



Simponi Aria[®] (golimumab) – New indications

- On October 20, 2017, [Janssen announced](#) the FDA approval of [Simponi Aria \(golimumab\)](#) infusion, for the treatment of adults with active psoriatic arthritis (PsA) or active ankylosing spondylitis (AS).
 - Simponi Aria is also indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) in combination with [methotrexate \(MTX\)](#).
- The safety and efficacy of Simponi Aria for the treatment of PsA was demonstrated in a placebo-controlled study of 480 patients. Patients received Simponi Aria 2 mg/kg or placebo at weeks 0, 4, 12 and 20. The primary endpoint was the percentage of patients achieving an American College of Rheumatology (ACR) 20 response at week 14.
 - Of the patients receiving Simponi Aria, 75% achieved ACR 20 response vs. 22% of the placebo patients ($p < 0.001$).
- The safety and efficacy of Simponi Aria for the treatment of AS was demonstrated in a placebo-controlled study of 208 patients. Patients received Simponi Aria 2 mg/kg or placebo at weeks 0, 4, and 12. The primary endpoint was the percentage of patients achieving an Assessment in Ankylosing Spondylitis (ASAS) 20 response at week 16.
 - Of the patients receiving Simponi Aria, 73% achieved ASAS 20 response vs. 26% of the placebo patients ($p < 0.001$).
- Simponi Aria carries a boxed warning for serious infections and malignancy.
- The recommended dosage of Simponi Aria for all indications is 2 mg/kg given as an intravenous (IV) infusion over 30 minutes at weeks 0 and 4, then every 8 weeks thereafter.
 - For patients with RA, Simponi Aria should be given in combination with MTX.
 - For patients with PsA or AS, Simponi Aria may given with or without MTX or other non-biologic disease-modifying antirheumatic drugs.
 - Corticosteroids, nonsteroidal anti-inflammatory drugs, and/or analgesics may be continued during treatment with Simponi Aria.
 - The efficacy and safety of switching between IV and SC formulations and routes of administration have not been established.



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