

YOUR INTRODUCTION TO



Ruxience[®] ▼
rituximab



Important Risk Minimisation Information for Patients:

You have been given this booklet because you have been prescribed Ruxience[®]. Inside you can find information about your treatment.

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to HPRÁ Pharmacovigilance, Website: www.hpra.ie

Your introduction to Ruxience® 1

Your doctor has prescribed you Ruxience®, and this booklet will serve as your introductory guide. It will provide you with important information about your therapy.

The booklet will 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. The booklet will tell you what the signs of an infection and PML are and tell you what to do if you think you are getting an infection or PML.

Please refer to the Package Patient Information Leaflet supplied with your medicine (which is also available from www.medicines.ie) for more information on possible side effects of Ruxience®.

Remember to contact your doctor or health care provider if you have any questions about Ruxience®.

WHAT IS RUXIENCE®?

Ruxience® contains the active substance “rituximab”. This is a type of protein called a “monoclonal antibody”. It sticks to the surface of a type of white blood cell called “B Lymphocyte”. When rituximab sticks to the surface of this cell, the cell dies.

WHAT RUXIENCE® IS USED FOR? 1

Ruxience® may be used for the treatment of several different conditions in adults. Your doctor may prescribe Ruxience® for the treatment of:

a) Rheumatoid arthritis

Ruxience® is used for the treatment of rheumatoid arthritis. Rheumatoid arthritis is a disease of the joints. B-lymphocytes are involved in the cause of some of the symptoms you have. Ruxience® is used to treat rheumatoid arthritis in people who have already tried some other medicines which have either stopped working, have not



worked well enough or have caused side effects. Ruxience® is usually taken together with another medicine called methotrexate.

Ruxience® slows down the damage to your joints caused by rheumatoid arthritis and improves your ability to do normal daily activities.

The best responses to Ruxience® are seen in those who have a positive blood test to rheumatoid factor (RF) and / or anti-Cyclic Citrullinated Peptide (anti-CCP). Both tests are commonly positive in rheumatoid arthritis and aid in confirming the diagnosis.

b) Granulomatosis with polyangiitis or microscopic polyangiitis

Ruxience® is used for the treatment of granulomatosis with polyangiitis (formerly called Wegener's granulomatosis) or microscopic polyangiitis, taken in combination with corticosteroids. Granulomatosis with polyangiitis and microscopic polyangiitis are two forms of inflammation of the blood vessels which mainly affects the lungs and kidneys but may affect other organs as well. B-lymphocytes are involved in the cause of these conditions.

c) Pemphigus vulgaris

Ruxience® is used for the treatment of patients with moderate to severe pemphigus vulgaris. Pemphigus vulgaris is an autoimmune condition that causes painful blisters on the skin and lining of the mouth, nose, throat and genitals.

Ruxience® is also used to treat people with cancers called non-Hodgkin's lymphoma and chronic lymphocytic leukaemia. Information on the use of Ruxience® for those conditions is not included in this booklet.

WHAT YOU NEED TO KNOW BEFORE YOU USE RUXIENCE® 1

Do not take Ruxience®

- if you are allergic to rituximab, other proteins which are like rituximab, or any of the other ingredients of this medicine.
- if you currently have a severe active infection.
- if you have a weak immune system.
- if you have severe heart failure or severe uncontrolled heart disease and have rheumatoid arthritis, granulomatosis with polyangiitis, microscopic polyangiitis or pemphigus vulgaris.

Ruxience® should not be administered if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before you are given Ruxience®.

Talk to your doctor, pharmacist or nurse before you are given Ruxience® if:

- you think you may have an infection, even a mild one like a cold. The cells that are affected by Ruxience® help to fight infection and you should wait until the infection has passed before you are given Ruxience®. Also please tell your doctor if you had a lot of infections in the past or suffer from severe infections.
- you have ever had or might now have a hepatitis infection. This is because in a few cases, Ruxience® could cause hepatitis B to become active again, which can be fatal in very rare cases. Patients who have ever had hepatitis B infection will be carefully checked by their doctor for signs of this infection.
- you have ever had heart problems (such as angina, palpitations or heart failure) or breathing problems.
- you think you may need any vaccinations, including vaccinations needed to travel to other countries. Some vaccines should not be given at the same time as Ruxience® or in the months after you receive Ruxience®. Your doctor will check if you should have any vaccines before you receive Ruxience®.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given Ruxience®. Your doctor may need to take special care of you during your treatment with Ruxience®.



HOW IS RUXIENCE® TAKEN? ¹

Ruxience® will be administered to you by a doctor or nurse who is experienced in the use of this treatment. They will watch you closely while you are being given this medicine. This is in case you get any side effects. You will always be given Ruxience® as a drip (intra-venous infusion).

POSSIBLE SIDE EFFECTS ¹

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are mild to moderate but some may be serious and require treatment. Rarely, some of these reactions have been fatal.

Infections

You might get infections more easily following treatment with Ruxience®.

Tell your doctor or nurse immediately if you get any of the following signs of infection:

- fever, cough, sore throat.
- weight loss.
- burning pain when passing urine.
- pain without injuring yourself.
- feeling weak or generally unwell.

Inform your partner or caregivers about your treatment and the risk of infections.

Progressive Multifocal Leukoencephalopathy (PML)

Rarely Ruxience® can cause a serious brain infection, called Progressive Multifocal Leukoencephalopathy or PML. This can be fatal.

Tell your doctor or nurse immediately if you feel any of the following:

- confusion, memory loss or problems thinking.
- loss of balance or change in the way you walk or talk.
- decreased strength or weakness on one side of your body.
- blurred or loss of vision.

Tell your doctor or nurse immediately if you get any of the signs of PML listed above during treatment or for up to 2 years after your last dose of Ruxience®. Inform your partner or caregivers about your treatment and the risk of PML since they may notice symptoms that you are not aware of.

PATIENT ALERT CARD

You will be given a patient alert card by your doctor or nurse with each infusion.

It is important that you keep this Alert Card and show it to your partner or caregiver because they may notice side effects that you are not aware of. Keep this card with you all the time - such as in your wallet or purse.

Show this card to any doctor, nurse or dentist you see - not just the specialist who prescribes your Ruxience®.

Keep this card with you for 2 years after your last dose of Ruxience®. This is because side effects can develop several months after you have had treatment.



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 this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

References

1. Ruxience® Patient Information Leaflet.

