VEOZA™▼
fezolinetant

Prescribing information and adverse event reporting information can be found at the bottom of this page.

This promotional material was developed by Astellas Pharma Ltd for use by UK healthcare professionals only.

This document is a product-focused promotional aid, not a guideline.

This material is not for onward distribution.

ADVICE AND GUIDANCE REGARDING VEOZA▼ (FEZOLINETANT)

INDICATION

VEOZA is a neurokinin 3 (NK3) receptor antagonist licensed for the **treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause**. It is non-hormonal.[1] VMS, more commonly known as hot flushes and night sweats, can also include heat in the upper body, particularly the face, neck, and chest and may be accompanied by perspiration, chills, anxiety, and occasionally, heart palpitations.[2]

NICE RECOMMENDATION

Fezolinetant can be used as an option to treat moderate to severe vasomotor symptoms associated with menopause when hormone replacement therapy is unsuitable.[3]

MECHANISM OF ACTION

VEOZA blocks neurokinin B (NKB) binding on the kisspeptin/neurokinin B/dynorphin (KNDy) neuron, which is postulated to restore the balance in KNDy neuronal activity in the thermoregulatory centre of the hypothalamus.[1]

DOSING AND ADMINISTRATION

Prior to the initiation or reinstitution of VEOZA, a careful diagnosis should be made, and complete medical history (including family history) must be taken. During treatment, periodic check-ups must be carried out according to standard clinical practice. Benefit of long-term treatment should be periodically assessed since the duration of VMS can vary by individual.[1]

1 Tablet VEOZA 45 mg[1]

Once daily[1] (About the same time each day)

With or without food[1]

Swallow whole[1]

May be initiated in primary care as per NICE guidance[3]

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Astellas Pharma Ltd on 0800 783 5018.

Please scan or click the QR code to access the Prescribing information for VEOZA

The website link above will take you to a non-Astellas website. Astellas do not endorse or accept liability for sites controlled by third parties.

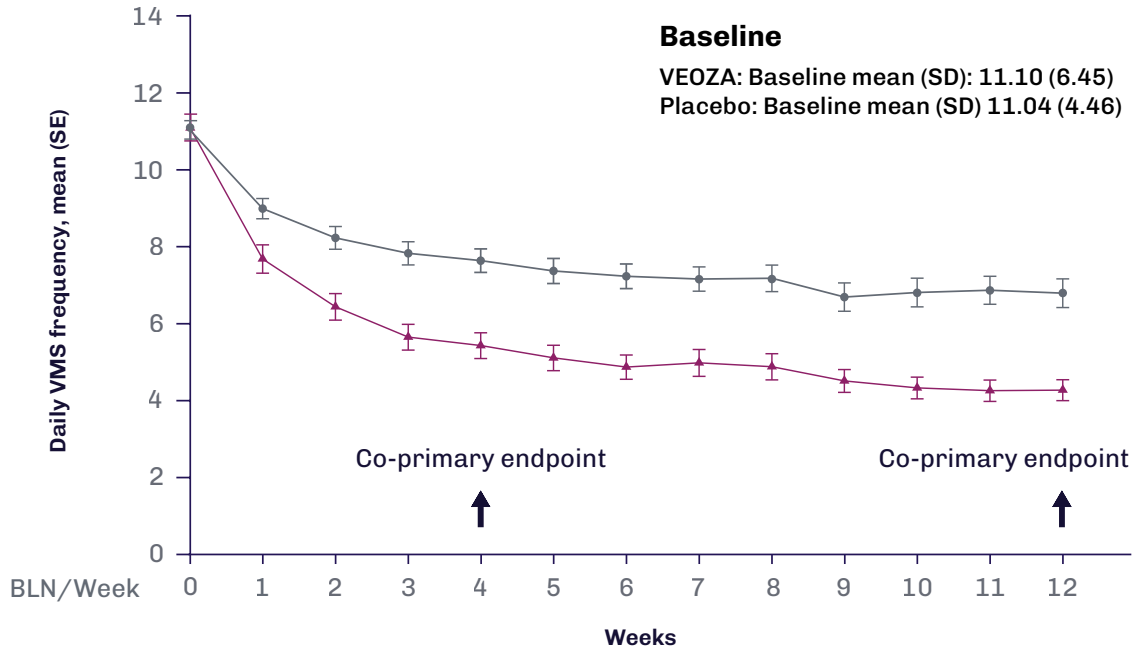
MAT-GB-VEO-2026-00067 | July 2026

CLINICAL TRIALS

- ✓ Clinical evidence for VEOZA is supported by the **SKYLIGHT 1** and **SKYLIGHT 2** clinical trials.[1]
- ✓ SKYLIGHT 1 & SKYLIGHT 2, are two 12-week, randomised, placebo controlled, double blind **phase 3** studies.[1]
- ✓ They compared VEOZA with placebo for **12 weeks** followed by a **40-week** uncontrolled extension treatment period (total of 52 weeks).[1]
- ✓ The co-primary endpoints were the mean change from baseline in moderate to severe VMS frequency and severity to Weeks 4 and 12.[1]
- ✓ Women in both trials were aged **40 to 65 years** (post-menopausal) with moderate to severe vasomotor symptoms.[1]
- ✓ VEOZA met all primary endpoints within the SKYLIGHT 1 and SKYLIGHT 2 trials. Patients taking VEOZA experienced a statistically significant reduction from baseline in VMS frequency at week 4 (53% reduction) and week 12 (63% reduction), compared to placebo which showed a 32% reduction at week 4 and a 40% reduction at week 12. (P=<0.001)[1]

CHANGE IN FREQUENCY OF MODERATE TO SEVERE VMS UP TO WEEK 12.
POOLED DATA FROM THE PHASE 3 STUDIES SKYLIGHT 1 AND SKYLIGHT 2[4]

▲ **VEOZA 45 mg** (n=341) ● **Placebo** (n=342)



Adapted from: Shapiro C.M M, *et al. Maturitas.* 2025;**203**:108740.[4]

The effects of VEOZA on the frequency of VMS were maintained up to week 52[5,6]

Note: Fezolinetant has not been directly compared with other non-hormonal treatments.

MONITORING

Liver function testing (LFT) requirements[1]

LFTs must be performed prior to initiation and whilst on fezolinetant, at the following timepoints:[1]

Baseline	Month 1/ Month 2/ Month 3	Further testing
Treatment should not be started if ALT or AST is ≥ 2 x ULN or if total bilirubin is elevated (e.g., ≥ 2 x ULN).[1]	LFTs performed monthly for the first 3 months[1]	Based on clinical judgement or when symptoms suggestive of liver injury occur[1]

Treatment should be discontinued in the following situations[1]	
Transaminase elevations > 5 x ULN	Transaminase elevations are ≥ 3 x ULN with: total bilirubin >2 x ULN OR symptoms of liver injury
Monitor LFTs until they have normalised[1]	

ALT: alanine aminotransferase, AST: aspartate aminotransferase, ULN: upper limit of normal

Patients should be informed about the signs and symptoms of liver injury and should be advised to contact their doctor immediately once these occur.[1]

ADVERSE REACTIONS

The most frequent adverse reactions were diarrhoea (3.2%) and insomnia (3.0%).[1]

Adverse reactions for fezolinetant 45 mg[1]

MedDRA system organ class	Frequency category	Adverse reaction
Psychiatric disorders	Common	Insomnia
Gastrointestinal disorders	Common	Diarrhoea, abdominal pain
Hepatobiliary disorders	Common	ALT increased, AST increased
	Not known	Drug-induced liver injury (DILI)*

Common (≥1/100 to <1/10); Not known (cannot be estimated from the available data)

ALT: alanine aminotransferase, AST: aspartate aminotransferase

*Serious cases with elevations of ALT and/or AST (> 10 x ULN) with concurrent elevations in bilirubin and/or alkaline phosphatase (ALP) were reported post-marketing.

The most frequent adverse reactions leading to dose discontinuation with VEOZA were alanine aminotransferase (ALT) increased (0.3%) and insomnia[1]

No serious adverse reactions were reported at an incidence greater than 1% across total study population[1]

Four serious adverse reactions were reported in the Phase 3 studies
- The most serious adverse reaction was an event of endometrial adenocarcinoma (0.1%)[1]
- Drug-induced liver injury has been observed in post-marketing (frequency unknown)[1]

CONTRAINDICATIONS

Concomitant use of moderate or strong CYP1A2 inhibitors.[1]

Known or suspected pregnancy.[1]

Hypersensitivity to the active substance or any of the excipients.[1]

SPECIAL POPULATION

ELDERLY

Fezolinetant has not been studied for safety and efficacy in women over **65 years** of age. No dose recommendation can be made for this population.[1]

HEPATIC IMPAIRMENT

Not recommended for use in individuals with Child-Pugh Class B (moderate) or C (severe) chronic hepatic impairment. The pharmacokinetics of VEOZA has not been studied in individuals with Child-Pugh Class C (severe) chronic hepatic impairment[1]

RENAL IMPAIRMENT

No dose modification is recommended for individuals with mild (eGFR 60 to <90 mL/min/1.73 m^2) or moderate (eGFR 30 to <60 mL/min/1.73 m^2) renal impairment. Fezolinetant is **not recommended** for use in individuals **with severe** (eGFR<30 mL/min/1.73 m^2) **renal impairment.** Fezolinetant has not been studied in individuals with end-stage renal disease (eGFR less than 15 ml/min/1.73 m^2) and is not recommended for use in this population.[1]

eGFR: estimated glomerular filtration rate

SPECIAL WARNINGS AND PRECAUTIONS

Known or previous breast cancer or oestrogen-dependent malignancies:

Women with **previous** breast cancer or other oestrogen-dependent malignancies and no longer on any oncologic treatment have not been included in the clinical studies. A **decision to treat** these women with fezolinetant should be based on a **benefit-risk consideration for the individual.**[1]

Women undergoing **current** oncologic treatment (e.g. chemotherapy, radiation therapy, antihormone therapy) for breast cancer or other oestrogen-dependent malignancies have not been included in the clinical studies. Therefore, fezolinetant is **not recommended** for use in this population as the safety and efficacy are unknown.[1]

Please consult the Summary of Product Characteristics for a full list of Special Warnings and Precautions.

Breast feeding:

Fezolinetant is not indicated during lactation. It is unknown whether fezolinetant and its metabolites are excreted in human milk.[1]

References:

1. VEOZA SmPC. Astellas Pharma Ltd. Summary of Product Characteristics
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. NICE TA1143. Technology Appraisal Guidance. Fezolinetant for treating moderate to severe vasomotor symptoms associated with menopause. 2026b. Available from: https://www.nice.org.uk/guidance/ta1143. [Accessed May 2026]
4. Shapiro M. *et al.* Maturitas. 2025;203:108740
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 2023;401(10382):1091-102