# PrTAVNEOS® (avacopan) capsules

# FACT SHEET

## Indication

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.

## Pharmacological classification

Complement 5a receptor antagonist

## Mechanism of action†

TAVNEOS (avacopan) is a small molecule C5a receptor antagonist that selectively blocks the effect of C5a through the receptor (C5aR1 or CD88), including blocking neutrophil chemoattraction and activation. It competitively inhibits the interaction between C5aR1 and the anaphylatoxin C5a.

C5a and C5aR1 play a central role in the pathogenesis of ANCA-associated vasculitis (AAV). C5a is released when neutrophils are stimulated by inflammatory cytokines and C5a primes and activates further neutrophils. C5a is a powerful neutrophil chemoattractant and increases neutrophil adhesion and decreases their deformability. C5a also activates vascular endothelial cells, promoting their retraction and increased permeability. The interaction between neutrophils and C5a generated through activation of the alternative complement pathway is critical to vascular inflammation and organ damage in AAV.

The specific and selective blockade of C5aR1 by TAVNEOS reduces the pro-inflammatory effects of C5a, which include neutrophil activation and migration, and decreases adherence to sites of small blood vessel inflammation, and vascular endothelial cell retraction and increased permeability.

TAVNEOS does not inhibit the formation of the membrane attack complex (MAC; composed of complement fragments C5b, C6, C7, C8 and C9) or terminal complement complex (TCC), which is important in fighting infections with encapsulated bacteria such as *Neisseria meningitidis*.

## Dosing

The recommended dose of TAVNEOS is 30 mg (3 capsules of 10 mg each) taken orally twice daily with food, in the morning and in the evening.

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

The capsules should be swallowed whole with water and must not be crushed, chewed, or opened.

Grapefruit and grapefruit juice can increase the concentration of TAVNEOS; therefore, grapefruit and grapefruit juice are to be avoided in patients treated with TAVNEOS.

*Please refer to the Product Monograph for complete information on dosing and drug interactions.*

## Dosage forms and packaging

TAVNEOS is available in bottles of 180 capsules.

| SKU | DIN | Description |
|---|---|---|
| 10 mg capsules | 517964 | 10 mg capsules 180's |


## Storage requirements

Store TAVNEOS at room temperature (15 °C to 30 °C) and in the original package.

PrTAVNEOS® (avacopan)

† Clinical significance is unknown.

## Clinical use

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

## Contraindications

PrTAVNEOS® is contraindicated in:

- Patients who are hypersensitive to avacopan or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.

## Warnings and precautions

**Hepatic:** Serious cases of hepatic injury have been observed. Obtain liver function tests (ALT, AST, alkaline phosphatase, and total bilirubin) before initiating treatment and monitor every 4 weeks after start of therapy for the first 6 months of treatment and as clinically indicated thereafter.

- If AST or ALT is >3 times the upper limit of normal, temporarily stop TAVNEOS until TAVNEOS drug-induced liver injury is ruled out.
- TAVNEOS is not recommended for patients with activated, untreated and/or uncontrolled chronic liver disease (e.g., chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis) and cirrhosis.

**Angioedema:** TAVNEOS may cause angioedema. If angioedema occurs, discontinue TAVNEOS immediately, provide appropriate therapy, and monitor for airway compromise. TAVNEOS should not be readministered unless another cause has been established.

**Infections:** Serious infections, including fatal infections, have been reported in patients receiving TAVNEOS. The most common serious infections reported in the TAVNEOS group were pneumonia (4.8%) and urinary tract infections (1.8%).

- *Pneumocystis jirovecii* pneumonia prophylaxis is recommended

## Relevant warnings and precautions

- Certain treatment regimens may carry an increased risk for cardiac disorders
- TAVNEOS may cause gastrointestinal symptoms such as dyspepsia, vomiting, nausea and diarrhoea
- TAVNEOS is not recommended for patients with activated, untreated and/or uncontrolled chronic liver disease
- Administer vaccination with live vaccines preferably prior to initiation of treatment with TAVNEOS
- Avoid use in patients with active serious infection, including localized infections
- Obtain liver function tests and Hepatitis B virus serology before initiating treatment
- Not recommended during pregnancy or in women of childbearing potential not using contraception
- The safety of TAVNEOS has not been evaluated during breastfeeding

## Drug interactions

TAVNEOS is a substrate of CYP3A4. Co-administration of inducers and inhibitors of this enzyme may affect the pharmacokinetics of TAVNEOS.

- The co-administration of TAVNEOS with moderate (e.g., bosentan, efavirenz, etravirine, and modafinil) and strong CYP3A4 enzyme inducers (e.g., carbamazepine, enzalutamide, mitotane, phenobarbital, phenytoin, rifampicin, and St. John's Wort) should be avoided. If co-administration cannot be avoided in a patient already using TAVNEOS, the patient should be monitored closely for recurrence of disease activity.
- Strong CYP3A4 enzyme inhibitors (e.g., boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, and voriconazole) should be used with caution in patients who are being treated with TAVNEOS. Administer TAVNEOS 30 mg once daily when co-administered with strong CYP3A4 inhibitors.

Orijin™ SUPPORT PROGRAM

### Continued support with the ORIJIN® Patient Support Program

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

**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.

**Reference:** PrTAVNEOS® Product Monograph. Otsuka Canada Pharmaceutical Inc.

Otsuka


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