

Patient educational leaflet for non-oncology indications

What you should know about Rixathon® (rituximab)

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See 'further information' section for how to report adverse reactions.

Important safety information for patients receiving Rixathon® therapy

- This brochure contains important safety information only.
- See the rituximab package leaflet for more information on possible side effects of rituximab

What you should know about rituximab

About rituximab

Rituximab affects your immune system, it may make you more likely to get an infection. Some infections may be serious and require treatment.

About having rituximab

Rituximab is given as an infusion into the vein.

Like all medicines, rituximab can cause side effects, although not everybody gets them and most are not serious.

- If you are given rituximab in combination with other medicines, some of the side effects you may experience may be due to the other medicines.
- Some side effects may be serious and require treatment. Rarely, some side effects may be life threatening.

If any of the side effects get serious, please tell your doctor, pharmacist or nurse immediately. If you have any further questions, ask your doctor, pharmacist or nurse.

Keep a list of all of your other medicines with you. You should show them to anyone who is giving you medical care, such as a doctor, pharmacist, nurse or dentist

About this guide

The information in this brochure is for patients who are being given rituximab Please read this brochure carefully – it is important for you to know about the benefits and the risks of rituximab

This brochure will:

- answer questions you may have about the potential risks with rituximab - this will help you and your doctor decide if it is the right treatment for you
- tell you about rituximab
- tell you what you need to know before having rituximab
- tell you about important side effects that you need to be aware of – this includes a rare but serious brain infection called 'Progressive Multifocal Leukoencephalopathy' or PML
- tell you what the signs of an infection and PML are

- tell you what to do if you think you are getting an infection or PML
- tell you about the Patient Alert Card

Before treatment with rituximab

Tell your doctor, pharmacist or nurse before taking rituximab if you have or have ever had any of the following:

Infections

Tell your doctor, pharmacist or nurse before having rituximab if you:

- currently have an infection (even a mild one like a cold). Your doctor, pharmacist or nurse may tell you to wait until the infection has gone before you are given rituximab
- get a lot of infections or have been getting many in the past
- have or have had a severe infection such as tuberculosis, blood poisoning (sepsis) or any other condition that weakens your immune system
- have a condition which may make you more likely to get a serious infection that needs treatment.

Other conditions

Tell your doctor, pharmacist or nurse before having rituximab if you:

- have heart disease
- have breathing problems
- are pregnant, trying to become pregnant, or are breastfeeding
- have or have ever had viral hepatitis or any other liver disease
- have had any abnormal results from your blood or urine lab tests.

Medicines

Tell your doctor, pharmacist or nurse before having rituximab if you:

- are taking medicines for high blood pressure
- are having or have ever had medicines that may affect your immune system - such as medicines that suppress your immune system called “immuno-suppressants” or a type of cancer treatment called chemotherapy
- have had chemotherapy that affects your heart (cardiotoxic chemotherapy)
- are taking or have recently taken any other medicines. This includes medicines bought from a pharmacy, supermarket or health store.

Vaccinations

Tell your doctor, pharmacist or nurse before having rituximab if you:

- think you may need to have a vaccination in the near future, including any vaccinations needed to travel to other countries.

Some vaccines should not be given at the same time as rituximab or for several months after you receive rituximab. Your doctor will check if you should have any vaccinations before you are given rituximab.

Tell your doctor, pharmacist or nurse if any of the above applies to you. If you are not sure, talk to your doctor, pharmacist or nurse before you are given rituximab.

During or after treatment with rituximab

rituximab affects your immune system and may make you more likely to get an infection. Some infections may be serious and require treatment.

Infections

Tell your doctor, pharmacist or nurse straight away if you get any of the following possible signs of infection:

- a high temperature (fever) with or without chills
- a cough which will not go away
- weight loss
- pain when you have not hurt yourself
- feeling generally unwell, tired or low in energy
- burning pain when passing urine.

Tell your doctor, pharmacist or nurse straight away if you get any of the signs of infection above.

Serious brain infection – called Progressive Multifocal Leukoencephalopathy (PML)

Rarely rituximab can cause a serious brain infection called ‘Progressive Multifocal Leukoencephalopathy’ or PML. This can lead to very severe disability and may be life threatening.

PML is caused by a virus. In most healthy adults, the virus remains inactive and is therefore harmless. It is not known why the virus is activated in some people, but it may be linked to having a weak immune system.

Tell your doctor, pharmacist or nurse straight away if you get any of the following signs of PML:

- confusion, memory loss or problems thinking straight
- loss of balance or a change in the way you walk or talk
- loss of strength or weakness on one side of the body

- blurred vision or loss of vision.

Tell your doctor, pharmacist or nurse straight away if you get any of the signs of PML above during treatment or for up to 2 years after your last dose of rituximab

Patient Alert Card

- A Patient Alert Card will be included in the carton. Your doctor, pharmacist or nurse should give you a copy of the Rixathon[®] Patient Alert Card every time you have a Rixathon[®] infusion.
- The Alert Card contains important safety information that you need to be aware of before you are given rituximab and during and after treatment with rituximab
- Keep the Alert Card with you all the time – for example, keep it in your wallet or purse.
- Show the Alert Card to **any** doctor, nurse or dentist you see – not just the specialist who prescribes your rituximab
- You should also tell your partner or caregiver about your treatment, and show them the Alert Card, since they may notice symptoms that you are not aware of.
- As the effect on the immune system caused by rituximab can last for several months, side effects may occur even after you have stopped treatment. Please therefore keep the Alert Card with you for 2 years after the last dose of rituximab

Keep the Patient Alert Card with you at all times

- Show it to your partner or caregiver
- Show it to any healthcare professional you see, for example your doctor, nurse or dentist

Keep it for 2 years after your last dose of rituximab. It is important to keep the card with you at all times.

Further Information:

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. Suspected adverse reaction should be reported to the HPRA at www.hpra.ie or to Rowex Ltd. Bantry, Co. Cork; email: pv@rowa-pharma.ie or phone 027 50077