TAVNEOS®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new. Please report side effects. See the full CMI for further details.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using Tavneos?

Tavneos contains the active ingredient avacopan. Tavneos is used in combination with other medicines to treat adults with anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA])**.**

For more information, see Section 1. Why am I using Tavneos? in the full CMI.

2. What should I know before I use Tavneos?

Do not use if you have ever had an allergic reaction to avacopan or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Tavneos? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Tavneos and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Tavneos?

- Use as directed by your doctor. Check with your doctor or pharmacist if you are not sure.
- The recommended dose is 3 capsules, twice daily.
- Take the capsules with food, in the morning and evening. Swallow the capsules whole with water.
- Do not crush, chew or open the capsules.

More instructions can be found in Section 4. How do I use Tavneos? in the full CMI.

5. What should I know while using Tavneos?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Tavneos. • If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Tavneos is not recommended for use during pregnancy and in women of childbearing potential not using contraception. • Ensure you keep all your doctor's appointments so that your doctor can monitor your blood tests.
Things you should not do	• Do not stop using this medicine suddenly, unless your doctor tells you to. • Do not take a missed dose if it is less than 3 hours to your next dose. • Do not give this medicine to children under 17 years of age.
Looking after your medicine	• Store below 30°C. • Store in the original package in order to protect from light. • Keep this medicine out of the sight and reach of children.

For more information, see Section 5. What should I know while using Tavneos? in the full CMI.

6. Are there any side effects?

The most common side effects are cold-like symptoms; sore or inflamed throat and nose; wheezing; flu-like symptoms; difficulty breathing; headache; nausea; vomiting; diarrhoea; upper stomach pain, viral and/or bacterial infections, decreased white blood cell count seen in blood tests and blood test showing increased levels of liver enzymes and bilirubin. Serious side effects include swelling of the tongue, face, lips, mouth, throat and/or body and difficulty breathing.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WARNING:

Liver injury, including a potentially fatal loss of the bile ducts in the liver, have been observed in patients taking Tavneos.

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects: feeling sick (nausea or vomiting), feeling tired, loss of appetite, yellowing of the skin or eyes, dark urine, itching, or upper stomach pain.

Your doctor will do regular blood tests to check your liver function.

TAVNEOS®

Active ingredient: *avacopan*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Tavneos. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Tavneos.**

Where to find information in this leaflet:

1. Why am I using Tavneos?
2. What should I know before I use Tavneos?
3. What if I am taking other medicines?
4. How do I use Tavneos?
5. What should I know while using Tavneos?
6. Are there any side effects?
7. Product details

1. Why am I using Tavneos?

Tavneos contains the active ingredient avacopan. Avacopan binds to a specific inflammation causing protein in the body, called complement 5a receptor and blocks its inflammatory effects. This prevents the inflammatory effects of white blood cells called neutrophils.

Tavneos is used in combination with other medicines for the treatment of adults with anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (diseases caused by inflammation of the small blood vessels), the types of ANCA vasculitis are known as GPA and MPA.

2. What should I know before I use Tavneos?

Warnings

Do not use Tavneos if:

- you are allergic to avacopan, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have or have had any other medical conditions:
  - liver disease
  - an infection such as hepatitis B, hepatitis C, HIV infection or tuberculosis
  - heart disease
  - have any infection, unexpected bruising and bleeding (these two are common signs of bone marrow failure)
  - any type of cancer
- take any medicines for any other condition (see Section 3. What if I am taking other medicines?).
- you are going to have a vaccination. Your doctor will tell you when the right time to have it is. Vaccinations should preferably be administered prior to having treatment with Tavneos or when there is no active disease.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Liver injury

Serious liver problems, including a potentially fatal liver injury called vanishing bile duct syndrome (VBDS) that can cause the loss of the bile ducts in the liver, have been observed in patients taking Tavneos. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant. Tavneos is not recommended for use during pregnancy and in women of childbearing potential not using contraception. Your doctor will discuss with you the benefits and risks of taking Tavneos while pregnant. It is not known if avacopan will harm your unborn baby.

It is unknown whether avacopan passes into breast milk. Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor will decide whether to stop treatment with Tavneos or stop breast-feeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

The following medicines can influence the effect of Tavneos:

- carbamazepine and phenytoin; medicines to treat epilepsy and other illnesses
- enzalutamide; a medicine to treat cancer
- rifampicin; a medicine to treat tuberculosis or certain other infections
- St. John's wort; a herb you may get from the health food shop
- alfentanil; a painkiller used during an operation with anaesthetics
- boceprevir, telaprevir; medicines to treat hepatitis C
- bosentan; a medicine to treat high blood pressure in the lungs, and sores on the fingers and toes called scleroderma
- clarithromycin and telithromycin; medicines to treat bacterial infections
- ciclosporin; a medicine to suppress the immune system, treat severe skin diseases and severe eye or joint inflammation
- fentanyl; a strong painkiller
- efavirenz, etravirine, lopinavir/ritonavir, ritonavir, saquinavir; medicines to treat HIV infections
- itraconazole, posaconazole, voriconazole; medicines to treat fungal infections
- ketoconazole; a medicine to treat symptoms caused by the body's excessive production of cortisol called Cushing's syndrome
- modafinil; a medicine to treat an extreme tendency to fall asleep
- phenobarbital; medicine to treat epilepsy
- sirolimus, tacrolimus; medicines to prevent transplant rejection and treat continuous or recurrent, non-contagious skin inflammation with severe itching
- dabigatran etexilate; a medicine that slows down the formation of blood clots.

The following medicines can be influenced by Tavneos:

- simvastatin: a medicine used to lower levels of total cholesterol, LDL cholesterol and fatty substances called triglycerides in the blood

Your doctor may do additional tests if you need to take any of the above medicines while using Tavneos.

Some food and drink may interfere with Tavneos and affect how it works.

Avoid grapefruit and grapefruit juice during treatment with Tavneos, as these can influence the effect of the medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Tavneos.

4. How do I use Tavneos?

How much to take

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose is 3 capsules, twice daily.
- Follow the instructions provided and use Tavneos until your doctor tells you to stop.

When to take Tavneos

- Tavneos capsules are to be taken with food, in the morning and in the evening.
- Swallow the capsules whole with one glass of water.
- **Do not** crush, chew or open the capsules.

If you forget to use Tavneos

Tavneos should be used regularly at the same time each day. If you miss your dose at the usual time, take the missed dose as soon as possible, unless within 3 hours of your next dose.

Do not take the missed dose if it is less than 3 hours to your next dose. Wait for the time for your next dose.

Do not take a double dose to make up for the dose you missed.

If you use too much Tavneos

If you think that you have used too much Tavneos, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Tavneos?

Things you should do

Call your doctor straight away and immediately stop treatment if you:

- have painful severe swelling of the face, lips, tongue, throat and/or body and difficulty breathing

- lung inflammation with symptoms that can be wheezing, difficulty breathing, or chest pain

Talk to your doctor during treatment if you have:

- any symptoms of liver injury such as feeling sick (nausea or vomiting), feeling tired, loss of appetite, yellowing of the skin or eyes, dark urine, itching or upper stomach pain
- an infection, unexpected bruising and bleeding
- if you have or have had hepatitis B, hepatitis C, HIV infection or tuberculosis
- heart disease or heart disorders such as myocardial infarction, heart failure or heart vasculitis
- any type of cancer

Prevention of the lung infection *Pneumocystis jirovecii* pneumonia is recommended during treatment.

Prior and regularly during treatment, your doctor will monitor your:

- liver enzymes and bilirubin by taking blood tests
- white blood cell count by taking blood tests.

Remind any doctor, dentist or pharmacist you visit that you are using Tavneos.

Things you should not do

- Do not stop taking this medicine suddenly without talking to your doctor, unless you have any swelling of the face, lips, tongue or throat or breathing difficulties occur.
- Do not take a double dose to make up for a forgotten dose.
- Do not use this medicine after the expiry date.
- Do not give this medicine to children under 17 years of age.

Driving or using machines

Tavneos has no or negligible influence on the ability to drive and use machines.

Looking after your medicine

- Store below 30°C.
- Store in the original bottle in order to protect from light.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Do not use this medicine after the expiry date which is stated on the carton and bottle after "EXP".

The expiry date refers to the last day of that month.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Infection related: • infection of the upper airways, including wheezing and difficulty breathing and/or shortness of breath • sneezing, itching, runny and blocked nose • sore and/or inflamed throat and nose • flu • oral herpes in the mouth that causes painful sores on your lips, gums, tongue or roof of your mouth or a yeast fungal infection caused by candida also known as oral thrush • middle ear infection • urinary tract infection • shingles; a viral infection that causes a painful rash • cellulitis; a bacterial infection that causes redness, swelling and pain in the infected area of the skin • inflammation of the sinuses or bronchial tubes • inflammation of the stomach and bowel lining • infection of the lower airways **Stomach related:** • feeling sick, also called nausea • vomiting • diarrhoea • upper stomach pain **Nervous system related:** • headache **Blood related:** • infections, fever or painful swallowing – these may be	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

symptoms of reduced number of white blood cells called neutrophils • muscle aches and pain, chest pain, confusion, muscle weakness or numbness of the body –these may be symptoms of increased blood level of creatine phosphokinase enzyme	

Serious side effects

Serious side effects	What to do
Lung Related: • lung inflammation with symptoms that can be wheezing, difficulty breathing, or chest pain **Allergic reaction:** • swelling of the tongue, face, lips, mouth, throat and/or body and difficulty breathing **Liver related:** • abnormal liver functions based on blood test. This may not cause symptoms, but your doctor will check for this periodically. • bile duct injury / loss (symptoms can be feeling sick (nausea or vomiting), feeling tired, loss of appetite, yellowing of the skin or eyes, dark urine, itching, or upper stomach pain).	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Tavneos contains

Active ingredient (main ingredient)	avacopan 10 mg
Other ingredients (inactive ingredients)	• PEG-40 hydrogenated castor oil • macrogol 4000 • gelatin • polysorbate 80 • titanium dioxide • iron oxide yellow • iron oxide red • iron oxide black • shellac • potassium hydroxide

Do not take this medicine if you are allergic to any of these ingredients.

What Tavneos looks like

Tavneos hard capsules is made of a yellow body and light orange cap with “CCX168” in black ink. The capsules are packed in plastic bottles with a child-resistant closure and available in packs containing 30 or 180 hard capsules.

(Aust R 381053).

Not all pack sizes may be marketed.

Who distributes Tavneos

Distributed in Australia by:

CSL Seqirus
655 Elizabeth Street
Melbourne, VIC 3000
Australia

1800 642 865 (Within Australia).

Sponsor

Seqirus Pty Ltd
63 Poplar Rd,
Parkville VIC 3052
Australia

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