

How can TAVNEOS® fit into your severe active GPA or MPA treatment plan?

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]).



Scan the QR code with your phone to learn more at TAVNEOS.com

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

IMPORTANT SAFETY INFORMATION

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)
- 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.

Please see additional Important Safety Information on pages 18-19 and click here for the <u>Full Prescribing Information</u> and <u>Medication Guide</u>.

What is severe active ANCA-Associated Vasculitis (AAV)?

AAV is a group of rare diseases that affects small- to medium-sized blood vessels in your body. These diseases involve inflammation of the blood vessels, which reduces blood flow and could lead to impaired organ function. While your genetics and environment are thought to be contributing causes of these diseases, the exact cause isn't known yet.

Granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA) are the 2 most common subtypes of AAV

Granulomatosis with polyangiitis (GPA)

GPA is generally characterized by inflammation of the blood vessels caused when immune cells clump together, which are known as granulomas. It has a wide range of presentations, though it often affects the lungs, kidneys, sinuses, ears, nose, and throat. GPA is more common than MPA.

Severe active GPA and MPA are serious but treatable diseases.

Your doctor will work with you to develop a treatment plan that suits your needs.









Microscopic polyangiitis (MPA) MPA shares many symptoms with GPA, but kidney impact tends to be more severe. MPA patients may be at particular risk of uncontrolled bleeding in the lungs.



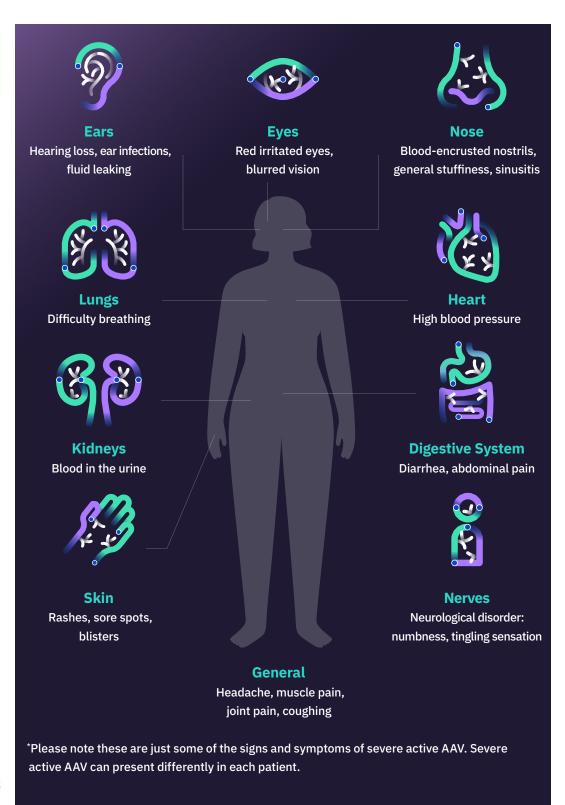


Identifying the signs and symptoms of severe active AAV early can lead to a timely diagnosis that can help you and your healthcare provider decide on a treatment plan to help manage your condition.*

*Active disease means that you have signs and/or symptoms of the disease that are new, not getting better, or getting worse. Severe disease is defined as AAV with signs and/or symptoms that are organ- or life-threatening.

What are the signs and symptoms?

Talk to your doctor if you are having issues in any of the areas listed below*:



AAV impacts the kidneys or another organ in about 80%-90% of cases, which can be considered active disease.

→ Multiple minor manifestations of AAV can also be considered active disease

What can I expect with treatment?

The goal of treatment is to achieve and maintain remission, as well as to reduce relapse

Remission

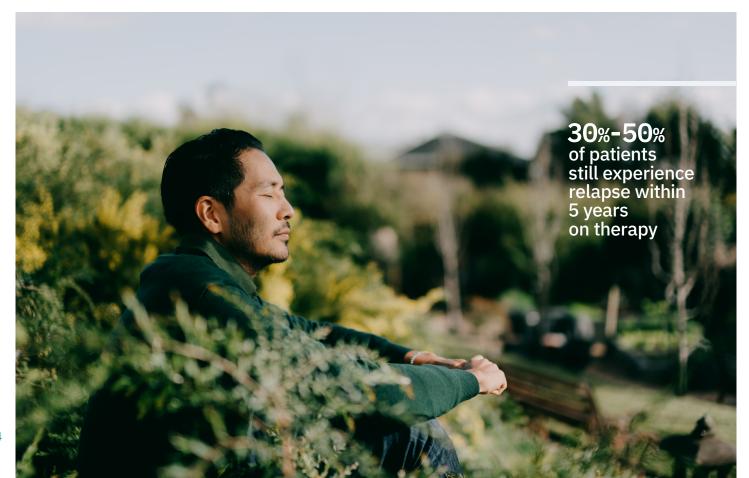
GPA or MPA symptoms have been reduced

Relapse

When GPA or MPA symptoms return after being previously controlled

Severe active GPA and MPA are long-term, progressive diseases that can have times when symptoms appear to worsen, as well as other times when they seem to be improving. There is currently no cure for severe active AAV, but there are treatments that can help patients achieve remission.

Even with treatment, some patients may continue to have symptoms. These patients may benefit from an update to their treatment plan. If you are having any symptoms that you think may be severe active GPA or MPA, be sure to talk to your doctor right away.



How are severe active GPA and MPA treated?

Finding the right treatment option can help make a difference when treating severe active AAV

For treatment, your doctor may prescribe steroids known as glucocorticoids, such as prednisone, as well as other immunosuppressants to help control disease activity.

Treatment with glucocorticoids

Glucocorticoids can be effective, but they can also cause a number of side effects. In fact, a lot of the side effects are often directly related to how long a patient is treated with glucocorticoids. For this reason, doctors have started to move toward treatments that can reduce exposure to high-dose glucocorticoids.

Treatment with other immunosuppressants

One way to induce remission while reducing glucocorticoid exposure is by using other immunosuppressants. Immunosuppressants are medications that target inflammation by lowering the activity of the body's immune system. Their usage has become part of the standard treatment for severe active GPA and MPA.

TAVNEOS® is a targeted oral treatment that is used with other medications to help treat adults with severe active GPA or MPA.

TAVNEOS® works differently than other immunosuppressants. Once added to your current treatment, TAVNEOS® is specifically designed to block a receptor involved in GPA and MPA, helping to reduce inflammation. The exact way in which TAVNEOS® works in severe active GPA and MPA isn't completely understood.

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.



Why should I add TAVNEOS® to my current severe active GPA or MPA treatment?

TAVNEOS® can help you achieve and stay in remission, and may help reduce the risk of relapse

TAVNEOS® in combination with additional immunosuppressive therapy* was comparable to standard therapy† at reaching remission at 6 months, and superior at sustaining remission at 1 year.‡

*Immunosuppressive therapy: rituximab, or cyclophosphamide followed by azathioprine.

†Standard therapy: immunosuppressive therapy and a gradual reduction of prednisone over time.

‡In the study, people were allowed glucocorticoids not supplied as part of the study medication.



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.



How can TAVNEOS® help me reach and stay in remission?

TAVNEOS® was studied in a clinical trial over 52 weeks involving 330 people living with GPA and MPA

Comparable at 6 months of treatment



of people treated with TAVNEOS® in combination with additional immunosuppressive therapy reached remission*



of people taking standard therapy

*In the study, remission was defined as achieving a Birmingham Vasculitis Activity Score (BVAS) of 0 and not taking glucocorticoids for treatment of ANCA-associated vasculitis within 4 weeks prior to Week 26.

Superior at 1 year of treatment



of people treated with TAVNEOS® in combination with additional immunosuppressive therapy stayed in remission[†]



of people taking standard therapy

[†]In the study, sustained remission was defined as remission at Weeks 26 and 52 without relapsing between Week 26 and Week 52. Remission at Week 52 was defined as BVAS of 0 and not taking glucocorticoids for treatment of ANCA-associated vasculitis within 4 weeks of Week 52.



Fewer relapses[‡] at 1 year of treatment

lower risk of relapse for people treated with TAVNEOS® in combination with additional immunosuppressive therapy compared to people treated with standard therapy

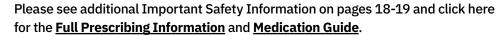
- → 21% of people treated with standard therapy relapsed vs 10% of people treated with TAVNEOS®
- → There is a possibility that the difference between treatments may have been due to chance alone and not due to TAVNEOS®, so these results were not considered significant and should be interpreted with caution.

[‡]In the study, relapse was defined as a return of GPA or MPA activity on the basis of at least of 1 major item, at least 3 non-major items, or 1 or 2 non-major items for at least 2 consecutive visits on the BVAS after BVAS of 0 had been achieved.

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.





Could TAVNEOS® help my quality of life?

TAVNEOS® helped improve quality of life in the study

According to a quality-of-life survey,* people treated with TAVNEOS® and additional immunosuppressive therapy had scores that showed greater improvement than those treated with standard therapy. From the start of the study to week 52, people in the TAVNEOS® group had an improvement in their overall:

- → Physical score of 5.0 compared to 2.6 in people on standard therapy
- → Mental score of 6.4 compared to 4.7 in people on standard therapy

The survey assessed both physical and mental health categories, which included:



- → Body pain
- → Physical functioning
- → Difficulties with work or daily activities due to physical health problems
- → General health perception



- → Mental health

→ Vitality

- → Difficulties with work or daily activities due to emotional health problems
- → Functioning in social settings

*Based on responses to the Short Form-36 version 2 (SF-36 V2) survey. SF-36 scores range from 0 (worst) to 100 (best). The SF-36 V2 survey was not developed specifically for people with severe active AAV. Additionally, there is a possibility that the difference between treatments may have been due to chance alone and not due to TAVNEOS®, so these results were not considered significant. Results should be interpreted with caution.

IMPORTANT SAFETY INFORMATION (CONT'D)

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.



Could TAVNEOS® help reduce my reliance on glucocorticoids or improve my kidney function?

Including TAVNEOS® with your therapy regimen may allow you to reduce your reliance on steroids



People who took TAVNEOS® with additional immunosuppressive therapy through Week 52 of the study used less glucocorticoids

Everyone in the study was allowed to use glucocorticoids as needed regardless of what treatment they used. However, those treated with TAVNEOS® in combination with additional immunosuppressive therapy compared to those treated with standard therapy had a lower median total dose of steroids of 81% (TAVNEOS® = 600 mg; Standard Therapy=3097.5 mg), and a lower mean total dose of steroids of 56% (TAVNEOS® = 1675.5 mg; Standard Therapy= 3846.9 mg).

Kidney function improved for adults who used TAVNEOS® in combination with additional immunosuppressive therapy

→ 81% of people had kidney involvement at the start of the study and were assessed

To see how well your kidneys are working, your doctor may check your estimated Glomerular Filtration Rate (eGFR). Generally, the higher the eGFR the better the kidney function.



→ At Week 52, people treated with TAVNEOS® with additional immunosuppressive therapy had a difference in eGFR of 7.3 mL/min/1.73m² compared to a 4.1 mL/min/1.73m² change for people treated with standard therapy

There is a possibility that the difference between treatments may have been due to chance alone and not due to TAVNEOS®, so these results were not considered significant. Also the difference between treatments was reduced when people stopped taking TAVNEOS® at the end of the study. Therefore, results should be interpreted with caution.

IMPORTANT SAFETY INFORMATION (CONT'D)

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.



Is TAVNEOS® right for me?

TAVNEOS® is a prescription treatment for adult patients with severe active GPA or MPA that is added to your current AAV treatment. It is not known if TAVNEOS® is safe and effective for children under the age of 18.

Patients may be eligible for TAVNEOS® when ALL of the following criteria are met:

- 1. Adults diagnosed with the following types of severe active AAV:
 - → Severe active GPA or MPA
- 2. Patient is currently (any of the below):
 - → In process of starting treatment for severe active GPA or MPA
 - → Currently on treatment for severe active GPA or MPA
 - → Experiencing relapse of severe active GPA or MPA

Talk with your doctor about whether TAVNEOS® is right for you

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.
- → **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 should I ask my doctor about TAVNEOS®?

- → What does successful management for my severe active GPA or MPA look like?
- → How could TAVNEOS® enhance my current treatment regimen?
- → How could TAVNEOS® help me achieve and stay in remission?
- → When could I start to see a difference from my severe active GPA or MPA treatment regimen?
- → What are the side effects of TAVNEOS®?
- → Could TAVNEOS® improve my quality of life?
- → Could TAVNEOS® reduce my need for other medications or steroids?
- → When do I add TAVNEOS® into my treatment regimen?



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)
 - 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.



How do I get started on TAVNEOS®?



Amgen can help support you throughout your TAVNEOS® journey with the TAVNEOS® Connect patient support program

This program can:

- → Help you understand your insurance benefits and assist eligible commercially-insured patients with their copay by lowering monthly out-of-pocket costs*
- → Offer resources to help you learn about your therapy

- → Provide medication to eligible patients who do not have insurance and who meet other program criteria
- → Connect you with patient communities that can support you during your treatment journey

Contact the TAVNEOS® Connect team to begin your enrollment process: 1-833-828-6367 (option 2). We're available Monday through Friday from 8 AM to 8 PM ET. For additional information, visit www.TAVNEOS.com/support



TAVNEOS® Connect services are only available for patients whose diagnosis is aligned with the FDA-approved indication for TAVNEOS®. Additional eligibility criteria may apply. Terms and conditions and other program restrictions apply.

*Other restrictions may apply. This program is not open to patients receiving prescription reimbursement under any federal, state or government funded healthcare program, or for cash patients. This is not insurance or a guarantee of payment. No cash value. Void where prohibited by law.

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.

Please see additional Important Safety Information on pages 18-19 and click here for the <u>Full Prescribing Information</u> and <u>Medication Guide</u>.



What is the process for receiving TAVNEOS®?

You and your doctor decide that TAVNEOS® is right for you

Your doctor and their support staff will submit your TAVNEOS® prescription to the TAVNEOS® Connect team or a specialty pharmacy.

You will receive a phone call

Make sure to answer your phone This call will come from either TAVNEOS® Connect or a pharmacy to talk to you about your prescription. This phone call may come from an unfamiliar phone number, such as:

- **→ 1-833-828-6367**,
- **→ 1-866-930-4146**,
- **→ 1-402-896-5000**,
- → 1-855-801-0694, or
- **→ 1-855-726-8479.**

If you aren't available to answer, they may leave a general message asking you to call back. It is important to return this call at your earliest convenience. You can also call 1-833-828-6367 (option 2) any time if you have questions.

TAVNEOS® will be delivered to your home

While you are taking TAVNEOS®, each month, the pharmacy will contact you to confirm the shipment and to schedule the TAVNEOS® delivery. You will need to speak with the pharmacy before each delivery, so be sure to answer these important calls.

If you have not heard back about your prescription, or if you have any questions, reach out to TAVNEOS® Connect and your doctor's office.

After you are first prescribed TAVNEOS®, make sure you follow up with your doctor to discuss long-term management of your severe active GPA or MPA.

For the most up-to-date information about TAVNEOS®, visit www.TAVNEOS.com.

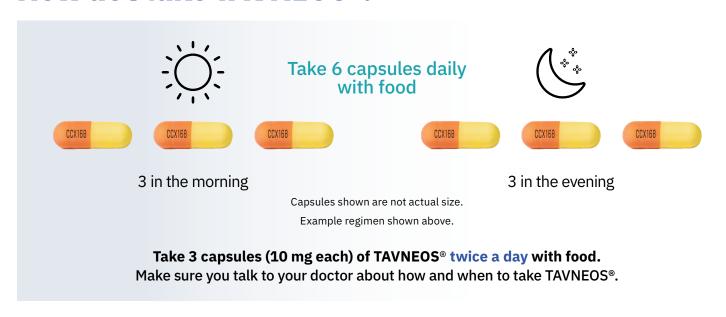
IMPORTANT SAFETY INFORMATION (CONT'D)

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.
- → 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.



How do I take TAVNEOS®?



Take TAVNEOS® exactly as your doctor tells you to take it.

- → Do not stop taking TAVNEOS® 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® 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)

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

If you have taken too much TAVNEOS®, 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, 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.



What are the possible side effects of TAVNEOS®?

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. These are not all the possible side effects of TAVNEOS®. Call your doctor for medical advice about side effects.

Seek medical help immediately if you experience any of the following:

- → Swollen lips/tongue/throat
- → Trouble swallowing

These could be signs of an allergic reaction. Do not take any more TAVNEOS® until you have consulted with your healthcare provider.



What should I consider before starting TAVNEOS®?

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-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

Who should not take TAVNEOS®?

- → Do not take TAVNEOS® if you are allergic to avacopan or any of the other ingredients of this medicine
- → See the Medication Guide for a complete list of the ingredients in TAVNEOS®



Are there other resources I should know about?

You're not alone. Below, you'll find a list of organizations that provide education, support, and resources that may help you or your loved one throughout the journey with AAV



The Vasculitis Foundation

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

Visit them at vasculitisfoundation.org



NORD (National Organization for Rare Disorders)

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, and patient services.

Visit them at raredisorders.org



The National Kidney Foundation

The National Kidney Foundation is the leading organization in the U.S. dedicated to the awareness, prevention, and treatment of kidney disease.

Visit them at kidney.org

Important Safety Information

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Important Safety Information (cont'd)

TAVNEOS may cause serious side effects, including:

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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.

These are not all the possible side effects of TAVNEOS. Call your doctor for medical advice about side effects. Please see the **Full Prescribing Information** and **Medication Guide** 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 www.fda.gov/medwatch or calling 1-800-332-1088.



Does TAVNEOS® fit your treatment needs?

Adding TAVNEOS® to your treatment plan may help you:



Achieve and sustain remission



Reduce your chance of relapse*



Reduce steroid use*



Improve quality of life*

*There is a possibility that the difference between treatments may have been due to chance alone and not due to TAVNEOS®, so these results were not considered significant and should be interpreted with caution.

Ask your doctor if TAVNEOS® is right for you or you have questions about treatment

To begin the enrollment process, contact the TAVNEOS® Connect team at 1-833-828-6367 (option 2). We're available Monday through Friday from 8 AM to 8 PM ET.



Scan the QR code with your phone to learn more at TAVNEOS.com

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