XPOSE® Program Enrollment and Consent Form

Reset Form

Please email or fax completed form.
Telephone: 1-844-279-7673
Fax: 1-877-222-9919
Email: rhapsido@xoseprogram.ca

Unless encrypted, be mindful that email communications may not be safe. **One form per email.**

RHAPSIDO® (remibrutinib) is indicated for the treatment of chronic spontaneous urticaria (CSU) in adult patients who remain symptomatic despite H1 antihistamine treatment.

PATIENT INFORMATION

First name _____ Last name _____ Date of birth (DD/MMM/YYYY) _____ ☐ Male ☐ Female ☐ Other

Health card number _____ Coverage: ☐ Public ☐ Private ☐ Other Language: ☐ English ☐ French

Address _____ City _____ Province _____ Postal code _____

Mobile phone _____ Other phone _____ Email _____ Preference: ☐ Phone ☐ Email ☐ SMS*

** Message frequency varies. Standard rates may apply.*

PRESCRIBER INFORMATION

First name _____ Last name _____ License # _____ Office contact name _____

Address _____ City _____ Province _____ Postal code _____

Telephone _____ Fax _____ Email _____ Preference: ☐ Phone ☐ Email ☐ Fax

MEDICAL HISTORY

☐ **I hereby confirm that the patient (REQUIRED):**

- Has completed a baseline UAS7; UAS7: _____ **(mandatory)**
- Is an adult (18+ years old)
- Has a confirmed diagnosis of CSU
- Remains symptomatic despite H1 antihistamine treatment

Treatment History

(E.g., Antihistamine/Biologic etc.)	Dose	Start (MMM/YYYY)	Stop (MMM/YYYY)	Clinical Results
				☐ I ☐ CI ☐ F
				☐ I ☐ CI ☐ F
				☐ I ☐ CI ☐ F
				☐ I ☐ CI ☐ F
				☐ I ☐ CI ☐ F

Legend: I = Intolerance, CI = Contraindication, F = Failure

PATIENT CONSENT

I would like to be enrolled in the Novartis XPOSE® Program for RHAPSIDO®. I have read and agree to the collection, use and disclosure of my personal information as explained in the consent section on the reverse side of this form.

Furthermore, I hereby request that the PSP administrator provide my prescription to my designated pharmacy, and I appoint the PSP administrator as my agent, or, if I reside in Quebec, as my mandatary, to perform any acts necessary to have my prescription filled by my designated pharmacy.

I understand that Novartis reserves the right to modify or terminate the Program without prior notice.

I understand that I am solely responsible for: (i) verifying with my financial advisor(s) and public or private drug benefit providers the impact of accepting financial assistance through the Program; and (ii) complying with all applicable laws, policies, or guidance from government agencies and public or private drug benefit providers if I choose to accept such assistance.

The Program may wish to contact me via electronic means; I will have the opportunity to opt out from such communications.

Consent obtained by the prescriber from: ☐ Patient ☐ Legal guardian

Name _____ Relationship _____

X _____ Signature _____ Date (DD/MMM/YYYY) _____

IMPORTANT: If written consent cannot be obtained from patient/legal representative, please document when verbal consent was obtained and by whom. This will allow the XPOSE® Program to proceed with enrollment.

Verbal consent obtained by:

Name of prescriber _____ Date (DD/MMM/YYYY) _____

PRESCRIPTION INFORMATION

RHAPSIDO® (remibrutinib) 25 mg p.o. b.i.d. (twice daily) 1 month supply.

Refills: _____ Samples given: _____ boxes

Notes: _____

PRESCRIBER CONSENT (MANDATORY)

X _____ Prescriber signature _____ Date (DD/MMM/YYYY) _____

ACKNOWLEDGEMENTS AND UNDERTAKINGS

- The above prescription parameters comply with the indications set forth in the Product Monograph. I represent, certify and warrant that I can legally order a prescription of the drug product in focus for this PSP.
- I have discussed the Patient Support Program ("PSP") with the patient who wishes to enroll and has consented that I share their personal information (name, email, contact number, prescription information) in this form with the PSP to contact patient and confirm enrollment. Additionally, I have explained the uses and communication of the patient's personal information to the patient, as described in the consent section (on the reverse side of this form).
- This prescription represents the original prescription drug order. I appoint the PSP to be my designated agent to forward this prescription by fax, or other mode of delivery, to the pharmacy chosen by the patient, which is the only intended recipient.

PERSONAL INFORMATION

I have read and agree to the collection, use and disclosure of my personal information for the purpose of managing the PSP, as set out in the consent section (on the reverse side of this form).

XPOSE® Program Enrollment and Consent Form

XPOSE® by Novartis

Rhapsido® (remibrutinib) 25mg tablets

Please email or fax completed form.
Telephone: 1-844-279-7673
Fax: 1-877-222-9919
Email: rhapsido@xposeprogram.ca

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Recommended dose:

- **For adults with chronic spontaneous urticaria (CSU):**
  - The recommended dose is 25 mg taken orally twice daily.

Welcome to the Novartis Pharmaceuticals Canada Inc. ("Novartis", "we") XPOSE® for RHAPSIDO®.

The PSP services are available to any patient meeting the eligibility requirements for enrollment, which typically consist at minimum in a prescription for a drug treatment from an HCP as well as current eligibility under a federal or provincial health insurance plan.

CONSENT TO THE COLLECTION, USE AND DISCLOSURE OF PERSONAL INFORMATION (for more information, see the "Details" section)

Why do we collect personal information for the PSP?

We collect personal information to provide our services. This information can directly identify you (like your name) or indirectly identify you (with enough details). We may also use personal information to comply with regulatory reporting requirements, and for analytical purposes. We will ask for your specific consent if we need to use it for other reasons, unless the law allows us to use it without your consent.

What type of personal information is collected?

Patients: We collect your name, address, phone number, date of birth, health information such as disease information and test results, and caregiver's name.

HCPs: We will collect your name, address, and information about your patients in the PSP, including the number of patients enrolled.

Caregivers or legal guardians: We collect your name, address, and phone number.

Who collects and has access to personal information?

Novartis or its appointed company manages the PSP. They collect and store your information securely and may share with HCPs, insurance companies, or other organizations, such as pharmacies, labs, and clinics that provide a service as part of the program.

Will we collect other personal information outside of the PSP?

No, we will ask for your additional consent to collect personal information not related to the PSP services. For example, we may ask for your permission to participate in market research.

How can you request access or corrections to your personal information in the PSP?

For questions, access or corrections to your information, or to withdraw consent, you can reach the Novartis Privacy Officer at global.privacy_operations@novartis.com or the XPOSE® Program for RHAPSIDO® at 1-844-279-7673.

For more information on our privacy practices, you may also consult our Canadian Privacy Notice at: https://www.novartis.com/ca-en/privacy.

How can you withdraw consent from the PSP?

You can withdraw consent anytime. Without it, we may not be able to provide services. Withdrawal stops future use of your information and new collection, but already collected information will remain in our database or adverse events database until it can be deleted as per health authorities' guidelines.

We may contact you by email or text to inform you about the PSP services. For SMS, message frequency varies and standard messaging rates may apply. You can opt out of these messages, but this may limit your use of the PSP services.

DETAILS ON HOW WE COLLECT, USE AND SHARE PERSONAL INFORMATION FOR THE PSP

Why do we collect personal information to run the PSP?

We collect personal information to:

- Confirm and manage prescriptions.
- Communicate with HCPs, patients or legal guardians/caregivers about treatment, patient care, and where applicable, for further information regarding any unwanted drug effects ("adverse drug events" or side effects) that may be experienced while taking the Medication or other medications made by Novartis.
- Ensure we are connecting with the right patient or caregiver.
- Process insurance claims.
- Coordinate with service providers.*
- Provide program services, like injection training, lab test coordination, and sending medical tests results.
- Arrange travel if the PSP offers travel assistance.
- Confirm patient prescriptions.
- Monitor the program's performance and service quality.
- Support business planning, optimization and strategy development.
- Compile information on treatment usage and disease management.

These future analyses help us improve our services, create awareness campaigns, patient brochures, and provide drug information for HCPs. Most analyses use de-identified (replacing identifying data with a code or label) or anonymized data.

* In the event that you opt to benefit from any external service provider, referred by the Program, you understand that these are third parties who are in no way affiliated with Novartis. Novartis cannot be held responsible for the information or services these third parties may provide to you.

Do we collect any other personal information not connected to a PSP service?

No, unless we have obtained additional consent to collect and use personal information for research to advance the knowledge and data on drug, treatment or disease. These analyses conducted may not benefit you directly but are valuable to the healthcare community.

Who collects the personal information, and how is it protected?

The program administrator, Novartis or a company acting on behalf of Novartis, collects and stores personal information in a secure database using:

Encryption (converting personal information into a secret code).

Restricted access (individual usernames and passwords).

Only authorized personnel can access your information, including:

- Call center agents managing PSP requests.
- PSP HCPs providing treatment training.
- PSP staff overseeing program activities or handling complaints.
- Patient safety agents for managing adverse events.

External service providers, including drug reimbursement specialists, travel agencies, pharmacies, labs, and clinics, must protect personal information similarly.

Novartis personnel may access your information for supervision, audits, or reporting adverse events.

Also, any entity who the law allows could have access to your personal information.

Can personal information be transferred outside your province or Canada?

Personal information may be transferred outside of your province of residence or of Canada when:

- it is stored in a database outside your province or country of residence.
- it must be reported to health authorities worldwide in case of an adverse event.

The privacy laws that apply where we store or process your personal information may differ from those that apply in your location. While personal information is stored in another location, it may be accessed by courts, law enforcement, and national security authorities. For more information about our policies and practices regarding international transfers of personal information, contact us at global.privacy_operations@novartis.com.

What happens if you withdraw your consent?

Without your consent, we may not be able to provide the services. Withdrawal stops future use and new collection of your information, but already collected information will remain in our database or adverse events database until it can be deleted as per legal requirements and health authority guidelines.

Consult the Product Monograph at www.novartis.com/ca-en/RhapsidoMonograph for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The Product Monograph is also available by calling 1-800-363-8883.

NOVARTIS

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Product Monograph available on request.
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