

## Adalimumab (Humira)

*This information leaflet is designed to answer common questions you may have if you have been given adalimumab for the treatment of Crohn's Disease. Further information can be found in the information leaflet supplied by the manufacturer or from your pharmacist or doctor.*

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

Adalimumab (Brand name Humira) is a medicine used to induce and maintain remission of Crohn's disease. It may be given to you if you have severe active disease that does not respond to standard treatments or if you are intolerant to or have medical reasons why you should not take such treatments.

### How does it work?

Adalimumab works with your body's immune system to block the action of an inflammatory agent, TNF-alpha (Tumour necrosis factor- alpha) found in the blood. As part of the immune response, your body naturally produces chemicals, such as TNF-alpha, to help fight infections, temporarily causing inflammation in the affected areas. In Crohn's disease the body produces too much TNF-alpha. This high concentration of TNF-alpha found in the lining of the inflamed intestine is believed to be one of the key drivers of chronic inflammation.

Adalimumab is a fully human monoclonal antibody. This means that it does not contain any components from other animals. It recognises and binds specifically to TNF-alpha and neutralises its biological function. It also lessens the movement of inflammatory cells, directed by TNF-alpha, into inflamed areas of the intestines. By altering your body's inappropriate immune response, adalimumab reduces inflammation and relieves the symptoms of Crohn's disease.

### How long will it take to work?

Many people notice a benefit after the first or second injection, but it may take 2 months before some patients 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 would need a regular medical follow up.

Adalimumab comes in a pre-prepared solution for injection either in the form of a pre-filled pen or 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.

Adalimumab is usually given initially in combination with corticosteroids, unless you cannot tolerate them or treatment with them is not appropriate. You may also continue on the other immunosuppressive medication that you have been taking whilst starting adalimumab therapy.

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

The recommended initial dose is 80 mg followed by 40 mg two weeks later. If you need a quicker response to treatment your doctor can increase this first dose to 160 mg followed by 80 mg after two weeks. There is though a higher risk of side effects at the higher doses. 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.

### **How safe is adalimumab?**

Adalimumab has been used to treat about 250,000 patients worldwide for rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis, in addition to Crohn's disease. Being a relatively new drug, long-term safety is still unknown, though it has been found to be generally safe and well tolerated.

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

There have been reports of serious infections including tuberculosis (TB) and, more rarely, sepsis and pneumonia, so it is important that particular checks are undertaken 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 yet known with certainty if these were directly caused by it.

### **What monitoring 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.

Before being prescribed adalimumab, you will have a screening check to assess your suitability for treatment.

- You will have to be checked for both active and inactive tuberculosis (TB). This will include telling your doctor of 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 cannot 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.
- Inform your doctor of any prolonged or abnormal symptoms or signs of infections or general deterioration in your health as you may have an unusual infection.
- If you have a fistula, tell your doctor if it is leaking pus.
- Inform your doctor if you have or have ever had hepatitis B, or have been told that you are a carrier of hepatitis B, or have been in close contact with someone who has hepatitis B.
- Let your doctor know if you have or have ever had a disease that affects the nervous system, including any symptoms of numbness, tingling or vision problems.
- Inform your doctor if you have or have ever had problems with your immune system, as adalimumab treatment may further reduce your immunity.
- Tell your doctor about any history of cancer you may have, 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.
- If you have or have ever had any problems with your blood, then you need to let your doctor know, as there are rare reports of adalimumab causing or worsening diseases of the blood.
- Inform your doctor of all the vaccinations you have had or are having, as some types may cause infections if you are taking adalimumab at the same time.
- Inform your doctor if you have or have ever had any heart problems, as adalimumab may make your symptoms worse.
- Tell your doctor if you are pregnant, planning to get pregnant or are breastfeeding. There is no information about the safety of adalimumab during pregnancy, nor whether the medicine passes into breastmilk.
- Inform your doctor of any other medications you are taking.
- Tell your doctor if you have an allergy to latex rubber, as the needle cover of the syringe contains natural rubber.

### **Will I need to take any special precautions while on adalimumab?**

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

- You should not receive any **live** vaccines while on adalimumab treatment. These include vaccinations 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 and the 'inactivated' version should also be given to those you are in close contact with. Flu vaccines and pneumovax are safe and recommended, as they are not live vaccines.
- If you are a woman of childbearing age, you should use adequate contraception to prevent pregnancy and to continue using it for at least 5 months after stopping taking adalimumab. This is because adalimumab may affect the immunity of your child.
- You should not breast feed for at least five months after the last adalimumab treatment.
- Tell your doctor or nurse specialist about any other medicines you are planning to take, including herbal, complementary or alternative therapies, as these may interact with adalimumab.
- If you see another doctor, nurse or dentist tell them that you are taking adalimumab. It is useful to carry the alert card provided by the drug manufacturer while on the medication and for 5 months after your last dose.

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

About 1 in 10 patients will experience some adverse reaction to the injection. These are usually mild and recover without requiring any treatment. One of the commonest side effects is pain at the injection site, sometimes with redness, itching and swelling. It may help to remove the drug from the fridge for approximately 15 minutes before using 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're going to inject before cleansing the skin with alcohol. Some people find inserting the needle quickly with one single motion and then slowly injecting the medicine helps. 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 the ice pack and your skin.

Other common side effects include:

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

You can get adverse reactions to adalimumab for up to five months after the last dose of the treatment as it takes about five months 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 of **ANY** reaction you get while on the treatment and up to five months after stopping adalimumab.

## 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, swallowing
- shortness of breath with exertion or upon lying down or swelling of the feet
- signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness
- signs of infection such as fever, fatigue, cough or flu

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

If you have any worries, questions or queries about taking adalimumab including why it has been prescribed, the dose and frequency, what monitoring is in place for adverse effects, and what alternatives are available to you for your own particular circumstances, then please contact your doctor or nurse specialist to discuss these issues.

You can also telephone the **NACC information line on 0845 130 2233** for general information.

NACC also provides 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 May 2008

*NACC publications are research based and produced in consultation with patients, NACC medical advisers and other health or associated professionals. They are not intended to replace specific advice from your own doctor or any other professional. NACC does not endorse or recommend any products mentioned.*

*We hope that you have found the information helpful and relevant. We welcome any comments from readers, or suggestions for improvements. Please send your comments to Helen Terry at NACC, 4 Beaumont House, St Albans, Herts AL1 5HH – or email [h.terry@nacc.org.uk](mailto:h.terry@nacc.org.uk).*

The National Association for Colitis and Crohn's Disease (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 in the first year and £10 subsequently. Additional donations to help the work of the Association are always welcomed.

