



27-July-2026

## **Tavneos® (avacopan) –Suspension of the marketing authorisation in Saudi Arabia**

Dear Healthcare Professional,

Vifor Fresenius Medical Care Renal Pharma France, the marketing authorisation holder of Tavneos (avacopan), in agreement with the Saudi Arabia Food & Drug Authority (SFDA), would like to inform you of the following:

### ***Summary***

- **Tavneos marketing authorisation in Saudi Arabia has been suspended.**
- **Health Care Professionals should discontinue use of Tavneos and discuss appropriate alternative treatment options with patients currently receiving Tavneos.**

### ***Background information***

Tavneos, in combination with a rituximab or cyclophosphamide regimen, is indicated for the treatment of adult patients with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA).

The European Medicines Agency's human medicines committee (CHMP) reviewed new information relating to the conduct and data reliability of the single pivotal phase 3 ADVOCATE study, which served as the primary basis for the approval of Tavneos. Following this review, the Committee determined that the available evidence was insufficient to adequately substantiate the medicine's efficacy and together with increased hepatic safety concerns the CHMP concluded that a favourable benefit-risk balance could no longer be established. The CHMP therefore recommended revocation of the EU marketing authorisation.

Based on this information, the SFDA has decided to suspend Tavneo's marketing authorization. Prescribers should discontinue use of Tavneos and contact patients currently receiving Tavneos to discuss alternative treatment options.

### ***Call for reporting***

Healthcare professionals should report any adverse events suspected to be associated with the use of Tavneos according to national reporting requirements.

Any suspected adverse reactions should be reported to Vifor Fresenius Medical Care Renal Pharma France at ([pv\\_ksa@viforpharma.com](mailto:pv_ksa@viforpharma.com)).

National Pharmacovigilance Center (NPC) - Saudi Food and Drug Authority:

- SFDA call center: 19999
- E-mail: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)
- Website: <http://ade.sfda.gov.sa/>





**Company contact point**

For further information, please contact [pv\\_ksa@viforpharma.com](mailto:pv_ksa@viforpharma.com).

Best regards,

**Rema AlKahtani**

**Local QPPV, Saudi Arabia**

Signed by:  
*Rema AlKahtani*

Signer Name: Rema Alkahtani  
Signing Reason: I approve this document  
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