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IN BRIEF

New Warning for Fezolinetant *(Veozah)*

The FDA has required a new warning in the label of the oral selective neurokinin 3 (NK3) receptor antagonist fezolinetant *(Veozah)* about the risk of hepatoxicity.[1,2] The label of fezolinetant, which was approved by the FDA in 2023 for treatment of moderate to severe vasomotor symptoms due to menopause, already contained a warning about hepatic transaminase elevations associated with use of the drug.

The new warning was based on a single post-marketing case of acute mixed hepatocellular cholestatic drug-induced liver injury. The patient presented with fatigue, nausea, itching, jaundice, light-colored stools, dark urine, and elevated hepatic enzyme and total bilirubin levels within 40 days of starting fezolinetant.

Serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), and bilirubin levels should be checked before starting fezolinetant, monthly for the first 3 months, and at 6 and 9 months after starting the drug. Fezolinetant should not be started if ALT or AST concentrations are ≥2 times the upper limit of normal (ULN) or if total bilirubin is elevated. The drug should be stopped if transaminase levels are >5 times the ULN or if transaminase levels are >3 times the ULN and total bilirubin level is >2 times the ULN. ■

1. FDA Drug Safety Communication. FDA adds warning about rare occurrence of serious liver injury with use of Veozah (fezolinetant) for hot flashes due to menopause. Stop medicine if signs and symptoms of liver injury occur. September 12, 2024. Available at: https://bit.ly/4ghd4MK. Accessed September 26, 2024.
2. Fezolinetant (Veozah) for menopausal vasomotor symptoms. Med Lett Drugs Ther 2023; 65:97.

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