



Patient & Family Guide
2022

Golimumab (Simponi®) Therapy for Inflammatory Bowel Disease (IBD)



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Golimumab (Simponi®) Therapy

Your health care provider feels that treatment with golimumab may help you manage your inflammatory bowel disease (IBD). The brand name for golimumab is Simponi®.

This pamphlet gives basic information about golimumab. It can help you choose whether to use this treatment. It does not take the place of information or instructions given to you by your health care provider or pharmacist.

What is IBD?

- In IBD, your immune system cannot tell the difference between foreign (from outside your body) substances and your body's own tissues. This can cause:
 - › Inflammation (swelling) of the bowel
 - › Ulceration (sores) of the bowel
 - › Diarrhea (loose, watery poops)
 - › Pain
- IBD is usually treated with medications that:
 - › Lower inflammation
 - › Suppress (lower) the immune system

What is golimumab?

- Golimumab is a biologic medication. A biologic medication is a special medication that treats inflammation.
- Tumour necrosis factor (TNF) is a part of your immune system involved in chronic (long-term) inflammation. It is a big part of what causes your IBD symptoms.
- Golimumab is an anti-TNF drug. It:
 - › suppresses your immune system.
 - › lowers the inflammation in your bowel.
 - › improves your symptoms.

How long will I need to take golimumab?

- Golimumab can take up to 4 months to work well. Your health care provider will check how you are responding to the medication and decide if it is right for you.
- You can check if the medication is working by keeping a record of your IBD symptoms. Your health care provider can also do the following tests:
 - › Stool (poop) sample
 - › Colonoscopy (scope of the bowel)

- Your health care provider may want you to stay on golimumab long-term (years) to treat your IBD if:
 - › the medication is helping your IBD symptoms.
 - › you are not having any major side effects.

How much does golimumab cost?

- Biologic medications like golimumab are very expensive. They can cost thousands of dollars a month.
- A Patient Support Program is available to help with the cost of this medication. They will work with your insurance company or Nova Scotia Pharmacare. Any part of the cost that is not covered by your insurance or Pharmacare is usually paid for by the Patient Support Program.
- A nurse coordinator for the Patient Support Program will stay in contact with you and your IBD health care providers. They will help you with any paperwork that may be needed to cover the cost of this medication.

How do I use golimumab?

- Golimumab is injected using a needle, usually in the front of the thigh or belly.
It cannot be taken by mouth. You will get:
 - › 2 injections (200 mg) at week 0
 - › 1 injection (100 mg) at week 2
 - › 1 injection (100 mg) every 4 weeks after that
- Injection instructions are in the medication guide that comes with your golimumab.
- You can choose to inject the medication yourself or go to a private clinic.
- If you choose to inject the medication yourself, the Patient Support Program will arrange for a nurse at the clinic to teach you how to inject the medication. **Do not try to inject this medication on your own until you have learned how.**
- If you choose not to inject the medication yourself, you can go to a private clinic for injections.

Before you start taking golimumab

- Before taking golimumab, there are things you can do to lower your risks (see page 12) and help the treatment work better.
- You will have blood tests, a tuberculosis (TB) skin or blood test, and a chest X-ray. These tests will check for active infections.
- Your health care provider may want you to update your vaccinations for tetanus, varicella (chickenpox), and pneumonia (lung infection).
- **If you have other health problems, they may change the way golimumab works. Be sure to tell your health care provider about any other health problems you have, like:**
 - › Allergies
 - › Chronic or recurrent (keep coming back) infections
 - › Blood conditions
 - › History of or exposure to TB
 - › Chronic obstructive pulmonary disease (COPD)
 - › Active cancer or a history of cancer
 - › Congestive heart failure (CHF)
- **Do not get any live vaccines (vaccines that have a weakened form of a virus in them) while taking golimumab.** You are at a higher risk of infection from the virus. If you are due for vaccinations or plan to be vaccinated, tell your health care provider.

- It is safe to get the yearly influenza vaccine (flu shot) while taking golimumab.
- **Do not start any new drug treatments.** Interactions between drugs (how they affect each other) may increase the risk of serious side effects. Ask your health care provider or pharmacist about possible complications before starting a new drug.
- Have regular blood tests and regular check-ups with your primary health care provider.
- **It is important to tell your health care provider if you are, or plan on getting, pregnant.** Tests have shown no harmful effects on pregnancy while taking golimumab.
 - › Your last dose will likely be planned for your third trimester.
 - › You can start taking golimumab again shortly after you give birth. It does not pass into your breast milk, so it is safe to breastfeed your baby.

Your baby may not be able to get any live vaccines (like the rotavirus vaccine) until after they are one year old. It is very important to talk about this with your health care provider.

What are the possible side effects of golimumab?

- Like any medication, golimumab has possible side effects. These include:
 - › Upper respiratory (breathing) infections: Symptoms may include runny nose, sore throat, and hoarseness or laryngitis (losing your voice)
 - › Reaction at the injection site: Symptoms may include redness, swelling, itching, pain, bruising, or tingling
 - › Viral infections (like flu or cold sores in the mouth)

Tell your health care provider if you have any of these side effects:

- › Fever (temperature above 38° C/100.4° F)
- › Sweating, chills
- › Muscle aches
- › Cough
- › Itching
- › Rash
- › Shortness of breath
- › Bringing up blood in mucus
- › Weight loss
- › Warm, red, or painful sores
- › Diarrhea or belly pain
- › Burning when you urinate (pee) or urinating more than usual
- › Feeling very tired

Life-threatening allergic reactions like anaphylaxis (a sudden and severe allergic reaction where you stop breathing) may also happen. If you have a severe (very bad) allergic reaction, go to the nearest Emergency Department right away.

Call 911 or go to the nearest Emergency Department right away if you suddenly have any of these symptoms:

- › Trouble breathing or shortness of breath
- › Chest pain
- › Swelling in your face, throat, legs, or feet

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

- › Shortness of breath
- › Swelling in your face, fingers, lower legs, or feet
- › Sudden weight gain

Higher risk of infection

- Anti-TNF drugs like golimumab work by lowering the immune responses that cause your IBD symptoms, but they also lower other immune responses. This means you may have a higher risk of infection.

There is a very small chance of getting an infection that could cause death.

- **Some patients on golimumab have had infections. These range from a cold to more serious infections which could cause death, like:**
 - › Tuberculosis (TB) (lung infection)
 - › Histoplasmosis
 - › Hepatitis B
 - › Other bacterial, fungal, and viral infections throughout the body

- **If you think you have an infection, visit your primary health care provider or go to a walk-in clinic. It is important to tell them that you are taking golimumab.**
- If you get an infection while taking golimumab, tell your IBD health care provider. They will tell you if you should delay your golimumab treatment and when you should start it again. If the infection becomes serious, your treatment may be stopped.

Are there any other risks of taking this medication?

Symptoms of lupus (systemic lupus erythematosus [SLE])

A small number of people who were taking golimumab developed symptoms of SLE. These people had abnormal blood test results where autoantibodies (antibodies that attack your own body) were found. When these people stopped taking golimumab, their blood tests went back to normal and the symptoms of SLE went away.

Tell your health care provider if you have any of these symptoms of SLE:

- › Chest discomfort or pain
- › Trouble breathing or shortness of breath
- › Joint pain
- › Rash on your cheeks or arms that gets worse in the sun

Cancer

A very small number of cases of lymphomas (blood cancers), including a cancer that can cause death, called hepatosplenic T-cell lymphoma, have been reported in people taking golimumab.

These types of cancers are thought to happen in about 6 out of every 10,000 people who take golimumab. This risk may be higher if you are also taking other medications that affect or suppress your immune system.

What should I do if I have side effects?

- If you notice any serious side effects, or you have side effects that do not go away, tell your health care provider right away. You may have to lower your dose (the amount you take) or stop taking golimumab. They will make changes to your medication, if needed.
- **It is important to talk with your health care provider as soon as you notice any changes in your side effects.** This will help you and your health care provider pick the treatment that is best for you.

It is very important that your health care provider checks your progress at regular visits to make sure this medication is working the right way. You will also need regular blood tests. Talk to your IBD health care provider about when you can expect them to follow up with you by phone or in person.

Looking for more health information?

Find this pamphlet and all our patient resources here: <https://library.nshealth.ca/PatientEducation>

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

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

Connect with a registered nurse in Nova Scotia any time: call 811 or visit <https://811.novascotia.ca>

Learn about other programs and services in your community: call 211 or visit <http://ns.211.ca>

Nova Scotia Health promotes a smoke-free, vape-free, and scent-free environment.

Please do not use perfumed products. Thank you!

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Prepared by: Nova Scotia Collaborative IBD Program

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The information in this pamphlet is for informational and educational purposes only.

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

If you have any questions, please ask your health care provider.

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