

OMALIZUMAB



WHAT ARE THE AIMS OF THIS LEAFLET?

This leaflet has been written to help you understand more about omalizumab. It explains who it is for, how it works, how it is used to treat skin conditions and where you can find more information.

WHAT IS OMALIZUMAB AND HOW DOES IT WORK?

Omalizumab is a drug that has been specially designed to resemble normal chemicals in our blood stream, and for this reason it is called a “biologic” drug. It mops up the natural antibodies (proteins in our blood stream) called IgEs which are responsible for allergic reactions and fighting against parasites. Omalizumab prevents IgEs from releasing histamine (the chemical that makes you itchy and gives you hives).

WHO IS OMALIZUMAB FOR?

Omalizumab is for people with severe urticaria or hives that has not got better with high doses of antihistamine drugs. Please see the British Association of Dermatology information leaflet on [urticaria and angioedema](#) for more information. Omalizumab is an add-on therapy, antihistamines should be continued at the same time. Your dermatology team will ask you to complete a 7-day diary of the severity of your itch or hives to see if it is bad enough to start omalizumab.

HOW IS OMALIZUMAB GIVEN?

Omalizumab is injected into the fat under the skin (subcutaneous) using either a pre-filled syringe or pen device.

In adults and young people of 12 years and over, a 300 mg dose of omalizumab is given

every 4 weeks. Once you have had 6 doses (after around 6 months) the course of treatment is complete.

You can receive the treatment at the hospital, or you can be trained to self-inject at home. A healthcare professional will teach you how to use the pen device to inject yourself, and details are also given in the package insert. In this case you will receive the first few doses at the hospital and can then continue the course of treatment at home if you wish.

After you receive your first dose, you will be monitored for 1-2 hours. This is to watch for any signs of an allergic reaction. After the 2nd and 3rd doses, you will be monitored for 30 minutes.

Please note that if you self-inject at home, you will not be monitored.

You will be assessed by your dermatology team, at or before your fourth dose to check that the urticaria or hives are getting better. The injections will be stopped at this point if there is no improvement.

If the urticaria comes back, and does not respond to standard treatment, omalizumab can be restarted once you have answered the questions again on the UAS7 score sheet. You do not need to be assessed after the fourth dose if you are having additional courses, and can have the entire 6-month course.

WHICH CONDITIONS ARE TREATED WITH OMALIZUMAB?

Omalizumab is used to treat patients 12 years or older with urticaria. It is also used to treat asthma.

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

You may notice an improvement in the itching and the rash within days, but some people take longer to respond. Clinical trials reported that half of the participants are much better after the third treatment.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF OMALIZUMAB?

Common and mild side effects include headache, abdominal pain, fever, joint pain and injection site reactions (bruising, swelling, **redness**, pain, warmth, stinging, itching). 'Common' means about 1 in 20 people. The side effects are usually mild and do not stop people continuing the injections.

Less-common side effects include flu-like symptoms, heart burn, nausea, diarrhoea, worsening urticaria or hives, coughing, fainting, flushing, and increased risk of parasitic (bugs) infection (patients who are planning to travel abroad or have been in areas with increased risk of parasitic infestation are advised to tell their dermatology team).

Anaphylaxis with angioedema (a swelling under the skin) is a serious allergic reaction which can **very** rarely occur after the injection, often within the first 2 hours. You are at a higher risk of this reaction if you have had previous anaphylaxis or if you have asthma.

You should inform your dermatology team or nurse if you notice any of the following during or immediately after your injection:

- itching or rash
- swelling
- difficulty in breathing or swallowing
- dizziness or faintness
- an upset stomach
- blurred vision

- chest pain
- fever or chills.

I AM PLANNING TO HAVE AN OPERATION OR DENTAL SURGERY – WHAT SHOULD I DO?

There are no reported cases of omalizumab affecting any local or general anaesthetics and so it is safe. However, it is important you inform your dermatology team or dentist that you are having urticaria treatment using omalizumab. The drug does not influence wound healing nor increase your risk of infection after your operation.

HOW WILL I BE MONITORED DURING TREATMENT?

Omalizumab is a very safe medication, but you will be observed initially after your first few injections. No routine blood tests are required. Before or when you have your fourth dose in your first course of treatment, the dermatology team will ask if the therapy is working (please see the section 'How is omalizumab given?' above).

DOES OMALIZUMAB AFFECT PREGNANCY?

Omalizumab has not been tested in pregnant women or nursing mothers so its effects on unborn children or babies being breast fed are unknown. There are reports of asthma patients who have continued low dose omalizumab during pregnancy and had no complications. Please inform your dermatology team if you are planning a pregnancy or become pregnant. Omalizumab does cross the placenta and therefore the baby can be exposed to the drug.

MAY I DRINK ALCOHOL WHILE I AM TAKING OMALIZUMAB?

It is safe to drink within the nationally recommended guidelines.

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



Most medicines are safe to take with omalizumab. It is important your dermatology team (GP) is aware that you are having this treatment. Please consider checking with your dermatology team before starting new medications if you are concerned.

WHERE CAN I GET MORE INFORMATION ABOUT OMALIZUMAB?

For further information about omalizumab, including a complete list of side effects, read the product information sheet which comes with the medicine. If you have any questions about your treatment, you should consult your dermatology team or pharmacist.

National charity and patient support group:

Allergy UK: <https://www.allergyuk.org/types-of-allergies/urticaria-hives-other-skin-allergy/>

Other sources of information include the NICE website:

<https://www.nice.org.uk/guidance/ta339>

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

PATIENT INFORMATION LEAFLET

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