

Your introduction to



SELECTED SAFETY INFORMATION

RUXIENCE can cause serious side effects that can lead to death, including:

- **Infusion-Related Reactions:** Infusion-related reactions are very common side effects of RUXIENCE treatment. Serious infusion-related reactions can happen during your infusion or within 24 hours after your infusion of RUXIENCE. Your healthcare provider should give you medicines before your infusion of RUXIENCE to decrease your chance of having a severe infusion-related reaction

Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an infusion of RUXIENCE:

- Hives (red itchy welts) or rash
- Itching
- Swelling of your lips, tongue, throat, or face
- Sudden cough
- Shortness of breath, difficulty breathing, or wheezing
- Weakness
- Dizziness or feel faint
- Palpitations (feel like your heart is racing or fluttering)
- Chest pain

Please see *Important Safety Information and Indications* on pages 8 and 9 and [full Prescribing Information, including BOXED WARNINGS and Medication Guide, at RUXIENCE.com](#).



What is RUXIENCE?

RUXIENCE (rituximab-pvvr) is an FDA-approved biosimilar* to Rituxan[®] (rituximab).

RUXIENCE is FDA approved to help treat:



Non-Hodgkin's Lymphoma (NHL)
alone or with other chemotherapy medicines



Chronic Lymphocytic Leukemia (CLL)
with the chemotherapy medicines fludarabine
and cyclophosphamide



**Granulomatosis with Polyangiitis (GPA)
(Wegener's Granulomatosis) and Microscopic
Polyangiitis (MPA)** with glucocorticoids

*Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar and the reference product.

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- **Severe Skin and Mouth Reactions:** Tell your healthcare provider or get medical help right away if you get any of these symptoms at any time during your treatment with RUXIENCE:
 - Painful sores or ulcers on your skin, lips, or in your mouth
 - Blisters
 - Peeling skin
 - Rash
 - Pustules

Please see *Important Safety Information and Indications on pages 8 and 9* and [full Prescribing Information, including BOXED WARNINGS and Medication Guide](#), at RUXIENCE.com.

What are biosimilars?

Biosimilars are highly similar to the original biologics. Although it is impossible to produce an identical copy of a biologic medicine, a biosimilar must be proven to show no clinically meaningful differences from a reference product.

Do biosimilars have the same side effects and safety profile as the reference products?

Biosimilars must demonstrate that they have no clinically meaningful differences from their reference products in terms of safety and effectiveness. They are expected to work the same way as the original medicines.

How long have biosimilars been available?

The first biosimilar was approved in the United States in 2015.

How will I receive RUXIENCE?

RUXIENCE is given by infusion through a needle placed in a vein, in your arm. Talk to your healthcare provider about how you will receive RUXIENCE.

Your healthcare provider may prescribe medicines before each infusion of RUXIENCE to reduce infusion side effects such as fever and chills.

Your healthcare provider should do blood tests regularly to check for side effects to RUXIENCE.

Before each RUXIENCE treatment, your healthcare provider or nurse will ask you questions about your general health. Tell your healthcare provider or nurse about any new symptoms.

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- **Hepatitis B Virus (HBV) Reactivation:** Before you receive your RUXIENCE treatment, your healthcare provider will do blood tests to check for HBV infection. If you have had hepatitis B or are a carrier of the hepatitis B virus, receiving RUXIENCE could cause the virus to become an active infection again. Hepatitis B reactivation may cause serious liver problems, including liver failure, and death. You should not receive RUXIENCE if you have active hepatitis B liver disease. Your healthcare provider will monitor you for hepatitis B infection during and for several months after you stop receiving RUXIENCE



What is the most important information I should know about RUXIENCE?

RUXIENCE can cause serious side effects that can lead to death, including:



Infusion-related reactions

Infusion-related reactions are very common side effects of RUXIENCE treatment. Serious infusion-related reactions can happen during your infusion or within 24 hours after your infusion of RUXIENCE. Your healthcare provider should give you medicines before your infusion of RUXIENCE to decrease your chance of having a severe infusion-related reaction.

Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an infusion of RUXIENCE:

- o hives (red, itchy welts) or rash
- o itching
- o swelling of your lips, tongue, throat, or face
- o sudden cough
- o shortness of breath, difficulty breathing, or wheezing
- o weakness
- o dizziness or feel faint
- o palpitations (feel like your heart is racing or fluttering)
- o chest pain



Severe skin and mouth reactions

Tell your healthcare provider or get medical help right away if you get any of these symptoms at any time during your treatment with RUXIENCE:

- o painful sores or ulcers on your skin, lips, or in your mouth
- o blisters
- o peeling skin
- o rash
- o pustules



Hepatitis B virus (HBV) reactivation

Before you receive your RUXIENCE treatment, your healthcare provider will do blood tests to check for HBV infection. If you have had hepatitis B or are a carrier of the hepatitis B virus, receiving RUXIENCE could cause the virus to become an active infection again. Hepatitis B reactivation may cause serious liver problems, including liver failure, and death. You should not receive RUXIENCE if you have active hepatitis B liver disease. Your healthcare provider will monitor you for hepatitis B infection during and for several months after you stop receiving RUXIENCE.

Tell your healthcare provider right away if you get worsening tiredness, or yellowing of your skin or white part of your eyes, during treatment with RUXIENCE.



Progressive multifocal leukoencephalopathy (PML)

PML is a rare, serious brain infection caused by a virus that can happen in people who receive RUXIENCE. People with weakened immune systems can get PML. PML can result in death or severe disability. There is no known treatment, prevention, or cure for PML.

Tell your healthcare provider right away if you have any new or worsening symptoms or if anyone close to you notices these symptoms:

- o confusion
- o dizziness or loss of balance
- o difficulty walking or talking
- o decreased strength or weakness on one side of your body
- o vision problems

See “What are the possible side effects of RUXIENCE?” on page 5 for more information about side effects.



What should you tell your doctor before receiving RUXIENCE?

Before receiving RUXIENCE, tell your doctor about all of your medical conditions, including if you:

 **Severe reactions**
Have had a severe reaction to RUXIENCE or another rituximab product

 **Heart problems**
Have a history of heart problems, irregular heartbeat, or chest pain

 **Lung problems**
Have lung problems

 **Kidney problems**
Have kidney problems

 **An infection or weakened immune system**
Have an infection or weakened immune system

 **Severe infections**
Have or have had any severe infections including:

- Hepatitis B virus (HBV)
- Hepatitis C virus (HCV)
- Cytomegalovirus (CMV)
- Herpes simplex virus (HSV)
- Parvovirus B19
- Varicella zoster virus (chickenpox or shingles)
- West Nile virus



Vaccinations

Have had a recent vaccination or are scheduled to receive vaccinations. You should not receive certain vaccines before or during treatment with RUXIENCE



Pregnancy

Are pregnant or plan to become pregnant. Talk to your healthcare provider about the risks to your unborn baby if you receive RUXIENCE during pregnancy. Women who are able to become pregnant should use effective birth control (contraception) while using RUXIENCE and for **at least 12 months** after finishing treatment. Talk to your doctor about effective birth control

Tell your healthcare provider right away if you become pregnant or think that you are pregnant during treatment with RUXIENCE

Are breastfeeding or plan to breastfeed. It is not known if RUXIENCE passes into your breast milk. Do not breastfeed during treatment and for **at least 6 months** after your last dose of RUXIENCE. You and your doctor should decide the best way to feed your baby if you receive RUXIENCE

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your doctor if you take or have taken:

- A tumor necrosis factor (TNF) inhibitor medicine
- A disease modifying anti-rheumatic drug (DMARD)



What are the possible side effects of RUXIENCE?

RUXIENCE can cause serious side effects, including:

- See “**What is the most important information I should know about RUXIENCE?**” on page 3
- **Tumor lysis syndrome (TLS).** TLS is caused by the fast breakdown of cancer cells. TLS can cause you to have:
 - kidney failure and the need for dialysis treatment
 - abnormal heart rhythm

TLS can happen within 12 to 24 hours after an infusion of RUXIENCE. Your healthcare provider may do blood tests to check you for TLS. Your healthcare provider may give you medicine to help prevent TLS.

Tell your healthcare provider right away if you have any of the following signs or symptoms of TLS:

- nausea
- vomiting
- diarrhea
- lack of energy
- **Serious infections.** Serious infections can happen during and after treatment with RUXIENCE, and can lead to death. RUXIENCE can increase your risk of getting infections and can lower the ability of your immune system to fight infections. Types of serious infections that can happen with RUXIENCE include bacterial, fungal, and viral infections. After receiving RUXIENCE, some people have developed low levels of certain antibodies in their blood for a long period of time (longer than 11 months). Some of these people with low antibody levels developed infections. People with serious infections should not receive RUXIENCE. Tell your healthcare provider right away if you have any symptoms of infection:
 - fever
 - cold symptoms, such as runny nose or sore throat, that do not go away
 - flu symptoms, such as cough, tiredness, and body aches
 - earache or headache
 - pain during urination
 - cold sores in the mouth or throat
 - cuts, scrapes, or incisions that are red, warm, swollen, or painful
- **Heart problems.** RUXIENCE may cause chest pain, irregular heartbeats, and heart attack. Your healthcare provider may monitor your heart during and after treatment with RUXIENCE

Please see Important Safety Information and Indications on pages 8 and 9 and [full Prescribing Information, including BOXED WARNINGS and Medication Guide](#), at [RUXIENCE.com](#).

if you have symptoms of heart problems or have a history of heart problems. Tell your healthcare provider right away if you have chest pain or irregular heartbeats during treatment with RUXIENCE

- **Kidney problems.** RUXIENCE can cause severe kidney problems that lead to death, especially if you are receiving RUXIENCE for NHL. Your healthcare provider should do blood tests to check how well your kidneys are working
- **Stomach and serious bowel problems that can sometimes lead to death.** Bowel problems, including blockage or tears in the bowel, can happen if you receive RUXIENCE with chemotherapy medicines. Tell your healthcare provider right away if you have any severe stomach-area (abdomen) pain or repeated vomiting during treatment with RUXIENCE

Your healthcare provider will stop treatment with RUXIENCE if you have severe, serious, or life-threatening side effects. The most common side effects of RUXIENCE include:

- infusion-related reactions (see “**What is the most important information I should know about RUXIENCE?**”)
- infections (may include fever, chills)
- body aches
- tiredness
- nausea

In adult patients with GPA or MPA, the most common side effects of RUXIENCE also include:

- low white and red blood cells
- swelling
- diarrhea
- muscle spasms

Other side effects with RUXIENCE include:

- aching joints during or within hours of receiving an infusion
- more frequent upper respiratory tract infections

These are not all of the possible side effects with RUXIENCE.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of RUXIENCE:

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about RUXIENCE that is written for healthcare professionals.



What financial support may be available for my RUXIENCE prescription?

At Pfizer Oncology Together™, we treat your individual needs as a priority. We'll help you identify financial assistance options so you can get your prescribed RUXIENCE, regardless of your insurance coverage: commercial, Medicare/government issued, or uninsured.

Eligible patients
may pay as little as

\$0

per treatment

- Pfizer Oncology Together Co-Pay Savings Program for Injectables
 - Eligible,* commercially insured patients[†] may pay as little as \$0 per treatment for RUXIENCE, regardless of income.[‡] Limits, terms, and conditions apply

FOR LIVE, PERSONALIZED SUPPORT

Call 1-877-744-5675 (Monday–Friday 8 AM–8 PM ET) or Visit [PfizerOncologyTogether.com](https://www.pfizer.com/oncologytogether)

***Terms and Conditions:** By using this program, you acknowledge that you currently meet the eligibility criteria and will comply with the terms and conditions below:

The Pfizer Oncology Together Co-Pay Savings Program for Injectables for RUXIENCE[®] is not valid for patients who are enrolled in a state or federally funded insurance program, including but not limited to Medicare, Medicaid, TRICARE, Veterans Affairs health care, a state prescription drug assistance program, or the Government Health Insurance Plan available in Puerto Rico (formerly known as "La Reforma de Salud"). Program offer is not valid for cash-paying patients. Patients prescribed RUXIENCE for pemphigus vulgaris and rheumatoid arthritis are not eligible for this co-pay savings program. With this program, eligible patients may pay as little as \$0 co-pay per RUXIENCE treatment, subject to a maximum benefit of \$25,000 per calendar year for out-of-pocket expenses for RUXIENCE including co-pays or coinsurances. The amount of any benefit is the difference between your co-pay and \$0. After the maximum of \$25,000 you will be responsible for the remaining monthly out-of-pocket costs. Patient must have private insurance with coverage of RUXIENCE. This offer is not valid when the entire cost of your prescription drug is eligible to be reimbursed by your private insurance plans or other private health or pharmacy benefit programs. You must deduct the value of this assistance from any reimbursement request submitted to your private insurance plan, either directly by you or on your behalf. You are responsible for reporting use of the program to any private insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled using the program, as may be required. You should not use the program if your insurer or health plan prohibits use of manufacturer co-pay assistance programs. This program is not valid where prohibited by law. This program cannot be combined with any other savings, free trial or similar offer for the specified prescription.

Co-pay card will be accepted only at participating pharmacies.

This program is not health insurance. This program is good only in the U.S. and Puerto Rico. This program is limited to 1 per person during this offering period and is not transferable. No other purchase is necessary. Data related to your redemption of the program assistance may be collected, analyzed, and shared with Pfizer, for market research and other purposes related to assessing Pfizer's programs. Data shared with Pfizer will be aggregated and de-identified; it will be combined with data related to other assistance redemptions and will not identify you. Pfizer reserves the right to rescind, revoke or amend this program without notice. This program may not be available to patients in all states. For more information about Pfizer, visit www.pfizer.com. For more information about the Pfizer Oncology Together Co-Pay Savings Program for Injectables, visit [pfizeroncologytogether.com](https://www.pfizer.com/oncologytogether), call 1-877-744-5675, or write to Pfizer Oncology Together Co-Pay Savings Program for Injectables, P.O. Box 220366, Charlotte, NC 28222. Program terms and offer will expire at the end of each calendar year. Before the calendar year ends, you will receive information and eligibility requirements for continued participation.

Are any other patient support resources available?

At Pfizer Oncology Together, our Care Champions, who have social work experience, can provide you resources that may help with some of your day-to-day challenges[§]:



Connections to emotional support resources

Connections to independent organizations that help eligible patients find free rides and lodging for treatment-related appointments



Educational information about physical and mental health, nutrition, and RUXIENCE

Information to help you prepare for leaving or returning to work



[†]For patients to be eligible for the Injectables Co-Pay Program for RUXIENCE, they must have commercial insurance that covers RUXIENCE and they cannot be enrolled in a state or federally funded insurance program. Whether a co-pay expense is eligible for the Injectables Co-Pay Program for RUXIENCE benefit will be determined at the time the benefit is paid. Co-pay expenses must be in connection with a separately paid claim for RUXIENCE administered in the outpatient setting.

[‡]The Injectables Co-Pay Program for RUXIENCE will pay the co-pay for RUXIENCE up to the annual assistance limit of \$25,000 per calendar year per patient.

[§]Some services are provided through third-party organizations that operate independently and are not controlled by Pfizer. Availability of services and eligibility requirements are determined solely by these organizations.

Please see Important Safety Information and Indications on pages 8 and 9 and full Prescribing Information, including BOXED WARNINGS and Medication Guide, at [RUXIENCE.com](https://www.pfizer.com/ruxience).



IMPORTANT SAFETY INFORMATION

RUXIENCE can cause serious side effects that can lead to death, including:

- **Infusion-Related Reactions:** Infusion-related reactions are very common side effects of RUXIENCE treatment. Serious infusion-related reactions can happen during your infusion or within 24 hours after your infusion of RUXIENCE. Your healthcare provider should give you medicines before your infusion of RUXIENCE to decrease your chance of having a severe infusion-related reaction

Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an infusion of RUXIENCE:

- Hives (red itchy welts) or rash
- Itching
- Swelling of your lips, tongue, throat, or face
- Sudden cough
- Shortness of breath, difficulty breathing, or wheezing
- Weakness
- Dizziness or feel faint
- Palpitations (feel like your heart is racing or fluttering)
- Chest pain
- **Severe Skin and Mouth Reactions:** Tell your healthcare provider or get medical help right away if you get any of these symptoms at any time during your treatment with RUXIENCE:
 - Painful sores or ulcers on your skin, lips, or in your mouth
 - Blisters
 - Peeling skin
 - Rash
 - Pustules
- **Hepatitis B Virus (HBV) Reactivation:** Before you receive your RUXIENCE treatment, your healthcare provider will do blood tests to check for HBV infection. If you have had hepatitis B or are a carrier of the hepatitis B virus, receiving RUXIENCE could cause the virus to become an active infection again. Hepatitis B reactivation may cause serious liver problems, including liver failure, and death. You should not receive RUXIENCE if you have active hepatitis B liver disease. Your healthcare provider will monitor you for hepatitis B infection during and for several months after you stop receiving RUXIENCE

Tell your healthcare provider right away if you get worsening tiredness, or yellowing of your skin or white part of your eyes during treatment with RUXIENCE.

- **Progressive Multifocal Leukoencephalopathy (PML):** PML is a rare, serious brain infection caused by a virus that can happen in people who receive RUXIENCE. People with weakened immune systems can get PML. PML can result in death or severe disability. There is no known treatment, prevention, or cure for PML

Please see [full Prescribing Information, including BOXED WARNINGS and Medication Guide, at RUXIENCE.com.](#)

Tell your healthcare provider right away if you have new or worsening symptoms or if anyone close to you notices these symptoms:

- Confusion
- Dizziness or loss of balance
- Difficulty walking or talking
- Decreased strength or weakness on one side of your body
- Vision problems, such as blurred vision or loss of vision

Before receiving RUXIENCE, tell your healthcare provider if you:

- Have had a severe reaction to RUXIENCE or a rituximab product
- Have a history of heart problems, irregular heartbeat, or chest pain
- Have lung or kidney problems
- Have had an infection, currently have an infection, or have a weakened immune system
- Have or have had any severe infections including:
 - Hepatitis B virus (HBV)
 - Hepatitis C virus (HCV)
 - Cytomegalovirus (CMV)
 - Herpes simplex virus (HSV)
 - Parvovirus B19
 - Varicella zoster virus (chickenpox or shingles)
 - West Nile Virus
- Have had a recent vaccination or are scheduled to receive vaccinations. You should not receive certain vaccines before or during treatment with RUXIENCE
- Have any other medical conditions
- Are pregnant or plan to become pregnant. Talk to your healthcare provider about the risks to your unborn baby if you receive RUXIENCE during pregnancy. Females who are able to become pregnant should use effective birth control (contraception) during treatment with RUXIENCE and for **at least 12 months** after the last dose of RUXIENCE. Talk to your healthcare provider about effective birth control. Tell your healthcare provider right away if you become pregnant or think that you are pregnant during treatment with RUXIENCE
- Are breastfeeding or plan to breastfeed. It is not known if RUXIENCE passes into your breast milk. Do not breastfeed during treatment and for **at least 6 months** after your last dose of RUXIENCE
- Are taking any medications, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take or have taken:
 - A tumor necrosis factor (TNF) inhibitor medicine
 - A disease modifying anti-rheumatic drug (DMARD)

If you are not sure if your medicine is one listed above, ask your healthcare provider.

(CONTINUED ON NEXT PAGE)



IMPORTANT SAFETY INFORMATION (CONTINUED)

RUXIENCE can cause serious side effects, including:

- **Tumor Lysis Syndrome (TLS):** TLS is caused by the fast breakdown of cancer cells. TLS can cause you to have:
 - Kidney failure and the need for dialysis treatment
 - Abnormal heart rhythm

TLS can happen within 12 to 24 hours after an infusion of RUXIENCE. Your healthcare provider may do blood tests to check you for TLS. Your healthcare provider may give you medicine to help prevent TLS. Tell your healthcare provider right away if you have any of the following signs or symptoms of TLS:

- Nausea
 - Vomiting
 - Diarrhea
 - Lack of energy
- **Serious Infections:** Serious infections can happen during and after treatment with RUXIENCE, and can lead to death. RUXIENCE can increase your risk of getting infections and can lower the ability of your immune system to fight infections. Types of serious infections that can happen with RUXIENCE include bacterial, fungal, and viral infections. After receiving RUXIENCE, some people have developed low levels of certain antibodies in their blood for a long period of time (longer than 11 months). Some of these patients with low antibody levels developed infections. People with serious infections should not receive RUXIENCE. Tell your healthcare provider right away if you have any symptoms of infection:
 - Fever
 - Cold symptoms, such as runny nose or sore throat, that do not go away
 - Flu symptoms, such as cough, tiredness, and body aches
 - Earache or headache
 - Pain during urination
 - Cold sores in the mouth or throat
 - Cuts, scrapes, or incisions that are red, warm, swollen, or painful
 - **Heart Problems:** RUXIENCE may cause chest pain, irregular heartbeats, and heart attack. Your healthcare provider may monitor your heart during and after treatment with RUXIENCE if you have symptoms of heart problems or have a history of heart problems. Tell your healthcare provider right away if you have chest pain or irregular heartbeats during treatment with RUXIENCE
 - **Kidney Problems:** RUXIENCE can cause severe kidney problems that lead to death, especially if you are receiving RUXIENCE for Non-Hodgkin's Lymphoma (NHL). Your healthcare provider should do blood tests to check how well your kidneys are working

- **Stomach and Serious Bowel Problems That Can Sometimes Lead to Death:** Bowel problems, including blockage or tears in the bowel, can happen if you receive RUXIENCE with chemotherapy medicines. Tell your healthcare provider right away if you have any stomach-area (abdomen) pain or repeated vomiting during treatment with RUXIENCE

Your healthcare provider will stop treatment with RUXIENCE if you have severe, serious, or life-threatening side effects.

Common side effects of RUXIENCE include:

- Infusion-related reactions
- Infections (may include fever, chills)
- Body aches
- Tiredness
- Nausea

In adult patients with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) or Microscopic Polyangiitis (MPA), the most common side effects of RUXIENCE also include:

- Low white and red blood cells
- Swelling
- Diarrhea
- Muscle spasms

Other side effects with RUXIENCE include:

- Aching joints during or within hours of receiving an infusion
- More frequent upper respiratory tract infections

These are not all of the possible side effects with RUXIENCE.

INDICATIONS

RUXIENCE[®] (rituximab-pvvr) is a prescription medicine used to treat adults with:

- Non-Hodgkin's Lymphoma (NHL): alone or with other chemotherapy medicines
- Chronic Lymphocytic Leukemia (CLL): with the chemotherapy medicines fludarabine and cyclophosphamide
- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA): with glucocorticoids

RUXIENCE is not indicated for treatment of children.

This information does not take the place of talking with your doctor. Discuss with your doctor any questions you have about your medical condition or your treatment.

Call your doctor for medical advice about side effects. You are encouraged to report adverse events related to Pfizer products by calling 1-800-438-1985. If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly. Visit www.fda.gov/MedWatch or call 1-800-FDA-1088.

Please see Important Safety Information and Indications on pages 8 and 9 and [full Prescribing Information, including BOXED WARNINGS and Medication Guide, at **RUXIENCE.com**.](#)

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To learn more,
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The health information contained herein is provided for educational purposes only and is not intended to replace discussions with a healthcare provider. All decisions regarding patient care must be made with a healthcare provider, considering the unique characteristics of the patient.

The product information provided in this brochure is intended only for residents of the United States. The products discussed herein may have different product labeling in different countries.

RUXIENCE is a registered trademark of Pfizer Inc.
Rituxan® (rituximab) is a registered trademark of Biogen, Inc.