Health Care Professional educational leaflet for non-oncology indications

Important information 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.

Information to assist healthcare professionals in

• communicating risk of Progressive multifocal leukoencephalopathy (PML) and Infections to patients receiving rituximab therapy for non-oncology indications

• caring for patients receiving rituximab therapy for non-oncology indications

About this guide

This guide is intended to review key facts and important safety information about rituximab in non-oncology diseases and to provide important patient counselling information to assist healthcare professionals in caring for patients receiving rituximab therapy. It does not contain all information about this product. You should always consult the Product Information before prescribing, preparing or administering rituximab.

During or after administration of rituximab therapy

Patients should be advised of the potential benefits and risks of treatment with rituximab. Patients should be closely monitored during administration of rituximab in an environment where full resuscitation facilities are immediately available. Use of rituximab may be associated with an increased risk of infections or Progressive Multifocal Leukoencephalopathy (PML).[1]

All patients treated with rituximab must be given the Rixathon® (rituximab) Patient Alert Card with each infusion. The Alert Card contains important safety information regarding potential increased risk of infections, including PML.

PML

About PML

PML is a rare, progressive, demyelinating disease of the central nervous system that can lead to severe disability or be fatal.[2] PML is caused by activation of the JC (John Cunningham) virus, a polyomavirus that is latent in up to 70% of healthy adults.[2] The JC virus usually only causes PML in immunocompromised patients.[3] The factors leading to activation of a latent infection are not fully understood.

Rituximab and PML in non-oncology diseases

A small number of confirmed cases of PML, some of which were fatal, have been reported worldwide in patients who have been treated with rituximab for non-oncology diseases. These patients had received various immunosuppressant therapy before or during their rituximab treatment. Most cases of PML were diagnosed within 1 year of their last infusion of rituximab; however, patients should be monitored for up to 2 years after treatment.

It is not clear how rituximab affects the development of PML. However, evidence suggests that some patients who receive rituximab may develop PML.

What to tell your patient

- Some patients treated with rituximab have developed a serious brain infection called PML, which in some cases has been fatal.
- To carry the Rixathon® Patient Alert Card, with them at all times. The Patient Alert Card will be given to them at each infusion.
- To tell caregivers or relatives about the symptoms to look out for.
- To contact their doctor, pharmacist or nurse immediately if they experience any of the following signs or symptoms suggestive of PML:
    - confusion, memory loss or problems thinking
    - loss of balance or a change in the way they walk or talk
    - decreased strength or weakness on one side of the body
    - blurred vision or loss of vision.

Patient monitoring

Monitor patients for any new or worsening neurological symptoms or signs suggestive of PML during treatment with rituximab and for up to 2 years after treatment. In particular, look out for those symptoms and signs the patient themselves may not notice such as cognitive, neurological or psychiatric symptoms.
Assess the patient promptly to determine if the symptoms are indicative of neurological dysfunction and if they are suggestive of PML.

Suspected PML

Suspend further dosing of rituximab until PML has been excluded.
To confirm diagnosis, consultation with a neurologist and further evaluation including an MRI scan (preferably with contrast), cerebrospinal fluid testing for JC viral DNA and repeat neurological assessments are recommended.

Diagnosed PML

rituximab must be permanently discontinued.
Stabilisation or improved outcome has been seen following reconstitution of the immune system in immunocompromised patients with PML.
It is unknown if early detection of PML and suspension of rituximab therapy may lead to similar stabilisation or improved outcome in patients treated with rituximab.

Infections

Tell patients to contact their doctor, pharmacist or nurse immediately if they experience any of the following signs of possible infection:

- fever
- persistent cough
- weight loss
- pain when they have not hurt themselves
- feeling generally unwell, tired or low in energy

• burning pain when passing urine.

Patients reporting signs of infection following rituximabtherapy should be promptly evaluated and treated appropriately. Before giving further rituximab treatment, patients should be re-evaluated for any potential risk of infections as indicated under “Do not give rituximabto patients who” and “Take special care before you give rituximabto patients who” headings.

Do not give rituximab to patients who:

• are allergic to rituximab or to any of the other ingredients
• are allergic to murine proteins
• have an active severe infection such as tuberculosis, sepsis, hepatitis or an opportunistic infection
• are severely immunocompromised, e.g. levels of CD4 or CD8 are very low.

Take special care before you give rituximab to patients who:

• have signs of an infection - signs may include fever, cough, headache or feeling generally unwell
• have an active infection or are being treated for an infection
• have a history of recurring, chronic or severe infections
• have, or have ever had, viral hepatitis or any other hepatic disease
• are taking, or have ever taken, medicines which may affect their immune system, such as chemotherapy or immunosuppressants
• are taking, or have recently taken, any other medicines (including those they have bought from a pharmacy, supermarket or health store)
• have recently received a vaccination or are planning to have one
• are taking medicines for high blood pressure
• are pregnant, trying to become pregnant or are breastfeeding
• have heart disease or have received cardiotoxic chemotherapy
• have breathing problems
• have an underlying condition which may further predispose them to a serious infection (such as hypogammaglobulinaemia).

Further information

Consult the Product Information before prescribing, preparing or administering Rixathon®

SPC is available on request from Rowex Ltd. or on the HPRA website

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

If you have any questions or problems:
Call: Rowex Ltd. Tel. 02750077 or email pv@rowa-pharma.ie

References

1. Rixathon® / Riximyo® (rituximab) Summary of Product Characteristics

2. Egli A, Infanti L, Dumoulin A, Buser A, Samaridis J, Stebler C, et al. Prevalence of polyomavirus BK and JC infection and replication in 400 healthy blood donors. J Infect Dis 2009;199:837–846.

3. Calabrese LH, Molloy ES, Huang D & Ransohoff RM. Progressive multifocal leukoencephalopathy in rheumatic diseases: evolving clinical and pathologic patterns of disease. Arthritis Rheum 2007; 56:2116–2128.

Important safety information

Rituximab in rheumatoid arthritis: Please refer to Rixathon®SPC

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