



Northwest Rheumatology Associates, P.C.
9555 SW Barnes Road - Suite 150 – Portland, Oregon 97225
Telephone: (503) 297-3384 - Fax: (503) 297-0863
www.nwrheumatology.org

INFORMED CONSENT FOR TREATMENT W/ SIMPONI-ARIA

Simponi Aria has been approved by the Food and Drug Administration (FDA) for the treatment of Rheumatoid Arthritis.

Simponi Aria blocks the action of a protein called Tumor Necrosis Factor (TNF). This blockade results in decreased swelling (inflammation) and decreased immune system function (immunosuppression). Simponi Aria is effective in treating Rheumatoid Arthritis since swelling and an overactive immune system probably play a role in these diseases.

WARNINGS:

Simponi Aria decreases immune system function (immunosuppression), which can result in serious infections including invasive fungal infections or worsening of an existing infection. Death from serious infections have been reported in patients receiving Simponi Aria.

Before starting treatment with Simponi Aria, you should have a tuberculosis skin test done to check for tuberculosis that may not be causing any symptoms (latent tuberculosis). If you have been diagnosed with tuberculosis, anti-tuberculosis medicines must be started before you start Simponi Aria therapy. This will reduce the likelihood of a serious tuberculosis infection. Tell your doctor if you have ever had tuberculosis or have come in contact with someone with tuberculosis. Tell your doctor if you have ever had a positive PPD (tuberculosis skin test) – this may require treatment.

Tell your doctor immediately if you have any complaints that may indicate an infection. These include but are not limited to pink eye, ear pain or drainage, sinus pain or drainage, sore throat, hoarse voice, cough, difficulty breathing, fevers, chills, sweats, vomiting, abdominal pain, diarrhea, burning with urination, increased frequency of urination, vaginal discharge, and cuts or wounds that are red, swollen or draining pus.

Tell your doctor if you have been diagnosed as having an infection, are on antibiotics or if you are prone to recurrent infections. You should not receive Simponi Aria while you have an infection or while you are on antibiotics. Simponi Aria can be restarted once you have completed your antibiotic course and your infection has resolved.

Tell your doctor if you have a planned surgery, as you will need to stop your Simponi Aria temporarily around the time of your surgery.

PRECAUTIONS:

Treatment with Simponi Aria may result in the formation of autoimmune antibodies and, rarely, may cause a lupus-like syndrome. In clinical trials, patients who developed a lupus-like syndrome have had resolution of the syndrome after treatment with Simponi Aria was stopped.

Patients with a long duration of inflammation and chronic exposure to immunosuppressant treatments are more prone to develop cancer, in particular lymphoma. The impact of Simponi Aria on this is not known. Possible long-term side effects such as the development of lymphoma or other cancers cannot be predicted.

It is not known if Simponi Aria can cause fetal harm when given during pregnancy, or if it is safe to receive Simponi Aria while breast feeding

Simponi Aria may worsen congestive heart failure. Some deaths have occurred in patients with congestive heart failure. Tell your doctor if you have been diagnosed with congestive heart failure.

Simponi Aria has been reported to cause liver test abnormalities and blood cell count abnormalities. The blood cell count abnormalities can be severe. You should let your doctor know if you notice bruising, bleeding or paleness of the skin.

Simponi Aria may cause the development of psoriasis or worsening of existing psoriasis.

There are rare reports of Simponi Aria causing damage to the nervous system, for eg. seizures, numbness, tingling, paralysis. Let your doctor know if you develop any such complaints.

You should not receive live vaccines (for eg. polio, smallpox) while on Simponi Aria, without speaking with your doctor. The injected flu vaccine and pneumonia vaccine can be safely administered while on Simponi Aria. The nasal spray version of the flu vaccine is a live vaccine and should not be administered while on Simponi Aria. Please inform your doctor if someone in your household has received or will receive a live virus vaccine.

INFUSION REACTIONS:

Infusion related reactions have occurred in about 1.1% of patients treated Simponi Aria in clinical trials. The following list of reactions may occur less than 3% of the time; upper respiratory tract infections, viral infections, bronchitis, hypertension, rash, fatigue, muscle pain, hives, chest pain, shortness of breath, feet swelling, anxiety, dizziness, and sun sensitivity.

All patients recovered with treatment, and/or with slowing down or stopping the infusion.

MEDICATION ADMINISTRATION:

Simponi Aria is administered as a single intravenous infusion lasting 30-45 minutes. You will be at the office approximately 1 hour. You will see your physician in follow-up to monitor your progress and response to the Simponi Aria. Also, please call us if you experience any side effects, and we will be available to you 24 hours a day if you experience any problems. We may give you additional medication to take before the infusion to reduce the risk of side effects.

EMERGENCY CONTACTS:

In case of emergency, you can contact our office at (503) 297-3384 from 8:00 am to 5:00 pm Monday – Friday, or after hours dial the above number to page your physician or call 911 or go to the emergency room.

I certify that I have read and understand this consent form and agree to receive Simponi Aria intravenous treatment. I have had an opportunity to discuss this treatment with my physician and ask questions regarding the treatment. I will be given a signed copy of this form for my records.

Patient signature

DOB

Date

Witness signature

Date