

Rituximab treatment in autoimmune blistering diseases

This leaflet explains more about having treatment with the medicine rituximab for an autoimmune blistering disease. It includes information about the benefits, risks and any alternatives and what you can expect when you come to hospital.

If you have any further questions, please speak to a doctor or nurse caring for you.

Along with this leaflet it is important that you read the following two leaflets:

- The manufacturer's leaflet for rituximab – ask your nurse for a copy or visit www.emc.medicines.org.uk
- Our leaflet, **Unlicensed Medicines – a guide for patients** – if you do not have a copy, please ask your nurse for one.

What is rituximab?

Rituximab is an antibody that acts against immune B cells in the blood. These cells are responsible for producing the damaging antibodies which lead to blistering in your skin.

The medicine was first used in B cell cancers with success but since then it has also been used successfully in many autoimmune diseases (where the body's immune system attacks the body's own cells). These include a number of blistering skin diseases with an autoimmune basis (such as pemphigus and pemphigoid) as well as rheumatoid arthritis and systemic lupus erythematosus.

Rituximab is given as an infusion through your vein (intravenous infusion).

What are the benefits - why should I have rituximab?

The aim of the treatment is to improve your disease and lead to clinical remission (where your symptoms are less severe). Remission following treatment with rituximab can last for between nine and 18 months, but varies from person to person.

What are the possible side effects?

The following are some of the more common side effects associated with rituximab treatment. For a complete list of side effects, please refer to the manufacturer's leaflet which is also supplied.

- **Flu-like symptoms**, such as chills, muscle aches and weakness, high temperature, dizziness and headaches. Sometimes these symptoms occur while you are having rituximab but they do not usually last very long.

- **Low blood pressure:** this can happen while you are receiving rituximab and we will monitor your blood pressure during the infusion.
- **Feeling sick:** some people feel sick when they are given rituximab and may be sick. You will be given anti-sickness medicines if this is the case.
- **Allergic reactions:** you may have an allergic reaction to rituximab infusion and you will be monitored during the treatment for this. The main symptoms are a skin rash, itching, wheezing or shortness of breath. Please tell your nurse immediately if you have any of these symptoms during the treatment. If you have these symptoms when you get home, please contact us straight away (our contact details are at the end of this leaflet).
- **Lowered resistance to infection:** rituximab can occasionally lower the number of white blood cells, which might make you more likely to get an infection such as a cold. Your white blood cell count will be monitored throughout the treatment.
- **Flushing:** you may feel a flushing and warm feeling in your face during the infusion.
- **PML:** in very rare cases, rituximab can cause a serious condition called progressive multifocal leukoencephalopathy (PML), which can damage the brain and spinal cord. You must see your doctor immediately if you notice any of the following: pins and needles, weakness, shaky movements, unsteadiness, loss of vision, speech problems, changes in your behaviour or mood, difficulty with moving your face, arms or legs. For more information about PML, ask for a copy of our leaflet, **Progressive multifocal leukoencephalopathy (PML)**.

Please tell the nurse looking after you if you have any of the above symptoms.

Pregnancy and breastfeeding/fathering children advice

It is not known how rituximab affects an unborn baby so we recommend that women do not get pregnant during treatment with rituximab and for 12 months after treatment is completed. Effective contraception should therefore be used during this time. If you suspect that you may be pregnant, please tell your doctor immediately. Before each infusion women of child-bearing potential will be asked to take a pregnancy test to ensure they are not pregnant.

There are limited data on the use of rituximab by men who are trying to conceive with their partner, but no concerns have been raised so far. If you would like further information please discuss this with your doctor.

Breastfeeding while receiving rituximab treatment and for 12 months after the completion of treatment is not advised. Please speak to your doctor or nurse if you need any further information.

Taking an unlicensed medicine

Rituximab is not licensed for the treatment of autoimmune blistering diseases in the UK, so its use in this way is called 'unlicensed'. There are times when doctors advise patients to use a medicine in a way that is not specified by the manufacturer of the medicine because they think it may work well to treat a particular condition. If you would like more information about unlicensed medicines, please ask for a copy of our leaflet, **Unlicensed medicines – a guide for patients**. Alternatively, you can call the Pharmacy Medicines Helpline (contact details are at the end of this leaflet).

Are there any alternatives?

There are many different treatments for autoimmune blistering diseases including steroids and other immunosuppressants, such as azathioprine, mycophenolate mofetil and cyclophosphamide. Some patients are also treated with an intravenous infusion of immunoglobulin. Your doctor should have discussed or tried these alternatives before referring you for treatment with rituximab.

How can I prepare for the treatment?

Once you have been assessed as suitable for this treatment, a request will be made to your local clinical commissioning group for funding. When funding has been secured, you will be contacted with a date to start your treatment.

Usually a blood test is needed before each infusion to make sure that you are fit to have the treatment. You can arrange this with the nursing staff. If your doctor decides that you may be at risk from a previous hepatitis B infection, they may also test your blood for the presence of hepatitis B. This is because rituximab may increase the risk of this infection being reactivated.

Giving my consent (permission)

We want to involve you in decisions about your care and treatment. If you decide to go ahead, you will be asked to sign a consent form. This states that you agree to have the treatment and you understand what it involves.

If you would like more information about our consent process, please speak to a member of staff caring for you.

How will rituximab be given?

1. Rituximab is given as an infusion through a cannula (a small needle) into a vein in your arm. It will be a course of two doses given two weeks apart. Treatment will take place under supervised conditions in the outpatient infusion suite at Guy's Hospital.
2. We will give you paracetamol an hour before the treatment. You will also be given an antihistamine and a steroid injection (hydrocortisone) before the rituximab infusion – these are given through the cannula. These medicines help to prevent reactions to rituximab.
3. Each infusion of rituximab will be given through the cannula over the course of a few hours.

Will I feel any pain?

You may feel some discomfort when the cannula is placed in a vein in your arm. This should only last for a few seconds and then wear off. If you continue to feel discomfort or notice swelling around the cannula, please tell your nurse.

Can other medicines be taken alongside rituximab?

You may be prescribed rituximab alongside other medicines including oral steroids. Discuss any new medicines with your doctor before starting them and always tell any other doctor treating you that you have been treated with rituximab. Do not take over the counter preparations or herbal remedies without discussing this first with your doctor, specialist nurse or pharmacist.

Can I have vaccinations?

Because rituximab affects your immune system, it is best to have any vaccinations before treatment or in between courses when your B-cells are back to normal levels. This includes flu and pneumococcal vaccines which should be given at least one month before a course of rituximab.

It is recommended that you avoid live vaccines including yellow fever and shingles. If a live vaccine is required you should discuss this with your doctor or nurse specialist.

What happens after the treatment?

You will be monitored by the nurses in the day unit for at least two hours after the treatment. You can go home that evening.

What do I need to do after I go home?

The infusion may make you feel tired so please rest that evening.

Will I have a follow-up appointment?

You will have a follow-up appointment in the immunobullous clinic two to four weeks after the last infusion.

You may need to have another course of treatment if you come out of remission and your symptoms come back.

Contact us

If you have any questions or concerns about rituximab, please contact Dr Groves' team on **020 7188 6279/7847** or the Guy's Infusion Suite helpline on **020 7188 5896** (Monday to Friday, 9am to 5pm).

Out of working hours the dermatology on-call team can be contacted through the hospital switchboard by calling **020 7188 7188** – state 'bleep desk' and then ask for bleep **2010**.

For more information leaflets on conditions, procedures, treatments and services offered at our hospitals, please visit www.guysandstthomas.nhs.uk/leaflets

Pharmacy Medicines Helpline

If you have any questions or concerns about your medicines, please speak to the staff caring for you or call our helpline.

t: 020 7188 8748 9am to 5pm, Monday to Friday

Your comments and concerns

For advice, support or to raise a concern, contact our Patient Advice and Liaison Service (PALS). To make a complaint, contact the complaints department.

t: 020 7188 8801 (PALS) e: pals@gstt.nhs.uk

t: 020 7188 3514 (complaints) e: complaints2@gstt.nhs.uk

Language Support Services

If you need an interpreter or information about your care in a different language or format, please get in touch:

t: 020 7188 8815 **e:** languagesupport@gstt.nhs.uk

NHS 111

Offers medical help and advice from fully trained advisers supported by experienced nurses and paramedics. Available over the phone 24 hours a day.

t: 111

NHS Choices

Provides online information and guidance on all aspects of health and healthcare, to help you make choices about your health.

w: www.nhs.uk

Get involved and have your say: become a member of the Trust

Members of Guy's and St Thomas' NHS Foundation Trust contribute to the organisation on a voluntary basis. We count on them for feedback, local knowledge and support. Membership is free and it is up to you how much you get involved. To find out more, and to become a member:

t: 0800 731 0319 **e:** members@gstt.nhs.uk **w:** www.guysandstthomas.nhs.uk/membership

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