

Taking adalimumab (Humira®) for inflammatory bowel disease (IBD)

The leaflet aims to give you information and answer your questions about taking adalimumab (Humira®) to treat your IBD. This leaflet should be read with the patient information sheet that accompanies the medication. If you have any questions or concerns, please speak to a pharmacist, doctor or nurse caring for you. Additionally, you will find the email address of the IBD advice line on the last page.

What is adalimumab?

Adalimumab (also known by the brand name Humira®), is used to treat moderate to severe, and active Crohn's disease and ulcerative colitis. It may be considered a suitable treatment when other drugs have not worked, were not tolerated, or are felt to be inappropriate, and when surgery is not considered the right option for you at this time. Adalimumab is given as an injection.

Research has shown that treatment with adalimumab can be effective in inducing and maintaining remission, as well as improving symptoms and quality of life in people with IBD.

How does it work?

Adalimumab is an antibody that binds to a protein in the body called TNF-alpha. TNF-alpha is produced by the body as part of its immune response, and its over-production is thought to be partly responsible for the inflammation seen in IBD. By binding to TNF-alpha and reducing its activity, adalimumab can help reduce the inflammation in IBD, and relieve symptoms.

How long will it take to work?

You may begin to feel better within a few days of your first dose, but for some patients it may take several months to feel a benefit. It is not possible to predict exactly how long adalimumab will take for you, and you should not be concerned if you do not feel a benefit after your first few injections.

How is adalimumab given?

Adalimumab is given as an injection under the skin (subcutaneous).

Your adalimumab treatment will be supervised by a specialist doctor experienced in the diagnosis and treatment of IBD. A nurse will train you to give the injections to yourself, and in some cases, it may be possible for someone else, such as a family member, to be trained to give you the injections.

Adalimumab comes ready-to-use in either a pre-filled syringe or a pre-filled injection pen. Most patients feel more comfortable using the pens and these are generally used at first. However, if you are having difficulties and would like to switch, that can be arranged. The injection is usually given under the skin of your thigh or stomach. It should not be given anywhere the skin is reddened, bruised or hard, and the new injection site should be at least 3cm away from any recent injection sites. If you use a syringe, the injection will take two to five seconds to give. If you use a pen it will take about 10 seconds.

What is the normal dose?

Adalimumab is supplied in 40mg doses. The usual adult induction (starting) dose is 160mg (four injections) followed by an 80mg (two injections) dose two weeks later. For ongoing treatment, the usual dose is then 40mg every other week. Depending on blood tests and your response to the drug, your doctor may increase the frequency of your dose to 40mg every week.

What should I do if I forget a dose?

If you miss a dose, inject as soon as you remember. Then take the next dose as you would have on your originally scheduled date. If you are unsure when to take your dose, contact the IBD team for advice.

Tips on injecting adalimumab

One of the most common side effects of adalimumab injections is pain at the injection site, sometimes with redness, itching and swelling. As adalimumab needs to be stored in the fridge, using the drug when it is at room temperature may help reduce this discomfort. We advise you to take the drug out of the fridge about 15 minutes before you use it. You could also apply an ice pack for two or three minutes to the area you are going to inject. If you do use an ice pack, place a light towel between it and your skin.

If you use the pre-filled syringe, some people find it less painful if they insert the needle quickly in a single motion and then inject the medicine slowly. If your skin hurts or is swollen after the injection, it may help to apply an ice pack or cold damp towel to the area for about 10 – 15 minutes.

How do I store adalimumab?

Adalimumab syringes/pens should be stored in a refrigerator (between 2°C and 8°C) and kept in the outer carton in order to protect them from light. Do not freeze. Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date stated on the label/blister/carton. The expiry date refers to the last day of that month.

When needed (for example, if you are travelling), a single adalimumab pre-filled syringe/pen may be stored at room temperature (up to 25°C) for a maximum period of 14 days – be sure to protect it from light. Once removed from the refrigerator for room temperature storage, the syringe must be used within 14 days or discarded, even if it is returned to the refrigerator. You should record the date when the syringe is first removed from refrigerator, and the date after which it should be discarded.

Do not throw any medicines away via wastewater or household waste. Ask your doctor or pharmacist how to throw away medicines you no longer want.

How long will I take it for?

Most patients will be treated with adalimumab for at least one year. Your treatment plan will need to be reassessed at least every 12 months, to check whether ongoing treatment with adalimumab is still right for you. Adalimumab may be stopped if you have significant side effects, or if you have not responded adequately when assessed 12 to 16 weeks from the start of treatment.

Should I take other IBD medicines with adalimumab?

Adalimumab is normally given in combination with other medicines that suppress the body's immune response (immunosuppressants), such as azathioprine, mercaptopurine, tioguanine or methotrexate. Sometimes a short course of steroids is prescribed to reduce your IBD symptoms.

Is it safe to take other medicines with adalimumab?

Adalimumab may interact with other medicines and should not be taken with the medicines anakinra or abatacept. Talk to your doctor or pharmacist if you are unsure about whether any medicines you are taking, or are planning to take, may interact with adalimumab. This includes any over-the-counter medicines and any herbal, complementary, or alternative medicines or therapies.

You should also tell any other doctor, dentist or health professional treating you that you are being treated with adalimumab.

What checks will I need?

Pre-treatment checks

We will need to carry out some tests before you start treatment with adalimumab, to check that it is suitable for you. The following will be organised for you

- blood test and chest x-ray for tuberculosis (TB)
- blood tests for HIV, hepatitis B and hepatitis C
- blood tests for full blood count, liver and kidney function

It is important to let a member of the IBD team know if you

- have a history of cancer
- have heart problems
- have a history of recurrent infections
- are pregnant, planning to become pregnant or are currently breastfeeding
- have ever had a disease that affects the nervous system, including any symptoms of numbness, tingling or vision problems

Ongoing checks during treatment

Once adalimumab has been started, you must have blood tests every three months. This monitoring ensures that your treatment continues to be safe and effective. Without these regular checks, we may not be able to continue prescribing your medicines. Your blood tests will be reviewed in our Virtual Biologics & Immunosuppressants Clinic (VBIC) and we will also arrange a face-to-face clinic appointment with you at least once a year.

Options for blood tests

- St Thomas' Blood Test Centre, ground floor. Monday to Friday, 7.30 to 17.45
- Guy's Outpatients Department, 2nd floor Southwark Wing. Monday **or** Wednesday 9am to 12.30pm
- Your GP's surgery

If you choose to have your blood tests at one of our hospitals, please contact the IBD nurses via email (see page 7) in order to request a blood form, and then let the nurses know when you have had the test completed.

If you choose to have your blood tests at your GP's surgery, you will need to arrange this directly with them. The tests required are FBC, U&Es, LFT, and CRP. Please ensure you forward any results to the IBD nursing team via the email provided.

It is your responsibility to cooperate with the IBD team to ensure that the necessary blood monitoring is carried out in a timely fashion.

Is there anything I need to be especially aware of while being treated with adalimumab?

Adalimumab affects the way in which your immune system works, so you may be more likely to get infections. If you are worried you have developed a significant infection please contact your GP or the IBD team.

You may also be at greater risk of becoming seriously ill from chickenpox, shingles and measles, particularly if you are also taking other immunosuppressants (for example, azathioprine, mercaptopurine or steroids). Contact the IBD Advice Line if you come into contact with anyone with these conditions, even if you do not feel unwell.

What are the most common side effects of adalimumab?

Like all drugs, adalimumab can cause side effects, but it is important to remember that many people taking it report no problems. Some side effects can happen almost immediately after the medicine is injected, while others may develop later. Most adalimumab side effects are mild and go away on their own, without the need for treatment or stopping the medicine. Others can be more serious and will require treatment, or may mean that adalimumab is no longer suitable for you. Some of the main side effects and symptoms are described below.

Immediate reactions

- **Reactions at the injection site** – such as pain, swelling, redness, bruising or itching. This is the most common side effect and happens to around one in 10 people. Your IBD nurse will be able to advise you on how to reduce this sort of reaction.
- **Allergic reactions** – rashes, hives, a swollen face, hands and feet, or **trouble breathing**. If any of these occur and don't disappear within a couple of hours you should seek medical attention from either your GP or local emergency department.

Other side effects

- **Increased risk of infections** such as colds and flu, as well as more serious infections such as pneumonia and septicaemia (infection in the blood). You may also be at greater risk of developing TB, or of reactivating underlying TB (this can happen even if your TB screening tests were negative). Symptoms of an infection often include fever, cough, excess sweating (especially at night), feeling very tired and/or losing weight. You may need to stop using adalimumab if you have an infection, but don't miss an injection without checking with a member of the IBD team first.
- **Skin reactions** such as psoriasis (scaly patches, often on the palms of hands or soles of feet), eczema or other types of rash can occur. Some of these can be treated without stopping adalimumab.
- There is a small increased risk of certain types of skin and other cancers, including lymphoma (cancer of the lymph glands). Taking immunosuppressive medicine (such as azathioprine or methotrexate) with adalimumab may also contribute to this increased risk. Because these cancers occur only very rarely it is difficult to know what the exact risk is.
- Rarely, hair loss can occur.
- Other very rare complications that have been linked to taking adalimumab include demyelination (damage to nerves) and some rare inflammatory conditions, such as lupus. These side effects are often reversible if the drug is stopped.

Seek medical attention **immediately** if you develop any of the following symptoms.

- A severe rash, hives (swollen red patches of skin) or other signs of allergic reaction
- Swollen face, hands and feet
- Trouble breathing or swallowing
- Shortness of breath
- Persistent fever, bruising or bleeding

It is best to let your pharmacist, doctor or IBD nurse know about any new symptoms you develop while on adalimumab, whenever they occur. Your IBD nurse should also be able to help with any queries and concerns.

Be sure to carry the alert card provided to you by the manufacturer at all times whilst on adalimumab and for four months after your last dose.

Can I have vaccines while on adalimumab?

Immunisation with live vaccines is considered unsafe and should be avoided while you are taking adalimumab. These include vaccines for polio, yellow fever, rubella (German measles), BCG (tuberculosis) and MMR (measles, mumps and rubella). The inactivated polio, flu and meningitis C vaccines are considered safe. If you need to have any vaccinations while you are being treated with adalimumab, please check with your doctor, nurse or pharmacist that they are appropriate.

The Department of Health recommends that everyone on medicines that affect the immune system (such as adalimumab) should have an annual flu vaccination. We advise that you contact your GP to arrange an annual flu vaccine, as well as a five-yearly pneumonia vaccination, while on adalimumab treatment

If anyone in your family or household is due to have a live vaccine, check with your IBD team whether you need to take any special precautions.

Does adalimumab affect pregnancy?

The evidence regarding the safety of adalimumab during pregnancy is growing. It has been found that adalimumab crosses the placenta in only very small amounts during the first and second trimesters (up to six months). However, during the last trimester (seven to nine months) of pregnancy, it readily crosses into the baby's blood stream. We have a great deal of experience of using adalimumab in pregnancy. We have not seen any significant problems for mothers or their babies when adalimumab is used in pregnancy. Research in this field is ongoing but currently there is no evidence to suggest that there are any long-term effects on babies born to mothers taking adalimumab.

Adalimumab has no known effect on the fertility of men, and there are also no concerns regarding fathering children while using it.

Babies born to mothers taking adalimumab should not be vaccinated with live vaccines until at least five months after the mother's last adalimumab injection during pregnancy. This is because adalimumab affects the immune response. It is important that any obstetricians and midwives caring for you and your baby are aware you are, or were, taking adalimumab.

Although the manufacturers recommend you should use adequate contraception while taking adalimumab, most IBD specialists feel that if the treatment is keeping your IBD under control, it is better to continue with it while trying to conceive and once pregnant. Your IBD team will discuss the risks and benefits of taking adalimumab while pregnant with you. You should also consider referring to the **BUMPS** leaflet, produced by the UK Teratology Information Service, as this is kept up-to-date and presents a balanced overview of the available information regarding risks versus benefits (www.medicinesinpregnancy.org/Medicine--pregnancy/Adalimumab/).

What about breastfeeding?

While tiny quantities of adalimumab may be present in breast milk, stomach acid will almost certainly destroy it so it is considered safe to breastfeed while using adalimumab. Although the manufacturer advises against breast feeding for at least five months after the last treatment, our department's current advice is to continue using adalimumab while breast feeding.

Can I drink alcohol while taking adalimumab?

Yes, it is safe to drink alcohol (within the amounts recommended by the Department of Health) while being treated with adalimumab.

How do I get a repeat prescription?

Prescriptions are organised through your IBD team at Guy's and St Thomas' but all supplies are delivered through a company called Healthcare at Home (HaH). You will receive your delivery of medication, and training to administer the injections, through this company. You should ensure your contact details are up to date at the hospital, as these are used to arrange deliveries. For any queries contact HaH Customer Service on 0333 103 9699 or email hahenquiries@hah.co.uk (Monday to Friday, 8am to 8pm or Saturday, Sunday and bank holidays, 8am to 4.30pm).

To ensure you continue to receive supplies, please ensure you comply with the blood test monitoring requirements as described on pages 3 and 4.

Useful sources of information

Crohn's and Colitis UK

w: www.crohnsandcolitis.org.uk – Information sheets, booklets and guides available for free.
Information Service **t:** 0300 222 5700, Monday to Wednesday and Friday 9am to 5pm, Thursday 9am to 1pm.

Contact us

If you have any questions or concerns about your treatment and condition, please contact the IBD Advice Line by email at ibdhelpline@gstt.nhs.uk or voicemail at **t:** 020 7188 2487. Please include your name, hospital number, contact details and the details of your enquiry. We will aim to respond to you by the end of the next working day, Monday to Friday. Out of hours, please contact NHS 111

The Gastroenterology department secretaries can also be contacted during office hours on **t:** 020 7188 2499 or **t:** 020 7188 1222 or via the main switchboard on **t:** 020 7188 7188.

For more information leaflets on conditions, procedures, treatments and services offered at our hospitals, please visit www.guysandstthomas.nhs.uk/leaflets

Pharmacy Medicines Helpline

If you have any questions or concerns about your medicines, please speak to the staff caring for you or call our helpline.

t: 020 7188 8748 9am to 5pm, Monday to Friday

Your comments and concerns

For advice, support or to raise a concern, contact our Patient Advice and Liaison Service (PALS). To make a complaint, contact the complaints department.

t: 020 7188 8801 (PALS) **e:** pals@gstt.nhs.uk

t: 020 7188 3514 (complaints) **e:** complaints2@gstt.nhs.uk

Language and Accessible Support Services

If you need an interpreter or information about your care in a different language or format, please get in touch:

t: 020 7188 8815 **e:** languagesupport@gstt.nhs.uk

NHS 111

Offers medical help and advice from fully trained advisers supported by experienced nurses and paramedics. Available over the phone 24 hours a day.

t: 111

NHS Choices

Provides online information and guidance on all aspects of health and healthcare, to help you make choices about your health.

w: www.nhs.uk

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