



INFORMATION SHEET

INFLIXIMAB

INTRODUCTION

This information sheet is a brief overview of some of the more important points about infliximab, which is used to treat Crohn's Disease or Ulcerative Colitis (UC) (the two main forms of Inflammatory Bowel Disease - IBD). It is about infliximab in general and is not intended to replace specific advice from your doctor or any other health professional. For further information, please talk to your doctor or specialist IBD team or look at the information sheet supplied with your medication, or from the website: www.medicines.org.uk

“My main concern with starting infliximab was the safety of the drug, both in the short and long term. Knowing that it had undergone rigorous clinical trials helped give me the confidence to go ahead with it. Five years on it's still allowing me to enjoy a normal quality of life.”

Rebecca, age 32
diagnosed with Crohn's Disease in 2007

OTHER NAMES FOR THIS MEDICINE

Infliximab is a biological drug. It is sometimes known by the brand names Remicade, Inflectra or Remsima.

Inflectra and Remsima are 'biosimilars' of Remicade, but work in the same way. They are very similar to Remicade, but made in a slightly different way that may lead to tiny differences, which should not affect how the drug works, or its safety and side effects. For more information about biosimilars, see our information sheet **Biological Drugs**.

WHY AM I BEING TREATED WITH THIS MEDICINE?

Infliximab is used to treat severe active Crohn's Disease and active fistulising Crohn's Disease in adults and in children aged 6 -17 years. It may be given to you if other drugs have not worked or are not suitable for you, or have caused bad side effects.

Infliximab is also used to treat adults with moderate to severely active Ulcerative Colitis if other drugs have not worked or are not suitable. It can also be used to treat children with severely active UC aged 6-17 years who have not responded or cannot have other drugs.

HOW DOES IT WORK?

Infliximab belongs to a group of medicines called 'biological drugs.' It is also referred to as an 'anti-TNF drug' because it works by targeting a protein in the body called TNF-alpha. Your body naturally produces TNF-alpha as part of its immune response to help fight infections by temporarily causing inflammation in affected areas.

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Over-production of this protein is thought to be partly responsible for the type of chronic (ongoing) inflammation found in 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 a few days or it may take between two to six weeks after your first treatment.

HOW DO I TAKE INFLIXIMAB?

Infliximab is given as an intravenous (IV) infusion – that is, through a drip into a vein in your arm. It cannot be given as tablets because your digestive system would destroy it.

Infliximab infusions are usually given in hospital by a trained member of staff. You will probably be treated as a day patient (unless you are already in hospital) and will be able to have the infusion while sitting in a chair, so you won't have to undress, get into bed or stay overnight. Some hospitals have a home care service which allows you to have your infusions in your own home.

The initial infusion itself usually takes about two hours, but subsequent infusions may be given faster depending on the local practice. For example, some clinics now use faster infusions for people who have had at least 3 successful treatments. If you have previously had an infusion reaction, the infusion time may be increased in order to decrease the risk of another reaction. You may be given paracetamol, antihistamine or hydrocortisone just before the infusion, to minimise the risk of side effects.

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. While the infusion itself takes two hours, most treatment sessions take 4-6 hours in total including monitoring time. However, different hospitals may do this differently, and some hospitals allow patients to go home as soon as the infusion has finished.

WHAT IS THE NORMAL DOSAGE?

The recommended dose is 5mg of infliximab for every kilogram you weigh. The hospital will work out how much you need and make up the infusion for you, so you won't need to do anything.

HOW OFTEN WILL I NEED AN INFUSION?

Most people with IBD have an initial infusion followed by another infusion two weeks later and a third after six weeks. If you respond well to the treatment, it is likely you will be put onto a maintenance programme of an infusion every eight weeks. If there has been no improvement after two or three doses, then infliximab is unlikely to be effective for you and an alternative treatment will be sought.

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When I was doing my PhD, whilst getting my infusions, I worked on chapters, and did some reading, editing and proof-reading of my text. This helped with seeing myself not just as a patient but also as a human being who could still do things despite being linked up to a machine!

”

Gillian, age 40
diagnosed with Crohn's Disease in 2002

HOW LONG WILL I BE ON INFLIXIMAB?

Some patients with Ulcerative Colitis may require 'rescue therapy' in order to try to prevent unplanned surgery, this treatment typically last three months or more. However, most patients with IBD will be treated for a minimum of 12 months.

Infliximab is a very expensive drug, so hospitals have to apply for funding before they can use it on a patient and must review how effective it is from time to time.

If you are on a planned course of infliximab infusions you should be reassessed at least every 12 months to see whether ongoing treatment is still right for you. If you relapse after treatment is stopped, you should have the option to start treatment again.

In some people, infliximab can lose its effectiveness over time. This means that to have the same effect, for example to keep someone in remission, the infliximab dose has to be increased or given more often. If you have lost response and still have ongoing inflammation, then another solution can be to switch to another biologic drug, such as adalimumab, golimumab or vedolizumab. Infliximab can also cause a range of side effects that might mean the treatment is no longer suitable for you.

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I've been having infliximab treatment for over 5 years, having suffered with UC for over 35 years with regular flare-ups. The treatment has enabled me to live a normal life without the need to take lots of tablets.

”

Claire, age 45
diagnosed with Ulcerative Colitis in 1980

HOW EFFECTIVE IS INFLIXIMAB?

Although not everyone responds to infliximab, a number of studies have shown that infliximab can be very effective at improving symptoms and in bringing about and maintaining remission in Crohn's Disease. It can reduce the need for hospitalisation and surgery, and reduce the risk of Crohn's returning after surgery, as well as successfully helping to heal fistulas.

One study has assessed the benefits of infliximab treatment in more than 600 people with Crohn's, over an average follow-up of nearly five years. It found that more than half the people continued to do well on infliximab throughout their treatment. Other studies of infliximab used long term show that if infliximab starts to work less well, in some people increasing the dose or taking another immunosuppressant drug such as azathioprine alongside infliximab can help regain effectiveness.

Infliximab has also been shown to induce and maintain remission in people with UC. It has also been shown to promote healing and reduce the need for surgery.

Research has also shown that infliximab may induce and maintain remission in children with Crohn's Disease.

It is important to talk to your IBD specialist team before you start your treatment with infliximab about all the possible benefits and risks, including the potential for side effects, as some of these can be serious.

WILL I BE PUT ON ANOTHER IMMUNOSUPPRESSANT DRUG ALONGSIDE INFLIXIMAB?

There is some evidence that combining infliximab with an immunosuppressant drug such as azathioprine or methotrexate may also be helpful for some people with IBD. The evidence is less for methotrexate, but azathioprine is thought to reduce the formation of antibodies to infliximab, reduce the likelihood of an infusion reaction, and increase the chance of remission.

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Also, because azathioprine may take 3-6 months to start working, it can be useful if patients start on it while they are on infliximab so that it has had a chance to start to work if infliximab is stopped.

However, some studies have suggested that combination therapies may also increase the risk of side effects, including infections and some types of cancer (see below). Also, some studies do not show so much evidence for their combined use. Your doctor should explain this to you, so that you can agree what is the best treatment option in your circumstances. Whether you are taking infliximab on its own or in combination with an immunosuppressant, your doctor will assess your progress every 12 months to decide whether you are still on the best treatment option for you.

WHAT CHECKS WILL I NEED BEFORE I START INFLIXIMAB?

Pre-treatment screening is essential to check your suitability for treatment with infliximab. Make sure the team treating you know:

- If you have any history of tuberculosis (TB) or any recent exposure to people with TB. You should not be given infliximab if you have active TB, and if you have underlying inactive TB, this will need to be treated before starting infliximab. Most doctors now use a blood test to check for underlying or inactive TB, but you may be given a chest x-ray as well.
- If you have been in contact with people who have chicken pox, shingles, measles or pneumococcal disease (an infection which can lead to pneumonia, meningitis and sepsis).
- If you are not already immune to chicken pox or measles, you may need vaccinations against these before starting treatment. You may also be advised to have a vaccination against pneumococcal disease.
- If you have heart problems, as infliximab might make your condition worse, and your heart will need to be monitored closely before, during and after treatment.
- If you have a history of cancer. Infliximab affects how the immune system works and you may have a slightly increased risk of developing some types of cancer. However, you may also be at risk even if you do not have a history of cancer.
- If you smoke, or have COPD (Chronic Obstructive Pulmonary Disease) as taking infliximab may increase your risk of lung cancer.
- If you have ever had HIV, hepatitis B or C (viral liver infections), are a carrier of hepatitis B or C or have recently been in close contact with someone who has hepatitis B or C. You will usually have a blood test to check for these viruses before starting infliximab, and also be monitored for six months after stopping infliximab.
- If you have ever lived in a region where certain fungal diseases (such as histoplasmosis, blastomycosis or coccidioidomycosis) are common (eg parts of USA, South America and Africa).
- If you have a fistula or an abscess. Infliximab can help to close fistulas but any abscess must be drained before treatment with infliximab.

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- If you have ever had a disease that affects the nervous system, such as multiple sclerosis, Guillain-Barre syndrome, or have experienced any numbness, tingling, fits, or visual disturbances.
- If you have diabetes or an immune system problem.
- If you have ever received phototherapy for psoriasis. This is because it can increase your risk of developing skin cancer.
- If you have a history of repeated infections or currently have an infection or have symptoms such as feeling feverish or generally unwell. If you have an infection your infliximab treatment may need to be postponed.
- If you are pregnant, planning to get pregnant, or are breastfeeding.
- About any medications you are taking and any recent vaccinations. Also, if you have ever taken any other biological drug.
- If you are going to have any operations or dental treatments.

Just before each infusion your blood pressure, pulse rate and temperature will be checked. You may also be asked to give urine or blood samples.

WILL I HAVE ONGOING CHECKS WHILE I AM ON INFLIXIMAB?

Once your treatment has started you will continue to need regular checks and may need additional blood tests. This can help to make sure that any complications are prevented or caught at an early stage. It is also important that you tell your doctor or the hospital team monitoring your treatment about any new symptoms you notice, whenever they occur.

At some hospitals you may also be given a special blood test to check the level of infliximab in the blood. This can help your doctor see how well the infliximab is working, and also if you have developed any antibodies to it. It can help the doctor to decide whether your dose needs changing. Your dose may be increased if infliximab is not being effective enough.

WILL I NEED TO TAKE ANY SPECIAL PRECAUTIONS WHILE BEING TREATED WITH INFLIXIMAB?

- Immediately after an infusion, you may feel tired and drowsy, especially if you have had medication to reduce side effects. For this reason, it could be a good idea to arrange for a taxi or for someone to drive you home after your infusion.
- Throughout your infliximab treatment, try to avoid close contact with people who have infections. Infliximab affects the way the body's immune system works, so you may be more prone to infections. Also, even a mild infection such as a cold or sore throat could develop into a more serious illness when you are taking infliximab. Contact your doctor if you begin to feel unwell and think you may have caught an infection.
- You may also be at greater risk of becoming seriously ill if you become infected with chickenpox, shingles, measles and pneumococcal disease. Tell your doctor if you come into contact with anyone with these conditions.

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I try to avoid people with infections, where possible. When I'm in the sun, I cover my arms and legs because I know my skin is more sensitive with taking infliximab.

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Jean, age 65
diagnosed with Crohn's Disease in 1998

- Take extra care with food hygiene and avoid eating raw eggs, pate or undercooked meat and poultry, as well as unpasteurised dairy products and soft or blue cheeses. You may be more open to the type of infections caused by bacteria such as listeria when being treated with infliximab.
- You will be advised to have an annual flu vaccine and pneumococcal vaccine while on infliximab treatment.
- Infliximab can increase the risk of skin reactions, and in rare cases skin cancer. You may wish to take extra precautions when in the sunlight, for example wearing a hat and high factor sunscreen.
- Be sure to attend when called for routine cervical screening by your GP. Pre-cancerous cervical changes are caused by the human papilloma virus (HPV) and there have been some isolated cases of immunosuppressed patients developing a reactivation of the virus. There is no evidence linking cervical cancer to the use of biologics. Your doctor may advise you to have the HPV vaccination if you are eligible and have not already been vaccinated.
- Consider carrying or wearing medical alert identification to show you are taking infliximab. Your hospital may give you a patient alert card to carry.

WHAT ARE THE MOST LIKELY SIDE EFFECTS OF INFLIXIMAB?

Like all drugs, infliximab can have side effects, although not everyone experiences these. Some side effects can happen almost immediately, in direct response to the infusion. Others may not appear for several days, weeks or even longer. It can take up to 6 months after the last dose for infliximab to be completely eliminated from the body, so some effects might appear during this time.

Some side effects are mild and will go away on their own, or following a slight change to the infusion programme. Others may be more serious and will require treatment.

Side effects of infliximab may include the following:

- Symptoms that may mean you are having a reaction to the infusion or an allergic reaction to infliximab. These might happen during or soon after your infusion, or could be delayed for up to 12 days. Tell the hospital staff treating you if you begin to experience any of these symptoms during your infusion, or contact your doctor straight away if you have them once you get home. They include:
 - hives (red, raised, itchy patches of skin) or other skin rashes
 - difficulty swallowing or breathing
 - pains in your chest or muscles or joints
 - fever or chills
 - swelling of the face or hands
 - headaches or a sore throat
- A greater chance of suffering from infections such as colds and flu, urinary tract infections, and conjunctivitis, and also some more serious infections such as pneumonia and sepsis (general inflammation and problems with blood clotting). You may also be at greater risk of developing tuberculosis (TB), or of having underlying TB reactivated while on infliximab. Tell your doctor if you begin to feel very tired or have a fever, a cough, flu-like symptoms or warm, red, painful skin.

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I was terrified about starting infliximab but I was pleased that I was monitored so closely with pre screening checks, regular blood tests and access to the IBD help line.

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Angela, age 36

diagnosed with Crohn's Disease in 2012

- Skin reactions such as psoriasis (red scaly patches), rashes and skin lesions, ulcers and hives, and swollen face and lips. Tell your doctor if you develop any of these symptoms.
- Blood problems. Your body may not make enough of the blood cells that help fight infections or help to stop bleeding. Symptoms include a fever that does not go away, bruising or bleeding very easily, sore throat, or looking very pale.
- A worsening of a heart problem. Let your doctor know if you notice any new or worse symptoms such as shortness of breath, swelling of the ankles or sudden weight gain.
- An increased risk of developing certain types of cancers including lymphoma (which affects the lymph glands). You may be more at risk if you are also taking immunosuppressive drugs such as azathioprine or methotrexate and it is more common in young men. However, it is difficult to know exactly what the risk is, as these cancers happen only rarely and very few people are affected. Infliximab therapy may not be advised if you have had previous cancer.
- In rare cases, liver problems. Tell your doctor if you notice a yellowing of the skin which may be a sign of jaundice, or feel very tired, have dark brown coloured urine or pain in the upper right side of the stomach area.
- Very rarely, nervous system problems. Tell your doctor if you get any numbness, tingling or problems with your sight.
- Lupus-like syndrome - chest discomfort or pain that does not go away, shortness of breath, joint pain, rash on the cheeks or arms that gets worse in the sun.
- In very rare instances, intestinal perforation. Symptoms include sudden and severe abdominal pain, fever, nausea and vomiting or swelling of the abdomen. These symptoms may be similar to those you already experience as part of your IBD, so at first it may be difficult to tell the difference. If in doubt, or if symptoms persist, go to your nearest accident and emergency (A&E) department.
- Infliximab may also cause side effects such as headaches, abdominal pain, nausea, joint pain, and fatigue, eye problems and depression.

As mentioned above, your doctor should talk through the risks and benefits before you start on infliximab. Let your doctor or IBD nurse know about any new symptoms you develop while on infliximab, whenever they occur. Your IBD team should also be able to help with any queries and concerns.

This is not a complete list of side effects of infliximab, for more information see the Patient Information Leaflet provided with your medication, or visit www.medicines.org.uk

CAN I HAVE IMMUNISATIONS WHILE ON INFLIXIMAB?

It may be unsafe to be immunised with certain vaccinations while on infliximab. You should not have any 'live' vaccines such as those for polio, yellow fever, rubella (German measles) MMR (measles, mumps and rubella) and BCG (tuberculosis). However, you may be able to have the inactivated polio vaccine. Flu jabs are currently safe as they are not live vaccines and the Department of Health recommends that everyone on drugs such as infliximab should have an annual flu vaccination. However, the children's nasal flu vaccine is live and should not be used.

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If anyone in your family or household is due to have a live vaccine, check with your IBD team whether you need to take any special precautions. You should also check with your IBD team if you are in contact with a baby or young child undergoing a vaccination programme.

CAN I TAKE OTHER MEDICINES ALONG WITH INFLIXIMAB?

Infliximab may interact with certain other drugs and should not be taken with medicines that contain anakinra or abatacept (these are drugs commonly used for Rheumatoid Arthritis).

Talk to your doctor if you are unsure about whether any medicines you are taking - or are planning to take - may interact with infliximab. This includes any over the counter medicines and any herbal, complementary, or alternative medicines or therapies. You should also tell any other doctor, dentist or health professional treating you that you are being treated with infliximab. You should carry the alert card provided by the manufacturer while on the medication and for six months after your last dose.

CAN I DRINK ALCOHOL WHILE TAKING INFLIXIMAB?

Alcohol is not known to have any interaction with infliximab, but for general health reasons it is best to keep within the Department of Health guideline limits.

DOES INFLIXIMAB AFFECT PREGNANCY?

The evidence about the safety of infliximab in pregnancy is growing. Some of the research has suggested that the risk of effects in pregnancy may be low. Several studies have found that birth outcomes for women with IBD who have taken infliximab while pregnant have been similar to those for women not on infliximab. However, research is still continuing, especially into the long term effects of infliximab on the baby. It has been found that although infliximab does not cross the placenta to the baby in the early stages of pregnancy, it can cross the placenta in the third trimester.

Drug manufacturers do not recommend using infliximab when pregnant. However, most doctors consider that if the infliximab treatment is keeping your IBD in check it may be better to continue with it, at least until the end of the second trimester (months 4-6). It is important that babies of women who have received infliximab during their pregnancy should not be given 'live' vaccinations until the age of six months. Your IBD team will be able to give you more information about this, and it is important that your GP and midwife are made aware.

If you are planning a pregnancy, please discuss this with your IBD team first, and if your pregnancy is unplanned, notify your IBD team as soon as possible.

WHAT ABOUT BREASTFEEDING?

Most of the research on infliximab has suggested that it does not pass into breast milk, although traces have been found in one study.

Research is continuing into possible effects of these biologics on the baby, especially in the longer term. Many doctors now recommend that women using infliximab should not be discouraged from breastfeeding.

WHO SHOULD I TALK TO IF I AM WORRIED?

If you are worried about your infliximab treatment or if you have any questions, contact your doctor or IBD nurse. They should be able to help you with queries such as why it has been prescribed, what the correct dose and frequency are, what monitoring is in place, and what alternatives may be available for you.

HELP AND SUPPORT FROM CROHN'S AND COLITIS UK

We offer more than 45 publications on many aspects of Crohn's Disease, Ulcerative Colitis and other forms of Inflammatory Bowel Disease. You may be interested in our comprehensive booklets on each disease, as well as the following publications:

- Living With IBD
- Biological Drugs
- Taking Medicines
- Azathioprine and Mercaptopurine
- Methotrexate

All publications are available to download from www.crohnsandcolitis.org.uk/publications. Health professionals can order some publications in bulk by using our online ordering system.

If you would like a printed copy of a booklet or information sheet, please contact our helpline.

Our helpline is a confidential service providing information and support to anyone affected by Inflammatory Bowel Disease. Our team can:

- help you understand more about IBD, diagnosis and treatment options
- provide information to help you to live well with your condition
- help you understand and access disability benefits
- be there to listen if you need someone to talk to
- put you in touch with a trained support volunteer who has a personal experience of IBD

Call us on **0300 222 5700** or email info@crohnsandcolitis.org.uk

See our website for WebChat (Live Online): www.crohnsandcolitis.org.uk/livechat

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We hope that you have found this leaflet helpful and relevant. If you would like more information about the sources of evidence on which it is based, or details of any conflicts of interest, or if you have any comments or suggestions for improvements, please email the Publications Team at publications@crohnsandcolitis.org.uk. You can also write to us at Crohn's and Colitis UK, 45 Grosvenor Road, St Albans, AL1 3AW or contact us through the **Helpline: 0300 222 5700**.

ABOUT CROHN'S & COLITIS UK

We are a national charity established in 1979. Our aim is to improve life for anyone affected by Inflammatory Bowel Disease. We have over 35,000 members and 50 Local Networks throughout the UK. Membership costs start from £15 per year with concessionary rates for anyone experiencing financial hardship or on a low income.

This publication is available free of charge, but we would not be able to do this without our supporters and members. Please consider making a donation or becoming a member of Crohn's and Colitis UK. To find out how call **01727 734465** or visit www.crohnsandcolitis.org.uk

