VEOZAH®
(fezolinetant) tablets 45mg

Full Prescribing Information

Important Safety Information

{{customText[Dear |Hello |Good afternoon |Good morning]}}
{{customText[Dr |Prof |Mr |Mrs |Ms |]}}
{{customText[##accLname##|##accFname##
##accLname##|##accFname##|]}},

{{customText [I hope all is well! |I hope you're doing well. |Thanks for a great meeting. |I'm sorry we haven't had a chance to connect.]}} Here is some information that you may find useful about the mechanism of action of VEOZAH.

VEOZAH is not a hormone. It is a first-in-class selective NK3R antagonist that works differently to directly block NKB, a known trigger of VMS, from binding on the KNDy neuron.[1,3,4]

IMPORTANT SAFETY INFORMATION

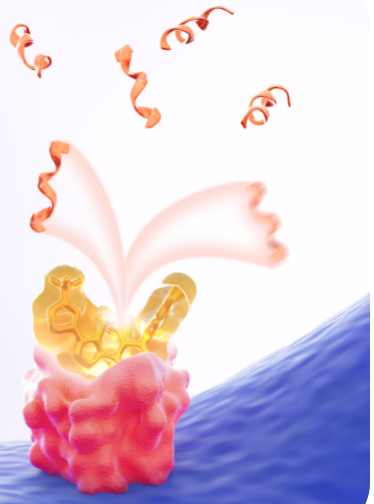
CONTRAINDICATIONS

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

Please see additional Important Safety Information below.

Watch the mechanism of action of VEOZAH

WATCH VIDEO



REDEFINE HOW YOU TARGET VMS

HOW VMS STARTS IN THE HYPOTHALAMUS

> KNDy neurons in the hypothalamus are inhibited by estrogen and stimulated by the neuropeptide NKB. This balance contributes to **body temperature regulation**.[5]
>
> Estrogen decline during the menopause transition disrupts this balance with NKB. **Unopposed, NKB signaling** causes heightened KNDy neuronal activity.[5]
>
> The thermoregulatory center **triggers heat dissipation mechanisms**, including vasodilation and sweating—VMS.[5]

HOW VEOZAH DISRUPTS HOT FLASHES

> VEOZAH is a nonhormonal selective NK3R antagonist that **blocks NKB** binding on the KNDy neuron to modulate neuronal activity in the thermoregulatory center. This action helps to reduce the number and intensity of hot flashes and night sweats.[1,5]
>
> VEOZAH directly targets NK3R with a high affinity, more than 450-fold higher than NK1 or NK2 receptors.[1]

Download the VEOZAH mechanism of action flashcard

DOWNLOAD

KNDy=kisspeptin/neurokinin B/dynorphin, NK3R=neurokinin 3 receptor, NKB=neurokinin B.

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

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

Hepatic Transaminase Elevation

Elevations in serum transaminase [alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST)] levels > 3x the upper limit of normal (ULN) occurred in 2.3% of women receiving VEOZAH and 0.9% of women receiving placebo in three clinical trials. No serum elevations in 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.

Perform baseline bloodwork to evaluate for hepatic function and injury prior to VEOZAH initiation. Do not start VEOZAH if concentration of ALT or AST is ≥ 2x ULN or if the total bilirubin is elevated (e.g., ≥ 2x ULN) for the evaluating laboratory. If baseline hepatic transaminase evaluation is < 2x ULN and the total bilirubin is normal, VEOZAH can be started. Perform follow-up evaluations of hepatic transaminase concentration at 3 months, 6 months, and 9 months after initiation of therapy and when symptoms (such as nausea, vomiting, or yellowing of the skin or eyes) suggest liver injury.

ADVERSE REACTIONS

The most common adverse reactions with VEOZAH ≥ 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 click here for full Prescribing Information for VEOZAH® (fezolinetant).

If you would like to schedule a visit to discuss VEOZAH, please contact me directly at the number or email below.

{{customText[Sincerely|Regards|Best]}},
{{userName}}, Sales Representative
Phone: {{User.Phone}}
Email: {{userEmailAddress}}

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. Sci Rep (Epub) 02-16-2015. **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.

This email was sent by: Astellas Pharma US, Inc.
2375 Waterview Drive, Northbrook, IL 60062, USA

astellas