COMMUNICATION

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17 SEPTEMBER 2024

URGENT PLEASE REVIEW

Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug safety information.

U.S. Food & Drug Administration Publication Date

9/12/2024

Drug Indication

Menopause Hot Flashes

Safety Topic

The FDA adds warning about rare occurrence of serious liver injury with use of Veozah (fezolinetant) for hot flashes due to menopause.

Serious Liver Injury with Use of Veozah™

It is for this reason that we are notifying you that on 9/12/2024 the U.S. Food and Drug Administration (FDA) published a safety communication for the following product(s): Veozah (fezolinetant).

Reason for Communication:

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 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.

Pharmacy Required Action:

Advise patients should stop taking medication 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.

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/.

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REFERENCES

1. U.S. Food and Drug Administration. (2024). **FDA adds warning about rare occurrence of serious liver injury with use of Veozah (fezolinetant) for hot flashes due to menopause** Retrieved September 12, 2024, from https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-warning-about-rare-occurrence-serious-liver-injury-use-veozah-fezolinetant-hot-flashes-due

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