Adalimumab

to treat inflammatory bowel disease (IBD)

Gastroenterology Department Liverpool Hospital

Please read this booklet and discuss any concerns with your IBD doctor.





How does Adalimumab (Humira®) work?

Adalimumab is a medicine used to treat inflammatory bowel disease (IBD), such as Crohn's disease and ulcerative colitis, in people who have not responded well to other treatments.

How is Adalimumab given?

Adalimumab is given as an injection, via a prefilled syringe or single-use pen under the skin of the abdomen or thigh area and usually given once every 2 weeks. It may be administered by your IBD doctor or nurse, or with training by yourself or your carer. If the injection is given by yourself or your carer, follow the detailed instructions provided by the IBD nurse and use the equipment provided.

Adalimumab injections **must be refrigerated**. They may be given to you in a single-use prefilled syringe or an injection pen.

Patients will usually receive an initial dose of 160mg, followed by 80mg two weeks later. After these first two doses, the usual dose for adults is 40mg **once every two weeks**.

If you **miss a dose**, use it as soon as you remember unless it is almost time for the next scheduled dose. Do not take a double dose to make up for any doses missed.

Use of Adalimumab with other medicines:

Tell your doctor (including your local doctor (GP), specialists and others) about all the medicines you are taking or planning to take. These include over the counter and herbal or naturopathic medicines. When you see a dentist or other health professional, you should tell them about your medication and treatment plan.

Most vaccines can be given safely but live vaccines, such as MMR (measles, mumps and rubella) or varicella (chickenpox) and yellow fever are not recommended. Influenza and pneumococcal vaccinations are safe.

Discuss any vaccinations that you may require with your IBD doctor.

Blood Tests:

You will be required to have blood tests during your treatment to monitor your condition and to determine the effectiveness of treatment and possible side effects.

Infections:

If you have an active infection, treatment with Adalimumab may not be given until the infection is treated successfully. It is important that you see your local doctor (GP) as soon as possible if you develop an infection and to let your IBD doctor and nurse know.

Adalimumab should not be given if you have a certain type of infection, such as tuberculosis or HIV, as it is likely to make these conditions worse. Before starting Adalimumab, a test is required to see if you have had these types of infection.

If you have had a **Hepatitis B infection** before, treatment with Adalimumab may reactivate the infection. Your IBD doctor will discuss treatment options with you and whether Adalimumab is suitable for you.

Heart condition:

Adalimumab should not be given to people with moderate to severe heart

failure. You should discuss with your IBD doctor if you have a heart condition.

Pregnancy and breastfeeding:

Good control of your IBD is the most important key to being able to fall pregnant and have a subsequent healthy pregnancy. Data suggests no increase in foetal abnormalities in those babies of mothers who were on Adalimumab during pregnancy.

The decision to continue or discontinue Adalimumab before, during or after pregnancy should be discussed with your IBD doctor.

If Adalimumab is given during pregnancy, giving the infant live vaccines should be avoided for the first twelve months of life.

It is considered safe to breast feed if you are on Adalimumab. Only extremely small amounts of Adalimumab are excreted in breast milk.

Surgery:

If you require surgery for any reason, treatment with Adalimumab may need to be stopped prior to, or for a period after, surgery. The decision to continue or discontinue Adalimumab will be made between your surgeon and your IBD doctor.

What can you expect from Adalimumab?

Adalimumab works relatively quickly and some relief of pain and diarrhoea may be noticed within the first few weeks of treatment.

If Adalimumab 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 to stop. If you do experience side effects and cannot contact your IBD doctor or nurse, it is advised that you discontinue treatment and contact us as soon as possible.

What are the possible side effects?

Adalimumab may cause some unwanted side effects in some patients. For a full list of side effects, please refer to a product information leaflet.

Listed below are some potentially serious side effects that Adalimumab may cause:

Get emergency medical help immediately if you have:

- Allergic reaction such as rash, itching, trouble breathing, tightness in chest, swelling of lips or tongue.
- Lung problems such as shortness of breath.
- Liver problems such as abdominal pain, yellowing of the eyes or skin, white or clay-coloured stools, or dark-brown coloured urine.
- **Drug-induced lupus** such as rash, fever and joint pain. This usually disappears when Adalimumab is stopped.
- Nerve problems such as muscle weakness, fatigue and changes to vision.

Studies have suggested Adalimumab has been associated with a minor increase of the incidence of **lymphoma** (a cancer of the lymph glands), especially when used in combination with Azathioprine or 6-mercaptopurine. It should be noted that patients with long standing and active inflammatory diseases, such as IBD, may already have a higher

risk of developing cancers, making it difficult to estimate the risk of developing cancers in these patients. If you have any concerns, you should discuss them with your IBD doctor.

Call your local doctor (GP) immediately at the first sign of infection such as fever (over 38°C by oral thermometer), chills, cough or burning when you pass urine.

Some more common side effects include:

Mild pain, redness, swelling or itching at the site of injections are very common, up to 20% of patient may experience this, but it can be reduced by applying ice and/or steroid creams if prescribed by your IBD doctor, to the injection site.

Headaches, dizziness, coughs and stomach or bowel discomfort may also occur. If you are affected by headaches and/or dizziness, you should avoid driving or operating heavy machinery.

As Adalimumab affects the immune system, **mild infections** particularly of the upper respiratory tract (e.g. colds and flu) may occur more frequently than usual.

It is important that you report any side effects that you might experience to your IBD doctor or nurse as soon as possible.

Remember:

- Keep all medicines out of reach of children.
- Store Adalimumab in the refrigerator (2-8°C).
- You should be seen regularly by your IBD doctor to optimise treatment and minimise any potential side effects.
- Have your regular blood tests, as arranged.

- If you have any questions or concerns write them down and discuss them with your IBD doctor.
- If you go to another doctor or dentist for treatment, tell them you are taking Adalimumab.

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