

Infliximab

This information leaflet aims to answer common questions you may have if your doctor has given you or has discussed using infliximab to treat your Crohn's Disease or Ulcerative Colitis. You can obtain further information from your pharmacist or doctor, from the information leaflet supplied with your prescription, or from the website: www.medicines.org.uk.

Why am I being treated with this medicine?

Infliximab is used to treat severe Crohn's Disease. It may be given to you when other drugs have not worked or have caused major side effects, and when surgery is not considered the right treatment option for you.

It may occasionally be used to treat severe Ulcerative Colitis. It is only recommended if you cannot take ciclosporin (see our Drug Treatment leaflet: *Ciclosporin* for more information) or if you are taking part in a clinical trial.

How does it work?

Infliximab targets a protein in the body called TNF-alpha (tumour necrosis factor-alpha). Your body naturally produces TNF-alpha as part of its immune response, to help fight infections by temporarily causing inflammation in affected areas. Over-production of this protein is thought to be partly responsible for inflammation in the intestine of people with IBD. Infliximab binds to TNF-alpha, helping to prevent inflammation and relieve symptoms.

How long will it take to work?

You may begin to feel better within 2-6 weeks of the first infusion.

How is infliximab given?

Infliximab is given in hospital by a doctor or specialist nurse. You are most likely to be treated as a day patient. Treatment usually takes 4-6 hours. You will usually be given infliximab while relaxing in a chair, so you won't have to undress, get into bed or stay overnight.

Infliximab is mixed with water and salt (saline solution) to make a clear liquid which you will receive as an infusion (a slow injection). The fluid flows from a sterile bag through plastic tubing and a small needle directly into a vein in your arm. You cannot swallow the drug, as your digestive system would destroy it. The infusion will take about 2 hours. To minimise the risk of side effects, you may be given paracetamol, antihistamine and hydrocortisone just before the infusion. You will be closely observed by your medical team during the infusion and for two hours afterwards to make sure that you do not develop an allergic reaction.

What is the normal dosage?

The recommended dose is 5mg of infliximab for every kilogram you weigh.

How long will I be taking it?

Many patients will have an initial infusion followed by additional infusions 2 and 6 weeks later. Sometimes a single infusion may be used. The drug may also be given at regular intervals (normally every 8 weeks) and this can continue for a long period, although your treatment is often reviewed after a year.

Will I need to take other medication?

You may be prescribed an immunosuppressant drug, such as azathioprine or methotrexate to help prevent an allergic reaction to infliximab or to stop the drug losing its effect (see our Drug Treatment leaflets for more details of these treatments). You may be more likely to need an immunosuppressant if you receive infliximab for symptom flare ups rather than as ongoing treatment.

How safe and effective is infliximab?

Several medical studies indicate that infliximab's safety is similar to that of other treatments for Crohn's Disease. Researchers studied the medical records of 734 patients who were treated with infliximab over 14 years and concluded long-term infliximab treatment has a good overall safety profile.

Studies have also shown that infliximab is effective in maintaining remission in patients with Crohn's Disease. One assessed the long-term benefits for more than 600 patients over nearly five years. It concluded that the drug was very effective in maintaining improvement and reduced the need for hospitalization and surgery.

However, there have been reports of serious infections, including tuberculosis (TB), occurring during and after treatment. So it is important that certain checks are carried out before you start receiving the drug. You should always inform your doctor of any symptoms you notice during and after treatment.

Rare cases of serious skin reactions have been reported. These include psoriasis (a chronic condition that usually appears as red scaly patches on the skin), rashes and skin lesions (growths or patches), mouth and genital ulceration, fever, hives, swollen lips, eyes and face.

Other uncommon disorders have rarely been associated with infliximab treatment including nerve inflammation similar to multiple sclerosis, and other inflammatory conditions which may affect organs such as the liver.

There have also been **rare** reports of cancers associated with the use of TNF alpha blocker drugs such as infliximab. These include Hodgkin's and non-Hodgkin's lymphoma, leukaemia, melanoma and organ cancers.

However, most people who developed cancers while taking infliximab were also using other immunosuppressants, such as azathioprine and methotrexate. So the slightly increased risk of cancer could be due to these immunosuppressant drugs. It is also difficult to know exactly what the risk is, as cancers in these cases happen rarely and very few people are affected.

It is important to talk to your doctor before starting treatment to weigh up the risks and benefits of using this drug: improving your quality of life against the small potential risk of serious side effects. Your doctor will also need to examine you on a regular basis to help prevent or identify and treat any complications.

What checks will I need?

During the infusion and for up to two hours afterwards you will be checked by a doctor or specialist nurse to make sure you do not develop an allergic reaction.

Pre-treatment screening is also essential to check your suitability for treatment. At this time tell your doctor:

- if you have heart problems, as infliximab could make your symptoms worse, and your heart will need to be monitored closely before and after treatment.
- if you have had recent exposure to people with tuberculosis (TB). If you have not had a chest x-ray recently or if you have not had a BCG vaccination, you will need a chest x-ray to check you have no underlying TB. If you have underlying, inactive TB, you should have treatment for it before starting infliximab. Many doctors now also use a blood test to check for this underlying TB before starting infliximab treatment, but this will depend on each particular situation.
- if you have been in contact with people who have chicken pox, shingles, measles or pneumococcal disease (an infection which mainly affects the lungs causing serious pneumonia). If you are not already immune you can be vaccinated before starting treatment.
- if you have a fistula and it is leaking pus.
- if you have ever lived in a region where certain fungal diseases (histoplasmosis or coccidioidomycosis) are common (eg parts of USA, South America and Africa).
- if you have a history of infections or currently have one. If you have an infection your infliximab treatment is likely to be postponed.
- if you have ever had a disease that affects the nervous system, or if you have experienced any numbness, tingling or visual disturbances.
- if you have or have ever had hepatitis B (a viral liver infection), have been told that you are a carrier of hepatitis B or have been in close contact with someone who has hepatitis B.
- if you are pregnant, planning to get pregnant or breastfeeding. (See page 5 for further information.)
- if you have a history of cancer, as infliximab affects how the immune system works and you may have a slightly increased risk of developing cancer.
- if you bruise or bleed easily, or if you have swollen lymph nodes in the neck, underarms or groin.

Checks before and during the infusion:

- You will have a urine sample taken to check for infections.
- You will have your blood pressure, pulse rate and temperature taken.

Will I need to take any special precautions while being treated with infliximab?

Although the infusion should not make you feel drowsy and you should be able to continue with normal activities, you may feel tired afterwards. You may be given medication to reduce possible side effects and some of these can cause drowsiness. For this reason, it might be a good idea to arrange for someone to drive you home or to organise a taxi beforehand. If you feel unwell or tired after treatment, do not drive or operate machinery. If you have no ill effects after your first infusion, you should be able to drive after future ones.

Try to avoid contact with people who have infections where possible. As infliximab affects the way the body's immune system works, you may be more prone to infections, such as colds and 'flu.

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.

The way infliximab acts upon the immune system also means you may be more open to infections that can come from undercooked or unhygienic food, such as salmonella and listeria. It is best to avoid foods such as raw eggs and undercooked meat and poultry and to be careful about washing your hands after handling raw meat or when preparing food.

Can I have immunisations while on infliximab?

It may be unsafe to be immunised with certain vaccinations while on infliximab. The way infliximab acts on the immune system means you may not respond well to live vaccines and could be at risk of complications. So you should avoid **live** vaccines such as polio, yellow fever, rubella (German measles) MMR (measles, mumps and rubella) and BCG (tuberculosis) while taking infliximab. An **inactivated** polio vaccine can be given instead of the live one and the inactivated version should also be given to those you are in close contact with. Flu vaccines, including Swine Flu (H1N1), and pneumovax are safe as they are not live vaccines.

Can I take other medicines along with infliximab?

There are few reports about interactions between infliximab and other medicines. However, it is important to tell your doctor or nurse specialist about any other medicines you are taking, including herbal, complementary or alternative therapies, as these may interact with infliximab. If you see another doctor, nurse or dentist, tell them that you are taking infliximab.

Does infliximab affect pregnancy?

A panel of medical experts from nine European countries recently agreed that infliximab is safe to use during the first three months of pregnancy. They consider that infliximab is the safest of the TNF-alpha blocker drugs for both men and women thinking of starting a family. However, the evidence about the effects of infliximab on pregnancy is still limited. Generally, it is best to avoid pregnancy if you or your partner are being treated with infliximab, and for at least six months after the last infusion.

What about breastfeeding?

The panel of experts mentioned above also consider that infliximab is safe to take while breastfeeding. However, there is limited evidence on whether infliximab passes into breast milk. The long-term effects of infliximab on a child's developing immune system are still not known. This means that it is better to avoid breastfeeding during treatment and for six months after your last infusion.

Can I drink alcohol while taking infliximab?

While alcohol does not appear to have any interaction with infliximab, as with any medication, it is better to avoid drinking excessive amounts of alcohol. The general recommendation from the Department of Health is a limit of 2-3 units a day for women and 3-4 units a day for men.

What are the possible side effects?

Around 1 in 10 patients will experience some sort of reaction to the infusion. These reactions are usually mild and go away on their own. They can occur during the infusion or over a few days afterwards. As infliximab may take up to six months to be completely eliminated from the body, some side effects may appear during this time. Rarely, reactions are severe and the infusion must be stopped. While most side effects are mild to moderate in severity, it is important to tell your doctor about any you experience.

Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping infliximab treatment.

Possible reactions during the infusion include:

- swelling of the hands, feet, ankles, face, lips, mouth or throat
- tenderness or pain in the chest, muscles, joints or jaw
- difficulty in swallowing or breathing
- fever
- rash
- itching
- change in blood pressure

These side effects may be reduced by slowing the rate of infusion or by stopping it for a while.

You may also experience other side effects such as:

- headaches
- sore throat
- rash
- hives (swollen, red, itchy patches of skin)
- joint or jaw pain
- nausea
- diarrhoea
- abdominal pain
- chills

Who should I talk to if I am worried?

If you are worried about your treatment or if you have any questions, contact your doctor or nurse specialist to discuss why it has been prescribed, what the correct dose and frequency are, what monitoring for adverse effects is in place, and what, if any, alternatives are available for you.

You can also telephone the **Crohn's and Colitis UK Information Line on 0845 130 2233** for general information or email info@crohnsandcolitis.org.uk

We also provide a supportive listening service run by trained volunteers with experience of IBD: **Crohn's and Colitis Support** on **0845 130 3344**, open **weekday afternoons 1-3.30pm and evenings 6.30-9pm**.

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We hope that you have found the information helpful and relevant. We welcome any comments from readers, or suggestions for improvements. References or details of the research on which this publication is based, and details of any conflicts of interest, can be obtained from us at the address below. Please send your comments to Helen Terry at Crohn's and Colitis UK, 4 Beaumont House, Sutton Road, St Albans, Herts AL1 5HH, or email h.terry@crohnsandcolitis.org.uk

Crohn's and Colitis UK is the working name for the National Association for Colitis and Crohn's Disease (NACC). NACC is a voluntary Association, established in 1979, which has 30,000 members and 70 Groups throughout the United Kingdom.

Membership of the Association costs £12 a year. New members who are on lower incomes due to their health or employment circumstances may join at a lower rate. Additional donations to help our work are always welcomed.