PATIENT INFORMATION ON RITUXIMAB

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This information sheet has been produced by the Australian Rheumatology Association to help you understand the medicine that has been prescribed for you. It includes important information about:

- how you should take your medicine
- · what are the possible side effects
- what tests you <u>will</u> have to monitor your condition
- other precautions you should take while you are taking rituximab.

Please read it carefully and discuss it with your doctor.

IMPORTANT THINGS TO REMEMBER

- While taking rituximab you must see your rheumatologist regularly to ensure the treatment is working and minimise any possible side effects.
- If you stop rituximab for any reason you must contact your doctor. Failure to do so may mean that your continued treatment will no longer be subsidised.
- If you are worried about any side effects you should contact your rheumatologist as soon as possible.
- It is important to tell your doctor if you have had cancer or if you develop cancer while you are taking rituximab.
- If you are taking rituximab and plan to become pregnant you must discuss the timing with your doctor.

For more information about RHEUMATOID ARTHRITIS and other inflammatory conditions see Arthritis Australia's website: www.arthritisaustralia.com.au

Brand names: Riximyo, Ruxience, Truxima

What is rituximab?

Rituximab (brand names include Riximyo, Ruxience, Truxima) belongs to a new class of medicines called **biological disease modifying antirheumatic drugs (biological DMARDs or bDMARDs).**

bDMARDs have now been given to over a million people worldwide since their initial use in the late 1990s.

B-cells are white blood cells, which normally produce 'antibodies'. Antibodies help protect the body from infections. In rheumatoid arthritis however, some B-cells produce harmful 'autoantibodies', which cause inflammation in the joints. These result in pain, joint swelling and stiffness, and can lead to joint damage.

By temporarily removing the harmful B-cells, rituximab reduces inflammation, lessens the symptoms and helps stop further joint damage. Rituximab also removes some 'good' B-cells, but these return some months after treatment.

Rituximab is also used in a number of other autoimmune conditions including:

- Lupus (SLE)
- Vasculitis
- Myositis

Because of its effects on harmful B-cells, rituximab has been used for many years to treat lymphoma, a cancer of the B-cells in lymph nodes.

What benefit can you expect from your treatment?

The improvement from rituximab may take a number of weeks. Benefits will usually be seen by 3 months.

Stopping rituximab

Continue with your treatment unless advised by your doctor or unless side effects develop (see *Side effects*). If you stop rituximab for any reason you <u>must</u> contact your doctor. Failure to do so may mean that your continued treatment may no longer be subsidised.





How will your condition be monitored?

In view of the current prescribing restrictions for all bDMARDs used in the treatment of rheumatoid arthritis:

- Rituximab will only be given if your disease is active and if standard treatments have been unsuccessful.
- It will not be continued unless it helps your condition. This will be assessed at least 12 weeks after the start of treatment.
- Blood tests will be required during your treatment to monitor your condition and to determine the effectiveness of treatment.
- The frequency of blood tests will depend on what other medicines you are taking and what other illnesses you might have. Your rheumatologist will determine the frequency of tests required.
- You may require blood tests to check your antibody and B-cell levels before you commence a course of treatment and before repeated treatment.

How is rituximab given?

- Rituximab is given as a drip (infusion) into the vein. The infusion normally takes 2 to 4 hours. You will need to stay for at least an hour after the infusion to make sure you don't have any side effects.
- Sometimes a boost of a steroid may be used as part of a premedication to reduce side effects (see Side effects).

What is the dosage?

A course of treatment usually consists of 2 doses given two weeks apart. The dosage is 1000mg for each of the infusions. Sometimes it is given weekly for 4 weeks. Different dosing regimens may be used for other autoimmune conditions.

Can other medicines be taken with rituximab?

Rituximab may be used with other arthritis medicines including:

- other DMARDs such as methotrexate
- steroid medicines such as prednisolone or cortisone injections into the joint
- anti-inflammatory medicines (NSAIDs) such as naproxen (Naprosyn) or ibuprofen (Brufen, Nurofen)
- simple pain medicines such as paracetamol.

There are separate information sheets for the medicines mentioned above.

Rituximab cannot be used with other bDMARDs. It should also not be given within 2 weeks of tofacitinib, 4 weeks of treatment with etanercept (Enbrel, Brenzys), within 8 weeks of receiving infliximab (Remicade), adalimumab (Humira), golimumab (Simponi), certolizumab (Cimzia), tocilizumab (Actemra) or abatacept (Orencia).

How long is the treatment continued?

A course of treatment is usually repeated every six months for rheumatoid arthritis. Your response will be monitored by your rheumatologist, with blood tests and examination, about 3 to 4 months after your last infusion. The course of treatment may be different for other autoimmune conditions.

Are there any side effects?

You might experience side effects with your treatment. Contact your doctor if you have any concerns about possible side effects. Many side effects disappear when rituximab treatment is stopped.

Most common possible side effects

- Blood pressure: Because rituximab may cause a drop in your blood pressure your doctor may advise you to stop taking your blood pressure medicine temporarily before your treatment.
- During infusion: Side effects may include fever, chills, shaking, fatigue, tongue swelling, itch, flushing, fast heartbeat, chest pain, shortness of breath or muscle and joint pain.
 - These effects can usually be reduced by giving corticosteroids (e.g. prednisone or cortisone), antihistamines and paracetamol before the treatment.
- Headaches, cough and stomach/ bowel discomfort may also occur.
- Infections: Infections (e.g. colds and sinusitis) may occur more frequently than usual
- Allergies: If you have received previous treatment with other biological medicines you may experience an allergic reaction with rituximab.
- After repeated infusions, the levels of infection fighting antibodies may decrease and increase the risk of infections.





Less common or rare possible side effects

- Serious infections: A rare viral infection of the brain (progressive multifocal leukoencephalopathy, or PML) is found more commonly in patients with immune diseases such as systemic lupus erythematosus (SLE) and rheumatoid arthritis than in the general population. It is thought to be more common in patients with SLE than rheumatoid arthritis but it is still very rare (less than 1 in 10 000 people). This may be increased further in patients with SLE or rheumatoid arthritis who are given rituximab.
- Diarrhoea.
- Muscle stiffness, pins and needles, or numbness in the skin.
- Nervousness, feeling anxious or agitated or inability to sleep.
- Sweating or night sweats.
- It is still unclear from research if there is an increased risk of cancer due to rituximab treatment (see Precautions).

What precautions are necessary? *Infections*

- If you have an active infection of any kind treatment with rituximab will not be given until the infection is treated successfully.
- Rituximab will not be given if you have active untreated HIV (AIDS) or Hepatitis B infection as it is likely to make these conditions worse.
- Hepatitis C infection or controlled HIV or Hepatitis B infection may not necessarily exclude treatment
- Because of the risks associated with infection the following tests may be conducted before commencing treatment with rituximab:
 - blood tests for Tuberculosis, hepatitis B and C
 - chest x-ray
 - HIV tests are required for those who are at risk of this infection.
- If you have an active infection of any kind, it should be treated quickly. See your doctor if you think you have an infection. Treatment with rituximab may be withheld until the infection is treated successfully.

Use with other medicines

- Rituximab can interact with other medicines. You should tell your doctor (including your general practitioner, rheumatologist and others) about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines.
- You should also mention your treatment when you see other health professionals.

Vaccines

- If you are on rituximab it is recommended that you should not be immunised with 'live' vaccines such as MMR (measles, mumps and rubella), Varicella vaccine (Chicken pox), Zostavax (Varicella Zoster or Shingles), OPV (oral polio virus), BCG (Bacillus Calmette Guerin) or yellow fever. Talk with your rheumatologist before receiving any vaccines.
- Pneumovax and the combined yearly seasonal flu/swine flu vaccinations are safe and recommended to reduce your risk of those infections.
- Because rituximab removes antibodyforming B-cells, vaccinations are less effective for several months after a course of treatment. You should plan vaccinations before a course of rituximab or between courses. You should discuss this with your rheumatologist or general practitioner.

For more information on vaccination including the COVID-19 vaccination go to: https://rheumatology.org.au/For-Patients/Adult-Medication-Information/Vaccinations-in-

Surgery

Rheumatology

 Rituximab treatment may be delayed if surgery is being planned. Infusions can be recommenced as long as wound healing has taken place and there are no signs of infection.

Cancer risk

- Lymphoma, a cancer of lymph glands, is found more commonly in patients with severe active rheumatoid arthritis than in the general population. To date there is no evidence to suggest that rituximab increases lymphoma.
- If cancer has been previously treated and cured it may be possible for rituximab to be used safely.
- For general cancer prevention, stopping smoking and taking skin cancer prevention measures are recommended. It is important to use sunscreen and avoid prolonged sun exposure. A yearly skin check is recommended.
- Talk to your doctor if you have any concerns about issues relating to cancer risk.





Use with alcohol

- You may drink alcohol while taking rituximab. However, if you are also taking methotrexate you should be cautious about your alcohol intake. It is not known precisely what level of drinking is safe when on methotrexate, however there is general agreement that 1 to 2 standard drinks taken once or twice a week is unlikely to cause a problem.
- Drinking more than 4 standard drinks on one occasion, even if infrequently, is strongly discouraged.

Use in pregnancy and when breastfeeding

- Not enough is known about the possible side effects of rituximab on the unborn baby. If you plan to become pregnant it is important to discuss this with your doctor as each case is different.
- You should not breastfeed when taking rituximab. It is not known whether rituximab passes into breast milk.
- If you do have a baby and have had rituximab in the preceding 6 months, it is recommended that the baby avoids live vaccines for the first 6 months of life, eg Rotavirus vaccine.

More detailed information is available at https://rheumatology.org.au/For-Patients/Pregnancy-Information

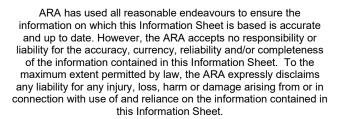
Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details

You should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.

This Information Sheet has been prepared using materials obtained from various sources which have been reviewed by the Australian Rheumatology Association (ARA). It contains general information only and does not contain a complete or definitive statement of all possible uses, actions, precautions, side effects or interactions of the medicines referenced. This information is not intended as medical advice for individual conditions nor for making an individual assessment of the risks and benefits of taking a particular medicine. Decisions regarding the assessment and treatment of patients are the sole responsibility of the treating medical professional, exercising their own clinical judgment and taking into account all of the circumstances and the medical history of the individual patient.



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