

Infliximab Patient Information



For more information, head to hunteribd.com or contact the team at hne-ibdprescription@health.nsw.gov.au

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Patient Information Leaflet

Brand Names: Remicade®, Inflectra®, Renflexis®, Avsola®



What is Infliximab?

Infliximab is a biologic medication belonging to a group of medicines called tumour necrosis factor (TNF) inhibitors. It is a monoclonal antibody, which is a type of protein designed to recognise and attach to a specific target in the body called TNF-alpha. TNF-alpha is a chemical messenger involved in inflammation. By blocking TNF-alpha, infliximab helps reduce inflammation in your body.

What is Infliximab used for?

Infliximab is approved in Australia for treating:

- Moderate to severe Crohn's disease in adults and children
- Moderate to severe ulcerative colitis in adults and children
- Severe active rheumatoid arthritis
- Active ankylosing spondylitis
- Psoriatic arthritis
- Chronic plaque psoriasis

For inflammatory bowel disease (Crohn's disease and ulcerative colitis), infliximab is typically prescribed when other treatments such as corticosteroids, immunomodulators, or aminosalicylates have not been effective or have caused significant side effects.

How is Infliximab given?

Infliximab is available in two formulations:

Intravenous (IV) infusion:

- Administered through an intravenous line directly into a vein
- The infusion is provided at a hospital or specialised infusion centre and typically takes about 2 hours

- After your infusion, you will need to stay for observation for a short period to monitor for any immediate reactions

Subcutaneous (SC) injection:

- A newer formulation that is injected under the skin
- Available as pre-filled syringes or pens (120mg per injection)
- Can be self-administered at home after proper training
- Typically used for maintenance therapy after induction with IV infusions, though some patients may now start with subcutaneous injections

Standard dosing schedule for IV infliximab:

- **Initial treatment phase:** Infusions at weeks 0, 2, and 6
- **Maintenance phase:** Infusions every 8 weeks thereafter

Standard dosing schedule for SC infliximab:

- **Initial treatment (if starting with SC):** 120mg injections at weeks 0, 1, 2, 3, and 4
- **If transitioning from IV to SC:** First SC dose is given instead of the next scheduled IV infusion
- **Maintenance phase:** 120mg injection every 2 weeks

Your doctor may adjust these schedules based on your response to treatment. The IV dose is calculated based on your body weight, usually 5mg per kilogram of body weight.

How long does Infliximab take to work?

The time to experience benefits from infliximab varies between individuals:



- Some patients notice improvement in symptoms (such as reduced pain, diarrhoea, or bleeding) within the first 1-2 weeks after the initial infusion.
- Others may take 6-8 weeks or longer to see significant benefits.
- Full effectiveness is typically assessed after completing the initial induction phase (first three infusions).

If you don't experience improvement after 12-14 weeks (following your third infusion), your doctor may consider adjusting your treatment plan

How should Infliximab be stored?

Intravenous infliximab:

As this is administered at a healthcare facility, you will not need to store the medication yourself. The healthcare facility will store infliximab in refrigerated conditions (2-8°C) as required.

Subcutaneous infliximab:

- Store in a refrigerator at 2°C to 8°C (36°F to 46°F)
- Do not freeze
- Keep the pre-filled syringe or pen in the original carton to protect from light
- Do not shake
- If needed, the subcutaneous pre-filled syringes or pens may be stored at room temperature up to 25°C (77°F) for a single period of up to 7 days in the original carton
- Once stored at room temperature, do not return to the refrigerator
- Discard if not used within 7 days at room temperature
- Keep out of reach of children

What monitoring is required while taking Infliximab?

Before starting infliximab:

- Tuberculosis (TB) screening (skin test, blood test, and/or chest X-ray)
- Hepatitis B and C testing
- HIV testing may be recommended
- General blood tests to check blood counts and liver function

During treatment:

- Regular blood tests to monitor:
 - Full blood count
 - Liver function
 - Kidney function
- Clinical assessment of your disease activity and symptoms
- Your doctor may occasionally check infliximab and antibody levels in your blood to ensure the medication is working effectively

What are the common side effects of Infliximab?

Common side effects (affecting more than 1 in 10 people):

- Headache
- Upper respiratory tract infections (common cold, sinusitis)
- Abdominal pain
- Nausea
- Infusion-related reactions
- Fatigue

Less common side effects (affecting between 1 in 100 and 1 in 10 people):

- Skin rash or itching
- Dizziness or vertigo
- Flushing
- Fever
- Urinary tract infections
- Joint pain or muscle pain
- Back pain
- Cough

What are the risks associated with Infliximab?

Serious risks:

1. **Infections:** Infliximab can reduce your ability to fight infections. This includes:
 - Upper respiratory tract infections
 - Serious infections such as pneumonia, sepsis, and tuberculosis
 - Opportunistic infections (infections that occur more frequently in people with weakened immune systems)
2. **Allergic and infusion reactions:**
 - Mild to severe allergic reactions can occur during or shortly after infusion
 - Symptoms may include fever, chills, chest pain, low or high blood pressure, shortness of breath, rash, or itching
 - Severe reactions are rare but can be serious
3. **Cancer risk:**
 - There is a slightly increased risk of certain cancers, particularly lymphomas
 - The risk is higher in patients who also take other immunosuppressant medications
 - Skin cancers may occur more frequently, so regular skin checks are recommended
4. **Reactivation of hepatitis B:**
 - If you have previously been infected with hepatitis B virus, infliximab may cause the virus to become active again
5. **Neurological disorders:**
 - Rare cases of nervous system disorders have been reported, including multiple sclerosis, seizures, and inflammation of the nerves of the eye
6. **Liver injury:**
 - Rare cases of liver injury have been reported
 - Symptoms include jaundice (yellowing of skin and eyes), right-sided abdominal pain, and severe fatigue
7. **Heart failure:**
 - Infliximab may worsen existing heart failure
 - New-onset heart failure has been reported in rare cases

Vaccinations and Infliximab

Before starting infliximab:

It is recommended to update all vaccinations according to the Australian Immunisation Schedule before starting treatment. This includes:

- Influenza vaccine (yearly flu shot)

- Pneumococcal vaccine
- Hepatitis B vaccine (if you are not immune)
- Consider COVID-19 vaccination as per current guidelines
- Consider zoster vaccine (Shingrix) if you are over 50 years old

During infliximab treatment:

- **Live vaccines** should be avoided, including:
 - Measles, mumps, rubella (MMR)
 - Varicella (chickenpox)
 - Zoster (Zostavax - but not Shingrix)
 - Oral typhoid
 - Yellow fever
 - BCG (tuberculosis)
 - Oral polio vaccine
- **Non-live vaccines** are generally considered safe, but may be less effective while on infliximab:
 - Influenza vaccine (yearly)
 - Pneumococcal vaccine
 - Tetanus booster
 - COVID-19 vaccines

Always discuss vaccination plans with your gastroenterologist before receiving any vaccine.

Infliximab and Pregnancy

Planning pregnancy:



Infliximab is classified as Category B1 in the Australian pregnancy categorisation system. This means that it has been taken by only a limited number of pregnant women without an observed increase in malformation or harmful effects on the foetus.

Current evidence suggests that infliximab:

- Is considered low risk during pregnancy
- Does not appear to increase the risk of birth defects
- May help maintain disease remission during pregnancy, which is important for healthy pregnancy outcomes

During pregnancy:



- Infliximab crosses the placenta, primarily during the third trimester
- Your doctor may recommend adjusting the timing of your last infusion before delivery to minimise infant exposure
- The decision to continue infliximab during pregnancy should be discussed with your gastroenterologist and obstetrician

Breastfeeding:

- Very small amounts of infliximab may pass into breast milk
- Current evidence suggests that breastfeeding while on infliximab is generally safe for the infant
- The benefits of breastfeeding and controlling your disease should be discussed with your healthcare providers

Special Precautions

Surgery:

If you are planning to have surgery, inform your surgeon that you are taking infliximab. Your doctor may recommend temporarily stopping infliximab before major surgery.

Travel:

- Consider carrying a letter from your doctor explaining your need for infliximab when travelling
- If travelling overseas, check if you need additional vaccinations and discuss with your doctor (as some travel vaccines are live vaccines)
- Plan your travel around your infusion schedule

Skin protection:

Due to the slightly increased risk of skin cancers, it is important to practise sun safety:

- Use sunscreen (SPF 30+ or higher)
- Wear protective clothing
- Seek shade when possible
- Have regular skin checks with your doctor

Where can I find more information?



- Speak to your gastroenterologist, IBD nurse, or pharmacist
- Contact the Gastroenterological Society of Australia (GESA): www.gesa.org.au
- Contact Crohn's & Colitis Australia: www.crohnsandcolitis.com.au or 1800 138 029
- Call Medicines Line: 1300 MEDICINE (1300 633 424)

This information leaflet is not intended to replace medical advice. Always consult your healthcare team with specific questions about your treatment.

