

INFLIXIMAB

What are the aims of this leaflet?

This leaflet has been written to help you understand more about 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 drug that has been designed in such a way that it mimics normal human molecules. For this reason it is classed as a 'biological treatment'. It can cut down inflammation and affect the body's own defence system (the immune system). One of its actions is to reduce the activity of a chemical in the body that is known as 'tumour necrosis factor alpha'. This chemical is too active in many diseases, such as psoriasis, in which it plays an important part in causing inflammation. Infliximab reduces the level of its activity and so helps to improve the psoriasis.

Which skin conditions are treated with infliximab?

Infliximab is used mainly to treat psoriasis, and occasionally to treat rare skin diseases such as pyoderma gangrenosum. It is also widely used in other specialties, for diseases such as rheumatoid arthritis.

Why have I been selected for treatment with infliximab?

Your dermatologist will be following the British Association of Dermatologists' guidelines when deciding who is and who is not suitable for this treatment. Infliximab may be given to patients with severe psoriasis when standard medical treatments (e.g. methotrexate, cyclosporin or phototherapy) are not suitable – perhaps because they have not helped in the past, or because they have caused side effects (see the separate British Association of Dermatologists leaflets on these drugs and on severe psoriasis).

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

Infliximab works more rapidly than other agents used for psoriasis, but it may still be 4-8 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 comes as a powder that has to be mixed with sterile water and infused into a vein by a doctor or nurse. It will take about 2 hours for you to receive one 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. An infusion will be given at the start of the course of treatment, and again after 2 and 6 weeks. After that, they are usually given every 8 weeks.

What side effects may occur during the infusion?

Infliximab can cause serious allergic reactions during the infusion, and for 2 hours afterwards. For this reason a doctor or nurse will monitor you during this period. You may also be given other medications to treat or prevent reactions to the infliximab.

You should tell your doctor or nurse if you have any of the following during or shortly after your infusion: hives; a rash; itching; swelling of the face, eyes, mouth, throat, tongue, lips, hands, feet, ankles, or lower legs; difficulty in breathing or swallowing; dizziness; fainting; an upset stomach; blurred vision; fever; chills; seizures; or 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 may have a reaction 3-12 days after you are given it. Tell your doctor if you have any of the following symptoms several days or even longer 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 disease;** 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;** your heart must be monitored closely before and during the treatment with infliximab. If you have had heart problems before starting infliximab, it is possible that these could worsen.

- **Serious infections;** Infliximab may lower your ability to fight infections and so increased the risk of getting a serious one. Stay away from people who are ill, and wash your hands often while you are on this medication. Tell your doctor if you have any current infection, including ones that come and go (such as cold sores), or chronic infections that do not go away. Also tell your doctor if you often get other types of infection, such as infections of the bladder. Tell your doctor too if you have ever had a disease that affected your immune system – such as cancer, a human immunodeficiency virus (HIV) infection, or acquired immunodeficiency syndrome (AIDS).

Tell your doctor if you have ever had tuberculosis (usually a type of lung infection), or if you have been around someone who has had tuberculosis. You may already be infected with tuberculosis even though you have not had any of its symptoms. If this is the case, infliximab may increase the risk of your infection becoming more serious and causing symptoms. Your doctor will assess the risk of your having tuberculosis and may treat you for it before you start on infliximab.

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

- **Nervous system diseases;** only very rarely does infliximab affect the nervous system. Signs of this happening include numbness or tingling throughout your body; problems with your vision, weakness in your arms and/or legs; and dizziness. Tell your doctor if you have or have ever had a disease that affected your nervous system, such as multiple sclerosis (loss of coordination, weakness, and numbness due to nerve damage) or the Gullian-Barré syndrome (weakness, tingling, and possible paralysis due to sudden nerve damage); numbness, burning or tingling in any part of your body; seizures.
- **Auto-immune;** Infliximab rarely causes lupus erthematosus, which is associated with sunlight sensitivity and joint pains. Blood tests for this condition, in which the body attacks its own tissues and organs, may be positive without any other sign of disease itself. Only if you have symptoms like those of lupus will there be a need to stop the infliximab.
- **Other side effects;** your immune system helps to stop you getting cancer. Infliximab prevents the immune system working properly, and may therefore increase your risk of developing cancer. If you have a history of cancer in any organs, such as breast cancer, or colon cancer, you should not receive this treatment. If you develop any signs of a malignancy, you should notify your doctor immediately.

I am planning to have an operation/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?

Before starting infliximab, you will have a series of blood tests and a chest x-ray. Once treatment has started, you will need to have blood tests done every 3 to 6 months. You will also be closely monitored in the clinic to assess your progress and to look out for side effects.

Patients on biological treatments are usually checked at 3 months, 6 months, and then every six months. Because the treatments are new, you will be asked to take part in the register for them. This collects information about all of the patients who are on biological treatments for psoriasis; and will provide valuable information about their side effects, benefits, and the best way to use them. If you start this type of treatment you will receive details of the register scheme, and be asked to sign a form giving your consent to inclusion in this register. Your dermatologist will also have to provide details about the results of your treatment and any side effects; and you will be asked to report the adverse effects of the treatment as well as its benefits.

Can I have vaccinations while I am on infliximab?

You should not be immunized with any of the 'live' vaccines such as polio, rubella (German measles) and yellow fever. An 'inactivated' polio vaccine can be given instead of the 'live' one, and the 'inactivated' version should also be given to the people you are in close contact with, such as members of your household.

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.

Does infliximab affect pregnancy?

Giving infliximab is not recommended during pregnancy. Women who may become pregnant must use adequate contraception and continue to use it for at least 6 months after the last infliximab treatment.

It is not known whether infliximab comes out in human milk or is absorbed after ingestion. Because special proteins called human immunoglobulins are excreted in the milk, women must not breast feed for at least 6 months after an infliximab treatment. Tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. Similarly, if you become pregnant whilst taking infliximab, tell your doctor.

May I drink alcohol while I am taking infliximab?

Yes. But remember that taking too much alcohol worsens psoriasis and should be avoided for this reason.

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

Tell your doctor and pharmacist what prescription and non-prescription medications, vitamins, nutritional supplements, and herbal products you are taking. Methotrexate can be taken along with infliximab.

Where can I find out more about infliximab?

This information sheet does not list all of the side effects of infliximab. If you want to know more about infliximab, or if you are worried about your treatment, you should speak to your doctor or pharmacist.

For fuller details, look at the drug information sheet which comes as an insert with your prescription for infliximab.