YOUR INTRODUCTION TO

Ruxience®▼

rituximab

Pfizer Oncology

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL Dublin 2. Tel:+353 1 6764971. Fax: +353 1 6762517. Website www.hpra.ie. E-mail: medsafety@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. **Please read the Package Leaflet supplied with your medicine (and available from www.medicines.ie) with this booklet, 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) Non-Hodgkin's Lymphoma

This is a disease of the lymph tissue (part of the immune system) that affects a type of white blood cell called B-Lymphocytes.

Ruxience® can be given alone or with other medicines called "chemotherapy".

In patients where the treatment is working, Ruxience® may be used as a maintenance treatment for 2 years after completing the initial treatment.

b) Chronic lymphocytic leukaemia

Chronic lymphocytic leukaemia (CLL) is the most common form of adult leukaemia. CLL affects a particular lymphocyte, the B cell, which originates from the bone marrow and develops in the lymph nodes. Patients with CLL have too many abnormal lymphocytes, which accumulate mainly in the bone marrow and blood. The proliferation of these abnormal B-lymphocytes is the cause of symptoms you may have. Ruxience® in combination with chemotherapy destroys these cells which are gradually removed from the body by biological processes.

Ruxience® is also used to treat people with conditions called rheumatoid arthritis, granulomatosis with polyangiitis or mircoscopic polyangiitis and pemphigus vulgaris. 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 intravenously or by drip 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.

POSSIBLE SIDE EFFECTS [1]

Like all medicines, this medicine can cause side effects, although not everybody gets them. Please refer to the Patient Information Leaflet for the full list of side effects.

Most side effects are mild to moderate but some may be serious and require treatment. Rarely, some of these reactions have been fatal.

Infusion reactions

Rarely, some of the following reactions have been fatal. During or within the first 24 hours of the infusion you may develop fever, chills and shivering. Less frequently, some patients may experience pain at the infusion site, blisters, itching, sickness (nausea), tiredness, headache, breathing difficulties, blood pressure raised, wheezing, throat discomfort, tongue or throat swelling, itchy or runny nose, vomiting, flushing or palpitations, heart attack or low number of platelets. If you have heart disease or angina, these reactions might get worse. **Tell the person giving you the infusion immediately** if you develop any of these symptoms, as the infusion may need to be slowed down or stopped. You may require additional treatment such as an antihistamine or paracetamol. When these symptoms go away, or improve, the infusion can be continued. These reactions are less likely to happen after the second infusion. Your doctor may decide to stop your Ruxience® treatment if these reactions are serious.

Infections

Tell your doctor immediately if you get signs of an infection including:

- fever, cough, sore throat, burning pain when passing urine or feeling weak or generally unwell.
- memory loss, trouble thinking, difficulty walking or sight loss – these may be due to a very rare, serious brain infection, which has been fatal (Progressive Multifocal Leukoencephalopathy or PML).

If you are being treated for rheumatoid arthritis, granulomatosis with polyangiitis, microscopic polyangiitis or pemphigus vulgaris, you will also find this information in the Patient Alert Card you have been given by your doctor. It is important that you keep this Alert Card and show it to your partner or caregiver.

Skin Reactions

Very rarely, severe blistering skin conditions that can be life-threatening may occur. Redness, often associated with blisters, may appear on the skin or on mucous membranes, such as inside the mouth, the genital areas or the eyelids, and fever may be present. **Tell your doctor immediately if you experience any of these symptoms**. For full information regarding side effects please refer to the Patient Information Leaflet.

NOTES

Ruxience®
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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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 16762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

References

1. RUXIENCE® Patient Information Leaflet.

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