

Drugs for Inflammatory Bowel Disease (IBD) – Infiximab (Remicade)

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Why am I being treated with this medicine?

Infiximab is used to treat severe active Crohn's Disease and active fistulating Crohn's Disease in adults and in children/young people aged 6 years and over.

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.

How does it work?

Infiximab belongs to a group of medicines that are sometimes called 'biological' or 'anti-TNF' drugs or therapies.

Infiximab works by targeting 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 the type of chronic (ongoing) inflammation found in IBD. Infiximab 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 up to six weeks after your first treatment session.

How do I take infiximab?

Infiximab comes in powder form and is made up into a liquid so it can be 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.

Infiximab infusions are usually given as a day patient (unless you are already in hospital) over two hours, and you 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.

You may be given paracetamol, antihistamine or hydrocortisone just before the infusion, to minimise the risk of side effects.

What is the normal dosage?

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

How often will I need an infusion?

Most people with IBD have an initial infusion followed by another infusion at two weeks and a third at six weeks.

If you respond well to these treatment sessions you may be put on a maintenance programme of an infusion every eight weeks. Sometimes, for UC, a shorter course of three infusions is used.

How long will I be on infiximab?

If you are on a planned course of infiximab 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.

Another solution can be to switch to another biologic drug, such as adalimumab. Infliximab can also cause a range of side effects that may mean the treatment is no longer suitable.

How effective is infliximab?

Not everyone responds to infliximab. However 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 has also been used successfully to help heal fistulas.

Infliximab has also been shown to bring on remission, promote healing and reduce the need for surgery in people with UC who were not responding to conventional therapy.

There is increasing evidence that combination therapy, using infliximab with another drug, (for example an immunosuppressant such as azathioprine), may be even more successful at inducing and maintaining remission.

However, combination therapy may also increase the risk of developing side effects, including infections and some types of cancer.

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.

What checks will I need?

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

- If you have had recent exposure to people with tuberculosis (TB). If you have not had a BCG vaccination, you may need a chest x-ray to check you have no underlying TB. If you do have underlying, inactive TB, you will need treatment for it before starting infliximab.
- If you have been in contact with people who have chicken pox, shingles, measles or pneumococcal disease. If you are not already immune, you may need vaccinations against these before starting treatment.
- If you have heart problems, Infliximab could make your symptoms worse, and your heart will need to be monitored closely before 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.
- If you smoke, or have COPD (Chronic Obstructive Pulmonary Disease) taking infliximab may increase your risk of lung cancer.
- If you have ever had HIV, hepatitis B or C (a viral liver infection), 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.
- If you have ever lived in a region where certain fungal diseases (such as histoplasmosis 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.

- If you have ever had a disease that affects the nervous system, or have experienced any numbness, tingling or visual disturbances.
- If you have a history of infections or currently have one. 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.

Just before each infusion nurse will check your blood pressure, pulse rate and temperature. You may also be asked to give a urine or blood sample.

You will be monitored all the time you are having the infusion and for about two hours afterwards to make sure you are not developing an allergic reaction.

Once your treatment programme has started you will continue to need regular checks and may need additional blood tests. This can help 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.

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. If you have no ill effects after your first infusion, you should be able to drive after future ones.

- 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 more seriously ill from the viruses that cause chickenpox and shingles, measles and pneumococcal disease. Tell your doctor if you come into contact with anyone with these conditions.
- Take extra care with food hygiene and avoid eating raw eggs or undercooked meat and poultry. You may be more open to infections such as listeria when being treated with infliximab.
- You will be advised to have an annual flu vaccine while on infliximab treatment.

What are the most likely side effects of infliximab?

Like all drugs, infliximab can have side effects, although not everyone will get them.

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 muscle or joint pain
 - fever or chills
 - swelling of the face or hands
 - headaches or a sore throat
- Serious infections, especially in people over 65. These include tuberculosis and other viral and bacterial infections. If you become ill with TB or another infection while taking infliximab you will need to have the infection treated.

Tell your doctor if you begin to feel very tired and have a fever, a cough, flu-like symptoms or warm, red, painful skin.
- 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.
- 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.

However, it is difficult to know exactly what the risk is, as cancers in these cases happen rarely and very few people are affected. Infliximab therapy may not be advised if you have had previous cancer.

- In rare cases, liver inflammation. Tell your doctor if you notice a yellowing of the skin which may be a sign of jaundice, or feel very tired.
- Very rarely, nervous system problems. Tell your doctor if you get any numbness, tingling or problems with your sight.

As discussed above, your doctor should talk through the risks and benefits before you start on infliximab. Your IBD nurse should also be able to help with any queries or concerns about your treatment.

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 vaccines are also safe as they are not live vaccines.

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.

Can I take other medicines along with infliximab?

There are few reports about interactions between infliximab and other medicines.

However, before you take any new medicines, check with your IBD team whether there might be an interaction with the infliximab. This includes any over the counter medicines and any herbal, complementary or alternative medicines or therapies.

You should also tell any other doctor or dentist treating you that you are on infliximab treatment.

Can I drink alcohol while taking infliximab?

There is no reason to avoid alcohol (within moderation) after having infliximab.

Does infliximab affect pregnancy?

The effect of Infliximab on fertility and unborn babies is unknown. Therefore we strongly recommend that women should not become pregnant for at least 6 months after their last Infliximab infusion.

In some cases the maternal benefits of therapy may outweigh the risk to the baby. Therefore you should discuss with your specialist the risks and benefits of taking infliximab whilst pregnant.

Men should not try for a baby with their partners for 6 months after their last Infliximab infusion.

It is very important that you inform your specialist nurse if you become pregnant whilst taking infliximab.

Infliximab should not be given to women in the third trimester of pregnancy.

What about breastfeeding?

Recent studies have suggested that infliximab does not pass into breast milk and that it may be safe to breastfeed while taking this drug.

As the evidence is limited most doctors still advise women not to breastfeed during treatment with infliximab or for six months after the last infusion.

Recent guidelines from the British Society of Gastroenterology (BSG) recommend that doctors discuss the risks and benefits with each woman on an individual basis. You may find it helpful to talk through your own options with your specialist IBD team.

Where can I get further information about Infliximab?

If you have any questions about Infliximab, ask your doctor, your IBD specialist nurse or your pharmacist.

Further Information:

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