

# DISCUSSION GUIDE

for active ankylosing spondylitis



## Trying to decide if SIMPONI ARIA® (golimumab) may be right for you?

First, take a few moments to think back on how you've felt over the past few months.

Then, fill out the questions on this page and share it with your doctor. Your answers can help start the conversation about whether or not SIMPONI ARIA® is right for you.

## QUESTIONS TO ASK YOURSELF

1. My back pain and stiffness have  gotten worse  been the same  improved

2. Everyday activities that require bending down or standing up straight 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. I have experienced symptoms of ankylosing spondylitis  more often  about the same  less often

Other things I have noticed: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

SIMPONI ARIA® (golimumab) is a biologic treatment for adults with moderate to severe rheumatoid arthritis (RA) taken with methotrexate, active psoriatic arthritis (PsA), and active ankylosing spondylitis (AS). 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.

## 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 pages 3-4 and the [Medication Guide](#), and talk with your doctor.



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It's important to make the most of your conversations with your doctor. Be sure to bring this sheet and ask questions during your next appointment.

The questions below can help you decide if SIMPONI ARIA® (golimumab) may be right for you.

## QUESTIONS TO ASK YOUR DOCTOR

1. What are the benefits and risks of SIMPONI ARIA®?

2. Does SIMPONI ARIA® help improve spinal mobility and range of motion?

3. Who would give me my SIMPONI ARIA® treatment?

4. Where would I go to receive infusions of SIMPONI ARIA®?

5. How often would I need to receive infusions of SIMPONI ARIA®?

6. How long does each infusion take?

7. Is there a savings program that can help with medication costs?

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# IMPORTANT SAFETY INFORMATION

## SERIOUS INFECTIONS

**SIMPONI ARIA® (golimumab) is a prescription medicine. SIMPONI ARIA® 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® 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® 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

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 ARIA® and during treatment with SIMPONI ARIA®. Even if your TB test is negative, your doctor should carefully monitor you for TB infections while you are taking SIMPONI ARIA®. People who had a negative TB skin test before receiving SIMPONI ARIA® have developed active TB. Tell your doctor if you have any of the following symptoms while taking or after taking SIMPONI ARIA®:

- cough that does not go away
- low grade fever
- weight loss
- loss of body fat and muscle (wasting)

## CANCER

**Unusual cancers have been reported in children and teenage patients taking Tumor Necrosis Factor (TNF)-blocker medicines.** For children and adults receiving TNF blockers, including SIMPONI ARIA®, 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® 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®. 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® 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®. Some of these cases have been fatal. Your doctor should do blood tests before and after you start treatment with SIMPONI ARIA®. 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
- dark urine
- skin or eyes look yellow
- little or no appetite
- vomiting

(continued on next page)

**Simponi ARIA®**  
golimumab  
for infusion

# IMPORTANT SAFETY INFORMATION (continued)

- muscle aches
- clay-colored bowel movements
- fever
- chills
- stomach discomfort
- skin rash

## HEART FAILURE

Heart failure can occur or get worse in people who use TNF blockers, including SIMPONI ARIA®. If you develop new or worsening heart failure with SIMPONI ARIA®, 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®, 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®. 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®. 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®. Tell your doctor if you have any symptoms of an allergic reaction while receiving SIMPONI ARIA® 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, are breastfeeding, or plan to breastfeed, or have a baby and received SIMPONI ARIA® 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® include: upper respiratory infection, abnormal liver tests, decreased blood cells that fight infection, viral infections, bronchitis, high blood pressure, and rash.

**Please read the full [Prescribing Information](#) and [Medication Guide](#) for SIMPONI ARIA® 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.**

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