Infliximab

to treat inflammatory bowel disease (IBD)

Gastroenterology Department Liverpool Hospital

Please read this booklet and discuss any concerns with your IBD doctor.





How does Infliximab (Remicade®) work?

Infliximab is a medicine used to treat inflammatory bowel disease (IBD) such as Crohn's disease and ulcerative colitis in people who have not responded well to other treatments.

Infliximab belongs to a group of medicines that are also called "biological" therapies. Infliximab works by targeting a specific protein in the body called Tumour Necrosis Factor (TNF). The body naturally produces TNF as part of the immune response to help fight infections. Over-production of TNF is thought to be partly responsible for the ongoing inflammation found in people with IBD, resulting in symptoms such as pain, diarrhoea and intestinal damage.

By blocking TNF, infliximab reduces inflammation which lessens the symptoms of IBD and helps stop bowel damage.

Biological therapies are usually expensive because the manufacturing process is very complex and specialised. Infliximab is funded by the Commonwealth government with some strict criteria which your IBD doctor and nurse will follow-up for each authority prescription. There is another brand of Infliximab now approved and available in Australia. It is important to continue with the same brand of Infliximab throughout your treatment. Changing brands of biological therapies is not as straight forward as with usual medicines and should only be done if your doctor advises

How is Infliximab given?

Infliximab is given as an intravenous infusion administered in the ambulatory care Clinic 116 (PIXI) at Liverpool Hospital in the Clinical Building Level 1.

The infusion normally takes 2 to 4 hours and you may need to stay in PIXI for at least one hour after the infusion to check you don't have any side effects.

After the first dose is given, the second dose is usually given 2 weeks later and the third dose is given 4 weeks after the second dose. Subsequent doses are then usually given every 8 weeks.

Infliximab is often given in combination with other medications and your specialist will explain this.

Use of Infliximab with other medicines:

Tell your doctor (including your local doctor (GP), specialists and others) about all the medicines you are taking or planning to take. These include over the counter and herbal or naturopathic medicines. When you see a dentist or other health professional, you should tell them about your medication and treatment plan.

Most vaccines can be given safely but live vaccines, such as MMR (measles, mumps and rubella) or varicella (chickenpox) and yellow fever are not recommended. Influenza and pneumococcal vaccinations are safe.

Discuss any vaccinations that you may require with your IBD doctor.

Blood Tests:

You will be required to have blood tests during your treatment to monitor your condition and to determine the effectiveness of treatment and

possible side effects.

Infections:

If you have an active infection, treatment with Infliximab may not be given until the infection is treated successfully. It is important that you see your local doctor (GP) as soon as possible if you develop an infection and to let your IBD doctor and nurse know.

Infliximab should not be given if you have a certain type of infection, such as tuberculosis or HIV, as it is likely to make these conditions worse. Before starting Infliximab, a test is required to see if you have had these types of infection.

If you have had a **Hepatitis B infection** before, treatment with Infliximab may reactivate the infection. Your IBD doctor will discuss treatment options with you and whether Infliximab is suitable for you.

Heart condition:

Infliximab should not be given to people with moderate to severe heart failure. You should discuss with your IBD doctor if you have a heart condition.

Pregnancy and breastfeeding:

Good control of your IBD is the most important key to being able to fall pregnant and have a subsequent healthy pregnancy. Data suggests no increase in foetal abnormalities in those babies of mothers who were on Infliximab during pregnancy. **The decision to continue or discontinue**

Infliximab before, during or after pregnancy should be discussed with your IBD doctor.

If Infliximab is given during pregnancy, giving the infant live vaccines should be avoided for the first twelve months of life.

It is considered safe to breast feed if you are on Infliximab. Only extremely small amounts of Infliximab are excreted in breast milk.

Surgery:

If you require surgery for any reason, treatment with Infliximab may need to be stopped prior to surgery. The decision to continue or discontinue Infliximab will be made between your surgeon and your IBD doctor.

What can you expect from Infliximab therapy?

Infliximab works relatively quickly and some relief of pain and diarrhoea may be noticed within the first few weeks of treatment.

If Infliximab is stopped for more than a few weeks, there is a risk that your condition may worsen. Continue with your treatment unless advised by your doctor to stop. If you do experience side effects and cannot contact your IBD doctor or nurse, it is advised that you discontinue treatment and contact us as soon as possible.

What are the possible side effects?

Infliximab may cause some unwanted side effects in some patients. For a full list of side effects, please refer to a product information leaflet.

Listed below are some potentially serious side effects that Infliximab may cause:

Get emergency medical help immediately if you have:

- Allergic reaction such as rash, itching, trouble breathing, tightness in chest, swelling of lips or tongue.
- Lung problems such as shortness of breath.
- Liver problems such as abdominal pain, yellowing of the eyes or skin, white or clay-coloured stools, or dark-brown coloured urine.
- Drug-induced lupus such as rash, fever and joint pain. This
 usually disappears when Infliximab is stopped.
- Nerve problems such as muscle weakness, fatigue and changes to vision.

Infliximab is associated with a small increased risk of developing **skin cancers**, therefore sun protection is extremely important, especially if you have a fair complexion. It is unclear if there is an increased risk of other cancers. It should be noted that patients with long standing and active inflammatory diseases, such as IBD, may already have a higher risk of developing cancers, making it difficult to estimate the risk of developing cancers in these patients. Studies have suggested Infliximab has been associated with a minor increase of the incidence of **lymphoma** (a cancer of the lymph glands), especially when used in combination with Azathioprine or 6-mercaptopurine. If you have any concerns, you should discuss them with your IBD doctor.

Call your local doctor (GP) immediately at the first sign of infection such as fever (over 38°C by oral thermometer), chills, cough or burning when you pass urine.

Some more common side effects include:

Some side effects can occur during the infusion itself. These include fever, chills, itch, chest pain, shortness of breath and changes in blood pressure. These are more likely to occur during the first or second infusion and can usually be reduced by giving steroids,

antihistamines and paracetamol before the treatment.

A similar reaction may rarely occur several days later (usually 5 to 7 days after the infusion) and is treated with the same type of medications. This may also occur if you have stopped treatment for some time and are restarting treatment.

If this occurs it is important that you contact your doctor as soon as possible.

Headaches, dizziness, coughs and stomach or bowel discomfort may also occur. If you are affected by headaches and/or dizziness, you should avoid driving or operating heavy machinery.

As Infliximab affects the immune system, **mild infections** particularly of the upper respiratory tract (e.g. colds and flu) may occur more frequently than usual.

It is important that you report any side effects that you might experience to your IBD doctor or nurse as soon as possible.

Remember:

- Keep all medicines out of reach of children.
- You should be seen regularly by your IBD doctor to optimise treatment and minimise any potential side effects.
- Have your regular blood tests, as arranged.
- If you have any questions or concerns write them down and discuss them with your IBD doctor.
- If you go to another doctor or dentist for treatment, tell them you are having Infliximab therapy.

• Keep to the same brand of Infliximab for the duration of your therapy.

For more information
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