

**MEDICATION GUIDE**  
**TAVNEOS® (tav' nee ose)**  
**(avacopan)**  
**capsules, for oral use**

**What is the most important information I should know about TAVNEOS?**

TAVNEOS may cause serious side effects, including:

- **Liver problems.** People taking TAVNEOS may have serious liver problems, including a type of liver injury called vanishing bile duct syndrome (VBDS) that causes the loss of bile ducts in the liver. VBDS is severe and can lead to death. VBDS has been reported predominantly in Japan in patients aged 65 years and older but can happen to anyone. Call your healthcare provider right away if you have unexplained symptoms such as:
  - yellowing of your skin or the white part of your eyes (jaundice)
  - itchy skin (pruritus)
  - pain on the upper right side of your stomach area (abdomen)
  - feeling tired
  - dark or brown (tea colored) urine
  - bleeding or bruising more easily than normal
  - loss of appetite

Your healthcare provider will do blood tests to check how well your liver is working before starting and during your treatment with TAVNEOS. If you are of Japanese descent, your healthcare provider may recommend additional liver function testing and monitoring.

**What is TAVNEOS?**

- TAVNEOS is a prescription medicine that is used with other medicines (such as glucocorticoids) to treat adults with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)- associated vasculitis (granulomatosis with polyangiitis [GPA], formerly known as Wegener's granulomatosis, and microscopic polyangiitis [MPA]).

**It is not known if TAVNEOS is safe and effective in children under the age of 18.**

**Do not take TAVNEOS:**

- if you are allergic to avacopan or any of the other ingredients in TAVNEOS. See the end of this Medication Guide for a complete list of the ingredients in TAVNEOS.
  - Get medical help right away if you experience swollen lips, tongue, throat, trouble swallowing, or difficulty breathing. These could be signs of an allergic reaction. **Do not** take more of TAVNEOS until you have consulted with your healthcare provider.

**Before taking TAVNEOS, tell your healthcare provider about all your medical conditions including if you:**

- have or have had abnormal liver blood tests.
- have or have had liver problems.
- have or think you may have hepatitis B or hepatitis C.
- have an infection.
- are pregnant or are planning to become pregnant. It is not known if TAVNEOS will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if TAVNEOS can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take TAVNEOS.

**Tell your healthcare provider about all the other medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. TAVNEOS and certain other medicines may affect each other and cause side effects. Keep a list of the medicines you take and show it to your healthcare provider and pharmacist.

- Some medicines should not be taken with TAVNEOS.
- Your healthcare provider may prescribe other medicines to treat your disease.

**How should I take TAVNEOS?**

- Take TAVNEOS exactly as your healthcare provider tells you to take it. Do not stop taking TAVNEOS unless your healthcare provider tells you to.
- Check with your healthcare provider or pharmacist if you are not sure.
- Take 3 capsules of TAVNEOS 2 times daily (morning and evening) with food.
- Your healthcare provider may tell you to take 3 capsules of TAVNEOS 1 time each day if you take certain medicines. Tell your healthcare provider about all the medicines you take.
- Swallow the capsules whole with water. Do not crush, chew or open the capsules.
- If you miss a dose of TAVNEOS, do not take the missed dose. Just take the next dose at your regular time. If you have taken too much TAVNEOS, call your doctor or a Poison Control Center, or go to the nearest hospital emergency room.

## What are the possible side effects of TAVNEOS?

TAVNEOS may cause serious side effects, including:

- See “What is the most important information I should know about TAVNEOS?”
- **Serious allergic reactions.** TAVNEOS may cause serious allergic reactions. Stop taking TAVNEOS and get emergency medical help right away if you have any of the following signs of a serious allergic reaction:
  - shortness of breath or trouble breathing
  - swollen lips, tongue, throat, or face
  - trouble swallowing
  - chest pain
  - feeling dizzy or faint
  - moderate or severe abdominal pain or vomiting
- **Hepatitis B virus (HBV) reactivation.** Before you take TAVNEOS, your healthcare provider will do blood tests to check for hepatitis B (HBV) infection. If you have had hepatitis B or are a carrier of hepatitis B virus, taking TAVNEOS could cause the virus to become an active infection again. Your healthcare provider may decide to stop TAVNEOS and any other medicines if you have active hepatitis B liver disease. Your healthcare provider will tell you if and when you can start taking TAVNEOS again. Your healthcare provider will monitor you for hepatitis B infection during and for six months after you stop taking TAVNEOS. Tell your healthcare provider right away if you get worsening tiredness or yellowing of your skin or white part of your eyes during treatment with TAVNEOS.
- **Serious infections.** Serious infections can happen in people taking TAVNEOS, and these infections can lead to death. The most common serious infections with TAVNEOS were pneumonia and urinary tract infections. People with serious infections should not take TAVNEOS. Tell your healthcare provider right away if you have any symptoms of infection:
  - fever
  - cold symptoms, such as runny nose or sore throat that do not go away
  - flu symptoms, such as cough, tiredness, and body aches
  - earache or headache
  - pain during urination
  - cold sores in mouth or throat
  - cuts, scrapes, or incisions that are red, warm, swollen, or painful

The most common side effects of TAVNEOS include:

- nausea
- diarrhea
- tiredness
- increase in blood creatinine
- headache
- vomiting
- stomach pain
- burning or prickling sensation
- high blood pressure
- rash
- dizziness

These are not all the possible side effects of TAVNEOS.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

## How should I store TAVNEOS?

Store TAVNEOS capsules at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep TAVNEOS and all medicines out of reach of children.**

## General information about the safe and effective use of TAVNEOS.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TAVNEOS for a condition for which it was not prescribed. Do not give TAVNEOS to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information that is written for healthcare professionals.

## What are the ingredients in TAVNEOS?

**Active ingredient:** avacopan

**Inactive ingredients:** Polyethylene glycol 4000 (PEG-4000), Polyoxyl-40 hydrogenated castor oil.

Manufactured for: ChemoCentryx, Inc., One Amgen Center Drive, Thousand Oaks, CA 91320-1799

Patent: <https://pat.amgen.com/tavneos>

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For more information, go to [www.TAVNEOS.com](http://www.TAVNEOS.com) or call Amgen at 1-800-772-6436.



This Medication Guide has been approved by the U.S. Food and Drug Administration

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