

OFF-LABEL USE OF RITUXIMAB IN AUTO-IMMUNE CONDITIONS

PATIENT FACT SHEET

This fact sheet contains important information about the medicine called rituximab when it is used off-label. It does not include all information. Brands of rituximab include Rixymo[®], Truxima[®] and Ruxience[®] but other brands may become available in the future.

WHAT IS RITUXIMAB & WHAT IS IT USED FOR?

Rituximab is a medicine used to treat some auto-immune conditions and some cancers that involve B-cells.

B-cells are white blood cells, which normally produce antibodies to help fight infections. But, in some auto-immune conditions, some B-cells produce harmful antibodies against parts of the body.

Rituximab helps remove harmful B-cells. This helps reduce swelling, lessen symptoms and stop further damage to the body. Rituximab also removes some 'good' B-cells, but these usually come back within a few months.

WHAT IS OFF-LABEL USE OF RITUXIMAB?

Pharmaceutical companies need approval from the Therapeutic Goods Administration (TGA) to market medicines for use in certain illnesses in Australia. The TGA tests the quality of the medicine and how the medicine helps certain illnesses using information from studies. A pharmaceutical company may not ask for approval from the TGA for every illness that the medicine could help. This has happened with rituximab.

Rituximab has approval for use in only a few illnesses. The Product Information lists the approved illnesses. An off-label use happens when a medicine is used outside its approved illnesses.

Some auto-immune illnesses may use off-label rituximab. This happens when other approved medicines are not suitable. For example, you may have tried other medicines that didn't work, or they caused side effects. Also, there needs to be a likelihood that rituximab will help your auto-immune illness without causing serious harm. There needs to be good evidence published in medical journals to support the off-label use.

Your doctor will talk with you about the effect and safety of rituximab for your illness. Because rituximab will be used 'off-label', you must give your consent before having rituximab. You can change your mind at any time.

WHAT SHOULD I TELL MY DOCTOR BEFORE STARTING RITUXIMAB?

Tell your doctor if:

- You have had an allergic reaction to rituximab in the past
- You have a current infection
- 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

WHAT ARE RITUXIMAB'S SIDE EFFECTS?

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

All medicines have side effects. Sometimes they are serious, but most of the time they are not. Most side effects go away with time or after you stop the medicine. You may need treatment if you have certain side effects. You may not have any side effects. This fact sheet lists the more common side effects of rituximab.

Common Side Effects (may affect more than 1 in 10 people)	What to do
<ul style="list-style-type: none"> • A low level of white blood cells and/or antibodies 	Blood tests check your levels. This is usually a mild or moderate reaction and is less likely to happen after the first dose. If the levels are too low, your doctor will treat it, if needed. Your doctor will decide whether you are able to have rituximab again.
<ul style="list-style-type: none"> • Infections such as urinary tract infections, colds and chest infections including pneumonia may occur more frequently than usual. 	Tell your doctor or nurse at once if you get fever, chills, cough, vomiting, diarrhoea or discomfort when urinating. You will probably need to take antibiotics.
<ul style="list-style-type: none"> • A drop in blood pressure may occur and cause dizziness. 	If you are being treated for high blood pressure, your doctor will tell you how to manage your blood pressure medicine.
<ul style="list-style-type: none"> • During intravenous administration. Tell your doctor or nurse at once if you get fever, chills, shivering, fatigue, tongue swelling, itch, flushing, fast heartbeat, chest pain, shortness of breath or muscle and joint pain. These effects are most likely to happen during the first 2 hours of having the first dose of rituximab. They do not last long and are less likely to happen after the first dose. Certain medicines given just before rituximab treatment can lessen these side effects. 	

Other Side Effects	What to do
<ul style="list-style-type: none"> • Muscle stiffness, aches or weakness • Headaches • Stomach or bowel discomfort (including indigestion) • Pins and needles, or numbness in the skin 	Speak to your doctor if you have any of these side effects and they worry you.
<ul style="list-style-type: none"> • A very rare virus infection of the brain (called progressive multifocal leukoencephalopathy, or PML). PML can cause severe disability or even death. 	Your doctor will watch for this very rare side effect. Rituximab will not be used again if it occurs.
<ul style="list-style-type: none"> • Allergic reactions 	The doctor will stop rituximab and give medicines if a serious reaction occurs.
To date, rituximab does not increase the risk of cancer.	

Please note: This is not a complete list of all side effects. More information on the side effects of rituximab is listed at the end of this fact sheet. Also, your doctor, pharmacist or nurse can give you a more complete list.

Always speak to your doctor, nurse or pharmacist before stopping any medicines.

REPORTING SIDE EFFECTS

You can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can provide more information about the safety of this medicine.

HOW IS RITUXIMAB GIVEN?

Your doctor will decide how you will get rituximab, what amount is right for you and how long you will be on rituximab. The amount and how often depends on your illness and varies between patients. You may have repeated rituximab treatments.

Rituximab is normally given into a vein (intravenous administration). You may get medicines that lower the chance of a reaction to rituximab before having rituximab. (See side effects section). Administration normally takes 2 to 4 hours.

Improvement in your illness may take some weeks to occur. You will likely see a change within 3 months and changes often last for 6 to 12 months, or even longer.

ARE THERE SPECIAL PRECAUTIONS WITH RITUXIMAB TREATMENT?

Infections

- If you have an active infection, the doctor will likely delay rituximab treatment until the infection has gone.
- Before starting rituximab treatment, tests will be done to check the risk of infection. These include:
 - blood tests for hepatitis B and C, and other serious infections;
 - chest x-ray;
 - tuberculosis check; and,
 - HIV test.

The effect of rituximab lasts for a long time. The doctor will check for infection or risk of infection for some months after you have rituximab.

Vaccinations

- Your doctor will check if you need any vaccinations before or during rituximab treatment.
- People having or who have had rituximab treatment should not have some vaccines.

Check with your doctor before having any vaccinations.

Use with Other Medicines including Herbal Medicines, Foods and Alcohol

- Rituximab may interact with other medicines. Tell your doctors (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 medicines such as vitamins, minerals or herbal products.
- There are no known interactions between rituximab and various foods.
- Alcohol does not affect rituximab. If you drink alcohol, limit your use to no more than the [Australian recommendations](#).

Fertility, Pregnancy and Breastfeeding

- Rituximab does not affect getting pregnant. Effective contraception should be used during, and for about 1 year after stopping, rituximab treatment.
- There is little information about the possible effects of rituximab on an unborn baby. Talk with your doctor if you plan to become pregnant, as each case is different.
- There is little information about the safety of rituximab during breastfeeding. Use rituximab with caution during breastfeeding, especially while breastfeeding a newborn or premature baby. Talk with your doctor about whether breastfeeding is possible. Contact [MotherSafe](#) Mon-Fri 9am-5pm for further information about rituximab use in pregnancy and breastfeeding.

MORE INFORMATION ON RITUXIMAB FOR AUTO-IMMUNE CONDITIONS

- [Patient Information Sheet on Rituximab](#) July 2023- Australian Rheumatology Association
- [Rixymo® \(rituximab\) Consumer Medicine Information](#): For treatment of Rheumatoid Arthritis, Granulomatosis with polyangiitis, Microscopic polyangiitis
- [Truxima® \(rituximab\) Consumer Medicine Information](#): Truxima® intravenous infusion: For the treatment of Rheumatoid Arthritis & Granulomatosis with polyangiitis and Microscopic polyangiitis, Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukaemia
- Visit our website for information about the development of this document: www.nswtag.org.au/off-label-use-of-medicines