XPOSE® PATIENT SUPPORT PROGRAM ENROLLMENT AND CONSENT FORM

For patients prescribed PrRIXIMYO® (rituximab)

Telephone: 1-888-449-7673 (1-888-44XPOSE)

Fax: 1-844-449-7673 (1-844-44XPOSE)

Monday–Friday: 8 AM–8 PM EST

Pr Riximyo rituximab | XPOSE Patient Support Program by Sandoz

Patient Information

Last Name _____ First Name _____

Sex: ☐ M ☐ F ☐ Other Date of Birth (dd/mmm/yyyy) _____

Address _____

City _____ Province _____

Primary Phone Number _____ Health Card # _____

Secondary Number _____ Leave a Message: ☐ Yes ☐ No

Email Address _____

Patient Consent

I have read and agree to the patient consent on the second page of this form.

X _____ Signature _____ Date (dd/mmm/yyyy) _____

☐ Verbal consent received by the patient to be contacted by the XPOSE® Patient Support Program

Verbal consent received by: _____

X _____ Signature _____ Date (dd/mmm/yyyy) _____

Referring Physician and Clinic Information

Physician Name (please print) _____ Physician Phone # _____

Address _____

City _____ Province _____

Postal Code _____ Fax # _____

Clinic Contact _____

Contact Email _____

Preferred Form of Communication: ☐ Email ☐ Fax ☐ Phone

Treatment Legend

Initial dose

255-minute infusion (4.25 hrs): RIXIMYO® 1000 mg IV at a rate of 50 mg/hr for the first 30 minutes, increasing 50 mg/hr every 30 minutes as tolerated, for a maximum rate of 400 mg/hr.

Subsequent doses

195-minute infusion (3.25 hrs): RIXIMYO® 1000 mg IV can be started at a rate of 100 mg/hr for the first 30 minutes, increasing 100 mg/hr every 30 minutes as tolerated, for a maximum rate of 400 mg/hr.

Alternative 120-minute subsequent infusions (4 mg/mL concentration in a 250 mL volume (RA Only): If patients did not experience a serious infusion-related adverse event during the previous infusion administered using the standard administration schedule, RIXIMYO® 1000 mg IV can be started at a rate of 250 mg/hr for the first 30 minutes (125 mg) and then 600 mg/hr for close to 90 minutes (875 mg). Not an option for all patients. Consult Product Monograph for information on alternative administration eligibility.

R_x — Please Mark Clearly

Please consult the RIXIMYO® Product Monograph for important information relating to dosing, administration, adverse reactions and drug interactions.

Indication: _____

ORDER FOR RIXIMYO®: ☐ 1st Treatment ☐ Subsequent Treatment

_____ OR ☐ To be determined by XPOSE®
Preferred Infusion Clinic Location

_____
Anticipated Infusion Date

☐ Dilute to a final concentration of 1 mg/mL to 4 mg/mL in an infusion bag containing either 0.9% Sodium Chloride USP, or 5% Dextrose Injection USP.

☐ Dilute RIXIMYO® in 250 mL of 0.9% Sodium Chloride Injection, USP IV (only for use in alternate 120 min/ 4 mg/mL infusion).

Other Instructions _____

X _____
Physician Signature

1st Treatment

Day 1 ☐ 255-minute infusion (4.25 hrs) x 1000 mg

Day 15 ☐ 195-minute infusion (3.25 hrs) x 1000 mg

OR ☐ Alternative 120-minute infusion (2 hrs) x 1000 mg*

Subsequent Treatments

Day 1 ☐ 255-minute infusion (4.25 hrs) x 1000 mg

OR ☐ Alternative 120-minute infusion (2 hrs) x 1000 mg*

Day 15 ☐ 195-minute infusion (3.25 hrs) x 1000 mg

OR ☐ Alternative 120-minute infusion (2 hrs) x 1000 mg*

***Alternative 120-minute infusion is not an option for all patients. Consult Product Monograph for information on alternative administration eligibility.**

☐ Other Dosing: _____

_____

Allergies: _____

Blood Pressure Meds on Hold: ☐ Y ☐ N Name of Drug: _____

Please Specify Directives: _____

Pre-Medications

☐ Acetaminophen 650 mg PO 30 min pre infusion

☐ Diphenhydramine 50 mg PO 30 min pre infusion

☐ Methylprednisolone 100 mg IV in 50 mL 0.9% Sodium Chloride Injection, USP 30 min pre infusion

☐ _____ Other

☐ **Pre-medications not required** _____

PRN Medications for Infusion Reactions

In the event of an infusion reaction, any/all of the following medications/treatments may be given to the patient unless otherwise indicated below:

☐ Acetaminophen 325-650 mg PO PRN q 4-6 hours, for pain and fever, chills

☐ Dimenhydrinate 25-50 mg PO/IV PRN q 4 hours, for nausea and vomiting

☐ Diphenhydramine 25-50 mg PO/IV/IM PRN q 4-6 hours for itching, urticaria, pruritus, hives

☐ Epinephrine (1:1000) 0.01 mL/kg (max. 0.5 mL) SC/IM PRN q 10-15 minutes x2 for severe anaphylactic reaction

☐ Hydrocortisone 100 mg IV PRN x 1 severe allergic/anaphylactic reaction

☐ Oxygen via mask/nasal prongs PRN for shortness of breath, wheezing

☐ Salbutamol 2 puffs q 4-6 hours via aerochamber PRN for dyspnea, wheezing

☐ _____ Other

☐ **PRN medications not required** _____

I have read and agree to the physician declaration on the reverse side of this form.

X _____ Physician Signature _____ Date (dd/mmm/yyyy) _____

I certify that this prescription order is an original prescription. The designated pharmacy is the only recipient. The original will not be reused.

For program-related inquiries, please call the XPOSE® Program at 1-888-44XPOSE (1-888-449-7673).

Physician Declaration

I have read the patient consent section of this form and confirm: (1) I agree to my patient being enrolled in the XPOSE® Program ("Program"); (2) I have prescribed the drug specified on this form in accordance with its product monograph; and (3) I have the patient's express consent to provide the Program with the information in this form and any other information relevant to provide the Program's services.

I accept that my information, including Personal Information, may be used by Sandoz Canada Inc. ("Sandoz") or its agents for reasons related to improving, monitoring and auditing its programs, for commercial or market research purposes, or as otherwise permitted by law. Details about how my file will be maintained, and how to access/correct my information, are as set out in the patient consent section.

I acknowledge that adverse events may be reported about my patients participating in the Program and understand I may be contacted by Sandoz or its agents to provide follow-up information. As adverse event reports may need to be processed in and outside of Canada and forwarded to Canadian and foreign regulatory authorities, I understand that my information may be stored or processed outside of Canada.

I have discussed the Program with the patient who wishes to enroll and has agreed that I share their Personal Information to the Program to contact the patient and confirm enrollment.

I certify that this prescription order is an original prescription. The designated pharmacy is the only recipient. The original will not be reused.

Patient Consent

What is XPOSE®?

XPOSE® is a patient support program ("Program") provided by Sandoz Canada Inc. and/or its affiliates (collectively "Sandoz", "we", "us", "our") to Canadian patients who have been prescribed RIXIMYO®. Your healthcare professional believes you could benefit from the Program. The Program services may include health/product information, insurance reimbursement assistance or treatment related services and support (the "Services").

A third-party service provider is the administrator of the Program: its employees and/or agents handle your Personal Information, which is processed in accordance with privacy laws and Sandoz privacy/data protection standards. You will be notified should the administrator of the Program change, including in the case of administration by a Sandoz department; your Personal Information will continue to be protected with equivalent safeguards.

Your participation in the Program is voluntary. If you choose not to participate, neither your medical treatment nor your insurance coverage eligibility will be impacted. However, if you do not participate, you cannot receive assistance or Services from the Program. The Program is not intended to provide medical advice or medical diagnoses. You agree to seek the advice of your physician or other qualified healthcare professional if you have health concerns, and not to disregard professional medical advice based on information obtained from the Program. Sandoz reserves the right to modify or terminate the Program at any time without prior notice.

In the event that you elect to benefit from any external support referral service offered by the Program to help you locate available resources in your community you understand that the third parties to whom you may be referred by the Program are in no way affiliated with, or monitored by, Sandoz. You understand that you are solely responsible for your interactions with these third parties and Sandoz cannot be held responsible for the information or services that these third parties may offer to you.

Why is Personal Information collected, for which purposes and with whom could it be shared?

Information, such as your date of birth, contact information, drug/medical, and insurance/financial information (collectively "Personal Information") is collected to communicate with you, provide you with the Program's Services, audit or monitor the Program, and perform certain activities as required or permitted by law, including to process and report adverse events ("AEs"). We may contact you at the contact information you have provided; e-mail, phone or other (if via cellular, we will not assume any resulting cellular phone charges). Only relevant personnel will have access to your Personal Information.

Your Personal Information may be collected from and disclosed to healthcare professionals, insurance providers or other third parties, as needed for the Program's administration and Services. Our third-party providers are contractually obliged to strict data protection and security requirements.

In the case of AE processing and reporting to regulatory authorities, if monitoring or auditing is performed, or if required and/or permitted by law, it may be that Sandoz employees or agents will have access to your Personal Information.

The Administrator or Sandoz' agents may de-identify, aggregate (combine with other data) and/or anonymize your Personal Information to conduct analyses for commercial, research/publication purposes or to improve the Program. Your Personal Information may be stored or processed outside of Canada, including for AE processing and reporting requirements. In such case, Sandoz ensures that your Personal Information is protected. Your Personal Information may be subject to the laws of foreign jurisdictions, with a different level of protection than your country of residence.

What happens if I withdraw from the Program?

You may revoke your consent at any time, by calling the Program at 1-888-449-7673. Withdrawing your consent will result in the termination of your participation in the Program and its Services. No new personal information will be collected; the file containing your Personal Information will be maintained during the term of the Program for monitoring and regulatory purposes; and de-identified, aggregated or anonymized data may continue to be used as described above.

You may request access or correction to your file by contacting the Administrator Privacy Officer at **xpose@sandozprogramsupport.ca**

By signing the consent, you agree to the collection, use and disclosure of your Personal Information as described herein. You can learn more about how Sandoz protects privacy at https://www.sandoz.com/privacy-policy.

RIXIMYO® (rituximab) is indicated for:

Non-Hodgkin's Lymphoma (NHL):

- the treatment of patients with relapsed or refractory low-grade or follicular, CD20 positive, B-cell non-Hodgkin's lymphoma.
- the treatment of patients with CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma (DLBCL) in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) chemotherapy.
- the treatment of patients with previously untreated Stage III/IV follicular, CD20 positive, B-cell non-Hodgkin's lymphoma in combination with CVP (cyclophosphamide, vincristine and prednisolone) chemotherapy.
- the maintenance treatment of patients with follicular non-Hodgkin's lymphoma who have responded to induction therapy with either CHOP or CHOP plus rituximab.
- single-agent maintenance treatment of previously untreated patients with advanced follicular non-Hodgkin's lymphoma with high tumour burden and who have responded to induction therapy with either CHOP plus rituximab or CVP plus rituximab.

Chronic Lymphocytic Leukemia (CLL):

- the treatment of patients with previously untreated or previously treated B-cell chronic lymphocytic leukemia (B-CLL), Binet Stage B or C, in combination with fludarabine and cyclophosphamide.

The use of RIXIMYO® in CLL is based on an improvement in progression-free survival. Overall survival benefit has not been demonstrated in patients with previous treatment for CLL. The efficacy of treatment with R-FC (rituximab-fludarabine and cyclophosphamide) in CLL patients who were previously treated with rituximab in combination with fludarabine and cyclophosphamide has not been studied.

Rheumatoid Arthritis (RA):

RIXIMYO® in combination with methotrexate is indicated in adult patients:

- to reduce signs and symptoms in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumour necrosis factor (TNF) inhibitor therapies.

Consult the Product Monograph at https://www.sandoz.ca/sites/www.sandoz.ca/files/Riximyo-Product-Monograph.pdf for contraindications, warnings, precautions, adverse reactions, drug interactions, dosing (do not administer as an intravenous push or bolus), conditions of clinical use, and other information, which have not been discussed in this piece. The Product Monograph is also available by calling 1-800-361-3062.

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Riximyo rituximab

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