

ANTI-TNF THERAPY

Medication Information

This information is intended as a guide only. Ask your doctor if you have any questions relating to this information.

WHAT ARE anti-TUMOUR NECROSIS FACTOR (anti-TNF) MEDICATIONS?

These medications are also called biologic medications. There are two of these on the market in Australia at present for inflammatory bowel disease (IBD).

- Infliximab (Remicade® or Inflectra®)
- Adalimumab (Humira®)

Anti-TNF medications are strong immunosuppressive drugs and can only be prescribed by your Gastroenterologist.

HOW DO THEY WORK?

TNF- α is a protein (cytokine) that is produced by the body during normal immune and inflammatory responses to help fight infections. In people with IBD, the body produces too much TNF- α , leading to tissue damage and chronic inflammation. Anti-TNF medications are antibodies that work by blocking TNF- α , in order to reduce inflammation and damage to gastrointestinal tract.

WHEN ARE anti-TNF DRUGS USED IN IBD?

Anti-TNF drugs are used to induce and maintain remission in patients suffering from Crohn's disease (CD) and ulcerative colitis (UC). They are usually used in patients who are intolerant of other therapies or have severe disease that has been resistant to other therapies. Both Infliximab and Adalimumab are available to patients with Crohn's disease (CD) or Ulcerative colitis (UC) on the Pharmaceutical benefits scheme.

HOW EFFECTIVE ARE THE anti-TNF MEDICATIONS?

Anti-TNF medications are effective for treating disease that is caused by active

inflammation of the bowel. They are not effective for treating symptoms related to other causes, such as scarring or stricturing of the bowel. If your symptoms are caused by irritable bowel syndrome, or narrowing or shortening of the bowel, then these medications are unlikely to be effective.

Anti-TNF medications may be effective if you have not responded to other medications that are available for the treatment of CD and UC. Responses to anti-TNF medications can vary between individuals. Symptoms may improve within days for some patients, however the response may be slower for other patients, and in some there may be no effect at all. In some cases, intolerance to the medication or gradual loss of response can develop.

Overall, these medications have been demonstrated to be safe and effective in the treatment of IBD (over more than 15 years) and most patients achieve a durable response.

HOW ARE THESE MEDICATIONS GIVEN?

Infliximab is administered by an infusion into a vein at a day procedure unit or hospital.

The infusion takes 2 – 3 hours, although after 4 infusions this can usually be given more rapidly (over 1 hour) to save time. You will be monitored during and after the infusion.

The first three doses are given close together at weeks 0, 2, and 6. Thereafter, infusions are scheduled for every 8 weeks.

There are currently two brands of Infliximab available (Remicade® & Inflectra®).

For your safety, it is important that you receive the same brand of Infliximab

each infusion as prescribed by your doctor.

It is important that you check which brand of Infliximab you are receiving each and every infusion to avoid an unintentional switch between brands.

Adalimumab (Humira®) is administered as a subcutaneous injection (under the skin) every 2 weeks. The first two doses are higher, giving you a loading dose. From the third injection onwards, the dose is 40 mg (one injection) once every two weeks. Most patients inject themselves with Humira, however some people prefer a family member or friend to do this. You or your family member/friend will be taught how to give the injection. The injections are only little and are not hard to give. Adalimumab is supplied as either a pre-filled syringe or as a Pen and you are free to choose which method you prefer. The pharmaceutical company who produce the drug (Abbvie®) offer a support program to support you called Abbvie® Care and we encourage the use of this. Visit <https://wellness.abbviecare.com.au/Public/Landing>

WHAT ARE THE RISKS OF TAKING anti-TNF MEDICATION?

Most patients will tolerate these medications well and most side effects are mild and manageable. However, as with all medications there are potential side effects and it is important that you are aware of these. Close monitoring is important to reduce the risk of harm with these medications. Your doctor will discuss these risks with you, and the steps to be taken to reduce the likelihood of side effects occurring. Below is a list of some (but not all) potential risks of anti-TNF medication.

More common

- Injection site skin reactions:
 - The symptoms of this are localized rash with burning or itching. These reactions can last up to a week.
- Flushing and fever.
- Nasal congestion.
- Headache.
- Chest or abdominal pain.
- Generalised ache of muscles and joints:
 - These are usually short lived and usually resolve soon after the injection.

Less common

- Serious infection:
 - Including reactivation of Hepatitis B or Tuberculosis in those previously infected.
- Malignancy:
 - Non-Hodgkin's lymphoma (NHL) and other rare lymphomas. There is a small increase in risk for NHL, particularly in older patients and those who have been taking the medication for a long time.
 - Melanoma.
- Auto-immune disease such as drug-induced lupus.
- Interstitial lung disease.
- Exacerbation of heart failure.
- Neurological disease (demyelinating disease).

You should see your doctor immediately if you develop any of the following whilst on therapy, or if you are concerned that you are having any other side effects of anti-TNF medication:

- A fever, sweats, sore throat or any other sign of infection.
- You develop unexpected weight loss.
- You become breathless or develop a cough.
- You develop a rash, joint pain, or neurological symptoms.

WHAT DO I NEED TO DO BEFORE I START TAKING anti-TNF THERAPY?

Before starting therapy with one of these medications, you will need to:

- Make an appointment with your GP to discuss starting this medication and

enlist their help with monitoring.

- Take bloods tests:
 - Baseline full blood count and liver function tests.
 - Hepatitis B serology. This is to ensure that you do not have active or latent infection that could become more active during therapy.
 - Varicella (chickenpox) serology. If you are not immune to chickenpox, you will need a vaccination prior to starting therapy.
 - Mycobacterium tuberculosis (TB) testing. A blood test to assess for past or current TB as well as a chest X-ray are usually performed, alongside a careful clinical history to see if you have any risk of being exposed to TB in the past.
- Ensure that you are up to date with your:
 - **Pneumococcal** vaccination (Pneumovax® - 5 yearly).
 - **Influenza** vaccination (Fluvax® - yearly).
 - **Human Papilloma** vaccination (Once - for females who are not yet sexually active).
 - **Varicella** vaccination (Once - if you have not had chicken pox).
- Ensure that your pap smears are up to date.
- Discuss your plans for pregnancy or whether you are thinking of starting a family.
 - There have been many successful pregnancies whilst taking these Infliximab and Adalimumab. If you are planning pregnancy, please tell your specialist.

Your doctor will:

- Take a history to see if you have had symptoms of a current infection or prior exposure to tuberculosis (TB).
- Review your medical history, particularly with regard to any previous infection, cancer, immune disease or heart failure.

WHAT DO I NEED TO DO AFTER STARTING anti-TNF MEDICATION?

Close monitoring is extremely important when taking anti-TNF medication, particularly blood tests and clinical

review. Monitoring helps to keep you safe and minimise any risks of harm related to therapy.

After starting anti-TNF medication, you will be asked to:

• Remain engaged with your specialist and ensure that you have a regular appointment at least every 6 months:

- Your specialist will need to renew your prescription at least every 6 months and the timing is important because a renewal application needs to be made to the Pharmaceutical Benefits Schedule (PBS) each and every time.
- If you do not see your specialist at the right time, you may miss out on your medication, which puts you at risk of a flare.
- Have regular bloods tests:
 - At least 6 monthly for as long as you are on treatment (these may need to be more frequent).
- Inform your doctor if you have any side effects:
 - If you develop new symptoms such as fever, you should see your doctor immediately.
- Avoid contact with people with infections.
- Ensure that you are up to date with your vaccinations:
 - **Pneumococcal** vaccination (Pneumovax® - 3 yearly).
 - **Influenza** vaccination (Fluvax® - yearly).
 - **Avoid live vaccines** (polio, yellow fever, MMR (measles, mumps, and rubella), and BCG (tuberculosis). These are dangerous while taking these medications and should be avoided. Inactivated vaccines such as the flu vaccination are perfectly safe and are recommended.
- Annual pap smears are recommended for sexually active women whilst on therapy.
- Take care in the sun. People on anti-TNF therapy are at increased risk of skin cancer and it is important to be vigilant with sun protection.

Please contact your doctor if you have any concerns.