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

09-12-2024 FDA Drug Safety Communication

What safety concern is FDA announcing?

The U.S. Food and Drug Administration (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.

What is FDA doing?

We added a warning about the risk of liver injury to the existing warning about elevated liver blood test values and required liver blood testing in the prescribing information for Veozah. We made this update after reviewing a postmarketing report of a patient with elevated liver blood test values and signs and symptoms of liver injury after taking the medicine for about 40 days. We also added new recommendations for patients and health care professionals about increasing the frequency of liver blood 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.

What is Veozah (fezolinetant) and how can it help me?

Veozah (fezolinetant) is a nonhormonal 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.

What should patients and parents/caregivers do?

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.

What should health care professionals do?

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.

What did FDA find?
We reviewed a postmarketing case* of serious liver injury in a patient who experienced symptoms of fatigue, nausea, itching, yellow eyes and skin, light-colored stools, and dark urine within 40 days of starting Veozah. The patient's liver blood test values were elevated, including abnormal liver enzymes and bilirubin levels. After stopping the medicine, the patient's symptoms gradually went away, and blood test values slowly returned to normal.

*The case was reported to the FDA Adverse Event Reporting System (FAERS) database.

What is my risk?
All medicines have side effects even when used correctly as prescribed. It is important to know that people respond differently to all medicines depending on their health, the diseases they have, genetic factors, other medicines they are taking, and many other factors. As a result, we cannot determine how likely it is that someone will experience these side effects when taking Veozah (fezolinetant). Your health care professionals know you best, so talk to them if you have questions or concerns about risks of taking Veozah (fezolinetant).

How do I report side effects from Veozah (fezolinetant)?
To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving Veozah (fezolinetant) or other medicines to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.

How can I get new safety information on medicines I'm prescribing or taking?
You can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Facts about Veozah (fezolinetant)

- Veozah is a nonhormonal prescription medicine approved by FDA to reduce moderate to severe hot flashes due to menopause. It is in the class of medicines called neurokinin 3 (NK3) receptor antagonists.
- Veozah 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 regulation of body temperature.
- Veozah is available as a tablet taken by mouth once daily.
- Common side effects include stomach pain, diarrhea, difficulty sleeping, back pain, hot flashes, or hot flushes.
- Veozah use in the U.S. has steadily increased since approval in May 2023. In May 2024, an estimated 28,700 patients were dispensed Veozah from U.S. outpatient retail pharmacies.[i]

Additional Information for Patients

- FDA is warning that Veozah (fezolinetant), a medicine used to treat moderate to severe hot flashes due to menopause, can cause rare but serious liver injury and we added a warning about this rare but serious risk of liver injury in the prescribing information for the medicine.
- Stop taking Veozah immediately and contact your health professional who prescribed the medicine if you experience signs and symptoms that suggest liver problems. These may 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. Stopping the medicine if there are signs and symptoms that suggest liver injury could prevent worsening liver injury and potentially return liver function to normal.
- Before prescribing Veozah, health care professionals will do blood tests to check and monitor how well your liver is working. Health care professionals will also do these blood tests every month for the first 3 months after you start taking the medicine, and then again at 6 and 9 months of treatment. If liver blood test values are elevated, the health care professional may advise you to stop treatment or request additional blood tests.
- Read the patient information leaflet you receive from the pharmacy every time you receive a prescription for Veozah (fezolinetant) because there may be new or important additional information about the medicine. The patient information leaflet explains the important things you need to know about the medicine. These include the side effects, what the medicine is used for, how to take and store it properly, and other things to watch out for when you are taking the medicine.
- For more information about menopause and how to treat the symptoms, visit the following FDA website on Menopause.
- To help FDA track safety issues with medicines, report side effects from Veozah (fezolinetant) or other medicines to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines and medical specialties of interest to you.

Additional Information for Health Care Professionals

- FDA is warning that Veozah (fezolinetant) used to treat moderate to severe 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.
- FDA added a warning about the risk of liver injury to the existing warning about elevated liver blood test values in the prescribing information for Veozah. We made this update after reviewing a postmarketing case about a patient with increased alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin and signs and symptoms of liver injury within 40 days of starting it. After stopping the medicine, the patient's symptoms gradually resolved, and blood test values slowly returned to normal.
- Steps to reduce the risk of liver injury cited in the prescribing information include the following.
- Before starting Veozah, perform baseline liver blood tests to assess liver function, including serum ALT, serum AST, serum ALP, and serum bilirubin (total and direct). During treatment, perform follow-up liver blood tests every month for the first three months, and then again at months 6 and 9 of treatment.

- Do not start Veozah if the concentration of ALT, AST, or total bilirubin is equal to or exceeds two times the upper limit of normal (ULN).
- Stop Veozah if transaminases exceed five times the ULN, or if transaminases exceed three times the ULN and total bilirubin is more than two times the ULN.
- Perform more frequent follow-up liver blood tests if the transaminases exceed three times the ULN, but the total bilirubin is not more than two times the ULN. If the liver blood test values are elevated, exclude alternative causes of liver injury.
- Inform patients about the risk of elevated liver blood test values during treatment and the rare but serious risk of liver injury, and discuss the need for regular liver test monitoring.
- Explain the signs and symptoms of liver problems to patients and instruct them to stop taking Veozah immediately and contact the health care professional who prescribed the medicine if they develop these symptoms and signs any time during treatment with Veozah.
- Encourage patients to read the patient information leaflet they receive with their Veozah (fezolinetant) prescriptions because there may be new or important additional information about the medicine.
- To help FDA track safety issues with medicines, report adverse events involving Veozah (fezolinetant) or other medicines to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines and medical specialties of interest to you.

Data Summary

FDA reviewed a postmarketing case of serious drug-induced liver injury that occurred in a patient who received Veozah to treat menopausal hot flashes caused. Before starting Veozah, the patient's liver blood test levels were normal. Within 40 days of starting it, several liver blood tests values were significantly elevated: alanine transaminase, more than 10 times of normal level; alkaline phosphatase, more than four times of normal level; and total bilirubin, more than 3 times of normal level. The patient reported symptoms of liver injury, including fatigue, nausea, decreased appetite, itching of hands and feet that later spread to the entire body, jaundice, pale feces, and dark urine. The patient's prescriber found no abnormalities when checking for other causes of liver injury, using ultrasonography of the liver and blood tests for viral hepatitis. With discontinuation of Veozah, the signs and symptoms gradually resolved, and liver blood test values returned to normal. We concluded this patient had liver injury as a result of Veozah treatment.

Related Information

- Menopause
- The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective
- Think It Through: Managing the Benefits and Risks of Medicines
- Find Information about a Drug

[i] IQVIA Total Patient Tracker™. Available at www.iqvia.com. Accessed 29 August, 2024.