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2. Simponi

Simponi

Generic name: [golimumab](#) [*goe-LIM-ue-mab*]**Brand names:** Simponi, Simponi SmartJect**Drug class:** [TNF alfa inhibitors](#)Medically reviewed by [Philip Thornton, DipPharm](#). Last updated on Aug 22, 2023.[Uses](#) [Warnings](#) [Before taking](#) [Dosage](#) [Side effects](#) [Interactions](#) [FAQ](#)

What is Simponi?

Simponi is used to relieve the symptoms of certain autoimmune disorders (conditions in which the immune system attacks healthy parts of the body and causes pain, swelling, and damage) including:

- rheumatoid arthritis (condition in which the body attacks its own joints causing pain, swelling, and loss of function) along with methotrexate (Otrexup, Rasuvo, Trexall) in adults,
- ankylosing spondylitis (condition in which the body attacks the joints of the spine and other areas causing pain and joint damage) in adults,
- psoriatic arthritis (condition that causes joint pain and swelling and scales on the skin) alone or in combination with methotrexate in adults, and
- ulcerative colitis (a condition which causes swelling and sores in the lining of the colon [large intestine] and rectum) when other medications and treatments did not help or could not be tolerated.

Simponi can also be given with steroid medicines to help with some symptoms, to get the ulcerative colitis under control and keep it under control, and to improve the way the lining of your large intestine looks during colonoscopy.

It is not known if Simponi is safe and effective in children under 18 years of age.

Warnings

You should not use Simponi if you are also using abatacept or anakinra.

Simponi affects your immune system. **You may get infections more easily, even serious or fatal infections.** Call your doctor if you have a fever, chills, aches, tiredness, cough, skin sores, [diarrhea](#), or burning when you urinate.

Serious and sometimes fatal infections may occur during treatment with Simponi, especially if you also use other medications that can weaken your immune system.

If you have ever had tuberculosis or hepatitis B, Simponi can cause these conditions to come back or get

worse. You should be tested for these conditions before you start using this medicine.

Some people using Simponi have developed a rare fast-growing type of lymphoma (cancer) that affects the liver, spleen, and bone marrow, and it can be fatal. This has occurred mostly in teenage boys and young men using Simponi.

Before taking this medicine

You should not use Simponi if you are allergic to rubber or latex.

To make sure Simponi is safe for you, tell your doctor if you have ever had:

- an active or chronic [infection](#);
- a nerve-muscle disorder such as [multiple sclerosis](#) or Guillain-Barré syndrome;
- [cancer](#) or [lymphoma](#);
- congestive [heart failure](#);
- [psoriasis](#); or
- recently received or scheduled to receive a live vaccine.

Tell your doctor if you've had or been exposed to [tuberculosis](#), or if you recently traveled. Some infections are more common in certain parts of the world, and you may have been exposed during travel.

Using Simponi may increase your risk of developing other cancers. Ask your doctor about this risk.

It is not known if golimumab will harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant.

Tell your baby's doctor if you used Simponi during pregnancy. It could affect your baby's vaccination schedule during the first 6 months of life.

Ask a doctor if it is safe to breastfeed while using Simponi.

 [Simponi pregnancy and breastfeeding warnings](#) (more detail)

How should I use Simponi?

Use Simponi exactly as prescribed by your doctor. Follow all directions on your prescription label and read all medication guides or instruction sheets.

If you have ever had tuberculosis or hepatitis B, Simponi can cause these conditions to come back or get worse. You should be tested for these conditions before you start this medicine. Your doctor may need to monitor you for signs and symptoms during treatment.

Simponi may also be injected under the skin once every 2 to 4 weeks. You may be able to give this injection to yourself.

Your healthcare provider will show you where to inject Simponi. Do not inject into the same place two times in a row.

Ask your doctor or pharmacist if you don't understand how to use an injection.

Prepare an injection only when you are ready to give it. Call your pharmacist if the medicine looks cloudy, has changed colors or has particles in it.

Simponi can weaken your immune system. Your blood will need to be tested often.

Store this medicine in its original container in the refrigerator, do not freeze. Protect from light.

Take the medicine out of the refrigerator and let it reach room temperature for 30 minutes before using. **Do not warm the medicine with hot water, sunlight, or a microwave.**

Throw away a prefilled syringe or auto-injector after one use, even if there is still medicine left inside.

Do not reuse a needle or syringe. Place them in a puncture-proof "sharps" container and dispose of it following state or local laws. Keep out of the reach of children and pets.

Dosing information

Usual Adult Dose of Simponi for Psoriatic Arthritis:

Subcutaneous: 50 mg once a month..

Usual Adult Dose of Simponi for Ulcerative Colitis:

Initial dose: 200 mg subcutaneously at week 0, followed by 100 mg at week 2

Maintenance dose: 100 mg subcutaneously every 4 weeks

Comments:

- Patients should be tested for hepatitis B viral infection before starting treatment.
- Evaluate patients for active tuberculosis and tested for latent infection before starting treatment.
- The safety and efficacy of switching between subcutaneous and IV formulations have not been established.

Use: For the treatment of patients with moderate to severe ulcerative colitis (UC) who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for:

- inducing and maintaining clinical response
- improving endoscopic appearance of the mucosa during induction
- inducing clinical remission
- achieving and sustaining clinical remission in induction responders

Usual Adult Dose of Simponi for Rheumatoid Arthritis:

Subcutaneous: 50 mg once a month.ereafter

Use: For the treatment of patients with moderately to severely active rheumatoid arthritis

Usual Adult Dose of Simponi for Ankylosing Spondylitis:

Subcutaneous: 50 mg once a month

Comments:

- This drug may be given with or without methotrexate or other nonbiologic disease modifying antirheumatic drugs (DMARDs).
- Corticosteroids, nonsteroidal anti-inflammatory drugs (NSAIDs), and/or analgesics may be continued during therapy.
- Patients should be tested for hepatitis B viral infection before starting treatment.
- Evaluate patients for active tuberculosis and tested for latent infection before starting treatment.
- The safety and efficacy of switching between subcutaneous and IV formulations have not been established.

Use: For the treatment of patients with active ankylosing spondylitis (AS)

 [Detailed Simponi dosage information](#)

What happens if I miss a dose?

Call your doctor for instructions if you miss a dose.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What should I avoid while using Simponi?

Avoid receiving a "live" vaccine, or you could develop a serious infection. Live vaccines include [measles](#), mumps, [rubella](#) (MMR), rotavirus, typhoid, yellow [fever](#), varicella (chickenpox), and zoster ([shingles](#)).

Simponi side effects

Get emergency medical help if you have **signs of an allergic reaction to Simponi**: hives, difficult breathing, swelling of your face, lips, tongue, or throat.

You may get infections more easily, even serious or fatal infections. Call your doctor right away if you have signs of infection such as:

- fever, chills, sweating, muscle aches, feeling very tired;
- cough, bloody mucus, shortness of breath;
- [weight loss](#);
- painful skin sores, warmth, or redness;
- [diarrhea](#), stomach pain; or
- increased urination, or burning when you urinate.

Also call your doctor at once if you have:

- skin growths or changes in skin appearance;
- swelling in your lower legs;
- vision changes;
- numbness or tingly feeling, weakness in your arms or legs;
- **heart problems** - swelling, rapid weight gain, feeling short of breath;
- **low blood cell counts** - fever, chills, tiredness, mouth sores, skin sores, easy bruising, unusual bleeding, pale skin, cold hands and feet, feeling light-headed or short of breath;
- **liver problems** - loss of appetite, stomach pain (upper right side), tiredness, itching, dark urine, clay-colored stools,

[jaundice](#) (yellowing of the skin or eyes);

- **new or worsening symptoms of lupus** - joint pain, and a skin rash on your cheeks or arms that worsens in sunlight; or
- **signs of psoriasis** - red or scaly patches of skin, flaking, pus.

Common Simponi side effects may include:

- [cold symptoms](#) such as stuffy nose, sneezing, [sore throat](#);
- abnormal liver function tests;
- [high blood pressure](#);
- skin rash;
- low blood cell counts; or
- pain, itching, redness, bruising, tingling or swelling where the medicine was injected.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

 [Simponi side effects](#) (more detail)

Related/similar drugs

Otezla

Otezla (apremilast) is used to treat plaque psoriasis, psoriatic arthritis, and oral ulcers ...

Reviews & ratings

5.2 / 10

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Stelara (ustekinumab) is used to treat Crohn's disease, ulcerative colitis, plaque psoriasis, and ...

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7.6 / 10

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Rinvoq

Rinvoq (upadacitinib) is used to treat rheumatoid arthritis, psoriatic arthritis, atopic ...

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Dexamethasone

Dexamethasone is used to treat inflammatory conditions such as allergies, skin conditions ...

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5.9 / 10

[162 Reviews](#)

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What other drugs will affect Simponi?

Sometimes it is not safe to use certain medicines at the same time. Some drugs can affect your blood levels of other drugs you use, which may increase side effects or make the medicines less effective.

Tell your doctor about all your other medicines, especially:

- [anakinra](#);

- [abatacept](#), [etanercept](#); or
- [adalimumab](#), [certolizumab](#), [infliximab](#), [rituximab](#), or [tocilizumab](#).

This list is not complete. Other drugs may interact with golimumab, including prescription and over-the-counter medicines, [vitamins](#), and [herbal products](#). Not all possible drug interactions are listed here.

 [Simponi drug interactions](#) (more detail)

Does Simponi interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

Simponi

+

Enter a drug name

Add

Ingredients

Active ingredient: golimumab

Inactive ingredients: L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sorbitol, and water for injection. Simponi does not contain preservatives.

Manufacturer

Janssen Biotech, Inc., Horsham, PA 19044 USA.

Simponi Biosimilars

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There are 2 for Simponi.

Simponi (golimumab) - Janssen Biotech, Inc.



Formulation type	Strength
Autoinjector	100 mg/mL
Autoinjector	50 mg/0.5 mL
Pre-Filled Syringe	100 mg/mL
Pre-Filled Syringe	50 mg/0.5 mL

Frequently asked questions

- [What are the new drugs for rheumatoid arthritis \(RA\)?](#)

References

1. [Simponi Product Label](#)

More about Simponi (golimumab)

- [Check interactions](#)
- [Compare alternatives](#)
- [Pricing & coupons](#)
- [Reviews \(118\)](#)
- [Drug images](#)
- [Side effects](#)
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- [During pregnancy](#)
- [FDA approval history](#)
- [Drug class: TNF alfa inhibitors](#)
- [Breastfeeding](#)

Patient resources

Other brands

[Simponi Aria](#)

Professional resources

- [Simponi prescribing information](#)
- [Golimumab \(AHFS Monograph\)](#)

Other brands

[Simponi Aria](#)

Related treatment guides

- [Ankylosing Spondylitis](#)
- [Rheumatoid Arthritis](#)

- [Psoriatic Arthritis](#)
- [Spondyloarthritis](#)
- [Ulcerative Colitis](#)

Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Simponi only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

[Medical Disclaimer](#)

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DRUG STATUS

Availability

Rx Prescription only

[Pregnancy & Lactation](#)

 Risk data available

CSA Schedule*

N/A Not a controlled drug



Approval History

10+ years FDA approved 2009



User Reviews & Ratings

6.4 / 10

[118 Reviews](#)

Images

[Simponi 50 mg/0.5 mL single-dose prefilled syringe](#)



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