



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Tavneos (*avacopan*)

An overview of Tavneos and why it is authorised in the EU

What is Tavneos and what is it used for?

Tavneos is a medicine used to treat adults with severe, active granulomatosis with polyangiitis (GPA or Wegener's granulomatosis) or microscopic polyangiitis (MPA), which are inflammatory conditions of the blood vessels. Tavneos is used as part of a combined treatment also including the medicines rituximab or cyclophosphamide.

Tavneos contains the active substance avacopan.

GPA and MPA are rare, and Tavneos was designated an 'orphan medicine' (a medicine used in rare diseases). Further information on the orphan designations can be found on the European Medicines Agency's website ([GPA](#): 19 November 2014; [MPA](#): 19 November 2014).

How is Tavneos used?

The medicine can only be obtained with a prescription. Treatment should be started and monitored by healthcare professionals experienced in the diagnosis and treatment of GPA or MPA.

The medicine is available as capsules and the recommended dose is 30 mg taken by mouth twice daily with meals. The doctor may have to interrupt or stop the treatment in case of certain severe side effects. Patients on Tavneos should avoid grapefruit and grapefruit juice as it can affect the way the medicine works.

For more information about using Tavneos, see the package leaflet or contact your doctor or pharmacist.

How does Tavneos work?

The active substance in Tavneos, avacopan, blocks the receptor (target) for a protein in the blood called complement 5a (or C5a), which forms part of the immune system (the body's natural defences).

When C5a attaches to its receptor, it activates immune cells called neutrophils, which contribute to the inflammation of small blood vessels in GPA and MPA. By blocking the receptor for C5a, Tavneos is expected to reduce inflammation of blood vessels, thus improving the symptoms of the disease.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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What benefits of Tavneos have been shown in studies?

In a study of 330 patients with GPA or MPA, Tavneos was compared with high-dose corticosteroids (other medicines for inflammatory diseases). All patients received standard treatment with either rituximab or a regimen consisting of cyclophosphamide followed by azathioprine. All patients also received additional corticosteroids as needed.

After 26 weeks of treatment with Tavneos 72% (120 out of 166) of patients were in complete remission, compared with 70% (115 out of 164) of patients given corticosteroids at high doses for 20 weeks. At week 52, 66% (109 out of 166) of patients on Tavneos and standard therapy were still in remission, compared with 55% (90 out of 164) of patients given corticosteroids and standard therapy.

What are the risks associated with Tavneos?

The most common side effects with Tavneos (which may occur in more than 1 in 10 people) are nausea (feeling sick), headache, decrease in white blood cell count, upper respiratory tract (nose and throat) infection, diarrhoea, vomiting, and nasopharyngitis (inflammation of the nose and throat).

The most common serious side effects are liver function abnormalities and pneumonia (infection of the lungs).

The full list of side effects and restrictions of Tavneos is presented in the package leaflet.

Why is Tavneos authorised in the EU?

Tavneos was shown to be at least as effective as high-dose corticosteroids in inducing remission in patients with GPA or MPA and to lead to better long-term remission rates. Tavneos' safety profile is acceptable. Abnormalities in patients' liver function were the most serious side effects, and were considered manageable with appropriate guidance presented in the product information. There is a high unmet need for medicines to treat GPA and MPA that will allow doses of corticosteroids to be reduced. The European Medicines Agency therefore decided that Tavneos' benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Tavneos?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Tavneos have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Tavneos are continuously monitored. Suspected side effects reported with Tavneos are carefully evaluated and any necessary action is/will be taken to protect patients.

Other information about Tavneos

Tavneos received a marketing authorisation valid throughout the EU on 11 January 2022.

Further information on Tavneos can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/tavneos

This overview was last updated in 12-2021.