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Important Safety Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC24-042-CG
September 20, 2024

FDA is warning that Veozah (fezolinetant), a medicine used to treat hot flashes due to menopause, can cause rare but serious liver injury. If there are signs and symptoms suggesting liver injury, stopping the medicine could prevent worsening liver injury and potentially return liver function to normal.

RECOMMENDATIONS

1. *Patients and Caregivers*

- Patients should stop taking Veozah immediately and contact your health care professional who prescribed the medicine if you experience signs and symptoms that suggest liver problems. These include feeling more tired than usual; nausea; vomiting; unusual itching; light-colored stools; yellowing of the eyes or skin, called jaundice; dark urine; swelling in the stomach or belly area, called the abdomen; or pain in the right upper abdomen.
- Your health care professional will do blood tests before starting Veozah and during treatment to check and monitor how well your liver is working.
- Talk to your health care professional about the risks and benefits of taking Veozah and discuss any questions or concerns you may have, including about possible alternative treatments.

2. *Health Care Professionals*

- Health care professionals should conduct hepatic laboratory testing before prescribing Veozah, then every month for the first three months after patients start treatment, and then at months 6 and 9 of treatment.
- When prescribing Veozah, inform patients about the risk of elevated liver blood test values that may occur during treatment and the rare but serious risk of liver injury, and advise them of the need for regular liver blood testing.
- Discuss the signs and symptoms of liver injury and instruct patients to stop Veozah immediately and contact the health care professional who prescribed the medicine if they develop these any time during treatment.

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3. Expect patients to visit your pharmacy asking for information on this safety issue and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

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FDA U.S. FOOD & DRUG ADMINISTRATION

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 - Drug Safety Communication

[Posted 9/12/2024]

AUDIENCE: Patient, Health Professional, OBGYN, Endocrinology

ISSUE: The FDA is warning that Veozah (fezolinetant), a medicine used to treat hot flashes due to menopause, can cause rare but serious liver injury. If there are signs and symptoms suggesting liver injury, stopping the medicine could prevent worsening liver injury and potentially return liver function to normal.

The FDA added a warning about the risk of liver injury to the existing warning about elevated liver function test values and required liver function testing in the prescribing information for Veozah. The FDA made this update after reviewing a post marketing report of a patient with elevated liver function test values and signs and symptoms of liver injury after taking the medicine for about 40 days. The FDA also added new recommendations for patients and health care professionals about increasing the frequency of liver function testing, adding monthly testing for the next 2 months after starting Veozah, and then at months 3, 6, and 9 of treatment as already recommended. The updated prescribing information also instructs patients to stop the medicine immediately and contact the health care professional who prescribed the medicine if signs and symptoms of liver injury occur.

BACKGROUND: Veozah (fezolinetant) is a non-hormonal prescription medicine approved in May 2023 to reduce the frequency and severity of moderate to severe hot flashes caused by menopause. The medicine is in a drug class called neurokinin 3 (NK3) receptor antagonists. It works to restore the balance between estrogen hormones and a brain chemical called neurokinin B (NKB) by blocking the activities of the NK3 receptor, which plays a role in the brain's control of body temperature.

RECOMMENDATIONS:

Patients and Caregivers

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- Your health care professional will do blood tests before starting Veozah and during treatment to check and monitor how well your liver is working.
- Talk to your health care professional about the risks and benefits of taking Veozah and discuss any questions or concerns you may have, including about possible alternative treatments.

Health Care Professionals

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- When prescribing Veozah, inform patients about the risk of elevated liver blood test values that may occur during treatment and the rare but serious risk of liver injury, and advise them of the need for regular liver blood testing.
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