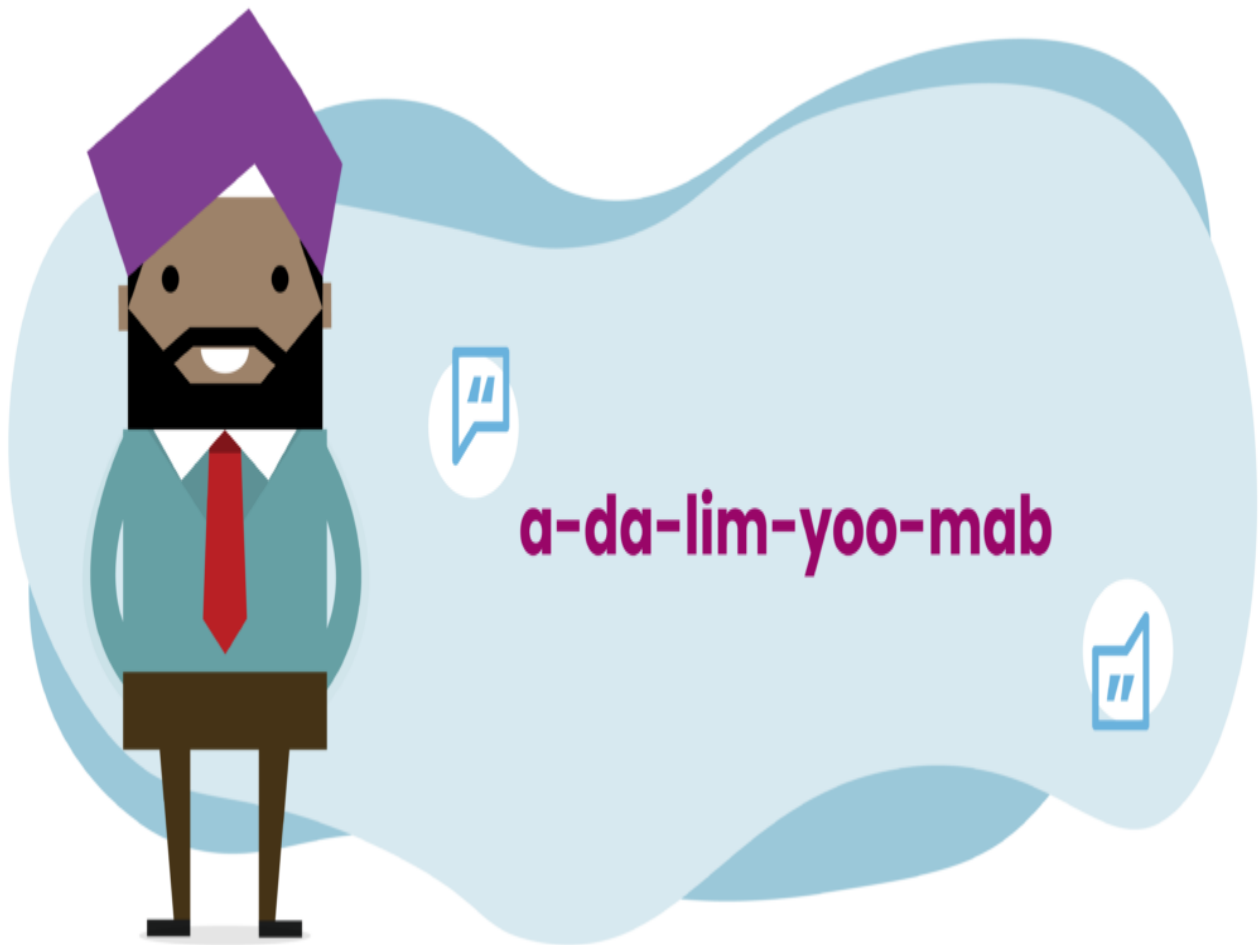


Resource

Adalimumab

Adalimumab is a 'biologic' drug. Biologic drugs are often referred to as 'targeted therapies' because they work on specific cells of the immune system. Adalimumab works on the TNF α cells.

[Print](#)



Name of Drug

How the
drug is taken

How it works

Blood tests

Adalimumab (ADA)
Amgevita – Amgen
Prefilled syringes 40mg
or 20mg
Prefilled pen 40mg

Humira – Pfizer
Prefilled syringe or pen
20mg, 40mg, 80mg

Syringe or
pen

Reduces over activity of the
immune system by
targeting TNF? cells

Mandatory – every
3 months initially

Hyrimoz – Sandoz
Imraldi – Biogen
Prefilled syringe or pen
40mg

Adalimumab was originally only available as Humira (brand name manufactured by Abbvie). This is also described as the 'originator' (original version of the drug). In the last few years 'biosimilar preparations' have become available. These are permitted once the patent has expired on the original drug. The biosimilar preparations are copies of the originator although their preparation, how they are produced, for example volume of fluid that contains the drug may be different.

Biosimilars for adalimumab include:

- Amgevita – Manufactured by Amgen Ltd.
- Hulio – Manufactured by Mylan
- Hyrimoz – Manufactured by Sandoz Ltd
- Imraldi – Manufactured by Biogen

TNF? is an inflammatory chemical produced naturally as part of the immune system. In JIA, TNF? is present in excess in the lining of the joints causing pain, swelling, redness and heat, all of which are symptoms of inflammation.

Background

Adalimumab was made available for rheumatoid arthritis in 2003 and subsequently for JIA from 2008 and subsequently for JIA from 2008. The National Institute for Health and Care Excellence (NICE) produced guidance for use in 2015 which was further reviewed by National Health Service England (NHSE) in 2017. This guidance is also accepted in Scotland. Adalimumab can be prescribed alone if necessary but is often added to methotrexate and this combination is also prescribed for uveitis associated with JIA.

How long does adalimumab take to work?

The benefit from Adalimumab may take several weeks to be felt or seen (2-12 weeks)

When can adalimumab be prescribed?

Adalimumab can only be prescribed for children and young people according to strict guidelines by paediatric and adolescent rheumatologists or specialist nurses who have undertaken non-medical prescribing qualifications.

Adalimumab may be prescribed together with methotrexate; the drugs combined assist better control of symptoms and help to prevent the body developing antibodies to the adalimumab.

Adalimumab may be used on its own when the child or young person is no longer able to cope with the side effects of methotrexate. It is always worth trying a smaller dose of methotrexate which may be less likely to cause side effects but will still prove beneficial to prevention of antibody formation.

Prior to starting treatment, additional checks are needed to establish if there is any history of tuberculosis (as this can be re-activated by adalimumab) or hepatitis B or C (this can also be reactivated by adalimumab). A record is taken of the vaccinations completed and any other information the specialist team requires. Additional caution is required with children and young people in heart failure.

Whether you are a young person with JIA or the parent of a child with JIA, it is important that you understand the intended treatment and any possible precautions. Equally important is a discussion about the evidence of the benefits of Adalimumab and the need for ongoing research into the long-term unknown facts.

You may be invited to participate in a post-marketing registry. This is a database that stores information on the use of biologic drugs and helps to increase the knowledge of these treatments. There is more confidence in the benefit of a treatment when increasing numbers of patients take it for increasing lengths of time without significant side effects. The rheumatology team caring for you will discuss this in more detail.

Prior to Adalimumab being prescribed, the paediatric and adolescent rheumatology doctors may complete regulatory documentation called Blueteq. This is to ensure and monitor eligibility to the medication. Prescribing outside of this guidance requires an Individual Funding Request (IFR). If this is the case, the rheumatology team will discuss this with you.

How is adalimumab given?

Adalimumab is given as a subcutaneous (meaning 'under the skin' and often called 'sub-cut') injection with a pen device or syringe, every 2 weeks. There are various ways that this can be organised. For example:

- parent(s) where possible will be taught to give their child's injection
- the child/young person may attend the local hospital or doctor's surgery to have the injection
- the young person, once old enough, can be encouraged to learn to inject themselves.

The dose is dependent on the child or young person's weight:

- Under 30kg given 20mg alternate weekly
- Over 30kg give 40mg alternate weekly

The management of this treatment is always discussed in detail at the start. Regular blood test monitoring is required; the frequency of which will depend on the prescribing specialist's advice. Failure to attend for regular blood tests may result in treatment being stopped until a blood test has been undertaken.

The medicines may be supplied from your hospital pharmacy or delivered to you by a homecare company.

What are the possible side effects?

As with any medication, adalimumab has possible side effects, although it is important to remember that these are only potential side effects and may not occur at all.

Infections

Adalimumab, like other biologic drugs, has been associated with increased susceptibility to infections; sometimes these can be severe e.g. reactivation of tuberculosis or milder infections such as skin infections. Due to the risk of infection, tattoos and body piercings are not recommended.

Other possible side effects include:

- An increased risk of food poisoning, therefore careful hand hygiene and food preparation are essential
- Pruritis (itching), injection site reactions
- Nausea, tummy pain
- Hypersensitivity reactions such as rash, bronchospasm (mimicking asthma), angioedema (swelling of lips, tongue, around the eyes)
- Fever, headache, depression
- Blood disorders, bruising or looking pale
- Neurological disorders
- Lupus-like syndrome
- May increase the risk lymphoma or leukaemia, however, this is very rare

More information on side effects can be found in the patient information leaflet for Adalimumab or the individual biosimilar.

Remember to report any concerns about possible side effects to the doctors or nurses

Adalimumab with other medicines

There are currently no specific prescribed medicines to be avoided when taking Adalimumab, but remember to take care when using any other medications or complementary therapies (even if bought 'over the counter' for colds or flu). Remember to check with a doctor, nurse or pharmacist that they are safe to take with Adalimumab and any other medication taken.

Only one biologic drug is prescribed at any one time. Adalimumab (a biologic drug) alongside methotrexate (a disease-modifying anti-rheumatic drug, or DMARD) is a common combination.

Adalimumab and immunisation/vaccination

Live vaccines [measles, mumps, rubella (MMR), chickenpox, oral polio (NOT injectable polio), BCG, oral typhoid and yellow fever] cannot be given to anyone already taking adalimumab. If adalimumab has not yet been started it is important to seek advice on how long a gap to leave after having a live vaccine.

Flu vaccine is now available in two forms, an injection and a nasal spray. Unlike the injection, the nasal spray is a live vaccine. There is limited research evidence around live vaccines in people with a lowered immune system (due to their medication). It is therefore important to discuss with the healthcare team which of these options would be best.

Vaccination of close family members can help to protect someone with a lowered immune system.

Adalimumab and pregnancy

There is not enough research information to give advice that either pregnancy or breastfeeding are safe.

A man or a woman taking Adalimumab should use reliable contraception during treatment and for 5 months after the last dose before planning to start a family.

Remember to ask your doctor or clinical nurse specialist for any further advice.

Adalimumab and alcohol

Alcohol can be consumed when taking adalimumab. However, caution may be required when taking other medications alongside this drug, for example methotrexate. Please see our separate articles on other JIA medications.

Tips regarding adalimumab

- DO NOT ADMINISTER abatacept to a child or young person if they have a high temperature or

you are concerned they are unwell with an infection – seek medical advice from your GP or rheumatology team.

- Stay safe on Adalimumab by remembering to have regular blood test monitoring as advised by the consultant or clinical nurse specialist
- A single syringe or pen device should be removed from the fridge for 15-30 minutes before using, in order to bring it to room temperature as this will help to avoid any stinging at the injection site
- To ease injection site reactions, choose alternate thighs for the injections and by differing the actual site around the mid thigh region
- An injection site reaction that includes a rash or redness can be eased with a cold compress
- Storage should be in a refrigerator (2°C – 8°C) and the syringes kept in the outer carton in order to protect them from light. Do not freeze
- A single adalimumab pre-filled syringe or pen device may be stored at temperatures up to a maximum of 25°C for a period of up to 14 days. The syringe must be protected from light and discarded if not used within the 14-day period

Alert Cards: your rheumatology nurse should provide you with one of these. This indicates to health professionals that you are on a drug to suppress your immune system and reminds them to be extra-vigilant if you are unwell or having a surgical procedure or dental care where treatment may need to be temporarily delayed.

Tips for travelling with adalimumab

- Before travelling it is important to keep up to date with vaccinations
- Live vaccines (see above 'Adalimumab with other medicines') must be avoided. It is important to check whether any required vaccines are 'live' before booking a holiday
- Adalimumab can now be stored at room temperature (up to 25°C) for a single period of up to 14 days, which makes it easier to carry when travelling by air. It should not be refrigerated after this
- Both the company providing the medication and the airline can supply more information on travelling with Adalimumab
- Your healthcare team can provide you with a letter of authorisation to travel with this drug. Homecare delivery companies also supply letters for travel.

Updated: 24/12/2019