VEOZAH™
(fezolinetant) tablets 45 mg

Contact:
Astellas Therapeutic Area Communications
Suzanne Johnson / +1 (847) 224-0875
suzanne.johnson@astellas.com

VEOZAH™ (fezolinetant) is a first-in-class, FDA-approved nonhormonal treatment option for moderate to severe vasomotor symptoms (VMS) due to menopause[1,6]

VEOZAH™ is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms (VMS) due to menopause. VMS is also known as hot flashes and/or night sweats.[1, 2]

VEOZAH was approved by the U.S. Food and Drug Administration in May 2023 and was shown in 12-week clinical trials to reduce the number and intensity of hot flashes.[1]

VEOZAH provides a new treatment option for women with moderate to severe VMS due to menopause.[1]

VMS are the most commonly reported symptoms of menopause for which women seek treatment.[2, 7] The median duration for VMS is 7.4 years with some women experiencing moderate to severe symptoms for more than 10 years after their final menstrual period.[3]

HOW IT WORKS

VEOZAH is not a hormone. It has a different mechanism of action to treat moderate to severe VMS by targeting the root cause of hot flashes and night sweats where they start, the hypothalamus in the brain, which is responsible for regulating body temperature.[3]

Before menopause, there is a balance between estrogens (hormones made by a woman's ovaries) and neurokinin B (NKB), a brain chemical.[4] The body relies on this balance to keep its internal thermostat in check.[4] During menopause, levels of estrogen and NKB become unbalanced.[4] When this occurs, the hypothalamus tells the body that it's hot when it is not.[4]

VEOZAH blocks NKB in the temperature control center to reduce the number and intensity of hot flashes.[1]

VEOZAH EFFICACY AND SAFETY PROFILE

The efficacy of VEOZAH for the treatment of moderate to severe vasomotor symptoms due to menopause was evaluated in the first 12-week, randomized, placebo-controlled, double-blind portion of each of two phase 3 clinical trials.[1] In each of these two trials, after the first 12 weeks, women on placebo were then re-randomized to VEOZAH for a 40-week extension to evaluate safety for up to 52 weeks total exposure.[1] Results showed a statistically significant and clinically meaningful (≥2 hot flashes over 24 hours) reduction from baseline in the frequency of moderate to severe VMS at Weeks 4 and 12 with VEOZAH 45 mg compared to placebo.[1] Data from each trial also demonstrated a statistically significant reduction from baseline in the severity of moderate to severe vasomotor symptoms (over 24 hours) at Weeks 4 and 12 for VEOZAH 45mg compared to placebo.[1]

The safety of VEOZAH was evaluated in three 52-week clinical trials (Trials 1, 2 and 3). Across the three clinical trials, a total of 1100 women received VEOZAH. In Trial 3, the most common adverse reactions with VEOZAH (at least 2% in VEOZAH 45 mg [n = 609] and greater than placebo [n = 610]) were: abdominal pain, diarrhea, insomnia, back pain, hot flush, and hepatic transaminase elevation.

IMPORTANT SAFETY INFORMATION

VEOZAH can cause serious side effects, including:
- have cirrhosis.
- have severe kidney problems or kidney failure.
- are taking certain medicines called CYP1A2 inhibitors. Ask your healthcare provider if you are not sure.

Before you use VEOZAH, tell your healthcare provider about all of your medical conditions, including if you:
- have liver disease or problems.
- have kidney problems.
- have any medical conditions that may become worse while you are using VEOZAH.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VEOZAH may affect the way other medicines work, and other medicines may affect how VEOZAH works.

Please see additional Important Safety Information on page 2 and **click here** for full Prescribing Information, and **click here** for Patient Information.

1. VEOZAH [package insert]. Northbrook, IL: Astellas 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. Freeman EW, Sammel MD, Sanders RJ. Risk of long-term hot flashes after natural menopause: evidence from the Penn Ovarian Aging Study cohort. Menopause 2014;21(9):924-32.
4. Krajewski-Hall SJ, Blackmore EM, McMinn JR, Rance NE. Estradiol alters body temperature regulation in the female mouse. Temperature (Austin) 2018;5(1):56-69.
6. 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.
7. Williams RE, Kalilani L, DiBenedetti DB, et al. Healthcare seeking and treatment for menopausal symptoms in the United States. Maturitas. 2007;58:348-358.

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What is VEOZAH™ (fezolinetant)?

VEOZAH is a prescription medicine used to reduce moderate to severe vasomotor symptoms due to menopause. VEOZAH is not a hormone. Vasomotor symptoms are the feelings of warmth in the face, neck, and chest, or sudden intense feelings of heat and sweating ("hot flashes" or "hot flushes").

IMPORTANT SAFETY INFORMATION

Who should not take VEOZAH?

Do not use VEOZAH if you:
- have cirrhosis.
- have severe kidney problems or kidney failure.
- are taking certain medicines called CYP1A2 inhibitors. Ask your healthcare provider if you are not sure.

What should I tell my doctor before taking VEOZAH?

Before you use VEOZAH, tell your healthcare provider about all of your medical conditions, including if you:
- have liver disease or problems.
- have kidney problems.
- have any medical conditions that may become worse while you are using VEOZAH.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VEOZAH may affect the way other medicines work, and other medicines may affect how VEOZAH works.

What are the possible side effects of VEOZAH?

VEOZAH can cause serious side effects, including:
- **increased liver blood test values.** Your healthcare provider will do a blood test to check your liver before you start taking VEOZAH. Your healthcare provider will also do this blood test at month 3, month 6, and month 9 after you start taking VEOZAH.

Call your healthcare provider right away if you have the following signs and symptoms of liver problems:
- nausea
- vomiting
- yellowing of the eyes or skin (jaundice)
- pain in the right upper stomach (abdomen)

The most common side effects of VEOZAH include:
- stomach (abdominal) pain
- diarrhea
- difficulty sleeping (insomnia)
- back pain
- hot flashes or hot flushes

These are not all the possible side effects of VEOZAH. Tell your healthcare provider if you have any side effect that bothers you or does not go away.

Call your healthcare provider for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information, talk to your healthcare provider and click here for Prescribing Information and click here for Patient Information.

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