



ADALIMUMAB

What are the aims of this leaflet?

This leaflet has been written to help you understand more about adalimumab (Humira™). It tells you what it is, how it works, how it is used to treat skin conditions, and where you can find out more about it.

What is adalimumab and how does it work?

Adalimumab is a powerful drug that has been specially designed to mimic normal human molecules, and for this reason it is classed as a biological drug. It reduces inflammation by inhibiting the activity of a chemical cytokine in the body called tumour necrosis factor alpha (TNF-alpha).

Which conditions are treated with adalimumab?

Adalimumab is used to treat psoriasis, psoriatic arthritis, and several other inflammatory conditions such as rheumatoid arthritis and Crohn's disease.

Why have I been selected for treatment with adalimumab?

The use of adalimumab is reserved for patients with severe psoriasis who either have not responded to or have not been able to tolerate or who have a contraindication to standard treatments such as methotrexate, ciclosporin or ultraviolet light therapy. There are national guidelines that assist dermatologists in identifying those patients that might benefit from adalimumab.

How long will I need to take adalimumab before it has an effect?

Adalimumab does not work immediately. It may be 3-12 weeks before you notice any benefit. In clinical trials, about 68% of patients achieved a good response (as indicated by 75% improvement in the score of their disease severity).

How do I take adalimumab?

Adalimumab is presented as a preloaded pen device which automatically injects the drug under the skin. A nurse or doctor will demonstrate how to use

the pen; details are also given in the package insert. It must be stored in a refrigerator (at 2-8 °C). Travelling with adalimumab, or transporting your treatment, requires a cool box or cool bag with icepacks to maintain these temperatures. Injections are made under the skin of the stomach, thighs or upper outer arms. You will be provided with sharps bins so that you can dispose of your syringes and needles safely.

What dose should I take?

The recommended dosage schedule of adalimumab for an adult patient with psoriasis is an initial loading dose of 80mgs, followed by 40mg every other week for four months starting one week after the initial dose. If the response at four months is deemed adequate by your dermatologist, treatment would then normally be continued to maintain improvement. If treatment is stopped, your psoriasis will probably recur but this is unlikely to happen in the first month.

What are the possible side effects of adalimumab?

Mild

- Reactions at the injection sites. These are usually mild and include redness, a rash, swelling, itching, or bruising. They usually go away within 3 to 5 days. If you have pain, redness or swelling around the injection site that doesn't go away, or gets worse, contact your doctor.
- Upper respiratory infections for example, sinus infections.
- Headaches, rash, nausea

Potentially severe:

- Serious infections. Adalimumab may decrease your ability to fight infection. Inform your doctor of any current or past infection (particularly tuberculosis), or if you are prone to infections such as cold sores or cystitis. Also tell your doctor if you have or have ever had any disease that affects your immune system, such as cancer, human immunodeficiency virus (HIV) infection, acquired immunodeficiency syndrome (AIDS), or viral hepatitis. Try to avoid close contact with anyone with a bad cold, influenza or chest infections, and wash your hands frequently when taking this medication. Avoid dairy foods that are not pasteurised, Camembert, Brie and blue cheeses, pâté or eggs, meat or poultry that are not adequately cooked and thus pose a risk of salmonella infection. Contact your doctor if you get an infection, or any symptom or sign of an infection, including: a fever, lethargy, a cough, influenza-like symptoms, warm, red or painful skin, and open sores on your body.
- Nervous system diseases. There have been rare cases of adalimumab affecting the nervous system. Symptoms of this include: numbness or tingling; problems with vision; weakness in the arms and/or legs; and dizziness. Tell your doctor if you have ever had a nervous system

complaint, such as multiple sclerosis, Guillain-Barré syndrome or seizures.

- *Blood problems.* Some patients taking adalimumab may fail to produce enough of the blood cells that help to fight infections or to stop bleeding. If you develop a fever that doesn't go away, bruise or bleed very easily, or look very pale, contact your doctor.
- *Heart problems.* You should also tell your doctor if you have ever been treated for heart failure. If you have, your doctor may choose not to start you on adalimumab, or may want to monitor you more closely.
- *Allergic reactions.* Some patients have had allergic reactions to adalimumab. If you develop a severe rash, a swollen face, or difficulty with breathing while taking adalimumab, attend a hospital A & E department and make sure that your dermatologist is informed.
- *Lupus-like reactions.* Some people taking adalimumab have developed symptoms (such as rash and joint pains) that resemble lupus erythematosus, and these usually go away when you stop taking adalimumab.
- *Cancers.* Many drugs that decrease the activity of the immune system can increase the chance of getting a cancer: the risk cannot be quantified, but is low. There have been rare reports of lymphoma (a tumour of the lymph glands) in patients taking adalimumab. Non-melanoma skin cancers have occurred in patients taking adalimumab and are more common if you have received a lot of ultraviolet light therapy. Your dermatologist should be consulted if you have any concerns about new skin lesions.

Before you start taking adalimumab, your dermatologist will go through a checklist for the following:

- *Tuberculosis* or close contact with someone who has had it. If you develop any symptoms of tuberculosis (e.g. a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor. You will need to be examined for tuberculosis and have a skin test.
- *Hepatitis or an HIV infection,* or if you think you are at risk of having these.
- *Numbness or tingling* or a disease that affects your nervous system like multiple sclerosis.
- *Congestive heart failure,* or if you are already being treated for it.
- If you are scheduled to have *major surgery.*
- If you are scheduled to have *any type of vaccination.*
- *Latex allergy.* Latex is present in the needle cover only in the prefilled syringe preparation not in the pen.

What will happen if I need an operation or dental surgery?

Adalimumab may increase your risk of getting an infection after a surgical procedure. You must tell the doctor or dentist that you are taking adalimumab.

How will I be monitored for the side effects of adalimumab treatment?

You will probably have a chest X-ray and blood tests before treatment starts; and blood checks need only be done 3 months after commencing adalimumab, and then every 6 months. Monitoring your response and looking out for side effects will take place at regular clinic visits.

The BAD Biologic Interventions Register (BADBIR)

Because adalimumab treatment for psoriasis is relatively new, you will be asked to take part in a national register if it is prescribed for you. This register will collect valuable information on side effects and benefits and will inform doctors on how best to use adalimumab and similar drugs. No information will be passed to the register without your informed consent.

Can I have immunizations (vaccinations) whilst on adalimumab?

Neither you nor close contacts should receive any of the 'live' vaccines such as those for polio, rubella (German measles) and yellow fever, although inactivated vaccines are safe. If you are on adalimumab you should avoid contact with children who have been given the live polio vaccine for 4-6 weeks after the vaccination. There is, however, an 'inactivated' polio vaccine available. If you require immunisation with a live vaccine, adalimumab should be stopped for at least 10 weeks before and until 2 weeks after the vaccination. Pneumovax and annual influenza vaccinations are safe and are recommended.

Does adalimumab affect pregnancy?

Adalimumab has not been studied in pregnant women or nursing mothers, and so we do not know what its effects are on unborn children or babies who are being breast fed. You should tell your doctor if you are pregnant, become pregnant, or are thinking about becoming pregnant.

May I drink alcohol while I am taking adalimumab?

There is no known interaction between alcohol and adalimumab.

Can I take other medicines at the same time as adalimumab?

Most medicines are safe to take with adalimumab. However, it is important that your GP and other doctors are aware that you are taking it if any new drug is prescribed. Your GP and dermatologist should be aware of all your

medications, including over-the-counter ones, and supplements, including herbal medicines. Methotrexate can be taken along with adalimumab. However, you should not take other immunosuppressives (medicines which suppress the immune system) while you are on adalimumab.

Can I sunbathe?

Sunbeds and sunbathing should be avoided to reduce the risk of skin cancer.

Where can I find out more about adalimumab?

This information sheet does not list all of the side effects of adalimumab. If you want to know more about adalimumab, or if you are worried about your treatment, you should speak to your doctor, specialist nurse or pharmacist. For fuller details, look at the drug information sheet which comes as an insert with your prescription for adalimumab.

Or visit the website <http://www.humira.com/>

This leaflet aims to provide accurate information about the subject and is a consensus of the views held by representatives of the British Association of Dermatologists: its contents, however, may occasionally differ from the advice given to you by your doctor.

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