

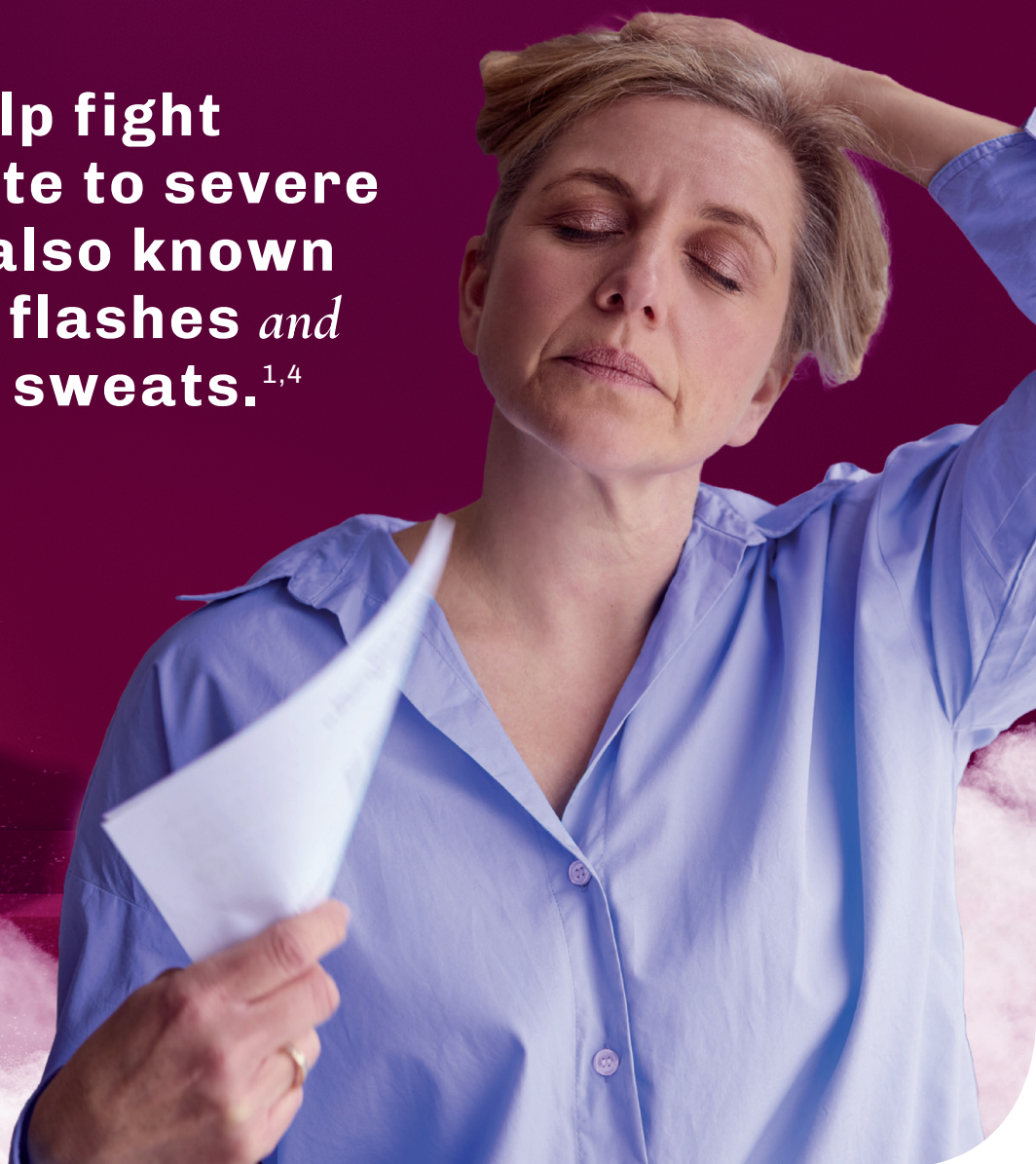
**The first non-hormonal
neurokinin B (NKB) antagonist**
indicated in the treatment of VMS
associated with menopause.^{1-3*}




Pr **VEOZAH**[®]
fezolinetant ^{45mg} tablets

VEOZAH (fezolinetant film-coated tablets) is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.¹

**Help fight
moderate to severe
VMS, also known
as hot flashes *and*
night sweats.**^{1,4}



* Comparative clinical significance is unknown.



Burden of VMS

VMS are a hallmark of menopause, affecting up to **80%** of women.^{2,4}

Severe, bothersome symptoms, with up to 20-30 episodes daily, affect up to **20%** of women.

VMS can result in a significant negative impact on women's health-related quality of life.

Patients experiencing VMS often report:⁴⁻⁷



Frequent
night sweats



Disturbed
sleep



Fatigue



Depressed mood
and anxiety
due to difficulty
sleeping



Palpitations

Data for VEOZAH on outcomes of VMS frequency and sleep disturbances are presented elsewhere in this piece. VEOZAH's effects on mood, anxiety, fatigue, palpitations and health-related quality of life have not been evaluated as predefined endpoints in prospectively designed, well-controlled, randomized trials.

Pathophysiology of VMS

KNDy neurons in the hypothalamus are inhibited by estrogen and stimulated by the neuropeptide NKB.^{2,4} The pathophysiology behind VMS is not completely understood.⁴

How VEOZAH works*

VEOZAH selectively binds to the NK3 receptor to block NKB from binding on the KNDy neuron. This action is believed to modulate the neuronal activity in the thermoregulatory center of the hypothalamus.¹

KNDy: kisspeptin/neurokinin B/dynorphin; NK3: neurokinin 3; NKB: neurokinin B; VMS: vasomotor symptoms.

* Clinical significance is unknown.

SKYLIGHT 2

VEOZAH reduced the frequency of moderate to severe VMS per 24 hours from baseline to Week 12 vs. placebo (coprimary endpoint)^{1*}

63.5% reduction in VEOZAH vs. 43.1% in placebo; $p < 0.001$ (LS mean change: -7.5 vs. -5.0, respectively)



VEOZAH demonstrated powerful reductions in self-reported sleep disturbances related to VMS, as measured by the PROMIS SD SF 8B (key secondary endpoint)^{8†}

In the management of VMS, VEOZAH improved sleep disturbances vs. placebo.⁸

Baseline mean (SD):

- 26.2 (6.6) in VEOZAH vs. 27.4 (7.0) in placebo

LS mean change from baseline (SE):

- -5.5 (0.5) in VEOZAH vs. -3.4 (0.5) in placebo

Difference vs. placebo (SE): -2.0 (0.7); $p = 0.007^{\ddagger}$

Menopause-Specific Quality of Life (MENQoL) questionnaire data from SKYLIGHT 2 trial



The content that follows is a prespecified exploratory endpoint of SKYLIGHT 2 trial and was not statistically powered to make inferences. Results from this analysis should be interpreted with caution.

Exploratory endpoint

Mean change from baseline in MENQoL[§] total score at Week 12⁸

- Placebo (n=167): LS mean change from baseline was -0.95 (SE 0.10)
- VEOZAH (n=167): LS mean change from baseline was -1.43 (SE 0.10)
- LS mean difference vs. placebo was -0.47 (SE 0.15); $p = 0.001$

Key study limitations:

The trial was not powered for this endpoint, and statistical analyses were not adjusted for multiplicity. P-values should therefore be interpreted with caution.

End of exploratory endpoint

LS: least squares; PROMIS SD SF 8b: Patient-Reported Outcomes Measurement Information System Sleep Disturbance – Short Form 8b; SD: standard deviation; SE: standard error; VMS: vasomotor symptoms.

* SKYLIGHT 2 was a phase 3, randomized, double-blind, placebo-controlled, parallel-group study in which post-menopausal women were randomized to VEOZAH 45 mg (n=167) or placebo (n=167) once daily for 12 weeks. After the 12-week double-blind treatment period, women on placebo were then re-randomized to VEOZAH for a 40-week extension to evaluate safety for up to 52 weeks of total exposure. The study included post-menopausal women who had a minimum average of 7 moderate to severe VMS per day. The coprimary efficacy endpoints were change from baseline in moderate to severe VMS frequency and severity to Weeks 4 and 12. Baseline mean frequency of moderate to severe VMS per 24 hours: 11.8 for VEOZAH, 11.6 for placebo.¹

† PROMIS SD SF 8b assesses self-reported sleep disturbance during the prior 7 days and includes perceptions of restless sleep; satisfaction with sleep; refreshing sleep; difficulties sleeping, getting to sleep, or staying asleep; amount of sleep; and sleep quality. Responses to the 8 items range from 1 to 5, and the range of possible summed raw scores is 8 to 40. Higher scores on PROMIS SD SF 8b indicate more disturbed sleep.⁸

‡ Two-sided unadjusted p-value.⁸

§ The MENQoL questionnaire is a validated, 29-item, self-administered scale that assesses the impact of menopausal symptoms over the prior week. It is comprised of four domains: vasomotor, psychosocial, physical, and sexual. Symptoms are rated on a scale from 0 (not bothersome) to 6 (extremely bothersome). A negative change in MENQoL score indicates an improvement from baseline.⁸

VEOZAH demonstrated safety and tolerability profile up to 1 year^{1*†}

12-WEEK SAFETY PROFILE

Adverse events that occurred in at least 2% in the VEOZAH 45-mg arm and greater than placebo in two trials¹

Combined SKYLIGHT 1 and 2		
	VEOZAH N=340 n (%)	Placebo N=342 n (%)
Gastrointestinal disorders		
Abdominal pain [‡]	7 (2.1%)	7 (2.0%)
Investigations		
Liver test elevation [§]	11 (3.2%)	9 (2.6%)

Adapted from the VEOZAH Product Monograph.

52-WEEK SAFETY PROFILE

During the 52-week placebo-controlled period in SKYLIGHT 4, the most frequent adverse drug reactions ($\geq 3\%$ in patients receiving VEOZAH 45 mg and greater than placebo) were headache (9.7%), liver test elevation (5.3%), abdominal pain (4.4%), diarrhea (3.9%), insomnia (3.9%), and nausea (3.1%).¹

A numerical imbalance was observed in the incidence of other malignancies between VEOZAH and placebo groups in the long-term safety trial SKYLIGHT 4. A causal relationship between VEOZAH and increased risk of malignancies has not been established.¹

VEOZAH: ONE dose, ONE tablet, ONCE a day



Flexible administration with 45 mg taken orally once daily, with or without food

Actual size shown. Tablet is 7 mm in diameter.

Perform baseline bloodwork to evaluate hepatic function and assess for injury including serum ALT, serum AST, serum ALP, and serum bilirubin (total and direct) before initiating treatment with VEOZAH.¹

While using VEOZAH, perform follow-up hepatic transaminase concentration monthly for the first 3 months, and at 6 and 9 months after initiation of therapy.

Please see the VEOZAH Product Monograph for complete adverse events information as well as dosing and administration instructions.

ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase.

* SKYLIGHT 1 and 2 were identically designed phase 3 efficacy and safety studies that were randomized, placebo-controlled, double-blind for 12 weeks, followed by re-randomization of women previously receiving placebo to VEOZAH (women on VEOZAH remained on VEOZAH) for an additional 40 weeks of active treatment.¹

† SKYLIGHT 4 was a phase 3, 52-week, randomized, placebo-controlled, double-blind, long-term safety study.¹

‡ Abdominal pain includes abdominal lower pain, abdominal upper pain, and abdominal tenderness.¹

§ Liver test elevation includes ALT abnormal/increased, AST abnormal/increased, blood ALP abnormal/increased, blood bilirubin increased, gamma-glutamyl transferase increased, hepatic enzyme abnormal/increased, transaminases increased, and liver function test abnormal/increased.¹

Consider VEOZAH



VEOZAH is a non-hormonal NK3 antagonist^{1-3*}

VEOZAH is a selective NK3 receptor antagonist that blocks NK3 from binding on the KNDy neuron*



Demonstrated efficacy and safety profile

- Reduced the frequency of moderate to severe VMS per 24 hours vs. placebo from baseline to Week 12
- Generally well-tolerated safety profile



Convenient once-daily dosing

45 mg orally once daily, with or without food¹

VEOZAH is covered by most private insurance plans^{9†}

Clinical use:

- Pediatrics (<18 years of age): not indicated
- Geriatric (≥65 years of age): no data available; therefore, an indication has not been recommended

Contraindications:

- Known cirrhosis
- Severe renal impairment or end-stage renal disease
- Patients using concomitant moderate or strong CYP1A2 inhibitors
- Known or suspected pregnancy

Relevant warnings and precautions:

- A numerical imbalance was observed in the incidence of other malignancies between VEOZAH and placebo groups reported in the long-term safety study. A causal relationship between VEOZAH and increased risk of malignancies has not been established.
- Across the three phase 3 studies, one case of endometrial hyperplasia and one case of endometrial malignancy, were identified in the VEOZAH group. The rate of these events was ≤1%, and within the upper bound of the one-sided 95% confidence limit of ≤4%. There was no case of endometrial hyperplasia or carcinoma in the placebo group.
- Benefit-risk consideration to treat women with known or previous breast cancer or other estrogen-dependent malignancies
- Risk of endometrial hyperplasia and endometrial carcinoma
- Not recommended in Child-Pugh Class B (moderate) chronic hepatic impairment; not studied in Child-Pugh Class C (severe) chronic hepatic impairment and is not recommended in this population
- Risk of hepatic transaminase elevation and hepatotoxicity

- Perform baseline bloodwork to evaluate hepatic function and assess for injury (including serum ALT, serum AST, serum ALP, and serum bilirubin [total and direct]) prior to initiating VEOZAH. Perform hepatic laboratory tests monthly for the first 3 months, at 6 months, and 9 months after initiation of therapy.
- Not recommended in breast-feeding women

For more information:

Consult the Product Monograph at www.veozahmonograph.ca for important information relating to adverse reactions, drug interactions and dosing information. The Product Monograph is also available by calling **1-888-338-1824**.

NK3: neurokinin 3; NK3: neurokinin B; KNDY: kisspeptin/neurokinin B/dynorphin; VMS: vasomotor symptoms.

* Clinical significance is unknown.

† Consult individual private payers for complete reimbursement information.

REFERENCES: 1. VEOZAH Product Monograph. Markham, ON: Astellas Pharma Canada, Inc. 2. The North American Menopause Society (NAMS). *Menopause*. 2023;30(6):573-590. 3. Data on file. Astellas Pharma Canada, Inc. February 2026. 4. Yuksel N, Evaniuk D, Huang L, et al. Guideline No. 422a: Menopause: vasomotor symptoms, prescription therapeutic agents, complementary and alternative medicine, nutrition, and lifestyle. *J Obstet Gynaecol Can*. 2021;43(10):1188-1204. 5. 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. 6. British Menopause Society; Women's Health Concern. BMS & WHC's 2020 recommendations on hormone replacement therapy in menopausal women [Internet]. London: British Menopause Society; 2020. Accessed Mar 4, 2026. Available from: <https://thebms.org.uk/publications/consensus-statements/bms-whcs-2020-recommendations-on-hormone-replacement-therapy-in-menopausal-women/>. 7. Society of Obstetricians and Gynaecologists of Canada. *Menopause*. Accessed on April 28, 2026. Available at <https://sogc.org/en/en/content/events/HUB-Pages/Menopause.aspx?hkey=55767821-2414-44ed-b3c5-f4354fa9d005>. 8. 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. 9. Data on file. Astellas Pharma Canada, Inc. April 2026.