

OFF-LABEL USE OF RITUXIMAB IN AUTO-IMMUNE CONDITIONS

PATIENT INFORMATION

This information sheet includes important information about the medicine called rituximab when it is used off-label. (MabThera® is the original brand but more brands are becoming available). This information sheet does not include all available information. Additional sources of information on rituximab are listed at the end of this Patient Information Sheet.

WHAT IS RITUXIMAB?

Rituximab is a monoclonal antibody. Monoclonal antibodies are proteins which specifically recognise and bind to other unique proteins in the body. Rituximab works by binding to a protein on the surface of certain white blood cells known as B-cells, which normally produce 'antibodies'.

WHAT IS RITUXIMAB USED FOR?

Antibodies help protect the body from infections. However, in some immune conditions, some B-cells produce harmful 'auto-antibodies', which cause inflammation in parts of the body. This often results in pain, swelling and damage to the body. Rituximab can be used to treat some immune conditions by temporarily removing the harmful B-cells. This can reduce inflammation, lessen symptoms and help stop further damage to the body. Rituximab also removes some 'good' B-cells, but these usually return within a few months of treatment.

Rituximab's effect on harmful B-cells has meant that it has been approved for many years to treat some types of lymphoma (cancer of the B-cells in the lymph nodes), and a type of leukaemia.

WHAT IS OFF-LABEL USE OF RITUXIMAB?

In order for medicines to be marketed in Australia, they must be sponsored by a pharmaceutical company and undergo and pass testing by the Australian Therapeutic Goods Administration (TGA) for safe and effective use in specific medical conditions.

However, for a variety of reasons, pharmaceutical companies may not sponsor the medicine for all potential medical conditions for which a medicine may be useful. This has occurred with rituximab, which is only approved for use (that is, registered) for certain medical conditions, which are listed in its Product Information. When a medicine is used outside the approved conditions for use, it is said to be an off-label use.

Rituximab is registered for use in Australia for the treatment of a number of immune conditions and cancers. Rituximab may also be recommended for off-label use for some other medical conditions. This may occur when other registered treatments for a medical condition are not considered to be suitable (that is, they have been tried and don't work or are not tolerated) and, when the harm from a medical condition outweighs the potential harm from rituximab treatment. Some good evidence of a response to rituximab must have been published in the medical literature to support the off-label use.

Your doctor will explain to you that the effectiveness or safety of rituximab in treating your medical condition is not fully known. Because rituximab is being used 'off-label', you must provide your consent before receiving rituximab. You can change your mind at any time.

WHAT SHOULD THE DOCTOR KNOW BEFORE STARTING RITUXIMAB?

Tell your doctor if:

- You have had an allergic reaction to rituximab in the past
- You have a current infection
- You think you may be pregnant or are planning to become pregnant
- You have a weak immune system
- You have severe heart disease
- You have ever had viral hepatitis B

HOW IS RITUXIMAB GIVEN?

Your doctor will decide what dose is right for you and for how long you will need to receive rituximab. The dosage schedule depends on the medical condition being treated and also varies between patients. Depending on the response, rituximab treatment may be repeated.

Rituximab is given by slow drip into a vein (intravenous administration) by a healthcare professional. Before it is given, you may receive medicines to reduce the chance of a reaction to rituximab (see below). Administration normally takes 2 to 4 hours.

The improvement in your condition may take a number of weeks to occur. Benefits are usually within 3 months of treatment and often last for 6 months to one year, or even longer.

WHAT ARE RITUXIMAB'S SIDE EFFECTS?

Tell your doctor as soon as possible if you do not feel well during rituximab therapy.

All medicines have side effects. Sometimes they are serious, but most of the time they are not, and many of them disappear with time or when treatment is stopped. You may need medical treatment if you get certain side effects. You may not experience any side effects.

The more common side effects to rituximab are listed in this information sheet.

Most Common Side Effects

(may affect more than 1 in 10 people)

- **During intravenous administration**
Tell your doctor or nurse immediately if you get fever, chills, shivering, fatigue, tongue swelling, itch, flushing, fast heart-beat, chest pain, shortness of breath or muscle and joint pain. These effects are most likely to occur during the first 2 hours of receiving the first dose of rituximab, are temporary and less likely to occur after the first dose. These effects can usually be reduced by certain medication given just before rituximab treatment.
- **Low level of white blood cells and/or antibodies:** this is detected by blood tests and can be treated if necessary.
- **Infections:** as rituximab affects the immune system, infections such as urinary tract infections, colds and chest infections including pneumonia may occur more frequently than usual. **Tell your doctor or nurse immediately if you get fever, chills, cough, vomiting, diarrhoea or discomfort when urinating.**
- **A drop in blood pressure** may occur and cause dizziness. If you are being treated for high blood pressure, **your doctor will advise you how to manage your blood pressure medicine.**

Other Side Effects

- Muscle stiffness, aches or weakness
- Headaches
- Stomach or bowel discomfort (including indigestion)
- Pins and needles, or numbness in the skin.
- Increased risk of a very rare virus infection of the brain (called progressive multifocal leukoencephalopathy, or PML). PML can cause severe disability or even death.
- To date, no increased risk of cancer has been identified.
- Allergic reactions: rituximab will be stopped and medicines given if a serious reaction occurs.

Please note: This is not a complete list of all possible side effects. Additional sources of information on the side effects of rituximab are listed at the end of this information sheet. Also, your doctor, pharmacist or nurse can provide you with a more complete list of side effects.

ARE THERE SPECIAL PRECAUTIONS WITH RITUXIMAB TREATMENT?

Infections

- If you have an active infection, rituximab treatment will usually be delayed until the infection is cleared.
- Because of the risks of infection, the following tests may be conducted before commencing treatment with rituximab:
 - blood tests for hepatitis B and C, and other serious infections,
 - chest x-ray,
 - tuberculosis check, and
 - HIV test.
- Because rituximab can have long-lasting effects, monitoring for infection or risk of infection will continue for some months-years after receiving rituximab.

Vaccinations

- Your doctor will check if you require vaccination before or throughout rituximab treatment.
- Always check with your doctor before having any vaccinations as some vaccines should not be given to patients receiving or who have received rituximab treatment.

Use with Other Medicines and Alcohol

- Rituximab may interact with other medicines. You should tell your doctors (medical specialist and general practitioner) and other health professionals (e.g. pharmacist, dentist, nurse) about all medicines you are taking or plan to take. This includes over the counter and complementary medicines e.g. vitamins, minerals, herbal or naturopathic medicines.

- Alcohol does not affect rituximab. If you drink alcohol, limit your intake to no more than the Australian recommendations.

Fertility, Pregnancy and Breastfeeding

- Rituximab does not affect fertility.
- There is limited information about the possible side effects of rituximab on an unborn baby. If you plan to become pregnant it is important to discuss this with your doctor as each case is different.
- There is limited information about the safety of rituximab during breastfeeding. Rituximab should be used with caution during breastfeeding, especially while nursing a newborn or pre-term infant. The possibility of breastfeeding will depend on your circumstances and discussion with your doctor is recommended.

ADDITIONAL INFORMATION ON RITUXIMAB

- [Patient Information Sheet on Rituximab](#) - Australian Rheumatology Association.
- MabThera® (rituximab) Consumer Medicine Information: [MabThera® intravenous infusion: For the treatment of Rheumatoid Arthritis & Granulomatosis with polyangiitis and Microscopic polyangiitis](#)

For information regarding the development of this document please visit our website:

www.nswtag.org.au/off-label-use-of-medicines