

## Adalimumab (Humira)

*This information leaflet aims to answer common questions you may have if your doctor has given you or has discussed using adalimumab to treat your Crohn's Disease. You can obtain further information from your pharmacist or doctor, or from the information leaflet supplied with your prescription or from the website: [www.medicines.org.uk](http://www.medicines.org.uk)*

### Why am I being treated with this medicine?

Adalimumab (brand name Humira) is used to treat severe Crohn's Disease. It is not licensed for the treatment of Ulcerative Colitis. It might 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.

### How does it work?

Adalimumab is a synthetic (man-made) antibody that works in a similar way to the natural antibodies produced by our immune system. Our natural antibodies recognise harmful substances and bind to them, helping our immune systems to attack them and protect us from infections. Adalimumab targets a protein in the body called TNF-alpha (tumour necrosis factor-alpha). Your body naturally produces TNF-alpha, as part of its immune response, to help fight infections, temporarily causing inflammation in affected areas. In Crohn's Disease the body produces too much TNF-alpha. Researchers believe that this high concentration of TNF-alpha found in the lining of the inflamed intestine is one of the major causes of chronic inflammation. By blocking TNF-alpha, adalimumab reduces inflammation and relieves the symptoms of Crohn's Disease.

### How long will it take to work?

You may begin to feel better after the first or second injection, but it may take up to 3 months before some people feel the full benefit of adalimumab.

### How is adalimumab given?

Adalimumab treatment should be supervised by a specialist doctor experienced in the diagnosis and treatment of Crohn's Disease. It is given as a subcutaneous injection (injection under the skin). It cannot be taken orally, because the digestive system would destroy the drug.

You may be able to self-inject, after proper training in injection technique, if you and your doctor decide that is suitable. Alternatively, it may be possible for someone else, such as a family member or friend, to give the injection, after appropriate training from a health care professional. In this case, or if you are self-injecting, you will need regular medical follow up.

Adalimumab comes in a pre-prepared solution for injection in the form of either a pre-filled pen or a syringe. These come in a pack, which also contains an alcohol pad for wiping the skin before injecting. The injection is usually given under the skin of your thigh or stomach and takes at least 10 seconds if using the pen and about 2-5 seconds for the syringe. The injection must not be given in any area where the skin is reddened, bruised or hard. The site of the injection should also be at least 3 cm away from any previous injection sites.

### **What is the normal dosage?**

The recommended initial dose is 80 mg followed by 40 mg two weeks later. However, your doctor may decide that a starter dose of 160 mg followed by 80 mg two weeks later is appropriate, depending on your medical condition. For ongoing treatment, the recommended dose is 40 mg every other week on the same day of the week. Depending on your response, your doctor may increase the frequency of your dose to 40 mg every week.

### **How long will I be taking it?**

This will depend on how you respond to treatment and the need to keep your Crohn's from relapsing. If you respond well and there are no adverse effects, you might be taking it for a year or more. If adalimumab is not immediately effective, it may be continued for up to 3 months to see whether there is any improvement. If there is none it is likely to be stopped.

If you continue treatment with adalimumab, you should be reassessed at least every 12 months to see whether ongoing treatment is still right for you. If you relapse after treatment is stopped, you should have the option to start treatment again.

### **Will I need to take other medication?**

Adalimumab is often given in combination with another immunosuppressive drug such as azathioprine or methotrexate. You may already be on a drug like this before beginning adalimumab. You may also be taking corticosteroid drugs, and these will be quickly tailed off after starting adalimumab.

### **How effective is adalimumab?**

Adalimumab has been used to treat about 250,000 people worldwide for a range of conditions including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and Crohn's Disease. Studies show that the treatment can be effective in bringing about and maintaining remission in people with Crohn's Disease. It can also be used when treatment with another similar drug, infliximab, has failed.

Research has found that approximately 6 out of 10 people respond well to adalimumab initially, and of those who respond, more than a third remain in remission after one year on continuing therapy. In a study of those who switched to adalimumab, following failure of infliximab, half had ongoing significant benefit at 1 year, and a third of them were in complete remission. Overall research shows that adalimumab can reduce hospital admissions, allow for withdrawal of steroids and improve quality of life.

### **What checks will I need?**

Adalimumab should only be prescribed by a doctor with expertise and experience in its use. Regular follow up and blood tests are essential to monitor the use of this drug.

Pre-treatment screening is also essential to check your suitability for treatment. At this time tell your doctor if you:

- have any history of TB or any recent or previous exposure to people with TB. You will most likely have to undergo a chest X-ray and might also have a skin test for TB. You should not be prescribed adalimumab if you have active TB. If inactive TB is diagnosed then you will need appropriate anti-TB treatment before being carefully considered for adalimumab injections.

- have any prolonged or abnormal symptoms, or signs of infections or general deterioration in your health, as you may have an unusual infection. Symptoms may include feeling generally unwell, loss of weight or sweating.
- have or have ever had hepatitis B, have been told that you are a carrier of hepatitis B, or have been in close contact with someone who has hepatitis B.
- have or have ever had a disease that affects the nervous system, including any symptoms of numbness, tingling or vision problems.
- have or have ever had problems with your immune system, as adalimumab treatment may further reduce your immunity.
- have a history of cancer, including any family history of cancers. Adalimumab affects the way in which your immune system works and may therefore slightly increase your risk of getting cancer.
- have or have ever had any problems with your blood, as there are rare reports of adalimumab causing or worsening diseases of the blood.
- have or have ever had any heart problems, as adalimumab may make your symptoms worse.
- are pregnant, planning to get pregnant or are breastfeeding. There is little research about the safety of adalimumab during pregnancy, or whether the drug passes into breast milk. (See below for further information).
- have an allergy to latex rubber, as the needle cover of the syringe contains natural rubber;
- and about any other medications you are taking and about all the vaccinations you have had or are having. This is because some vaccinations may cause infections if you are taking adalimumab at the same time. (See below for further information.)

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

Try to avoid contact with people who have infections, as adalimumab may reduce your immunity so that you are more likely to develop illnesses such as chest and fungal infections, colds, flu and fever.

### **Can I have vaccinations or immunisations while on adalimumab?**

You should not have any **live** vaccines while on adalimumab treatment. These include jabs for polio, yellow fever, rubella (German measles), BCG (Tuberculosis) and MMR (measles, mumps and rubella). An **inactivated** polio vaccine can be given instead of the live one. The inactivated version should also be used by people you are in close contact with, should they need a polio vaccination. Flu vaccines, including the one for Swine Flu (H1N1) and pneumovax, are safe as they are not live vaccines.

### **Can I take other medicines along with adalimumab?**

It is important to tell your doctor about any other medicines you are planning to take, including herbal, complementary or alternative therapies, as these may interact with adalimumab. If you are being treated by another health professional, such as a dentist, it is important to tell them that you are taking adalimumab. It is useful to carry the alert card

provided by the manufacturer while on the medication and for 5 months after your last dose.

### **Does adalimumab affect pregnancy?**

There have been several reports of successful pregnancies in women with Crohn's on adalimumab before conception or during pregnancy. Because the drug is relatively new the clinical evidence is limited. Therefore, 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 it for at least 5 months after stopping taking adalimumab. However, in many cases the risks of active Crohn's disease outweigh the risks of the drug, even during pregnancy, and if you are thinking of trying for a baby, you should discuss this with your doctor. For example, if your Crohn's has previously been severe and you do not want to wait before trying for a baby, your doctor may help you to weigh up the risk of stopping against the benefits of continuing with your treatment.

If you become pregnant while using adalimumab there may be reasons why your doctor will advise you to continue with your treatment throughout the first 6 months of pregnancy, and it is not advisable to stop the drug without consulting your doctor. In the last 3 months of pregnancy adalimumab should only be used with caution, and on advice from your doctor, as it will cross the placenta and might affect the immune system of your baby.

### **What about breastfeeding?**

As the long-term effects of adalimumab on a child's developing immune system are still not known, it is recommended that you do not breast-feed during treatment or for six months after your last dose.

### **Can I drink alcohol while taking adalimumab?**

While alcohol does not appear to have any interaction with adalimumab, as with any medication, it is better to avoid drinking excessive amounts of alcohol. The general recommendation from the Department of Health is a limit of 2-3 units a day for women and 3-4 units a day for men.

### **How safe is adalimumab in the long term?**

There is little data on the long-term safety of adalimumab, being a relatively new drug, though it has been found to be generally safe and well tolerated. However, your doctor should discuss the risks and benefits of therapy with you and advise you about what remains unknown about the drug.

There have been reports of serious infections including tuberculosis (TB) and, more rarely, other types of infection, including pneumonia. So it is important that medical checks are carried out beforehand and that you inform your doctor of any symptoms you notice during and after treatment.

There have also been some rare reports of cancers associated with adalimumab, although it is not certain if these were directly caused by it. Therapy is usually not advisable if you have had previous cancer.

New cases of the skin conditions psoriasis and eczema have also been reported in people receiving TNF blocking drugs, including adalimumab.

Other very rare complications include damage to nerves (demyelination), similar to multiple sclerosis and some rare inflammatory conditions, such as lupus. These may improve if the drug is stopped.

There have been single reports of other associations, but it is difficult to know whether they are truly related to adalimumab treatment and further studies will be required.

### **What are the possible side effects?**

Like all medicines, adalimumab can have side effects, although not everybody gets these. Side effects may occur up to 5 months after the last treatment. Most are mild to moderate. Some, however, as mentioned above, may be serious and require treatment.

About 1 in 10 people will experience some sort of reaction to the injection. These are usually mild and go away on their own. One of the most common side effects is pain at the injection site, sometimes with redness, itching and swelling. It may help to remove the drug from the fridge about 15 minutes before use, to allow it to warm up to room temperature. You could also apply an ice pack for 2 to 3 minutes to the area you are going to inject, before cleansing the skin with alcohol. Some people find it helps to insert the needle quickly with one single motion and then inject the medicine slowly. If your skin hurts or is swollen at the injection site afterwards, you could apply an ice pack or cold damp towel to the area for 10 to 15 minutes every 1 to 2 hours. If you use an ice pack, place a light towel between it and your skin.

Other common side effects include:

- stuffy nose, sinus pain
- headaches
- nausea, abdominal pain
- mouth ulcers
- rash

You can get reactions to adalimumab for up to five months after the last dose as it takes around this time to clear from the body. While most side effects are mild to moderate, some may be serious and require treatment. You must tell your doctor about **ANY** reaction you get while on the treatment, as well as up to five months after stopping it.

### **Tell your doctor immediately if you develop any of the following symptoms:**

- severe rash, hives (swollen, red, itchy 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, paleness
- fatigue, cough or flu

### **Who should I talk to if I am worried?**

If you are worried about your treatment, or if you have any questions, such as why adalimumab has been prescribed, about the correct dose and frequency, about monitoring for adverse effects, and what, if any, alternatives are available, contact your doctor or nurse specialist.

You can also telephone our **Information line on 0845 130 2233** for general information.

We also provide a supportive listening service run by trained volunteers who have IBD or a relative with IBD: **NACC-in-Contact** on **0845 130 3344** open **weekday afternoons 1-3.30pm** and **evenings 6.30-9pm**.

© **NACC 2010**

**Adalimumab (Humira) – Edition 2**

**Last review July 2010**

**Next review due 2012.**

***Crohn's and Colitis UK's publications are research based and produced in consultation with patients, medical advisers and other health or associated professionals. They are prepared as general information on a subject with suggestions on how to manage particular situations, but they are not intended to replace specific advice from your own doctor or any other professional. Crohn's and Colitis UK does not endorse or recommend any products mentioned.***

***We hope that you find the information helpful and relevant. We welcome any comments from readers, or suggestions for improvements. References or details of the research on which this publication is based can be obtained from Crohn's and Colitis UK at the address below. Please send your comments to Helen Terry at Crohn's and Colitis UK, 4 Beaumont House, St Albans, Herts AL1 5HH, or email [h.terry@crohnsandcolitis.org.uk](mailto:h.terry@crohnsandcolitis.org.uk).***

**Crohn's and Colitis UK is the working name of the National Association for Colitis and Crohn's Disease (NACC). NACC is a voluntary Association, established in 1979 which has 30,000 members and 70 Groups throughout the United Kingdom.**

**Membership of the Association costs £12 a year. New members who are on lower incomes due to their health or employment circumstances may join at a lower rate. Additional donations to help the work of the Association are always welcomed.**