Simponi® golimumab

NOW APPROVED
in **pediatric patients** with moderately to severely active **ulcerative colitis** who weigh at least 15 kg

Image is for illustrative purposes only; people depicted serve as models.

Advancing **Pediatric Ulcerative Colitis** Treatment Options With SIMPONI®

Discover a treatment to **help pediatric patients reach and maintain remission with subcutaneous administration every 4 weeks** after 2 or 3 induction doses, depending on body weight.

Relief that's fast. Remission that lasts.

58% (n=38/66) of pediatric patients had clinical response at Week 6.[1]
32% (n=21/66) of pediatric patients were in clinical remission at Week 6.[1]
57% (n=12/21) of pediatric patients who were in clinical remission at Week 6 maintained clinical remission of symptoms at Week 54.[1]

See pages 2-4 for study details and complete dosing information.

SIMPONI® is a tumor necrosis factor (TNF) blocker indicated for the treatment of[1]:
- Adults and pediatric patients weighing at least 15 kg with moderately to severely active ulcerative colitis (UC)

SELECTED IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with SIMPONI® (golimumab), including infections due to tuberculosis, invasive fungal infections (eg, histoplasmosis), bacterial, viral, or other opportunistic pathogens. Prior to initiating SIMPONI® and periodically during therapy, patients should be evaluated for active tuberculosis and tested for latent infection. Lymphoma, including a rare and fatal type called hepatosplenic T-cell lymphoma (HSTCL), and other malignancies, can occur in adults and children, and can be fatal. Other serious risks include melanoma and Merkel cell carcinoma, congestive heart failure, demyelinating disorders, hepatitis B reactivation, lupus-like syndrome, and hypersensitivity reactions. Prior to initiating SIMPONI®, patients should be tested for hepatitis B viral infection. Please see related and other Important Safety Information on pages 5-6.

cp-172791v5

For pediatric patients weighing at least 15 kg with moderately to severely active UC

SIMPONI® (golimumab) Offers **Established Efficacy in Pediatric UC**

With SIMPONI®, **Pediatric Patients Were in Clinical Remission and Had Improvement in UC Symptoms** by Week 6 in an Open-Label Phase 3 Study[1]

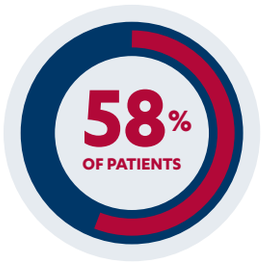
AT WEEK 6 **PRIMARY ENDPOINT**

32% OF PATIENTS

Clinical Remission[*†] (n=21/66)

PRIMARY ENDPOINT
The primary endpoint was clinical remission at Week 6 as measured by the Mayo score (defined as ≤2 points, with no individual subscore >1).

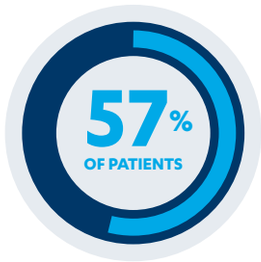
Fast Response[*‡] and **Sustained Clinical Remission**[*†§] in Pediatric Patients[1]



AT WEEK 6

SECONDARY ENDPOINT[1]

Clinical response:
58% of pediatric patients (n=38/66)



AT WEEK 54

ADDITIONAL SECONDARY ENDPOINTS[1]

Maintenance of clinical remission:
57% of pediatric patients (n=12/21)[*†§]

Clinical remission: 34% of pediatric patients (n=13/38) were in clinical remission among those who had clinical response at Week 6.[*†]

Pediatric UC Study Design[1]

OBJECTIVE
To evaluate the efficacy and safety of SIMPONI® in a Phase 3 multi-center, open-label study in 66 pediatric patients who weigh at least 15 kg with moderately to severely active UC.

INCLUSION CRITERIA
Patients presented with a Mayo score of 6 to 12 with an endoscopy subscore of ≥2 who had an inadequate response to corticosteroids, 6-MP, or AZA, or who were intolerant to or had medical contraindications for such therapies. Patients with prior exposure to TNF blockers were ineligible for participation.

TREATMENT REGIMEN
Patients weighing 15 kg to less than 45 kg received SIMPONI® subcutaneously 120 mg/m^2 at Week 0, 60 mg/m^2 at Week 2, and 60 mg/m^2 every 4 weeks from Week 6 onward. Patients weighing ≥45 kg received SIMPONI® 200 mg at Week 0, 100 mg at Week 2, and 100 mg every 4 weeks from Week 6 onward. The recommended body-weight tiered dosage for pediatric patients weighing 15 to less than 40 kg and 40 to less than 45 kg differs from the body surface area-based dosage administered in this study. There are no anticipated clinically relevant differences in efficacy between the recommended and studied pediatric dosages of SIMPONI®.

*See complete study design for endpoint definitions and trial details.
†Clinical remission is defined as a Mayo score ≤2 points, with no individual subscore >1.
‡Clinical response is defined as a decrease from baseline in the Mayo score by ≥30% and ≥3 points, with either a decrease from baseline in the rectal bleeding subscore of ≥1 or a rectal bleeding subscore of 0 or 1.
§Endpoint is evaluated among patients in clinical remission at Week 6.

AZA, azathioprine; MP, mercaptopurine; TNF, tumor necrosis factor; UC, ulcerative colitis.

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For pediatric patients weighing at least 15 kg with moderately to severely active UC

SIMPONI® (golimumab) Offers One Injection Every 4 Weeks, **After 2 or 3 Induction Doses** Depending on Weight

SIMPONI® Recommended Dosage for Pediatric UC[1]

The recommended SIMPONI® subcutaneous dosage for pediatric patients weighing at least 15 kg with moderately to severely active UC depends on body weight as shown in the table below:

	INDUCTION		MAINTENANCE
Pediatric Weight	**Week 0**	**Week 2**	**Week 6 and Every 4 Weeks Thereafter**
40 kg and greater	200 mg	100 mg	100 mg
At least 15 kg to less than 40 kg	100 mg	50 mg	50 mg

How Supplied[1]

50 mg/0.5 mL single-dose prefilled syringe
NDC 57894-070-01

OR

100 mg/mL single-dose prefilled syringe
NDC 57894-071-01

- For pediatric patients weighing 15 kg or greater, administer the appropriate dose using the prefilled syringe (50 mg/0.5 mL or 100 mg/mL)

Prior to initiating SIMPONI®, evaluate patients for active tuberculosis and test for latent infection, test patients for Hepatitis B viral infection; and, if possible, complete all age-appropriate vaccinations according to current immunization guidelines.

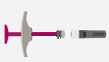
SIMPONI® is intended for use under the guidance and supervision of a healthcare provider.

SIMPONI® Requires Nearly Half the Injections Compared With Humira® (adalimumab) (per first year of treatment)[1,2]

SIMPONI®*

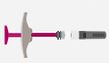
INDUCTION		MAINTENANCE		
2 OR 3	**1** or **2** injections at Week 0 (depending on body weight) **1** injection at Week 2	+ **12**	1 injection at Week 6 and **every 4 weeks thereafter**	= **14 OR 15** **Total Injections** Per First Year§

Humira®*†‡



INDUCTION		MAINTENANCE		
3 OR 4	**1** or **2** injections on Day 1 (depending on body weight) **1** injection on Day 8 **1** injection on Day 15	+ **25**	1 injection starting on Day 29 and **every 2 weeks thereafter**	= **28 OR 29** **Total Injections** Per First Year§

Humira®*†‡



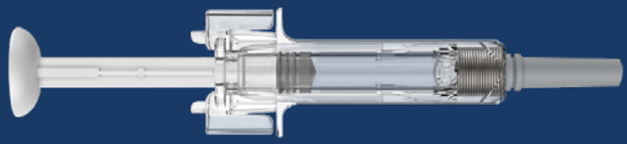
INDUCTION		MAINTENANCE		
3 OR 4	**1** or **2** injections on Day 1 (depending on body weight) **1** injection on Day 8 **1** injection on Day 15	+ **49**	1 injection starting on Day 29 and **every week thereafter**	= **52 OR 53** **Total Injections** Per First Year§

This presentation is not intended to compare the safety, efficacy, or indications of these treatments. While these factors are important, there are additional considerations for selecting treatment. Please refer to each product's Prescribing Information for additional information, including recommended dosing and administration.

*Trademarks are the property of their respective owners.
†Number of Humira® induction injections calculated using 80-mg, 40-mg, and 20-mg formulations.[2]
‡Humira® is administered by SC injection. Humira® dosing for pediatric patients with moderately to severely active ulcerative colitis is based on body weight: For patients weighing between 20 kg (44 lbs) to less than 40 kg (88 lbs), the recommended Day 1 dosage is 80 mg, Day 8 dosage is 40 mg, Day 15 dosage is 40 mg, and beginning on Day 29 the dosage is 20 mg every week or 40 mg every other week. For patients weighing 40 kg (88 lbs) or greater, the recommended Day 1 dosage is 160 mg, Day 8 dosage is 80 mg, Day 15 dosage is 80 mg, and beginning on Day 29, the dosage is 40 mg every week or 80 mg every other week.[2]
§"Per first year" refers to Weeks 0 to 52.

For Your Pediatric Patients, SIMPONI® Is Available in a Single-Dose Prefilled Syringe[1]

Pediatric patients **12 years of age and older may self-inject** with SIMPONI® prefilled syringe, if a physician determines that it is appropriate. Instruct patients to follow the directions provided in the Instructions for Use.



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SELECTED IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with SIMPONI® (golimumab), including infections due to tuberculosis, invasive fungal infections (eg, histoplasmosis), bacterial, viral, or other opportunistic pathogens. Prior to initiating SIMPONI® and periodically during therapy, patients should be evaluated for active tuberculosis and tested for latent infection. Lymphoma, including a rare and fatal type called hepatosplenic T-cell lymphoma (HSTCL), and other malignancies, can occur in adults and children, and can be fatal. Other serious risks include melanoma and Merkel cell carcinoma, congestive heart failure, demyelinating disorders, hepatitis B reactivation, lupus-like syndrome, and hypersensitivity reactions. Prior to initiating SIMPONI®, patients should be tested for hepatitis B viral infection. Please see related and other Important Safety Information on pages 5-6.

For pediatric patients weighing at least 15 kg with moderately to severely active UC

SIMPONI® (golimumab) Has an **Established Safety Profile** in Pediatric UC

The Safety of SIMPONI® Has Been Established in the PURSUIT-2 Open-Label Phase 3 Study

Treatment-Emergent Adverse Events of SIMPONI® in the PURSUIT-2 Open-Label Phase 3 Study Through Week 6 and Week 54[3]

Adverse Reaction	Induction Phase Weeks 0-6 (N=69)	Maintenance Phase Weeks 6-54 (N=62)*
Average duration of follow-up (weeks)	6.3	40.0
Average exposure (number of administrations)	2.0	9.0
Patients with ≥1, n (%)†‡		
AEs	47 (68.1)	58 (93.5)
Serious AEs	10 (14.5)	21 (33.9)
AEs leading to death	0	0
AEs leading to discontinuation	6 (8.7)	9 (14.5)
Infections	17 (24.6)	38 (61.3)
Serious infections	1 (1.4)§	9 (14.5)‖
Malignant neoplasms	0	0
Injection-site reactions	2 (2.9)	3 (4.8)

Adverse reactions reported in the clinical trial of pediatric patients weighing at least 15 kg with UC were also similar to those reported in clinical trials of adults with UC and the other indicated populations. Additional adverse reactions reported in at least 10% of pediatric patients in the trial were headache (17%) and pyrexia (10%).[1]

*Included patients who received ≥1 dose (complete or partial) of SIMPONI® during the maintenance phase.[3]
†AEs were coded using MedDRA version 26.1.[3]
‡Patients were only counted once for any given event, regardless of the number of times they experienced the event.[3]
§One case of pseudomembranous colitis.[3]
‖Two cases each of cytomegalovirus colitis and pneumonia, and one case each of *Clostridium difficile* infection, COVID-19, stump appendicitis, and fungal test positive (*candida*). One case of "UC worsening" was classified as "infection" though the investigator later confirmed no evidence of infection was found.[3]

AE, adverse event; COVID-19, coronavirus disease 2019; MedDRA, Medical Dictionary for Regulatory Activities; UC, ulcerative colitis.

J&J withMe

Support For Your Patients

Once you have made the clinical decision to prescribe a J&J medicine, Johnson & Johnson has resources to help you support your patients.

J&J withMe Is Your Single Source for Access, Affordability, and Treatment Support for Your Patients

Visit www.JnJwithMe.com/hcp/simponi to learn more about J&J withMe patient support resources.

The patient support and resources provided by J&J withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe a J&J medicine.

Visit **www.SIMPONIhcp.com** to learn more about SIMPONI®.

SELECTED IMPORTANT SAFETY INFORMATION

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INDICATIONS

SIMPONI® 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 (MTX)
- Adult patients with active psoriatic arthritis (PsA) alone, or in combination with MTX
- Adult patients with active ankylosing spondylitis (AS)
- Adults and pediatric patients weighing at least 15 kg with moderately to severely active ulcerative colitis (UC)

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with SIMPONI® (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® if a patient develops a serious infection.

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

- **Active tuberculosis (TB), including reactivation of latent TB. Patients frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent TB before SIMPONI® use and during therapy. Treatment for latent infection should be initiated prior to SIMPONI® 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.**

The risks and benefits of treatment with SIMPONI® should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Do not start SIMPONI® 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®, 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® included sepsis, pneumonia, cellulitis, abscess and hepatitis B infection.

MALIGNANCIES

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers of which SIMPONI® is a member. 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 all TNF-blocking agents including SIMPONI®, more cases of lymphoma have been observed among patients receiving TNF-blocking treatment compared with control patients. In the Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), and Ankylosing Spondylitis (AS) clinical trials, the incidence of lymphoma per 100 patient-years of follow-up was 0.21 (95% CI: 0.03, 0.77) in the combined SIMPONI® group compared with an incidence of 0 (95% CI: 0, 0.96) in the placebo group. In clinical trials, the incidence of malignancies other than lymphoma was not increased with exposure to SIMPONI® and was similar to what would be expected in the general population. In controlled and uncontrolled portions of the Phase 2/3 studies in ulcerative colitis (UC) with a mean follow-up of approximately 1 year, there were no cases of lymphoma with SIMPONI®. Short follow-up periods, such as those of 1 year or less in the studies above, may not adequately reflect the true incidence of malignancies. Cases of acute and chronic leukemia have been reported with TNF-blocker use, including SIMPONI®. 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 UC, 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®. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

CONGESTIVE HEART FAILURE

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

DEMYELINATING DISORDERS

TNF-blocking agents, of which SIMPONI® is a member, have 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 with SIMPONI®. Exercise caution in considering the use of SIMPONI® in patients with these disorders. Consider discontinuation if these disorders develop.

Continued on next page.

IMPORTANT SAFETY INFORMATION
(cont'd)

HEPATITIS B REACTIVATION

The use of TNF-blocking agents including SIMPONI® has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic hepatitis B carriers (i.e., surface antigen positive). 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.

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® for patients identified as carriers of HBV and closely monitor for active HBV infection during and following termination of therapy with SIMPONI®. Discontinue SIMPONI® in patients who develop HBV reactivation and initiate antiviral therapy with appropriate supportive treatment. Exercise caution when considering resumption of SIMPONI® and monitor patients closely.

AUTOIMMUNITY

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

HEMATOLOGIC CYTOPENIAS

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

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® 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® with biologics approved to treat RA, PsA, or AS is not recommended because of the possibility of an increased risk of infection.

VACCINATIONS/THERAPEUTIC INFECTIOUS AGENTS

People receiving SIMPONI® can receive vaccinations, except for live vaccines. Use of live vaccines could result in clinical infections, including disseminated infections. If possible, it is recommended that prior to initiating therapy with SIMPONI®, pediatric patients be brought up to date with all immunizations in agreement with current immunization guidelines. Administration of live vaccines to infants exposed to SIMPONI® *in utero* is not recommended for 6 months following the mother's last SIMPONI® injection during pregnancy due to an increased risk of infection. It is recommended that therapeutic infectious agents not be given concurrently with SIMPONI® due to the possibility of clinical infections, including disseminated infections.

HYPERSENSITIVITY REACTIONS

Serious systemic hypersensitivity reactions (including anaphylactic reaction) have been reported with SIMPONI®, some occurring after the first dose. If an anaphylactic or other serious allergic reaction occurs, discontinue SIMPONI® immediately and institute appropriate therapy.

ADVERSE REACTIONS

The most serious adverse reactions were serious infections and malignancies.

Upper respiratory tract infection and nasopharyngitis were the most common adverse reactions reported in the combined Phase 3 RA, PsA, and AS trials in adults through Week 16, occurring in 7% and 6% of patients treated with SIMPONI® as compared with 6% and 5% of patients in the control group, respectively. The rate of injection-site reactions was 6% with RA, PsA, and AS patients treated with SIMPONI® compared with 2% of patients in the control group.

In general, adverse reactions reported in adult patients with UC in Trials UC-1, UC-2, and UC-3 were similar to those reported in clinical trials of patients with RA, PsA, and AS. The rate of injection site reactions through Week 6 was 3.4% of SIMPONI-treated UC patients compared with 1.5% in control-treated patients. Adverse reactions reported in the clinical trial of pediatric patients weighing at least 15 kg with UC were also similar to those reported in clinical trials of adults with UC and the other indicated populations. Additional adverse reactions reported in at least 10% of pediatric patients in the trial were headache (17%) and pyrexia (10%).

cp-51205v8

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

References: 1. SIMPONI® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Humira® [Prescribing Information]. Chicago, IL: AbbVie, Inc. **3.** Turner D, Lomax K, Veereman G, et al. Efficacy, safety, and pharmacokinetics of golimumab in pediatric patients with moderately to severely active ulcerative colitis: results from the phase 3 open-label PURSUIT 2 study. Abstract presented at: Digestive Disease Week; May 3-6, 2025; San Diego, CA.

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