SIMPONI® (subcutaneous golimumab)
Use of SIMPONI in Women During Pregnancy

SUMMARY

- The company cannot recommend any practices, procedures, or usage that deviate from the approved labeling.
- Please refer to the local labeling for relevant information regarding the use of SIMPONI during pregnancy.
- Data from clinical trials, registries, spontaneous reports, and case reports describing the pregnancy outcomes in women exposed to SIMPONI are described below.[1-8]

CLINICAL DATA

Cases from Clinical Trials, Registries, and Spontaneous Reports - Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Ulcerative Colitis, and Other

Company's Global Safety Database

Otero-Lobato et al (2024)[1] evaluated pregnancy outcomes in individual case reports of patients treated with SIMPONI during pregnancy or within 3 months prior to conception.

- A total of 543 pregnancy cases, with 552 outcomes (including 9 pregnancies with twins), through May 31, 2022; were reported in the global safety database. Among these, outcomes for 261 prospective pregnancies, including seven set of twins, are presented.
    - Prospective pregnancy cases were included from solicited/noninterventional studies (n=170; 65.2%), spontaneous reporting (n=48; 18.4%), interventional clinical studies (n=40; 15.3%), and reports from literature (n=3; 1.1%).
- The average maternal age was 31.8 years (data available for 246 of 261 cases). The majority of patients received subcutaneous (SC) SIMPONI (n=245; 93.9%), and the remaining patients were administered intravenous (IV) SIMPONI (n=16; 6.1%).
- Trimester exposure data for SIMPONI were available for 196 cases, with 180 (91.8%) patients being exposed at least during the first trimester of pregnancy (T1).
- Seven congenital anomalies were reported in the prospective cases:
    - Four anomalies were reported in cases of maternal rheumatic disease; 1, in a case of maternal ulcerative colitis (UC); and 2, in cases where the maternal indications were not reported.
- The trimester of SIMPONI exposure was reported for 4 cases (T1 for 2 cases and all trimesters [T1/T2/T3] for 2 cases).
- In accordance with the European Registry of Congenital Anomalies and Twins version 1.4 classification, congenital anomalies were classified as major congenital anomalies (MCA) in 5 of the 7 cases.
    - Down syndrome, congenital toxoplasmosis (case reported positive serum test but no MCA [hydrocephaly, other structural anomalies], congenital foot malformation (sixth toe on right foot), polydactyly (hands), and developmental hip dysplasia (ultrasound results at 6 weeks after birth were not available in the report).
    - Additionally, there was 1 case of pyelocaliectasis and 1 unspecified congenital anomaly.
- Four of the MCA were reported in live births (n=4/214; 1.8%).
- Pregnancy outcomes reported in patients treated with SIMPONI with known outcomes by maternal indication, trimester of exposure, and infants with congenital anomalies are presented in Table: Pregnancy Outcomes in Patients Treated with SIMPONI.
- Study limitations include lack of a direct comparison group, the variable amount of data available in the reports, inconsistency in reporting of infant outcomes at birth, and lack of outcomes data from long-term follow-up in infants.

Pregnancy Outcomes in Patients Treated with SIMPONI[1]

	Total	SIMPONI Maternal Indication (n=261)			SIMPONI Trimester of Exposure (n=261)								Number of Infants with CA
		Rheum[a]	UC	Other[b]	NR	T1	T1/T2	T1/T2/T3	T1/T3	T2	T2/T3	T3	
Pregnancy outcomes	261	182	60	19	65	124	15	40	1	4	7	5	7 (2.7)[c]
Live birth, n (%)	214 (82.0)[d]	147 (80.8)[e]	51 (85.0)	16 (84.2)	54	89	14	40	1	4	7	5	5 (2.3)[f]
Live birth with no adverse event, n	184	125	45	14	51	72	12	35	1	4	4	5	0
Live birth premature, n	12	9	3	0	0	9	0	1	0	0	2	0	0
Live birth with adverse event, n	18	13	3	2	3	8	2	4	0	0	1	0	5
Spontaneous abortion, n (%)	31 (11.9)[g]	26 (14.3)[h]	4 (6.6)	1 (5.2)	8	23	0	0	0	0	0	0	1 (3.2)[i]
Elective/induced abortion, n (%)	13 (5.0)	8 (4.4)[j]	3 (5.0)	2 (10.2)	2	11	0	0	0	0	0	0	1 (7.7)[k]
Intrauterine death/still birth, n (%)	2 (0.8)	1 (0.5)	1 (1.7)	0	0	1	1	0	0	0	0	0	0
NR/ongoing[l], n (%)	1 (0.4)[l]	0	1	0	1	0	0	0	0	0	0	0	0

Abbreviations: CA, congenital anomaly; EUROCAT, European Registry of Congenital Anomalies and Twins; NR, nonreported; Rheum, rheumatologic indications; T1, trimester 1; T2, trimester 2; T3, trimester 3; UC, ulcerative colitis.

[a]Rheum, refers to rheumatologic indications that includes rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, nonradiographic axial spondyloarthropathy, and juvenile idiopathic arthritis)

[b]Other refers to off-label/nonreported indication

[c]Five of 214 (2.3%) were live births, 1 of 31 (3.2%) was a spontaneous abortion, and 1 of 13 (7.7%) was an elective/induced abortion.

[d]Six pregnancy cases with twins.

[e]Concomitant use of methotrexate in 8 pregnancy cases (methotrexate dosage reported as 7.5 mg weekly in 1 out of 8 cases).

[f]Four were major CAs following EUROCAT classification (version 1.4).

[g]One pregnancy case with twins.

[h]Concomitant use of methotrexate in 4 pregnancy cases (methotrexate dosage not reported in any of the 4 cases).

[i]Unspecified CA with concomitant use of methotrexate; dosage not reported.

[j]Concomitant use of methotrexate in 3 pregnancy cases (methotrexate dosage not reported in any of the 3 cases).

[k]Down syndrome (major CA following EUROCAT classification, version 1.4); congenital toxoplasmosis (positive serum test but no major CA [hydrocephaly, other structural anomalies]; however, since spontaneous reporting may be incomplete, the case was conservatively classified as major CA); congenital foot malformation, polydactyly (both hands), and developmental hip dysplasia (results of ultrasound examination 6 weeks after birth were not reported; thus, the case was conservatively classified as major CA); and one CA of pyelocaliectasis (resolved spontaneously).

[l]Fetus with an adverse event (fetal hypokinesia).

Register-based Study

Karlsson et al (2024)[2] reported the main findings of a multinational, register-based, post authorization safety study assessing the pregnancy and infant outcomes for pregnant patients with rheumatic disease or UC in a clinical care setting.

- A total of 134 infants (Denmark, n=34; Finland, n=19; Sweden, n=81) were born to patients treated with SIMPONI before or during pregnancy (131 pregnancies involving 121 patients).
- Pregnancy periods were defined as follows:
  - T0, pre-pregnancy (last menstrual period [LMP]-90 days to LMP-1 day)
  - T1, first trimester (LMP to LMP+90 days)
  - T2, second trimester (LMP+91 days to LMP+180 days)
  - T3, third trimester (LMP+181 days to delivery).
- SIMPONI exposure occurred primarily during T0 (n=121 infants; 90%), with 73, 21, and 9 infants exposed during T1, T2, and T3, respectively. Most infants were exposed to SIMPONI only during T0 (n=53; 39.5%) or during T0 and T1 (n=41; 30.6%).
- Unadjusted odds ratios (ORs) and 95% confidence intervals (CIs) indicated no association between prenatal exposure to SIMPONI and MCA or inpatient infections when compared with the other 3 drug-exposure groups.
- Adjusted analyses comparing the SIMPONI group with the nonbiologic systemic therapy group yielded an OR of 0.79 (95% CI, 0.35-1.81) for MCA, while comparison with the general population yielded an OR of 0.95 (95% CI, 0.42-2.16).
- General population was defined as infants born to patients with no maternal diseases of interest and no prenatal exposure to any of the drugs of interest.
- The pregnancy and infant outcomes after prenatal exposure to SIMPONI, other antitumor necrosis factor (anti-TNF) biologics, other biologics, nonbiologic systemic therapy, and the general population in Denmark, Finland, and Sweden (2006-2019) are presented in Table: Select Summary of Pregnancy and Infant Outcomes.

Select Summary of Pregnancy and Infant Outcomes[2]

Outcome	SIMPONI	Other Anti-TNF Biologics	Other Biologics	Nonbiologic Systemic Therapy	General Population[a]
Total number of infants	134	2273	64	10,823	3,067,204
Gestational age at birth, weeks, n (%)					
≥37	124 (92.5)	2004 (88.2)	48 (75.0)	9552 (88.3)	2,867,834 (93.5)
≤36	9 (6.7)	265 (11.7)	15 (23.4)	1250 (11.5)	182,193 (5.9)
Birth weight (g), n (%)					
≤2500	<5	196 (8.6)	6 (9.4)	865 (8.0)	139,434 (4.5)
2501-4499	126 (94.0)	2015 (88.6)	57 (89.1)	9692 (89.6)	2,811,606 (91.7)
≥4500	<5	55 (2.4)	0 (0.0)	226 (2.1)	93,727 (3.1)
Any MCAs, n (%)	6 (4.5)	154 (6.8)	7 (10.9)	599 (5.5)	139,847 (4.6)
Stillbirth, n (%)	0 (0.0)	<5	0 (0.0)	50 (0.5)	9825 (0.3)
Any infection, n (%)	46 (34.3)	647 (28.5)	23 (35.9)	2864 (26.5)	746,077 (24.3)
Infections, inpatient care, n (%)	15 (11.2)	233 (10.3)	7 (10.9)	1135 (10.5)	286,150 (9.3)

Note: Exact values for <5 counts are not shown due to data privacy policies in the contributing countries. To prevent back-calculation of exact counts, the number of infants with missing values for each outcome is not reported.
Abbreviations: MCA, major congenital anomaly; TNF, tumor necrosis factor.
[a]General population defined as infants born to patients with no maternal diseases of interest and no prenatal exposure to any of the drugs of interest.

- Limitations of the study include a small number of exposed pregnancies, lack of data on disease severity, and patient inclusion being restricted to Nordic populations.

Individual cases reported to the manufacturer

Esslinger et al (2019)[3] evaluated pregnancy outcomes in patients treated with SIMPONI in individual case reports.

- Individual cases of maternal exposure to SIMPONI during pregnancy or within 3 months prior to conception and a reported pregnancy outcome that were reported to the manufacturer through 06 April 2019 were collected.
- Cases were collected from various sources, including spontaneous reporting, clinical studies, and registries.
- Cases were either prospectively reported (pregnancy outcome not known when first reported), or retrospectively reported (pregnancy outcome known when first reported).
- As shown in Table: Summary of Pregnancy Outcomes in Patients Treated with SIMPONI, 208 pregnancy reports were identified, of which 119 pregnancy cases were prospective and 89 pregnancy cases were retrospective (131 rheumatological [rheumatoid arthritis, RA; psoriatic arthritis, PsA; and ankylosing spondylitis, AS]; 43 UC; 34 other).
- Overall, 9 congenital anomalies were reported (2 prospective and 7 retrospective cases).
- There were 211 reported birth outcomes (3 cases reported twin pregnancies).
- The average maternal age was 31.9 years.

Summary of Pregnancy Outcomes in Patients Treated with SIMPONI[3]

Pregnancy Outcome	Count (%)	RA, PsA, AS	UC	Other	Congenital Anomaly	MTX Use[a]
Prospective outcomes						
Live birth, n (%)[b]	89 (74.8)	58 (73.4)	21 (75.0)	10 (83.3)	1[c]	9
Spontaneous abortion, n (%)	19 (16.0)	15 (19.0)	3 (10.7)	1 (8.3)	0	8
Elective/induced abortion, n (%)	10 (8.4)	6 (7.6)	3 (10.7)	1 (8.3)	1[d]	3
Ectopic pregnancy, n (%)	1 (0.8)	0 (0.0)	1 (3.6)	0 (0.0)	0	0
Total	**119**	**79**	**28**	**12**	**2**	**20**
Retrospective outcomes						
Live birth, n (%)[e]	54 (60.7)	29 (55.8)	9 (60.0)	16 (72.7)	5[f]	4
Spontaneous abortion, n (%)	28 (31.5)	19 (36.5)	5 (33.3)	4 (18.2)	0	3
Elective/induced abortion, n (%)	5 (5.6)	2 (3.8)	1 (6.7)	2 (9.1)	2[g]	1
Ectopic pregnancy, n (%)	2 (2.2)	2 (3.8)	0 (0.0)	0 (0.0)	0	2
Total	**89**	**52**	**15**	**22**	**7**	**10**
Grand Total	**208**	**131**	**43**	**34**	**9**	**30**

Abbreviations: AS, ankylosing spondylitis MTX, methotrexate; RA, rheumatoid arthritis; PsA, psoriatic arthritis; UC, ulcerative colitis.
[a]Patient received MTX at the time of conception/during pregnancy.
[b]Count includes 7 cases with pregnancy outcome live birth with adverse event: low birth weight baby (3), premature baby (3), jaundice (3), feeding disorder neonatal (1), immunodeficiency (1), and 1 case of live birth with congenital anomaly. Additionally, 2 cases reported twin pregnancies.
[c]One live birth with congenital anomaly: fetal macrosomia.
[d]One case of elective/induced abortion with congenital anomaly: Down's syndrome.
[e]Count includes 5 cases with pregnancy outcome live birth with AEs: premature baby (2), inadequate diet (1), bradycardia fetal (1), hematochezia (1), neonatal respiratory depression (1), ulcerative colitis (1), sepsis (1), fungal infection (1), low birth weight baby (1), milk allergy (1), rash generalized (1), and 5 cases of live birth with congenital anomaly. Additionally, 1 case reported twin pregnancy.
[f]Five live births with congenital anomaly: atrial septal defect; cataract congenital, galactosemia; unspecified congenital anomaly; hypoplastic left heart syndrome; heart disease congenital.
[g]Two elective/induced abortions with congenital anomaly: multiple congenital anomalies and unspecified congenital anomaly.

- For 183 of the 208 pregnancy cases with reported outcomes, the trimester of exposure to SIMPONI was known, as shown in Table: Trimester Exposure and Pregnancy Outcome Reported in Pregnancies with SIMPONI Use.
- Among the 110 prospectively reported cases, 82 (74.5%) cases were exposed during trimester 0 or 1. Of these, 19 had concomitant exposure to methotrexate (MTX), with the following birth outcomes: 8 live births, 8 spontaneous abortions, and 3 elective/induced abortions.
- Limitations include lack of a direct comparison group, the variable amount of data available in the reports, and the possible bias of retrospective outcomes.

Trimester Exposure and Pregnancy Outcome Reported in Pregnancies with SIMPONI Use[3]

Reported Trimester of Exposure with SIMPONI[a]	Number of Pregnancies in Trimester	Pregnancy Outcome				MTX Use[b]
		Live Birth	Spontaneous Abortion	Elective/ Induced Abortion	Ectopic Pregnancy	
Prospective						
0	10	7	2	1	0	6[c]
1st	72	49	15	7	1	13[d]
1st, 2nd	5	4	1	0	0	0
1st, 2nd, 3rd	18	18	0	0	0	1[e]
2nd	2	2	0	0	0	0
2nd, 3rd	1	1	0	0	0	0
3rd	2	2	0	0	0	0
Total	**110**	**83**	**18**	**8**	**1**	**20**
Retrospective						
0	4	3	1	0	0	0
1st	49	21	23	3	2	7[f]
1st, 2nd	5	4	0	1	0	0
1st, 2nd, 3rd	13	13	0	0	0	0
2nd, 3rd	1	1	0	0	0	0
3rd	1	1	0	0	0	0
Total	**73**	**43**	**24**	**4**	**2**	**7**
Grand Total	**183**	**126**	**42**	**12**	**3**	**27**

Abbreviations: MTX, methotrexate.
[a]0, 1st, 2nd, 3rd trimester (<3 months before conception, first, second, third trimester, respectively.
[b]Patient received MTX at the time of conception/during pregnancy.
[c]Count includes 1 live birth without adverse event/congenital anomaly, 2 live births with adverse event, 2 spontaneous abortions, and 1 elective/induced abortion.
[d]Count includes 4 live births without adverse event/congenital anomaly, 1 live birth with adverse event, 6 spontaneous abortions, and 2 elective/induced abortions.
[e]Count includes 1 live birth with adverse event.
[f]Count includes 1 live birth without adverse event/congenital anomaly, 1 live birth with congenital anomaly, 3 spontaneous abortions and 2 ectopic pregnancy cases.

Lau et al (2014)[4] evaluated pregnancy outcomes in patients treated with SIMPONI in individual case reports.

- Individual cases of maternal exposure to SIMPONI during pregnancy or within 2 months prior to conception that were reported to the manufacturer through 06 October 2013 were collected.
- Cases were collected from various sources, including spontaneous reporting, clinical studies, and registries.
- Cases were either prospectively reported (pregnancy outcome not known when first reported), or retrospectively reported (pregnancy outcome known when first reported).
- Forty-seven pregnancy reports were identified, of which 35 were prospective and 12 were retrospective (30 RA; 1 PsA; 5 AS; 11 UC).
- As seen in Table: Summary of Pregnancy Outcomes in Patients Treated with SIMPONI for RA, PsA, AS, and UC, 1 congenital anomaly (unspecified birth defect resulting in intrauterine death) and 13 spontaneous abortions were reported from 47 pregnancy

cases. In the 1 pregnancy with a congenital anomaly, the patient had used MTX, but the timing of MTX use was not available.
- Of the reports with a pregnancy outcome of spontaneous abortion, 30.8% (n=13) of patients received concomitant MTX, compared with 19.2% (n=26) of reports in the SIMPONI-exposed pregnancies that resulted in live births.
- Limitations include lack of a direct comparison group, the variable amount of data available in the reports, and the possible bias of retrospective outcomes.

Summary of Pregnancy Outcomes in Patients Treated with SIMPONI for RA, PsA, AS, and UC[4]

	Count n (%)	Congenital Anomaly	MTX[a]
Live birth	26 (55.3)	0	5
Spontaneous abortion	13 (27.7)	0	4
Elective/induced abortion	6 (12.8)	1	2
Abortion planned	1 (2.1)	0	0
Ectopic pregnancy	1 (2.1)	0	1

Abbreviations: AS, ankylosing spondylitis; MTX, methotrexate; PsA, psoriatic arthritis; RA, rheumatoid arthritis; UC, ulcerative colitis.
[a]Patient received MTX at the time of conception/during pregnancy.

Single Case Reports

Moriya et al (2024)[5] reported a concurrent case of UC in a 30-year-old female with RA who received treatment with biologics.

- The patient achieved clinical remission with a combination of certolizumab pegol and MTX, which was subsequently maintained with certolizumab pegol monotherapy.
- The patient became pregnant after 1.5 years of treatment; thus, she was followed without medication.
- During the 14th week of pregnancy, the patient experienced diarrhea, and her symptoms (including hematochezia) worsened; thus, she was hospitalized.
- After additional clinical and laboratory assessments, the patient was diagnosed with moderate UC.
- Treatment with oral mesalamine (4000 mg/day) and granulocyte apheresis therapy failed to induce clinical remission.
- Prednisolone (30 mg/day) was completely ineffective; IV infliximab (5 mg/kg) was then administered to induce remission. After administration of the first dose of infliximab, there was an improvement in the clinical symptoms. The patient's condition improved following the second dose 2 weeks later, and the patient was discharged thereafter.
- However, during administration of the third dose of infliximab, the patient suddenly developed transient dyspnea and facial flushing (most likely an infusion reaction) and infliximab was discontinued.
- The patient was subsequently switched to SIMPONI (100 mg SC injection every 4 weeks) until the 33rd week of gestation, followed by a period of temporary withdrawal.
- The patient delivered a healthy infant at week 39 of gestation through cesarean section.
- During the 60-week follow-up period after delivery, the patient and baby were healthy, and remission of UC was successfully maintained with a combination therapy of SIMPONI and oral mesalamine (4000 mg/day).
- Pancolitis endoscopic remission of UC was confirmed in the 22nd postpartum week.
    - Total colonoscopy showed multiple pseudopolyposis findings in addition to scarring changes after healing of extensive mucosal inflammation involving the entire colon (including the cecum).

Miyai et al (2021)[6] reported the case of a 33-year-old woman with ulcerative colitis who initiated treatment with SIMPONI during her second pregnancy.

- Prior to her pregnancy, the patient was receiving oral mesalazine and IV prednisone, with no improvement. Azathioprine was initiated but was discontinued upon learning of her pregnancy. The patient was then started on SIMPONI, which was the first anti-TNF agent.
- During this second pregnancy, the patient experienced a more extreme hypertensive disorder vs her first pregnancy without the use of SIMPONI. However, it was unclear whether SIMPONI induced this symptom.
- Her infant developed hypoxemia and a low birth weight (assumed due to her short stature). The patient was diagnosed with neonatal transient polypnea and recovered in 5 days.

Benoit et al (2019)[7] described the use of SIMPONI in a 28-year-old pregnant female with UC.

- Before pregnancy, the patient had been treated with mesalazine and SIMPONI 100 mg every 2 weeks.
- SIMPONI was continued during her pregnancy.
- The patient delivered a healthy baby boy weighing 2805 g at 37 weeks, 6 days (3 days after the last dose of SIMPONI).
- Immediately after delivery, golimumab concentrations reached 6.6 µg/mL in the maternal plasma and 8.0 µg/mL in the neonate blood cord (121% of maternal concentrations).
- There were no complications reported at 7 months of follow-up.

Patel et al (2014)[8] described the use of SIMPONI in a 26-year-old pregnant female with UC.

- The patient had an approximately 6-year history of UC and was previously treated with mesalamine, steroids, azathioprine, and infliximab (escalated to 10 mg/kg every 6 weeks).
- The patient was in clinical remission when she became pregnant.
- During the first trimester, the patient required a hospitalization for a flare, requiring transfusion of 4 units of packed red blood cells for severe iron deficiency anemia (hemoglobin of 5 g/dL).
- IV steroids improved her diarrhea from 15 to 10 bowel movements per day.
- The patient was switched to adalimumab and oral prednisone; however, she continued to have hematochezia, diarrhea, and urgency (including nocturnal symptoms).
- During the second trimester, the patient required a second hospitalization where she received 2 units of packed red blood cell transfusions, repeat IV steroid infusion, and was discharged on oral prednisone 40 mg per day.
- The patient was followed by a high-risk obstetrician and her baby was found to have intrauterine growth restriction on ultrasound.
- Due to lack of efficacy on adalimumab 40 mg weekly, the patient started on SIMPONI during week 26 of gestation.
- After induction therapy, the patient was tapered off prednisone completely and had resolution of gastrointestinal symptoms with no diarrhea, no hematochezia, and no additional hospitalizations during follow-up.
- The patient delivered a healthy baby who weighed 6.6 pounds at term.

LITERATURE SEARCH

A literature search of MEDLINE®, Embase®, BIOSIS Previews®, and DERWENT® (and/or other resources, including internal/external databases) was conducted on 06 September 2024.

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