PATIENT INFORMATION ON
ADALIMUMAB

[Add-a-LIM-you-mab]

(Examples of brand names: (Amgevita, Hadlima, Humira, Hyrimoz, Idacio)

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 <u>will</u> have to monitor your condition**
- **other precautions you should take while you are taking adalimumab.**

Please read it carefully and discuss it with your doctor.

IMPORTANT THINGS TO REMEMBER

- You must see your rheumatologist regularly to make sure the treatment is working and check for possible side effects.
- You should have regular blood tests as suggested by your rheumatologist.
- It is important to tell your rheumatologist if you have a new serious illness such as a serious infection, cancer or heart failure.
- If you are worried about any side effects, you should contact your rheumatologist as soon as possible.
- If you stop adalimumab for any reason, you must contact your rheumatologist. Failure to do so may mean that your treatment may no longer be funded.
- If you plan to become pregnant, you must discuss the timing with your rheumatologist

For more information about inflammatory conditions associated with arthritis, see Arthritis Australia's website:
www.arthritisaustralia.com.au

What is adalimumab?

Adalimumab belongs to a class of medicines called **biological disease modifying antirheumatic drugs (biological DMARDs or bDMARDs). Specifically, it is a TNF inhibitor.**

bDMARDs have now been given to over a million people worldwide since their first use in the late 1990s.

These medicines block substances, produced by arthritic tissues, called cytokines. These cytokines are found in excessive amounts in the blood and joints of people with rheumatoid arthritis, psoriatic arthritis, juvenile arthritis and ankylosing spondylitis.

They 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 lessens inflammation, pain symptoms and helps stop further joint damage.

What benefit can you expect from your treatment?

You may notice lessening of joint swelling, pain and stiffness, often within the first 8 weeks of starting.

Stopping adalimumab

If you stop or delay your adalimumab treatment, you may worsen again. Keep on your treatment, unless told by your rheumatologist to stop or unless side effects occur (see *Side effects*).
If you stop adalimumab for any reason, you **<u>must</u>** contact your rheumatologist.

Failure to do so may mean that your treatment may no longer be funded.

Brands of adalimumab

There are also biosimilar adalimumab medicines. A biosimilar is a version of adalimumab that has been shown to have similar benefits and safety as the original brand. You should not switch between different brands of adalimumab unless told to do so by your rheumatologist. Make sure

you are given the same brand each time. If you need to change brands, your rheumatologist will advise you and will check for side

How will you be checked while on adalimumab?

- Medicines like adalimumab are very expensive and highly funded by Medicare. Certain conditions must be met to receive it.
- Adalimumab will only be given if your disease is active and if standard treatments have not worked.
- It will only be kept going if it helps your condition. This must be checked between 12 and 16 weeks after the start of treatment.
- Blood tests are needed during your treatment to watch for side effects and decide if the treatment is working.
- How often you have blood tests will depend on what other medicines you are taking and what other illnesses you might have. Your rheumatologist will advise on this.

How is adalimumab taken?

Adalimumab is injected under the skin of the abdomen or thigh. It comes in a pen or a syringe injection.

It can be injected by your doctor, nurse, carer or by you. If injecting yourself, be sure to follow the detailed instructions carefully to ensure the best response. It is particularly important to change where you inject each time.

What is the dosage?

The usual dose for adults with arthritis is 40mg once every two weeks.

Can other medicines be taken with adalimumab?

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)
- simple pain medicines such as paracetamol.

Adalimumab cannot be used with other bDMARDs.
There are separate information sheets for the medicines mentioned above.

Are there any side effects?

You might experience side effects with your treatment. Contact your rheumatologist if you have any concerns about possible side effects. Many side effects disappear when adalimumab treatment is stopped.

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 and/or leaving the medicine out of the refrigerator for 30 minutes before injecting.
- Headaches, cough, stomach and bowel discomfort may also occur.
- As adalimumab affects the immune system, mild infections, mainly the upper respiratory tract (e.g. colds, sinusitis) may occur more often. Treatment with adalimumab may need to be briefly stopped for a serious infection so contact your rheumatologist for advice.

Less common or rare possible side effects

- Serious infections such as tuberculosis (TB) are seen rarely, and screening for TB is needed before treatment begins.
- Rarely, adalimumab may cause an allergic reaction with itchy, red skin, a rash or a feeling of tightness in the chest and trouble breathing.
- Side effects involving the nerves, such as inflammation of the nerve to the eye, may also occur rarely, causing changes in vision or sensation.
- Very rarely ‘drug-induced lupus’ has occurred with symptoms of rash, fever and increased joint pain.
- Annual skin checks are suggested with any medications that can suppress the immune system as there is a slight increase in risk in skin cancers. To date research and use over 20 years, have not shown an increase in risk of other cancers.

What precautions are necessary?

Infections

- If you have a current infection of any kind treatment with adalimumab should not be given until the infection is treated.
- You will need some blood tests and a chest X-Ray to exclude some chronic infections before your first bDMARD.

Use with other diseases

Worsening may occur of the following conditions:

- multiple sclerosis
- moderate to severe heart failure.
- systemic lupus erythematosus (lupus/SLE) People with SLE are not often given adalimumab but each case will be assessed whether safe by your rheumatologist

Use with other medicines

Adalimumab can interact with other medicines. You should tell all your doctors about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines.

Vaccines

- If you are taking adalimumab you should not be immunised with 'live' vaccines such as: MMR (measles, mumps and rubella), Varicella vaccines (Chicken pox/Shingles), OPV (oral polio virus), BCG (Bacillus Calmette Guerin), Japanese Encephalitis or Yellow Fever. Talk with your rheumatologist before receiving any vaccines.
- Pneumococcal vaccines and the yearly seasonal flu vaccinations are encouraged.

For more information on vaccination including the COVID-19 vaccination go to the ARA website; https://rheumatology.org.au/ patients, medication information, vaccinations.

Surgery

- If you need surgery for any reason, adalimumab should be stopped before surgery. It can start again after the operation at a time decided by your surgeon and rheumatologist (often once the wound has healed there is no infection).

Use with alcohol

- You may drink alcohol while taking adalimumab. If you are also taking methotrexate you should be cautious about how much alcohol you drink.

Use in pregnancy and when breastfeeding

- It is important to discuss with you doctor if you are planning a pregnancy while on adalimumab.
- It may be used in pregnancy and in men trying to father a child.
- If adalimumab is kept going beyond 4 months of pregnancy it may increase the risk of infection in the newborn when live vaccines may be due. Therefore, vaccines such as Rotavirus should not be given before the baby is 6 months old. MMR may be given at 6 months.
- There is only limited information regarding adalimumab in breast milk and while small amounts may occur, it does not seem to be harmful.

More detailed information is available at: https://rheumatology.org.au/gps/documents/ARAPrescribersinfoonmedicationsinpregnancy27Apr21_Final.pdf

How to store adalimumab

- Adalimumab *should normally be kept refrigerated. If needed, for example when travelling, it may be stored below 25°C for up to 2 weeks and then used or discarded.*
- Keep all medicines out of reach of children.

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details

You should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.

How to help us help you

Sign up to the ARAD project now!

The Australian Rheumatology Association collects information on how well these drugs work and how often they cause problems.

The best way to get this information is from you!

Contact us in any of the following ways:

Email: ARAD@monash.edu
Telephone: 03 9508 3424
Visit our website: www.ARAD.org.au