



RITUXIMAB

What are the aims of this leaflet?

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

What is rituximab and how does it work?

Rituximab is a medicine known as a biological therapy or 'biologic'. It reduces the number of a type of blood cell which defends the body against infection. These are known as immune cells or B cells. Rituximab does this by binding to a protein called CD20 on their surface. B cells can cause diseases known as inflammatory and autoimmune conditions. B cells do this by producing harmful autoantibodies. Autoantibodies are proteins produced by the immune system against our own tissues and cause inflammation. By removing B cells, autoantibody levels are reduced, and inflammation and its effects can be reduced.

What skin conditions are treated with rituximab?

Rituximab is licenced to treat rheumatoid arthritis, some types of vasculitis and certain blood disorders. A licenced medication is one that has been awarded a market authorisation (MA) by the UK Medicines Healthcare Products Regulatory Agency (MHRA). The reasons a drug has not been awarded MA by a country are because the company producing it has not applied for a license in a specific condition, or because safety and efficacy data are insufficient.

Rituximab has not been licenced to treat any skin conditions yet but there is evidence that it can be helpful in some. It has been approved by NHS England to treat pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid and linear IgA disease if other

options have been tried first and have failed. It has also been used to treat lupus and dermatomyositis. NHS England oversees the budget, planning, delivery and day-to-day operation of the National Health Service in England.

What are the contraindications to having rituximab?

Contraindications are conditions or circumstances which may make treatment with rituximab inadvisable. These include if you have an active infection, severe heart problems, get breathless easily, or if your immune system is very suppressed.

Why have I been selected for treatment with rituximab?

Treatment with rituximab is considered for people whose disease is severe and active, and standard treatments have either not worked, cannot be used or have caused serious side-effects.

Will rituximab cure my skin condition?

The diseases treated with rituximab are often 'chronic' conditions which are long-term problems suppressed by treatment but not cured. The aim of treatment will usually be to control the underlying condition and allow reduction in the doses of any other treatments, such as steroid tablets. Response to treatment is very variable: some patients are able to come off treatment altogether whilst others may need to continue other medicines or need regular rituximab infusions to control their condition.

How do I take rituximab?

Rituximab is given through a drip into a vein (intravenous infusion) in hospital. The first infusion will take several hours but further infusions are usually quicker. Each course of rituximab is usually given as two infusions. Each infusion is given two weeks apart. Sometimes four infusions are given, each a week apart. Treatment can be repeated when the effect is wearing off, which is often 12-18 months after the first infusion is given but can be much longer in some patients.

How long will I need to take rituximab before it has an effect?

If you respond to Rituximab, you will begin to feel better in 2-16 weeks.

Before starting treatment with rituximab

Before rituximab, it is important to rule out certain conditions because they may mean it is not advisable to be treated. Please tell your doctor if any of the following apply to you:

- You are pregnant, breast feeding or thinking of starting a family
- You have a disease or treatment that affects your immune system including: cancer, human immunodeficiency virus (HIV) infection, acquired immunodeficiency syndrome (AIDS).
- You have had any infections, particularly viral hepatitis or tuberculosis, or you have had close contact with someone who has had tuberculosis. If you develop any symptoms of tuberculosis (e.g. a dry cough that doesn't go away, weight loss, fever, night sweats) you should let your doctor know. You will need to be examined and tested for tuberculosis.
- Heart failure
- Neurological (brain & nerves) condition or symptoms e.g. multiple sclerosis, pins and needles in your hands and feet.
- You need any vaccinations, including those for travel abroad.
- You are scheduled to have major surgery.

You should make sure that you have regular tests to screen for common cancers, e.g. cervical smears and mammograms, if you are at the age when these are recommended. Please ask your GP if you are unsure.

Should I take specific precautions whilst on rituximab?

To reduce your risk of catching infections, try to avoid close contact with anyone who has a bad cold, influenza or chest infections, and wash your hands frequently. Avoid dairy foods and eggs that are not pasteurised including cheese such as camembert, brie and blue cheeses. Avoid meat or poultry that are not adequately cooked as this can put you at risk of salmonella infection.

While on treatment you should inform your dermatologist and/or your GP if you develop swelling of the feet, shortness of breath on exertion or on lying flat. Your dermatologist should be consulted if you have any concerns about new skin lesions.

What are the common side effects of rituximab?

Like all medicines, there are potential side effects with rituximab. Not everyone will get them, and most are not serious.

Some people can experience side effects whilst the rituximab is being given, often called 'infusion reactions'. This can include itching, a rash, flushing, fever, chills, wheezing, shortness of breath or a fall in blood pressure. To reduce the chance of this happening, it is common for other medicines to be given before the infusion, including anti-histamines and paracetamol. If an infusion reaction does occur, it can be helped by slowing the infusion down. If symptoms are severe then the treatment may need to be stopped, but this is rare.

Rituximab increases the risk of picking up infections which may be serious and require treatment. You must seek advice straight away from your GP or dermatology team if you develop a sore throat, high temperature, burning sensation on passing urine, dental problems, red or painful skin, open sores on your body or a persistent cough. You must see your dermatologist or family doctor if you develop shingles or chicken pox or if you come into contact with someone who has these. You may need treatment with anti-viral medication.

What are the rare side effects of rituximab?

Very rarely, severe skin reactions can develop with rituximab up to four months after an infusion. You should inform your doctor or dermatology nurse if this occurs.

Very rarely, in less than one person in every 10,000 who are treated, patients treated with rituximab can develop a serious brain infection called progressive multifocal leukoencephalopathy (PML) caused by a virus which is inactive in healthy people. This can cause permanent damage to the brain and spinal cord and is life threatening. Symptoms include: confusion or memory loss, changes in mood or behaviour, pins and needles, weakness, unsteadiness, shaky movements, loss of balance, blurring or loss of vision, speech problems, difficulty moving your face/arms or legs. Before rituximab treatment, tell your doctor if you have ever had a neurological diagnosis or symptom, such as multiple sclerosis, Guillain-Barré syndrome or seizures.

How will I be monitored for the side effects of rituximab treatment?

You will probably have a physical examination, chest X-ray and blood tests before treatment starts. Blood tests then need only be done 3 months after

commencing rituximab, and then every 6 months. Regular clinic visits will monitor your response and look out for side effects. You should contact your dermatology team if you have any concerns about side effects which develop in between your clinic appointments.

What will happen if I need an operation or dental surgery whilst on rituximab?

Planned operations should be scheduled at least one month after your last infusion. Therefore, it is important you tell your surgeon/dentist if you have had rituximab or are planning to receive it.

Rituximab may increase your risk of infection after surgery or dental work. You must tell your doctor or dentist if you have had rituximab or are planning to receive it.

Can I have immunisations (vaccinations) whilst on rituximab?

Before rituximab treatment, it is advisable to get up-to-date with any vaccinations because they may not be as effective if given after treatment. Ideally, they should be given 4 weeks or more before rituximab. It is recommended that any patient receiving rituximab should have the pneumococcal vaccine (a vaccine used to give protection against pneumonia) and the annual flu vaccination if possible before treatment.

After rituximab, patients should avoid 'live' vaccines such as oral polio, rubella (German measles), BCG, measles, oral typhoid, yellow fever and the nasal flu vaccine. This includes any 'live' vaccines needed for travel abroad. 'Inactivated' vaccines are safe although may not be as effective after rituximab treatment due to suppression of the immune system. Patients should have annual flu vaccines (not the nasal version). If immunisation with a live vaccine, such as the shingles vaccine, is needed, this should be given before starting rituximab or when the B-cell levels have returned to normal. This will need to be checked by your dermatology team.

Does rituximab affect fertility, pregnancy or breastfeeding?

Rituximab has not been studied in pregnant women or nursing mothers, and so its effects on unborn children or babies who are being breast fed are unknown. At present, it is advised that pregnancy should be avoided for at least 6 months after treatment and effective contraception should be used by women who are at risk of becoming pregnant. It is also advised that women who have had rituximab should not breastfeed. However, men who are trying to father a child can still have rituximab.

You should tell your doctor if you are pregnant or become pregnant and should discuss with your doctor any plan to become pregnant.

Can I drink alcohol while taking rituximab?

There is no known interaction between alcohol and rituximab, but it is recommended that you keep within the recommended weekly limits for adults i.e. 14 units per week. For more information please visit the NHS website:

<https://www.nhs.uk/live-well/alcohol-support/calculating-alcohol-units/>

Can I travel abroad whilst on rituximab?

Please discuss with your dermatologist if you are planning to travel abroad. Depending on where you are travelling, precautions may need to be taken against infections. Your dermatologist may be able to advise you on this.

Can I take other medicines at the same time as rituximab?

Most medicines are safe to take with rituximab. However, it is important that your GP and other doctors are aware that you are on rituximab if any new drug is prescribed. Your GP and dermatologist should be made aware of all your medications. Over the counter preparations and/or herbal remedies should be discussed with your dermatologist prior to taking them. Steroid tablets (prednisolone) can be taken alongside rituximab. However, you should not take other immunosuppressive medication (medicines which suppress the immune system) while you are on rituximab, unless it has been discussed with your dermatologist.

Can I sunbathe?

Sunbeds and sunbathing should be avoided to reduce the risk of skin cancer. Further information on skin cancer and prevention can be found at:

<http://www.bad.org.uk/for-the-public/patient-information-leaflets>

<https://www.cancerresearchuk.org/about-cancer/skin-cancer>

Where can I get more information about rituximab?

This information sheet does not list all of the side effects of rituximab. If you wish to find out more or if you are worried about your treatment, you should speak to your doctor, specialist nurse or pharmacist. Other sources of information include:

<https://www.dermnetnz.org/topics/rituximab/>
<https://www.medicinenet.com/rituximab/article.htm>
<https://bnf.nice.org.uk/drug/rituximab.html>
<http://www.io.nihr.ac.uk/wp-content/uploads/2018/03/11097-Rituximab-for-Pemphigus-vulgaris-V1.0-MAR2018-NON-CONF.pdf>

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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