

Patient Information
Drugs for Inflammatory Bowel Disease –
Adalimumab (Humira)

Lead Clinical Nurse Specialist - Allyson Lewis
Clinical Nurse Specialist – Gareth Lloyd-Ford
Clinical Nurse Specialist – Lynsey Hook

Adalimumab (Humira) is used to treat severe Crohn's Disease. It may be given to you when other drugs have not worked or have caused major side effects, and when surgery is not considered the right treatment option for you.

What is Adalimumab?

This drug works by reducing inflammation. A protein called TNF-alpha is an important protein in inflammatory diseases and this protein is blocked by Adalimumab. This drug has been used to treat many patients with Crohn's Disease and Rheumatoid Arthritis.

How is Adalimumab given?

Adalimumab is given by injection under the skin every two weeks. We will teach you the way to give yourself the injection. It may be possible for somebody else, such as a family member or friend to give the injection after training from a healthcare professional. Treatment is usually given for a year to start with but can continue long term.

We will review the need for continuing treatment with you after 3 months and again after one year.

What dose of Adalimumab do I have?

There are two possible starting doses and your doctor will determine the appropriate dose for you. You will either receive a first dose of 160mg followed by 80mg two weeks later or a first dose of 80mg followed by 40mg two weeks later. For ongoing treatment, the recommended dose is 40mg every other week on the same day of the week. In some cases this may be increased to a weekly injection.

How long will it take to work?

The response to treatment varies. Most people feel better within two to six weeks but it may take up to 3 months. Some people find they are better within a few days. Some patients do not respond to Adalimumab in which case other treatment will be discussed.

How do I know it is safe for me to receive Adalimumab?

Before you are able to receive the drug there are a number of questions you will be asked to ensure that Adalimumab is safe for you. This will include questions about your general health, any medication you are taking and vaccines you have received in the past. You will also be asked if you are allergic to Latex rubber as the needle cover of the syringe contains natural rubber.

You will be advised to have a flu vaccine every year and also a vaccine for pneumonia. In some cases other vaccines may also be advised.

Do I need investigations before commencing Adalimumab?

Yes. You will need to have some up to date blood tests and may also have tests for Hepatitis B and HIV (these are viral infections). If you have not had chicken pox you will also need a blood test to see if you are immune.

You will need to have a chest X- ray within the 3 months before starting Adalimumab. This is to ensure that you do not have tuberculosis (TB), as Adalimumab can, in some cases, re-activate old TB. If necessary a blood test to check for underlying TB will be arranged. It takes a few weeks to get the results of this test before treatment can be started.

What are the benefits of Adalimumab?

Adalimumab can be useful for treating severe Crohn's Disease and keeping it under good control. It may be used when other treatments have failed.

What are the side effects?

General side effects

Side effects are uncommon (fewer than one in ten people) and usually mild. One of the commonest side effects after Adalimumab injection is pain at the injection site, sometimes with redness, itching and swelling.

Other common side effects include: blocked or runny nose, headache, shivering, flushing or rash, swelling of hands, feet, lips or mouth, difficulty in swallowing or breathing, nausea, diarrhoea or abdominal pain.

Rarely, patients have an allergic reaction.

If you develop these symptoms and you are on Adalimumab, you must tell your doctor or IBD Specialist Nurse immediately.

Infections

Because Adalimumab works by suppressing the immune system the risk of infections are increased. Some patients develop simple infections such as a common cold, while other patients have had more severe infections such as pneumonia. Rarely, serious infections including septicaemia (infection of the blood) have been reported with Adalimumab.

If you are unwell on the day of treatment, such as suffering from a cold or have a high temperature, you must tell your nurse or doctor.

This is important, as it may be necessary to delay treatment until you are feeling better.

If you come into contact with someone with chicken pox or shingles, you should see your family doctor (GP) immediately and contact your IBD Specialist Nurse as you may need to attend hospital to have a blood test and start treatment.

Some patients have had reactivation of Hepatitis B virus after starting on Adalimumab. You should tell us if you have had Hepatitis B in the past or have been in contact with someone who has had Hepatitis B.

There have been cases of Tuberculosis (also called TB: a type of bacterial infection) reported in patients treated with Adalimumab and some have led to death. Although the risk is unknown, it is possible that you may have a higher chance of getting TB whilst on Adalimumab. If you, or any close members of your family, have a history of TB you should tell your doctor or IBD Nurse. We perform checks to see if you have been exposed to TB before you start on Adalimumab.

Other side effects

A few patients on Adalimumab have developed certain abnormal blood results and some symptoms (such as fever, weight loss, muscle or joint pain or a rash) that are found in patients with an immunological condition called Systemic Lupus Erythematosus. All patients recovered after treatment was stopped.

Skin reactions have been reported rarely with Adalimumab. These include psoriasis (red scaly patches). You should also avoid becoming sunburnt by covering up in the sun and using sun tan cream as there may be a slightly increased risk of some forms of skin cancer.

Rare side effects have been reported on the nervous system with features similar to Multiple Sclerosis. Likewise, it is possible that Adalimumab could worsen Multiple Sclerosis and should not be given to people who have a history of this. You should tell your doctor or IBD Nurse if you have ever been diagnosed with Multiple Sclerosis.

There have been rare reports of people developing cancer whilst on Adalimumab. These include cancers of the blood such as Lymphoma and Leukaemia. However, most of these people have been on other drugs (such as Azathioprine, Mercaptopurine or Methotrexate) which are known to increase the risk of these cancers. Therefore it is difficult to know the contribution Adalimumab has to these cancers developing. It is difficult to give a precise risk, but it is rare (less than 1 in 1000).

Are there alternative treatments available?

This should be discussed with the Consultant responsible for your care as well as your IBD nurse. Other drug treatments may be available or surgery may be an option. You should continue with your usual medication until you are told to stop it.

What If I decide not to have Adalimumab?

If you decide not to have Adalimumab then alternative treatments will be discussed with you. These may not work as well as Adalimumab and may also have side effects. The risk of needing an operation may be increased and this may result in the need for a stoma (bag) formation.

Do I continue my other medications for Inflammatory Bowel Disease?

Usually, yes, but please discuss this with your doctor or IBD Nurse.

Can I take other medication along with Adalimumab?

Yes, all the medications used to treat Crohn's Disease can be used together with Adalimumab. Please tell your doctor or IBD nurse about any medicines you are taking including any you have bought yourself. You will be told if you need to stop any.

Do I need any special checks following Adalimumab?

You should have a blood test every 2 to 3 months. Adalimumab and other medications you may be taking can lower your resistance to infection. You should inform your GP or IBD Specialist Nurse if you develop a sore throat, fever (high temperature) or any other infection and may be advised to have an extra blood test at this time.

Try to avoid contact with people who have infections where possible as you may be at risk of severe infection from the germs which cause chickenpox, shingles, influenza (flu), measles and pneumonia. If you come into contact with anyone who has any of these conditions, tell your doctor or nurse as soon as possible.

Can I have immunisations after having Adalimumab?

You should have a flu vaccine every year. Flu vaccinations are safe following Adalimumab treatment. You should also have a Pneumovax vaccine to protect against some forms of pneumonia. Your practice nurse or GP will arrange these for you.

You should avoid '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 this is needed. An 'inactivated' version should also be given to those with whom you are in contact.

If you require vaccinations, please let your doctor or practice nurse know that you are receiving Infliximab treatment.

Can I drink alcohol following Adalimumab?

There is no reason to avoid alcohol in moderation.

Does Adalimumab affect fertility or pregnancy?

Please inform your Consultant or IBD Specialist Nurse if you are planning to have a baby so that your medication can be reviewed.

There have been several reports of successful pregnancies in women with Crohn's on Adalimumab before conception and during pregnancy. However, because the drug is fairly new there is not much clinical evidence. If you are a woman of childbearing age it is recommended that you use contraception while on Adalimumab and for 5 months after you have stopped taking it.

It should be remembered that in many cases the risk of active Crohn's is higher than the risk of continuing Adalimumab even if you become pregnant and this should be discussed with your doctor before trying for a baby. If you do become pregnant while on Adalimumab please do not stop taking it without talking to your doctor first. You may be advised to continue Adalimumab in the first 6 months of pregnancy but would usually be advised to stop it for the last 3 months.

What about breastfeeding?

Information on whether breastfeeding is safe if you are having Adalimumab is limited, therefore it is better to avoid breast-feeding whilst on Adalimumab and for 6 months after the last dose.

Where can I obtain further information about Adalimumab?

If you have any questions about Adalimumab, ask your doctor, IBD Specialist Nurse or your pharmacist.

Please contact the IBD Nurse Specialists:

Allyson Lewis, Lead Clinical Nurse Specialist (IBD)

Victoria Burn, Clinical Nurse Specialist (IBD)

Karen Evans, Clinical Nurse Specialist (IBD)

On the following number:- 01633 656055 – answer phone or email:- IBDHelp@wales.nhs.uk if you require further information.