



SIMPONI ARIA INFORMED CONSENT FORM

Your physician has recommended a SIMPONI ARIA infusion for the treatment. Before agreeing to this treatment, it is important that you read and understand the following explanation of the SIMPONI ARIA infusion process. This statement will describe the procedure, benefits, discomforts, risks and precautions.

SIMPONI ARIA is a medication that keeps the immune system from attacking healthy tissues in the body. The immune system also defends the body against infections caused by bacteria and viruses. SIMPONI interferes with an important step in this attack. By decreasing the immune system's attack on normal tissues, SIMPONI ARIA can reduce pain and joint inflammation, and can slow the damage to your bones and cartilage.

Indications

SIMPONI ARIA is indicated and FDA approved for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, as well as ulcerative colitis.

Dosage and Administration

SIMPONI ARIA is administered by intravenous infusion that will last a minimum of 30 minutes. One should allow sufficient time for pre and post infusion evaluation. We will place an IV in your arm, which may be uncomfortable.

A full clinical response may not be evident for several weeks following the infusion. You should continue to take all of your other medications, unless otherwise indicated by your physician.

Potential Adverse Reactions

SIMPONI ARIA is generally well tolerated and most reported reactions are mild to moderate, transient and manageable. The following adverse reactions are the most commonly reported:

- Upper respiratory infection
- Viral infection
- Bronchitis
- Hypertension
- Rash

Some more severe side effects have been reported including:

- Serious infection
- Allergic reactions. These reactions are usually mild or moderate, but can be severe.
- There have been rare cases of certain kinds of cancer in patients receiving SIMPONI ARIA. The role of SIMPONI ARIA in the development of cancer is not known.

- Congestive heart failure
- Demyelinating disorders including MS and Guillain-Barre syndrome

Prior to using SIMPONI ARIA, please tell your physician or nurse if you (please initial):

- _____ Have had any allergic reaction to any other TNF inhibitors such as Enbrel, Humira, Cimzia, or Remicade
- _____ Have been previously exposed to tuberculosis (TB)
- _____ Have has Hepatitis B or C Infection
- _____ Pregnant or breast feeding
- _____ Have new symptoms or medical problems
- _____ Have had any live vaccinations recently (These include measles, mumps, rubella, oral polio (the injectable polio vaccine is not live), oral typhoid (typhoid injection is not live), BCG, yellow fever)
- _____ Any Fever or Current Signs/Symptoms of an Infection
- _____ Any Acute Cut, Wound or Rash

I understand all possible side effects from this medication may not have been completely identified and as new information becomes available I will be notified.

I have had the opportunity to fully read, understand and discuss this consent form with my physician and the nurses. By signing this consent, I am agreeing to treatment with SIMPONI ARIA.

Patient's Name

Witness' Name

Patient's Signature

Witness' Signature

Date

Date