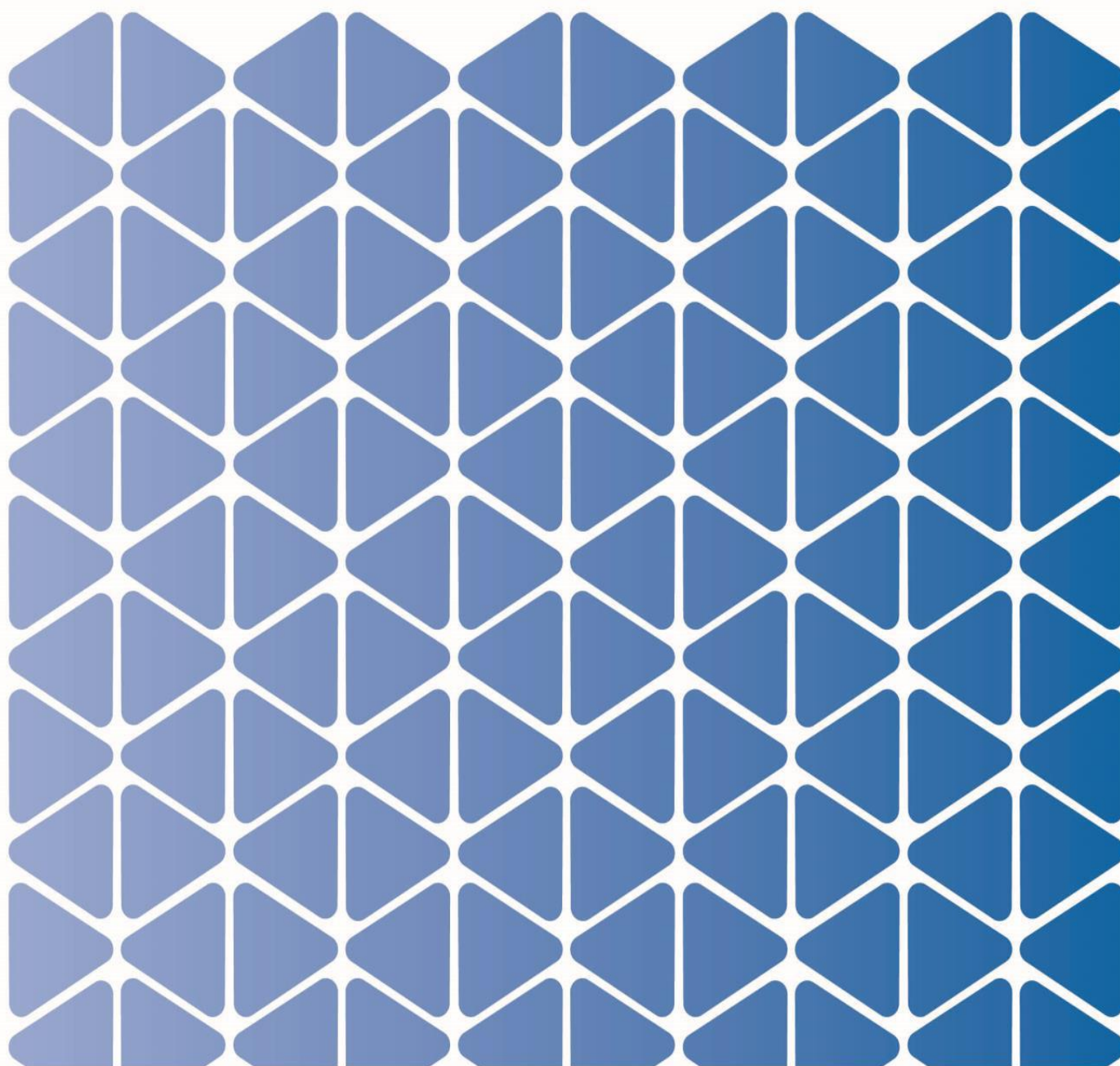


PATIENT INFORMATION**Paediatric Department****Name of treatment: Omalizumab for the
treatment of Chronic Spontaneous Urticaria**

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This leaflet explains some of the benefits, risks and alternatives to receiving treatment with Omalizumab for Chronic Spontaneous Urticaria (CSU). We want you and your child to have an informed choice so you can make the right decision. Please ask your healthcare team about anything you do not fully understand or want to be explained in more detail.

We recommend that you read this leaflet carefully. You and your doctor (or other appropriate health professional) will also need to record that you agree for your child to have the procedure by signing a consent form, which your health professional will give you.

What is Omalizumab?

Omalizumab (also known under the brand name, Xolair®) is a class of drug called a monoclonal antibody. It works by binding to Immunoglobulin E (IgE). This prevents IgE from attaching to mast cells and the production of excess histamine and other inflammatory substances, which cause the urticarial rash.

Why has my child been offered treatment with Omalizumab?

Omalizumab is a treatment for patients over 12 years old who have not responded to the usual standard treatments to treat chronic urticaria, for example: H1 antihistamines (cetirizine, loratadine), and leukotriene antagonist therapy (montelukast). Omalizumab is an add-on therapy and standard antihistamines should be continued whilst on this treatment course.

Are there any alternative treatments?

Omalizumab is currently the first line add-on treatment. There are other medicines called immunosuppressants. These treatment options offer an option for patients unable to take Omalizumab and will be discussed with you and your child as appropriate.

How is Omalizumab given?

Two injections are administered into the fatty tissue, usually on the upper part of the arm. Each injection contains 150 mg of omalizumab so two injections are needed to give a total dose of 300mg. They are given every 4 weeks.

Your child will be assessed at, or after your 4th dose (4th appointment), to determine whether they have had a response to the treatment. The injections will be stopped at this point if there has not been any significant improvement. If they have responded to

the treatment, a further 6-course dose will continue. If the urticaria comes back after you have finished this further course, then the treatment can start again if your doctor advises this.

Benefits of the treatment

Response to this treatment varies. You and your child may notice an improvement in the itching and the rash within days after the first injection. Lots of individuals notice a good improvement or complete resolution of symptoms after 3 months of injections.

What are the possible risks?

The most common side effects of the treatment (about 1 in 10) are reported to be:

- Reactions at the injection site: pain, swelling, redness and itching.
- Headaches
- Respiratory tract infections such as the common cold
- Feeling of pressure and pain behind the cheeks and eyes (sinusitis).
- Pain in joints (arthralgia)
- Feeling dizzy

These side effects are not usually severe and you should be able to continue the treatment course.

Less common side effects include:

- Feeling sleepy or tired
- Tingling or numbness of the hands or feet
- Fainting, low blood pressure while sitting or standing, flushing
- Sore throat, coughing, acute breathing problems
- Feeling sick (nausea), diarrhoea, indigestion
- Itching, hives, rash, increased sensitivity of the skin to sun
- Weight increase
- Flu-like symptoms
- Swelling arms

Anaphylaxis has occurred in a very small number of people receiving Omalizumab. Anaphylaxis is a serious, life threatening allergic reaction which can develop rapidly after administration of the medication or up to 24 hours later. Signs of an anaphylaxis are:

- Sudden onset shortness of breath, wheezing, chest tightening and difficulty breathing
- Sudden changes in conscious level including dizziness, fainting and confusion

Your child will be cared for by a skilled team of doctors, nurses and other healthcare professionals. If an allergic reaction arises, we will be able to assess them and treat them appropriately.

Preparation

If your child has asthma, it is important that their asthma is well controlled and stable on the day of the injections. If they have been prescribed inhalers, you must continue to use the preventer (brown, orange, purple or red) inhalers, including on the morning of each injection. However, please contact the allergy team if your child needs to use their blue inhaler (Salbutamol) more regularly in the week leading up to the injection or if they are unwell with a fever and viral infection.

Please also continue to use their regular antihistamines if they are prescribed them.

What do I need to bring in with me?

You will need to bring in with you your weekly urticarial scores and diary so that we can monitor the effects of the treatment. We will not be able to continue with the treatment if you and your child do not complete their urticaria scores. Please also bring in all their prescribed medication.

You are welcome to bring in some food and drink for your child.

Your child's admission to the Children's Clinic.

Your child will be admitted to a day case bed in the Children's Clinic at Worcester Royal Hospital. We will check your child's details and fasten an armband containing their hospital information to his or her wrist.

Before the injections are given

We will ask you some questions about your child's health to make sure that they are well enough to continue with the treatment. We will listen to their chest and perform some observations. We will ask you to sign the consent form on the first appointment. The healthcare team looking after your child will check the emergency equipment and medication are appropriately prepared. A urine sample will be checked on all girls as it is not possible to give this medication to someone who is pregnant.

The procedure

The injections are quick but some people report that they are a little painful. We can use a numbing cream that you can place on the skin before you come into hospital or we may use inhaled nitrous oxide and oxygen (Entonox®) to relieve any pain or anxiety.

After the procedure

We will then observe your child for 2 hours for the first 3 appointments. After this we will only observe your child for 1 hour. If they are well and not showing any signs of an allergic reaction, then we will do some observations before you go home. If there are any signs of an allergic reaction, we will treat them accordingly.

They may have to stay longer if they have a reaction and require some treatment such as antihistamines. The nurses will continue to check your child's observations. Your child will be allowed home if there are no signs of an allergic reaction or in the unlikely event of a reaction, after it has stabilised.

Contact details

If you have any specific concerns that you feel have not been answered and need explaining, please contact the following.

- Children's Clinic Worcestershire Royal Hospital (phone 01905 760588)
- The allergy team: Mobile number – 07564 848463
Email address – wah-tr.paediatricallergy@nhs.net

Other information

The following internet websites contain information that you may find useful.

- <https://www.nhs.uk/conditions/allergies/>

If your symptoms or condition worsens, or if you are concerned about anything, please call your GP, 111, or 999.

Patient Experience

We know that being admitted to hospital can be a difficult and unsettling time for you and your loved ones. If you have any questions or concerns, please do speak with a member of staff on the ward or in the relevant department who will do their best to answer your questions and reassure you.

Feedback

Feedback is really important and useful to us – it can tell us where we are working well and where improvements can be made. There are lots of ways you can share your experience with us including completing our Friends and Family Test – cards are available and can be posted on all wards, departments and clinics at our hospitals. We value your comments and feedback and thank you for taking the time to share this with us.

Patient Advice and Liaison Service (PALS)

If you have any concerns or questions about your care, we advise you to talk with the nurse in charge or the department manager in the first instance as they are best placed to answer any questions or resolve concerns quickly. If the relevant member of staff is unable to help resolve your concern, you can contact the PALS Team. We offer informal help, advice or support about any aspect of hospital services & experiences.

Our PALS team will liaise with the various departments in our hospitals on your behalf, if you feel unable to do so, to resolve your problems and where appropriate refer to outside help.

If you are still unhappy you can contact the Complaints Department, who can investigate your concerns. You can make a complaint orally, electronically or in writing and we can advise and guide you through the complaints procedure.

How to contact PALS:

Telephone Patient Services: 0300 123 1732 or via email at: wah-tr.PALS@nhs.net

Opening times:

The PALS telephone lines are open Monday to Friday from 8.30am to 4.00pm. Please be aware that you may need to leave a voicemail message, but we aim to return your call within one working day.

If you are unable to understand this leaflet, please communicate with a member of staff.