

GOLIMUMAB

What is Golimumab?

Golimumab (Simponi®) is an antibody against a pro-inflammatory protein (cytokine) called tumor necrosis factor α (anti-TNF). It is approved for the treatment of ulcerative colitis.

How is it administered?

Golimumab is a self-administered subcutaneous injection. It can be given using either an auto-injector pen or as a pre-filled syringe with a needle. Both are equally effective. The common sites of administration are your thighs or your abdomen.

The first dose is given as 200mg (2 pens). Two weeks later, you will receive 100mg (1 pen) and beginning 4 weeks after this second dose, you will take 100mg every 4 weeks.

You will receive teaching on how to do the injections at your first appointment which will be with an IBD nurse.

When can I expect to respond to Golimumab?

Some patients may feel a benefit within the first week of initiating therapy. Typically, up to 6 weeks is required to see a benefit, though many notice an improvement in symptoms with the first two injections of Golimumab.

Approximately 7 out of 10 patients will respond to Golimumab. The medication may stop working in up to 10% of patients every year. To ensure that it remains effective, it is important to be regular in your injection schedule without gaps in treatment. Sometimes your doctor will also start a second immunosuppressive medication along with Golimumab to help it work better and remain effective longer.

Studies have shown that early effective therapy for Crohn's disease or ulcerative colitis is associated with long-term benefit including decreasing likelihood of needing surgery or hospitalization for these conditions.

What testing is needed on Golimumab therapy?

You will need blood testing to check for exposure to hepatitis B and tuberculosis infection prior to beginning treatment with Golimumab. You may also need testing for tuberculosis exposure annually. Blood counts and liver tests are routinely drawn every 4 months while on Golimumab. At times, your doctor may also check your Golimumab level to ensure that you are receiving adequate dosing.

What are the potential side effects related to Golimumab?

Side effects with Golimumab are uncommon. Patients may develop allergic reactions to Golimumab as with any other medication. This is uncommon and can be treated with steroids and anti-histamines.

Fewer than 10% of patients may develop an injection site reaction which involves pain, redness, and swelling at the site of the injection. This usually does not last longer than 2-3 days after each injection and sometimes will be treated with anti-histamine medications.

As with other medications that act on the immune system, Golimumab can increase your risk of infections. Serious infections are uncommon, occurring in fewer than 2 or 3 out of 100 people. Significant medical conditions like uncontrolled diabetes or lung disease may increase this risk.

Golimumab can also increase the risk of lymphoma, a form of cancer of the lymph node. The frequency of this in the general population is estimated to be around 2 out of 10,000 people. In those on Golimumab, this risk may increase to 3-4 in 10,000. Rarely, Golimumab may cause paradoxical immune reaction such as psoriasis or lupus. These occur in 1-3% of patients.

Individuals with demyelinating diseases (like multiple sclerosis or optic neuritis), untreated active malignancy, prior history of melanoma, or history of congestive heart failure should discuss the safety of Golimumab with their gastroenterologists.

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

Is Golimumab safe during pregnancy and breast feeding?

Maternal and paternal use of Golimumab has not been associated with impairment of fertility, miscarriage, birth defects, preterm birth, still births, or other adverse pregnancy outcomes. You may get your last dose of Golimumab early in the third trimester of your pregnancy. If you are on Golimumab during pregnancy, it is recommended that your infant not receive live virus vaccines such as the rotavirus vaccine within the first 6 months. It is safe to breastfeed while on Golimumab. This has not been shown to have any adverse impact of the baby. It is important to discuss with your provider about continuing Golimumab before and during and after pregnancy, but most patients will continue the treatment during their pregnancy.

Health maintenance on Golimumab therapy

It is important to be up to date with your health maintenance while on Golimumab therapy. This includes being current on all the recommended vaccines including annual influenza vaccine and pneumococcal vaccines. You should not receive live virus vaccines while on Golimumab therapy or within 3 months of stopping (or starting it).

It is also important to be up to date in your general cancer screening including mammograms and pap smears for women, and dermatologic (skin check-ups) for both men and women. Make sure to speak to your primary care doctor about whether you are up-to-date on all your cancer screening and immunizations.

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

There are a number of foundations that provide assistance to cover cost for patients on Golimumab therapy. The manufacturer of Golimumab has a patient assistance program for patients on Golimumab, called Janssen Carepath. Please go to <http://www.janssenprescriptionassistance.com/simponi-cost-assistance> for more information on this program.