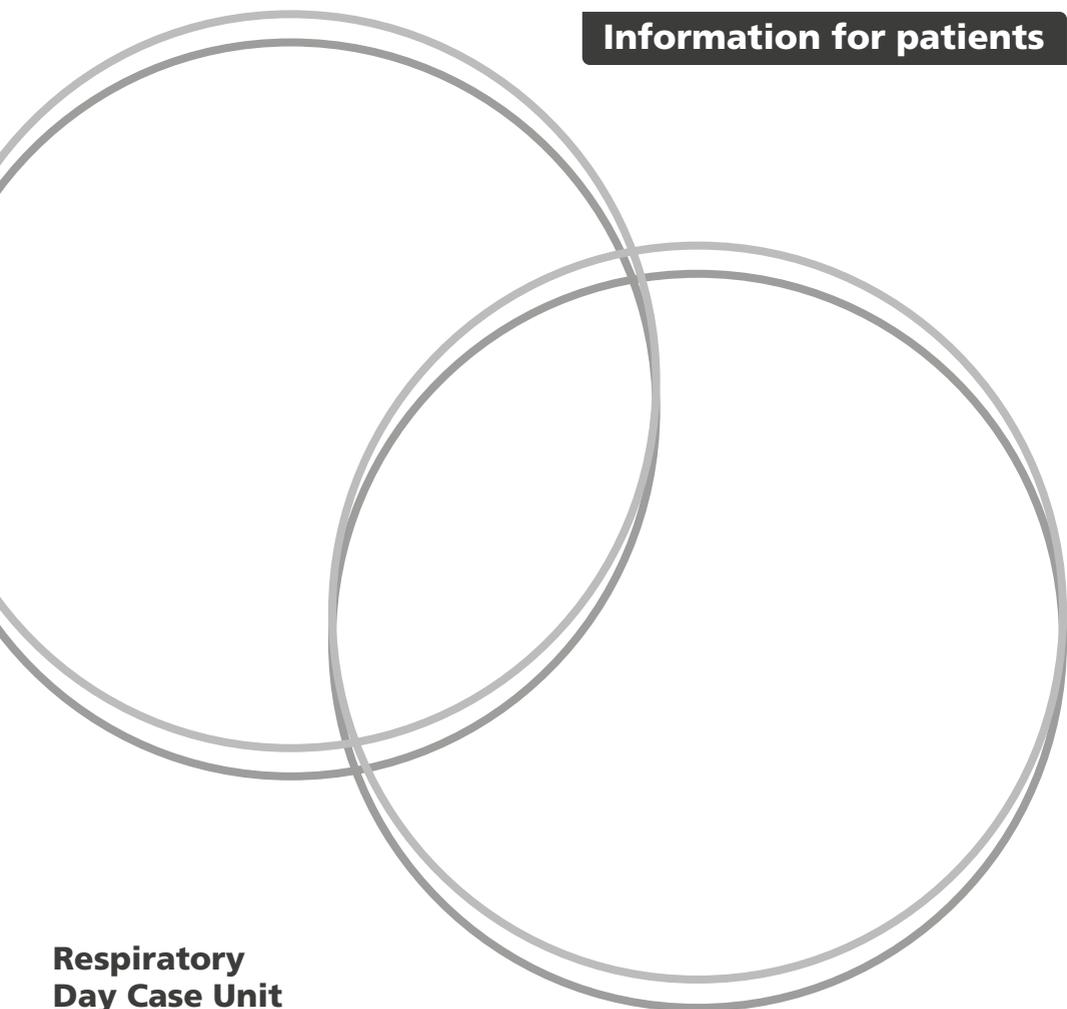


Omalizumab (Xolair[®]) and the Risk of an Allergic Reaction (Anaphylaxis)

Information for patients



What is severe allergic asthma?

Asthma is a condition that affects the airways. It causes the muscles around the walls of the airways to tighten and narrow. The lining of the airways also becomes inflamed and starts to swell.

Some people have severe asthma, some have allergic asthma and some have both.

Severe asthma involves on-going (chronic) asthma symptoms, which continue despite taking regular medications (such as inhalers).

Allergic asthma is caused or made worse by an allergy to one or more substances (allergens) in the environment.

What is Omalizumab?

Omalizumab is used as an additional treatment for severe allergic asthma. It is also known under the brand name of Xolair.

You will have been recommended to use Omalizumab if you have severe, persistent allergic asthma, which is not well controlled by your current medication.

For you to be prescribed Omalizumab, your weight needs to be between certain limits. The level of IgE in your blood will also need to be checked and be between certain levels.

What is IgE?

IgE (immunoglobulin E) is an antibody that is involved in allergic reactions.

When you have an allergy, your body produces too much IgE. This may lead to the development of allergic reaction symptoms, such as shortness of breath and chest tightness.

How does Omalizumab work?

Omalizumab works by attaching itself to the IgE in the blood. By doing this, Omalizumab stops the IgE attaching to other cells in the body which cause an allergic reaction.

How will I be given Omalizumab?

Omalizumab is injected into the subcutaneous layer (fatty layer just under the skin) on your upper arm, every 2 to 4 weeks. The dose and how often you'll have the injection will depend on your weight and IgE level. It is not likely to change unless your weight changes significantly.

16-week trial

To start with, you will have a 16-week trial of Omalizumab, as not everyone benefits from this medication.

Within the 16 weeks, you will hopefully feel improvements in your asthma. The tests you have throughout the 16-week trial will help your doctors and nurses know whether the Omalizumab is reducing your asthma symptoms.

If you don't experience any improvement in your symptoms or spirometry readings, it is likely that the Omalizumab will be stopped.

How long will it be before I notice a difference?

Every response time is different, but you should notice a difference within the first 16 weeks.

What happens if I miss a dose?

For Omalizumab treatment to be of benefit, it is important that you have your injections as prescribed.

If you are unable to come for your injection appointment you must contact us to make another appointment.

Can I stop taking my other asthma medication?

No. You must continue all your other asthma medications as prescribed.

If your asthma improves we may review your treatments, but this will need to be discussed with your doctors. Never stop taking your medications without speaking with your doctor or nurse.

Omalizumab does not interfere with any known medications.

If I respond to treatment, does this mean I will have no further asthma attacks?

No. Asthma is complex and reducing the effects of your allergy is only one aspect of treating the condition.

Evidence suggests that you will have a significant improvement in your quality of life and asthma symptoms, but the response does vary from person to person.

Are there side effects?

Common side effects which may affect up to 1 in 10 people include:

- reactions at the injection site, including pain, swelling, itching and redness
- headache
- upper respiratory tract infection, such as inflammation of the pharynx (area behind your nose and mouth) and a common cold
- feeling of pressure or pain in the cheeks and forehead (sinusitis, sinus headache)
- pain in the joints (arthralgia).

Uncommon side effects which may affect up to 1 in 100 people include:

- feeling dizzy, sleepy or tired
- tingling or numbness of the hands or feet
- low blood pressure while sitting or standing (postural hypotension), fainting, flushing
- sore throat, coughing, sudden breathing problems
- feeling sick (nausea), diarrhoea, indigestion
- itching, hives, rash, increased sensitivity of the skin to sun
- weight increase
- flu-like symptoms.

If any of these side effects occur, please let a member of the Oxford Severe Asthma team know. Contact details are at the end of the leaflet.

You must also tell your doctor or nurse if:

- you become pregnant, are breastfeeding or intend to breastfeed, as your treatment may need to be stopped
- your asthma gets worse.

Important side effect

A severe allergic reaction called anaphylaxis (or anaphylactic shock) can happen when you are given Omalizumab. The reaction can occur after the first dose, or after many doses. It may occur straight after an Omalizumab injection or up to 24 hours afterwards. Anaphylaxis is a life-threatening condition and can lead to death.

Anaphylaxis has occurred in a very small number of people after they have received Omalizumab. In clinical trials to test this medicine the number of people who had an anaphylactic reaction was less than 1 in 1,000 (0.1%).

Anaphylaxis is your body's immune system reacting badly to the presence of a substance (such as nuts or a wasp's sting). It affects your whole body. This usually happens within minutes of contact with the substance, but sometimes the reaction can take place hours later.

What are the signs and symptoms of anaphylaxis?

Symptoms can vary from a mild skin reaction to more severe reactions, including:

- wheezing, shortness of breath, cough, chest tightness or trouble breathing
- low blood pressure, dizziness, fainting, rapid or weak heartbeat, anxiety, or feeling of 'impending doom'
- flushing, itching, hives, or feeling warm
- swelling of the throat or tongue, throat tightness, hoarse voice, or trouble swallowing.

Some of these symptoms require immediate treatment, as they can be life threatening.

How long after having Omalizumab could anaphylaxis occur?

The reaction may be immediate, happening within 2 hours of receiving the Omalizumab injection.

It could also be a delayed reaction, occurring between 2 and 24 hours after the injection.

Please note: It is possible to develop anaphylactic shock after any Omalizumab injection, not just after the first dose.

The risk of an anaphylactic allergic reaction is greatest within the first hour after the Omalizumab injection.

When you have your first injection, you will be monitored closely for symptoms of anaphylaxis and for 4 hours after the injection.

For your second injection we will monitor while you are receiving Omalizumab and for 2 hours afterwards.

For subsequent injections, you will be monitored closely for symptoms of anaphylactic reaction while you are receiving Omalizumab and for 1 hour afterwards.

If you notice any of the signs of anaphylactic shock while you are in the hospital during your observation period, tell your nurse immediately.

What should I do if I have an anaphylactic reaction after leaving the hospital?

As the anaphylactic reaction can occur up to 24 hours after an Omalizumab injection, we will give you 2 Epipens (injections containing adrenaline) to take home with you. You must carry these with you and use them if you have an anaphylactic reaction after you have left the hospital.

During your first visit for your Omalizumab injection, we will teach you how to recognise an anaphylactic reaction and how to use an Epipen.

It is a good idea to make sure that members of your family and your friends or colleagues also know you might have a reaction after an Omalizumab injection. Show them this leaflet, so they can learn to recognise the symptoms of an anaphylactic reaction and know what to do if this happens.

If you notice any signs of an allergic reaction after you have left the hospital (within 24 hours of your last Omalizumab injection), you should use your Epipen(s) as instructed and then call 999 immediately.

Important information to remember

Omalizumab does not work to treat a sudden asthma attack. Make sure you still have your reliever inhaler with you at all times, in case you have an asthma attack.

How to contact us

If you experience any problems, or have any questions about your treatment, please contact the Oxford Severe Asthma Team.

Telephone: **01865 227 242**

(9.00am to 5.00pm, Monday to Friday)

Email: **orh-tr.severeasthmaclinic@nhs.net**

Further information

If you would like an interpreter, please speak to the department where you are being seen.

Please also tell them if you would like this information in another format, such as:

- Easy Read
- large print
- braille
- audio
- electronic
- another language.

We have tried to make the information in this leaflet meet your needs. If it does not meet your individual needs or situation, please speak to your healthcare team. They are happy to help.

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Oxford University Hospitals NHS Foundation Trust
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charity@ouh.nhs.uk | 01865 743 444 | hospitalcharity.co.uk

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