

Teva is proud to offer the
TEVA SUPPORT SOLUTIONS®
Patient Support Program

 **To enroll your patients**, simply complete one enrolment form per patient and fax or email them to us.
Fax: 1-833-981-2254
Email: tss.info@truximacanada.com

Teva is proud to offer the Teva Support Solutions® Patient Support Program to your RA, GPA and MPA patients who have been prescribed TRUXIMA®.

The Teva Support Solutions® Patient Support Program has professional case managers who can support your patients and offer a variety of services, such as welcome calls, educational materials, reimbursement services and more!

 **For more information**, contact us.
Phone: 1-877-714-2469
Email: tss.info@truximacanada.com

Clinical use:
TRUXIMA® in combination with methotrexate has been shown to reduce the rate of progression of joint damage as measured by x-ray.
Consideration should be given to current treatment guidelines for vasculitis.
TRUXIMA® has not been studied in pediatrics or geriatrics.

Contraindications:

- 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).
- Not recommended for use in patients with severe, active infections.

Most serious warnings and precautions:
Risk of severe and life-threatening adverse reactions:
Several adverse reactions are associated with TRUXIMA®, some of which are severe and life-threatening. Should only be used by health professionals experienced in treating Non-Hodgkin's Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL), or RA, GPA (also known as Wegener's Granulomatosis) and MPA. Treat where full resuscitation facilities are immediately available, and where medications and supportive care measures for the treatment of hypersensitivity reactions (e.g., epinephrine, antihistamines, glucocorticoids) are immediately available in the event of an allergic reaction during administration.

Infusion Reactions: Deaths within 24 hours of infusion have occurred. Approximately 80% of these occurred in association with the first infusion. Carefully monitor patients during infusions. Discontinue infusion and provide medical treatment for Grade 3 or 4 infusion reactions.

Progressive Multifocal Leukoencephalopathy (PML):
Patients with RA, NHL or CLL may have an increased risk of PML, which can cause disability or death. Patients should be monitored for any new sign or symptom that may be suggestive of PML. Further treatment with TRUXIMA® should be withheld immediately at the first sign or symptom suggestive of PML.

Hepatitis B Virus (HBV) Reactivation: HBV reactivation has occurred, in some cases resulting in fulminant hepatitis, hepatic failure, and death. All patients should be screened for HBV before treatment and should be monitored during and after treatment. In the event of HBV reactivation, discontinue TRUXIMA® and concomitant medications.

Mucocutaneous Reactions: Severe, including fatal, mucocutaneous reactions including Toxic Epidermal Necrolysis (TEN) and Stevens Johnson Syndrome (SJS) have occurred. Discontinue treatment and seek prompt medical evaluation.

RA: rheumatoid arthritis; GPA: granulomatosis with polyangiitis; MPA: microscopic polyangiitis.

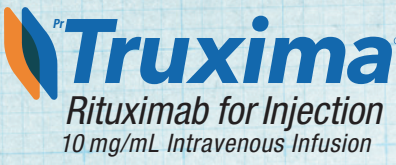
Infections: Serious, including fatal, bacterial, fungal, and new or reactivated viral infections can occur during or following therapy. Do not initiate treatment in patients with severe active infections. Screen patients for infectious disease history.

Cardiovascular: Serious and potentially fatal cardiovascular events have been reported rarely.

Other relevant warnings and precautions:

- Should be administered as an IV infusion through a dedicated line. Do not administer as an intravenous push or bolus
- The trade name of the administered product should be clearly recorded in the patient file
- Due caution should be exercised when driving or operating a vehicle, or potentially dangerous machinery
- Anaphylaxis including fatalities
- In patients of child-bearing age, use effective contraception during and for up to 12 months following treatment
- Hypotension may occur during infusion with TRUXIMA®. Consider withholding anti-hypertensive medications 12 hours prior to and throughout infusion
- In patients with RA, observe carefully for signs of infection if biologics are used concomitantly with disease-modifying antirheumatic drugs (DMARDs)
- Presence of human anti-chimeric antibody (HACA)
- Vaccination with live virus vaccines is not recommended during treatment or during peripheral B-cell depletion. Vaccination should be completed at least 4 weeks prior to first administration of TRUXIMA®. Patients may receive non-live vaccinations but the response rate could be reduced
- Use in patients with RA who have no prior inadequate response to one or more TNF antagonists is not recommended
- Women should be advised to discontinue nursing until circulating drug levels are no longer detectable

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 relating to adverse reactions, drug interactions, and dosing and administration, which have not been discussed in this piece. The Product Monograph is also available by calling Teva Canada Innovation at 1-833-662-5644.



**Biosimilar by design.
Biologic by essence.**

-  **TRUXIMA® was demonstrated to be pharmacokinetically similar to Rituxan® and MabThera® as shown by AUC_{0-last} and AUC_{0-inf}^{1*}**
-  **In the phase 3 RA study, 14.9% and 23.2% of patients at week 24, and 4.9% and 9.2% of patients at week 48 in the TRUXIMA® and the reference products (Rituxan®/MabThera®) groups tested ADA positive, respectively¹**
-  **Demonstrated to be therapeutically similar to the combined reference products (Rituxan® + MabThera®) based on changes from baseline in disease activity measured by DAS28-CRP at week 24¹**
-  **The types, frequency and severity of adverse events were comparable between TRUXIMA® and the reference biologic drug¹**

 **TRUXIMA®: A proud offering from Teva Canada Innovation.**



* Comparative clinical significance is unknown.

AUC_{0-last}: area under the concentration-time curve from time 0 to the last measurable concentration over both doses of the 1st treatment course; AUC_{0-inf}: area under the concentration-time curve from time 0 extrapolated to infinity over both doses of the 1st treatment course; RA: rheumatoid arthritis; ADA: anti-drug antibody; DAS28-CRP: DAS28 C-reactive protein.

References: 1. TRUXIMA® Product Monograph. Teva Canada Limited. August 22, 2024. 2. Data on File. First to market rituximab biosimilar. Teva Canada. May 31, 2019. 3. Jennette JC, *et al.* 2012 revised International Chapel Hill Consensus Conference Nomenclature of Vasculitides. *Arthritis Rheum.* 2013;65(1):1-11. 4. TRUXIMA® Summary of Product Characteristics. Biotech Services International Ltd. Available at: https://www.ema.europa.eu/en/documents/product-information/truxima-epar-product-information_en.pdf. Accessed July 8, 2025.

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

Rituxan® is a registered trademark of IDEC Pharmaceuticals Corporation, used under license.

MabThera® is a registered trademark of F. Hoffmann-La Roche AG.

†TRUXIMA® is a registered trademark of Celtrion Inc.

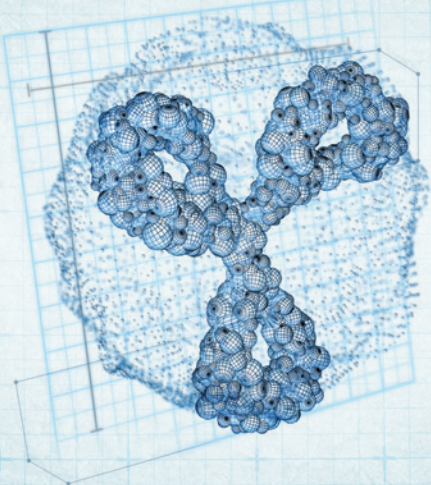
© 2025 Teva Canada Innovation G.P. - S.E.N.C. Montreal, Quebec, H2Z 1S8



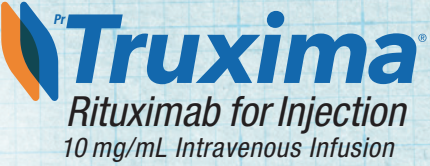
TRUX-CA-00155E 11/2026 

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

The first Rituxan® (rituximab) biosimilar available in Canada^{1,2*}



Creative representation of a molecule.



**Biosimilar by design.
Biologic by essence.**

Consider P^rTRUXIMA® for your RA, GPA and MPA patients¹
TRUXIMA® is indicated in RA and in two types of ANCA-associated vasculitis^{1,3†}

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 tumour necrosis factor (TNF) inhibitor therapies.¹

GPA MPA

TRUXIMA® in combination with glucocorticoids is indicated for the induction of remission in adult patients with severely active GPA (also known as Wegener's granulomatosis) and MPA.¹

Available in the EU since 2017.^{4*}

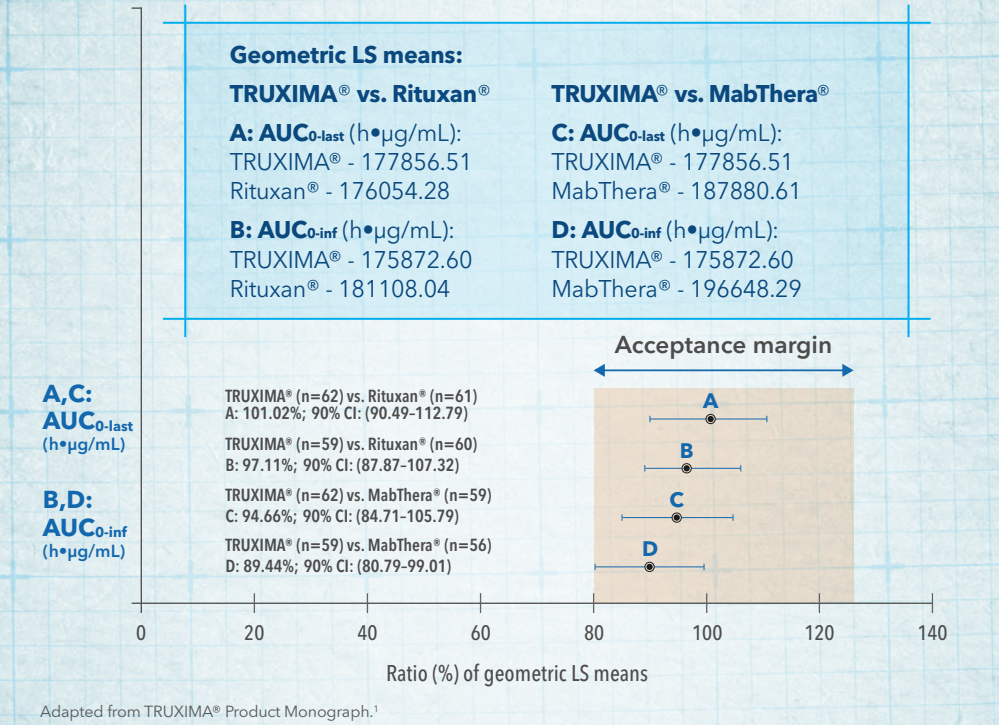
* Comparative clinical significance is unknown.
† Indications have been granted on the basis of similarity between TRUXIMA® and the reference biologic drug Rituxan®.

RA: rheumatoid arthritis; GPA: granulomatosis with polyangiitis;
MPA: microscopic polyangiitis; ANCA: antineutrophil cytoplasmic antibody;
EU: European Union.

TRUXIMA® was demonstrated to be pharmacokinetically similar to Rituxan® and MabThera® as shown by AUC_{0-last} and AUC_{0-inf}^{1*†‡}

- In the primary analysis, the 90% CIs of the ratios (%) of the geometric LS means for AUC_{0-last} and AUC_{0-inf} over the first treatment course were contained within the acceptance margin of 80% to 125%.
- Rituxan® Roche (US) and MabThera® Roche (EU) were used as comparators.

Ratios (%) of geometric LS means of AUC_{0-last} and AUC_{0-inf} for TRUXIMA® vs. Rituxan® and TRUXIMA® vs. MabThera® up to week 24 (ANCOVA)^{§¶}



Rituximab exposures from TRUXIMA® were shown to be similar to those from Rituxan® and MabThera® in each comparison (i.e. TRUXIMA® and Rituxan®, TRUXIMA® and MabThera®).¹

* Comparative clinical significance is unknown.

† In many other countries including the EU, Rituxan® is marketed under the name MabThera®.

‡ Results from study CT-P10 3.2: A 2-part, phase 3, randomized, controlled, multicenter, 3-arm, parallel-group, double-blind, prospective study in patients with RA who previously experienced inadequate response to an anti-TNFα agent (N=372). Part 1 was designed to establish similarity in pharmacokinetics between TRUXIMA® (n=64), MabThera® (n=60) and Rituxan® (n=65). Each patient received 1000 mg of the designated drug by intravenous infusion and 2 courses of treatment if the patient met pre-defined safety criteria: each course consisted of 2 infusions with a 2-week interval. Methotrexate (7.5-25 mg/week orally or parenterally) and folic acid (≥5 mg/week) were coadministered. The primary efficacy endpoints in the comparative pharmacokinetic study were AUC_{0-last}, AUC_{0-inf}, C_{max}, T_{max} and T_{1/2}.

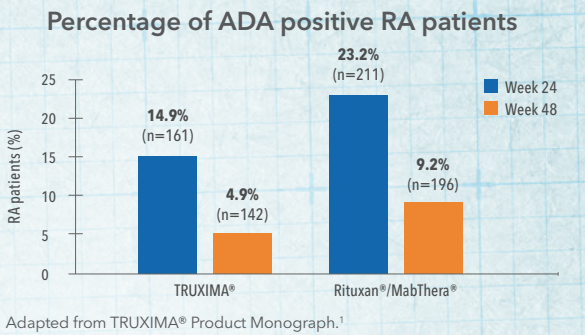
§ 2 patients that were detected as outliers for AUC were excluded in this analysis based on the robust regression detection method.

¶ Clinical significance is unknown.

AUC_{0-last}: area under the concentration-time curve from time 0 to the last measurable concentration over both doses of the 1st treatment course; AUC_{0-inf}: area under the concentration-time curve from time 0 extrapolated to infinity over both doses of the 1st treatment course; CI: confidence interval; LS: least squares; US: United States; EU: European Union; ANCOVA: analysis of covariance; RA: rheumatoid arthritis; TNFα: tumour necrosis factor alpha; C_{max}: observed maximum concentration after the 2nd infusion; T_{max}: time to maximum concentration; T_{1/2}: elimination half-life.

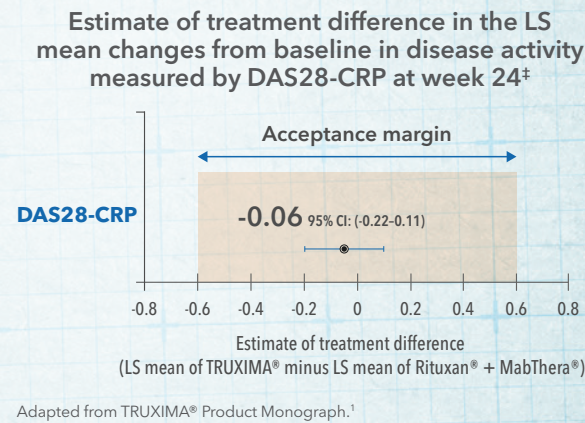
Percentage of patients with ADA positive results from TRUXIMA®-treated and reference products (Rituxan®/MabThera®) groups at weeks 24 and 48 in the phase 3 RA study^{1*}

- Immunogenicity was determined using both an immunoassay for the presence of ADAs and an assay for the presence of NABs. The ADA assay involved screening and confirmatory stages to confirm positive results.
- In the subset of patients that received both the 1st and 2nd treatment course, the cumulative rates of ADA positivity up to week 48, defined by the number of patients (%) who had at least one post-treatment positive in the TRUXIMA® and the reference products groups, were 26/142 (18.3%) and 49/196 (25%), respectively.



TRUXIMA® was demonstrated to be therapeutically similar to the reference products (Rituxan® + MabThera®) based on changes from baseline in disease activity measured by DAS28-CRP at week 24^{1†}

- Equivalence in DAS28-CRP was concluded as the 95% CI of the estimated treatment difference of -0.06 between TRUXIMA® (n=158) and the combined reference products (Rituxan® + MabThera®) (n=210) was contained within the acceptance margin of -0.6 and +0.6.
- The LS mean changes from baseline in DAS28-CRP for TRUXIMA® and the reference products (Rituxan® + MabThera®) were observed to be -1.63 (SE: 0.117) and -1.57 (SE: 0.117), respectively.



* Comparative clinical significance is unknown.

† Results from study CT-P10 3.2: A 2-part, phase 3, randomized, controlled, multicenter, 3-arm, parallel-group, double-blind, prospective study in patients with RA who previously experienced inadequate response to an anti-TNFα agent (N=372). Part 2 was designed to demonstrate therapeutic similarity, in terms of the difference in the change in DAS28-CRP score from baseline to week 24, between the TRUXIMA® arm (n=161) and the combined MabThera® (n=60) and Rituxan® (n=151) arms. Each patient received 1000 mg of the designated drug by intravenous infusion and 2 courses of treatment if the patient met pre-defined safety criteria: each course consisted of 2 infusions with a 2-week interval. Methotrexate (7.5-25 mg/week orally or parenterally) and folic acid (≥5 mg/week) were coadministered. In the comparative efficacy study, the primary efficacy endpoint was the difference between TRUXIMA® and the reference product, in the change from baseline in disease activity measured by DAS28-CRP at week 24.

‡ The result is based on an analysis of repeated measures using mixed effect model comparing the change from baseline of DAS28-CRP up to 24 weeks

of treatment between two groups [TRUXIMA® vs. reference products (Rituxan® + MabThera®)] considering treatment, gender, region, race, study part, interaction of treatment group with study part, prior anti-TNFα blocker status at baseline (intolerance vs. inadequate response), and RF or anti-CCP status at baseline (both positive vs. both negative vs. either RF or anti-CCP negative) as covariates. Patients with unknown prior anti-TNFα blocker status were excluded from the analysis. Patients who had joint surgery prior to and including the week of interest were excluded from the analysis. Patients were also excluded at each visit that was considered to be affected by receipt of prohibited medication. Adjusted LS means and SE, estimate of treatment difference [TRUXIMA® - reference product (Rituxan® + MabThera®)] and 2-sided 95% CI were calculated using a mixed effect model for repeated measures.

ADA: anti-drug antibodies; RA: rheumatoid arthritis;
NABs: neutralizing antibodies; DAS28: Disease Activity Score 28;
DAS28-CRP: DAS28 C-reactive protein; CI: confidence interval;
LS: least squares; SE: standard error; TNFα: tumour necrosis factor alpha;
RF: Rheumatoid Factor; anti-CCP: anti-Cyclic Citrullinated Peptide.

The types, frequency and severity of adverse events were comparable between the biosimilar and the reference biologic drug.¹

- The adverse drug reaction profiles reported in clinical studies that compared TRUXIMA® to the reference biologic drug were comparable.

The description of adverse events below is based on clinical experience with the reference biologic drug.

Summary of adverse events occurring in at least 3% of patients in either treatment group (MTX + placebo or rituximab + MTX) during phase 2 and 3 clinical studies¹

Body System	Incidence			
	Pooled Phase 2 Study Population	Phase 3 Study Population		
	MTX + placebo N=189 n (%)	Rituximab + MTX N=232 n (%)	MTX + placebo N=209 n (%)	Rituximab + MTX N=308 n (%)
Acute Infusion Reactions*				
Hypertension	10 (5%)	22 (9%)	11 (5%)	21 (7%)
Nausea	14 (7%)	19 (8%)	5 (2%)	22 (7%)
Rash	6 (3%)	18 (8%)	9 (4%)	17 (6%)
Pyrexia	1 (<1%)	12 (5%)	7 (3%)	15 (5%)
Pruritus	1 (<1%)	14 (6%)	4 (2%)	12 (4%)
Urticaria	0	2 (<1%)	3 (1%)	10 (3%)
Rhinitis	2 (1%)	6 (3%)	4 (2%)	8 (3%)
Hypotension	11 (6%)	10 (4%)	1 (<1%)	5 (2%)
Chills	3 (2%)	13 (6%)	6 (3%)	3 (<1%)
Gastrointestinal Disorders				
Dyspepsia	3 (2%)	9 (4%)	0	7 (2%)
Abdominal pain upper	3 (2%)	7 (3%)	1 (<1%)	4 (1%)
Infections and Infestations				
Any infection	56 (30%)	85 (37%)	78 (37%)	127 (41%)
Urinary tract infections	8 (4%)	14 (6%)	17 (8%)	15 (5%)
Upper respiratory tract infections	28 (15%)	31 (13%)	26 (12%)	48 (16%)
Lower respiratory tract infections/pneumonia	10 (5%)	9 (4%)	5 (2%)	8 (3%)
Musculoskeletal Disorders				
Arthralgia/musculoskeletal pain	8 (4%)	18 (7%)	6 (3%)	17 (7%)
Nervous System				
Paresthesia	2 (1%)	4 (2%)	1 (<1%)	8 (3%)

Adapted from TRUXIMA® Product Monograph.¹

* Reactions occurring within 24 hours of infusion.

MTX: methotrexate.