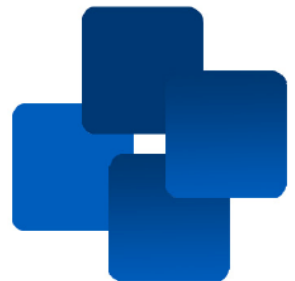


Patient Information

Rituximab

Renal Department



Rituximab

This patient information leaflet is for patients who have been prescribed rituximab by the renal team. The leaflet is not meant to replace talking to your doctor about your condition or treatment. Please speak to your doctor if you have any questions about your treatment with rituximab.

What is rituximab?

Rituximab (trade name Truxima[®]) is a medicine used to reduce the activity of the immune system. It is also used in the treatment of certain cancers. Occasionally we use a different brand called MabThera[®].

The immune system

The immune system makes antibodies and immune cells, which are in the blood to help your body to fight infections, such as those caused by bacteria and viruses. In certain illnesses the immune system becomes too active and fights the person's own body instead of helping to protect it. These kinds of diseases are called auto-immune diseases. Two examples of an auto-immune disease are Systemic Lupus Erythematosus (SLE) and Vasculitis.

How does rituximab work?

B cells are a type of white blood cell found in your blood and are involved in making the antibodies which are causing your illness. Rituximab works by removing these B cells from the blood for several months. After this time, levels will slowly return to normal. Clinical trials have shown that following the removal of B cells there is an improvement in diseases, such as SLE and vasculitis.

Why am I being prescribed rituximab?

At present, rituximab only has a license for use in a few auto-immune diseases and a type of cancer called lymphoma. Research is being carried out into its effect on SLE and other renal diseases. Patients with renal auto-immune diseases are firstly treated using conventional drugs. However, if these drugs have not worked for you, your consultant may, at their discretion, prescribe rituximab.

You will be asked to sign a consent form so we know you understand why you will be receiving rituximab and that you know the risks involved.

Does rituximab work?

Within research carried out on patients with SLE and vasculitis where conventional drugs failed to work, it has been shown that rituximab has a major benefit for 80% of patients¹. It allows other immunosuppressive drugs (cyclophosphamide, mycophenolate mofetil etc.) to be stopped and reduce steroids to a safer level. Patients receiving rituximab have fewer hospital admissions and improved quality of life².

Rituximab has also been shown to help reduce relapses in patients with membranous nephritis and minimal change disease.

What I should tell my doctor before treatment with rituximab?

Tell your doctor about all your medical conditions, including:

- If you have had a bad reaction to rituximab in the past or are allergic to similar products;
- If you are pregnant or breastfeeding;
- If you could be pregnant or are planning to have a baby. This is important for men and for women.

Also tell your doctor:

- If you have heart or lung problems (angina, palpitations, heart failure, breathlessness)
- If you have an infection (even a mild one, such as a cold) or have suffered from lots of infections in the past
- If you think you have or have had a hepatitis infection
- If you have just had or are going to have a vaccination, i.e. flu, hepatitis b, etc.
- If you are going to have surgery
- If you are taking blood pressure tablets - these sometimes need to be stopped as your blood pressure can drop while having rituximab

How is rituximab given?

Rituximab is given as an infusion into a vein (intravenous/IV infusion) in your arm by a specially trained nurse. You will be prescribed other medications before the infusion to prevent pain, and to reduce fever or other effects that can be caused by the infusion.

The first infusion takes up to 6 hours. You will be admitted to the Renal Intervention Treatment Area (RITA) whilst this takes place. You will need to bring your other medicines you are taking with you and an overnight bag in case you need to stay in.

How long does rituximab take to work?

Rituximab takes about 4-6 weeks to work and depending on your renal disease, your other immunosuppressant drugs need to be continued for 4-8 weeks, or stopped on the first dose. The effect of rituximab usually lasts for between six and nine months. The first two doses are given two weeks apart. Further treatment will be assessed by your consultant, if necessary.

What are the possible side effects of rituximab?

For most people, rituximab is safe and well-tolerated and they have very few side effects. Over half a million patients worldwide have received rituximab and serious side effects are very rare. Side effects can begin during the first dose of the drug and may continue for a few hours afterwards, but are usually milder with further doses.

Side effects may include:

- Flu like symptoms.
- Low blood pressure may occur during the infusion, so your blood pressure will be checked every 30 minutes. You may be asked not to take your blood pressure tablets for 12 hours before being given rituximab.
- Sickness (nausea).
- Allergic reactions, skin rashes and breathlessness (let the nurse or doctor know immediately if you experience any of these)
- Lowered resistance to infection.
- Rituximab may worsen heart problems for people who have significant heart disease.

If you notice any side effects, either listed in this leaflet or not, please tell the nurse or doctor immediately. Please see the appendix (page 9) for more detailed information on side effects.

Susceptibility to Infection

There is a theoretical risk of increased infections after rituximab but this is very rare. However, you should be on the look out for any of these symptoms:

- Fever
- Cough
- Sore throat
- Burning pain when passing urine
- Diarrhoea
- Generally feeling weak or unwell.

Please also avoid any unnecessary contact with people known to have an infection. Should you develop any of these complaints, you should arrange to see your GP without delay. If your GP is at all concerned, we will gladly arrange an earlier review in clinic or for you to be seen in the Renal Intervention Treatment Area (RITA) near Ward 6B.

Do I need any special checks while on rituximab?

You will have a physical examination and your blood tests checked before the first infusion. A doctor will see you at the end of each infusion to make sure you are okay and are well enough to go home. Clinic appointments and blood tests will be arranged for one week after each dose. If necessary, any changes to your medication will be made. The usual blood tests to monitor your disease will be taken, and your B cell counts (CD20) taken monthly for 6 months and then every 2 months thereafter.

Can I take other medicines along with rituximab?

Tell your doctor if you plan to take any new medicines before starting them. Also tell any other doctor treating you that you are taking rituximab. Rituximab can interfere with the blood thinning drug warfarin.

Do not take any 'over-the-counter' medicines or herbal remedies without first discussing it with your kidney doctor or pharmacist.

Complementary preparations and vitamins

Medicines can interact with complementary preparations and vitamins. These are sometimes called natural products. In general, there is not much information available about interactions between medicines and complementary preparations or vitamins.

If you are planning to take or are already taking any complementary preparations and vitamins, you should ask your doctor whether there are any known interactions with rituximab.

Your doctor or pharmacist can advise whether it is appropriate for you to take combinations that are known to interact. They can also discuss with you the possible effect that the complementary preparations and vitamins may have on your condition.

If you experience any unusual effects while taking rituximab in combination with complementary preparations and vitamins, you should tell your doctor, nurse or pharmacist.

Can I have vaccinations while on rituximab?

Tell your doctor/nurse you are receiving rituximab. If vaccinations are needed they should be given at least two weeks before rituximab.

Live vaccines, such as rubella (German measles), MMR, yellow fever, BCG, typhoid and polio should **not** be given.

Can I drink alcohol while getting rituximab?

Yes, in moderation as there are no known interactions between alcohol and rituximab. Follow the recommended safe limits for alcohol of one or two units a day, maximum weekly limit of 14 for women and 14 for men.

Diet

Medicines can interact with certain foods. In some cases, this may be harmful and your prescriber may advise you to avoid certain foods.

In the case of rituximab, there are no specific foods that you must exclude from your diet when having rituximab.

Driving and operating machinery

When taking any medicine you should be aware that it might interfere with your ability to drive or operate machinery safely.

Like all medicines, rituximab can cause side effects. You should see how this medicine affects you and then judge if you are safe to drive or operate machinery. If you are in any doubt, talk to your doctor.

What if I am thinking of having a baby?

It is not known if rituximab harms an unborn baby, or how long to wait after treatment to try to conceive. We would generally recommend a gap of at least 12 months after the end of rituximab treatment and trying for a baby. Please let the doctor know if you think you are pregnant or are thinking of becoming pregnant in the near future or if you are not using contraception.

If you are a man and wish to start a family, we would suggest waiting for 12 months before trying for a baby. Please let the doctor know if this is something you are thinking about.

Breastfeeding

Certain medicines can pass into breast milk and may reach your baby through breastfeeding.

In the case of rituximab:

- women who are having rituximab **should not** breastfeed during treatment and for at least 12 months after having the last dose of rituximab.

Before you have your baby you should discuss breastfeeding with your doctor or midwife. They will help you decide what is best for you and your baby based on the benefits and risks associated with this medicine.

Appendix

Possible side effects of rituximab

Each person's reaction to rituximab is different; some patients experience very few side effects, while others may experience more. Infusion related side effects are the most common. Side effects can begin during the first dose of the drug and may continue for a few hours afterwards, but these are usually milder with further doses.

- **Flu like symptoms** may develop during the rituximab infusion, such as high temperature (fever), chills, weakness, muscle aches, tiredness, dizziness, headaches and sudden warmth in your face, which may turn flushed and red. This may occur for a short period of time during the infusion and will improve by temporarily stopping the infusion. Occasionally, more antihistamines and steroids are needed. The infusion will be restarted at a slower rate.
- **Low blood pressure** may occur during the infusion, so your blood pressure will be checked every 30 minutes. If you normally take medicines to lower blood pressure, you may be asked not to take your blood pressure tablets for 12 hours before being given rituximab.
- **Feeling sick** (nausea) and occasional vomiting may be prevented or greatly reduced by taking anti-sickness drugs.
- **Allergic reactions** can sometimes occur: skin rashes and itching; a feeling of swelling in the tongue or throat; irritation of the nasal passages; wheezing; a cough and breathlessness. To help reduce the chance of developing an allergic reaction, antihistamines are routinely given before the infusion. You will be monitored closely during your treatment, but let your nurse or doctor know if you develop any of these symptoms. The infusion will be stopped and further steroids and antihistamines given.

- If you have a severe allergic reaction, rituximab treatment will be abandoned. For milder reactions, the infusion may be restarted cautiously at a slower rate, once all signs of the reaction have settled.
- **Lowered resistance to infection** - Rituximab can reduce the production of white blood cells by the bone marrow, making you more prone to infection. This is less likely than with other immunosuppressant drugs you may have taken before. Your blood counts will be carefully monitored so it is important for you to attend for your blood tests.
- Rarely, the production of platelets and red cells is affected. Inform your doctor if you notice any unusual bruising and/or bleeding, such as nosebleeds, blood spots or rashes on the skin or if you become very breathless or tired.
- Rituximab may worsen heart problems for people who have significant heart disease.
- Rituximab may cause reactivation of hepatitis B infection so we will test your blood before you start rituximab.
- Rarely, rituximab can cause a serious brain infection, called progressive multifocal leukoencephalopathy (PML). This can be fatal. Signs of PML include confusion, loss of balance, muscle weakness or blurred vision.

If you notice any side effects, either listed in this leaflet or not, please tell the nurse or doctor immediately.

Other common side effects

More than 1 in 100 people who have rituximab may get one or more of the following side effects:

- bronchitis
- depression
- diarrhoea
- feeling anxious
- feeling dizzy
- gastroenteritis
- gastro-oesophageal reflux
- hair loss
- high levels of cholesterol in the blood
- indigestion
- joint problems
- migraine
- mouth ulcers
- muscle, joint or bone pain
- osteoarthritis
- paraesthesia (sensation of tingling, burning, pricking, or numbness of a person's skin)
- sciatica

Despite this list of side effects, over half a million patients worldwide have received rituximab and serious side effects have been rare. For the great majority of patients, rituximab is safe and well-tolerated.

If you notice any side effects, either listed in this leaflet or not, please tell the nurse or doctor immediately.

Further information

If you would like any further information about rituximab, or if you have any questions or concerns about your treatment, you should discuss this with your consultant, the ward 6b manager or renal pharmacist.

Dr B Thompson, Renal Consultant (or other renal consultant)

Renal Ward 6b, Lister Hospital

☎ 01438 284164

Sister Angela Bernard, Ward 6b Manager

Renal Ward 6b, Lister Hospital

☎ 01438 284777

Clare Morlidge, Renal Pharmacist

Pharmacy Department, Lister Hospital

☎ 01438 284677

Additional Information

See web site: www.cancerbackup.org.uk

(This information relates to rituximab's more common use in cancer)

References

- ◆ ¹ M Walsh, D Jayne. Rituximab in the treatment of anti-neutrophil cytoplasm antibody associated vasculitis and systemic lupus erythematosus: past, present and future. *Kidney International* (2007) 72, 676–682
- ◆ ² Professor D Jayne. The case for Rituximab in refractory vasculitis
June 2007
- ◆ This leaflet has been adapted from a patient information leaflet produced by Addenbrookes Hospital, Cambridge.

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