



INFORMATION SHEET

ADALIMUMAB

INTRODUCTION

This information sheet is a brief overview of some of the more important points about adalimumab for Crohn's Disease or Ulcerative Colitis (UC) (the two main forms of Inflammatory Bowel Disease - IBD). It is about adalimumab in general and is not intended to replace specific advice from your doctor or any other health professional. For further information, please talk to your doctor or specialist IBD team or look at the information sheet supplied with your medication, or from the website: www.medicines.org.uk

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Adalimumab is my little bit of magic in a pen: I have been on this treatment over 3 years.

”

Thea, 47

Diagnosed with Crohn's Disease in 1986

OTHER NAMES FOR THIS MEDICINE

Adalimumab is sometimes known by the brand name 'Humira'.

WHY AM I BEING TREATED WITH ADALIMUMAB?

Adalimumab can be used to treat moderate to severe active Crohn's Disease in adults and severe active Crohn's in children aged 6-17. It may be considered a suitable treatment when other drugs have not worked or have caused major side effects, and when surgery is not considered the right option for you. Adalimumab is also licensed to treat moderate to severe active Ulcerative Colitis (UC) in adults who have not responded to, or cannot have, treatment with other IBD medicines.

HOW DOES IT WORK?

Adalimumab is a biological drug made from a synthetic (man-made) antibody. It belongs to a group of medicines called 'anti-TNF' drugs or therapies. This is because it works by targeting a protein in the body called TNF-alpha (tumour necrosis factor-alpha). Your body naturally produces TNF-alpha as part of its immune response, in order to help fight infections by temporarily causing inflammation in affected areas. Over-production of this protein is thought to be partly responsible for the type of chronic (ongoing) inflammation found in the digestive system of people with Inflammatory Bowel Disease (IBD). Adalimumab binds to the TNF-alpha and this helps to reduce the inflammation and relieve symptoms.

HOW LONG WILL IT TAKE TO WORK?

You may begin to feel better within a few days or it may take up to three months after the first treatment session.

HOW IS ADALIMUMAB GIVEN?

Adalimumab is given as a subcutaneous injection (injection under the skin). It cannot be taken orally (in tablet form), because your digestive system would destroy it.

Your adalimumab treatment will be supervised by a specialist doctor experienced in the diagnosis and treatment of IBD. To begin with, a doctor or nurse will give you the injections. Once you are used to having the treatment, you may be able to self-inject, if you and your doctor feel this is appropriate, and after you have had the proper training in injection techniques. If you prefer, it may be possible for someone else, such as a family member or a friend, to be trained to give the injections, although self injecting may give you more independence.

Adalimumab for adult use comes ready to use in either a pre-filled syringe or a pre-filled injection 'pen'. The syringes or pens come in a pack, which also contains an alcohol pad for cleaning the skin before injecting. The injection is usually given under the skin of your thigh or stomach, but not in the area around your stomach button (navel). It should not be given in any area where the skin is reddened, bruised or hard, and a new injection site should be at least 3cm away from any previous injection sites. If you use a syringe the injection will take about 2-5 seconds. If you use a pen it will take about 10 seconds. Adalimumab for children may come in a vial (small bottle) designed to fit onto a syringe using an adapter.

Normally, the adalimumab will be delivered directly to your home by a special delivery company. Adalimumab has to be kept in the fridge at all times, or it will not work. However, when needed, for example if you are travelling, adalimumab can be stored at room temperature out of sunlight for a maximum of 14 days – if it is kept out for longer than this it should be thrown away. Even if you return it to the fridge within 14 days of it being taken out, it still must be used within 14 days of the initial removal from the fridge.

TIPS ON INJECTING ADALIMUMAB

One of the most common side effects of adalimumab injections is pain at the injection site, sometimes with redness, itching and swelling. Using the drug when it is at room temperature may help reduce this, so try taking it out of the fridge about 15 minutes before you need it. You could also apply an ice pack for two or three minutes to the area you are going to inject, before cleansing the skin with the alcohol wipe. Some people who use the syringe form find it makes it less painful if they insert the needle quickly in a single motion and then inject the medicine slowly. If your skin hurts or is swollen at the injection site after you have the injection, it may help to apply an ice pack or cold damp towel to the area for about 10-15 minutes. If you do use an ice pack, place a light towel between it and your skin.

WHAT IS THE NORMAL DOSAGE?

The dose you are prescribed and how often you need to take it will vary according to your condition. Children will be given smaller doses than adults. The usual adult induction (starting) dose is 160 mg followed by an 80 mg dose two weeks later, although some people may start with a dose of 80 mg followed by a 40 mg dose after two weeks. For ongoing treatment, the usual dose is then 40 mg every other week. Depending on your response, your doctor may increase the frequency of your dose to 40 mg every week. Each adalimumab pre-filled pen or syringe contains 40mg of the drug, which means you will need more than one injection when you have the initial induction doses.

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The thought of injecting myself filled me with dread, but it was so easy and is now just a part of my life that I don't even think about!

”

Karen, 55
diagnosed with Crohn's Disease in 1990

HOW LONG WILL I BE TAKING IT?

If you respond well to adalimumab and there are no serious adverse effects, you may be put onto a planned course of treatment lasting up to a year or longer. However, your treatment plan will need to be reassessed at least every 12 months to check whether ongoing treatment with adalimumab is still right for you. If, at the end of the year you are in remission, it may be decided that you have to stop taking adalimumab. However, if you then have a relapse, you should have the option to restart your treatment.

You may also be taken off adalimumab if you have serious side effects or if you have not responded strongly enough within 12 weeks of starting your treatment if you have Crohn's Disease, or 8 weeks if you have Ulcerative Colitis.

IS ADALIMUMAB USED IN COMBINATION WITH OTHER DRUG TREATMENTS FOR IBD?

Your doctors will advise you on this as they plan your treatment. Adalimumab is sometimes given in combination with steroids to help bring on remission and allow the steroid treatment to be reduced. Adalimumab may also be given in combination with immunosuppressants such as azathioprine or methotrexate.

HOW EFFECTIVE IS ADALIMUMAB?

Adalimumab has been widely used to treat a range of conditions including rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis as well as IBD.

Research has found that treatment with adalimumab can be effective in bringing about and maintaining remission in people with Crohn's Disease. It can help to reduce the need for hospitalisation and surgery, and has also been used successfully to treat Crohn's Disease fistulas. In some cases, it may be effective when treatment with another similar drug, infliximab, has failed. Adalimumab has also been used to help bring on and maintain remission in people with Ulcerative Colitis who were not responding to conventional therapy.

There is some evidence that combination therapy, using adalimumab with another drug, for example an immunosuppressant such as azathioprine or methotrexate,

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may also be helpful for some people with IBD by reducing the risk of developing antibodies to the drug. However, studies have suggested that combination therapies may also increase the risk of side effects, including infections and some types of cancer (see below).

It is important to talk to your IBD specialist doctor before you start your treatment with adalimumab about all the possible benefits and risks, including the potential for side effects, as some of these can be serious.

WHAT CHECKS WILL I NEED?

Pre-treatment screening is essential to check your suitability for treatment with adalimumab. Make sure the doctors treating you know:

- if you have any history of tuberculosis (TB) or any recent exposure to people with TB. You should not be given adalimumab if you have active TB, and if you have underlying inactive TB, this will need to be treated before starting adalimumab. Most doctors now use a blood test to check for underlying or inactive TB, but you may be given a chest x-ray as well.
- if you have or have ever had HIV, hepatitis B or C (a viral liver infection), are a carrier of hepatitis B or C, or have been in close contact with someone who has hepatitis B or C. You will usually have a blood test to check for these diseases before starting adalimumab.
- if you have a history of infections, currently have an infection or have symptoms such as feeling feverish or generally unwell. If you do have an infection your adalimumab treatment may need to be postponed.
- if you have heart problems, as adalimumab may make your symptoms worse, and your heart will need to be monitored closely before, during, and after treatment.
- if you have a history of cancer. Adalimumab affects the way in which your immune system works and you may have an increased risk of developing some types of cancer. However, you may also be at risk even if you do not have a history of cancer.
- if you smoke or have COPD (Chronic Obstructive Pulmonary Disease).
- if you have ever had a disease that affects the nervous system, including any symptoms of numbness, tingling or vision problems. Also if you have multiple sclerosis.
- if you have had kidney or liver disease.
- if you are pregnant, planning to get pregnant or are breastfeeding.
- about any other medications you are taking and any recent vaccinations.
- if you are having any surgery.

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- if you travel to regions of the world where TB or fungal infections, such as histoplasmosis, coccidioidomycosis or blastomycosis are common.
- if you have or have not been exposed to chicken pox in the past. If you have not had chicken pox, you may be able to be vaccinated against it before you start adalimumab.

WILL I NEED ONGOING CHECKS?

Once your treatment has started you will need regular checks and may need additional blood tests. Monitoring your treatment in this way helps your doctors fit your treatment to your needs. It can also make sure that any complications or problems with your treatment are avoided or caught at an early stage.

At some hospitals, you may also be given a special blood test to check the levels of adalimumab in your blood. This can help your doctor see how well the adalimumab is working, and whether you have developed antibodies to it.

WILL I NEED TO TAKE ANY SPECIAL PRECAUTIONS WHILE BEING TREATED WITH ADALIMUMAB?

- Try to avoid close contact with people who have infections. Adalimumab affects the way your immune system works, so you may be more prone to infections. Also, even a mild infection such as a cold or sore throat could develop into a more serious illness if you are taking adalimumab. Contact your doctor or the hospital if you begin to feel unwell and think you may have caught an infection.
- You may also be at greater risk of becoming more seriously ill from viruses and bacteria such as those that cause chickenpox and shingles, measles, and pneumococcal disease. Tell your doctor if you come into contact with anyone with these conditions even if you do not feel unwell.
- Take care with food hygiene and avoid eating raw eggs or undercooked pate, meat and poultry, as well as unpasteurised dairy products and soft or blue cheeses. You may be more open to the type of infections caused by bacteria such as listeria when being treated with adalimumab.
- You will be advised to have an annual flu vaccine and a pneumonia vaccination while on adalimumab treatment.
- Adalimumab can increase the risk of skin reactions, and in rare cases skin cancer. You may wish to take extra precautions when in the sunlight, for example wearing a hat and high factor suncream

WHAT ARE THE MOST LIKELY SIDE EFFECTS OF ADALIMUMAB?

Like all drugs, adalimumab can have side effects, although not everybody will get them. Some side effects can happen almost immediately, others may develop later. It can take up to six months after the last dose for adalimumab to completely leave the body, so some effects might appear even after stopping treatment.

Some adalimumab side effects are likely to be quite mild and may go away on their own. Others can be more serious and will require treatment, or may mean that adalimumab is not suitable for you.

Some of the main side effects and symptoms are described below.

IMMEDIATE REACTIONS

- Reactions to the injection such as pain or swelling, redness, bruising and itching. This can be very common, affecting at least one in 10 people. Using the adalimumab when it is at room temperature or cooling your skin with an ice pack may help. (See **Tips on injecting adalimumab**). Your doctor or IBD nurse should also be able to advise you on how to reduce this sort of reaction.
- Symptoms that mean you are having an allergic reaction to adalimumab. For example, rashes, hives (a raised itchy rash that appears on the skin), a swollen face, hands and feet, or trouble breathing and shortness of breath.
- Some of the more common side effects of adalimumab include abdominal pain, nausea, headaches, fatigue and joint pain.

OTHER SIDE EFFECTS:

- A greater chance of suffering from infections such as colds and flu and also some more serious infections such as pneumonia and sepsis (general inflammation and problems with blood clotting). You may also be at greater risk of developing tuberculosis (TB), or of having underlying TB reactivated while on adalimumab. Symptoms of an infection often include feeling very tired, fever, cough, and warm painful skin. You may need to stop the adalimumab if you have an infection, so check with your medical team first if you think you have or are developing an infection.
- Blood problems. Your body may not make enough of the blood cells that help fight infections or help to stop bleeding. Symptoms include a fever that does not go away, bruising or bleeding very easily, sore throat, or looking very pale.
- Liver problems, you should contact your doctor if your skin or eyes look yellow, you feel very tired with a lack of appetite, or you have a persistent pain on the right hand side of your stomach. Adalimumab can also activate viral hepatitis if you carry it in your blood. Your doctor should check whether you are a carrier before you start treatment, and continue with blood tests while you are on the drug to make sure it does not activate.

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I have to cope with certain side effects such as pain at the site of injecting and flu-like symptoms such as headache and general achiness but this usually subsides within a couple days. Don't be scared – it is easier than it seems at first.

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Emily, 21
diagnosed with UC in 2014

- Skin reactions such as psoriasis (scaly patches) and eczema, other skin rashes and ulcers. Some of these can be treated without stopping your adalimumab.
- Some types of skin cancer. You must tell your doctor if you have a bump or open sore which is not healing. There have also been reports of other cancers including lymphoma (cancer of the lymph glands) as an uncommon side effect of adalimumab, and more rarely still, leukaemia. You may be more at risk if you are also taking immunosuppressive drugs such as azathioprine or methotrexate. However, it is difficult to know what the exact risk is, as cancers in these circumstances happen rarely and very few people are affected.
- New heart failure or worsening of heart failure you already have. Call your doctor right away if you get new or worsening symptoms of heart failure while taking adalimumab, including shortness of breath, swelling of your ankles or feet, or sudden weight gain
- Other very rare complications that have been linked to taking adalimumab include demyelination (damage to nerves) and some rare inflammatory conditions, such as lupus (an autoimmune condition). Many of these serious side effects are reversible if the drug is stopped.

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TELL YOUR DOCTOR IMMEDIATELY IF YOU DEVELOP ANY OF THE FOLLOWING SYMPTOMS.

- A severe rash, hives (swollen red patches of skin) or other signs of allergic reaction
- Swollen face, hands and feet
- Trouble breathing or swallowing
- Shortness of breath
- Persistent fever, bruising, bleeding or paleness
- Fatigue, cough, or flu-like symptoms

Overall, it is best to let your doctor or IBD nurse know about any new symptoms you develop while on adalimumab, whenever they occur. Your IBD team should also be able to help with any queries and concerns.

This is not a complete list of side effects for adalimumab, for more information see the Patient Information Leaflet provided with your medication, or visit www.medicines.org.uk

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CAN I HAVE IMMUNISATIONS WHILE ON ADALIMUMAB?

It may be unsafe to be immunised with certain vaccinations while on adalimumab. You should not have any 'live' vaccines such as those for polio, yellow fever, rubella (German measles), BCG (tuberculosis) and MMR (measles, mumps and rubella). However, you may be able to have the inactivated polio vaccine. Flu jabs are currently safe as they are not live vaccines and the Department of Health recommends that everyone on drugs such as adalimumab should have an annual flu vaccination. However, the nasal spray used for children's vaccines is live, and should not be used.

If anyone in your family or household is due to have a live vaccine, check with your IBD team whether you need to take any special precautions.

IS IT SAFE TO TAKE OTHER MEDICINES ALONG WITH ADALIMUMAB?

Adalimumab may interact with certain other drugs and should not be taken with medicines that contain the active substances anakinra or abatacept (these are drugs commonly used for Rheumatoid Arthritis). Talk to your doctor if you are unsure about whether any medicines you are taking - or are planning to take - may interact with adalimumab. This includes any over the counter medicines and any herbal, complementary, or alternative medicines or therapies. You should also tell any other doctor, dentist or health professional treating you that you are being treated with adalimumab. You should carry the alert card provided by the manufacturer while on the medication and for 5 months after your last dose.

DOES ADALIMUMAB AFFECT PREGNANCY?

The evidence about the safety of adalimumab in pregnancy is still fairly limited. It has been found that although adalimumab is unlikely to cross the placenta during the first and second trimesters (months 1-6), it may do so during the last three months of a pregnancy. There have been a number of reports of successful pregnancies in women with IBD who have taken adalimumab before conception or during pregnancy. But research is still ongoing, especially into the possibility of long-term effects of adalimumab on the baby. Live vaccinations should not be given to the baby until it is at least 6-9 months old if the mother has been on adalimumab - you should discuss this with your doctor and healthcare team.

Because there is not yet that much clear evidence, the manufacturers recommend that if you are a woman of childbearing age and are prescribed adalimumab, you should use adequate contraception to prevent pregnancy and continue to use contraception for at least 5 months after stopping adalimumab. However, some doctors consider that if the adalimumab treatment is keeping your IBD in check, it may be better to continue with it, at least until the end of the second trimester (month 6). Recent guidelines recommend that doctors should discuss the risks and benefits of taking adalimumab while pregnant with each woman on an individual basis. You may find it helpful to talk through your own options with your specialist IBD team.

There is less evidence for men wanting to father a child while on adalimumab, but it is thought that it is safe for a man to conceive a child while taking the drug.

WHAT ABOUT BREASTFEEDING?

Adalimumab is present in breast milk in very small amounts. Research is continuing into possible effects this might have on the baby, especially in the longer term. Most doctors recommend that women using adalimumab should not be discouraged from breastfeeding, although the evidence is uncertain.

CAN I DRINK ALCOHOL WHILE TAKING ADALIMUMAB?

Alcohol is not known to have any interaction with adalimumab, but for general health reasons it is best to keep within the Department of Health guideline limits.

WHO SHOULD I TALK TO IF I AM WORRIED?

If you are worried about your adalimumab treatment or have any questions, contact your doctor or your IBD nurse. They should be able to help you with queries such as why it has been prescribed, what the correct dose and frequency are, what monitoring is in place, and what alternatives may be available for you.

FURTHER HELP

Crohn's and Colitis UK Information Line: 01727 734 470, open Monday to Friday, 9 am to 5 pm, except Thursday open 9 am to 1 pm, and excluding English bank holidays. An answer phone and call back service operates outside these hours. You can also contact the service by email info@crohnsandcolitis.org.uk or letter (addressed to our St Albans office). Trained Information Officers provide callers with clear and balanced information on a wide range of issues relating to IBD.

Crohn's and Colitis Support: 0121 737 9931, open Monday to Friday, 1 pm to 3.30 pm and 6.30 pm to 9 pm, excluding English bank holidays. This is a confidential, supportive listening service, which is provided by trained volunteers and is available to anyone affected by IBD. These volunteers are skilled in providing emotional support to anyone who needs a safe place to talk about living with IBD.

All our information sheets and booklets are available free from our office and downloadable from our website: www.crohnsandcolitis.org.uk

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ABOUT CROHN'S & COLITIS UK

We are a **national** charity established in 1979. Our aim is to improve life for anyone affected by Inflammatory Bowel Diseases. We have over 28,000 members and 50 Local groups throughout the UK. Membership starts at £15 per year with concessionary rates for anyone experiencing financial hardship or on a low income.

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