



Omalizumab treatment of chronic spontaneous urticaria (CSU)

Information for patients from the Department of Allergy and Immunology

What is Omalizumab?

Omalizumab is used to treat CSU in patients who:

- · are 12 years of age and over; and
- have not responded to high doses of antihistamine and other medications.

Omalizumab is a commercially produced antibody. It blocks immunoglobulin E receptors on mast cells, the main histamine producing cells of the body.

How does it work?

We do not fully understand how Omalizumab works. However, we do know it binds the IgE allergic antibody and prevents the mast cells from becoming activated.

How is it given?

Omalizumab can be given as two 150mg prefilled injections in hospital. The injections are given under the skin, usually in the upper outer arms (deltoid region).

If you want, we can show you how to inject yourself (self-administer) in your abdomen (tummy area).

Injections are given once every 4 weeks to complete a course of 6 months. After 6 months we will review your condition.

Do I need to wait in the clinic after my first injection?

Yes. You will be asked to wait in clinic for 1 hour following your first injection. This is so we can check that you are not allergic to the Omalizumab. Your specialist nurse will do this by checking your pulse and blood

pressure, before they discharge you from the clinic.

What is a treatment course?

A treatment course is usually 6 doses given every 4 weeks.

Your response to the treatment is usually assessed after your 3rd dose. This will determine whether the further 3 injections are given.

In order to assess your response, it is important that you complete a symptom diary during treatment. This will allow us to accurately assess your response to the treatment.

After receiving 6 doses you have a follow-up appointment 8 weeks after your last dose. This appointment may be at the hospital or over the phone.

When can I expect my symptoms to improve?

It can take days to several weeks for your symptoms to improve. It is not possible to predict who will or will not respond. Most patients will have a good response.

Are there any side effects?

Although Omalizumab is a safe treatment, some side effects have been reported. Most information comes from patients receiving Omalizumab for asthma. Asthma patients are given a higher dose than patients treated for urticaria.

- Less than 1 in 100,000 patients can have a severe allergic reaction called anaphylaxis. This may occur soon after your first injection. Anaphylaxis can affect breathing and cause low blood pressure. If this happens you will need urgent medical attention. This is why we need you to stay in the clinic for 1 hour after your first dose.
- More commonly, some patients experience redness and swelling at the injection site.
- A small number of people have reported the following symptoms.
 - Headache
 - Sinus problems
 - Fatigue (feeling very tired)
 - Dizziness
 - Tummy pain
 - Diarrhoea (poo is loose / runny and watery).
- Folliculitis and hair loss have been reported. Folliculitis is a common skin condition that happens when hair follicles become inflamed.

If you have any concerns about theses side effects, please talk to your specialist nurse.

What do I do if I feel unwell after leaving the clinic?

- Do not worry about minor symptoms, such as headache or tummy discomfort, these will settle.
- If you develop a mild rash, take an antihistamine tablet. Examples of antihistamine tablets include Piriton, cetirizine, or loratadine.
- If you have more serious symptoms, call 999 immediately. These symptoms include:
 - · difficulty breathing
 - chest pain
 - · throat or tongue swelling; or
 - o feeling faint.

Do I have to have all my injections in hospital?

No, NICE licensed Omalizumab for home therapy in 2018. NICE is the National Institute of Health and Clinical Excellence.

Who can have home therapy with Omalizumab?

Each patient wishing to start home therapy will be assessed individually. Some of the assessment criteria include the following.

- Your first course of treatment will include at least 2 doses of the injections. These injections will be given under the supervision of a healthcare professional in hospital.
- You must show that you can self-inject safely, following training by a healthcare professional.
- You must not have had a hypersensitivity (allergic) reaction to the injections.
- You must be trained to recognise side effects, including serious allergic reactions. Serious allergic reactions at home are rare, as most patients will display symptoms after their first dose in hospital. This is why we need to monitor you for 1 hour after your first dose in hospital.

Do I have to have home therapy?

No, this is your decision. Your choice will not affect your care.

Can my relative or friend administer the treatment?

Yes. As long as they have received the training and have the competency to administer your treatment.

Can I continue having Omalizumab indefinitely?

Each course of treatment is decided against criteria agreed by NICE. Currently there are no limitations on the number of courses of Omalizumab.

Can I continue with my other medications?

Yes. Continue taking your other medications, unless your specialist tells you otherwise. Other medication can include antihistamine(s) prescribed for CSU.

Omalizumab will not affect your treatment with other medications. Do not stop taking prescribed medications that are important for your well-being. For example, treatment for diabetes, high blood pressure, and asthma. Please speak to your doctor if you have any questions.

Can Omalizumab be given in pregnancy and during breast feeding?

There is no data available in humans confirming safety in pregnancy and during breast feeding. Your specialist will advise you to stop treatment with Omalizumab and discuss other treatment options.

Who can I contact if I need help?

If you have any questions, please speak with your nurse specialist.

Contact details

• Department of Allergy and Immunology

Telephone: 01227 864316 (between 8am and 4pm); please leave a message Email (ekhuft.immunology-allergy@nhs.net)

References

- National Institute for Health and Care Excellence (NICE). Omalizumab for previously treated chronic spontaneous urticaria. Technology appraisal guidance TA339. Published 08 June 2015. (https://www.nice.org.uk/guidance/ta339/chapter/1-Recommendations)
- Xolair Omalizumab. Self-injecting XOLAIR. (https://www.xolair.com/allergic-asthma/injections/self-injection.html)
- Denman S, El-shanaway T, Carne E, et al. Multicentre experience of home omalizumab treatment for chronic spontaneous urticaria: short report. European Journal of Hospital Pharmacy 2020; 27 (6): 367-368. (https://ejhp.bmj.com/content/27/6/367)

Ask 3 Questions

There may be choices to make about your healthcare. Before making any decisions, make sure you get the answers to these three questions:

What are my choices?

- · What is good and bad about each choice?
- How do I get support to help me make a decision that is right for me?

Your healthcare team needs you to tell them what is important to you. It's all about shared decision making.

What do you think of this leaflet?

We welcome feedback, whether positive or negative, as it helps us to improve our care and services.

If you would like to give us feedback about this leaflet, please fill in our short online survey. Either scan the QR code below, or use the web link. We do not record your personal information, unless you provide contact details and would like to talk to us some more.

Giving feedback about this leaflet



https://www.smartsurvev.co.uk/s/MDOBU4

If you would rather talk to someone instead of filling in a survey, please call the Patient Voice Team.

Patient Voice Team

Telephone: 01227 868605

Email (ekhuft.patientvoice@nhs.net)

This leaflet has been produced with and for patients.

Please let us know:

- If you have any accessibility needs; this includes needing a hearing loop or wanting someone to come with you to your appointment.
- · If you need an interpreter.
- If you need this information in another format (such as Braille, audio, large print or Easy Read).

You can let us know this by:

- Visiting the Trust web site (https://www.ekhuft.nhs.uk/ais).
- Calling the number at the top of your appointment letter.
- Adding this information to the Patient Portal (https://pp.ekhuft.nhs.uk/login).
- Telling a member of staff at your next appointment.

Any complaints, comments, concerns or compliments, please speak to a member of your healthcare team. Or contact the Patient Advice and Liaison Service on 01227 783145 or email (ekhtr.pals@nhs.net).

Patients should not bring large sums of money or valuables into hospital. Please note that East Kent Hospitals accepts no responsibility for the loss or damage to personal property, unless the property has been handed into Trust staff for safe-keeping.

Further patient information leaflets are available via the East Kent Hospitals' web site (https://www.ekhuft.nhs.uk/patient-information).

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