RUXIENCE® Patient Guide

WHAT YOU SHOULD KNOW ABOUT RUXIENCE®* (rituximab)

Important Safety Information for patients receiving RUXIENCE® therapy

- See the RUXIENCE® package leaflet for more information on possible side effects of RUXIENCE®
- The RUXIENCE® package leaflet is available on the European Medicines Agency website:
- https://www.ema.europa.eu/en/documents/product-information/ruxience-epar-product-information_en.pdf

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

*This educational material is provided by Pfizer and is mandatory as a condition of the Marketing Authorisation in order to further minimise important selected risks.

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ABOUT THIS GUIDE

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

- This guide will
- Answer questions you may have about the potential risks with RUXIENCE®– this will help you and your doctor decide if it is the right treatment for you
- Explain what RUXIENCE® is
- Tell you what you need to know before starting RUXIENCE®
- Tell you about important side effects that you need to be aware of–these include a rare but serious brain infection called progressive multifocalleukoencephalopathy, 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

WHAT YOU SHOULD KNOW ABOUT RUXIENCE®

About RUXIENCE ®

RUXIENCE® affects your immune system; it may make you more likely toget an infection. Some infections may be serious and require treatment.

Taking RUXIENCE ®

RUXIENCE® is given as an infusion into the vein.

Like all medicines, RUXIENCE® can cause side effects. When experiencing side effects, consider the following:

- If you are prescribed RUXIENCE® in combination with other medicines, ask your doctor or pharmacist if there is the potential for increased side effects
- Some side effects may be serious and require treatment. Rarely, some side effects may be life-threatening

If you experience any side effect that bothers you or that does not go away, please tell your doctor, pharmacist, or nurse immediately. If you have any further questions about RUXIENCE® or its potential side effects, 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.

Tell your doctor, pharmacist, or nurse before taking RUXIENCE® if you meet any of the following criteria.

Infections

Tell your doctor, pharmacist, or nurse before taking RUXIENCE® if you

- Currently have an infection (even a mild one, such as a cold). Your doctor, pharmacist, or nurse may tell you to wait until the infection is gone before you are prescribed RUXIENCE®
- Experience a lot of infections or have experienced many in the past
- Experience or have experienced a severe infection such as tuberculosis, blood poisoning (sepsis), or any other condition that weakens your immune system
- Have a condition that may make you more likely to get a serious infection that needs treatment

Other conditions

Tell your doctor, pharmacist, or nurse before taking RUXIENCE® 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

Tell your doctor, pharmacist, or nurse before taking RUXIENCE® if you

- Are taking medicines for high blood pressure
- Are taking or have ever taken medicines that may affect your immune system; these include immunosuppressants (medicines that suppress your immune system) 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. These include medicines bought from a pharmacy, supermarket, or health store

Vaccinations

Tell your doctor, pharmacist, or nurse before taking RUXIENCE® if you

- Think you may need to have a vaccination in the near future, including any vaccinations required to travel to other countries

Some vaccines should not be given at the same time as RUXIENCE® or for several months after you receive RUXIENCE®.

Your doctor will check if you should receive any vaccinations before you are prescribed RUXIENCE®.

Tell your doctor, pharmacist, or nurse 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®.

DURING OR AFTER TREATMENT WITH RUXIENCE®

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

Tell your doctor, pharmacist, or nurse immediately if you experience any of the following possible signs of infection:

- A high temperature (fever) with or without chills
- A cough that will not go away
- Pain when you have not hurt yourself
- Feeling generally unwell, tired, or lethargic
- Burning pain when passing urine

Serious brain infection called progressive multifocal leukoencephalopathy (PML)

Rarely, RUXIENCE® 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 immediately 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 immediately if you get any of the signs of PML above during treatment or for up to 2 years after your last dose of RUXIENCE®.

PATIENT ALERT CARD

The Patient Alert Card contains Important Safety Information that you need to know before, during, and after treatment with RUXIENCE®.

- Your doctor, pharmacist, or nurse should give you a RUXIENCE® Patient Alert Card every time you have a RUXIENCE® infusion
- Keep the Patient Alert Card with you all the time. You can keep it in your wallet or purse
- Show the Patient Alert Card to any doctor, nurse, or dentist you see-not just the specialist who prescribes you RUXIENCE®
- Tell your partner or caregiver about your treatment, and show them the Patient Alert Card because they may notice side effects that you are not aware of
- Keep the Patient Alert Card with you for 2 years after your last dose of RUXIENCE®. This is because the side effects of RUXIENCE® on the immune system can last for several months, so side effects can occur even when you are no longer being treated with RUXIENCE®

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 leaflet.

ADR Reporting

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to;
P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000
E: postlicensing.medicinesauthority@gov.mt
Alternatively, you may also report such events promptly to Pfizer at Pfizer Hellas S.A., 243 Messoghion Ave. N.Psychiko, Athens GR-15451, Greece. Pfizer Hellas Pharmacovigilance Department contact details: +30 210 67 85 908 and +30 210 67 85 808 (24hour line), fax: +30 210 81 99 096, or via the webportal Pfizer's Adverse Event Reporting Portal (pfizersafetyreporting.com). Healthcare professionals should report adverse events or reactions by brand name and batch number.