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.]}} See how **VEOZAH® (fezolinetant)** helps treat VMS day and night, and dive into the safety results. **Check out the data**.[1]

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.

Explore the effect of VEOZAH on VMS frequency and severity

SEE CLINICAL DATA

Efficacy

Study Design

The efficacy of VEOZAH was studied in two 12-week, randomized, placebo-controlled, double-blind Phase 3 studies (Trials 1 and 2). 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 coprimary efficacy endpoints for Trials 1 and 2 were mean change from baseline in moderate to severe VMS frequency and severity to weeks 4 and 12.[1]

Results

VEOZAH demonstrated statistically significant reductions from baseline in the *frequency and severity* of moderate to severe VMS versus placebo at weeks 4 and 12[1]*†

Clinically meaningful reductions in the number of daily hot flashes and night sweats[1‡]

Reductions day and night measured over 24 hours[1]

Safety

Study Design

The safety of VEOZAH was evaluated in three 52-week clinical trials (Trials 1, 2, and 3) with 1100 women receiving VEOZAH. Trial 3 was a randomized, placebo-controlled, double-blind study evaluating the safety of VEOZAH for 52 weeks.[1]

Select Results

The most common adverse reactions (≥2% in VEOZAH and > placebo) reported in Trial 3 were abdominal pain (4.3%), diarrhea (3.9%), insomnia (3.9%), back pain (3.0%), hot flush (2.5%), and hepatic transaminase elevation (2.3%)[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, ULN=upper limit of normal.

*Statistically significantly superior compared to placebo at the 0.05 level with multiplicity adjustment.[1]

†The difference vs placebo in the mean change from baseline for mean frequency of moderate to severe VMS for VEOZAH (in Trials 1 and 2, respectively) was -2.1 (*P*<0.001) and -2.6 (*P*<0.001) at week 4 and -2.6 (*P*<0.001) and -2.5 (*P*<0.001) at week 12. The difference vs placebo in the mean change from baseline for mean severity of moderate to severe VMS for VEOZAH was -0.2 (*P*=0.002) and -0.3 (*P*<0.001) at week 4 and -0.2 (*P*=0.007) and -0.3 (*P*<0.001) at week 12.[1]*

‡"Clinically meaningful" is defined as a reduction in ≥2 hot flashes per 24 hours versus placebo.[1]

Looking for more clinical trial information?

REQUEST A REP

EXPLORE DATA

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

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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.

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