

# Doctor Discussion Guide



## Before you talk to your doctor, take a few moments to think back.

By discussing not just the last couple of weeks, but the last few months, you can help your doctor identify an appropriate treatment choice. Use the questions in this discussion guide to have a conversation with your doctor at your next appointment, and to find out if SIMPONI ARIA® is right for you.



**QUESTIONS  
TO ASK  
YOURSELF**

1. My joint pain, stiffness, and swelling have  
 gotten worse     been the same     improved
2. Everyday activities such as getting dressed, walking, and running errands have become  
 more difficult     about the same     easier
3. My overall physical well-being has  
 gotten worse     been the same     improved
4. My overall emotional well-being has  
 gotten worse     been the same     improved
5. The frequency of my symptoms has  
 increased     stayed the same     decreased
6. My current treatment provides the symptom relief I expect  
 not at all     sometimes     most of the time

Other things you have noticed: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

SIMPONI ARIA® (golimumab) is a biologic treatment for adults with moderate to severe rheumatoid arthritis (RA), used with the medicine methotrexate. SIMPONI ARIA® is prepared and given by your healthcare provider as a 30-minute infusion every 8 weeks after 2 starter infusions, given 4 weeks apart. The infusion is given through a needle placed in your vein, usually in your arm. Methotrexate is taken as directed.

### SELECTED IMPORTANT SAFETY INFORMATION

SIMPONI ARIA® (golimumab) can lower your ability to fight infections. Serious and sometimes fatal events may occur. There have been reports of serious infections including tuberculosis (TB) and infections caused by bacteria, fungi, or viruses that have spread throughout the body. Other possible serious side effects may include lymphoma, a rare and fatal cancer called hepatosplenic T-cell lymphoma, skin cancer, other cancers, hepatitis B, heart failure, nervous system problems, lupus-like symptoms, or allergic reactions. To learn more about these and other risks, please read the Important Safety Information on page 3 and the [Medication Guide](#), and talk with your doctor.

# Doctor Discussion Guide



QUESTIONS  
TO ASK YOUR  
DOCTOR

1. How would I know if I have joint damage? Does my current medication help stop joint damage?

---

---

2. Could I do better on another treatment?

---

---

3. How is a biologic medication different from my current treatment?

---

---

4. How is SIMPONI ARIA® given? Where would I go for treatment?

---

---

5. How often would I go for treatment? How long would each treatment take?

---

---

6. What are the benefits and risks of SIMPONI ARIA®? Is SIMPONI ARIA® right for me?

---

---

Other questions you may have

---

---

## SELECTED IMPORTANT SAFETY INFORMATION

SIMPONI ARIA® (golimumab) can lower your ability to fight infections. Serious and sometimes fatal events may occur. There have been reports of serious infections including tuberculosis (TB) and infections caused by bacteria, fungi, or viruses that have spread throughout the body. Other possible serious side effects may include lymphoma, a rare and fatal cancer called hepatosplenic T-cell lymphoma, skin cancer, other cancers, hepatitis B, heart failure, nervous system problems, lupus-like symptoms, or allergic reactions. To learn more about these and other risks, please read the Important Safety Information on page 3 and the [Medication Guide](#), and talk with your doctor.

## IMPORTANT SAFETY INFORMATION

### SERIOUS INFECTIONS

**SIMPONI ARIA<sup>®</sup> (golimumab) is a prescription medicine. SIMPONI ARIA<sup>®</sup> can lower your ability to fight infections. There are reports of serious infections caused by bacteria, fungi, or viruses that have spread throughout the body, including tuberculosis (TB) and histoplasmosis. Some of these infections have been fatal. Your doctor will test you for TB before starting SIMPONI ARIA<sup>®</sup> and will closely monitor you for signs of TB during treatment. Tell your doctor if you have been in close contact with people with TB. Tell your doctor if you have been in a region (such as the Ohio and Mississippi River Valleys and the Southwest) where certain fungal infections like histoplasmosis or coccidioidomycosis are common.**

You should not receive SIMPONI ARIA<sup>®</sup> if you have any kind of infection. Tell your doctor if you are prone to or have a history of infections or have diabetes, HIV or a weak immune system. You should also tell your doctor if you are currently being treated for an infection or if you have or develop any signs 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 than normal
- feel very tired

### CANCER

**Unusual cancers have been reported in children and teenage patients taking TNF-blocker medicines.** For children and adults receiving TNF blockers, including SIMPONI ARIA<sup>®</sup>, the chances for getting lymphoma or other cancers may increase. Hepatosplenic T-cell lymphoma, a rare and fatal lymphoma, has occurred mostly in teenage or young adult males with Crohn's disease or ulcerative colitis who were taking a TNF blocker with azathioprine or 6-mercaptopurine. You should tell your doctor if you have had or develop lymphoma or other cancers.

Some people treated with SIMPONI ARIA<sup>®</sup> developed skin cancer. Tell your doctor if any changes in the appearance of your skin or growths on your skin occur during or after your treatment with SIMPONI ARIA<sup>®</sup>. Your doctor should periodically examine your skin, especially if you have a history of skin cancer.

### USE WITH OTHER DRUGS

Tell your doctor about all the medications you take including ORENCIA (abatacept), KINERET (anakinra), ACTEMRA (tocilizumab), RITUXAN (rituximab), or another TNF blocker, or if you are scheduled to or recently received a vaccine. People receiving SIMPONI ARIA<sup>®</sup> should not receive live vaccines or treatment with a weakened bacteria (such as BCG for bladder cancer).

### HEPATITIS B INFECTION

Reactivation of hepatitis B virus has been reported in patients who are carriers of this virus and are receiving TNF-blocker medicines, such as SIMPONI ARIA<sup>®</sup>. Some of these cases have been fatal. Your doctor should do blood tests before and after you start treatment with SIMPONI ARIA<sup>®</sup>. Tell your doctor if you know or think you may be a carrier of hepatitis B virus or if you experience signs of hepatitis B infection, such as:

- 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

(continued)

## IMPORTANT SAFETY INFORMATION (continued)

### HEART FAILURE

Heart failure can occur or get worse in people who use TNF blockers, including SIMPONI ARIA<sup>®</sup>. If you develop new or worsening heart failure with SIMPONI ARIA<sup>®</sup>, you may need treatment in a hospital, and it may result in death. Your doctor will closely monitor you if you have heart failure. Tell your doctor right away if you get new or worsening symptoms of heart failure like shortness of breath, swelling of your lower legs or feet, or sudden weight gain.

### NERVOUS SYSTEM PROBLEMS

Rarely, people using TNF blockers, including SIMPONI ARIA<sup>®</sup>, can have nervous system problems such as multiple sclerosis or Guillain-Barré syndrome. Tell your doctor right away if you have symptoms like vision changes, weakness in your arms or legs, or numbness or tingling in any part of your body.

### IMMUNE SYSTEM PROBLEMS

Rarely, people using TNF blockers have developed lupus-like symptoms. Tell your doctor if you have any symptoms such as a rash on your cheeks or other parts of the body, sensitivity to the sun, new joint or muscle pain, becoming very tired, chest pain or shortness of breath, swelling of the feet, ankles or legs.

### LIVER PROBLEMS

Serious liver problems can happen in people using TNF blockers, including SIMPONI ARIA<sup>®</sup>. Contact your doctor immediately if you develop symptoms such as feeling very tired, skin or eyes look yellow, poor appetite or vomiting, or pain on the right side of your stomach.

### BLOOD PROBLEMS

Low blood counts have been seen with people using TNF blockers, including SIMPONI ARIA<sup>®</sup>. If this occurs, your body may not make enough blood cells to help fight infections or help stop bleeding. Your doctor will check your blood counts before and during treatment. Tell your doctor if you have signs such as fever, bruising, bleeding easily, or paleness.

### ALLERGIC REACTIONS

Allergic reactions can happen in people who use TNF-blocker medicines, including SIMPONI ARIA<sup>®</sup>. Tell your doctor if you have any symptoms of an allergic reaction while receiving SIMPONI ARIA<sup>®</sup> such as hives, swollen face, breathing trouble, or chest pain. Some reactions can be serious and life-threatening.

### OTHER CONSIDERATIONS TO TELL YOUR DOCTOR

Tell your doctor if you have psoriasis.

Tell your doctor if you are pregnant, planning to become pregnant or are breastfeeding or have a baby and received SIMPONI ARIA<sup>®</sup> during pregnancy. Tell your baby's doctor before your baby receives any vaccine because of an increased risk of infection for up to 6 months after birth.

### COMMON SIDE EFFECTS

The most common side effects of SIMPONI ARIA<sup>®</sup> include: upper respiratory infection, viral infections, bronchitis, high blood pressure, and rash.

**Please read the Medication Guide for SIMPONI ARIA<sup>®</sup> and discuss any questions you have with your doctor.**

**Please read the full Prescribing Information and Medication Guide for SIMPONI ARIA<sup>®</sup> and discuss any questions you have with your doctor.**

**You are encouraged to report negative side effects of prescription drugs to the FDA.**

**Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**