PATIENT INFORMATION LEAFLET

ADALIMUMAB

WHAT ARE THE AIMS OF THIS LEAFLET?

This leaflet has been written to help you understand more about adalimumab. This medicine may also be referred to by its brand names, which include Amgevita®, Hulio®, Humira®, Hyrimoz®, Idacio® and Imraldi®. It tells you what it is, how it works, how it is used to treat skin conditions, and where you can find out more about it.

WHAT IS ADALIMUMAB AND HOW DOES IT WORK?

Adalimumab is a biologic medicine. Biologic medicines are made using living cells, designed to reduce inflammation by acting on the immune system. They are used to treat inflammatory skin conditions including psoriasis and hidradenitis suppurativa. Adalimumab specifically targets a chemical messenger (known as a 'cytokine') in the body. This cytokine is called 'tissue necrosis factor alpha' (TNFα). We know that TNFα is one of the main causes of inflammation in some skin conditions. By blocking it adalimumab can improve symptoms in those conditions.

WHAT SKIN CONDITIONS ARE TREATED WITH ADALIMUMAB?

Adalimumab has been designed to treat a number of inflammatory conditions. This includes inflammatory skin conditions, such as:

- psoriasis
- hidradenitis suppurativa

Psoriatic arthritis is a type of arthritis that can be linked with psoriasis and can also be treated with adalimumab.

WHY HAVE I BEEN SELECTED FOR TREATMENT WITH ADALIMUMAB?

The use of adalimumab is reserved for a severe enough condition to require treatment based on national guidelines.

Usually, this is because your condition has not improved with other standard treatments. Alternatively, there may be safety reasons why you cannot receive other standard treatments, or they may have been tried but caused you problems, so you had to stop them.

HOW LONG WILL I NEED TO TAKE ADALIMUMAB BEFORE IT HAS AN EFFECT?

Adalimumab does not work immediately and can take around 3 to 12 weeks before you notice any benefit. For example, in clinical trials, more than 30 out of 100 patients with psoriasis were clear or nearly clear of psoriasis by 4 months. If you are taking adalimumab for another skin condition, then your doctor will be able to give you more information on when you can expect to see a benefit.

HOW DO I TAKE ADALIMUMAB?

Adalimumab is given as an injection under your skin (subcutaneously) using a pre-filled pen or pre-filled syringe device. A nurse or doctor will teach you how to use the pen or syringe to inject yourself, and details are also given in the package leaflet. Injections are made under the skin of the stomach, thighs or upper outer arms. You will be provided with a special bin so that you can dispose of your injections safely.

Adalimumab must be stored in a refrigerator (between 2 to 8°C). Keep the

pre-filled syringe in its outer carton in order to protect it from light.

If you are travelling with your treatment, you should have a cool box or cool bag with icepacks to maintain the recommended temperature. Once adalimumab has been removed from the refrigerator and has reached room temperature (up to 25°C), it may be kept at room temperature for a single period of between 14 to 28 days depending on the brand (see product packaging leaflet for more information). After this, it must either be used or thrown away – it should not be put back in the fridge.

HOW SHOULD I TAKE ADALIMUMAB?

Each syringe or pen contains either 20 mg, 40 mg or 80 mg of adalimumab. Therefore, depending on the skin condition being treated you will need to inject either:

- Psoriasis: you will have **an initial dose of 80 mg** (this could be made up of two 40 mg injections or one 80 mg injection). **Then 1 week later** you will have **ONE 40 mg injection**, and thereafter you will continue with **ONE 40 mg injection every 2 weeks**. If the treatment is effective, it can be continued in the long-term to control psoriasis. However, if not, your dermatologist may recommend a higher dose or more frequent injections after 16 weeks of treatment.
- Hidradenitis suppurativa: you will have an **initial dose of 160 mg** (which can be made up of four 40 mg injections or two 80 mg injections and can be split over 2 days). Then **2 weeks after** you will have an **80 mg dose** (this could be made up of two 40 mg injections or one 80 mg injection) **and then 2 weeks after this** you will begin your maintenance dose of **ONE 40 mg injection ONCE a week**. If the treatment is effective, it can be continued in the long term to control your hidradenitis suppurativa.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF ADALIMUMAB?

Most of the side effects reported during clinical trials of adalimumab were mild, easily manageable, and did not require discontinuation of the treatment.

Mild

Reactions at the injection sites are usually mild and include redness, a rash, swelling, itching, or bruising. They usually go away within 3 to 5 days. If you have pain, redness or swelling around the injection site that doesn't go away, or gets worse, contact your dermatologist.

- Cold and flu symptoms, sore throat
- Sinus infection (sinusitis)
- Urinary tract infections
- Mild fungal infections such as athlete's foot
- Skin infections (cellulitis)
- Cold sores (herpes simplex infections)
- Nausea
- Headaches (including migraine), dizziness
- Rashes, itching (pruritus)

Potentially severe

Fewer than 2 out of every 100 individuals treated with adalimumab experience a serious adverse effect in the first 3 to 4 months of treatment.

Serious infections. Adalimumab may decrease your ability to fight infection. Your doctor will ask you about any current or past infections (particularly tuberculosis), or if you are prone to infections such as cold sores or urinary tract infections. If you develop any symptoms of tuberculosis (for example, a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor. Your doctor will also ask if you have or have ever had any disease that affects your immune system, such as cancer, human immunodeficiency virus (HIV) infection or viral hepatitis. It is advisable to avoid close contact with anyone with a bad cold,

influenza or chest infections, and wash your hands frequently during the course of treatment.

Allergic reactions. It is possible that some patients could experience an allergic reaction to adalimumab. Severe reactions requiring emergency treatment (for example, anaphylaxis) are very rare.

Blood problems. Some patients taking adalimumab may be unable to produce enough of the blood cells that help to fight infections or to stop bleeding.

Nervous system conditions. Adalimumab has rarely been reported to cause problems with the nervous system. Symptoms of this include numbness or tingling; problems with vision; weakness in the arms and/or legs; and dizziness. You will be asked if you have experienced any of these symptoms or have been affected by a neurological condition, such as multiple sclerosis, Guillain-Barre syndrome or have experienced seizures. If you have, adalimumab may not be appropriate for you.

Liver problems. Rarely patients taking adalimumab may experience inflammation of the liver (hepatitis). Your dermatologist will monitor your liver enzymes as part of your routine blood tests while on this treatment. If there are small increases in liver enzymes, you will not necessarily need to stop taking the medication.

Heart problems. Your dermatologist will ask you if you have ever been treated for heart failure. If you have, adalimumab may not be appropriate for you.

Lupus-like reactions. Some people taking adalimumab and other medicines which block TNFα have developed symptoms (such as rash and joint pains) that resemble lupus erythematosus, and these usually go away when treatment is stopped.

Cancers: Biologics affect parts of the immune system. Careful safety studies have been ongoing over recent years to check if these drugs increase the risk of cancer. So far, these studies are reassuring and do not show any increase in risk of cancer. We advise everyone, including people taking biologics, to participate in appropriate cancer screening programmes, which can be accessed via your GP. You should also wear sunscreen and regularly check your skin for any new spots or changes in freckles or moles. Ask your dermatologist if you have any concerns about this.

HOW CAN THE RISK OF SIDE EFFECTS BE MINIMISED?

Before you start taking adalimumab, you will have a thorough consultation with your dermatologist/team including a clinical examination and a number of blood tests. Additional investigations may be required depending on your medical history (for example, a chest Xray or other imaging).

Your dermatologist will go through the below checklist. These situations do not necessarily mean that you cannot be treated with adalimumab but may mean that other precautions are needed for you to have this treatment safely. Your dermatologist would discuss your individual situation and explain more about this.

- *Tuberculosis* or close contact with someone who has had it.
- *Hepatitis or an HIV infection*, or if you think you are at risk of having these.
- *Infection and vaccination history.* If you are scheduled to have *any type of vaccination.*
- *Numbness or tingling* or a condition that affects your nervous system like multiple sclerosis.
- If you are being treated for *congestive heart failure*
- If you are scheduled to have *major surgery*.
- If you are *pregnant* or *breastfeeding* or are *planning a family*.

You are encouraged to take part in any *National Health screening programmes* at the routine time points recommended (for example, with cervical smears, mammograms).

During your treatment with adalimumab you will be asked about side effects and have blood tests from time to time (for example every 6 months) at your clinic appointments. Keep your own doctor and/or your dermatology team informed at all times of changes to your medications, planned procedures and surgery or health problems including:

- If you get an infection, or any symptom or sign of an infection that doesn't go away, including fever, lethargy, cough, influenza-like symptoms, burning on passing urine, dental problems, night sweats. Your dermatologist may suggest stopping adalimumab temporarily.
- If you bruise or bleed very easily or look very pale.
- If you develop swelling of your feet or have shortness of breath when active or when lying down.
- If you experience numbness or tingling; problems with vision; weakness in the arms and/or legs; and dizziness
- If you develop signs of a severe allergic reaction, such as a swollen face/tongue, throat tightness or difficulty with breathing (known as anaphylaxis), dial 999 for an ambulance immediately and go to a hospital Accident and Emergency department. Afterwards you should make sure that your dermatologist has been informed.

WHAT WILL HAPPEN IF I NEED AN OPERATION OR DENTAL SURGERY?

Adalimumab comes under the category of an 'immune suppressant' and therefore may increase your risk of getting an infection after a surgical procedure. For planned procedures, you may be advised to stop adalimumab prior to the surgery. Please discuss this with your doctor or dentist.

CAN I HAVE IMMUNISATIONS (VACCINATIONS) WHILST ON ADALIMUMAB?

People on adalimumab treatment should not get vaccinated with 'live' vaccines. These include:

- the flu vaccine administered through the nose
- measles, mumps and rubella (MMR)
- yellow fever
- Bacillus Calmette-Guérin (BCG)
- rotavirus
- oral typhoid
- varicella (chickenpox)
- herpes zoster (shingles).

If you require immunisation with a live vaccine, you should stop adalimumab for at least 12 months before getting vaccinated. You should then wait for 4 weeks after the vaccination before you can restart adalimumab treatment. You will be able to discuss this further with your dermatology team.

'Inactivated' vaccines are safe and recommended. Some examples include Pneumovax, the COVID-19 vaccine and the annual flu vaccine administered by injection.

Shingrix® is an inactivated version of the shingles vaccine. Further information is available in the British Association of Dermatologists patient information leaflet on shingles.

Keep up to date with COVID-19 vaccine schedules according to national policy.

It is important to always discuss your immunisation plan with your healthcare professional. You must always inform them that you are on adalimumab treatment.

DOES ADALIMUMAB AFFECT PREGNANCY?

Use of adalimumab in pregnancy has been studied in more than 1,500 women. There is no suggestion that adalimumab affects a baby's development, but ongoing data collection is ideally required to confirm this. Therefore the manufacturer advises that women of childbearing potential should consider the use of adequate contraception to prevent pregnancy and continue its use for at least 5 months after the last adalimumab treatment.

Adalimumab used in later pregnancy can potentially affect the baby's immune system for up to six months after birth. Live vaccines in the baby should be avoided during this time.

No effects on the breastfed newborns/infants are expected. Therefore, adalimumab can be used during breastfeeding.

CAN I TRAVEL ABROAD WHILE TAKING ADALIMUMAB?

Please discuss with your dermatologist if you are planning to travel abroad. Depending on where you are travelling, precautions may need to be taken against infections. Depending on the length of your travel plans, you may need a cool box to take the medication with you.

MAY I DRINK ALCOHOL WHILE TAKING ADALIMUMAB?

There is no known interaction between alcohol and adalimumab.

CAN I TAKE OTHER MEDICINES AT THE SAME TIME AS ADALIMUMAB?

Most medicines are safe to take with adalimumab. However, it is important that your GP and other doctors are aware that you are taking it, especially if any new drugs are prescribed. Your GP and dermatologist should be aware of all your medications, including your over-the-counter ones, and supplements, including herbal medicines. Methotrexate can be taken along with adalimumab. However, you should not take any other immunosuppressives (medicines which suppress the immune system) while you are on adalimumab.

The BAD Biologic Interventions Register (BADBIR)

You may be asked to take part in a national register if you are prescribed a biologic medication. This register will collect valuable information on side effects and benefits of the drug. It will also inform doctors on how best to use biologic drugs. No information will be passed to the register without your informed consent.

WHERE CAN I GET MORE INFORMATION ABOUT ADALIMUMAB?

This information sheet does not list all of the side effects of adalimumab. If you wish to find out more about adalimumab, or if you are worried about your treatment, please speak to your doctor, specialist nurse or pharmacist.

For further details, refer to the drug information sheet which comes as an insert with your prescription for adalimumab.

This leaflet aims to provide accurate information about the subject and is a consensus of the views held by representatives of the British Association of Dermatologists: individual patient circumstances may differ, which might alter both the advice and course of therapy given to you by your doctor.

This leaflet has been assessed for readability by the British Association of Dermatologists' Patient Information Lay Review Panel

BRITISH ASSOCIATION OF DERMATOLOGISTS

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