Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate the latest up-to-date drug safety information.

FDA Identifies Cases of Serious Liver Injury in Patients Taking Tavneos (avacopan) for Severe Active ANCA-associated Vasculitis

U.S. Food & Drug Administration Publication Date:

03/31/2026

Drug Indication:

To treat adults with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis and microscopic polyangiitis).

Safety Topic:

The FDA alerted patients and health care professionals about serious postmarketing cases, including fatal cases, of drug-induced liver injury (DILI) associated with Tavneos (avacopan).

It is for this reason that we are notifying you that on March 31, 2026, the U.S. Food and Drug Administration (FDA) published a safety communication for the following product(s): Tavneos (avacopan).

Reason for Communication

The FDA is alerting patients and health care professionals about serious postmarketing cases, including fatal cases, of drug-induced liver injury (DILI) associated with Tavneos (avacopan). Some cases involved vanishing bile duct syndrome (VBDS), which is characterized by progressive destruction and disappearance of the bile ducts in the liver. This condition can slow or stop the flow of bile and may lead to permanent liver damage. VBDS is often accompanied by the yellowing of skin or eyes (jaundice), itchiness, and tiredness.

Although hepatotoxicity is a serious adverse reaction for Tavneos identified in premarket clinical trials and described in product labeling, VBDS and DILI cases with fatal outcomes represent new safety concerns. FDA is continuing to monitor postmarketing cases of DILI, including VBDS, involving Tavneos and will provide updates as appropriate.

Pharmacy Required Action

Advise patients that they should contact their health care professional immediately if they develop any signs or symptoms that may indicate liver injury, such as feeling more tired than usual; nausea; vomiting; unusual itching; light-colored stools; yellowing of skin or eyes; dark urine; swelling in the stomach or abdomen; or pain in the right upper abdomen. Patients should talk to their health care professional about the safety risks associated with Tavneos and whether to continue therapy or switch to alternative treatments.

Assess whether the potential benefits of continuing the drug outweigh the potential risks highlighted in this safety communication.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252-ext.219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

REFERENCES:
1. U.S. Food and Drug Administration. (2026). *FDA Identifies Cases of Serious Liver Injury in Patients Taking Tavneos (avacopan) for Severe Active Anti-neutrophil Cytoplasmic Autoantibody (ANCA)-associated Vasculitis.* https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-cases-serious-liver-injury-patients-taking-tavneos-avacopan-severe-active-anti