VEOZAH™ (fezolinetant) for the Treatment of **Moderate to Severe Vasomotor Symptoms Due to Menopause**

A first-in-class, oral, nonhormonal treatment option

Sponsored by Astellas Pharma US, Inc.

The goal of this program is to provide health care professionals with:

- A brief overview of vasomotor symptoms due to menopause
- A thorough review of the FDA-approved treatment option, VEOZAH[™], including its indication, mechanism of action, and clinical safety and efficacy.

An expert faculty member will lead the presentation. Logistical details are included below.

LIVE EVENT INFORMATION:

WHEN:

Thursday, September 11, 2025 6:30 PM CT

WHERE:

Metropolitan 9181 Town Square Boulevard Amarillo, Texas

PRESENTED BY:

Joanna Wilson, DO

Creator; HerCare at Amarillo Diagnostic Clinic; Clinical Associate Professor; Texas Tech University Health Sciences Center Amarillo, TX

TO RSVP:

To RSVP, please scan the QR code, visit https://astellas.virtualspeakercast.net/2253, or contact James Rawls at 806-577-6671 or randy.rawls@astellas.com by Thursday, September 4, 2025

RSVP BY:



INDICATIONS AND USAGE

VEOZAH™ (fezolinetant) is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.

IMPORTANT SAFETY INFORMATION

WARNING: RISKS OF HEPATOTOXICITY

Hepatotoxicity has occurred with the use of VEOZAH in the postmarketing setting.

- Perform hepatic laboratory tests prior to initiation of treatment to evaluate for hepatic function and injury. Do not start VEOZAH if either aminotransferase is \geq 2x the upper limit of normal (ULN) or if the total bilirubin is \geq 2x ULN for the evaluating laboratory.
- Perform follow-up hepatic laboratory testing monthly for the first 3 months, at 6 months, and 9 months of treatment.
- Advise patients to discontinue VEOZAH immediately and seek medical attention including hepatic laboratory tests if they experience signs or symptoms that may suggest liver injury (new onset fatigue, decreased appetite, nausea, vomiting, pruritus, jaundice, pale feces, dark urine, or abdominal pain).
- Discontinue VEOZAH if transaminase elevations are > 5x ULN, or if transaminase levations are > 3x ULN and the total bilirubin level is > 2x UL
- If transaminase elevations > 3x ULN occur, perform more frequent follow-up hepatic laboratory tests until resolution.

CONTRAINDICATIONS

VEOZAH is contraindicated in women with any of the following: • Known cirrhosis • Severe renal impairment or end-stage renal disease • Concomitant use with CYP1A2 inhibitors

WARNINGS AND PRECAUTIONS

Hepatotoxicity

In 3 clinical trials, elevations in serum transaminase (alanine aminotransferase [ALT] and/or aspartate aminotransferase [AST]) levels > 3x ULN occurred in 2.3% of women receiving VEOZAH and 0.9% of women receiving placebo. No elevations in serum total bilirubin (> 2x ULN) occurred. Women with ALT or AST elevations were generally asymptomatic. Transaminase levels returned to pretreatment levels (or close to these) without sequelae with dose continuation, and upon dose interruption, or discontinuation. Women with cirrhosis were not studied.

In the postmarketing setting, cases of drug-induced liver injury with elevations of ALT, AST, alkaline phosphatase (ALP), and total bilirubin occurred within 40 days of starting VEOZAH. Patients reported a general sense of feeling unwell and symptoms of fatigue, nausea, pruritus, jaundice, pale feces, and dark urine. The patients' signs and symptoms gradually resolved after discontinuation of VEOZAH.

Perform baseline hepatic laboratory tests to evaluate for hepatic function and injury (including serum ALT, serum AST, serum ALP, and serum bilirubin [total and direct]) prior to VEOZAH initiation. Do not start VEOZAH if ALT or AST is $\geq 2x$ ULN or if the total bilirubin is $\geq 2x$ ULN for the evaluating laboratory.

Perform follow-up hepatic laboratory tests monthly for the first 3 months, at 6 months, and 9 months after initiation of therapy.

See BOXED WARNING for full hepatic laboratory testing protocol and discontinuation **criteria**. Exclude alternative causes of hepatic laboratory test elevations.

ADVERSE REACTIONS The most common adverse reactions with VEOZAH \geq 2% and > placebo (VEOZAH % vs. placebo %) are: abdominal pain (4.3% vs. 2.1%), diarrhea (3.9% vs. 2.6%), insomnia (3.9%

vs. 1.8%), back pain (3.0% vs. 2.1%), hot flush (2.5% vs. 1.6%), and hepatic transaminase elevation (2.3% vs. 0.8%).

Please <u>CLICK HERE</u> for full Prescribing Information, including BOXED WARNING,



for VEOZAH™ (fezolinetant) tablets.

Astellas will not pay for or provide alcohol at this speaker program.

Astellas Pharma US, Inc. ("Astellas") is subject to U.S. Federal and State transparency laws that require Astellas to track and report meals and other transfers of value provided to certain U.S. health care professionals (including physicians). To comply with these obligations, for attendees who receive any portion of the meal provided at this program, Astellas will report the attendee's name and the value of the meal received. Astellas offers you the option to attend the event but not receive the meal. Please ask the Program Organizer for more information about this opt-out option.

Additional restrictions apply to the following individuals:

For U.S. Healthcare Providers in Vermont or those affiliated with the U.S. Department of Veterans Affairs or Department of Defense: Several states and federal agencies in the United States restrict your interactions with Astellas, including the provision of in-kind benefits (such as meals) at company-sponsored events. If you are a healthcare professional in Vermont or are affiliated with the U.S. Department of Veterans Affairs, Department of Defense, or other federal executive branch entity, Astellas policy prohibits providing you a meal at this program. If you would like to attend, but not partake in the meal, please refer to the opt-out option below.

For U.S. Licensed Prescribers in Minnesota: Under Minnesota law, Astellas may provide meals and other transfers of value to Minnesota licensed prescribers if the <u>annual (calendar year)</u> aggregate total of all value transfers of any kind from Astellas to a Minnesota prescriber does not exceed \$50.00 USD, subject to some exceptions. Astellas has policies and procedures that are intended to help ensure compliance with this annual aggregate limit. If you have questions about your annual aggregate value transfers from Astellas or the impact of accepting the meal provided at this event on your annual total, please consult the Program Organizer. In addition, if you would like to attend, but not partake in the meal, please refer to the opt-out option below.

For State Government Employees: State ethics laws may prohibit you from accepting a meal. Astellas policy prohibits: (1) Colorado State Employees from accepting from Astellas more than \$50 annually in transfers of value, including meals; (2) Louisiana State Employees from accepting a meal that exceeds \$60 in value; and (3) New York State Employees from accepting a meal that exceeds \$15 in value. If you would like to attend, but not partake in the meal, please refer to the opt-out option below.

For Foreign Healthcare Providers: Some foreign countries restrict the provision of or require the reporting of in-kind benefits (such as meals) to health care professionals at company-sponsored events. Astellas has policies and procedures that are intended to help ensure compliance with these requirements and restrictions. To help ensure compliance with applicable requirements, Astellas policy prohibits providing a meal to you in conjunction with this event. If you would like to attend, but not partake in the meal, please refer to the opt-out option below.

Opt-Out Option: Astellas offers an opt-out option that allows you to still attend this event but not receive the meal. Please ask the Program Organizer for more information about the opt-out option.

Astellas has adopted the PhRMA Code on Interactions with Healthcare Professionals, which is designed to foster ethical relationships with healthcare professionals. In accordance with the PhRMA Code, we will not pay for the expenses of a healthcare professional's spouse or guest, and such individuals should not attend the program, unless they have a bona fide professional interest in the information being shared at the program. We appreciate your understanding and support of our commitment to these ethical standards.

For important state pricing disclosure information, click here.

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