

# **Rituximab: A drug Information Sheet**

## **What is rituximab?**

Rituximab (brand name MabThera) is a new type of drug which removes antibody-producing white blood cells called B-cells. Antibodies are proteins which are produced by the body in response to germs, viruses or any other substances which the body sees as foreign or dangerous. However, in people with recurrent transverse myelitis or neuromyelitis optica some B-cells produce harmful 'autoantibodies', such as NMO antibodies. The purpose of rituximab is to remove these B-cells. Rituximab also removes B-cells which make useful antibodies, but these return after some months.

## **Why am I being prescribed rituximab?**

Rituximab is used for diseases associated with autoantibodies, such as lupus and rheumatoid arthritis. At present there is reason to think rituximab would be useful for recurrent transverse myelitis.

Although rituximab is also used for certain cancers like non-hodgkin lymphoma, this is not the reason your child has been prescribed the drug.

## **When and how do I take rituximab?**

Rituximab is given by intravenous infusion ('drip') in a hospital clinic. A steroid injection is usually given first. Usually two infusions are given 2 weeks apart. This 'course' of treatment is repeated only when there are signs that improvement is wearing off, which can be anything from 12 months to 3 years later.

If you are prescribed rituximab it is recommended that you carry a biological therapy alert card. This is because if you become unwell, anyone treating you will know that you have received rituximab and that your B-cell count may be low.

## **How long will rituximab take to work?**

If you respond to rituximab improvement may take several weeks to 3 months. The effect of rituximab lasts for a variable period between six and greater than eighteen months. If repeated courses are needed this will be discussed with you accordingly.

## **What are the possible risks or side-effects?**

Experience with using rituximab in children with recurrent transverse myelitis is still relatively limited, although many people have received it for other conditions. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects.

## Many people using this medication do not have serious side effects.

A small number of people have a **reaction to the infusion** causing temperature, rash, wheeze and sometimes a drop in blood pressure. Very rarely the infusion will need to be stopped as a result. To reduce the risk of this happening steroids are given as an intravenous treatment (into a drip) about half an hour before the rituximab treatment. This may infrequently cause serious (sometimes fatal) side effects including severe breathing problems (e.g., hypoxia, pulmonary infiltrates, acute respiratory distress syndrome) or heart problems (e.g., heart attack, irregular heartbeat, low blood pressure). These effects are more likely if you already have heart or lung problems. Your doctor will carefully watch you during treatment and may stop or slow down your treatment if you have any signs of a reaction. If these serious side effects occur, it will usually be within 30 minutes to 2 hours of receiving this drug. The risk is also higher during your first treatment. However, severe side effects may occur several weeks to months after your last treatment. **Seek immediate medical attention if you have trouble breathing (e.g., cough, wheezing), itching, swelling (especially of the throat/lips), dizziness, fast/slow/irregular heartbeat, or chest pain.**

Rarely, serious (sometimes fatal) **skin reactions** (e.g., Stevens-Johnson syndrome) have occurred in people taking this medication. **Seek immediate medical attention if you develop any rash, blisters, peeling skin, or sores.** These reactions can occur weeks to months after your treatment has ended.

There is a theoretical **risk of increased infection** after rituximab but this is very unusual in practice.

- The levels of useful antibodies in the blood may go down. If you do get symptoms suggesting an infection for example cough, fever or pain passing water you must contact either the hospital of your GP for advice.
- A decline in immunoglobulins may make children more susceptible to infections, especially Varicella. However, overall, total immunoglobulin levels are well preserved and preliminary studies suggest that patients do not appear to be at risk of major infection or opportunistic infection due to Rituximab treatment.
- If you have a current or past infection with hepatitis B or other virus infections (e.g., herpes, virus), rituximab may infrequently cause the infection to return or worsen. This may happen during treatment or up to 1 year after treatment is finished.
- Rarely, a serious (sometimes fatal) brain infection (**Progressive Multifocal Leukoencephalopathy-PML**) has occurred in people taking this medication. **Seek immediate medical attention if you develop any signs of PML, including vision problems, loss of balance/coordination, or confusion**
- This medication can cause a **decrease in blood cells (cytopenia), which can lower the body's ability to fight an infection.** This serious side effect can happen days, weeks, or months after your treatment has finished. **Notify your doctor promptly if you develop any of the following side effects: easy bleeding/bruising, black/tarry stools, vomit that looks like coffee grounds, signs of an infection (e.g., fever, chills, persistent sore throat, painful urination).**

This medication can cause a decrease in blood cells (cytopenia), which can **cause bleeding problems**. This serious side effect can happen days, weeks, or months after your treatment has finished. **Notify your doctor promptly if you develop any of the following side effects: easy bleeding/bruising, black/tarry stools, vomit that looks like coffee grounds.**

**If you get any side effects from the treatment please contact your hospital doctor, GP, emergency department or the helpline number.** All calls to the helpline will be answered within one working day Monday to Friday.

## **Can I go to school? Or will I get infected?**

Yes, you can go to school. Try to avoid sick children and children with chickenpox.

## **What can I do to prevent infection?**

- Wash your hands well to prevent the spread of infections.
- To lower your risk of getting cut, bruised, or injured, use caution with sharp objects like razors and nail cutters, and avoid activities such as contact sports.
- Do not have immunizations/vaccinations without the consent of your doctor, and avoid contact with people who have recently received oral polio vaccine or flu vaccine inhaled through the nose. Avoid people who have chicken pox.

## **What other treatments could be used instead of rituximab?**

A number of other drugs are used in the treatment of recurrent transverse myelitis like azathioprine and mycophenolate. Your doctor will discuss these other options with you.

## **Do I need any special checks while on rituximab?**

There will be regular blood tests. Before your course of treatment, almost weekly in the first months and then monthly. You should have blood tests to check your blood count, renal function and antibody and B-cell levels.

## **May I take other medicines after a course of rituximab?**

You should discuss any new medications with your doctor before starting them, and you should always tell any other doctor treating you that you are having, or have recently had, treatment with rituximab. Do not take over-the-counter preparations without discussing this first with your doctor or pharmacist.

## **What About Vaccinations?**

Vaccinations are unlikely to work if given shortly after treatment with rituximab. This is because vaccines need antibody-producing B cells to be effective. To ensure sufficient protection you should have received all your vaccinations at least 4 weeks before starting treatment, including those needed for travel. You may want to consider to be vaccinated with the chicken pox vaccine. However this may delay treatment. Vaccines can be given again 7 months after the rituximab treatment when the B cell levels are returning to normal. Pneumovax and flu vaccines are safe and are recommended in autumn to reduce your risk of chest infections during the winter.

It is not known whether patients may need re-immunisation of previous killed vaccines following Rituximab. Some studies have shown that Rituximab did not affect anti-tetanus antibody titres.

## **May I drink alcohol after a course of rituximab?**

You may drink alcohol while taking rituximab. However, if you are also taking methotrexate, you should only drink alcohol in small amounts because methotrexate and alcohol can interact and damage your liver.

## **Does rituximab affect pregnancy?**

We do not yet know if it is harmful to a baby if conceived shortly after the mother has received rituximab. The manufacturer suggests that avoiding pregnancy for up to 12 months might be advisable, but we have no way of knowing if such a long interval is necessary. You should take care to avoid becoming pregnant after treatment with rituximab unless you have discussed this in detail with your doctor. You should not receive rituximab during pregnancy.

## **What about breastfeeding?**

Rituximab is an artificially produced antibody of a sort known to be secreted in breast milk. You should not receive rituximab if you are breastfeeding, and should not breastfeed for 12 months following a course of rituximab, because the baby's B-cells might be affected.

## Where can I obtain further information?

If you would like any further information about rituximab, or if you have any concerns about your treatment, you should discuss this with your doctor or pharmacist. You will also find a lot of information on the internet. This may include information about treatment for cancer. Please do not be concerned about this – although rituximab is used for certain types of cancer, this is not the reason for prescribing rituximab for you.

Remember to keep all medicines out of reach of children.

**PLEASE NOTE:** We have made every effort to ensure that the content of this information sheet is correct at time of going to press, but remember that information about drugs may change. This sheet does not list *all* the uses and side-effects associated with this drug. For full details please see the drug information leaflet which comes with your medicine. Your doctor will assess your medical circumstances and draw your attention to any information or side-effects which may be relevant in your particular case.