

Golimumab - Medication Information

What is golimumab?

Golimumab (brand name: Simponi®) is a medication used to treat ulcerative colitis. It is in a class of medications called anti-TNFs, which are immunosuppressants that slow down the immune system's activity to heal inflammation.

How is golimumab given?

Golimumab is an injection, or shot, that you can give yourself subcutaneously (just under the skin). They come either as an auto-injector pen or as a pre-filled syringe with a needle. Both are equally effective. They are usually given on your thighs or stomach area. An IBD nurse or pharmacist will show you how to do the injections at your first appointment.

The first dose is given as 200 mg (2 pens total, 100 mg each). Two weeks later, you will be given 100 mg (1 pen). After that, 100 mg will be given every 4 weeks.

When can I expect golimumab to work?

Some patients may feel an improvement in symptoms as soon as the first week of starting golimumab. Typically, up to 6 weeks is required to see a benefit.

Golimumab works for most patients. The medication may stop working in up to 10% (1 in 10) of patients every year. To make sure that it keeps working, it is important to stay on track with your injection schedule and do not miss any injections. In some cases, your doctor may also have you start a second immunosuppressive medication along with golimumab to help it work better and remain effective longer.

Studies have shown that early effective treatment for ulcerative colitis is associated with long-term benefits including lowering the likelihood of needing surgery or hospitalization for health problems related to ulcerative colitis.

What tests are needed while I am on golimumab?

Before beginning golimumab treatment, you will need blood tests to check for hepatitis B and tuberculosis infections. You may also need to test for tuberculosis every year. Blood counts and liver tests are done every 4 months while on golimumab. At times, your doctor may also check your golimumab level to make sure the dose is working well for you.

What are the potential side effects related to golimumab?

Side effects with golimumab are uncommon, but may include:

Allergic reaction: Patients may develop allergic reactions to golimumab as with any other medication. Reactions may include rash, hives, swelling of the lips or throat. This is uncommon and can be treated with steroid and anti-histamine medications.

Injection site reaction: A small number of patients may develop an injection site reaction such as pain, redness, or swelling where the injection was given. This usually goes away within 2-3 days after each injection and sometimes can be treated with antihistamine medications.

Infection: As with other medications that act on the immune system, golimumab can increase your risk of infections. Serious infections are uncommon, but serious medical conditions like uncontrolled diabetes or lung disease may increase this risk.

Lymphoma: Golimumab can also increase the risk of lymphoma, a form of cancer of the lymph node. In the general population, about 2 out of 10,000 people get diagnosed with lymphoma every year. With golimumab, this risk may increase to 3-4 out of 10,000 people.

Opposite immune reaction: Rarely, golimumab may cause an opposite immune reaction such as psoriasis or lupus. These occur in 1-3% of patients.

Skin cancer: Golimumab may also increase the risk for skin cancer. This is rare, but taking proper precautions to lower skin cancer risk is recommended such as wearing protective clothing, applying sunscreen, and avoiding being outside for extended periods of time when the UV index is high.

Medical history: Individuals with demyelinating diseases (like multiple sclerosis or optic neuritis), active cancer, history of skin cancer, or history of congestive heart failure should discuss the safety of golimumab with their gastroenterologist (GI doctor).

Please see the medication package insert for the full list of potential side effects.

Is golimumab safe during pregnancy and breastfeeding?

Based on limited study data, women and men on golimumab have not been associated with fertility problems, miscarriages, birth defects, preterm births, stillbirths, or other pregnancy-related problems. If you are on golimumab while pregnant, live virus vaccines such as the rotavirus vaccine are not recommended for your baby within the first 6 months of age. It is likely safe to breastfeed while on golimumab. This has not been shown to have any negative impacts on the baby.

It is important to discuss with your provider about continuing golimumab before, during, and after pregnancy.

How can I take care of my health while on golimumab?

It is important to be up to date with your health maintenance while on golimumab. This includes being current on all the recommended vaccines such as the flu, COVID-19, pneumococcal, and shingles vaccines. You should only get the recombinant shingles vaccine (brand name: Shingrix®). Do not get the older shingles vaccines that contain the live but weakened virus. You should not get any live virus vaccines while on golimumab or for 3 months after stopping it.

It is also important to be up to date in your general cancer screening including mammograms and pap smears for women, and skin check-ups for both men and women.

Speak to your primary care doctor about whether you are up to date on all your vaccines and cancer screening.

What if my out-of-pocket costs are high with this treatment?

Our pharmacy team will work with you to see if you qualify for patient assistance and help with the application process.

The manufacturer of golimumab has a patient assistance program called Janssen Carepath for patients on the medication. Please go to [janssenprescriptionassistance.com/simponi-cost-assistance](https://www.janssenprescriptionassistance.com/simponi-cost-assistance) for more information on this program.

What if I have questions about golimumab?

Talk with your provider about any questions or concerns you may have about golimumab.

This document has been reviewed for plain language by Blum Center staff.

