

KNDy=kisspeptin/neurokinin B/dynorphin, NK1=neurokinin 1, NK2=neurokinin 2.

Watch the mechanism of action of VEOZAH at VEOZAHhcp.com/MOAvideo

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 ≥ 2x the upper limit of normal (ULN) or if the total bilirubin is ≥ 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 elevations are > 3x ULN and the total bilirubin level is > 2x ULN.
- If transaminase elevations > 3x ULN occur, perform more frequent follow-up hepatic laboratory tests until resolution.



A NONHORMONAL OPTION FOR PATIENTS WITH MODERATE

TO SEVERE VASOMOTOR SYMPTOMS (VMS) DUE TO MENOPAUSE¹

REDEFINE how YOU TARGET VMS

VEOZAH directly targets a source of VMS—kisspeptin/neurokinin B/dynorphin (KNDy) neurons in the hypothalamus. Give your patients another way to treat the heat day and night.^{1,2}



Block
THE BINDING
OF NKB

Reduce
KNDY NEURONAL
ACTIVITY

Balance
THERMOREGULATORY
ACTIVITY

Explore the mechanism of action of VEOZAH at VEOZAHhcp.com/MOAvideo

IMPORTANT SAFETY INFORMATION (cont'd)

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 ≥ 2x ULN or if the total bilirubin is ≥ 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%).

<u>Please click here for full Prescribing Information, including BOXED WARNING, for VEOZAH (fezolinetant)</u>.

REFERENCES: 1. VEOZAH [package insert]. Northbrook, IL: Astellas Pharma US, Inc. 2. Thurston RC. Vasomotor symptoms. In: Crandall CJ, Bachman GA, Faubion SS, et al., eds. Menopause Practice: A Clinician's Guide. 6th ed. Pepper Pike, OH: The North American Menopause Society, 2019:43-55. 3. The North American Menopause Society. The 2023 nonhormone therapy position statement of the North American Menopause Society. Menopause 2023;30(6):573-90. 4. Jayasena CN, Comninos AN, Stefanopoulou E, et al. Neurokinin B administration induces hot flushes in women. [Published online February 16, 2015]. Sci Rep. 2015. 5. Depypere H, Lademacher C, Siddiqui E, Fraser GL. Fezolinetant in the treatment of vasomotor symptoms associated with menopause. Expert Opin Investig Drugs 2021;30(7):681-94.



