Patient Support Program

PfizerFlex

ENROLMENT FORM
Rheumatoid Arthritis

Ruxience® rituximab

call **1-855-935-FLEX (3539)**
fax **1-833-958-FLEX (3539)**
email **ruxience@pfizerflex.com**

Download contact information

PATIENT INFORMATION

Name: _____

Address: (No. & street name) _____

(City, Province) _____

(Postal code) _____

Tel. (Home): _____ **Tel.** (Cell): _____

Leave messages: ☐ Yes ☐ No **Send text** (SMS): ☐ Yes ☐ No

Best time to be contacted: ☐ AM ☐ PM ☐ Night

Email: _____

Date of birth: DD/MM/YYYY **Known allergies**: ☐ Yes ☐ No

If Yes, please specify: _____

Health card number: _____

PHYSICIAN INFORMATION

Physician name: _____

License no.: _____

Address: (No. & street name) _____

(City, Province) _____

(Postal code) _____

Tel. (Office): _____

Fax (Office): _____

Office contact name: _____

Email: _____

PHYSICIAN PRESCRIBING SECTION

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

Diagnosis: ☐ **Moderately to severely active rheumatoid arthritis (RA)** Provincial formulary code (if applicable): _____

Notes: _____

ORDER FOR RUXIENCE

☐ **First treatment** ☐ **Subsequent treatment(s)**

Anticipated infusion date: DD/MM/YYYY

First treatment:

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

Day 15 ☐ 195-minute infusion (3.25 hrs) × 1000 mg **OR**

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

Subsequent treatments:

Day 1 ☐ 255-minute infusion (4.25 hrs) × 1000 mg **OR**

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

Day 15 ☐ 195-minute infusion (3.25 hrs) × 1000 mg **OR**

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

Need for re-treatment† evaluated in: _____ weeks

Additional notes: _____

TREATMENT LEGEND

255 minutes (4.25 hrs): RUXIENCE 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.

195 minutes (3.25 hrs): RUXIENCE 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.

120 minutes (2 hrs): If patients did not experience a serious infusion-related adverse event during the previous infusion administered using the standard administration schedule, an alternative 120-minute infusion of a concentration at 4 mg/mL in a 250 mL volume can be administered for the second infusion. Initiate at a rate of 62.5 mL/hour (125 mg) given in the first 30 minutes and 150 mL/hour (875 mg) given over the next 90 minutes. If the 120-minute infusion is tolerated, the same alternative 120-minute infusion rate can be used when administering subsequent infusions and courses. Not an option for all patients. Consult the Product Monograph for information on alternative administration eligibility.

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

† The need for further courses should be evaluated 24 weeks following the previous course with retreatment given based on residual disease or disease activity returning to a level above a DAS28-ESR of 2.6 (treatment to remission). Patients may receive further courses no sooner than 16 weeks following the previous course.

☐ **Other dosing:** _____

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

Comments: _____

Blood pressure meds on hold: ☐ Yes ☐ No Please specify: _____

PRE-MEDICATION ORDER

☐ Acetaminophen 650 mg PO 15–30 minutes prior to infusion

☐ Diphenhydramine 50 mg PO 15–30 minutes prior to infusion

☐ Methylprednisolone 100 mg IV in 50 mL 0.9% Sodium Chloride Injection, USP 15–30 minutes prior to infusion

☐ Other (indicate): _____

☐ **Pre-medications not required**

Please specify: _____

PRN MEDICATIONS FOR INFUSION REACTIONS

☐ 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 × 2 for severe anaphylactic reaction

☐ Hydrocortisone 100 mg IV PRN × 1 for 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 (indicate): _____

☐ **PRN medications not required** Please specify: _____

PHYSICIAN SIGNATURE

Do you accept that Pfizer Canada's Drug Safety Unit contact you regarding information shared on this form or any accompanying document? ○ YES ◉ NO

Notes: _____

☐ **I have read, understand, and agree to the physician consent statement on the reverse.**

SIGN HERE: _____ Date‡: DD/MM/YYYY

‡ Effective date. Order(s) expires one year from the date of signature. Prescriber certification: I certify that this prescription is an original prescription and this pharmacy is the only receiver. The original will not be reused.

PATIENT SIGNATURE

SIGN HERE: _____ Date: DD/MM/YYYY

☐ I have read and understood the Patient Consent text printed on the back of this form and agree to the collection, use and disclosure of my Health Information in accordance with these terms.

☐ I consent to the receipt of electronic communications containing information and updates relating to the **PfizerFlex Program**. The **Administrators** (the service providers elected by Pfizer to administer the **PfizerFlex Program** offerings) are seeking your consent on behalf of Pfizer Canada ULC, the sponsor of the Program. You can withdraw your consent to receive electronic communications by following the instructions provided in the electronic communication. You can contact the Program Administrators at any time by calling 1-855-935-FLEX (3539) or at: **PfizerFlex Program**, P.O. Box 34586, 3131 Côte-Vertu Blvd, Ville St-Laurent, QC H4R 2P4.

Fax completed form to **1-833-958-FLEX (3539)**

PATIENT CONSENT

Agreement to Disclose Personal Information – PfizerFlex Program

Special Instructions: This consent form may contain words or phrases that are new to you. If any part of this form is not clear to you, please ask the person who gave you this form to explain it to you. Words that are written in **bold type** are explained on the bottom of this section.

We are asking for your permission to collect, to use and to share your **Personal Information***. The patient assistance program for RUXIENCE, called **PfizerFlex**† ("Program") is a free Program offered to all patients who have been prescribed RUXIENCE. The Program can help you in a number of ways. Sharing your Personal Information as described on this form will help us figure out which Program services and materials are best for you.

For you to take part in the Program and for us to carry out the Program activities for you, you agree to:

- Allow your **Healthcare Providers**‡, the Administrators (the service providers elected by Pfizer to administer the program offerings) and the **PfizerFlex Program Personnel**§ ("Program Personnel") to collect, use, share with each other, and store your Personal Information. These people are described at the bottom of this form.
- Allow the Program Personnel to use the Personal Information that you provide to contact you, and to collect other Personal Information from you that is needed or related to the administration of the Program. For example, this may include asking for your feedback on the quality of the services offered by the Program or any other related services, or your progress while taking the medication RUXIENCE, and may include limited market research, such as surveys on your experiences, so that Pfizer may better understand and improve its products and programs. Program Personnel may leave messages for you at the phone number you give them, if you have checked the *Leave messages* box on this enrolment form.
- Allow Pfizer Canada (the company that sells RUXIENCE) and its affiliates ("Pfizer") to collect your Personal Information and information on any unwanted drug effects ("adverse drug events", or side effects) that you may have while taking RUXIENCE, or other medications made by Pfizer. Commonly, Pfizer and Health Canada ask for this information to track the safety record of these medications. The information collected from you and others taking these medications allows them to better understand how these medications can affect the patients who take them. This information may be provided to Health Canada or to another regulatory agency to report any adverse drug events, or as otherwise may be required by law. Pfizer may also contact your Healthcare Providers if they need more information.
- Allow Pfizer, or a service provider hired by Pfizer, to have access to your Personal Information in order to audit the Program or provide recommendations on how to improve the Program. For example, Pfizer or its service provider may review documents that contain your Personal Information, or monitor phone conversations between you and Program Personnel for quality control purposes. Any service provider will be required to only use your Personal Information for purposes relating to the audit/Program administration, and will not disclose your Personal Information to third parties.
- Allow Pfizer to collect, share, and publish anonymized statistical data with healthcare providers and third parties for reimbursement, publication, or commercial purposes.
- The Administrator and Program Personnel can administer the prescribed RUXIENCE medication to me during a pre-scheduled specialty clinic appointment. Such treatment shall include administration of prescribed pre-medication and management of infusion related reactions or emergencies during the infusion treatment appointment.

By giving your consent, you understand that:

- You agree to receive Program services, support and materials suitable for your needs.
- The Program Personnel are not allowed to collect, use, share or store your Personal Information for anything other than the activities described in this consent form. They cannot share any of your Personal Information with anyone other than your Healthcare Providers, unless the **Health Information*** that identifies you is removed. For example, your name, address and any personal identifiers must be removed if any of your Health Information is shared with anyone who is not your Healthcare Provider. Health Information which does not have your name, address or personal identifiers could still be shared after you withdraw your consent.
- You may take back your consent at any time by calling the Administrators at 1-855-935-FLEX (3539) or sending a request with your signature to the Administrators by fax to 1-833-958-FLEX (3539). Your consent is needed to receive services from the PfizerFlex Program. If you decide to take back your consent, you will no longer be enrolled in the PfizerFlex Program. This means that you will not be able to receive any support services from the Program, and you may not be able to get financial assistance for RUXIENCE if you are eligible.
- Except where prohibited by law, you may have a copy of your Personal Information. You can correct any mistakes and/or ask the Administrators any questions about the collection, use, sharing and storage of your Personal Information. You may contact the Administrators by calling 1-855-935-FLEX (3539) or by faxing your request to 1-833-958-FLEX (3539).
- Any calls to or from the Administrators while providing services of the Program may be monitored or recorded for control of quality and to train their personnel.
- Your Personal Information may be collected, used, shared and/or stored outside of your province or territory or country. The laws of those countries regarding privacy may be less strict than the laws of Canada and its provinces.
- Your Personal Information may also be disclosed and/or transferred to a third party in the event of a proposed or actual purchase, sale (including a liquidation, realization, foreclosure or repossession), lease, amalgamation or any other type of acquisition, disposal, transfer, conveyance or financing of all or any portion of Pfizer Canada or of any of the business or assets or shares of Pfizer Canada or a division thereof.
- Pfizer Canada has the right to modify or cancel the Program and the services offered by the Program at any time without prior notice to you.
- If at any time and for any reason Pfizer Canada appoints new Program Administrators, you will allow the transfer of your Personal Information by the Administrators or by Pfizer to the new Administrators in order to continue your participation in the Program.
- You will not seek to have the amount of support you receive by way of this program counted in any Government out-of-pocket expenses for prescription drugs.
- Unless your consent is withdrawn, your consent is valid for as long as you receive services from the Program and for a reasonable time thereafter.

* Your **Personal Information** includes your individual information (name, gender, address, phone number, date of birth, etc.), your financial information and your **Health Information** (medical history, medical condition(s), information relating to your treatment, and information relating to your health insurance, etc.).

† The **PfizerFlex Program** is sponsored by Pfizer Canada to help patients get access to RUXIENCE, and to help them manage their treatment plan for the indications authorized for use for the indications authorized for use.

‡ **Healthcare Providers** include all of your doctors, nurses, pharmacists or pharmacy support staff, private insurance company(s), public payer(s) and any other healthcare provider or payer that may possess the necessary information.

§ **PfizerFlex Program Personnel** include the employees and consultants of the Administrators, as well as any service providers that are engaged by the Administrators to manage or perform Program services and activities.

PHYSICIAN CONSENT

My signature acknowledges that:

- I am the prescribing physician of this patient;
- I have prescribed this patient RUXIENCE for an authorized indication;
- Subject to the above-noted patient's consent and only to the extent of such patient's consent:
  - I consent to the **PfizerFlex Program Personnel**¶ contacting me with regard to the above-noted patient to assist it in administering the program, and without limitation with regard to patient reimbursement, and patient care;
  - I consent to the Administrators (the service providers elected by Pfizer to administer the program offerings) receiving, collecting, storing, using and disclosing any of my information that I provide in respect to the patient that is necessary to assist the patient in obtaining any services or assistance the patient has authorized and consented to;
  - I consent to Pfizer Canada (the company who sells RUXIENCE) and its affiliates ("Pfizer") to contact me with regard to the above-noted patient if they require further information on adverse drug events pertaining to RUXIENCE, or other medications manufactured by Pfizer;
  - I agree to allow the Administrators to provide this prescription to the pharmacy chosen by the above-named patient or another pharmacy (where applicable) to ensure the patient obtains access to the therapy I have prescribed;
  - I agree to allow the Administrators to contact me for any other information regarding the **PfizerFlex Program**** that would result in enhancing the delivery or the quality of services offered by this program to my patient.

¶ **PfizerFlex Program Personnel** include the employees and consultants of the Administrators elected by Pfizer to administer the Program.

** The **PfizerFlex Program** is sponsored by Pfizer Canada to help patients get access to RUXIENCE, and to help them manage their treatment plan for the indications authorized for use.

For more information, please refer to the RUXIENCE Product Monograph.
The Product Monograph is available upon request or it can be accessed at https://www.pfizer.ca/en/our-products/ruxience-rituximab-injection.

Pr Ruxience® rituximab

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MEMBER OF INNOVATIVE MEDICINES CANADA

REVIEWED BY PAAB

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