Intended for UK healthcare professionals only.

VEOZA™ fezolinetant

VEOZA (fezolinetant) is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.[1]

VMS are also known as hot flushes* and night sweats.[2]

The Adverse Event Reporting Information can be found at the bottom of this page.
The Prescribing Information for VEOZA (fezolinetant) can be accessed by scanning or clicking the QR code on the final page.

FIGHT *the* FIRE
WITH NON-HORMONAL VEOZA

VEOZA directly targets a source of VMS-specific neurons in the hypothalamus.[1]

NON-HORMONAL

VEOZA is the first-in-class selective neurokinin 3 (NK3) receptor antagonist to be licensed. It 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.[1,3,4]

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

*Hot flushes are also known as hot flashes.[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.

REDEFINE HOW YOU TARGET VMS

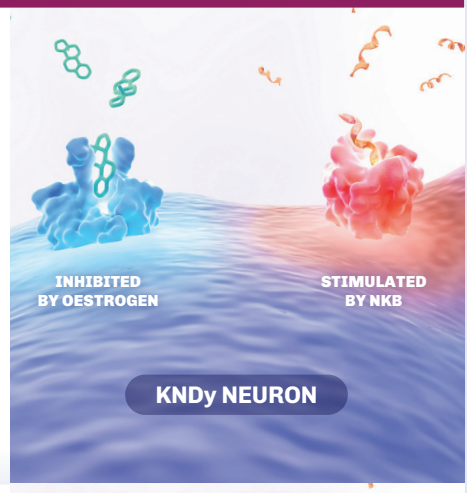
NON-HORMONAL

VEOZA IS NOT A HORMONE.[1]

It is the first-in-class selective NK3 receptor antagonist to be licensed. It 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.[1,3,4]

Homeostasis

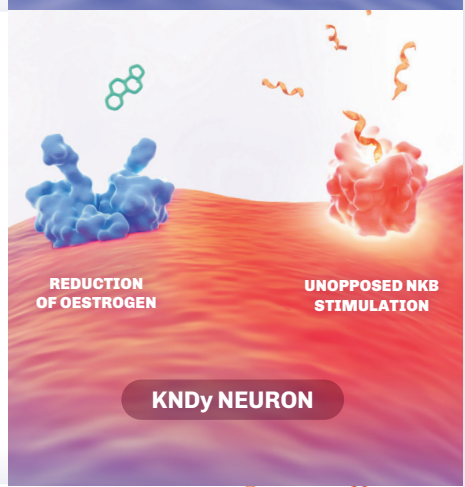
KNDy neurons in the hypothalamus are inhibited by oestrogen and stimulated by the neuropeptide, NKB. This balance contributes to **body temperature regulation**.[3]



Menopause

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

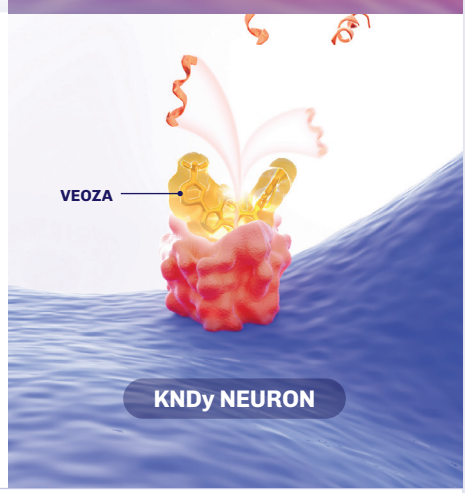
This **triggers heat dissipation** mechanisms, including vasodilation and sweating – VMS.[3]



Blocking NKB to reduce the heat

VEOZA selectively binds to the NK3 receptor to **block NKB**.[1]

This action moderates NKB signalling and KNDy neuron activity, helping to restore thermoregulatory balance and better control VMS.[1,3]



OESTROGEN | OESTROGEN RECEPTOR ALPHA (ORα) | NKB | NK3 RECEPTOR

KNDy: kisspeptin/neurokinin B/dynorphin, NK3: neurokinin 3, NKB: neurokinin B, ORα: oestrogen receptor alpha, VMS: vasomotor symptoms.

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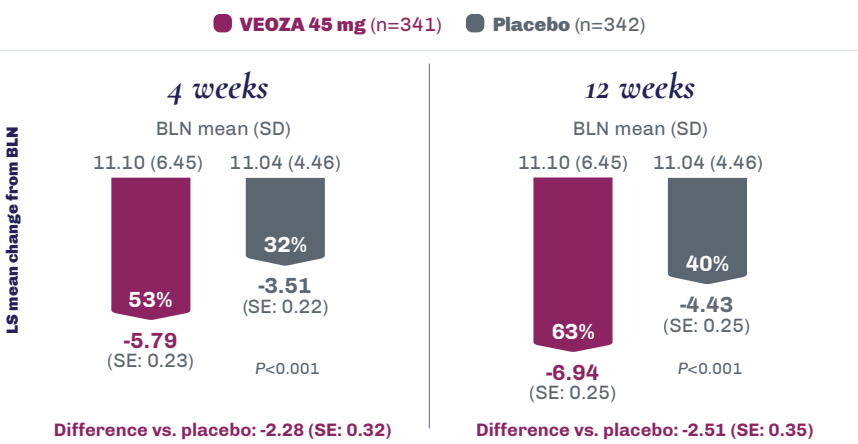
ACHIEVE FEWER AND LESS SEVERE VMS EPISODES WITH VEOZA VS. PLACEBO

The efficacy of VEOZA was evaluated in two identical 12-week, randomised, placebo-controlled, double-blind Phase 3 studies, followed by a 40-week extension no-control treatment period.[1]

VEOZA demonstrated statistically significant reductions in VMS frequency and severity at Weeks 4 and 12 vs. placebo.[1]

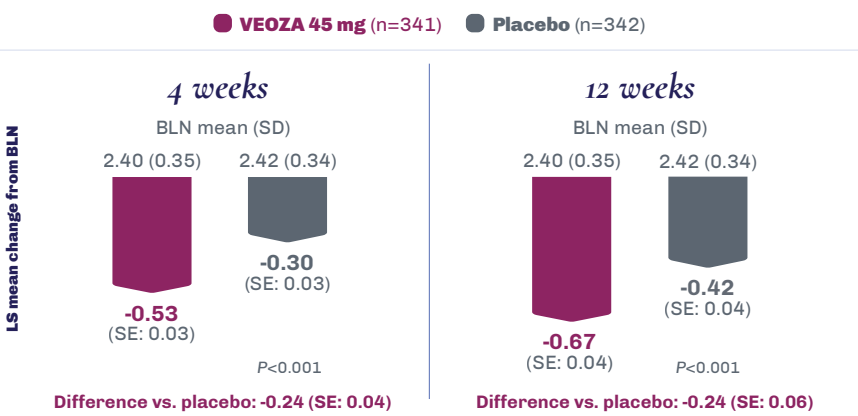
MEAN CHANGE FROM BASELINE (BLN) IN MODERATE TO SEVERE VMS FREQUENCY OVER 24 HOURS[1]

POOLED CO-PRIMARY ENDPOINT DATA FROM THE PHASE 3 STUDIES SKYLIGHT 1 AND SKYLIGHT 2



MEAN CHANGE FROM BASELINE (BLN) FOR MEAN SEVERITY OF MODERATE TO SEVERE VMS OVER 24 HOURS[1]

POOLED CO-PRIMARY ENDPOINT DATA FROM THE PHASE 3 STUDIES SKYLIGHT 1 AND SKYLIGHT 2



VEOZA provided a greater reduction in moderate to severe VMS *over 24 hours vs. placebo at Weeks 4 and 12.*[1]

Frequency and severity data contain a pooled analysis of SKYLIGHT 1 and SKYLIGHT 2.

Least squares (LS) mean estimated from a mixed model for repeated measures analysis of covariance.[1]

Patients taking VEOZA experienced a significant reduction in moderate to severe VMS frequency by Week 4 vs. placebo, which was sustained through 52 weeks.[1]

BLN: baseline, LS: least squares, SD: standard deviation, SE: standard error, VMS: vasomotor symptoms.

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EVALUATED FOR SAFETY

SAFETY PROFILE[1]

The safety of VEOZA was evaluated in Phase 3 clinical studies with 2203 women receiving VEOZA.[1]

SKYLIGHT 1 & 2

TWO identical Phase 3 efficacy and safety studies that were randomised, placebo-controlled, double-blind for 12 weeks, followed by re-randomisation of women previously receiving placebo to VEOZA (women on VEOZA remained on VEOZA) for an additional 40 weeks of uncontrolled treatment.[5,6]

SKYLIGHT 4

ONE Phase 3, 52-week, randomised, placebo-controlled, double-blind study evaluating safety.[7]

Across the Phase 3 studies, the most common adverse reactions with VEOZA were diarrhoea (3.2%) and insomnia (3.0%).[1]

The most frequent adverse reactions leading to dose discontinuation with VEOZA were ALT increased (0.3%) and insomnia (0.2%).[1]

There were no serious adverse reactions reported at an incidence greater than 1% across the 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]

Adverse reactions observed during the clinical studies and from spontaneous reporting are listed in the table below.

Adverse reaction[1]	Frequency[1]
Diarrhoea	Common*
Abdominal pain	Common*
Insomnia	Common*
Alanine aminotransferase (ALT) increased	Common*
Aspartate aminotransferase (AST) increased	Common*
Drug-induced liver injury (DILI)†	Frequency not known**

*Common is a frequency of ≥ 1/100 to < 1/10.
**Frequency not known - cannot be estimated from the available data.

†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. In some cases, elevated liver function tests were associated with signs and symptoms suggestive of liver injury such as fatigue, pruritus, jaundice, dark urine, pale faeces, nausea, vomiting, decreased appetite, and/or abdominal pain. Elevated liver function tests and/or symptoms suggestive of injury were generally reversible on discontinuation of therapy.[1]

For further safety information for VEOZA please refer to the Summary of Product Characteristics.

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ASSESSED FOR ENDOMETRIAL SAFETY

In the long-term safety data, VEOZA was evaluated for tolerability and endometrial safety compared to placebo over 52 weeks.[1,7]

- Endometrial safety of VEOZA was assessed by transvaginal ultrasound and endometrial biopsies, 304 women had baseline and post-baseline endometrial biopsies during the 52 weeks of treatment[1]
- 1 case of endometrial adenocarcinoma was observed[1]
- Endometrial biopsy assessments did not identify an increased risk of endometrial hyperplasia or malignancy according to prespecified criteria for endometrial safety[1]
- Transvaginal ultrasound did not reveal increased endometrial thickness[1]

VEOZA is an option you can offer your eligible patients impacted by VMS

VMS: vasomotor symptoms.

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DOSING AND ADMINISTRATION

LFTs must be performed prior to treatment initiation with fezolinetant.[1]

Treatment should not be started if ALT or AST is ≥ 2 x ULN or if total bilirubin is elevated (e.g., ≥ 2 x ULN).

45 mg orally once daily[1]

Taken with liquid and swallowed whole. Tablets are not to be broken, crushed or chewed. Can be taken with or without food.

About the same time each day, taken every day[1,8]

If a dose is missed or not taken at the usual time, patients should take the missed dose as soon as possible on the same day, unless there are fewer than 12 hours before the next scheduled dose. Patients/individuals should return to the regular schedule the following day. In the case of overdose, the individual should be closely monitored, and supportive treatment should be considered based on signs and symptoms.

While using VEOZA[1]

Perform LFTs monthly for the first 3 months of treatment, then based on clinical judgement or if symptoms suggestive of liver injury occur.[1]

Discontinue VEOZA if:

- Transaminase elevations are ≥ 3 x ULN with: total bilirubin > 2 x ULN OR symptoms of liver injury.
- Transaminase elevations > 5 x ULN.

Monitoring of liver function should be maintained until they have normalised.

The benefit of long-term treatment should be periodically assessed since the duration of VMS can vary by individual.[1]

Special populations[1]

Renal impairment

VEOZA is not recommended for use in individuals with severe renal impairment* or end-stage renal disease.** No dose modification is needed in mild/moderate renal impairment.

Hepatic impairment

VEOZA is not recommended for use in individuals with Child-Pugh Class B or C (moderate to severe chronic hepatic impairment). No dose adjustment is needed in Class A (mild) chronic hepatic impairment.

Elderly

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

Please refer to the Summary of Product Characteristics for more information on special populations and warnings & precautions, including use in patients with known/previous breast cancer or oestrogen-dependent malignancies.

VEOZA is an option you can offer your eligible patients impacted by VMS

*eGFR less than 30 ml/min/1.73 m^2.
**End-stage renal disease is eGFR below 15 ml/min/1.73 m^2.

ALT: alanine aminotransferase, AST: aspartate aminotransferase, eGFR: estimated glomerular filtration rate, ULN: upper limit of normal, VMS: vasomotor symptoms.

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POTENTIAL TO HELP REDUCE THE IMPACT VMS MAY HAVE ON YOUR ELIGIBLE PATIENTS[1]

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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 and severity over 24 hours at Weeks 4 and 12, compared to placebo.[1]

VEOZA SUSTAINED EFFICACY OVER 52 WEEKS[1,5,6]

THE SAFETY OF VEOZA WAS EVALUATED OVER 52 WEEKS

Across the Phase 3 studies, the most common adverse reactions with VEOZA were diarrhoea (3.2%) and insomnia (3.0%).[1]

ONCE-DAILY ORAL DOSING

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

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

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For further information about VEOZA please visit www.veoza.co.uk

Please scan or click on the following Quick Response (QR) code to access the Prescribing Information for VEOZA

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The hyperlink for the Adverse Event Reporting will take you to non-Astellas websites. Astellas does not endorse or accept liability for sites controlled by third-parties.

REFERENCES: 1. VEOZA 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.** Depypere H, Lademacher C, Siddiqui E, *et al.* 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.** Neal-Perry G, Cano A, Lederman S, *et al.* Safety of fezolinetant for vasomotor symptoms associated with menopause: a randomized controlled trial. *Obstet Gynecol.* 2023;141(4): 737–47. **8.** VEOZA Patient Information Leaflet.

MAT-GB-VEO-2025-00127. February 2026.