

For Severe Active ANCA-Associated Vasculitis: GPA and MPA

### TAVNEOS<sup>®</sup> could help you reach and stay in remission\*

\*In the TAVNEOS® clinical study, remission was evaluated at 6 and 12 months.



Visit TAVNEOS.com to learn more



### Ask your doctor about adding TAVNEOS®

AAV = ANCA-associated vasculitis; GPA = granulomatosis with polyangiitis; MPA = microscopic polyangiitis.

#### 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.

### **IMPORTANT SAFETY INFORMATION**

### TAVNEOS may cause serious side effects, including:

- → Liver problems.
- → Serious allergic reactions.
- → Hepatitis B virus (HBV) reactivation.
- → Serious infections.

The most common side effects of TAVNEOS include:

→ nausea, headache, high blood pressure, diarrhea, vomiting, rash, tiredness, stomach pain, dizziness, increase in blood creatinine, and burning or prickling sensation.

Please see additional **Important Safety Information** on pages 13-14 and **Full Prescribing Information** and **Medication Guide** for TAVNEOS.

### What is AAV (GPA and MPA)?

GPA and MPA are 2 subtypes of AAV. They are rare diseases that cause inflammation of mainly small- to medium-sized blood vessels, which leads to:

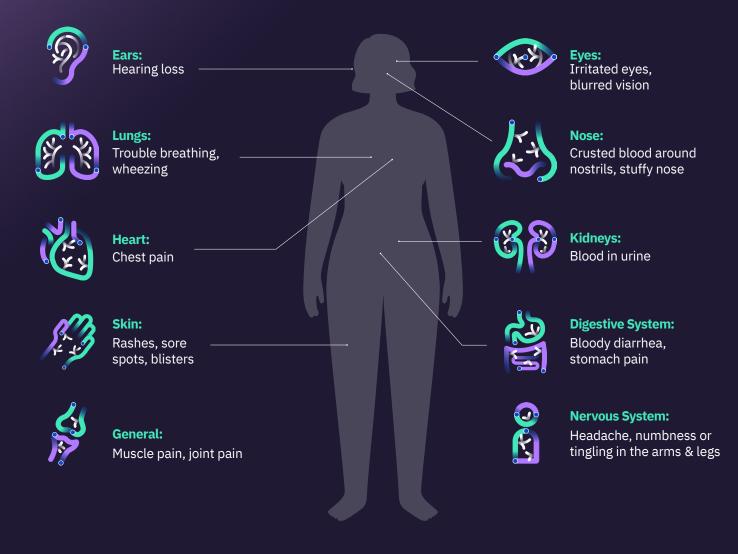
- → Reduced blood flow
- → Impaired organ function

A goal of GPA and MPA treatment is to **reach remission and stay in remission, and reduce the risk of relapse** 

**Remission:** Absence of GPA or MPA signs and/ or symptoms, on or off treatment

**Relapse:** When GPA or MPA signs and/or symptoms return after being in remission





Everyone experiences GPA or MPA differently, and these are just some of the signs and symptoms.

# TAVNEOS<sup>®</sup> is the only oral targeted treatment that is FDA approved for adults with severe active GPA or MPA

### You may be eligible for TAVNEOS<sup>®</sup> if you are an adult with severe active GPA or MPA and you are:



Starting treatment for the first time



Having ongoing signs and/or symptoms despite being on treatment



Experiencing relapse

Once added to your treatment, TAVNEOS<sup>®</sup> is specifically designed to block a receptor involved in GPA and MPA, helping to reduce inflammation. The exact way in which TAVNEOS<sup>®</sup> works in GPA and MPA isn't completely understood.

## If you're having new, worsening, or ongoing symptoms, talk to your doctor right away.

### **IMPORTANT SAFETY INFORMATION (CONT'D)**

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

TAVNEOS can cause serious side effects, including:

- → Liver problems. People taking TAVNEOS may have serious liver problems. 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)
  - pain on the upper right side of your stomach area (abdomen)



## TAVNEOS<sup>®</sup> was studied for 1 year in people living with GPA or MPA

### The clinical study included 330 people People in the TAVNEOS<sup>®</sup> Group received:

- → TAVNEOS<sup>®</sup> + rituximab or
- → TAVNEOS<sup>®</sup> + cyclophosphamide, followed by azathioprine or mycophenolate mofetil\*

### People in the Comparison Group received:

- → Prednisone (with a gradual reduction over time) + rituximab or
- → Prednisone (with a gradual reduction over time)
  + cyclophosphamide, followed by azathioprine or mycophenolate mofetil\*

People in both groups could have received glucocorticoids, often called steroids, prescribed by their doctor as needed.

Disease activity in the study was measured using the **Birmingham Vasculitis Activity Score (BVAS)**, which measures **new**, **worsening**, **or ongoing** GPA and MPA disease activity. A higher BVAS means more disease activity.

\*If azathioprine was not tolerated.

### **IMPORTANT SAFETY INFORMATION (CONT'D)**

### What is the most important information I should know about TAVNEOS? (cont'd)

TAVNEOS can cause serious side effects, including: (cont'd)

- → Liver problems (cont'd)
  - 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.



## TAVNEOS<sup>®</sup> can help you reach and stay in remission



#### → 72% of people in the TAVNEOS® Group reached remission<sup>†</sup> vs 70% of people in the Comparison Group

<sup>†</sup>In the study, remission was reaching a BVAS of 0 and not taking steroids for GPA or MPA within 1 month before month 6.



### → 66% of people in the TAVNEOS<sup>®</sup> Group stayed in remission<sup>‡</sup> vs 55% of people in the Comparison Group

<sup>‡</sup>In the study, sustained remission was a BVAS of 0 at month 6 and at 1 year, not using steroids for GPA or MPA within 1 month before month 6 and 1 year, and not relapsing between month 6 and 1 year.

#### **IMPORTANT SAFETY INFORMATION (CONT'D)**

# Do not take TAVNEOS if you are allergic to avacopan or any of the other ingredients in TAVNEOS.

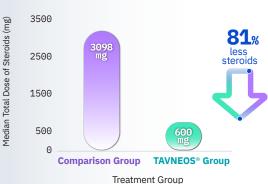
→ Get medical help right away if you experience swollen lips, tongue, throat, trouble swallowing, or difficulty breathing. These could be signs of an allergic reaction. Do not take more TAVNEOS until you have consulted with your healthcare provider.



### Including TAVNEOS® in your treatment may allow you to reduce your steroid use

People in the TAVNEOS® Group used less steroids compared to people in the Comparison Group at 1 year

Median\* Total Dose of Steroids



### People in the TAVNEOS® Group used an average

#### People in the TAVNEOS® Group used an average total steroid dose of 1676 mg, which is



### 56% less steroids

compared to people in the Comparison Group (3847 mg)

People in both groups could have received steroids prescribed by their doctor as needed.

\*The median total dose is the middle number in a set of numbers ordered from the lowest to the highest.

### **IMPORTANT SAFETY INFORMATION (CONT'D)**

#### 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 C.
- → have an infection.







### Considering TAVNEOS<sup>®</sup> as a treatment option?

#### Scan the code and sign up to receive:

- → Information about TAVNEOS<sup>®</sup>
- → A helpful suite of tools
- → Support throughout your journey

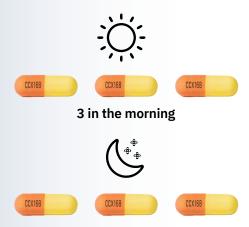
#### IMPORTANT SAFETY INFORMATION (CONT'D) Before taking TAVNEOS, tell your healthcare provider about all your medical conditions, including if you: (cont'd)

- → 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.



### Take 6 capsules daily with food



3 in the evening

Capsules shown are not actual size. Example regimen shown above.

### Take 3 capsules (10 mg each) of TAVNEOS® twice a day with food.

Make sure you talk to your doctor about how and when to take TAVNEOS®.

### Keep TAVNEOS<sup>®</sup> and all medicines out of reach of children.

If you have taken too much TAVNEOS<sup>®</sup>, call your doctor or a Poison Control Center, or go to the nearest hospital emergency room.

### **IMPORTANT SAFETY INFORMATION (CONT'D)**

### Tell your healthcare provider about all the other medicines you take, (cont'd)

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

### TAVNEOS may cause serious side effects, including:

→ Liver problems (see previous mention).



### Take TAVNEOS<sup>®</sup> exactly as your doctor tells you to take it

- → Do not stop taking TAVNEOS<sup>®</sup> unless your doctor tells you to
- Check with your doctor or pharmacist if you are not sure

### Your doctor may tell you to take 3 capsules of TAVNEOS<sup>®</sup> once each day if you take certain medicines

→ Tell your doctor 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

- → Take the next dose at your regular time
- → Do not double the next dose

### Store TAVNEOS® capsules at room temperature

→ Temperature of 68°F to 77°F (20°C to 25°C)

### **IMPORTANT SAFETY INFORMATION (CONT'D)**

TAVNEOS may cause serious side effects, including: (cont'd)

→ 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.



### Amgen can help you get started

### The TAVNEOS® team can:

- → Help you understand your insurance benefits
- → Assist with screening to provide medication to eligible people who do not have insurance and who meet other program criteria
- → Assist eligible commercially insured people with enrolling in the TAVNEOS® Copay Program, which can lower monthly out-of-pocket costs to as little as \$0 for a month's supply of TAVNEOS®\*



\*Eligibility criteria and program maximums apply. See <u>www.tavneos.com/copay</u> for full Terms and Conditions.

### We're available at 1-833-828-6367 Monday through Friday from 8 AM to 8 PM ET. For additional information, visit <u>www.TAVNEOS.com</u>

#### **IMPORTANT SAFETY INFORMATION (CONT'D)**

TAVNEOS may cause serious side effects, including: (cont'd)

→ Hepatitis B virus (HBV) reactivation. If you have had HBV or are a carrier of HBV, taking TAVNEOS could cause the virus to become an active infection again. Tell your healthcare provider right away if you get worsening tiredness or yellowing of your skin or the white part of your eyes during treatment with TAVNEOS.



### Below you'll find a list of organizations that provide education, support, and resources throughout your journey with AAV

These resources are not owned or controlled by Amgen, and Amgen is not responsible for their content.



**The Vasculitis Foundation** supports, inspires, and empowers individuals with vasculitis and their families through a wide range of education, research, clinical, and awareness initiatives.

Visit them at vasculitisfoundation.org



### NORD (National Organization for Rare Disorders)

is a patient advocacy organization committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research.

#### Visit them at rarediseases.org

### 🚺 American Kidney Fund®

**The American Kidney Fund (AKF)** works on behalf of Americans living with and at risk of kidney disease with programs that support people from prevention through transplant and beyond.

Visit them at kidneyfund.org

### **IMPORTANT SAFETY INFORMATION**

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  - yellowing of your skin or the white part of your eyes (jaundice)
  - 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.

### Do not take TAVNEOS if you are allergic to avacopan or any of the other 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 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 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-thecounter 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.

Please click here for <u>Full</u> <u>Prescribing Information</u> and <u>Medication Guide</u> for TAVNEOS.



### **IMPORTANT SAFETY INFORMATION (CONTD)**

### TAVNEOS may cause serious side effects, including:

- → Liver problems (see previous mention).
- → 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. If you have had HBV or are a carrier of HBV, taking TAVNEOS could cause the virus to become an active infection again. Tell your healthcare provider right away if you get worsening tiredness or yellowing of your skin or the 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 that do not go away, flu symptoms, pain during urination, or other signs of infection.

The most common side effects of TAVNEOS include:

→ nausea, headache, high blood pressure, diarrhea, vomiting, rash, tiredness, stomach pain, dizziness, increase in blood creatinine, and burning or prickling sensation.

### What is TAVNEOS?

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

These are not all the possible side effects of TAVNEOS. Call your doctor for medical advice about side effects. Please see the <u>Full Prescribing Information</u> and <u>Medication Guide</u> for further details.

TAVNEOS is available as a 10 mg capsule.

You are encouraged to report negative side effects to Amgen at 1-833-828-6367 or to the FDA by visiting <u>www.fda.gov/medwatch</u> or calling 1-800-332-1088.

Please click here for <u>Full</u> <u>Prescribing Information</u> and <u>Medication Guide</u> for TAVNEOS.



# Adding TAVNEOS® to your treatment plan may help you:



Reach and stay in remission



Reduce steroid use\*

\*People in both groups of the study could have received steroids prescribed by their doctor as needed.

# Ask your doctor if TAVNEOS® is right for you.

Scan the code to prepare for your next doctor's appointment.



#### **IMPORTANT SAFETY INFORMATION (CONT'D)**

#### TAVNEOS may cause serious side effects, including:

- → Liver problems.
- → Serious allergic reactions.
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