INFLIXIMAB/ ADALIMUMAB

INFORMATION FOR PATIENTS REQUIRING BIOLOGIC MEDICATION FOR INFLAMMATORY BOWEL DISEASE
**Introduction**

This leaflet is for patients who are about to start taking or are currently taking biologic therapy medication to treat your Crohn’s disease or Ulcerative Colitis, together known as Inflammatory Bowel Disease (IBD).

**Why am I prescribed Infliximab or Adalimumab?**

Infliximab or Adalimumab are used to treat severe crohn’s disease., and occasionally Infliximab can be used to treat severely active ulcerative colitis. It may be given to you when other drugs have not worked or have caused side effects, and when surgery is not considered the right treatment option for you.

**What are Infliximab and Adalimumab?**

These drugs are similar and work by reducing inflammation. A protein called TNF-alpha is an important protein in inflammatory diseases and this protein is blocked by Infliximab and Adalimumab. These drugs have been used to treat many thousands of patients with crohn’s disease, ulcerative colitis and other inflammatory conditions.

**How often do I have Infliximab or Adalimumab?**

Infliximab is given as an infusion (drip) into a vein, which means having a drip in your arm or back of your hand. It is usually infused over two hours and you will need to stay in hospital for approximately two hours after the infusion has finished, so that you can be monitored for any side effects before being discharged home. This is done in the Medical Investigations/ Day Unit and is given while you are relaxing in chair. Usually further infusions are given 2 and 6 weeks later. If you are responding adequately then the infusions are given every 8 weeks. Treatment can continue long-term. After four successful Infliximab infusions without any side effects the infusion can be given more quickly. This is an unlicensed method of administration but means that you will not have to wait as long for the infusion to finish. The doctor or inflammatory bowel disease nurse will discuss with you whether you are happy for this to be done.

Adalimumab is given by injection under the skin every 2 weeks. We will teach you the way to give yourself the injection. It may be possible for somebody else, such as a family member or friend to give the injection after training from a health care professional. Treatment can continue long-term.

We will assess your response to treatment after the first 3 doses and will continue treatment if we feel it has been of benefit in controlling your disease.

We will review the need for continuing treatment with you usually after a year.

**What dose of Infliximab or Adalimumab do I have?**

For infliximab the usual dose is based on your weight (usually five milligrams per kilogram).

For Adalimumab, the recommended initial dose is 80 mg followed by 40 mg two weeks later. Sometimes if a quicker response is needed your doctor can increase
this first dose to 160 mg followed by 80 mg after two weeks. For ongoing treatment, the recommended dose is 40 mg every other week on the same day of the week.

**How long will it take to work?**
The response to the treatment varies. Most people feel better within 2-6 weeks. Some people find they feel better within a few days.

**Do I need any investigations before having Infliximab or Adalimumab?**
You will need to have a chest x-ray (if you have not a chest x-ray in the last three months). This is to ensure that you do not have tuberculosis (TB), as these drugs can, in some cases, re-activate old TB. We usually also check a blood test to check for underlying TB. This test takes a few weeks to get the result. In addition we will take additional blood tests to screen for Hepatitis B and C and HIV and to check you have immunity to chicken pox.

**What are the side effects?**
Side effects are uncommon (fewer than 1 in 10 people) and usually mild. With Infliximab, they are most likely to happen during the infusion, or in the few days afterwards. One of the commonest side effects after Adalimumab injection is pain at the injection site, sometimes with redness, itching and swelling.

Other common side effects include: blocked or runny nose, headache, shivering, dizziness, flushing or rash, swelling of hands, feet, lips or mouth, difficulty in swallowing or breathing, nausea, diarrhoea or abdominal pain. Rarely, patients may have an allergic reaction. If these occur during the Infliximab infusion, the infusion would be stopped. It may be possible to restart the infusion at a lower rate depending on your symptoms. If you develop these symptoms and you are on Adalimumab, you must tell your doctor immediately.

If you are unwell on the day of treatment, such as suffering from a cold or have a high temperature, you must tell the nurse or your doctor. This is important, as it may be necessary to delay treatment until you are feeling better.

A few patients on Infliximab or Adalimumab have developed certain abnormal blood results and some symptoms (such as fever, weight loss, muscle or joint pain or a rash) that are found in patients with an immunological condition called systemic lupus erythematosus. All patients recovered after treatment was stopped.

Because Infliximab and Adalimumab work by suppressing the immune system the risk of infections are increased. Some patients develop simple infections such as a common cold, while other patients have had more severe infections such as pneumonia. Rarely, serious infections including septicaemia (infection of the blood) have been reported with Infliximab.
If you come into contact with someone with chicken pox or shingles, you should see your GP immediately and contact your inflammatory bowel disease specialist nurse as you may need to attend hospital to have a blood test and start treatment.

Some patients have had reactivation of hepatitis B virus after starting on infliximab or adalimumab. You should tell us if you have had hepatitis B in the past or have been in close contact with someone who has hepatitis B.

There have been cases of tuberculosis (also called TB: a type of bacterial infection) reported in patients treated with Infliximab, and some have lead to death. Although the risk is unknown, it is possible that you may have more of a chance of getting tuberculosis while on infliximab. If you or any of your close family members have a history of tuberculosis you should tell your doctor or IBD nurse. We perform checks to see if you have been exposed to TB before you start on Infliximab or Adalimumab.

Initial results of a clinical trial of infliximab in patients with moderate-to-severe congestive heart failure (CHF - a condition in which the heart is unable to pump enough blood to maintain normal physical activity), suggest that Infliximab treatment in these patients may increase the risk of worsening heart failure. You should tell your doctor or with inflammatory bowel disease nurse if you have ever been diagnosed as having heart failure.

Skin reactions have been reported rarely with Infliximab and Adalimumab. These include psoriasis (red scaly patches).

Rare side effects have been reported on the nervous system with features similar to multiple sclerosis. Likewise, it is possible that Infliximab could worsen multiple sclerosis and should not be given to people who have a history of this. You should tell your doctor or inflammatory bowel disease nurse if you have ever been diagnosed as having multiple sclerosis.

There have been rare reports of people developing cancer whilst on Infliximab or Adalimumab. These include cancers of the blood such as lymphoma and leukaemia. However most of these people have been on other drugs (such as Azathioprine or Methotrexate) which are known to increase the risk of these cancers. Therefore it is difficult to know the contribution Infliximab or Adalimumab have to these cancers developing. It is difficult to give a precise risk but it is rare (less than 1 in 1,000)

**Can I take other medication along with Infliximab or Adalimumab?**

Yes, all the medications used to treat Crohn’s disease and ulcerative colitis can be used together with Infliximab and Adalimumab. Most patients also receive either Azathioprine or Methotrexate (immunosuppressant drugs) – these not only help to keep the disease suppressed but also help to prevent your own immune system from reacting against the Infliximab or Adalimumab.
Do I need any special checks following Infliximab or Adalimumab?
Infliximab and the combination of other medications you may be taking can lower your resistance to infection. You should inform your GP or IBD specialist nurse if you develop a sore throat, fever or any other infection.

Try and avoid contact with people who have infections where possible. You may also be at risk of severe infection from the viruses which cause chickenpox and shingles, measles and pneumococcal disease (an infection which mainly affects the lungs causing serious pneumonia). If you come into contact with anyone who has any of these conditions tell your doctor or nurse as soon as possible, as you may be able to have a protective injection.

Can I have immunisations after having Infliximab or Adalimumab?
Flu vaccinations are safe following Infliximab treatment, but you should avoid immunisations with ‘live’ vaccines such as polio, BCG (Tuberculosis), MMR (measles, mumps and rubella). An ‘inactive’ polio vaccine can be given instead of a ‘live’ one. If you require any vaccinations, let your doctor know when you last had infliximab.

Does Infliximab or Adalimumab affect fertility and pregnancy?
Infliximab and Adalimumab are felt to be safe in the first 3 months of pregnancy. However there is not a lot of evidence available. Generally it is better to avoid pregnancy for at least six months after having the last dose of Infliximab or Adalimumab. Men should not try for a baby with their partners for six months after having the last dose of Infliximab or Adalimumab.

Information on whether breastfeeding is safe if you are having Infliximab or Adalimumab is limited, therefore it is better to avoid breast-feeding whilst on these drugs.

For further information you can contact your IBD Nurse Specialist or Gastroenterology Specialist.

Further Useful information
You may find the following sources of information useful.

Crohn's and Colitis UK
www.crohnsandcolitis.org.uk

Digestive Disorders Foundation (CORE)
www.digestivedisorders.org.uk
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