

Infliximab

Medicines Information for Patients



The aim of this leaflet is to:

Answer some common questions patients ask. Further information can be found in the information leaflet supplied by the manufacturer or from your pharmacist, IBD nurse specialist or doctor.

Why am I having infliximab?

Infliximab is used for patients:

- Who have active Crohn's disease or ulcerative colitis, whose condition has not responded adequately to treatment with a corticosteroid and/or immunomodulator (azathioprine, mercaptopurine, methotrexate) or who are intolerant or have contra-indications to these treatments.
- Or they are intolerant or have contra-indications
- Or there are intolerances or contra-indications to them.

Infliximab is only given in hospital. Most patients will attend as a day case to receive treatment.

How does it work?

Infliximab is a type of medicine that interrupts the inflammatory process in the bowel associated with Crohn's disease or ulcerative colitis. In these conditions a protein involved in this inflammation called tumour necrosis factor alpha (TNF α) is increased. TNF α may cause damage to the cells lining the digestive tract causing pain, cramping and diarrhoea. It can also get into the bloodstream and cause less specific symptoms such as loss of appetite and fever. Infliximab is an anti-TNF antibody or protein which works by binding to TNF α , blocking its harmful effects. Adalimumab is also an "anti-TNF" drug that works in a similar way and has similar risks and benefits.

How long does it take to work?

Benefit is usually seen within a few days. Unfortunately, some patients may respond initially but the effects of treatment may not last for ever.

What dose of infliximab do I have ?

The dose of infliximab is based on your weight. To enable the drug to be ordered in advance we usually base the dose on your last weight in clinic. We will recheck your weight on admission.

You will usually receive a dose at weeks 0 and 2 and 6. If you show a response to these three doses then you will receive regular maintenance doses every 8 weeks after that. We routinely measure the level of infliximab in your blood via a blood rest prior to every infusion and may adjust the dose depending on the result.

How is infliximab given?

Each dose is given as a drip infusion through a vein in your arm. Each infusion will take 2 hours. The infusion time may be reduced after several doses have been given if you have tolerated them well. Your blood pressure and pulse will be checked every 30 minutes during the infusion.

After the infusion has finished you will need to stay on the ward or daycase unit for a further hour so that the nurses can continue to monitor your blood pressure and pulse.

If you have not been taking an immunomodulator, e.g. azathioprine or methotrexate, for more than 3 months or if you have had a minor reaction to previous treatment with infliximab, you will receive a drug (hydrocortisone) before the infliximab infusion to reduce the risk of an allergic reaction.

You will have a chest X-Ray before receiving infliximab. This is to check that you do not have tuberculosis or have latent infection

which could be activated by receiving infliximab. You must tell your doctor if you have ever had tuberculosis or have been in close contact with someone who has had it.

What are the side effects?

You should not be given infliximab if you have any allergies to the medication or its excipients or if you have any active severe infection e.g. tuberculosis or hepatitis. If one of your blood tests indicates you have been exposed to hepatitis B in the past we will offer you some additional treatment to prevent reactivation of infection.

Most side effects experienced with infliximab are mild. However, like other medicines that affect your immune system, serious side effects can occur, some up to 6 months after treatment.

MINOR SIDE EFFECTS

Allergic Reactions

Some patients experience an allergic reaction after receiving infliximab, usually during the infusion or shortly afterwards. (This is the main reason for receiving infliximab in hospital). These reactions are usually mild, but on rare occasions may be severe. The symptoms of an allergic reaction are most commonly skin rash, hives, fatigue, swelling of the feet, a drop in blood pressure, wheezing, difficulty in breathing or swallowing and chest pain. Tell your nurse or doctor immediately if you start experiencing these side effects.

If the symptoms occur during your infusion it may be slowed down or stopped and restarted once the symptoms go away. Your doctor may treat your symptoms with other medicines. Some patients who have been taking infliximab have had allergic reactions 3 to 12 days after receiving their treatment. The symptoms of this type of delayed reaction may include fever, joint pain, rash, headache or muscle pain. Call your doctor immediately if you develop any of these symptoms or any other unusual symptoms such as difficulty swallowing.

Delayed reactions can also occur if infliximab is re-administered after a prolonged period (more than 15 weeks). Contact your doctor immediately if you develop the signs described above.

Other mild side effects include: fatigue, nausea, headache, double vision, tingling, cough, increased risk of infection. You should inform your doctor if you get any signs of infection after you leave hospital, such as fever, malaise, a wound that won't heal, dental problems.

MAJOR SIDE EFFECTS

Allergic reactions

Rarely allergic reactions maybe severe and life-threatening.

In an emergency please call an ambulance immediately.

Infections

Some patients have had serious infections while receiving infliximab and some of the patients have died from these infections. Serious infections include TB (tuberculosis), pneumonia and infections caused by viruses, fungi or bacteria that have spread throughout the body. If you develop a fever, feel very tired, have a cough, or have flu-like symptoms, these could be signs that you may be getting an infection.

If you have any of these symptoms while you are taking or after you have taken infliximab, you should tell your doctor immediately.

Heart failure

If you have been told that you have a heart problem called congestive heart failure and you are currently being treated with infliximab, you will need to be closely monitored by your doctor. If you develop new or worse symptoms that are related to your heart condition, such as shortness of breath or swelling of your ankles or feet, you must contact your doctor immediately.

Nervous system

There have been rare cases where people taking infliximab have developed disorders that affected their nervous system, similar to multiple sclerosis. Signs that you could be having a problem include changes in your vision, weakness in your arms and/or legs, and numbness or tingling in any part of your body.

Cancer

Reports of a type of blood cancer called lymphoma in patients on infliximab or other TNF blockers are very rare. You should tell your specialist Gastroenterologist if you have had lymphoma or other cancers before you start infliximab so that the risks and benefits can be discussed in detail. There is a particularly rare type of lymphoma (about 15 cases after a million treatments with infliximab over 10 years) that seems to occur in adolescents or young adults also treated with azathioprine.

Liver injury

There have been rare cases where people taking infliximab have developed serious liver problems, some fatal. Signs that you could be having a problem include: jaundice (skin and eyes turning yellow), dark brown-coloured urine, or fever.

You should contact your doctor immediately if you develop any of these symptoms.

Blood problems

In some patients the body may fail to produce enough of the blood cells that help your body fight infections or help you stop bleeding. Some of the patients have died from this very rare failure to produce blood cells. If you develop a fever that doesn't go away, bruise or bleed very easily or look very pale, call your doctor immediately. Your doctor may decide to stop your treatment.

Lupus-like syndrome

Some patients have developed symptoms that can resemble a disease called lupus. Lupus-like symptoms may include chest discomfort or pain that doesn't go away, shortness of breath, joint pain, or a rash on the cheeks or arms that gets worse in the sun. If you develop any of these symptoms your doctor may decide to stop your treatment with infliximab.

Does infliximab interfere with my other medicines?

You should inform your doctor of all the medicines you are currently taking, even those not prescribed. However, there are no known interactions between infliximab and other medications.

You should avoid having 'live' vaccines whilst receiving inflixmab e,g, Mumps, measles and rubella (MMR), yellow fever, BCG, some Typhoid vaccines, Varicella vaccines. If you require travel vaccines or your doctor, nurse or pharmacist advise that you need a vaccine always tell the healthcare professional that you are taking inflixmab. Seasonal vaccination against influenza, Pneumococcal and COVID vaccinations are recommended for adults receiving infliximab. Page **9**

Is infliximab OK in pregnancy and breastfeeding?

Infliximab has been used during pregnancy without any adverse effects in several hundred pregnancies. However, it is very important that you talk to your doctor if you think you are pregnant while on infliximab or are planning to become pregnant.

Although very low amounts of infliximab may be transferred into breast milk, there is no risk to the baby, because infliximab is a protein that is digested, so cannot be absorbed.

Keep all medicines out of the reach of children. Never give any medication prescribed for you to anyone else. It may harm them even if their symptoms are the same as yours.

Useful contacts:

Gastroenterology pharmacist: 01865 221523

or email: ibd.homecare@nhs.net

IBD Advice Line: 01865 228772

or email: ibd.advice@nhs.net

Further information

If you would like an interpreter, please speak to the department where you are being seen.

Please also tell them if you would like this information in another format, such as:

- Easy Read
- large print
- braille
- audio
- electronic
- another language.

We have tried to make the information in this leaflet meet your needs. If it does not meet your individual needs or situation, please speak to your healthcare team. They are happy to help.

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