SIMPONI ARIA® (golimumab)

DOSING AND ADMINISTRATION GUIDE FOR ADULT PATIENTS

SIMPONI ARIA® is a tumor necrosis factor (TNF) blocker indicated for the treatment of:

- Adult patients with moderately to severely active Rheumatoid Arthritis (RA) in combination with methotrexate
- Active Psoriatic Arthritis (PsA) in patients 2 years of age and older
- Adult patients with active Ankylosing Spondylitis (AS)

SELECTED IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with SIMPONI ARIA® (golimumab), including infections due to tuberculosis, invasive fungal infections (eg, histoplasmosis), bacterial, viral, or other opportunistic pathogens. Prior to initiating SIMPONI ARIA® and periodically during therapy, evaluate patients for active tuberculosis and test for latent infection. Lymphoma, including a rare and fatal cancer called hepatosplenic T-cell lymphoma, and other malignancies can occur and can be fatal. Other serious risks include melanoma and Merkel cell carcinoma, heart failure, demyelinating disorders, lupus-like syndrome, hypersensitivity reactions, and hepatitis B reactivation. Prior to initiating SIMPONI ARIA®, test patients for hepatitis B viral infection. Please see related and other Important Safety Information on pages 14-17.

Simponi ARIA® golimumab for infusion

Janssen Immunology

PHARMACEUTICAL COMPANIES OF Johnson & Johnson

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Dosing regimen[1]

Adult patients with RA, PsA, and AS:
– 2 mg/kg intravenous infusion over 30 minutes at Weeks 0 and 4, and every 8 weeks thereafter

– For patients with RA, SIMPONI ARIA® should be given in combination with methotrexate

Indications[1]

SIMPONI ARIA® is a tumor necrosis factor (TNF) blocker indicated for the treatment of:
- **Adult patients with moderately to severely active RA in combination with methotrexate**
- **Active PsA in patients 2 years of age and older**
- **Adult patients with active AS**

SELECTED IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with SIMPONI ARIA® (golimumab), including infections due to tuberculosis, invasive fungal infections (eg, histoplasmosis), bacterial, viral, or other opportunistic pathogens. Prior to initiating SIMPONI ARIA® and periodically during therapy, evaluate patients for active tuberculosis and test for latent infection. Lymphoma, including a rare and fatal cancer called hepatosplenic T-cell lymphoma, and other malignancies can occur and can be fatal. Other serious risks include melanoma and Merkel cell carcinoma, heart failure, demyelinating disorders, lupus-like syndrome, hypersensitivity reactions, and hepatitis B reactivation. Prior to initiating SIMPONI ARIA®, test patients for hepatitis B viral infection. Please see related and other Important Safety Information on pages 14-17.

PERSPECTIVES ON IV ADMINISTRATION

IV therapy is an important treatment option that offers[2]:

- Administration in a clinically controlled environment in the presence of a healthcare professional (HCP)
- Close monitoring for hands-on management and control during administration
- The opportunity to observe patient progress when administered in a physician's office
- Regularly scheduled infusion appointments that may help HCPs know that treatment was received on schedule
- One-on-one interaction with patients, which can help foster a positive infusion experience

Simponi ARIA® golimumab for infusion

OVERVIEW: SIMPONI ARIA® (golimumab)

Indications[1]

SIMPONI ARIA® is a tumor necrosis factor (TNF) blocker indicated for the treatment of:

- Adult patients with moderately to severely active RA in combination with methotrexate
- Active PsA in patients 2 years of age and older
- Adult patients with active AS

Administration overview[1]

30
MINUTE INFUSION
GIVEN ONCE EVERY 8 WEEKS AFTER STARTER DOSES[1]

AS FEW AS
6
INFUSIONS/YEAR
AFTER 2 STARTER DOSES AT WEEKS 0 AND 4[1]

NO RECONSTITUTION REQUIRED
LIQUID IN SINGLE-DOSE VIAL[1]

- SIMPONI ARIA® is given as a 2 mg/kg IV infusion over 30 minutes at Weeks 0 and 4, and every 8 weeks thereafter for adult patients with RA, PsA, and AS[1]
- For patients with RA, SIMPONI ARIA® should be given in combination with methotrexate
- Short infusion time allows for flexible scheduling
- Infusion visit serves as an opportunity for patient monitoring

For complete product information about SIMPONI ARIA®, please visit:

SimponiAriaHCP.com

SELECTED IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with SIMPONI ARIA® (golimumab), including infections due to tuberculosis, invasive fungal infections (eg, histoplasmosis), bacterial, viral, or other opportunistic pathogens. Prior to initiating SIMPONI ARIA® and periodically during therapy, evaluate patients for active tuberculosis and test for latent infection. Lymphoma, including a rare and fatal cancer called hepatosplenic T-cell lymphoma, and other malignancies can occur and can be fatal. Other serious risks include melanoma and Merkel cell carcinoma, heart failure, demyelinating disorders, lupus-like syndrome, hypersensitivity reactions, and hepatitis B reactivation. Prior to initiating SIMPONI ARIA®, test patients for hepatitis B viral infection. Please see related and other Important Safety Information on pages 14-17.

Administration supplies

Infusion materials needed are listed below. These items may be ordered through your wholesaler or distributor. Please note that vials of SIMPONI ARIA® must be purchased separately.

Quantity	Description
1	Primary infusion set with Y site close to patient*
1	100-mL IV bag of 0.9% sodium chloride injection, USP OR 100-mL IV bag of 0.45% sodium chloride injection, USP
1	Safety IV catheter: 22- or 24-gauge x 1" maximum length
1	Antiseptic swab
1	2" x 2" gauze
1	Adhesive strip
As needed	Tourniquet (nonlatex)
As needed	Gloves

*Infusion sets should meet the Needlestick Safety and Prevention Act of 2001 requiring needle safety systems. Use only an infusion set with an inline, sterile, nonpyrogenic, low protein-binding filter (pore size 0.22 micrometer [micron] or less).

How supplied/storage and handling[1]

SIMPONI ARIA® is available in packs of 1 vial: NDC 57894-350-01.

Vials

- Each single-dose vial contains 50 mg of golimumab per 4 mL of solution (12.5 mg of golimumab per mL)

Storage and stability

- Refrigerate SIMPONI ARIA® at 36°F to 46°F (2°C to 8°C) and protect from light. Keep the product in the original carton to protect from light until the time of use
- Do not freeze. Do not shake. Do not use SIMPONI ARIA® beyond the expiration date (EXP) on the vial
- If needed, SIMPONI ARIA® may be stored at room temperature up to 77°F (25°C) for a maximum single period of 30 days in the original carton to protect from light. Once SIMPONI ARIA® has been stored at room temperature, do not return the product to the refrigerator. If not used within 30 days at room temperature, discard SIMPONI ARIA®

Simponi ARIA® golimumab for infusion

DOSING AND ADMINISTRATION

For the treatment of:
- **Adult patients with moderately to severely active RA in combination with methotrexate**
- **Active PsA in patients 2 years of age and older**
- **Adult patients with active AS**

SIMPONI ARIA® (golimumab) is given as a 2 mg/kg IV infusion over 30 minutes at Weeks 0 and 4, and every 8 weeks thereafter for adult patients with RA, PsA, and AS.

For patients with RA, SIMPONI ARIA® should be given in combination with methotrexate.

Adult patient dosing calculator

- Calculate the appropriate dose of SIMPONI ARIA® based on patient weight
  - —Convert patient weight in pounds to kilograms if needed (1 lb=0.453592 kg)
  - —Multiply weight in kg by 2 for **total dose in milligrams (mg)**

    Example: Patient weight in kg x 2 = total dose (mg)

- Identify number of single-dose vials required
  - —Each single-dose vial of SIMPONI ARIA® contains 50 mg of golimumab per 4 mL of solution: 12.5 mg of golimumab per mL
  - —Divide the calculated total dose in milligrams by 50 for the **number of vials required**

    Example: Total dose (mg)/50 = number of vials required

- Calculate total volume to be withdrawn from the vial(s)
  - —Multiply the number of vials required by 4 for **total volume to be withdrawn from the vials**

    Example: Number of vials required x 4 = total volume to be withdrawn

SELECTED IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with SIMPONI ARIA® (golimumab), including infections due to tuberculosis, invasive fungal infections (eg, histoplasmosis), bacterial, viral, or other opportunistic pathogens. Prior to initiating SIMPONI ARIA® and periodically during therapy, evaluate patients for active tuberculosis and test for latent infection. Lymphoma, including a rare and fatal cancer called hepatosplenic T-cell lymphoma, and other malignancies can occur and can be fatal. Other serious risks include melanoma and Merkel cell carcinoma, heart failure, demyelinating disorders, lupus-like syndrome, hypersensitivity reactions, and hepatitis B reactivation. Prior to initiating SIMPONI ARIA®, test patients for hepatitis B viral infection. Please see related and other Important Safety Information on pages 14-17.

Adult patient dosing calculator (continued)

- If documentation of vial wastage is required, subtract total volume to be withdrawn from volume in number of full vials required

  Example: (Total number of full vials required x 4 mL) – total volume to be withdrawn = wastage

For dilution and infusion preparation instructions, please refer to the Important Administration Instructions on pages 12-13 of this guide.

Helpful tools for properly dosing SIMPONI ARIA®

It is important to determine the exact dosing for each patient. Please use the SIMPONI ARIA® Dosing Calculator for guidance: SimponiAriaHCP.com/dosing/dosing-calculator.

You can also download this brochure from the website, which contains a complete dosing guide in 1-lb increments for a broad range of patient weights.

Janssen Medical Information

Please contact us at 1-800-JANSSEN:

- For medical information inquiries
- To report adverse events
- To submit product quality complaints

Simponi ARIA® golimumab for infusion

DOSING AND ADMINISTRATION FOR ADULTS ONLY

SIMPONI ARIA® (golimumab) (12.5 mg/mL in 4-mL vial)						
Patient Weight		Total Dose (mg) (kg x 2)*		Total Volume to Be Withdrawn (mL) (Total dose/ 12.5 mg)	Vials Required (#)	Wastage (mL) ([Full vials x 4 mL] – total volume)
Weight (lb)	Weight (kg) (lb x 0.453592)*					
85	39	77		6.2	2	1.8
90	41	82		6.5	2	1.5
95	43	86		6.9	2	1.1
100	45	91		7.3	2	0.7
105	48	95		7.6	2	0.4
110	50	100		8.0	2	0.0
115	52	104		8.3	3	3.7
120	54	109		8.7	3	3.3
125	57	113		9.1	3	2.9
130	59	118		9.4	3	2.6
135	61	123		9.8	3	2.2
140	64	127		10.2	3	1.8
145	66	132		10.5	3	1.5
150	68	136		10.9	3	1.1
155	70	141		11.2	3	0.8
160	73	145		11.6	3	0.4
165	75	150		12.0	3	0.0
170	77	154		12.3	4	3.7
175	79	159		12.7	4	3.3
180	82	163		13.1	4	2.9
185	84	168		13.4	4	2.6
190	86	172		13.8	4	2.2

*Rounded to nearest whole number.

(continued on next page)

Please note: The chart on pages 8-11 provides dosing in 5-lb increments and is only meant as a guide. Proper dosing must be according to exact patient weight. Please refer to SimponiAriaHCP.com/dosing/dosing-calculator to access the dosing calculator or download this brochure, which contains a complete dosing guide in 1-lb increments for a broad range of patient weights.

Please see related and other Important Safety Information on pages 14-17.

Simponi ARIA® golimumab for infusion

DOSING AND ADMINISTRATION FOR ADULTS ONLY (CONTINUED)

SIMPONI ARIA® (golimumab) (12.5 mg/mL in 4-mL vial)						
Patient Weight		Total Dose (mg) (kg x 2)*		Total Volume to Be Withdrawn (mL) (Total dose/ 12.5 mg)	Vials Required (#)	Wastage (mL) ([Full vials x 4 mL] – total volume)
Weight (lb)	Weight (kg) (lb x 0.453592)*					
195	89	177		14.2	4	1.8
200	91	181		14.5	4	1.5
205	93	186		14.9	4	1.1
210	95	191		15.2	4	0.8
215	98	195		15.6	4	0.4
220	100	200		16.0	4	0.0
225	102	204		16.3	5	3.7
230	104	209		16.7	5	3.3
235	107	213		17.1	5	2.9
240	109	218		17.4	5	2.6
245	111	222		17.8	5	2.2
250	113	227		18.1	5	1.9
255	116	231		18.5	5	1.5
260	118	236		18.9	5	1.1
265	120	240		19.2	5	0.8
270	123	245		19.6	5	0.4
275	125	250		20.0	5	0.0
280	127	254		20.3	6	3.7
285	129	259		20.7	6	3.3
290	132	263		21.0	6	3.0
295	134	268		21.4	6	2.6
300	136	272		21.8	6	2.2

*Rounded to nearest whole number.

Please note: The chart on pages 8-11 provides dosing in 5-lb increments and is only meant as a guide. Proper dosing must be according to exact patient weight. Please refer to SimponiAriaHCP.com/dosing/dosing-calculator to access the dosing calculator or download this brochure, which contains a complete dosing guide in 1-lb increments for a broad range of patient weights.

Please see related and other Important Safety Information on pages 14-17.

Simponi ARIA® golimumab for infusion

IMPORTANT ADMINISTRATION INSTRUCTIONS

SIMPONI ARIA® (golimumab) solution for IV infusion should be diluted by an HCP using aseptic technique as follows[1]:

Calculate

1 Calculate the dosage and the number of SIMPONI ARIA® single-dose vials needed based on the recommended dosage of 2 mg/kg and the patient's weight. Each 4-mL vial of SIMPONI ARIA® contains 50 mg of golimumab.

Examine

2 Check that the solution in each vial is colorless to light yellow. The solution may develop a few fine translucent particles, as golimumab is a protein. Do not use if opaque particles, discoloration, or other foreign particles are present.

Dilute

3 To prepare the solution for infusion:

- Dilute the total volume of the SIMPONI ARIA® solution with 0.9% (w/v) sodium chloride for infusion to a final volume of 100 mL
- For example, this can be accomplished by withdrawing a volume of the 0.9% (w/v) sodium chloride solution from the 100-mL infusion bag or bottle equal to the total volume of SIMPONI ARIA®
- Slowly add the total volume of SIMPONI ARIA® solution to the 100-mL infusion bag or bottle
- Gently mix
- Discard any unused solution remaining in the single-dose vials

Alternatively, SIMPONI ARIA® can be diluted using the same method described above with 0.45% (w/v) sodium chloride for infusion.

SELECTED IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with SIMPONI ARIA® (golimumab), including infections due to tuberculosis, invasive fungal infections (eg, histoplasmosis), bacterial, viral, or other opportunistic pathogens. Prior to initiating SIMPONI ARIA® and periodically during therapy, evaluate patients for active tuberculosis and test for latent infection. Lymphoma, including a rare and fatal cancer called hepatosplenic T-cell lymphoma, and other malignancies can occur and can be fatal. Other serious risks include melanoma and Merkel cell carcinoma, heart failure, demyelinating disorders, lupus-like syndrome, hypersensitivity reactions, and hepatitis B reactivation. Prior to initiating SIMPONI ARIA®, test patients for hepatitis B viral infection. Please see related and other Important Safety Information on pages 14-17.

Inspect

4 Prior to infusion, visually inspect the diluted SIMPONI ARIA® (golimumab) solution for particulate matter or discoloration. Do not use if these exist.

Caution

5 Use only an infusion set with an inline, sterile, nonpyrogenic, low protein-binding filter (pore size 0.22 micrometer [micron] or less).

Warning

6 Do not infuse SIMPONI ARIA® concomitantly in the same IV line with other agents. No physical biochemical compatibility studies have been conducted to evaluate the use of SIMPONI ARIA® with other agents in the same IV line.

Infuse

7 Infuse the diluted solution over 30 minutes.

Storage

8 Once diluted, the infusion solution can be stored for 4 hours at room temperature.

Simponi ARIA® golimumab for infusion

INDICATIONS

SIMPONI ARIA® (golimumab) is a tumor necrosis factor (TNF) blocker indicated for the treatment of:

- Adult patients with moderately to severely active Rheumatoid Arthritis (RA) in combination with methotrexate
- Active Psoriatic Arthritis (PsA) in patients 2 years of age and older
- Adult patients with active Ankylosing Spondylitis (AS)

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with SIMPONI ARIA® (golimumab) are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Discontinue SIMPONI ARIA® if a patient develops a serious infection.

Reported infections with TNF blockers, of which SIMPONI ARIA® is a member, include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before SIMPONI ARIA® use and during therapy. Initiate treatment for latent infection prior to SIMPONI ARIA® use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including *Legionella* and *Listeria*.**

Consider the risks and benefits of treatment with SIMPONI ARIA® prior to initiating therapy in patients with chronic or recurrent infection. Do not start SIMPONI ARIA® in patients with clinically important active infections, including localized infections. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with SIMPONI ARIA®, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy, who are on treatment for latent TB, or who were previously treated for TB infection.

Risk of infection may be higher in patients greater than 65 years of age, patients with co-morbid conditions and/or patients taking concomitant immunosuppressant therapy. Other serious infections observed in patients treated with SIMPONI ARIA® included sepsis, pneumonia, cellulitis, and abscess.

MALIGNANCIES

Malignancies, some fatal, have been reported in children, adolescents, and young adult patients treated with golimumab. Approximately half the cases were lymphomas, including Hodgkin's and non-Hodgkin's lymphoma. The other cases represented a variety of malignancies, including rare malignancies usually associated with immunosuppression and malignancies not usually observed in children or adolescents. Malignancies occurred after a median of 30 months after the first dose of therapy. Most of the patients were receiving concomitant immunosuppressants.

In the controlled portions of clinical trials of TNF blockers including the subcutaneous formulation of golimumab, more cases of lymphoma have been observed among patients receiving anti-TNF treatment compared with patients in the control groups. In clinical trials, the incidence of malignancies other than lymphoma and non-melanoma skin cancer per 100 patient-years of follow-up was 0.56 (95% CI: 0.01, 3.11) in the SIMPONI ARIA® group compared with an incidence of 0 (95% CI: 0.00, 3.79) in the placebo group. Cases of acute and chronic leukemia have been reported with TNF-blocker use, including SIMPONI ARIA®. The risks and benefits of TNF-blocker therapy should be considered prior to initiating therapy in patients with a known malignancy or who develop a malignancy.

Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers. These cases have had a very aggressive disease course and have been fatal. Nearly all reported cases have occurred in patients with Crohn's disease or ulcerative colitis, and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. A risk for the development for HSTCL in patients treated with TNF blockers cannot be excluded.

Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF-blocking agents, including SIMPONI ARIA®. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

HEPATITIS B REACTIVATION

The use of TNF blockers, of which SIMPONI ARIA® is a member, has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic hepatitis B carriers. In some instances, HBV reactivation occurring in conjunction with TNF-blocker therapy has been fatal. The majority of these reports have occurred in patients who received concomitant immunosuppressants.

(continued on next page)

Simponi ARIA® golimumab for infusion

IMPORTANT SAFETY INFORMATION (CONTINUED)

HEPATITIS B REACTIVATION (CONTINUED)

All patients should be tested for HBV infection before initiating TNF-blocker therapy. For patients who test positive for hepatitis B surface antigen, consult a physician with expertise in the treatment of hepatitis B before initiating TNF-blocker therapy. Exercise caution when prescribing SIMPONI ARIA® for patients identified as carriers of HBV and closely monitor for active HBV infection during and following termination of therapy with SIMPONI ARIA®. Discontinue SIMPONI ARIA® in patients who develop HBV reactivation, and initiate antiviral therapy with appropriate supportive treatment. Exercise caution when considering resumption of SIMPONI ARIA®, and monitor patients closely.

CONGESTIVE HEART FAILURE

Cases of worsening congestive heart failure (CHF) and new-onset CHF have been reported with TNF blockers, including SIMPONI ARIA®. Some cases had a fatal outcome. Exercise caution in CHF patients receiving SIMPONI ARIA® and monitor them closely during therapy. Discontinue SIMPONI ARIA® if new or worsening symptoms of heart failure appear.

DEMYELINATING DISORDERS

Use of TNF blockers, including SIMPONI ARIA®, has been associated with rare cases of new-onset or exacerbation of demyelinating disorders, including multiple sclerosis (MS) and Guillain-Barré syndrome. Cases of central demyelination, MS, optic neuritis, and peripheral demyelinating polyneuropathy have rarely been reported in patients treated with golimumab. Exercise caution in considering the use of SIMPONI ARIA® in patients with these disorders. Consider discontinuation if these disorders develop.

AUTOIMMUNITY

Treatment with TNF blockers, including SIMPONI ARIA®, may result in the formation of antinuclear antibodies. Rarely, treatment with TNF blockers may result in a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

USE WITH OTHER DRUGS

The concomitant use of a TNF blocker and abatacept or anakinra was associated with a higher risk of serious infections, therefore the use of SIMPONI ARIA® in combination with these products is not recommended. Care should be taken when switching from one biologic to another since overlapping biological activity may further increase the risk of infection. A higher rate of serious infections has also been observed in RA patients treated with rituximab who received subsequent treatment with a TNF blocker. The concomitant use of SIMPONI ARIA® with biologics approved to treat RA is not recommended because of the possibility of an increased risk of infection.

HEMATOLOGIC CYTOPENIAS

There have been reports of pancytopenia, leukopenia, neutropenia, agranulocytosis, aplastic anemia, and thrombocytopenia in patients receiving SIMPONI ARIA®. Exercise caution when using SIMPONI ARIA® in patients who have or had significant cytopenias.

VACCINATIONS/THERAPEUTIC INFECTIOUS AGENTS

Live vaccines or therapeutic infectious agents should not be given with SIMPONI ARIA® due to the possibility of clinical infections, including disseminated infections.

Update vaccinations prior to initiation of treatment in accordance with current vaccination guidelines. Advise patients to discuss with the physician before seeking any immunizations. At least a 6-month waiting period following birth is recommended before the administration of any live vaccine to infants exposed *in utero* to SIMPONI ARIA®.

HYPERSENSITIVITY REACTIONS

Serious systemic hypersensitivity reactions (including anaphylaxis) have been reported following administration of the subcutaneous formulation of golimumab and SIMPONI ARIA®, some occurring after the first dose. Hypersensitivity reactions including hives, pruritus, dyspnea, and nausea, were reported in association with infusions of SIMPONI ARIA®. If an anaphylactic or other serious allergic reaction occurs, discontinue SIMPONI ARIA® immediately and institute appropriate therapy.

ADVERSE REACTIONS

The most serious adverse reactions were serious infections and malignancies.

The most common adverse reactions (incidence ≥ 3%) reported in clinical trials were: upper respiratory tract infection, alanine aminotransferase increase, viral infection, aspartate aminotransferase increase, neutrophil count decrease, bronchitis, hypertension, and rash. In the controlled phase of Trial RA, the rate of infusions associated with an infusion reaction was reported in 1.1% of SIMPONI ARIA® infusions compared with 0.2% of infusions in the control group.

The adverse reactions observed in pediatric patients with polyarticular Juvenile Idiopathic Arthritis (pJIA) were consistent with the established safety profile of SIMPONI ARIA® in adult patients with RA and PsA.

Please see the enclosed full Prescribing Information and Medication Guide for SIMPONI ARIA®. Provide the Medication Guide to your patients and encourage discussion.

Simponi ARIA® golimumab for infusion

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INFUSION CONSIDERATIONS

Preinfusion considerations

Before every infusion, assess patient's current health status:

- Changes to medical history
- Medication history
- Allergies (eg, medications)
- Current weight
- Vital signs

Patients should be given the Medication Guide for SIMPONI ARIA® (golimumab), which is included in the full Prescribing Information. Please provide patients the opportunity to read this information and discuss any questions they may have.

SELECTED IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with SIMPONI ARIA® (golimumab), including infections due to tuberculosis, invasive fungal infections (eg, histoplasmosis), bacterial, viral, or other opportunistic pathogens. Prior to initiating SIMPONI ARIA® and periodically during therapy, evaluate patients for active tuberculosis and test for latent infection. Lymphoma, including a rare and fatal cancer called hepatosplenic T-cell lymphoma, and other malignancies can occur and can be fatal. Other serious risks include melanoma and Merkel cell carcinoma, heart failure, demyelinating disorders, lupus-like syndrome, hypersensitivity reactions, and hepatitis B reactivation. Prior to initiating SIMPONI ARIA®, test patients for hepatitis B viral infection. Please see related and other Important Safety Information on pages 14-17.

Preinfusion considerations (continued)

Discuss the following topics with the patient before the infusion[1]:

- Serious infections
- Malignancies
- Hepatitis B reactivation
- Heart failure
- Demyelinating disorders
- Autoimmunity
- Use with other drugs
- Hematologic cytopenias
- Vaccinations/therapeutic infectious agents
- Hypersensitivity reactions
- Adverse reactions

Postinfusion considerations

HCP follow-up:

- Notify appropriate HCP of patient progress on therapy and any side effects
- If appropriate, provide referring HCP a copy of infusion documentation as requested

Patient follow-up:

- Schedule follow-up appointment

Simponi ARIA® golimumab for infusion

SIMPONI ARIA® (golimumab) PROVIDES BENEFITS FOR YOUR PATIENTS

30
MINUTE INFUSION
GIVEN ONCE EVERY 8 WEEKS AFTER STARTER DOSES[1]

AS FEW AS
6
INFUSIONS/YEAR
AFTER 2 STARTER DOSES AT WEEKS 0 AND 4[1]

NO RECONSTITUTION REQUIRED
LIQUID IN SINGLE-DOSE VIAL[1]

- SIMPONI ARIA® is given as a 2 mg/kg IV infusion over 30 minutes at Weeks 0 and 4, and every 8 weeks thereafter for adult patients with RA, PsA, and AS[1]
- For patients with RA, SIMPONI ARIA® should be given in combination with methotrexate
- Short infusion time allows for flexible scheduling
- Infusion visit serves as an opportunity for patient monitoring

SIMPONI ARIA® is indicated for the treatment of:

- **Adult patients with moderately to severely active RA in combination with methotrexate**
- **Active PsA in patients 2 years of age and older**
- **Adult patients with active AS**

SELECTED IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with SIMPONI ARIA® (golimumab), including infections due to tuberculosis, invasive fungal infections (eg, histoplasmosis), bacterial, viral, or other opportunistic pathogens. Prior to initiating SIMPONI ARIA® and periodically during therapy, evaluate patients for active tuberculosis and test for latent infection. Lymphoma, including a rare and fatal cancer called hepatosplenic T-cell lymphoma, and other malignancies can occur and can be fatal. Other serious risks include melanoma and Merkel cell carcinoma, heart failure, demyelinating disorders, lupus-like syndrome, hypersensitivity reactions, and hepatitis B reactivation. Prior to initiating SIMPONI ARIA®, test patients for hepatitis B viral infection. Please see related and other Important Safety Information on pages 14-17.

References: 1. SIMPONI ARIA® (golimumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Bolge SC, Vanderpoel J, Eldridge H, et al. Perceived benefits and disadvantages of intravenous (IV) biologic therapy among patients with immunology conditions. Poster presented at: 16th Annual International Meeting of the International Society for Pharmacoeconomics and Outcomes Research; May 21-25, 2011; Baltimore, MD.

Simponi ARIA® golimumab for infusion

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