

# Pr RUXIENCE® Patient Enrolment, Rx and Consent Form for Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)

Please fax to 1-833-958-3539 or 1-833-958-FLEX upon completion. To speak to a clinic representative, call toll-free 1-855-935-3539 or 1-855-935-FLEX.

PATIENT INFORMATION	PHYSICIAN INFORMATION
Name: _____	Physician Name: _____
Address: _____	Address: _____
Tel. (Home): _____ Tel. (Other): _____	Tel. (Office): _____
Okay to leave messages: <input type="checkbox"/> Yes <input type="checkbox"/> No	Fax (Office): _____
Best time to be contacted: <input type="checkbox"/> AM <input type="checkbox"/> PM <input type="checkbox"/> Night	Office Contact Name: _____
Email: _____ Date of birth: DD/MM/YYYY	Email: _____
Known allergies: <input type="checkbox"/> No <input type="checkbox"/> Yes If Yes, please specify: _____	

## PHYSICIAN PRESCRIBING SECTION

Please consult the RUXIENCE® Product Monograph for important information relating to dosing, administration, adverse reactions and drug interactions. Confirmed diagnosis of:  **Granulomatosis with Polyangiitis (GPA, also known as Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)**

RUXIENCE® DOSING	RUXIENCE® DOSE AND INFUSION FREQUENCY
Calculate the patient's body surface area (BSA)* using weight and height:	<b>Weekly dose (mg) = 375 mg/m<sup>2</sup> x patient's BSA m<sup>2</sup></b>
Weight: _____ kg Height: _____ cm	Ordered RUXIENCE® dose = Weekly dose x 4 weeks
Mitte: _____ dose(s) Repeats: _____	375 mg/m <sup>2</sup> x [patient's BSA m <sup>2</sup> ] = [weekly RUXIENCE® dose mg] x 4 (weeks)
Patient's BsA* = _____	= [Ordered Dose (total over 4 weeks)]
* Formula for calculating BSA: BSA in m <sup>2</sup> = (Weight in kg) <sup>0.425</sup> x (Height in cm) <sup>0.725</sup> x 0.007184 Do not round until the end of calculation.	<input type="checkbox"/> 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
	Other instructions: _____
	Comments: _____
	<b>Blood pressure meds on hold:</b> <input type="checkbox"/> YES <input type="checkbox"/> NO Please specify: _____
	RUXIENCE® should be given in combination with glucocorticoids.

## PRE-MEDICATION ORDER PRN MEDICATIONS FOR INFUSION REACTIONS

<input type="checkbox"/> Acetaminophen 650 mg PO 15-30 min pre infusion	<input type="checkbox"/> Acetaminophen 325-650 mg PO PRN q 4-6 hours, for pain and fever, chills
<input type="checkbox"/> Diphenhydramine 50 mg PO 15-30 min pre infusion	<input type="checkbox"/> Dimenhydrinate 25-50 mg PO/IV PRN q 4 hours, for nausea and vomiting
<input type="checkbox"/> Methylprednisolone 100 mg IV in 50 mL 0.9% sodium chloride injection, USP 15-30 min prior to infusion	<input type="checkbox"/> Diphenhydramine 25-50 mg PO/IV/IM PRN q 4-6 hours for itching, urticaria, pruritus, hives
<input type="checkbox"/> Other (indicate): _____	<input type="checkbox"/> Epinephrine (1:1000) 0.01 mL/kg (max. 0.5 mL) SC/IM PRN q 10-15 minutes x 2 for severe anaphylactic reaction
<input type="checkbox"/> Pre-medications not required Please specify: _____	<input type="checkbox"/> Hydrocortisone 100 mg IV PRN x 1 for severe allergic/anaphylactic reaction
	<input type="checkbox"/> Oxygen via mask/nasal prongs PRN for shortness of breath, wheezing
	<input type="checkbox"/> Salbutamol 2 puffs q 4-6 hours via aerochamber PRN for dyspnea, wheezing
	<input type="checkbox"/> Other (indicate): _____
	<input type="checkbox"/> 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<sup>1</sup>: DD/MM/YYYY

<sup>†</sup> 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 1-855-935-3539 or 1-855-935-FLEX or at: **PfizerFlex Program**, P.O. Box 34586, 3131 Côte-Vertu, Ville St-Laurent, QC H4R 2P4.



Fax completed form to **1-833-958-3539** or **1-833-958-FLEX**

## 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 *can leave a message* box on this enrollment 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 (the government body that approves the use of this and other medications) 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.
- 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 approved by Health Canada.

‡ **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 a Health Canada approved 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 event 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 approved by Health Canada.

For more information, please refer to the RUXIENCE® Product Monograph.

The Product Monograph is available upon request or it can be accessed at <http://pfizer.ca/pm/en/RUXIENCE.pdf>.



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