HCQ), low dose corticosteroids (equivalent to < 10 mg of prednisone a day), and/or NSAIDs during the trial. The use of other DMARDs including cytotoxic agents or other biologics was prohibited.

The primary endpoint was the percentage of patients achieving an ASsessment in Ankylosing Spondylitis (ASAS) 20 response at Week 14. Placebo-controlled efficacy data were collected and analyzed through Week 24.

In Study AS, the median duration of AS disease was 5.6 years, median duration of inflammatory back pain was 12 years, 83% were HLA-B27 positive, 24% had prior joint surgery or procedure, and 55% received at least one DMARD in the past. During the trial, the use of concomitant DMARDs and/or NSAIDs was as follows: MTX (20%), SSZ (26%), HCQ (1%), low dose oral steroids (16%), and NSAIDs (90%).

Clinical Response in Patients with AS

In Study AS, SIMPONI ± DMARDs treatment, compared with placebo ± DMARDs, resulted in a significant improvement in signs and symptoms as demonstrated by the proportion of patients with an ASAS 20 response at Week 14 (see Table 6). There was no clear evidence of improved ASAS response with the higher SIMPONI dose group (100 mg) compared to the lower SIMPONI dose group (50 mg). Table 7 shows the percent improvement in the components of the ASAS response criteria for the SIMPONI 50 mg ± DMARDs and placebo ± DMARDs groups in Study AS.

The percent of patients achieving ASAS 20 responses by visit for Study AS is shown in Figure 3. ASAS 20 responses were observed in 48% of patients in the SIMPONI 50 mg + MTX group at the first assessment (Week 4) after the initial SIMPONI administration.

Table 6. Study AS – Proportion of ASAS Responders at Weeks 14 and 24

	Placebo ± DMARDs[a]	**SIMPONI 50 mg ± DMARDs[a]**
N[b]	78	138
Responders, % of patients		
ASAS 20		
Week 14	22%	**59%**
Week 24	23%	56%
ASAS 40		
Week 14	15%	45%
Week 24	15%	44%

a During the trial, the concomitant use of stable doses of DMARDS was as follows: MTX (21%), SSZ (25%), and HCQ (1%). About 16% and 89% of patients received stable doses of low dose oral steroids and NSAIDs during the trial, respectively.

b N reflects randomized patients.

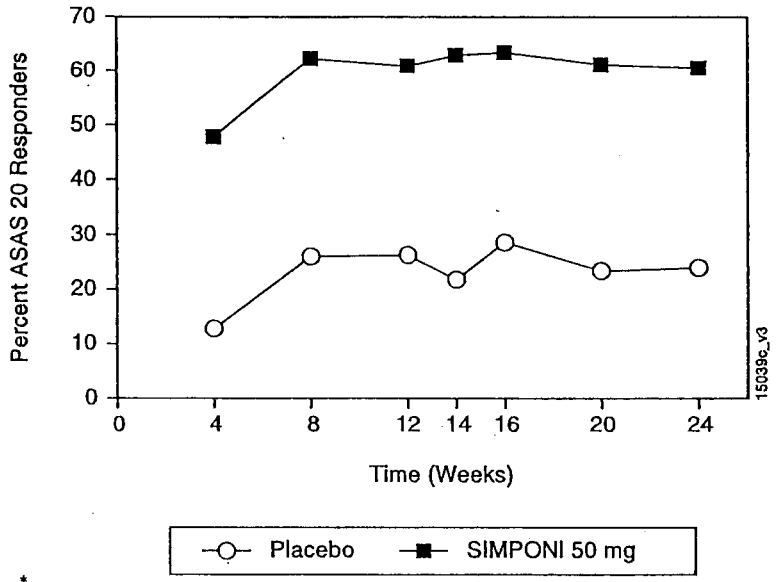
Bold text indicates primary endpoint

Table 7. Study AS — Median Percent Improvement in ASAS Components at Week 14

	Placebo ± DMARDs[a]	SIMPONI 50 mg ± DMARDs[a]
N[b]	78	138
ASAS components		
Patient global assessment (0-10)		
Baseline	7.2	7.0
Week 14	13%	47%
Total back pain (0-10)		
Baseline	7.6	7.5
Week 14	9%	50%
BASFI (0-10)[c]		
Baseline	4.9	5.0
Week 14	-3%	37%
Inflammation (0-10)[d]		
Baseline	7.1	7.1
Week 14	6%	59%

a During the trial, the concomitant use of stable doses of DMARDS was as follows: MTX (21%), SSZ (25%), and HCQ (1%). About 16% and 89% of patients received stable doses of low dose oral steroids and NSAIDs during the trial, respectively.
b N reflects randomized patients
c BASFI is Bath Ankylosing Spondylitis Functional Index
d Inflammation is the mean of two patient-reported stiffness self-assessments in the Bath AS Disease Activity Index (BASDAI)

Figure 3. Study AS – Percent of AS Patients Achieving ASAS 20 Response by Visit: Randomized Patients*



* The same patients may not have responded at each timepoint.

15.0 REFERENCES

1. SEER [database online]. US Population Data – 1969-2004. Bethesda, MD: National Cancer Institute. Release date: January 3, 2007. Available at: http//seer.cancer.gov/popdata/.

16.0 HOW SUPPLIED/STORAGE AND HANDLING

Each SIMPONI prefilled autoinjector or prefilled syringe is packaged in a light-blocking, cardboard outer carton. SIMPONI is available in packs of 1 prefilled syringe NDC 57894-070-01 or 1 prefilled SmartJect autoinjector NDC 57894-070-02.

Prefilled SmartJect Autoinjector

Each single dose SmartJect autoinjector contains a prefilled glass syringe (27 gauge ½ inch) providing 50 mg of SIMPONI per 0.5 mL of solution.

Prefilled Syringe

Each single dose prefilled glass syringe (27 gauge ½ inch) contains 50 mg of SIMPONI per 0.5 mL of solution.

Storage and Stability

SIMPONI must be refrigerated at 2°C to 8°C (36°F to 46°F) and protected from light. Keep the product in the original carton to protect from light until the time of use. Do not freeze. Do not shake. Do not use SIMPONI beyond the expiration date (EXP) on the carton or the expiration date on the prefilled syringe (observed through the viewing window) or the prefilled SmartJect autoinjector.

17.0 PATIENT COUNSELING INFORMATION

See Medication Guide (17.3)

17.1 Patient Counseling

Patients should be advised of the potential benefits and risks of SIMPONI. Physicians should instruct their patients to read the Medication Guide before starting SIMPONI therapy and to read it each time the prescription is renewed.

Infections

Inform patients that SIMPONI may lower the ability of their immune system to fight infections. Instruct the patient of the importance of contacting their doctor if they develop any symptoms of infection, including tuberculosis, invasive fungal infections, and hepatitis B reactivation.

Malignancies

Patients should be counseled about the risk of lymphoma and other malignancies while receiving SIMPONI.

Allergic Reactions

Advise latex-sensitive patients that the needle cover on the prefilled syringe as well as the prefilled syringe in the prefilled SmartJect autoinjector contains dry natural rubber (a derivative of latex).

Other Medical Conditions
Advise patients to report any signs of new or worsening medical conditions such as congestive heart failure, demyelinating disorders, autoimmune diseases, liver disease, cytopenias, or psoriasis.

17.2 Instruction on Injection Technique
The first self-injection should be performed under the supervision of a qualified healthcare professional. If a patient or caregiver is to administer SIMPONI, he/she should be instructed in injection techniques and their ability to inject subcutaneously should be assessed to ensure the proper administration of SIMPONI [*see Medication Guide (17.3)*].

Prior to use, remove the prefilled syringe or the prefilled SmartJect autoinjector from the refrigerator and allow SIMPONI to sit at room temperature outside of the carton for 30 minutes and out of the reach of children.

Do not warm SIMPONI in any other way. For example, do not warm SIMPONI in a microwave or in hot water.

Do not remove the prefilled syringe needle cover or SmartJect autoinjector cap while allowing SIMPONI to reach room temperature. Remove these immediately before injection.

Do not pull the autoinjector away from the skin until you hear a first "click" sound and then a second "click" sound (the injection is finished and the needle is pulled back). It usually takes about 3 to 6 seconds but may take up to 15 seconds for you to hear the second "click" after the first "click." If the autoinjector is pulled away from the skin before the injection is completed, a full dose of SIMPONI may not be administered.

A puncture-resistant container for disposal of needles and syringes should be used. Patients or caregivers should be instructed in the technique of proper syringe and needle disposal, and be advised not to reuse these items.

17.3 Medication Guide
Rx Only

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 Orencia (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.

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:

Serious Infections

(See **"What is the most important information I should know about SIMPONI?"**).

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

Cancer

- 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.
- If you use SIMPONI or other TNF-blockers, your risk of getting lymphoma or other cancers may increase.

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 TNF-blocker medicines including SIMPONI had new psoriasis or worsening of psoriasis that they already had. Symptoms of psoriasis include: red scaly patches or raised bumps that are filled with pus on the skin. Psoriasis may go away or get better after stopping SIMPONI in some people.

- **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 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.

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

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.

It is important to read, understand, and follow these instructions so that you inject SIMPONI the right way. Call your doctor if you or your caregiver has any questions about the right way to inject SIMPONI.

Important information about your SmartJect autoinjector:

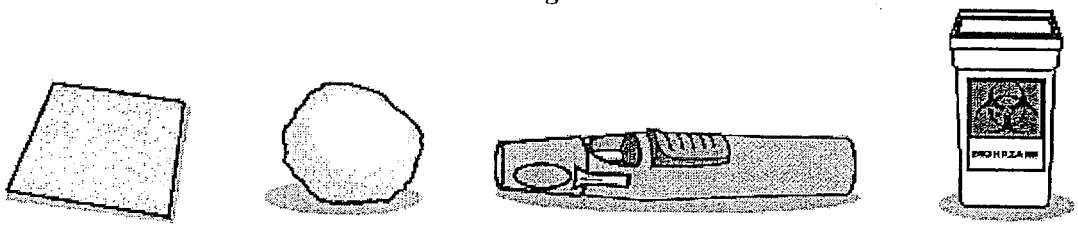
- When the button on the SmartJect autoinjector is pressed to give the dose of SIMPONI you will hear a loud 'click' sound. It is very important that you practice injecting SIMPONI with your doctor or nurse so that you are not startled by this click when you start giving the injections to yourself at home.
- If you pull the SmartJect autoinjector away from the skin before the injection is completed, you may not get your full dose of medicine and may lose some of the medicine.

Do not:
- shake the SmartJect autoinjector at any time
- remove the SmartJect autoinjector cap until you get to that step

Step 1: Gather and inspect the supplies for your injection

You will need these supplies for an injection of SIMPONI. See Figure 1.
- 1 alcohol swab
- 1 cotton ball or gauze
- 1 SIMPONI prefilled SmartJect autoinjector
- sharps container for autoinjector disposal

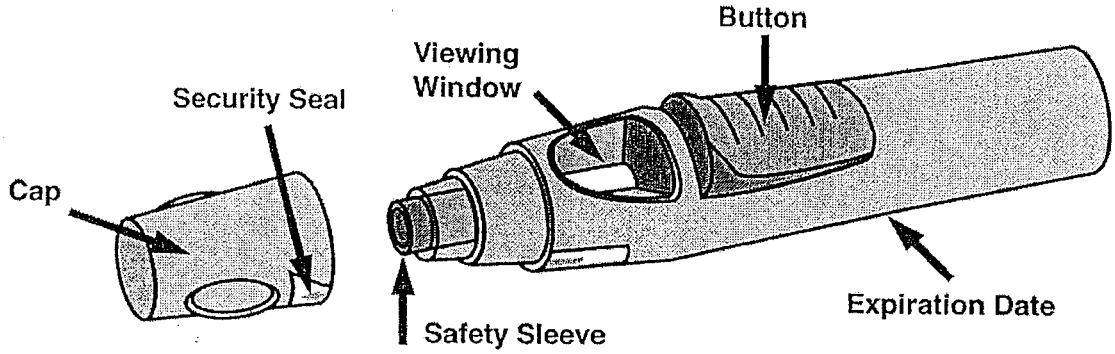
Figure 1



1 alcohol swab | 1 cotton ball or gauze | 1 SIMPONI single use SmartJect autoinjector | sharps container for syringe disposal

The figure below shows what the SmartJect autoinjector looks like. See Figure 2.

Figure 2



1.1 Check Expiration Date

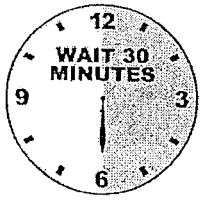
- Check the expiration date ("EXP") on the SmartJect autoinjector.
- You can also check the expiration date printed on the carton.
- If the expiration date has passed, do not use the SmartJect autoinjector. Call your doctor or pharmacist, or call 1-800-457-6399 for help.

1.2 Check Security Seal

- Check the security seal around the cap of the SmartJect autoinjector. If the security seal is broken, do not use the SmartJect autoinjector.

1.3 Wait 30 minutes

- To ensure proper injection, allow the autoinjector to sit at room temperature outside the carton for 30 minutes and out of the reach of children.



Do not warm the SmartJect autoinjector in any other way (For example, **do not** warm it in a microwave or in hot water).
Do not remove the SmartJect autoinjector cap while allowing it to reach room temperature.