

Points to remember

- Infliximab is a safe and effective medication to treat inflammatory bowel disease (IBD).
- Always attend your scheduled clinic appointments to ensure that you have access to an approved prescription in time for your next infliximab dose.

What is infliximab and how does it work?

Infliximab is a complex biologic drug known as a monoclonal antibody. Monoclonal antibodies can target very specific parts of your immune system to control inflammation. Infliximab 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. Infliximab stops the action of TNF- α , reducing the inflammation and allowing the bowel to heal.

Why have I been prescribed infliximab?

Infliximab is used to treat moderate to severe Crohn's disease and ulcerative colitis. It is prescribed if other medications have not worked or are not suitable for you. Infliximab can be used in fistulising Crohn's disease as a first-line treatment.

How do I take infliximab?

Intravenous (IV) infliximab:

Infliximab can be given as an IV infusion in a day infusion centre, usually at a hospital. The first three infusions are given close together in a 6-week period and then every 8 weeks ongoing. When starting the infusion will take around 2 hours to run but this time may be reduced if you receive multiple infusions without complications.

Infliximab for IBD

Subcutaneous infliximab:

Infliximab can also be given as a subcutaneous (under the skin) injection. Your IBD team will train you how to handle, inject and dispose of the device. Additional resources such as video tutorials may be available to guide you. Initially, IV infusions are required to be given before the subcutaneous injections can commence. The number and frequency of these infusions may vary based on your IBD, but generally at least two infusions are required. After switching to subcutaneous injections the dose is given every 2 weeks ongoing.

Your IBD team will monitor your response to this medication. You may require more frequent or higher doses of infliximab depending on your disease and response to therapy.

There are several versions of infliximab. All of these have different brand names. Your IBD team will let you know what brand of infliximab you should be on and remain on unless told otherwise.

Important information about your access to infliximab

Infliximab 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 infliximab, 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 infliximab?

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

How long will I be on infliximab?

If you respond to infliximab it may be used for the long term. In some people, infliximab may lose its effectiveness over time. Infliximab blood levels may be measured by your IBD team. Low levels of infliximab may indicate that the dose may need to be increased or be given more often.

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

Your IBD team will instruct you on the medications you will need to commence, remain on or cease. There is some evidence that combining infliximab with medication such as azathioprine, mercaptopurine or methotrexate may be more effective than infliximab alone.

Fertility, pregnancy and breastfeeding

Infliximab 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.

Infliximab is generally considered safe in pregnancy. Most IBD doctors recommend continuing infliximab 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. Infliximab is considered safe in breastfeeding.

Mothers on infliximab 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 infliximab?

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

Some side effects may occur at your infusion and others may not appear until some time later.

Immediate reactions related to the infusion will be monitored for whilst you receive infliximab. These may include fast heartbeat, light-headedness, nausea, rashes and shortness of breath. Some medications may be given before your infusion or during your infusion to manage these.

You may also experience mild to moderate symptoms in the days to weeks after the infusion including headache, nausea, tiredness and runny nose or sore throat. In many cases, the symptoms will go away, but in some cases they may be serious and require treatment. If the symptoms are severe or continue or bother you, please let your IBD team know.

Infliximab 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 and worsening of heart problems. Infliximab 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.

If using subcutaneous injections of infliximab, injection site reactions 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 reaction.

What can I do to keep myself healthy on infliximab?

 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 infliximab, and for some time after stopping it. Please refer to the <u>Vaccinations and IBD information</u> <u>sheet</u> 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 infliximab. 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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