

Adalimumab Patient Information Leaflet

Adalimumab 20mg/40mg solution for injection in pre-filled syringe

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What is Adalimumab?

Adalimumab is a type of drug known as an anti-TNF (anti- tumour necrosis factor). In children and young people with inflammatory diseases a protein called TNF is overproduced in the body, causing inflammation and damage. Anti-TNF drugs block its action and so can reduce this inflammation.

Adalimumab is used in patients with Juvenile Idiopathic Arthritis with associated Uveitis who have not got better whilst taking Methotrexate.

Why is Adalimumab used for the treatment of Juvenile Idiopathic Arthritis with associated Uveitis?

Early results of a trial called SYCAMORE (A Randomised Controlled Trial of the Effectiveness, Safety and Cost Effectiveness of Adalimumab in Combination with Methotrexate in Patient's with Active Juvenile Idiopathic Arthritis Associated Uveitis) has shown that Adalimumab is beneficial in treating Juvenile Idiopathic Arthritis with associated Uveitis. Full results of the trial will be available when all data has been looked at.

How to use Adalimumab?

Adalimumab is given by subcutaneous (under the skin) injection every 2 weeks. The dose will be based on body weight (20mg for patients weighing <30kg or 40mg for patients weighing >30kg).

Adalimumab should be taken exactly as your Doctor or Pharmacist has told you. If you are not sure please check with your Doctor or Pharmacist.

Each vial is intended for a single dose to a single patient. Discard any remaining solution in vials.

Patients should continue to take Methotrexate whilst taking Adalimumab

What are the possible side effects?

Adalimumab has effects on the immune system (the body's own defence system) and therefore may make you more likely to develop infections. You should tell your doctor straight away if you develop any of the following:

- A sore throat
- A fever
- They develop chickenpox.
- Any other symptoms of infection
- If you have not had chickenpox and you come into contact with someone who has chicken pox or shingles

Chickenpox and shingles can be very severe in people who are on treatments such as Adalimumab and therefore you may need antiviral treatment immediately.

Very rarely, people taking Adalimumab may develop a condition called 'drug- induced lupus', which is usually mild. If this is the case then you would stop taking Adalimumab and the condition would usually disappear once the treatment has been stopped.

It is possible that there may be a slightly increased risk of certain types of cancer in patients using anti-TNF drugs. Such a link has not been proven but is the subject of current research. Please discuss this with your Doctor if you are concerned.

Adalimumab may cause a reaction at the injection site. You may experience redness, swelling or pain etc. These reactions are usually not serious.

How to store Adalimumab

Keep Adalimumab out of the sight and reach of children. Do not use Adalimumab after the expiry date. The expiry date refers to the last day of that month. Store Adalimumab in a refrigerator (2°C – 8°C) and do not freeze. Keep the pre-filled syringe in the outer carton in order to protect from light.

What does Adalimumab contain?

Adalimumab is a clear, colourless solution presented in a single-use glass vial for subcutaneous injection.

Adalimumab contains Mannitol, Citric acid monohydrate, Sodium citrate, Disodium phosphate dehydrate, Sodium dihydrogen phosphate dehydrate, Sodium Chloride, Polysorbate 80, Water for injections, Sodium hydroxide added as necessary to adjust pH.

Who is eligible for treatment with Adalimumab?

To be eligible for the use of Adalimumab for the treatment of uveitis children have to meet the criteria laid down in NHS England's commissioning policy which states that the uveitis has to be persistent and severe despite treatment with methotrexate (or alternative immunosuppressive agent if the child cannot tolerate methotrexate) and steroid eye drops.

Once on treatment with adalimumab, children have to be assessed at least every 3 months. If your child's uveitis has been controlled for 18 months on Adalimumab then your doctor will consider if it is appropriate to try stopping Adalimumab to see if the uveitis has gone into remission. At this stage a trial of withdrawal of Adalimumab is undertaken and depending on your child's response it may or may not be necessary to restart treatment.

What to do if your child has any problems whilst on this adalimumab?

If you have any concerns whilst your child is on treatment you should contact your child's rheumatologist, paediatrician or ophthalmologist. They will give you their contact details when your child starts treatment.