



OMALIZUMAB

What are the aims of this leaflet?

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

What is omalizumab and how does it work?

Omalizumab is a drug that has been specially designed to mimic normal human molecules, and for this reason is classified as a biologic drug. It interferes with natural antibodies called IgEs in the body and prevents them from causing histamine release from certain cells.

Who is it for?

Omalizumab is for patients who suffer with chronic spontaneous urticaria and have a weekly urticaria activity score of 28 or more. Please see the British Association of Dermatology information leaflet on 'Urticaria and Angioedema' for more information on this condition. Patients who have failed to respond to the usual standard treatments e.g. H₁ antihistamines (cetirizine, loratadine), H₂ antihistamines (ranitidine) and leukotriene antagonist therapy (montelukast) may be offered omalizumab. Please note that omalizumab is an add-on therapy i.e. standard antihistamine should be continued whilst taking this.

How is omalizumab given?

Omalizumab is given as two injections subcutaneously (under the skin) each monthly appointment. Each injection contains 150 mg of omalizumab so two injections are needed to give a total dose of 300mg. It is delivered in a hospital outpatient setting by a trained nurse or doctor. The injections are quick but you will need to be monitored in hospital for 2 hours after the first injection for any signs of an allergic reaction. For subsequent injections monitoring is only half an hour. The treatment

dose of 300 mg (i.e. two separate injections) is usually given every 4 weeks for up to 6 months initially.

You will be assessed at or after your 4th dose, to determine whether you have had a response to treatment. The injections will be stopped at this point if there has not been any significant improvement. If you have responded to the treatment, the 6-course dose will continue. If the urticaria comes back after you have finished the course then the treatment can start again if your doctor advises this and your urticaria activity score is sufficiently elevated, subsequently the score only needs to reach 16 or over.

Which conditions are treated with omalizumab?

Omalizumab is used to treat patients 12 years or older with severe chronic spontaneous urticaria. It is also licensed to treat severe asthma and is currently being trialled for use in other medical conditions as well.

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 after the first injection. Clinical trials reported that half of the participants noticed a good improvement or complete resolution of symptoms after 3 months of injections.

What are the possible side effects of omalizumab?

All medicines can cause side effects and these can vary from person to person. Common and mild side effects include headache, abdominal pain, fever, joint pain and injection site reactions (bruising, swelling, redness, pain, warmth, stinging, itching). These are not usually severe and you should be able to continue the medication.

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

Anaphylaxis with angioedema is a potentially serious allergic reaction which can very rarely occur after the injection, often within the first 2 hours. You are at a higher risk of getting this type of reaction if you have had previous anaphylaxis to food or medications or if you have asthma.

You should inform your doctor or nurse if you notice any of the following during or after your injection: itching or rash, swelling of the face, neck, tongue, hands and feet, difficulty in breathing or swallowing, dizziness or faintness, an upset stomach, blurred vision, chest pain, fever or chills

Can omalizumab cause cancer?

There is no evidence that omalizumab increases your risk of developing cancers. Studies using omalizumab have observed patients for up to one year after treatment and therefore long-term side effects are unknown.

Can omalizumab increase the risk of having blood clots or a stroke?

In a study of patients with asthma, it was reported that there was a small risk of developing blood clots in the legs, lungs, heart and brain. This has not been found in studies of patients treated for chronic spontaneous urticaria.

I am planning to have an operation or dental surgery – what should I do?

There are no reported cases of omalizumab interacting with local or general anaesthetic and so it is thought to be safe. However, it is important you inform your doctor or dentist that you are taking omalizumab. The drug does not affect wound healing or increase your risk of post-operative infection.

How will I be monitored during treatment?

Omalizumab is a very safe medication however, you will be observed in hospital for 2 hours after the first injection to ensure you do not develop any signs or symptoms of an allergic reaction and then for half hour after subsequent injections. No routine blood tests are required. You will be seen by your dermatologist for a review after your 4th treatment, as explained above in the section ‘How is omalizumab given?’

Does omalizumab affect pregnancy?

Omalizumab has not been tested in pregnant females or nursing mothers so its effects on unborn children or babies being breast fed are unknown. Most clinical trials have stopped treatment if the participant became pregnant. There are reports of asthma patients who have continued low dose omalizumab and had no complications. Please inform your doctor 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?

There is no known interaction between omalizumab and alcohol and so 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 that your doctor is aware that you are having this treatment. Your GP and dermatologist should be aware of all your medications, including over-the-counter medicines and

supplements (including vitamins and herbal medicines). Do not start any new treatments without discussing this first with your doctor.

Where can I find out more 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 doctor or pharmacist.

Other sources of information include the NICE website:

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

and a national charity and patient support group:

<https://www.allergyuk.org/skin-allergy/urticaria-and-angiodema>

For details of source materials used please contact the Clinical Standards Unit (clinicalstandards@bad.org.uk).

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

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