Pr Truxima® Rituximab for Injection 10 mg/mL Intravenous Infusion

TEVA SUPPORT SOLUTIONS® Patient Support Program

PrTRUXIMA® for rheumatoid arthritis (RA) enrolment form[1]

To enroll your patients in the Teva Support Solutions® Patient Support Program, please fax this form to **1-833-981-2254** or email it to **tss.info@truximacanada.com**

PATIENT INFORMATION[2]

Last name _____ First name _____ Birthday (DD/MMM/YY) _____

Sex ☐ F ☐ M Home address _____ City _____

Province _____ Postal code _____ Phone #1 _____ Phone #2 _____

Email _____ Patient has private insurance ☐ Yes ☐ No ☐ Don't know

Insurance company _____ Limited Use (LU) code (Ontario patients only) ☐ 575 ☐ 576

PRESCRIPTION[1]

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

ORDER FOR TRUXIMA®[1]

Anticipated infusion date (DD/MMM/YY) _____

	☐ First treatment		☐ Retreatment	
	Day 1	Day 15	Day 1	Day 15
255 minute infusion (4.25 hrs) x 1000 mg	☐		☐	
195 minute infusion (3.25 hrs) x 1000 mg		☐		☐
Alternative 120 minute infusion (2 hrs) x 1000 mg*		☐	☐	☐

☐ Other dosing _____

☐ Dilute TRUXIMA® in 250 mL of 0.9% Sodium Chloride Injection USP or 5% Dextrose Injection USP to final concentration of 1 to 4 mg/mL.

Other instructions _____

Blood pressure meds on hold ☐ Yes ☐ No

Please specify _____

Treatment legend:

255 minute infusion (4.25 hrs): TRUXIMA® 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 minute infusion (3.25 hrs): TRUXIMA® 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 minute infusion (2 hrs): TRUXIMA® 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 the next 90 minutes (875 mg). Not an option for all patients. Consult Product Monograph for information on alternative administration eligibility.

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

PRE-MEDICATIONS[1,3]

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

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

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

☐ Other _____ ☐ Pre-medications not required Please specify _____

PRN MEDICATIONS FOR INFUSION REACTIONS[1,3]

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 q4–6 hours for pain, fever, and chills

☐ Dimenhydrinate 25–50 mg PRN q4 hours for nausea and vomiting ☐ PO ☐ IV

☐ Diphenhydramine 25–50 mg PRN q4–6 hours for itching, urticaria, pruritus, and hives ☐ PO ☐ IV ☐ IM

☐ Epinephrine (1:1000) 0.01 mL/kg (max. 0.5 mL) PRN q10–15 minutes x2 for severe anaphylactic reactions ☐ SC ☐ IM

☐ Hydrocortisone 100 mg IV PRN x1 for severe allergic/anaphylactic reactions

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

☐ Salbutamol 2 puffs q4–6 hours via aerochamber PRN for dyspnea and wheezing

☐ Other _____

☐ PRN medications not required Please specify _____

PHYSICIAN INFORMATION AND AUTHORIZATION

I authorize the Teva Support Solutions® Patient Support Program to be my designated agent to forward the prescription indicated above by fax or other mode of delivery to the pharmacy chosen by the above named patient. This original prescription constitutes a legal prescription for the patient for TRUXIMA®. The pharmacy chosen by the patient is the only pharmacy to receive this prescription for dispensing. The original prescription will not be re-used.

Last name _____ First name _____ Specialty _____

License number _____ Work phone _____ Fax _____

Email _____ Date (DD/MMM/YY) _____ Signature _____

PATIENT CONSENT

I have read, understand and agree to the collection, use, and disclosure of my personal information by the Teva Support Solutions® in accordance with its privacy policy, which I have had an opportunity to review and which is attached. I consent to the secure storage of my personal information outside Canada, including within the European Union, the USA, or Israel, in accordance with the attached privacy policy.

☐ By ticking this box, I consent to the use of my personal information to be further used for research and development in order to improve Teva's products and services.

☐ By ticking this box, I consent to have my personal information shared with external firms, which would be engaged by Teva to conduct pharmaceutical market research on Teva's behalf, and which may contact me for the sole purpose of gathering market research information.

☐ Verbal consent Date (DD/MMM/YY) _____ Initials from HCP/RA nurse _____

☐ Written consent Date (DD/MMM/YY) _____ Patient signature _____

LU (Reason for Use [RFU]) code and clinical criteria (Ontario patients only)[2]

Code 575: For the treatment of adults with severe active RA (greater than or equal to 5 swollen joints and rheumatoid factor positive and/or anti-cyclic citrullinated peptide [anti-CCP] positive, and radiographic evidence of RA) who meet ALL the following criteria:

1. Patient has experienced failure to respond, documented intolerance, or contraindication to optimal use of one of the following disease modifying, anti-rheumatic (DMARD) regimens:
   - A. i) Methotrexate (20 mg/week) for at least 3 months, AND
     ii) Leflunomide (20 mg/day) for at least 3 months, in addition to
     iii) An adequate trial of at least one combination of DMARDs for 3 months; OR
   - B. i) Methotrexate (20 mg/week) for at least 3 months, AND
     ii) Leflunomide in combination with methotrexate for at least 3 months; OR
   - C. i) Methotrexate (20 mg/week), sulfasalazine (2 g/day) and hydroxychloroquine (400 mg/day) for at least 3 months. (Hydroxychloroquine is based by weight up to 400 mg per day.)
2. Patient has experienced failure to respond, documented intolerance, or contraindication to an adequate trial of at least ONE anti-tumour necrosis factor (anti-TNF) agent (e.g., adalimumab, etanercept, infliximab, golimumab, certolizumab pegol).
3. Patient is not using rituximab in a maintenance setting.
4. Patient is not using a treatment course of rituximab earlier than 6 months after the completion of a prior course of rituximab.
5. Rituximab is not used in combination with another biologic to treat the patient's RA.
6. Treatment must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

One course of treatment is 1000 mg followed two weeks later by the second 1000 mg dose.

LU Authorization Period: 3 months

Code 576: For the re-treatment of patients with severe active RA (greater than or equal to 5 swollen joints, and rheumatoid factor positive and/or anti-CCP positive, and radiographic evidence of RA) who meet ALL the following criteria:

1. Patient has met the initiation criteria for rituximab in accordance with RFU 575;
2. Patient has experienced loss of effect after having responded to the prior treatment course of rituximab (response is defined as a 20% reduction in the swollen joint count compared to the joint count prior to the first, pre-treatment course evaluated at 3 to 4 months following the administered course AND improvement in 2 swollen joints); AND
3. Patient is not using rituximab in a maintenance setting; AND
4. Patient is not using a treatment course of rituximab earlier than 6 months after the completion of a prior course of rituximab; AND
5. Rituximab is not used in combination with another biologic to treat the patient's RA.
6. Treatment must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

One course of re-treatment is 1000 mg followed two weeks later by the second 1000 mg dose.

LU Authorization Period: 3 months

Indications have been granted on the basis of similarity between TRUXIMA® and the reference biologic drug Rituxan®.[1]

RA

TRUXIMA® in combination with methotrexate is indicated to reduce signs and symptoms in adult patients with moderately to severely active RA who have had an inadequate response or intolerance to one or more TNF inhibitor therapies.[1]

For more information:

Please consult the Product Monograph at tevacanada.com/globalassets/canada-scs-files---global/product-monographs/truxima-product-monograph_en.pdf for important information about:

- Contraindications in patients with known Type I hypersensitivity or anaphylactic reactions to murine proteins, Chinese Hamster Ovary (CHO) cell proteins, or to any component of this product, patients who have or have had progressive multifocal leukoencephalopathy (PML) and patients with severe, active infections.
- The most serious warnings and precautions regarding risk of severe and life-threatening adverse reactions, infusion reactions, PML, hepatitis B virus (HBV) reactivation, mucocutaneous reactions, infections, and cardiovascular events.
- Other relevant warnings and precautions regarding driving or operating a vehicle or potentially dangerous machinery, anaphylaxis, use of effective contraception in patients of child-bearing age, hypotension, signs of infection if biologics are used concomitantly with DMARDS, presence of human anti-chimeric antibody (HACA), vaccinations, TNF antagonists, and women who are breast-feeding. The trade name of the administered product should be clearly recorded in the patient file.
- Adverse reactions, drug interactions, dosing, administration (administered as an IV infusion through a dedicated line, not administered as an IV push or bolus) and conditions of clinical use.

The Product Monograph is also available by calling Teva Canada Innovation at 1-833-662-5644.

References: 1. TRUXIMA® Product Monograph. Teva Canada Limited. August 22, 2024. **2.** Ontario Ministry of Health. Ontario Drug Benefit Formulary: TRUXIMA®. Available at: https://www.formulary.health.gov.on.ca/formulary/results.xhtml?q=truxima&type=2. Accessed April 8, 2026. **3.** Data on File. Letter of attestation regarding pre-medications and PRN medications for TRUXIMA®. July 5, 2022.

teva | Canada
Brands. Generics. **Biosimilars.**

Montreal, Quebec, H2Z 1S8 TRUX-CA-00164E 05/2027

REVIEWED BY PAAB

PrTruxima
Rituximab for Injection
10 mg/mL Intravenous Infusion

TEVA SUPPORT SOLUTIONS
Patient Support Program

Truxima® Rituximab for Injection 10 mg/mL Intravenous Infusion

TEVA SUPPORT SOLUTIONS® Patient Support Program

Teva Support Solutions®
Patient Support Program privacy policy

The Teva Support Solutions® Patient Support Program respects your privacy and is strongly committed to protecting your personal information. This privacy policy explains the information we may collect and how we use and safeguard that information. If you have any questions, or if you wish for more explanation about the manner in which we or our authorized service providers treat your personal information, or to access your personal information in our records, do not hesitate to contact us at the information provided below.

Why we ask you for personal information

In order for the Teva Support Solutions® Patient Support Program to offer you the services you require, we may request that you provide certain personal information to us, or we may obtain certain personal information from your referring physician, pharmacist, insurance company, public payer or any other healthcare provider or payer that may possess the requisite information. We will not collect or use any of your personal information unless you have provided your consent. We will only ask for personal information necessary to serve you and to research, develop and improve our services. Some of the services provided by the Teva Support Solutions® Patient Support Program include:

- providing you with personalized services to meet your specific needs;
- determining the suitability of our services to your needs;
- determining your eligibility for our products and services;
- determining eligibility for reimbursement assistance;
- providing you with information about RA, and about our products and services.

What is personal information?

Personal information is any information that could personally identify you. It includes, but is not limited to, your name, mailing address, email address, phone number, gender, or age. If you request reimbursement assistance, we may ask you to provide your financial statements, income tax records, employment records and your social insurance number.

When we ask for your personal information, we will make sure we obtain your consent, which is an informed permission you give us to store your information in our databases and to use it for the purposes we will inform you about.

Access and use of information

The personal information you provide us will be accessed only by the Teva Support Solutions® Patient Support Program, our affiliates and authorized agents and each of our respective staff. By agreeing to provide your information in accordance with the terms of this privacy policy, you are giving your consent for us to share relevant information from your file with your referring physician, as well as our affiliates and authorized third parties who assist us in providing services to you (i.e. only the information required for the execution of the service being required from the third party). These third parties include:

- our healthcare providers for providing appointment reminders, coordinating appointments, offering advice or follow-up about your therapy;
- our service providers for therapy coverage;
- our mailing house (responsible for sending printed information and publications); or
- potential payers or reimbursement organizations.

We might also share information with external firms which would be engaged by us to conduct pharmaceutical market research on our behalf, and who may contact you for the sole purpose of gathering market research information.

Furthermore, your information might also be shared with others if explicitly authorized or required by applicable law.

Any data which we might have shared with such third parties will be held on a confidential basis and will only be kept by them for as long as it is reasonably needed for the intended purpose of the services they are providing, after which the data in their possession will be securely destroyed.

At no time and under no circumstances, would your information be sold to any third party for any reason. The data contained in your file will only be kept for as long as it is reasonably needed, and it will only be used for the purpose stated in your file. Once the purpose has been achieved, your file will be deleted unless you require further services, or unless we are required to maintain a copy under applicable law.

You may choose to withhold some or all personal information at any time. However, please understand that your decision may prevent us from providing you with services and information that you request.

Protection

Your information will be stored on a confidential basis at the Teva Support Solutions® Patient Support Program offices and/or secure locations both inside and outside of Canada, including within the European Union, Israel, or the USA. It is a condition of receiving services from the Teva Support Solutions® Patient Support Program that you expressly consent to the secure storage of your personal information outside Canada. It is protected by various physical, technical and administrative security measures such as magnetic locks, data encryption and a system of individual usernames and passwords for every member of the staff.

Contact on behalf of another person

The Teva Support Solutions® Patient Support Program must deal directly and exclusively with you; therefore, it is not possible for others to contact the Teva Support Solutions® Patient Support Program on your behalf. If you wish for a family member or a friend or anybody else who is affected by GPA or MPA to receive services from us, please give him/her our phone number.

Keeping your information accurate

We are committed to keeping your personal information accurate as long as we need it for the purposes previously described. You play an important role in helping us achieve this goal. You may update your information by contacting us either by phone at 1-877-714-2469 or by email. Your prompt notification of any contact information changes will assist us in providing you the requested services.

Changes to the privacy policy

The Teva Support Solutions® Patient Support Program reserves the right to change, modify or amend this policy at any time. However, when a significant change has been made, you will be notified within a reasonable time either by phone, mail or email.

Teva Support Solutions® Patient Support Program Privacy Officer

1080 Beaver Hall Hill, Suite 1200
Montreal, Quebec H2Z 1S8
TCI.PrivacyOfficer@tevapharm.com
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