



INFLIXIMAB

What are the aims of this leaflet?

This leaflet has been written to help you understand more about infliximab (Remicadei®). 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 psoriasis, psoriatic arthritis, and several other inflammatory conditions, including rheumatoid arthritis.

Why have I been selected for treatment with infliximab?

The use of infliximab for psoriasis is reserved for those patients with severe psoriasis who have either not responded to, who have not been able to tolerate, or who have a contra-indication to standard treatments such as methotrexate, ciclosporin, acitretin or ultraviolet light therapy. There are national guidelines that assist dermatologists in identifying those patients who might benefit from infliximab.

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

Infliximab tends to work more rapidly than other agents used for psoriasis, but it may still be 4 to 8 weeks before you notice any benefit. About 75% of

patients respond to their first course of treatment, but later courses may be less effective.

How is infliximab given?

Infliximab has to be given by injection into a vein, 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 asked to wait for a while 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?

Occasionally (in approximately 5 % of patients), an allergic reaction may occur 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?

Infliximab can cause some rare but potentially serious side effects. These include:

- **Allergic reactions.** Infliximab can cause chest pain, fever, chills, itching, hives, flushing of the face, or troubled breathing within a few hours of the treatment. If you have been treated with infliximab before, and are now starting a second course of treatment, you could have a reaction up to 3 to 12 days afterwards. Contact your doctor if you have any of the following symptoms for several days after your treatment:

muscle or joint pain; fever; rash; hives; itching; swelling of the hands, face, or lips; difficulty swallowing; sore throat; and headache.

- **Liver inflammation.** Check with your doctor immediately if you have any symptoms suggesting a possible liver problem. These include your skin and eyes turning yellow, dark-brown urine, right-sided abdominal pain, fever or severe tiredness.
- **Heart problems.** Infliximab may worsen heart failure. If you have a history of heart problems, you must inform your dermatologist.
- **Severe infections.** Infliximab may decrease your ability to fight infection. Let your doctor know of any current or past infection (particularly tuberculosis), or if you are prone to infections such as cold sores or cystitis. Please inform your doctor if you have, or have ever had, any disease that affects your immune system, such as cancer, human immunodeficiency virus (HIV) infection, acquired immunodeficiency syndrome (AIDS) or viral hepatitis. Try to avoid close contact with anyone with a bad cold, flu or chest infections, and wash your hands often while you are taking this medication.

If you have any of the following during or shortly after your course of treatment with infliximab, you should notify your doctor: sore throat, cough, fever, chills, flu-like symptoms, extreme tiredness, night sweats, weight loss, and other signs of infection.

Your doctor may temporarily withhold the treatment if you are feeling unwell or suffering from any infection.

- **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 have ever had a nervous system complaint such as multiple sclerosis, Guillain-Barré syndrome or seizures.
- **Lupus erythematosus-like reaction.** Some people taking infliximab have developed symptoms (such as rash and joint pains) that resemble lupus erythematosus, and these usually go away when you stop taking infliximab.
- **Blood problems.** Some patients taking infliximab may fail to produce enough of the blood cells that help to fight infections or to stop bleeding. If you develop a fever or sore throat that does not settle, or if you notice bruising or bleeding, or simply look pale, contact your doctor. Blood clots can rarely occur.

- **Cancers.** Many drugs that decrease the activity of the immune system can increase the chance of getting a cancer. This risk cannot be quantified, but is low.

Other less serious side effects include: nausea, diarrhoea, constipation, abdominal pain, chest pain, flushing, fever, headaches, fatigue, depression, dizziness, faints, drowsiness, confusion, agitation, amnesia, insomnia, palpitations, joint pains, rash, itch and inflammation at the site of injection.

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 probably have a chest X-ray and blood tests before treatment starts. Blood checks need to be done only 3 months after commencing infliximab, and 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)

Because infliximab treatment for psoriasis is relatively new, you will be asked to take part in a national register if it is prescribed for you. This register will collect valuable information on side effects and benefits and will inform doctors on how best to use infliximab and similar 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 8 weeks before and until 2 weeks after vaccination.

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: its contents, however, may occasionally differ from the advice 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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