

# Rituximab in neurological disease: patient information sheet

## What is rituximab?

Rituximab is a type of intravenous medication called a monoclonal antibody. It is given as an intravenous infusion (through a drip into a vein). It works by sticking to and killing B-cells, a type of white blood cell that produces antibodies and activates the immune system. Rituximab is therefore used to treat B-cell cancers (e.g. some types of lymphoma) and many 'autoimmune conditions', where the immune system is overactive and attacks healthy body tissue. Rituximab starts acting within a few days and its effect lasts for several months.

## Is rituximab licensed for my condition?

Drugs are licensed to treat specific disorders. Rituximab is licensed to treat rheumatoid arthritis and some types of lymphoma and vasculitis (inflammation of the blood vessels). It is not licensed to treat any neurological conditions, but this does not mean that it is ineffective or unsafe. Rituximab is increasingly used to treat inflammatory neurological conditions like neuromyelitis optica spectrum disorder, autoimmune encephalitis, vasculitis and myasthenia gravis. These conditions are uncommon or rare, so it is difficult to perform the large clinical trials which are needed to gain a drug license. However, many experts that care for patients with these conditions have found rituximab to be effective, particularly in cases where other standard treatments have failed. There is published evidence of benefit and safety in growing numbers of neurological patients. We also have a lot of information about side-effects and safety from its use in rheumatoid arthritis and lymphoma.

Many drugs are prescribed 'off-license'. This is common when treating rare conditions. In these circumstances, the doctor prescribing rituximab and the hospital where it is given will take full responsibility for the prescription. You will have the benefits and risks explained and will be asked to read and sign a consent form.

## How do I take rituximab?

Rituximab given through a drip into a vein (intravenous infusion) in hospital. The first infusion takes approximately six hours, but following infusions will usually take less time. A dose of intravenous steroid will usually be given just before the rituximab infusion to reduce the risk of allergic reactions. You will also be monitored by nursing staff during the infusion.

### Depending on your medical condition, you may receive:

- two infusions given two weeks apart
- or, four infusions given every week for four weeks

You may be given a single course of rituximab or have further infusions, usually after 6-12 months. This depends on the condition being treated. In some cases, blood tests may help to decide on the exact timing of future infusions.

**Before you receive rituximab, you must tell your doctor:**

- If you have had an allergic reaction to rituximab in the past
- If you have a weak immune system
- If you have severe heart disease
- If you have ever had viral hepatitis (e.g. hepatitis B or C)
- If you think you may have an infection at the moment
- If you think you may be pregnant

These are all reasons that rituximab may not be appropriate for you, or that you may need additional tests and closer monitoring. If you are unsure, please talk to your doctor.

**What are the possible risks and side-effects of rituximab?**

Like all medications, rituximab can cause side-effects, although not everybody gets them. Most side-effects are mild to moderate but some may be serious and require treatment. Very rarely, some of these reactions have been fatal.

The main issue with rituximab is infusion reactions, as described below. Interestingly, although rituximab affects the immune system, the risk of developing infections is actually relatively low.

**Very common side-effects (may affect more than 1 in 10 people):**

- Mild infusion reactions. These usually occur early during the infusion, but can occur up to 24 hours afterwards. Symptoms include headache, changes in blood pressure, nausea, rash, fever, itch, runny or blocked nose, sneezing, rapid heart rate and tiredness. These symptoms will usually resolve if the infusion is paused or slowed down, and if medications like paracetamol or anti-histamines are given.
- Colds, chest and urinary tract infections
- A decrease in antibody levels. This is mainly seen in people who receive multiple infusions over many years. It is detected by blood tests. Some people with low antibody levels are more vulnerable to chest and sinus infections, but not everybody. It can be treated if causing recurrent infections.

**Common side-effects (may affect up to 1 in 10 people):**

- Infusion reactions that include facial fullness, throat irritation, abdominal pain, vomiting and diarrhoea, breathing problems, back and joint aches, tingling sensations and dizziness.
- Fungal foot infections (Athlete's foot) and bronchitis
- Hair loss (usually mild thinning)

**Uncommon side-effects (may affect up to 1 in 100 people):**

- Infusions reactions that include rash, itching, cough, wheezing, breathlessness, fluid retention, swelling of the face and tongue and collapse. The infusion will be stopped. Specific treatments will be given and you may stay overnight in hospital.

- A low level of white blood cells, called neutropenia. This can occur several months after the infusion and is usually transient. It may cause no problems but increases the risk of serious infections. It is treatable if needed.

Very rare side-effects (may affect up to 1 in 10,000,000 people):

- Infusion reactions that include heart attack, heart failure and death
- Severe blistering skin, mouth and eyelid reactions
- Reactivation of hepatitis B infection. You will be tested for previous hepatitis B infection before receiving rituximab and receive treatment if needed.
- A serious viral brain infection called progressive multifocal leukoencephalopathy (PML). This may cause memory problems, confusion, sight loss and difficulty walking. It can be fatal. It has occurred in roughly 1 in 30,000 people exposed to rituximab. Those who have had chemotherapy or other immunosuppressive treatments seem to be most at risk.

**Can rituximab affect other medicines and treatments?**

- Live vaccinations (e.g. yellow fever and chicken pox / shingles vaccines) should not be given to people treated with rituximab. Other vaccinations (e.g. influenza vaccine and pneumococcal vaccine) are safe but they may be less effective.
- You may be asked not to take your blood pressure medication on the day of your infusion, due to the risk of rituximab causing low blood pressure.
- Other immunosuppressive medications (e.g. methotrexate and azathioprine) may increase the risk of infections. Your doctor will advise you whether to continue or stop these medications.

**Does rituximab affect fertility, pregnancy or breastfeeding?**

Rituximab does not affect fertility. It is likely to be safe in early pregnancy, but there is not enough experience of using rituximab in pregnancy to confirm this. In late pregnancy, rituximab does cross the placenta and may have some effects on the baby's immune system. There is very little information about the safety of rituximab while breastfeeding. However, it is very unlikely to be passed into breastmilk in significant quantities.

**Can I drink alcohol while I'm on rituximab?**

There is no interaction between rituximab and alcohol. We advise that people drink alcohol within standard UK governmental recommendations (i.e. up to 14 units weekly).