

# **Biological Medication for Inflammatory Bowel Disease** (page 1 of 3)



## **Introduction**

This leaflet is for patients who are about to start taking, or are currently taking, biological therapy medication to treat Crohn's Disease or Ulcerative Colitis, together known as inflammatory bowel disease (IBD).

## **What is a biological drug?**

Biological drugs (known as biologics) are made from proteins and other substances which occur in nature. They are produced by a biological, rather than a chemical, process - for example they can be created inside living cells. Biological drugs are a lot larger in size and more complicated than normal chemical drugs used in IBD, such as steroids, 5-ASAs and Azathioprine.

## **What biological drugs are used in IBD?**

There are several different biologics used in IBD. These are:

- Infliximab (brand names Remicade and the biosimilars Inflectra and Remsima)
- Adalimumab (brand name Humira)
- Golimumab (brand name Simponi)
- Vedolizumab (brand name Entyvio)

The 3 most common biologics currently used in IBD are Infliximab, Adalimumab and Golimumab. These are referred to as 'anti-TNF drugs' because they work by targeting a protein in the body called TNF alpha. This protein is found in everyone's blood as part of the body's response to infection. However, in people with IBD, too much TNF alpha is produced and this causes excessive inflammation. Anti-TNF drugs block the action of TNF alpha and reduce inflammation.

Vedolizumab is a newer biologic which works in a different way to the anti-TNF drugs, because it is a 'gut-selective integrin blocker'. White blood cells are made by the immune system to fight against infection. However, in Crohn's Disease and Ulcerative Colitis, overproduction of white blood cells leads to inflammation. Vedolizumab works by stopping the white blood cells from entering the lining of the gut. This means that the drug only targets the gut rather than the whole of the body like the anti-TNF drugs.

If you need your information in another language or medium (audio, large print, etc) please contact Customer Care on 0800 374 208 or send an email to: [customer care@salisbury.nhs.uk](mailto:customer care@salisbury.nhs.uk)

You are entitled to a copy of any letter we write about you. Please ask if you want one when you come to the hospital.

If you are unhappy with the advice you have been given by your GP, consultant, or another healthcare professional, you may ask for a second (or further) opinion.

The evidence used in the preparation of this leaflet is available on request. Please email: [patient.information@salisbury.nhs.uk](mailto:patient.information@salisbury.nhs.uk) if you would like a reference list.

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## How long do they take to work?

Most people notice a response to the treatment quite quickly, usually within the first 2 weeks. However every one is different and it can take up to 3 months for the full effects of the drug to be felt.

## What are the side effects?

Side effects are uncommon (fewer than 1 in 10 people) and are usually mild. With infusions, they are most likely to occur during the infusion, or in the few days afterwards. One of the commonest side effects after injections is pain at the injection site, sometimes with redness, itching and swelling. Other common side effects include: blocked or runny nose, headache, shivering, dizziness, flushing or rash, swelling of hands, feet, lips or mouth, difficulty in swallowing or breathing, nausea, diarrhoea or abdominal pain. Patients rarely have an allergic reaction. If these occur during an infusion it would be stopped. It may be possible to restart the infusion at a lower rate depending on the side effects. If you develop any of the side effects listed and you are on injections, you must tell your doctor or nurse immediately.

Because biologics work by suppressing the immune system, the risk of infections are increased. Rarely, serious infections including septicaemia (infection of the blood) have been reported. Other rare but more serious side effects include:

- skin reactions such as psoriasis (red scaly patches), rashes and skin lesions, ulcers and hives, swollen face and lips.
- the worsening of a heart problem. Let your nurse know if you have any current heart defects.
- 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.
- very rarely, nervous system problems.

## What checks will I need?

Pre-treatment screening is essential to check your suitability for treatment with biologics. You will need to have a chest X-ray if you have not had one in the last 3 months. This is to ensure that you do not have tuberculosis (TB), as these drugs can, in some cases, re-activate old TB. In addition we will take blood tests to screen for Hepatitis B and C, and HIV, and check you have

immunity to chicken pox.

## **Will I need to take any special precautions while being treated with Biologics?**

Immediately after an infusion, you may feel tired and drowsy, especially if you have had medication to reduce side effects. For this reason, it would be a good idea to arrange for a taxi or someone to drive you home after your first infusion. Thereafter, if you suffer no ill effects, you should be able to drive without any problems.

Throughout your treatment try to avoid close contact with people who have infections. Biologics affect the way the body's immune system works so you may be more prone to infections. You will be advised to have an annual flu vaccine while on anti-TNF treatment.

## **Can I have immunisations after having Infliximab or Adalimumab?**

Flu vaccinations are safe following Infliximab treatment, but you should avoid immunisations with 'live' vaccines such as polio, BCG (Tuberculosis), MMR (measles, mumps and rubella). An 'inactive' polio vaccine can be given instead of a 'live' one. If you need any vaccinations let your nurse or doctor know.

## **Do biologics affect fertility and pregnancy?**

Infliximab and Adalimumab are felt to be safe until the third trimester of pregnancy. Recent research shows that breastfeeding is unaffected but the evidence is still quite limited and so restarting biologics at this time should be taken on a case-by-case basis. In men, research suggests that there is no need to avoid fathering a child when you are taking biologics.

## **Other information**

More information on biologics can be found at the Crohn's and Colitis UK website:

[www.crohnsandcolitis.org.uk](http://www.crohnsandcolitis.org.uk)

Please contact your IBD nurse specialist if you have any questions or concerns: 01722 336262 ext 4893.

Infusions are given in the Nunton Unit on level 2 of the main hospital: 01722 336262 ext 4457