Information about



Golimumab for IBD

Points to remember

- Golimumab is a safe and effective medication to treat inflammatory bowel disease (IBD).
- Always attend your scheduled appointments with your IBD team to ensure that you have access to an approved prescription for ongoing golimumab.

What is golimumab and how does it work?

Golimumab is a complex biologic drug known as a monoclonal antibody. Monoclonal antibodies can target very specific parts of your immune system to control inflammation. Golimumab targets a molecule called tumour necrosis factor-alpha (TNF- α). Your body naturally produces TNF α as part of its immune response. Overproduction of TNF- α is thought to be responsible for ongoing inflammation in IBD. Golimumab stops the action of TNF- α , reducing the inflammation and allowing the bowel to heal.

Why have I been prescribed golimumab?

Golimumab is used to treat moderate to severe ulcerative colitis. It is prescribed if other IBD medications have not worked or are not suitable for you.

How do I take golimumab?

Golimumab is given as a subcutaneous (under the skin) injection. Golimumab comes in an injection pen. Your IBD nurse will train you how to handle, inject and dispose of golimumab. Additional resources such as video tutorials may be available to guide you.

To start, golimumab is given as multiple doses closer together and is then given as an injection every 4 weeks ongoing. Generally, the initial and ongoing dosing is as follows.

- Initially 2 injections (2 x 100mg) on one day.
- Then 1 injection (1 x 100mg) two weeks later.
- Then 1 injection (1 x 100mg) every four weeks ongoing.

Important information about your access to golimumab

Golimumab is an expensive medication. Hence, it is subject to strict governmental restrictions and regulations to be subsidised on the PBS. To ensure ongoing supply of golimumab, you will be required to undergo assessment of your IBD every 6 months. This may include regular blood tests and an appointment with your IBD team.

Do I need any tests before I start golimumab?

Pre-treatment screening is essential to check your suitability for treatment with golimumab. The screening may include blood tests and chest x-ray to assess infection risk. You may be advised to have one or more vaccines prior to commencing golimumab. Please refer to the <u>Vaccinations and IBD information sheet</u>.

How long will I be on golimumab?

If you respond to golimumab it may be used for the long term. In some people, golimumab can lose its effectiveness over time, and the dose may be increased or given more often.

Will I have to take other medications as well as golimumab?

Your IBD team will instruct you on the medications you will need to commence, remain on or cease. Sometimes golimumab may be combined with medication such as azathioprine, mercaptopurine or methotrexate.

Fertility, pregnancy and breastfeeding

Golimumab does not affect fertility. It is important your IBD is controlled on effective medication before becoming pregnant. Tell your doctor if you are thinking of becoming pregnant or find you are pregnant.

Golimumab is generally considered safe in pregnancy. Most IBD doctors recommend continuing golimumab while pregnant as there may be a greater risk to the baby if you become unwell from stopping treatment. Timing of doses may be changed during pregnancy so it is important to plan ahead by talking with your IBD team. Golimumab is considered safe in breastfeeding.

Mothers on golimumab should discuss vaccination of their infant with their IBD team, as the medications taken during pregnancy can influence the safety of live vaccinations after birth. The main one affected on the schedule in Australia is rotavirus vaccine. You can ask your IBD team for a medical exemption letter for a vaccine your child cannot receive.

What are the possible side effects of golimumab?

All medications can cause side effects, but not everyone experiences them. You will be monitored for side effects by your IBD team.

Immediate reactions to golimumab injections are rare but include fever, rash, hives, facial swelling, headache, dizziness and joint pains. If you experience a reaction to golimumab, notify your doctor or IBD team as soon as possible.

An injection site reaction can manifest as a patch of raised, red, itchy area of skin where the injection was administered. Antihistamine treatment can reduce the symptoms of injection site reactions.

Golimumab can uncommonly increase the risk of infection. This may include serious infections such as tuberculosis, pneumonia and chicken pox. You will be screened for this risk and vaccinated where possible. Rare side effects have been described in a few people. These include psoriasis-like rashes, a lupus-like condition, worsening of heart problems or changes in the liver. Golimumab may increase your risk of getting some types of cancer, including melanoma and lymphoma (cancer of the lymph glands) and may very rarely cause a condition similar to multiple sclerosis. These risks are very small and need to be balanced against the benefits of taking the drug. Talk to your doctor about the risks and benefits for you so that decisions can be made based on your individual health and circumstances.

What can I do to keep myself healthy on golimumab?

- Avoid close contact with people with transmissible infections. Tell your doctor if you have come in contact with anyone who has an infectious condition such as chicken pox, shingles, whooping cough or measles.
- You should have the flu vaccine every year, and the COVID-19, pneumonia, and human papilloma virus (HPV) vaccines according to the recommended schedule. You should not have live vaccinations while taking golimumab, and for some time after stopping it. Please refer to the <u>Vaccinations and IBD</u> information sheet for further information.
- Women should have regular cervical screening tests as recommended by your GP.
- You should use a strong sunscreen and protect your skin when outside. Annual skin checks are recommended.
- Always check with your IBD team before starting new medications to avoid unwanted interactions.

Contact the IBD team or your GP if you have an infection or persistent fever.

This information leaflet has been designed to provide you with some important information about golimumab. This information is general and not intended to replace specific advice from your doctor or any other health professional. For further information please speak to your pharmacist, doctor or IBD nurse.

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