



Patient & Family Guide
2016

Golimumab (Simponi®) Therapy



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Golimumab (Simponi®) Therapy

Your healthcare provider feels that treatment with golimumab may be helpful in managing your inflammatory bowel disease (IBD). The brand name for golimumab is Simponi®.

This pamphlet gives information about golimumab to help you make an informed decision about whether or not to use this treatment.

This pamphlet will give you some basic information. It is not to take the place of any information or instructions that your healthcare provider or pharmacist gives you.

If you have any questions, please ask.

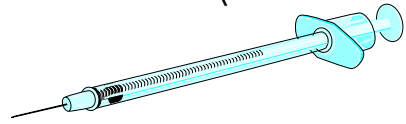
We are here to help you.

What is golimumab?

- One part of the immune system is called “tumour necrosis factor” (TNF). TNF is involved in chronic inflammation (swelling), which is a major factor in causing your IBD symptoms.
- Golimumab is an anti-TNF drug which suppresses (slows down) the immune system, lessens the inflammation in your bowel, and improves your symptoms.
- IBD is known for inflammation and ulceration (pus formation) of the bowel. In IBD, your immune system cannot tell the difference between foreign (from outside your body) substances and your body’s own tissues. This causes inflammation of the bowel and many of the other symptoms you may have (like diarrhea or pain).
- IBD is usually treated with medications to lower inflammation or infection, as well as medications which suppress the immune system.

How do I use golimumab?

Golimumab is given by subcutaneous (under the skin) injection, usually in the front of the thigh or abdomen



(belly). It cannot be taken by mouth because your digestive system will destroy the drug. You will get 2 injections (200 mg) at week 0 and 1 injection (100 mg) at week 2, followed by 1 injection (100 mg) every 4 weeks.

You can choose to inject the medication yourself or go to a clinic. If you choose to self-inject, you will be taught how to do injections.

Do not try to inject this medication on your own until you completely understand how to do it.

Injection instructions are in the medication guide that comes with your golimumab. If you choose not to self-inject, you can go to a clinic every 4 weeks for injections.

Precautions before you start golimumab

Before starting golimumab therapy, precautions can be taken to lower risks. Taking these precautions often results in successful treatment with very few downsides.

- You will have a tuberculosis (TB) skin test and chest X-ray along with some blood work, so your healthcare provider knows you don't have TB or active infections.
- Your healthcare provider may suggest you update your immunizations which may include tetanus, varicella (chicken pox), and pneumococcal (pneumonia) vaccines.
- Have routine blood testing and a regular check-up with your healthcare provider.
- Be sure to tell your healthcare provider about any other health problems you have because these may change how well golimumab works. This includes any allergies, blood problems, chronic or repeated infections, chronic obstructive pulmonary disease (COPD), active cancer or a history of cancer, diabetes, or tuberculosis.

- Because of increased infection risk, avoid live vaccinations (vaccines that have a weakened form of a virus in them) while being treated with golimumab. If you are due for vaccinations or plan to be vaccinated, tell your healthcare provider.
- Do not start any new drug treatments. Interactions between drugs may increase the risk of serious side effects. Ask your healthcare provider about possible complications before starting a new drug.
- **It is also important to tell your healthcare provider if you are, or plan on becoming, pregnant.** Tests have shown no harmful effects on pregnancy while taking golimumab, and your last dose is usually planned within your 3rd trimester of pregnancy. Golimumab is started again after you give birth. As it is a large molecule, it will not pass into your breast milk, so you can safely breastfeed your baby.

In the first year after birth, your baby should not get any live vaccines. It is very important to talk about this with your healthcare provider.

What are the possible side effects of golimumab?

Like any medication, golimumab has some common side effects such as:

- Upper respiratory infection (runny nose, sore throat, and hoarseness or laryngitis)
- Reaction at the injection site (redness, swelling, itching, pain, bruising, or tingling)
- Viral infections (flu or oral cold sores)

Tell your healthcare provider about any of these side effects:

- Fever, sweats, chills
- Muscle aches
- Cough
- Itching
- Rash
- Shortness of breath
- Blood in phlegm
- Weight loss
- Warm, red, or painful sores on your body
- Diarrhea or stomach (belly) pain
- Burning when you urinate (pee) or urinating more than usual
- Feeling very tired

Very serious life-threatening allergic reactions such as anaphylaxis (a sudden and severe allergic reaction) may also happen. If you have a severe allergic reaction, go to the closest Emergency Department.

Call 911 or go to the closest emergency department if you have any of these symptoms that come on all of a sudden:

- › Swelling of the face, throat, legs, or feet
- › Trouble breathing
- › Chest pain

Tell your healthcare provider right away if you have any of these symptoms related to congestive heart failure:

- Shortness of breath
- Swelling of the face, fingers, feet, or lower legs
- Sudden weight gain

Higher risk of infection

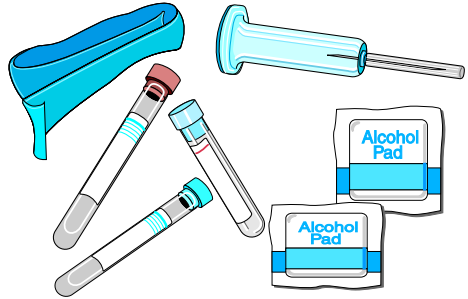
- Anti-TNF drugs like golimumab, work by stopping the immune responses which cause your IBD symptoms, but they also lessen other immune responses. This means you may have a high risk of infection.

There is a very small chance of getting a life-threatening infection which may cause death.

- **Some patients on golimumab have had problems ranging from the common cold to more serious and possibly life-threatening infections like:**
 - › Tuberculosis (TB)
 - › Histoplasmosis
 - › Hepatitis B
 - › Other bacterial, fungal, and viral infections throughout the body
- If you get an infection while taking golimumab, you will be checked closely and treated if needed. If the infection becomes serious, your golimumab therapy may be stopped.

Systemic lupus erythematosus (SLE)

Some patients treated with golimumab have had abnormal blood test results where autoantibodies (antibodies targeting your own body) were found. This is called systemic lupus erythematosus (SLE) and is caused by taking golimumab.



- **Tell your healthcare provider if you have any of these symptoms of SLE:**
 - › Chest discomfort or pain
 - › Shortness of breath
 - › Joint pain
 - › Rash on cheeks or arms that gets worse in the sun

When these patients stopped golimumab therapy, their blood tests went back to normal.

A very small number of cases of lymphomas and other cancers have been reported, including a fatal cancer called hepatosplenic T-cell lymphoma.

Talk with your healthcare provider

- If you notice any serious side effects, or any side effects that do not go away, it is important to tell your healthcare provider so changes can be made.
- Usually, golimumab dosage (the amount you take) can be changed to get rid of unwanted side effects. Stopping the therapy often stops harmful side effects as well.
- Talking with your healthcare provider when you notice any changes in side effects will help you pick the therapy that works best for you.

Looking for more health information?

This pamphlet and all our active patient pamphlets are searchable here:

<http://bit.ly/NSHApamphlets>

Contact your local public library for books, videos, magazines, and other resources.

For more information go to <http://library.novascotia.ca>

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Nova Scotia Health Authority

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Prepared by: Holly Mathias and Jennifer Stewart; Division of Gastroenterology ©

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The information is not intended to be and does not constitute healthcare or medical advice.

If you have any questions, please ask your healthcare provider.

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The information in this pamphlet is to be updated every 3 years or as needed.