ACR/ARP Medication Guide

American College of Rheumatology
Empowering Rheumatology Professionals

Association of Rheumatology Professionals
The Interprofessional Division of the American College of Rheumatology

Golimumab (Simponi®, Simponi Aria®)

Golimumab (Simponi Aria®) is a human IgG1K monoclonal antibody specific for human tumor necrosis factor alpha (TNFα), a cytokine protein. Golimumab is an antibody with human-derived antibody variable and constant regions. Golimumab binds to both soluble and transmembrane bioactive forms of TNFα, blocking the binding of TNFα to its receptors and inhibiting the biologic activity of TNFα.

Resources from Manufacturer

Simponi Patient Medication Guide
Simponi Full Prescribing Information
Simponi Aria Medication Guide
Simponi Aria Full Prescribing Information
Simponi Aria Dosing Calculator
Simponi Co-pay Assistance Program
Janssen Patient Assistance Foundation
J&J Patient Assistance Foundation

FDA-Approved Indications and Dosing in Rheumatology

Golimumab is indicated for:

- Adults with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
- Adult patients with active Ankylosing Spondylitis (AS)
- Active Psoriatic Arthritis (PsA) in patient 2 years of age and older
- Active polyarticular Juvenile Idiopathic Arthritis (PJIA) in patients 2 years of age and older

Dosing:

Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), and Ankylosing Spondylitis (AS)

- IV infusion: 2mg/ over 30 minutes at weeks 0 and 4 and then every 8 weeks thereafter
- Subcutaneous: 50 mg subcutaneous once a month
- Golimumab can be given in combination with methotrexate. Other non-biologic DMARDS, corticosteroids, and nonsteroidal anti-inflammatory drugs (NSAIDS) and/or other analgesics may be continued during treatment.

Pediatric patients with polyarticular Juvenile Idiopathic Arthritis (PJIA) and Psoriatic Arthritis

- IV Infusion: 80 mg/m2 over 30 minutes at weeks 0 and 4 and then every 8 weeks thereafter.

Contraindications

Specific contraindications have not been determined.

Warnings and Precautions

- Serious Infections–Do not initiate golimumab during an active infection. If a serious infection develops, discontinue golimumab until the infection is controlled.
- Hepatitis B reactivation–Monitor HBV carriers during and several months after therapy. If reactivation occurs, stop golimumab and begin anti-viral therapy.
- Malignancies–Patients with highly active forms of rheumatoid arthritis and other chronic inflammatory diseases who are exposed to immunosuppressant therapy may be at a higher risk for developing lymphomas than the general population. Risks and benefits of treatment should be evaluated in patients with a known malignancy.
- Congestive heart failure (CHF)–Closely monitor patients with CHF that are initiated on golimumab. Discontinue golimumab if new or worsening signs of CHF appear.

Warnings and Precautions *continued*

- Demyelinating disorder–New onset or exacerbation of demyelinating disorders may occur. Discontinuing golimumab should be considered if these disorders develop.
- Lupus-like syndrome–Discontinue if symptoms occur.
- Use with abatacept–Not recommended due to greater risk of serious infection and lack of improved clinical benefit for treatment of rheumatoid arthritis
- Use with anakinra–Not recommended due to increased risk of serious infections and no additional benefit of combination therapy.
- Switching between biological disease modifying anti rheumatic drugs (DMARDs)–Caution should be taken due to increased risk of infection from overlapping biological activity
- Hematologic cytopenia–Caution should be taken in patients who have or have had significant cytopenias
- Live vaccination–Avoid use with golimumab
- Therapeutic infectious agents–Avoid use with golimumab
- Hypersensitivity reaction–Discontinue golimumab if anaphylaxis or other serious allergic reaction occurs

Adverse Reactions (>5%)

Most common adverse reactions for subcutaneous golimumab (>5%):

- Upper respiratory tract infections
- Nasopharyngitis
- Injection site reactions

Most common adverse reactions for IV golimumab (≥3%):

- Upper respiratory tract infection
- Viral infection
- Increased LFTs
- Decreased neutrophils
- Bronchitis
- Hypertension
- Rash

Medication Strength and Preparations

- Single-dose pre-filled syringe: 50 mg/0.5 mL, 100 mg/mL
- Single-dose prefilled auto-injector: 50 mg/0.5 mL, 100 mg/mL
- Solution in single-dose vial (for IV infusion): 50 mg/4 mL

Medication Administration and Storage

- Store in original carton to protect from light
- Store in refrigerator at 2°C to 8°C (36°F to 46°F) –do not freeze
- Needle cover of pre-filled syringe and auto-injector contains latex

Subcutaneous Administration

- Before injecting, allow injection to warm to room temperature for 30–90 minutes prior to administration
- Inject subcutaneously into front of thigh, lower abdomen (avoid injecting within 2 inches of navel), or outer area of upper arm
- Do not administer into tender, bruised, red or hard skin
- Rotate injection sites (≥ 1 inch apart)
- Safe at room temperature (defined as 20°C and 25°C (68°F and 77°F)) for up to 30 days

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Intravenous Administration Pre-Infusion Checklist

- **Confirm the following:**
  - ❑ Negative PPD or IGRA
  - ❑ Positive PPD/IGRA with negative chest radiograph or at least 4 weeks post-initiation of latent tuberculosis infection treatment
  - ❑ Negative hepatitis B serologic tests
- **Ask the patient if he/she:**
  - ❑ Has a current or recent infection or illness
  - ❑ Is taking antibiotics
  - ❑ Has an upcoming surgery
- If the answer is yes to any of these questions, notify the ordering provider before initiating the infusion therapy.

Intravenous Medication Preparation

1. Calculate the dose of golimumab based on patient's weight and indication. Each 4 mL vial contains 50 mg of golimumab.
2. Verify that the solution in each vial is colorless to light yellow. It may contain a few fine particles. Do not use if there is opaque particles or discoloration is present.
3. Dilute the total volume of golimumab to a final infusion volume of 100mL with either 0.9% w/v sodium chloride (NS) or 0.45% w/v of sodium chloride (1/2 NS). Gently mix the diluted solution. Discard any unused golimumab solution remaining in the vials.
4. Prior to infusion visually inspect the diluted golimumab solution for any particulate matter or discoloration. Do not use if these are present.
5. Once diluted the infusion solution can be stored for 4 hours at room temperature.

Intravenous Medication Administration and Monitoring

1. Use an infusion set with an in-line, sterile, nonpyrogenic, low binding filter (pore size 0.22 micrometer or less).
2. Do not infuse golimumab concomitantly in the same IV line with other agents. No physical biochemical or compatibility studies have been conducted.
3. Infuse the diluted solution over 30 minutes.

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