

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 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 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 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), ACTEMRA (tocilizumab) 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

- 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.
- Some people receiving medicines that are like SIMPONI, called TNF blockers, developed a rare type of cancer called hepatosplenic T cell lymphoma. This type of cancer often results in death. Most of these people were male teenagers or young men. Also, most people were being treated for Crohn's disease or ulcerative colitis with a TNF blocker and another medicine called azathioprine or 6 mercaptopurine (6-MP).
- Some people treated with SIMPONI have developed certain kinds of skin cancer. If any changes in the appearance of your skin or growths on your skin occur during or after your treatment with SIMPONI, tell your doctor.
- You should see your doctor periodically for skin examinations, especially if you have a history of skin cancer.

What is SIMPONI?

SIMPONI is a prescription medicine called a Tumor Necrosis Factor (TNF) blocker. SIMPONI is used to treat:

- adults with the medicine methotrexate to treat moderately to severely active rheumatoid arthritis (RA)
- adults with active psoriatic arthritis (PsA) alone or with methotrexate
- adults with active ankylosing spondylitis (AS)
- adults and children weighing at least 33 pounds (15 kg) with moderately to severely active ulcerative colitis (UC)

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.

It is not known if SIMPONI is safe and effective in children under 18 years of age in RA, PsA, and AS or weighing less than 33 pounds (15 kg) in pediatric ulcerative colitis.

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 an infection.
- 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 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 bladder cancer). People taking SIMPONI can receive non-live vaccines.
- have a baby and you were using SIMPONI during your pregnancy. Tell your baby’s doctor before your baby receives any vaccine. Your baby may have an increased chance of getting an infection for up to 6 months after birth.
- 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 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:

- use ORENCIA (abatacept) or KINERET (anakinra). You should not take SIMPONI while you are also taking ORENCIA (abatacept) or KINERET (anakinra).
- use other TNF blocker medicines, including REMICADE (infliximab), HUMIRA (adalimumab), ENBREL (etanercept), or CIMZIA (certolizumab pegol).
- receive RITUXAN (rituximab) or ACTEMRA (tocilizumab).

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

Keep a list of all your medicine 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).
- SIMPONI comes in a prefilled syringe or SmartJect® autoinjector. Your doctor will prescribe the type that is best for you.
- If your doctor decides that you, your child, 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.**
 - Adults and children 12 years of age and older may self-inject with SIMPONI prefilled syringe.
 - Only adults may self-inject with SIMPONI SmartJect® autoinjector.
- Use SIMPONI exactly as prescribed by your doctor. Your doctor will tell you how much SIMPONI to inject and when to inject it depending on your medical condition.
- See the detailed **Instructions for Use** that comes with your SIMPONI for information about the right way to prepare and give your SIMPONI injections at home.
- Do not miss any doses of SIMPONI. If you miss a dose of SIMPONI, inject the missed dose as soon as possible. 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 of SIMPONI?

SIMPONI can cause serious side effects, including:

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

Serious Infections.

- Some patients have an increased chance of getting serious infections while receiving SIMPONI. These serious infections include TB and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some patients die from these infections. **Do not** start using SIMPONI if you have an active infection. If you get an infection while receiving treatment with SIMPONI your doctor will treat your infection and may need to stop your SIMPONI treatment. Tell your doctor right away if you have any of the following signs of an infection while taking or after taking SIMPONI:
 - a fever
 - feel very tired
 - have a cough
 - have flu-like symptoms
 - warm, red, or painful skin
- Your doctor will examine you for TB and perform a test to see if you have TB. If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with SIMPONI and during treatment with SIMPONI. Even if your TB test is negative your doctor should carefully monitor you for TB infections while you are taking SIMPONI. People who had a negative TB skin test before receiving SIMPONI have developed active TB. Tell your doctor if you have any of the following symptoms while taking or after taking SIMPONI:
 - cough that does not go away
 - low grade fever
 - weight loss
 - loss of body fat and muscle (wasting)

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 should 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
 - dark urine
 - skin or eyes look yellow
 - little or no appetite
 - vomiting
 - muscle aches
 - 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, 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.
- Call your doctor right away if you get 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).

Nervous System Problems. 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
- weakness in your arms or legs
- numbness or tingling in any part of your body

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, or legs

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 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? (continued)

Allergic Reactions. Allergic reactions can happen in people who use TNF-blocker medicines, including SIMPONI. Some reactions may be serious and can be life-threatening. Some of these reactions can happen after receiving your first dose of SIMPONI. Stop using SIMPONI and call your doctor right away if you have any of these symptoms of an allergic reaction:

- hives
- swollen face
- breathing trouble
- chest pain

The most common side effects of SIMPONI include:

- upper respiratory infection (runny nose, sore throat, and hoarseness or laryngitis)
- reaction at the site of injection (redness, swelling, itching, pain, bruising, or tingling)
- viral infections such as flu and oral cold sores

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.

These are not all of the possible side effects of 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 FDA at 1-800-FDA-1088.

How should I store SIMPONI?

- Refrigerate SIMPONI between 36 °F to 46 °F (2 °C to 8 °C).
- If needed, you may store SIMPONI at room temperature up to 77 °F (25 °C) for one period of time up to 30 days.
 - Write the date of that you remove SIMPONI from the refrigerator on the carton.
 - If SIMPONI has reached room temperature, **do not** put it back in the refrigerator.
 - Throw away SIMPONI if it has been kept at room temperature for 30 days and has not been used.
- **Do not** freeze SIMPONI.
- Keep SIMPONI in the original carton to protect it from light when not being used.
- **Do not** shake SIMPONI.
- Do not use SIMPONI after the expiration date on the carton or on the prefilled syringe or SmartJect® autoinjector.

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

General information about the safe and effective use 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. 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.simoni.com or call 1-800-JANSSEN (1-800-526-7736).

What are the ingredients in SIMPONI?

Active ingredient: golimumab.

Inactive ingredients: L-histidine, and L-histidine monohydrochloride monohydrate, polysorbate 80, sorbitol, and water for injection. SIMPONI does not contain preservatives.

Manufactured by: Janssen Biotech, Inc. Horsham, PA 19044, USA. U.S. License No. 1864.

For patent information: www.janssenpatents.com

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