

Omalizumab (Xolair)

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 and where you can find out more about it.

What is omalizumab and why is it being prescribed?

Omalizumab is a medicine prescribed for patients with:

1. Chronic Idiopathic Urticaria or hives that last 6 weeks or more and have no known cause. 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. It is given in patients aged 12 and over.
2. Moderate to severe asthma that is not currently controlled with inhaled corticosteroids and is sensitive (allergic) to perennial (year-round) aeroallergens (for example: dust mites, animals, mould, cockroach, and certain pollens). It is given in patients aged 6 and over.

How does it work?

In people with chronic idiopathic urticaria or asthma their body makes too much of a certain protein in the body called IgE antibody. The overproduction of this protein may result in the development of various allergic conditions such as allergic rhinitis (hayfever), allergic asthma, venom sensitivity, food or drug allergy. Omalizumab is a drug that acts by binding to the IgE allergic antibody in the blood stream and hence blocks its actions.

Benefits

Omalizumab has been shown to decrease the number of asthma attacks in patients with more moderate to severe asthma, and in some patients it allows a reduction of other asthma medications.

For patients with chronic idiopathic urticaria, clinical trials have reported that half of the participants noticed a good improvement or complete resolution of symptoms after 3 months of injections.

How is it administered, how often is it given and for how long?

Omalizumab is an injection given under the skin (subcutaneous) every 2-4 weeks by a nurse or doctor. Your Omalizumab dose will be chosen based on your body weight and the results of a blood test that measures your level of IgE. You will receive 1-2 injections of Omalizumab in your upper arm depending on these factors. Unless your weight changes significantly, the dose and injection schedule should not change once your treatment has started.

In chronic idiopathic urticaria you are usually given an injection every 4 weeks on 6 occasions. The course can be repeated at a later date if required.

In asthmatic patients omalizumab is an ongoing treatment and it may take several months before you begin to notice the benefits. However, once benefits are observed, they should last for as long as you continue to receive your regular injections. If for some reason your injections are stopped, we would expect the effects to wear off within 6 months to a year. There are no lasting benefits from taking this drug.

Please note that omalizumab is an add-on therapy i.e. standard antihistamine or regular asthma medications should be continued whilst taking this.

Where will it be administered?

Since the possibility exists that an omalizumab injection may cause a generalized allergic reaction, we initially require that omalizumab be administered in the hospital at Bramble Day Case Unit. You can also be assessed for receiving home injections at this point.

You will be initially observed for 2 hours after each injection. If after 3 doses you have not experienced any complications then we usually reduce the observation time to 1 hour following your injection.

A doctor who can treat severe reactions to the drug will be available in the clinic during the time that you are present. If a severe allergic reaction to omalizumab occurs, you will not receive any additional omalizumab treatments. If you develop a delayed reaction to your omalizumab injection (after you leave our facility) please either return to the day case unit or proceed to the nearest emergency department and then contact us as soon as possible.

What are the risks?

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. This can happen after the first dose or after many doses. 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. Your doctor or nurse will monitor you closely for symptoms of an allergic reaction while you are receiving omalizumab and for a period of time after your injection. 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.

Are there any serious long term risks to Omalizumab?

Is there any association with cancer?

A panel of cancer specialists were asked to review all the information on Omalizumab, and concluded that there was no evidence that this drug causes cancer.

The original studies in adults found that cancers were seen in one of every 200 Omalizumab - treated study volunteers [20 of 4127 (0.5%)] compared with one of every 500 control volunteers (patients who did not take the drug in studies of asthma and other allergic disorders [5 of 2236 (0.2%)]). The panel were clear that these cancers were unrelated to Omalizumab, and would have occurred in these adults whether they were in the trial or not.

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 idiopathic urticaria.

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 can contact us on **rde-tr.paediatricallergy@nhs.net** or **rde-tr.paediatricrespiratorynurses@nhs.net**

Other sources of information include the NICE website:

www.nice.org.uk/guidance/ta339

and a national charity and patient support group:

www.allergyuk.org/skin-allergy/urticaria-and-angiodema

References

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