

MEDICATION GUIDE

SIMPONI ARIA®
(SIM-puh-nee AHR-ee-uh)
(golimumab)
For Infusion

Read the Medication Guide for SIMPONI ARIA before each infusion. 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 receiving SIMPONI ARIA.

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

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

You should not receive SIMPONI ARIA if you have any kind of infection unless your doctor says it is okay.

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

Cancer

- For children and adults receiving TNF-blocker medicines, including SIMPONI ARIA, 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 especially those with very active disease, may be more likely to get lymphoma.
- Some people receiving medicines that are like SIMPONI ARIA, 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.
- Some people treated with SIMPONI ARIA 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 ARIA, tell your doctor.
- You should see your doctor periodically for skin examinations, especially if you have a history of skin cancer.

What is SIMPONI ARIA?

SIMPONI ARIA is a prescription medicine called a Tumor Necrosis Factor (TNF) blocker. SIMPONI ARIA is used with the medicine methotrexate to treat adults with moderately to severely active rheumatoid arthritis (RA).

SIMPONI ARIA is not for children under 18 years of age.

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

SIMPONI ARIA may not be right for you. Before receiving SIMPONI ARIA, 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 ARIA?")
- 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 a skin problem called psoriasis
- have recently received or are scheduled to receive a vaccine. People receiving SIMPONI ARIA should not receive live vaccines or treatment with a weakened bacteria (such as BCG for bladder cancer). People receiving SIMPONI ARIA can receive non-live vaccines.
- have a baby and you received SIMPONI ARIA 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 planning to become pregnant. It is not known if SIMPONI ARIA will harm your unborn baby.

- are breastfeeding. It is not known if SIMPONI ARIA passes into your breast milk. You and your doctor should decide if you will receive SIMPONI ARIA 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 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 ARIA 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 medications with you to show your doctor and pharmacist each time you get a new medicine.

How should I receive SIMPONI ARIA?

- SIMPONI ARIA 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 ARIA you will receive based on your weight. Your usual schedule for receiving SIMPONI ARIA after your first treatment should be:
 - 4 weeks after your first treatment
 - every 8 weeks after that
- If you forget or miss an appointment to receive SIMPONI ARIA, make another appointment as soon as possible.
- You may continue to use other medicines for your treatment while taking SIMPONI ARIA, such as non-steroidal anti-inflammatory drugs (NSAIDs), prescription steroids, and pain relief medicines.

What are the possible side effects of SIMPONI ARIA?

SIMPONI ARIA can cause serious side effects, including:

- See **“What is the most important information I should know about SIMPONI ARIA?”**
- **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 receive SIMPONI ARIA. Your doctor should do blood tests before you start treatment with SIMPONI ARIA and while you are receiving SIMPONI ARIA. Tell your doctor if you have any of the following symptoms of a possible hepatitis B infection:
 - feel very tired
 - clay-colored bowel movements
 - dark urine
 - fevers
 - skin or eyes look yellow
 - little or no appetite
 - vomiting
 - muscle aches
 - 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 including SIMPONI ARIA.

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

- **Nervous System Problems**

Rarely, people using TNF-blocker medicines, including SIMPONI ARIA, 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

- **Liver Problems**

Liver problems can happen in people who use TNF-blocker medicines, including SIMPONI ARIA. 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 TNF-blockers, including SIMPONI ARIA. 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 ARIA.

- **Allergic Reactions**

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

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

Other side effects with SIMPONI ARIA 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, or legs

These are not all of the side effects with SIMPONI ARIA. 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.

General Information about SIMPONI ARIA

Medicines are sometimes prescribed for purposes other than those listed in the Medication Guide. Do not use SIMPONI ARIA for a condition for which it was not prescribed.

This Medication Guide summarizes the most important information about SIMPONI ARIA. If you would like more information, talk to your doctor. You can ask your doctor or pharmacist for information about SIMPONI ARIA that is written for health professionals.

For more information go to www.SimponiAria.com or call 1-800-JANSSEN (1-800-526-7736).

What are the ingredients in SIMPONI ARIA?

Active ingredient: golimumab

Inactive ingredients: L-histidine, polysorbate 80, and sorbitol. SIMPONI ARIA does not contain preservatives, natural rubber or latex.

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

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