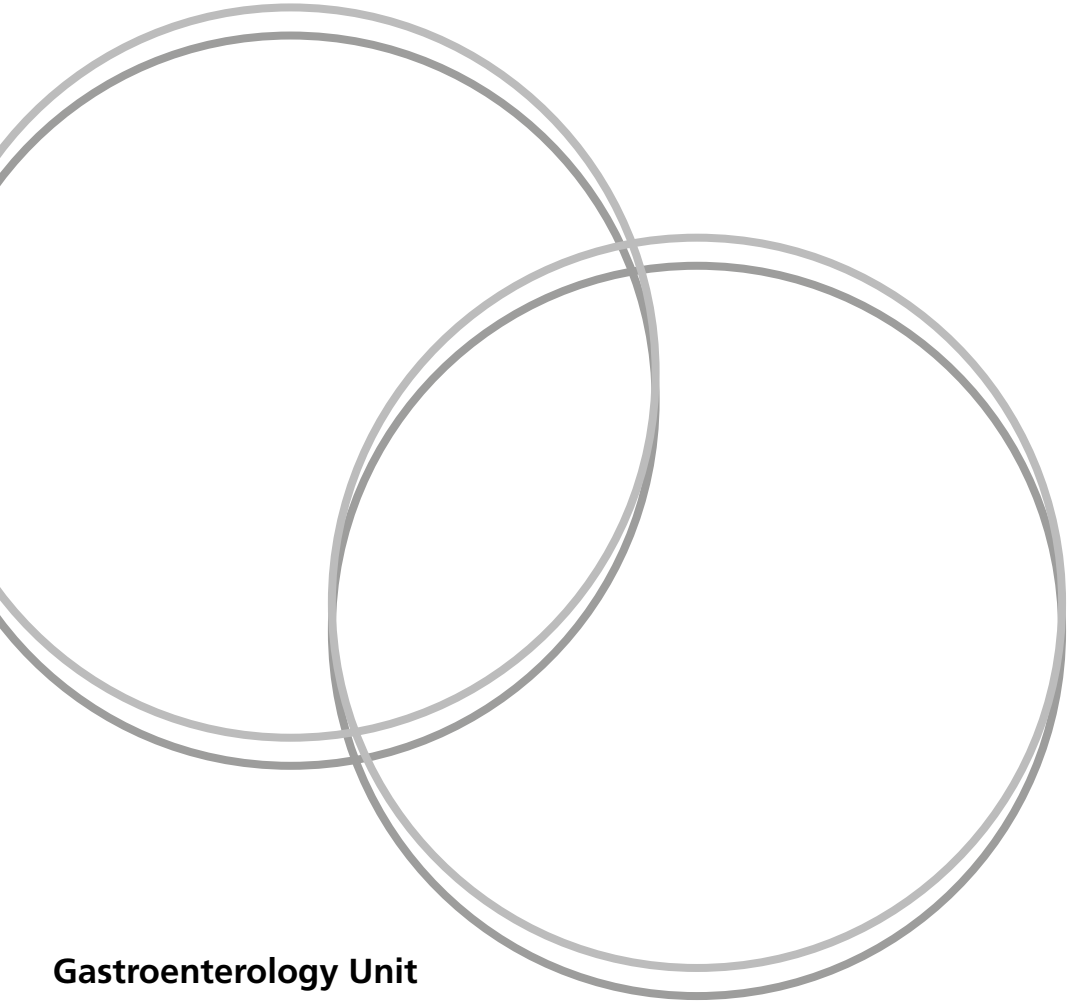
Oxford University Hospitals
NHS Foundation Trust

Adalimumab

(also known as Humira®, Imraldi®, Amgevita®, Hulio®, Hyrimoz®, Idacio®)

Medicines information for patients



Gastroenterology Unit

Adalimumab

This leaflet answers some common questions patients ask about adalimumab.

Further information can be found in the information leaflet supplied by the manufacturer or from your pharmacist, IBD nurse specialist or doctor.

Why am I having adalimumab?

Adalimumab is licensed for patients with active Crohn's disease or ulcerative colitis, whose condition has not responded adequately to treatment with a corticosteroid (prednisolone or hydrocortisone) and/or an immunomodulator (azathioprine, mercaptopurine or methotrexate) or who are intolerant to or have contra-indications to these treatments.

How does it work?

Adalimumab is type of medicine that interrupts the inflammatory process in the bowel associated with Crohn's disease or ulcerative colitis.

In patients with Crohn's disease or ulcerative colitis, a protein involved in this inflammation, called tumour necrosis factor alpha (TNFa), is increased. TNFa may cause damage to the cells lining the digestive tract, causing pain, cramping and diarrhoea. It can also get into the bloodstream and cause less specific symptoms such as loss of appetite and fever.

Adalimumab is an anti-TNF antibody or protein which works by binding to TNFa, blocking its harmful effects.

How long does it take to work?

You will be reviewed in clinic after 4 to 8 weeks (or after 2-3 doses) to see how well you are responding to the treatment. 80% of patients (8 in every 10) will show a good response within this time.

What dose do I have?

Adalimumab comes as a pre-filled pen or syringe. Each pen or syringe contains 40mg of adalimumab. Each dose is injected under the skin (subcutaneous) into the thigh or stomach. The first dose will be given either in hospital or by a trained nurse at home. You will be shown how to administer further injections yourself.

All patients receive 160mg (4 pens or syringes) as a single dose on week zero, 80mg (two pens or syringes) as a single dose on week 2 and then 40mg (one pen or syringe) on alternate weeks thereafter.

You will be provided with a specific bin (known as a sharps bin) to dispose of the empty syringes or pens safely.

We will continue to monitor the effect of your treatment and it is important that you attend any outpatient clinic appointments to enable us to do this. In certain circumstances e.g. your symptoms are not as well controlled as we would like or you have low drug levels, we may ask you to increase your dose to 40mg every week. A member of the Gastroenterology Team will contact you if you need to change your dose. **You must not increase the dose yourself unless you have been told to do so. If you feel unwell you should contact the IBD advice line**.

If you forget a dose, inject it as soon as you remember. Take your next dose on your original scheduled day.

How should adalimumab be stored?

Adalimumab should be stored in the fridge. It can stay out of the fridge for up to 24 hours and then be put back in the fridge with no effect on the expiry date. This should happen once only. Alternatively, an injection can be kept at room temperature for up to 14-28 days depending on the brand (please check with a pharmacist) but must be used within that time – it cannot go back into the fridge. We would advise you to keep your injections in the fridge whenever possible until you need to use them.

If you are travelling you are recommended to store the drug in a cool bag and to make sure that there is a fridge at your destination. As for any medication, if you are travelling abroad you are advised to take a letter with you from your doctor explaining the reasons for treatment. The home delivery company can provide you with the relevant paperwork. Please ask the GI Pharmacist or IBD Nurse specialist for further advice about travel.

Are there differences between the types of adalimumab?

The original adalimumab was called Humira® and the other types named on this leaflet are termed 'biosimilars'. All have been extensively tested to demonstrate their similarity in terms of how effective they are and their safety. They have all been approved by the UK and European regulatory authorities. They are so similar that the same tests for measuring drug levels and immune response can be used for all of them – and if there is response or loss of response to one type, then that will apply to all types. Nevertheless, the types are not identical and for that reason the best current advice is to avoid multiple switching between types. There are differences in the presentation of each product (device).

How long will treatment continue?

If you show a good response you will stay on maintenance treatment every 2 weeks (or weekly if you are advised to increase your dose). Treatment will initially be for one year and then reassessed. It is important that you attend all your clinic appointments so we can monitor you closely. Failure to attend repeated clinic appointments may result in us stopping treatment.

What are the potential side effects?

(Please also refer to manufacturer's patient leaflet)

Most side effects experienced with adalimumab are mild and most people do not experience side effects. However, like other medicines that affect your immune system, serious side effects can occur, some up to 4 months after treatment.

The most common side effects (in more than 1 in 10 patients) are pain and discomfort at the injection site, respiratory tract infections (including runny nose, cold, sinus infection), headache, cough, sore throat, nausea, diarrhoea, abdominal pain, musculoskeletal pain.

Other less common side effects (1 in 100 patients but less than 1 in 10) include more serious infections, mood swings, anxiety, difficulty in sleeping, vision disturbances, rash, itching, hair loss, fatigue, a rise in blood pressure, shortness of breath.

More serious but very rare side effects (less than 1 in 1000 patients) include low white cell counts and opportunistic infections such as tuberculosis.

Reports of a type of blood cancer called lymphoma in patients on adalimumab or other TNF blockers are exceptionally rare. You should tell your doctor if you have had lymphoma or other cancers before you start treatment.

Do I need any regular checks while on adalimumab?

You should not be given adalimumab if you have any allergies to the medication or its excipients or if you have any active severe infection e.g. tuberculosis or hepatitis. You will receive a chest X-ray before receiving adalimumab. This is to check you do not have tuberculosis. You must tell your doctor if you have ever had tuberculosis or have been in close contact with someone who has had it. If one of your blood tests indicates you have been exposed to hepatitis B in the past we will offer you some additional treatment.

It is important that you attend regular follow up appointments so we can monitor blood count, kidney and liver functions while you are on treatment.

We may also measure the level of drug in your blood, particularly if your symptoms are not controlled on treatment.

You should not administer adalimumab if you experience the following. Please contact a Gastroenterology doctor at the hospital for advice:

Allergic reaction e.g. chest tightness, wheezing, dizziness, swelling or rash, shortness of breath
Signs of infection (long term or localised) e.g. fever (hot or cold spells), stinging on passing urine, an open cut or wound, feeling tired, productive cough or sputum, feeling sick, toothache/dental problems
Changes in vision
If you have ever had tuberculosis or come into close contact with someone who has.
Develop new or worsening heart failure e.g. shortness of breath, swelling of ankles/feet.
Bruising or bleeding very easily or look very pale.
Joint swelling.
Tingling sensation or numbness

Does adalimumab interfere with my other medicines?

You should inform your doctor of all the medicines you are currently taking, even those not prescribed.

You should avoid having 'live' vaccines whilst taking adalimumab e.g., mumps, measles and rubella (MMR), yellow fever, BCG, some typhoid vaccines, and varicella vaccines. If you require travel vaccines or your doctor, nurse or pharmacist advise that you need a vaccine, always tell the healthcare professional that you are taking adalimumab. Seasonal vaccination against influenza and pneumococcal vaccines are also recommended for adults taking adalimumab.

Is adalimumab ok in pregnancy or breastfeeding?

If you are planning a pregnancy or are already pregnant and are receiving adalimumab, you must let your specialist know so we can discuss the potential benefits and risks to both yourself and your baby in continuing treatment.

It is safe to breastfeed whilst taking adalimumab. Small amounts of adalimumab may be transferred into breast milk, but there is no risk to the baby as adalimumab is a protein that is broken down/ digested in the gut and so cannot be absorbed into the body tissues.

Information changes rapidly, so it is important to discuss all aspects of pregnancy and breasfeeding with a Gastroenterologist before you start treatment.

Useful contacts

Gastroenterology pharmacist
Tel: **01865 221 523**
Email: **ibd.homecare@nhs.net**

IBD Advice Line
Tel: **01865 228 772**
Email: **ibd.advice@nhs.net**

Keep all medicines out of the reach of children.

Never give any medication prescribed for you to anyone else.

It may harm them even if their symptoms are the same as yours.

Further information

If you would like an interpreter, please speak to the department where you are being seen.

Please also tell them if you would like this information in another format, such as:

- Easy Read
- large print
- braille
- audio
- electronic
- another language.

We have tried to make the information in this leaflet meet your needs. If it does not meet your individual needs or situation, please speak to your healthcare team. They are happy to help.

Authors: Sarah Cripps, Gastroenterology Pharmacist, November 2007
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