

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^PTAVNEOS[®]

Avacopan oral capsule

Read this carefully before you start taking TAVNEOS and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about TAVNEOS.

What is TAVNEOS used for?

TAVNEOS is used to treat adults with conditions known as severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis.

- These include granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA).
- TAVNEOS is used along with other medicines to treat your condition.

How does TAVNEOS work?

TAVNEOS binds to a receptor in the body and blocks inflammation. This can be detected within hours. Your symptoms may improve within the first 4 weeks.

What are the ingredients in TAVNEOS?

Medicinal ingredient: avacopan

Non-medicinal ingredients: black iron oxide, gelatin, macrogol 4000, macrogolglycerol hydroxystearate, polysorbate 80, potassium hydroxide, red iron oxide, shellac, titanium dioxide, yellow iron oxide

TAVNEOS comes in the following dosage forms:

As 10 mg capsules.

Do not use TAVNEOS if:

- You are allergic to avacopan or to any of the ingredients in TAVNEOS (see What are the ingredients in TAVNEOS).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TAVNEOS. Talk about any health conditions or problems you may have, including if you:

- have liver problems.
- have hepatitis B virus (HBV) infection.
- are pregnant, think you might be pregnant or are planning to become pregnant. It is not known if TAVNEOS may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if TAVNEOS can pass into your milk and harm your baby. Talk to your healthcare professional about the best way to feed your baby if you take TAVNEOS.
- have an infection or infections that often come back.
- have heart problems.
- are planning to receive a vaccine. It is recommended that you receive vaccinations before starting treatment with TAVNEOS.

- are taking the medicines cyclophosphamide and azathioprine

Other warnings you should know about:

Liver problems: Serious liver problems have happened to patients taking TAVNEOS. Your healthcare professional will monitor your liver function before you start TAVNEOS and while you are taking it. They might decide to stop treatment based on these test results. Talk to your healthcare professional if you get any symptoms of liver problems. These include: yellow skin or whites of eyes, nausea, tiredness or feeling unwell, loss of appetite, fever, skin rash, abdominal pain, pale stool or dark coloured urine.

Angioedema (Serious swelling under the skin): TAVNEOS can cause a serious reaction called angioedema. See “Serious side effects and what to do about them” for symptoms and what to do if you get them.

Infections: Serious infections can happen in people taking TAVNEOS and these infections can lead to death. The most common serious infections were pneumonia and urinary tract infections. Other infections can also happen. See “Serious side effects and what to do about them” for symptoms and what to do if you get them. Your healthcare professional will monitor you for infections while you are taking TAVNEOS. They might stop and restart your treatment. It is recommended that you have treatment to prevent the lung infection *Pneumocystis jirovecii* pneumonia during treatment with TAVNEOS.

Hepatitis B virus reactivation: Before you take TAVNEOS, your healthcare provider will do blood tests to check for hepatitis B infection. If you have HBV infection, TAVNEOS could cause you to have an active infection again. Your healthcare professional will monitor your HBV infection during treatment with TAVNEOS. Talk to your healthcare professional if you get any of the following symptoms: fever, tiredness, yellow skin or to the whites of eyes, abdominal pain, diarrhea.

Macrogolglycerol hydroxystearate: TAVNEOS contains macrogolglycerol hydroxystearate as a non-medicinal ingredient. This may cause stomach upset, diarrhea, vomiting and nausea.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TAVNEOS:

- boceprevir, telaprevir, used to treat hepatitis C infection
- bosentan, used to treat high blood pressure in the lungs, and certain skin hardening or abscesses
- carbamazepine and phenytoin, used to treat epilepsy and other illnesses
- clarithromycin and telithromycin, used to treat bacterial infections
- conivaptan, used to treat low blood sodium levels
- enzalutamide and mitotane: medicines to treat cancer
- indinavir, efavirenz, etravirine, lopinavir, nelfinavir, ritonavir and saquinavir, used to treat HIV infections
- itraconazole, ketoconazole, posaconazole and voriconazole, used to treat fungal infections
- mibefradil, used to treat irregular heart rhythm and high blood pressure
- modafinil, used to treat an extreme tendency to fall asleep
- nefazodone and St. John’s Wort, used to treat depression
- phenobarbital, used to treat epilepsy
- rifampicin, used to treat tuberculosis or certain other infections

Grapefruit and grapefruit juice are not recommended during treatment with TAVNEOS, as they can influence the effect of the medicine.

Drinking alcohol while taking TAVNEOS can change the way your liver works. Talk to your healthcare professional about limiting your alcohol intake.

How to take TAVNEOS:

- Take TAVNEOS exactly as your healthcare professional tells you to.
- It will be prescribed to you by a healthcare professional with experience in the diagnosis and treatment of GPA and MPA.
- Take TAVNEOS with food.
- Swallow the capsules whole with water. Do not crush, chew or open the capsules.
- Check with your healthcare professional if you are not sure how to take TAVNEOS.

Usual dose:

Adult: Take 3 capsules with food in the morning and 3 capsules with food in the evening.

Overdose:

If you think you, or a person you are caring for, have taken too much TAVNEOS, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take the missed dose as soon as you remember. However, do not take the missed dose if it is within 3 hours to your next dose. Never take two doses at the same time.

What are possible side effects from using TAVNEOS?

These are not all the possible side effects you may have when taking TAVNEOS. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- high blood pressure, fatigue
- nausea, vomiting, diarrhea, pain in the belly
- headache
- rash
- flu, cold
- cold sore
- gastroenteritis (stomach flu)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Increased levels of a blood enzyme (creatine phosphokinase): cramps, muscle pain, tenderness and stiffness.		X	
Infection of the respiratory system, mouth, skin or ear: fever, chills, sore throat that does not go away, white patches in your mouth, pain when swallowing, cough, stuffy nose that does not go away, pain or pressure in your face, fatigue, body aches, earache, headache, red, swollen, painful or itchy areas of the skin, rash, numbness or tingling of your skin, skin blisters.		X	
Liver problems: yellow skin or to the whites of eyes, nausea, tiredness or feeling unwell, loss of appetite, fever, skin rash, abdominal pain, pale stool or dark coloured urine.		X	
Pneumonia (infection of the lungs): cough with or without mucus, fever, chills, shortness of breath.		X	
Urinary tract infection: Pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine, fever.		X	
UNCOMMON			
Allergic Reaction: difficulty swallowing or breathing, wheezing, swelling of the face, lips, tongue or throat.			X
Angioedema (Serious swelling under the skin): swelling of the face, throat, arms, legs or genitals, rash or hives, pain and warmth of affected areas, throat tightness, difficulty breathing, trouble			X

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
swallowing, abdominal pain, vomiting, feeling dizzy, chest pain.			
Decreased levels of white blood cells: infections, fatigue, fever, aches, pains and flu-like symptoms.		X	
Hepatitis B virus reactivation: fever, tiredness, yellow skin or to the whites of eyes, abdominal pain, diarrhea.		X	
Nausea	X		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

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

Keep out of reach and sight of children.

If you want more information about TAVNEOS:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.otsukacanada.com), or by calling 1-877-341-9245.

This leaflet was prepared by Otsuka Canada Pharmaceutical Inc.

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