26 June 2026
EMA/143819/2026

EMA recommends revoking marketing authorisation for Tavneos

Benefits no longer proven to outweigh risks of treatment

EMA's human medicines committee (CHMP) has concluded its review of the medicine Tavneos (avacopan) and has recommended that the medicine's marketing authorisation in the European Union be revoked because its benefits are no longer proven to outweigh its risks. Tavneos is used to treat adults with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA), two rare inflammatory conditions of the blood vessels.

The review was initiated to assess new information that raised questions regarding data integrity of the main study (the Advocate study) supporting the medicine's marketing authorisation in the EU.

In the Advocate study, which included 331 patients with GPA or MPA, a 52-week course of Tavneos was compared with placebo (a dummy treatment) together with a 20-week course of corticosteroids (medicines used to treat inflammatory diseases), both in addition to standard treatment (either rituximab or a regimen consisting of cyclophosphamide followed by azathioprine). Based on data from this study, at the end of EMA's evaluation of the marketing authorisation application, Tavneos was found to be at least as effective as the 20-week course of high-dose corticosteroids in inducing remission in patients with GPA or MPA, and to lead to better long-term (52 weeks) remission rates than the comparator.

After reviewing the totality of the available data and new information on how the study data were handled, the CHMP concluded that the Advocate study was conducted in breach of good clinical practice (GCP) principles. Study data provided at the time of the assessment of the marketing authorisation application were found to be incorrect and misleading and could no longer be relied upon for demonstrating Tavneos' effectiveness. Supportive post-marketing data and other post-hoc analyses of the Advocate study are not considered sufficient to demonstrate the benefits of the medicine.

The committee has therefore recommended that the medicine's marketing authorisation be revoked in the EU. In reaching its conclusion, the committee also considered the views of patient and healthcare professional representatives, as well as written interventions received from third parties. If this recommendation is confirmed by the European Commission, Tavneos will no longer be authorised in the EU.

The CHMP is recommending that no new patients should start treatment with Tavneos, and that existing patients should be switched to suitable alternatives.

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 An agency of the European Union

As Tavneos is associated with an increased risk of drug-induced liver injury (DILI) and vanishing bile duct syndrome (VBDS, a rare condition where the small bile ducts inside the liver are gradually damaged and disappear over time), including cases with a fatal outcome, the liver function of patients treated with Tavneos should be closely monitored until treatment is permanently stopped.

For patients treated with Tavneos for less than three months before stopping treatment, liver function should be monitored at least every two weeks until three months have passed since the start of treatment. For patients who received Tavneos for longer than three months, liver function should be monitored every four weeks for up to six months, and then as considered necessary. If VBDS is suspected, Tavneos must be immediately discontinued.

Information for patients

- A recent review has found that the data used to support the authorisation of Tavneos cannot be relied upon to demonstrate the medicine's effectiveness.
- EMA has therefore recommended that Tavneos should no longer be marketed in the European Union, because its benefits are no longer proven to outweigh its risks. If this recommendation is confirmed by the European Commission, Tavneos will no longer be authorised in the EU.
- No new patients should start treatment with Tavneos. If you are taking Tavneos, your doctor will discuss with you other treatment options.
- Tavneos is associated with a risk of serious liver problems (drug-induced liver injury (DILI) and vanishing bile duct syndrome (VBDS), including cases with a fatal outcome. These side effects mostly occur during the first three months of treatment with Tavneos.
- For patients treated with Tavneos for less than three months before stopping treatment, liver function should be monitored with appropriate tests at least every two weeks until three months have passed since the start of treatment.
- For patients who received Tavneos for longer than three months, liver function should be monitored every four weeks for up to six months, and then as considered necessary by the treating doctor.
- If you are taking Tavneos and have any questions, you should speak to your doctor.

Information for healthcare professionals

- Due to breaches of good clinical practice (GCP), the data from the pivotal trial on which the marketing authorisation of Tavneos was based can no longer be relied upon to demonstrate the medicine's efficacy.
- No reliable, randomised, controlled data are available to confirm efficacy of Tavneos.
- EMA has therefore recommended that the marketing authorisation for Tavneos be revoked in the European Union, because its benefits are no longer proven to outweigh its risks. If this recommendation is confirmed by the European Commission, Tavneos will no longer be authorised in the EU.
- No new patients should be started on Tavneos. Patients currently on treatment with Tavneos should be switched to alternative treatment options.

- Tavneos is associated with an increased risk of drug-induced liver injury (DILI) and vanishing bile duct syndrome (VBDS), including cases with a fatal outcome; most cases occurred within three months of treatment initiation.
- To mitigate these risks, the liver function of patients recently treated with Tavneos should be closely monitored until treatment is effectively discontinued:
  - for patients in the first three months of treatment: at least every two weeks;
  - for patients already treated for more than three months: every four weeks until six months of treatment, and as clinically indicated thereafter.
- If VBDS is suspected, Tavneos must be immediately discontinued.

A direct healthcare professional communication (DHPC) including the above information and recommendations will be sent in due course to healthcare professionals prescribing, dispensing or administering the medicine. The DHPC will also be published on a dedicated page on the EMA website.

More about the medicine

Tavneos is a medicine used to treat adults with severe, active granulomatosis with polyangiitis (GPA) 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.

More information on Tavneos is available on the medicine's page.

More about the procedure

The review of Tavneos was initiated at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004.

The review has been carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which has adopted the Agency's opinion. The CHMP also took into account the assessment of the recent periodic safety update report (PSUR) carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which made a set of recommendations about reinforced liver function monitoring requirements.

The CHMP opinion will now be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.