VEOZAH™
(fezolinetant) tablets 45mg

For the treatment of moderate to severe Vasomotor Symptoms (VMS) due to menopause, commonly referred to as hot flashes and night sweats[1,2]

FIGHT *the* FIRE

WITH NONHORMONAL VEOZAH

VEOZAH directly targets a source of VMS—specific neurons in the hypothalamus.[1]

NONHORMONAL

VEOZAH is the first and only selective neurokinin 3 (NK3) receptor antagonist that blocks NKB from binding on KNDy neurons to **help reduce heat signals** that trigger VMS.[1,3]

Give patients another way to treat the heat day and night. Visit VEOZAHhcp.com

KNDy=kisspeptin/neurokinin B/dynorphin, 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

Please see additional Important Safety Information throughout.
Please click here for full Prescribing Information for VEOZAH™ (fezolinetant).

REDEFINE *how* YOU TARGET VMS

NONHORMONAL

VEOZAH IS NOT A HORMONE.
It's a first-in-class NK3R antagonist that works differently to directly block NKB, a known trigger of VMS, from binding on the KNDy neuron[1,3-5]

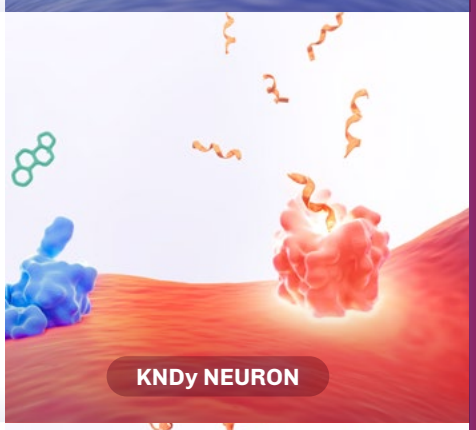
Thermoregulatory homeostasis

KNDy neurons in the hypothalamus are inhibited by estrogen and stimulated by the neuropeptide NKB. This balance contributes to **body temperature regulation.**[3]

Impact of NKB

Estrogen decline during the menopause transition disrupts this balance with NKB. **Unopposed, NKB signaling** causes heightened KNDy neuronal activity.[3]

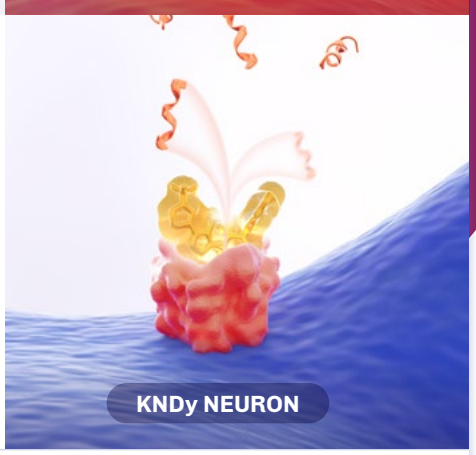
This **triggers heat dissipation mechanisms**, including vasodilation and sweating—VMS.[3]



VEOZAH inhibits binding of NKB to NK3R

VEOZAH 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]

VEOZAH directly targets NK3R with a high affinity, more than 450-fold higher than NK1 or NK2 receptors.[1]



ESTROGEN | ESTROGEN ALPHA RECEPTOR | NKB | NK3 RECEPTOR

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

IMPORTANT SAFETY INFORMATION (cont'd)
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.

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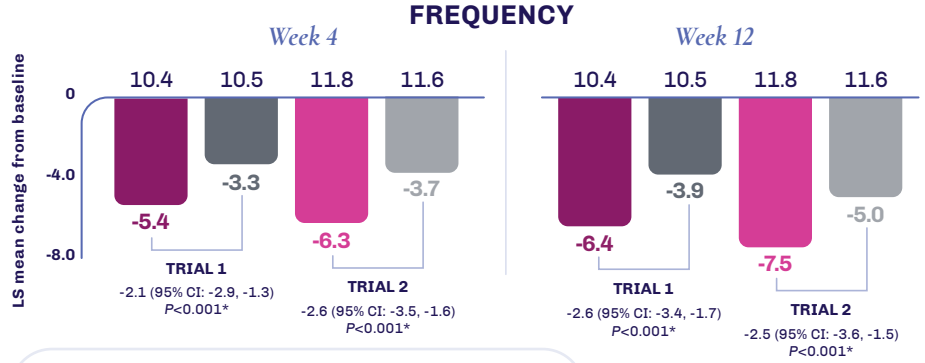
REDUCE *and* RELIEVE VMS

VEOZAH demonstrated statistically significant reductions in VMS frequency and severity at weeks 4 and 12 vs placebo[1]

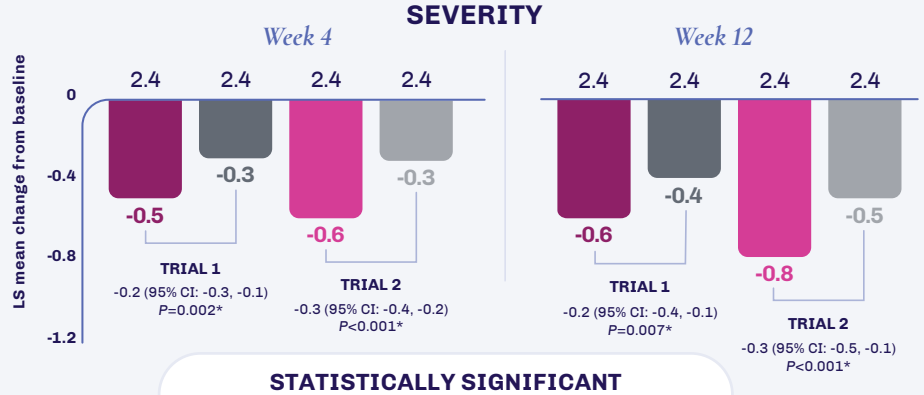
MEAN CHANGE FROM BASELINE IN MODERATE TO SEVERE VMS
OVER 24 HOURS (COPRIMARY ENDPOINTS)[1]

FREQUENCY



HOT FLASHES CUT IN HALF
by week 4 vs ~one-third with placebo

SEVERITY



STATISTICALLY SIGNIFICANT
reduction in severity in both trials

TRIAL 1: VEOZAH 45 mg (n=174) | Placebo (n=175)
TRIAL 2: VEOZAH 45 mg (n=167) | Placebo (n=167)

*Statistically significantly superior compared to placebo at the 0.05 level with multiplicity adjustment.[1]
LS=least squares mean estimated from a mixed model for repeated measures analysis of covariance.[1]

STUDY DESIGN: The efficacy of VEOZAH was studied in two 12-week, randomized, placebo-controlled, double-blind Phase 3 studies. In each of these 2 trials, after the first 12 weeks, women on placebo were rerandomized to VEOZAH for a 40-week extension to evaluate safety for up to 52 weeks total exposure.[1]

The effect of VEOZAH on VMS frequency and severity was evident by week 1.† There was no evidence of loss of effect through 52 weeks.[5,6‡]

†Mean change in frequency and severity of VMS from baseline to each week up to week 12 were secondary endpoints and were not adjusted for multiplicity.[5,6]

‡Mean change in the frequency and severity of VMS from baseline to each visit in the extension period was an exploratory endpoint. Assessments after the 12-week placebo-controlled period were descriptive only.[5,7]

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1 TABLET *a* DAY

DOSING & ADMINISTRATION[1]

Perform hepatic transaminase evaluation before initiating treatment

Include ALT, AST, and serum bilirubin (total and direct) in the evaluation. If baseline hepatic transaminase evaluation is <2x the ULN and the total bilirubin is normal, VEOZAH can be started. Do not start VEOZAH if ALT or AST is ≥2x the ULN or total bilirubin is elevated (eg, ≥2x the ULN) for the evaluating laboratory. While using VEOZAH, perform follow-up evaluations at 3 months, 6 months, and 9 months after initiation of treatment, and when symptoms (such as nausea, vomiting, or yellowing of the skin or eyes) suggest liver injury

45 mg orally once daily

Take with liquids and swallow whole. Do not cut, crush, or chew tablets. Can be taken with or without food

Same time, every day

Take at about the same time each day

Tablet is not actual size.

Now you can prescribe once-daily VEOZAH for your patients

EVALUATED *for* SAFETY

SAFETY PROFILE[1]

The safety of VEOZAH was evaluated in three Phase 3 clinical studies for 52 weeks (Trials 1, 2, and 3; N=1100)

Adverse reactions in Trial 3[1] (≥2% in VEOZAH 45 mg and > placebo)	VEOZAH 45 mg (n=609) Total Person-Years=504.2 n (%, EAIR*)	Placebo (n=610) Total Person-Years=475.0 n (%, EAIR*)
Abdominal pain†	26 (4.3%, 5.2)	13 (2.1%, 2.7)
Diarrhea	24 (3.9%, 4.8)	16 (2.6%, 3.4)
Insomnia	24 (3.9%, 4.8)	11 (1.8%, 2.3)
Back pain	18 (3.0%, 3.6)	13 (2.1%, 2.7)
Hot flush	15 (2.5%, 3.0)	10 (1.6%, 2.1)
Hepatic transaminase elevation‡	14 (2.3%, 2.8)	5 (0.8%, 1.1)

In the pooled laboratory data of Trials 1, 2, and 3, elevated hepatic transaminases (>3x the ULN) occurred in 25 women (2.3%, 2.7 EAIR) exposed to VEOZAH 45 mg (n=1100, 912.1 total person-years) as compared to 8 women (0.9%, 1.5 EAIR) exposed to placebo (n=952, 549.1 total person-years).[1]

EAIR=exposure-adjusted incidence rate.

*Measured as EAIR, meaning the number of individuals experiencing an adverse event divided by exposure time (total person-years) x 100.[1]

†Abdominal pain (including abdominal pain, abdominal pain lower, abdominal pain upper).[1]

‡Hepatic transaminase elevations (including alanine aminotransferase [ALT] abnormal, ALT increased, aspartate aminotransferase [AST] abnormal, AST increased).[1]

In patients receiving VEOZAH 45 mg across the Phase 3 studies:

- Endometrial biopsy assessments identified 1 case of endometrial hyperplasia and 1 case of endometrial malignancy
- The rate of these events was ≤1%, with the upper bound of the one-sided 95% confidence limit being ≤4%
- Disordered proliferative endometrium was reported in 5 patients receiving VEOZAH 45 mg (EAIR of 1.4 per 100 person-years) and 4 patients receiving placebo (EAIR of 2.0 per 100 person-years)

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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%).

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HELP YOUR PATIENTS ACCESS VEOZAH

IT'S EASY TO GET STARTED

Copay assistance with the VEOZAH Savings Program:

Commercially-insured patients may pay **$0** for the first monthly prescription and may pay as little as **$30** per monthly refill*†

How:

Receive VEOZAH Savings Card from your Astellas representative that you can give to your commercially-insured patients to present at their preferred pharmacy

OR

Your patients can go directly to **www.activatethecard.com/8083** to request and/or activate the VEOZAH Savings Card

Additional support for your patients

VEOZAH SUPPORT SOLUTIONS℠

- Benefits verification
- Information regarding prior authorization processes
- Eligibility information for VEOZAH Support Solutions programs
- Information about other potential assistance options that may be available, such as Medicare Extra Help

For more information or to request assistance, call 1-866-239-1637 or visit VEOZAHSupportSolutions.com

***Eligibility requirements and terms and conditions apply:**

- A patient must have a valid prescription for VEOZAH, meet the eligibility requirements, and present the VEOZAH Savings Card to their preferred pharmacy
- The Program has an annual maximum copay assistance limit of $1,300
- There are no income requirements
- The Program is not valid for patients whose prescription claims are reimbursed, in whole or in part, by any state or federal government program

†See additional terms and conditions on the opposite page.

VEOZAH SAVINGS PROGRAM TERMS AND CONDITIONS

By enrolling in the VEOZAH Savings Program ("Program"), the patient acknowledges that they currently meet the eligibility criteria and will comply with the following terms and conditions: The Program is for eligible patients with commercial prescription insurance for VEOZAH™ (fezolinetant) and is good for use only with a valid prescription for VEOZAH at the time the prescription is dispensed by the pharmacy. The Program has an annual maximum copay assistance limit of $1,300, with the annual period starting on the date of Program card activation. After the annual maximum on copay assistance is reached, the patient will be responsible for the remaining monthly out-of-pocket costs for VEOZAH™. **The Program is not valid for patients whose prescription claims are reimbursed, in whole or in part, by any state or federal government program, including, but not limited to, Medicaid, Medicare, Medigap, Department of Defense (DoD), Veterans Affairs (VA), TRICARE, Puerto Rico Government Insurance, or any state patient or pharmaceutical assistance program.** Patients who move from commercial insurance to federal or state prescription health insurance will no longer be eligible, and agree to notify the Program of any such change. Patients agree not to seek reimbursement from any health insurance or third party for all or any part of the benefit received by the patient through the Program. This offer is not conditioned on any past, present, or future purchase of VEOZAH. This offer is not transferable, has no cash value, and cannot be combined with any other offer, free trial, prescription savings card, or discount (including any program offered by a third party payer or pharmacy benefit manager, or an agent of either, that adjusts patient cost-sharing obligations, through arrangements that may be referred to as "accumulator" or "maximizer" programs). The full value of the Program benefits is intended to pass entirely to the eligible patient. No other individual or entity (including, without limitation, third party payers, pharmacy benefit managers, or the agents of either) is entitled to receive any benefit, discount, or other amount in connection with this Program. This offer is not health insurance and is only valid for patients in the 50 United States, Washington DC, and Puerto Rico. This offer is not valid for cash paying patients. This Program is void where prohibited by law. No membership fees. It is illegal to sell, purchase, trade, counterfeit, duplicate, or reproduce, or offer to sell, purchase, trade, counterfeit, duplicate, or reproduce the card. This offer will be accepted only at participating pharmacies. Certain rules and restrictions apply. Astellas reserves the right to revoke, rescind, or amend this offer without notice for any reason (including to ensure that the offer is utilized solely for the patient's benefit).

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.** 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. **4.** Jayasena CN, Comninos AN, Stefanopoulou E, et al. Neurokinin B administration induces hot flushes in women. Sci Rep (Epub) 02-16-2015. **5.** Johnson KA, Martin N, Nappi RE, et al. Efficacy and safety of fezolinetant in moderate to severe vasomotor symptoms associated with menopause: a phase 3 RCT. J Clin Endocrinol Metab (Epub) 02-03-2023. **6.** Lederman S, Ottery FD, Cano A, et al. Fezolinetant for treatment of moderate-to-severe vasomotor symptoms associated with menopause (SKYLIGHT 1): a phase 3 randomised controlled study. Lancet (Epub) 03-13-23. **7.** Astellas. VEOZAH. Data on File.

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HELP REDUCE THE IMPACT VMS MAY HAVE *on* YOUR PATIENTS' DAYS AND NIGHTS[1]

A FIRST-IN-CLASS MOA

VEOZAH is not a hormone. It's a selective NK3R antagonist that works differently to directly block NKB, a known trigger of VMS, from binding on the KNDy neuron[1,3-5]

VMS RELIEF DAY AND NIGHT

In two 12-week studies, VEOZAH demonstrated statistically significant reduction from baseline in the frequency and severity of moderate to severe VMS over 24 hours compared to placebo, at weeks 4 and 12[1]

ONCE-DAILY DOSING

The recommended dose of VEOZAH is 45 mg taken orally with or without food[1]

SAFETY PROFILE OVER 52 WEEKS

The most common adverse events ≥2% and > placebo reported in Trial 3 were abdominal pain, diarrhea, insomnia, back pain, hot flush, and hepatic transaminase elevation[1]

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

INDICATIONS AND USAGE

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