

INFLIXIMAB

What are the aims of this leaflet?

This leaflet has been written to help you understand more about the medication infliximab. It tells you what it is, how it works, how it is used to treat skin conditions, and where you can find out more about it.

What is infliximab and how does it work?

Infliximab is a powerful anti-inflammatory drug that has been designed to resemble normal human molecules, and is therefore classed as a "biological" treatment. It reduces inflammation by inhibiting the activity of a chemical ("cytokine") in the body called 'tumour necrosis factor alpha' (TNF-alpha).

Which skin conditions are treated with infliximab?

Infliximab is used to treat <u>psoriasis</u>, psoriatic arthritis, and several other inflammatory conditions, including other inflammatory skin diseases.

How long will I need to take infliximab before it has an effect?

Infliximab tends to work rapidly, but it still may be 4 to 8 weeks before you notice any benefit. About 75% of patients respond to treatment.

How is infliximab given?

Infliximab has to be given by injection into a vein (infusion), via a drip, which is supervised by a doctor or nurse. It normally takes about 2 hours for you to receive the full dose of infliximab, and you will usually be monitored initially for 1-2 hours after the infusion to make sure you do not develop an allergic reaction. Treatment is

repeated 2 weeks and 6 weeks after the initial infusion, and then normally every 8 weeks. If there has been no response by 14 to 16 weeks, it is usually stopped.

What side effects may occur during the infusion?

Approximately 5% of patients will develop an allergic reaction during or immediately after an infliximab infusion. A doctor or nurse will closely monitor you during this period. You may be given medications to treat or prevent reactions to the infliximab.

You should inform your doctor or nurse if you notice any of the following during or shortly after your infusion:

- hives (nettle rash) or any other rash
- itching
- swelling of the face, neck, tongue, hands and feet
- difficulty in breathing or swallowing
- dizziness or faintness
- an upset stomach
- blurred vision
- fever or chills
- chest pain

What are the possible side effects of infliximab?

The most common side effects are: viral infections, such as influenza, colds, cold sores; headache; inflammation of the sinuses; nausea; and abdominal pain.

Avoid close contact with anyone with a bad cold, flu or chest infection whilst taking infliximab, and observe excellent hand hygiene.

It is essential that you inform your doctor or nurse if you are feeling unwell or suffering from any infection as your treatment may be temporarily withheld.

Infliximab can also rarely cause some potentially serious side effects; these include the following:

Allergic reactions

Infliximab can cause chest pain, fever, chills, itching, hives, rash, flushing of the face, difficulty breathing, muscle or joint pain, swelling of the hands, face or lips, difficulty swallowing, headache or sore throat, within a few hours of the treatment. If you have

been treated with infliximab before, and are starting a second course of treatment, you could develop a reaction up to 12 days after an infusion. Contact your doctor if you have any of the above symptoms. If you have a severe allergic reaction, you should not receive infliximab again.

Blood problems

Some patients taking infliximab may fail to produce enough of the blood cells that help fight infections or stop bleeding. If you develop a fever or sore throat that does not settle, or if you notice bruising or bleeding, or persistently look pale, contact your doctor. Blood clots can rarely occur.

Cancers

Drugs that decrease the activity of the immune system can increase the chance of developing cancer. This risk cannot be quantified, but is low. Please inform your doctor if you have a history of cancer.

Heart problems

Infliximab may worsen heart failure. If you have a history of heart problems, you must inform your doctor prior to starting treatment and if you develop new symptoms.

Liver inflammation

Check with your doctor immediately if you have any symptoms suggesting a possible liver problem. These include itchy skin, yellow discolouration of the skin and / or eyes, dark-brown urine, pale fatty stools, right-sided abdominal pain, nausea, fever or severe tiredness.

Lupus erythematosus-like reaction

Some people taking infliximab have developed symptoms (such as rash and joint pains) that resemble lupus erythematosus. These usually go away when you stop taking infliximab.

Nervous system diseases

There have been rare cases of infliximab affecting the nervous system. Symptoms of this include numbness or tingling, problems with vision, weakness in the arms and/or legs, and dizziness. Tell your doctor if you or a family member have ever had a nervous system complaint such as multiple sclerosis, Guillain-Barré syndrome or seizures.

Severe infections

Infliximab may decrease your ability to fight infection. Let your doctor know of any current or past infections (particularly tuberculosis), or if you are prone to infections such as cold sores or cystitis. Please inform your doctor if you take any medications that affect your immune system; if you have received a transplant; or have, or have ever had, any disease that affects your immune system, such as, human immunodeficiency virus (HIV) infection, acquired immunodeficiency syndrome (AIDS) or viral hepatitis.

I am planning to have an operation or dental surgery – what should I do?

Infliximab may increase your risk of getting an infection after a surgical procedure. You must tell the doctor or dentist that you are taking infliximab.

How will I be monitored for the side effects of infliximab treatment?

You will have a chest X-ray and blood tests before treatment starts. You will be required to have a blood test 3 months after commencing infliximab, and then 6 monthly thereafter. Monitoring your response and looking out for side effects will take place at regular clinic visits.

The BAD Biologic Interventions Register (BADBIR)

You may be asked to take part in a national register if you are prescribed a biologic medication. This register will collect valuable information on side effects and benefits of the drug. It will also inform doctors on how best to use biologic drugs. No information will be passed to the register without your informed consent.

Can I have vaccinations while I am on infliximab?

Neither you nor close contacts should receive any of the 'live' vaccines such as polio, rubella (German measles) and yellow fever, although 'inactivated' vaccines are safe. If you are on infliximab, you should avoid contact with children who have been given the 'live' polio vaccine for 4-6 weeks after the vaccination: there is, however, an 'inactivated' polio vaccine available. If you require immunization with a live vaccine, infliximab should be stopped 6 months before and until 4 weeks after vaccination.

Yearly flu injections are recommended (however, the nasal flu vaccine is 'live' and must be avoided) and pneumococcal vaccine may be also be necessary especially if you are a smoker.

Does infliximab affect pregnancy?

It is not known whether infliximab can harm an unborn baby or pass into breast milk. It is advised that if pregnancy is a possibility, adequate contraception should be used for the duration of treatment with infliximab and for 6 months thereafter. Breast-feeding should also be avoided for at least 6 months after treatment with infliximab. Inform your doctor if you become pregnant, plan to become pregnant, or are breast-feeding.

May I drink alcohol while I am taking infliximab?

There is no known interaction between alcohol and infliximab.

Can I take other medicines at the same time as infliximab?

Most medicines are safe to take with infliximab. However, drugs that suppress the immune system, such as steroids, should be avoided. It is important that any doctor who prescribes for you is aware that you are taking this treatment. Your GP and dermatologist should be aware of all your medications, including over-the-counter medicines and supplements (including vitamins and herbal medicines). Do not start any new treatments without discussing it first with your doctor or pharmacist.

Where can I find out more about infliximab?

This information sheet does not list all of the side effects of infliximab. For full details about infliximab, including a complete list of side effects, read the product information sheet which comes with the medicine.

If you are worried about your treatment, you should consult your doctor or pharmacist.

This leaflet aims to provide accurate information about the subject and is a consensus of the views held by representatives of the British Association of Dermatologists: individual patient circumstances may differ, which might alter both the advice and course of therapy given to you by your doctor.

This leaflet has been assessed for readability by the British Association of Dermatologists' Patient Information Lay Review Panel

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