The first and only C5a receptor antagonist indicated in the treatment of ANCA-associated vasculitis (GPA/MPA)[1]*

PrTAVNEOS®
(avacopan)

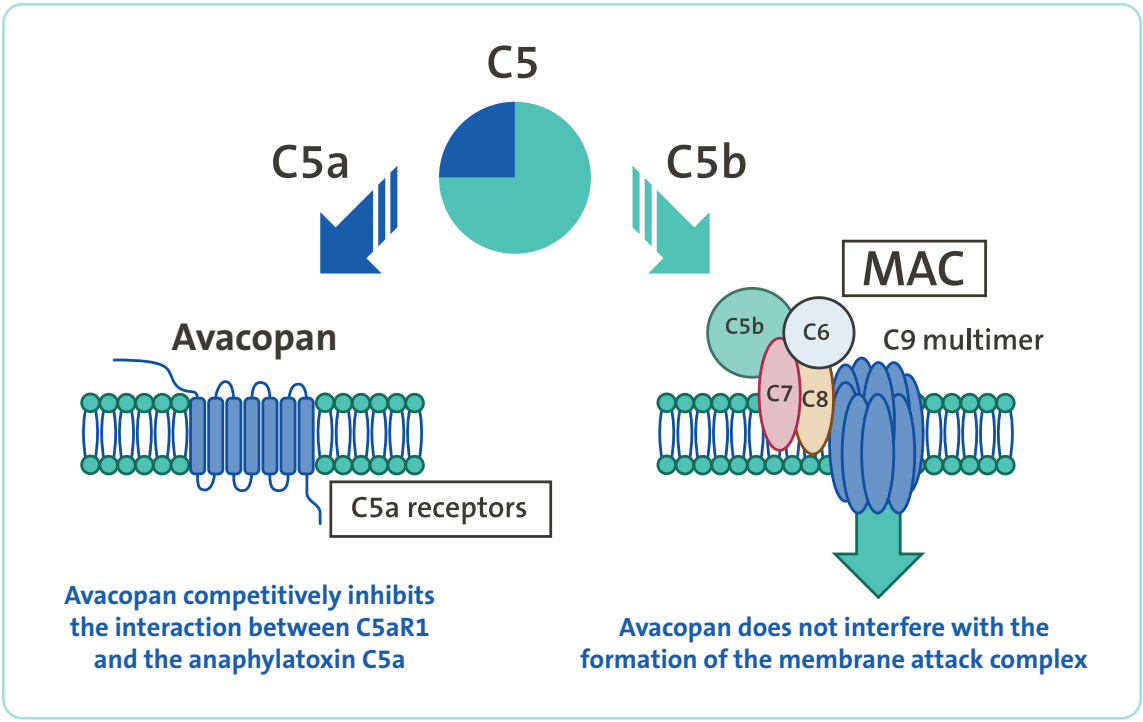
Turn to PrTAVNEOS®

A new treatment in AAV (GPA/MPA)

PrTAVNEOS® (avacopan capsules) is indicated for the adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard background therapy including glucocorticoids. TAVNEOS does not eliminate glucocorticoid use.[2]

* Comparative clinical significance has not been established.

PrTAVNEOS® reduces the pro-inflammatory effects of C5a



Adapted from the Product Monograph.

AVACOPAN REDUCES THE EFFECTS OF C5a ON VASCULAR INFLAMMATION, INCLUDING:[2]

- Neutrophil activation and migration
- Adherence to sites of small blood vessel inflammation
- Vascular endothelial cell retraction and increased permeability

AVACOPAN DOES NOT INHIBIT:[2]

- The formation of the membrane attack complex (MAC)
- The terminal complement complex (TCC), which is important in fighting infections with encapsulated bacteria

ADVOCATE trial study design[2]

IN THE PHASE 3 ADVOCATE TRIAL, PATIENTS WITH NEWLY DIAGNOSED OR RELAPSING ACTIVE ANCA-ASSOCIATED VASCULITIS RECEIVED EITHER:†‡

Pr**TAVNEOS®-based group** (n=166)	**Prednisone-based group** (n=164)
TAVNEOS and prednisone-matching placebo	Prednisone and TAVNEOS-matching placebo

One of the following standard immunosuppressive regimens:

- IV cyclophosphamide followed by oral azathioprine or mycophenolate mofetil
- Oral cyclophosphamide followed by oral azathioprine or mycophenolate mofetil
- Rituximab

Patients were stratified at randomization based on three factors:

- Receiving either intravenous (IV) rituximab, IV cyclophosphamide, or oral cyclophosphamide
- Having proteinase 3 (PR3) or myeloperoxidase (MPO) ANCAs
- Newly diagnosed or relapsing disease

PRIMARY ENDPOINTS

- Remission at week 26: Birmingham Vasculitis Activity Score (BVAS)=0 and no glucocorticoid use for AAV within 4 weeks before week 26
- Sustained remission at week 52: remission at week 26 and week 52, without relapse through week 52, and no glucocorticoid use for AAV within 4 weeks before week 52

AAV: ANCA-associated vasculitis

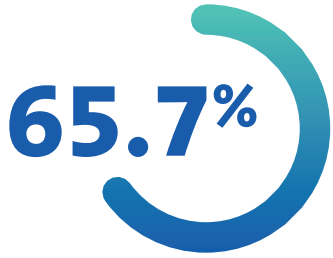
† The ADVOCATE trial was a phase 3, randomised, double-blind, double-dummy, active-controlled clinical trial, assessing the efficacy, safety profile, and tolerability of avacopan in subjects with newly diagnosed or relapsing active ANCA-associated vasculitis when administered against a standard background cyclophosphamide or rituximab regimen. The trial treatment period was 52 weeks with an 8-week follow-up period.

‡ Subjects received either 30 mg TAVNEOS twice daily for 52 weeks plus prednisone-matching placebo tapering regimen over 20 weeks in the TAVNEOS-based group (n=166), or TAVNEOS-matching placebo twice daily for 52 weeks plus prednisone (tapered from 60 mg/day to 0 over 20 weeks) in the prednisone-based group (n=164). In addition, all patients received standard immunosuppressive regimens of:

- IV cyclophosphamide for 13 weeks (15 mg/kg up to 1.2 g every 2 to 3 weeks) followed by oral azathioprine (1 mg/kg daily with titration up to 2 mg/kg daily; mycophenolate mofetil 2 g daily was allowed in place of azathioprine) starting on week 15, or
- oral cyclophosphamide for 14 weeks (2 mg/kg daily) followed by either oral azathioprine or mycophenolate mofetil (same dosing regimen as IV cyclophosphamide) starting at week 15, or
- rituximab at the dose of 375 mg/m² for 4 weekly IV doses.

Demonstrated efficacy and safety profiles[2]

PrTAVNEOS® ACHIEVED SUPERIOR SUSTAINED REMISSION COMPARED TO PREDNISONE-BASED GROUP AT 52 WEEKS (PRIMARY ENDPOINT, ITT POPULATION)†

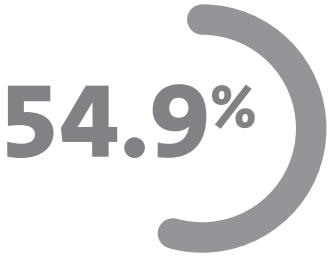


n=109/166

TAVNEOS-based group‡

vs.

p=0.0066
for superiority

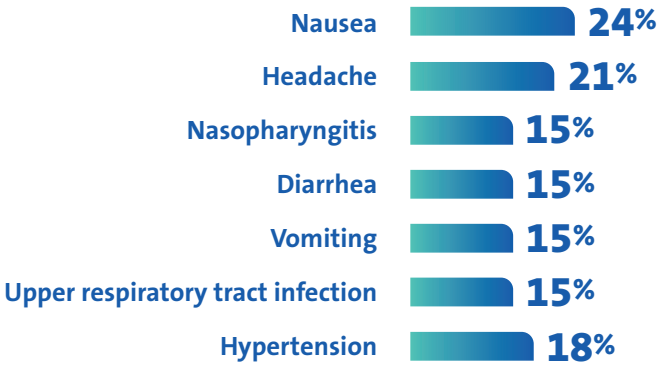


n=90/164

Prednisone-based group‡

At 26 weeks, TAVNEOS demonstrated non-inferiority in the proportion of subjects achieving remission vs. prednisone-based group: 72.3% vs. 70.1%, respectively (primary endpoint; *p*<0.0001 for non-inferiority)[2†]

MOST COMMON ADVERSE REACTIONS OBSERVED IN TAVNEOS PATIENTS



Please refer to the Product Monograph for a complete list of adverse reactions.

Twice-daily oral dose[2]

PrTAVNEOS® (avacopan)

3 CAPSULES IN THE MORNING + **3 CAPSULES IN THE EVENING**

TAVNEOS capsules should be swallowed whole with water. They should not be crushed, chewed, or opened. Please refer to the Product Monograph for complete dosing and administration instructions.

30 mg PrTAVNEOS®
(3 capsules of 10 mg each)

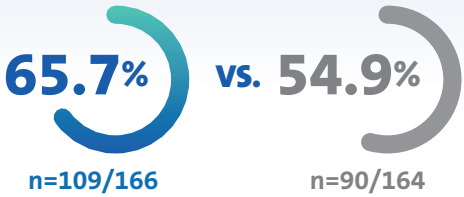
Taken orally twice daily

With food

No dosage adjustments are required in patients aged 65 years and older.

PrTAVNEOS®: Demonstrated sustained efficacy

- At 52 weeks, TAVNEOS demonstrated superior sustained remission vs. prednisone-based regimen: **65.7%** vs. **54.9%** respectively (p=0.0066 for superiority; primary endpoint)[2]



- Sustained remission was defined as: remission at week 26 and week 52, without relapse through week 52, and not taking glucocorticoids for ANCA-associated vasculitis within 4 weeks before week 52[2]

Continued support with the ORIJIN® Patient Support Program

The ORIJIN Patient Support Program helps both patients and healthcare professionals with key services:

- **Reimbursement navigation assistance**
- **Co-pay for patients with coverage**
- **Transition support between in-patient and community settings**

To learn more about ORIJIN services for TAVNEOS patients, call **1-844-254-6272**

Orijin™ SUPPORT PROGRAM

Clinical use:
- Not for pediatric use
- No difference in effectiveness in geriatric patients

Contraindications:
- Hypersensitivity to avacopan or any ingredients in the formulation

Relevant warnings and precautions:
- Increased risk for cardiac disorders with certain treatment regimens
- Gastrointestinal symptoms
- Risk of hepatic injury
- Monitor liver function every 4 weeks after the start of therapy for the first 6 months of treatment and as clinically indicated thereafter
- Not recommended for patients with activated, untreated and/or uncontrolled chronic liver disease
- Angioedema
- Immunization with live vaccines
- Avoid use in patients with active serious infection, including localized infections
- Obtain liver function tests and Hepatitis B virus serology before initiating treatment
- Pregnancy
- Women of childbearing potential not using contraception
- Breast-feeding

For more information:

Scan the QR code or consult the Product Monograph at https://otsukacanada.com/product_monographs/TAVNEOS_EN_PM.pdf for adverse reactions, interactions, dosing, monitoring tests and conditions of clinical use. The Product Monograph is also available by calling 1-877-341-9245.

References: **1.** Data on file. Otsuka Canada Pharmaceutical Inc. **2.** PrTAVNEOS® Product Monograph. Otsuka Canada Pharmaceutical Inc.

Otsuka

MEMBER OF INNOVATIVE MEDICINES CANADA

REVIEWED BY PAAB

PrTAVNEOS® (avacopan)

Orijin™ SUPPORT PROGRAM