



Australian  
Rheumatology  
Association

# PATIENT INFORMATION ON

# ADALIMUMAB

(Brand name: Humira)

This information sheet has been produced by the Australian Rheumatology Association to help you understand the medicine that has been prescribed for you. It includes important information about:

- **How you should take your medicine;**
- **What are the possible side effects;**
- **What tests you must have to monitor your condition and to detect unwanted effects; and**
- **Other precautions you should take.**

Please read it carefully and discuss with your doctor.

## What is adalimumab?

Adalimumab (brand name Humira) belongs to a new class of medicines called **biological disease modifying antirheumatic drugs (biological DMARDs)**.

These medicines block natural substances called cytokines, which are found in excessive amounts in the blood and joints of people with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, psoriasis and Crohn's disease.

The increased levels of cytokines cause inflammation, which results in symptoms of pain, joint swelling and stiffness, and can lead to joint damage.

By blocking the cytokine called Tumour Necrosis Factor (TNF), adalimumab reduces inflammation, lessens the symptoms and helps stop further joint damage.

**For more information about RHEUMATOID ARTHRITIS see the Arthritis Australia website [www.arthritisaustralia.com.au/index.php/arthritis-information/information-sheets.html](http://www.arthritisaustralia.com.au/index.php/arthritis-information/information-sheets.html).**

## What benefit can you expect from your treatment?

Unlike many standard DMARDs, adalimumab works relatively quickly and some relief of joint swelling, pain and stiffness may be noticed within the first 4 weeks of treatment.

If adalimumab treatment is stopped for more than a few weeks there is a risk that your condition may worsen. Continue with your treatment unless advised by your doctor or unless side effects develop.

Current Australian prescribing restrictions for all biological DMARDs mean adalimumab will only be given if your disease is active and standard treatments have been unsuccessful. It will only be continued if the response is adequate. Initial response will be assessed at least 12 weeks after the start of treatment.

## How is adalimumab given?

Adalimumab is given as an injection under the skin of the abdomen or thighs. It can be injected by your doctor, nurse, carer or by you. If injecting yourself follow the detailed instructions to ensure the best response. It is particularly important to change the injection site each time.

The medicine must also be kept refrigerated. The usual dose for adults with rheumatoid arthritis is 40mg once every two weeks.

Adalimumab may be used with other arthritis medicines including:

- other DMARDs such as methotrexate;
- steroid medicines such as prednisolone or cortisone injections into the joint;
- anti-inflammatory medicines (NSAIDs) such as naproxen (Naprosyn) or ibuprofen (Brufen, Nurofen); and/or
- simple pain medicines such as paracetamol.

Adalimumab should not be given with other biological DMARDs.

## Are there any possible side effects?

Biological DMARDs have now been given to over 750,000 people worldwide since initial use in the late 1990s.

Below are side effects that you might experience with your treatment. Tell your doctor if you experience any side effects.

### Most common possible side effects:

- *Mild pain, swelling or itching* at the site of the injection are very common (up to 20% of patients) but can be reduced by applying ice, and antihistamine/steroid creams to the injection site.
- *Headaches, cough and stomach and bowel discomfort* may also occur.
- As adalimumab affects the immune system, *mild infections*, particularly of the upper respiratory tract (e.g. colds, sinusitis) may occur more frequently than usual.

**Tell your doctor if you experience any possible side effects.**

### Less common or rare possible side effects:

- *Serious infections* such as Tuberculosis (TB) are seen rarely. Screening for TB is needed before treatment begins (see below).
- Rarely adalimumab may cause an *allergic reaction* with itchy, red skin or a rash, or a feeling of tightness in the chest and difficulty breathing.
- Side effects involving the *nerves*, such as inflammation of the nerve to the eye, may also occur rarely.
- Very rarely '*drug-induced lupus*' has occurred with symptoms of rash, fever and increased joint pain. This usually disappears when adalimumab treatment is stopped.
- *Cancer*: It is unclear if there is an increased risk of cancer when adalimumab is used to treat rheumatic diseases.

Lymphoma, a cancer of lymph glands, is found more commonly in patients with persistent active rheumatoid arthritis than in the general population. Studies are in

progress to see if this is changed by treatment with adalimumab.

If cancer has been previously treated and cured it is unclear whether a TNF-biological DMARD such as adalimumab can be used safely. At present an interval of 5-10 years is recommended between cure of a cancer and starting TNF biological DMARDs.

For general cancer prevention, stopping smoking is recommended, so too are skin cancer prevention measures (see *Precautions* overleaf).

Talk to your doctor, if you have any concerns about issues relating to cancer risk.

## What precautions are necessary?

### Infections:

- Adalimumab should not be given if you have active tuberculosis (TB) or HIV (AIDS) infection, as it is likely to make these conditions worse.
- If you have latent (inactive) TB, preventative anti-TB treatment will be started 4 to 6 weeks before adalimumab. The anti-TB treatment may need to be taken for up to 9 months.
- Hepatitis B infection presents a risk but you may still be able to receive treatment with adalimumab. This medicine can usually be given safely if you have Hepatitis C.
- The following tests are required before commencing treatment with adalimumab:
  - blood tests for Hepatitis B and C;
  - chest x-ray and two step Tuberculin Skin Test (Mantoux) or QuantiFERON assay for tuberculosis (TB).
- HIV tests are required only for those who are at risk of this infection.
- If you have an active infection of any kind, treatment with adalimumab will not be given until the infection is treated successfully.

### Ongoing blood tests:

- Blood tests will also be required during your treatment to monitor your condition and to determine the effectiveness of treatment.
- The frequency of blood tests depends on what other medicines you are taking and what other illnesses you might have. Your rheumatologist will determine the frequency of tests required.

