

ข้อมูลยาสำหรับผู้ป่วย

MEDICATION GUIDE
SIMPONI IV® (SIM-po-nee)
(INN: golimumab)
injection, for intravenous use

What is the most important information I should know about SIMPONI IV?

SIMPONI IV is a medicine that affects your immune system. SIMPONI IV can lower the ability of your immune system to fight infections. Some people have serious infections while receiving SIMPONI IV, 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 IV.
- Your doctor should monitor you closely for signs and symptoms of TB during treatment with SIMPONI IV.

You should not start receiving SIMPONI IV if you have any kind of infection unless your doctor tells you to.

Before receiving SIMPONI IV, 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 IV. 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 (abatcept), KINERET (anakinra), ACTEMRA (tocilizumab) or RITUXAN (rituximab).

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

Cancer

- For children and adults receiving Tumor Necrosis Factor (TNF)-blocker medicines, including SIMPONI IV, the chances of getting cancer may increase.
- There have been cases of unusual cancers in children and teenage patients receiving TNF-blocking agents.
- People with inflammatory diseases, including rheumatoid arthritis (RA), especially those with very active disease, may be more likely to get lymphoma.
- Some people receiving TNF-blockers, like SIMPONI IV, 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 IV developed skin cancer. If any changes in the appearance of your skin or growths on your skin occur during or after your treatment with SIMPONI IV, tell your doctor.
- You should see your doctor periodically for skin examinations, especially if you have a history of skin cancer.

What is SIMPONI IV?

SIMPONI IV is a prescription medicine called a TNF-blocker. SIMPONI IV is used to treat:

- Adults with the medicine methotrexate (MTX) to treat moderately to severely active RA.
- Active psoriatic arthritis (PsA) in people 2 years of age and older.
- Adults with active ankylosing spondylitis (AS).
- Active polyarticular juvenile idiopathic arthritis (pJIA) in people 2 years of age and older.

It is not known if SIMPONI IV is safe and effective in children with PsA and pJIA under 2 years of age or in children with conditions other than PsA and pJIA

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

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

Before starting SIMPONI IV, 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 have had heart failure.
- have or have had a condition that affects your nervous system, such as multiple sclerosis or Guillain-Barré syndrome.
- have a skin problem called psoriasis.
- have recently received or are scheduled to receive a vaccine. People receiving SIMPONI IV should not receive live vaccines or treatment with a weakened bacteria (such as BCG for bladder cancer). People receiving SIMPONI IV can receive non-live vaccines.
- have a baby and you were receiving SIMPONI IV 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 pregnant or plan to become pregnant. It is not known if SIMPONI IV will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if SIMPONI IV passes into your breast milk. You and your doctor should decide if you will receive SIMPONI IV 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 receive SIMPONI IV while you are also receiving 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 or pharmacist for a list of these medicines if you are not sure.

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

How should I receive SIMPONI IV?

- SIMPONI IV is prepared and given by a healthcare provider through a needle placed in your vein (infusion). The infusion is usually given in your arm and should take 30 minutes.
- Your doctor will decide how much SIMPONI IV you will receive. Your usual schedule for receiving SIMPONI IV after your first treatment should be:
 - 4 weeks after your first treatment
 - every 8 weeks after that
- If you miss an appointment to receive SIMPONI IV, make another appointment as soon as possible.

What are the possible side effects of SIMPONI IV?

SIMPONI IV can cause serious side effects, including:

See "**What is the most important information I should know about SIMPONI IV?**"

Serious Infections.

- Some patients have an increased chance of getting serious infections while receiving SIMPONI IV. 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. If you get an infection while receiving

treatment with SIMPONI IV your doctor will treat your infection and may need to stop your SIMPONI IV treatment. Tell your doctor right away if you have any of the following signs of an infection while receiving or after receiving SIMPONI IV:

- 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 IV and during treatment with SIMPONI IV. Even if your TB test is negative your doctor should carefully monitor you for TB infections while you are receiving SIMPONI IV. People who had a negative TB skin test before receiving SIMPONI IV have developed active TB. Tell your doctor if you have any of the following symptoms while receiving or after receiving SIMPONI IV:
 - 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 IV. Your doctor should do blood tests before you start treatment with SIMPONI IV and while you are receiving SIMPONI IV.

- 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 IV. If you develop new or worsening heart failure with SIMPONI IV, you may need to be treated in a hospital, and it may result in death.

- If you have heart failure before starting SIMPONI IV, your condition should be watched closely during treatment with SIMPONI IV.
- Call your doctor right away if you get new or worsening symptoms of heart failure during treatment with SIMPONI IV (such as shortness of breath or swelling of your lower legs or feet, or sudden weight gain).

Nervous System Problems. Rarely, people receiving TNF-blocker medicines, including SIMPONI IV, 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 receiving 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 receive TNF-blocker medicines, including SIMPONI IV. These problems can lead to liver failure and death. Call your doctor right away if you have any of these symptoms:

- feel very tired
- poor appetite or vomiting

- skin or eyes look yellow
- pain on the right side of your stomach (abdomen)

Blood Problems. Low blood counts have been seen with SIMPONI IV. 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 IV.

Allergic Reactions. Allergic reactions can happen in people who receive TNF-blocker medicines, including SIMPONI IV. Some reactions may be serious and can be life-threatening. Some of these reactions can happen after receiving your first dose of SIMPONI IV. 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 IV include:

- upper respiratory infection (runny nose, sore throat, and hoarseness or laryngitis)
- abnormal liver tests
- decreased blood cells that fight infection
- viral infections, such as flu and cold sores in the mouth
- bronchitis
- high blood pressure
- rash

These are not all of the possible side effects of SIMPONI IV.

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.

General information about the safe and effective use of SIMPONI IV.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your doctor or pharmacist for information about SIMPONI IV that is written for health professionals.

What are the ingredients in SIMPONI IV?

Active ingredient: golimumab.

Inactive ingredients: L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sorbitol, and water for injection. SIMPONI IV is preservative-free and is not made with natural rubber latex.

Storage and Handling:

Store in a refrigerator 2°C-8°C (36°F to 46°F) and protect from light. Keep the product in the original carton to protect from light until the time of use. Do not freeze. Do not shake.

If needed, SIMPONI IV may be stored at temperature up to 25°C (77°F) for a maximum single period of 30 days in the original carton to protect from light. Once SIMPONI IV has been stored at room temperature, do not return the product to the refrigerator. If not used within 30 days at room temperature, discard SIMPONI IV.

Keep this medicine out of the sight and reach of children.

Nature and Content of Container: Each single-dose vial contains 50 mg of SIMPONI IV per 4 mL of solution. Injection is a colorless to light yellow solution available in packs of 1 vial.

Manufacturer name and address	Marketing Authorization Number	Date of Authorization
-------------------------------	--------------------------------	-----------------------

Cilag AG, Schaffhausen, Switzerland	1C 15076/64 (NBC)	07-Jul-2021
--	-------------------	-------------

This leaflet was last revised in: 14-Mar-2024 (USPIL V Sep 2020)

Imported by
Janssen-Cilag Ltd., Bangkok, Thailand

To report Suspected Adverse Reactions, please contact us at aepqcjacth@its.jnj.com
For any product information, please contact us at medinfosea@its.jnj.com

Please see full prescribing information at <https://ndi.fda.moph.go.th>