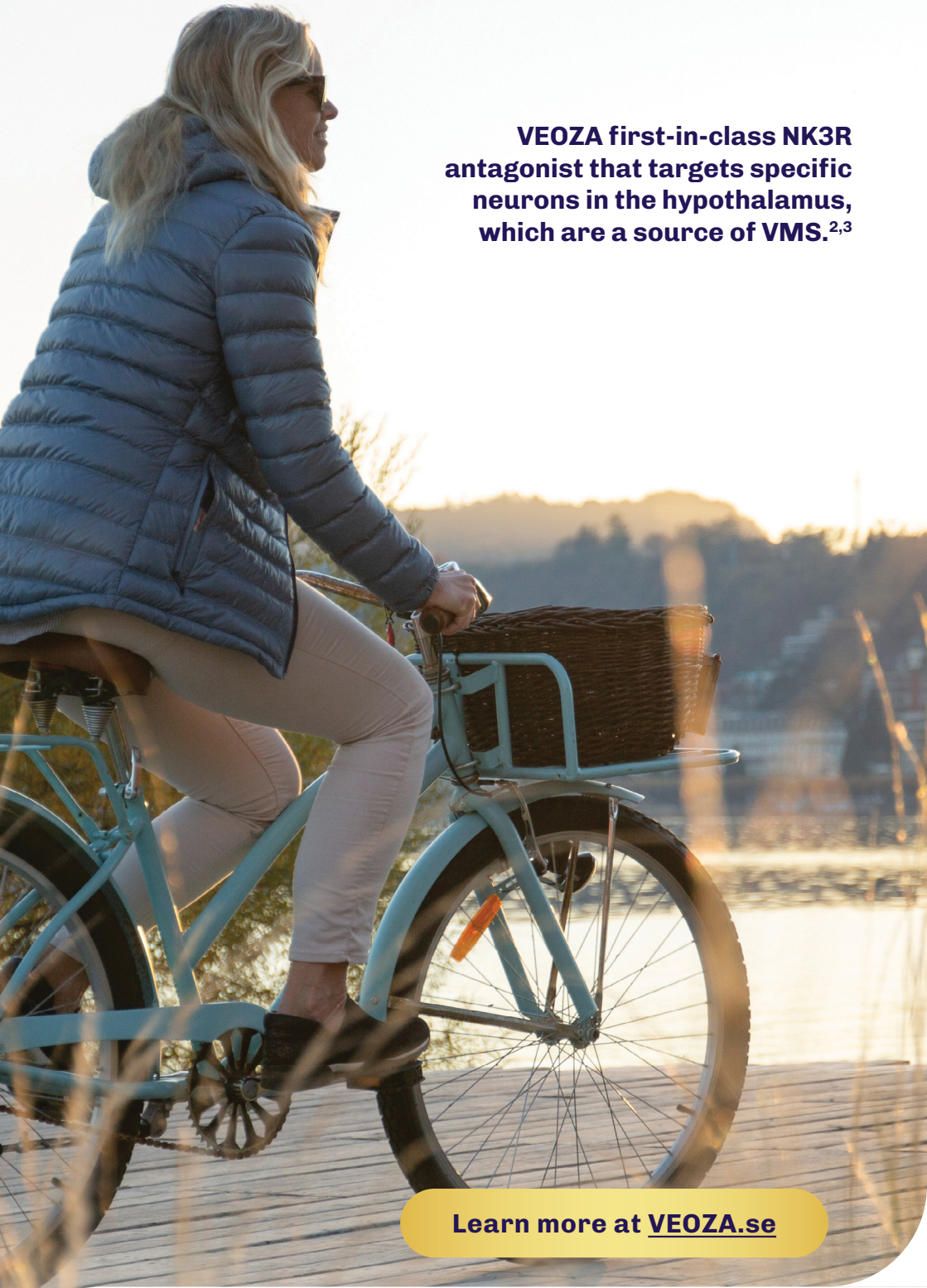
VEOZA™ (fezolinetant) is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause*[1]

VEOZA™
fezolinetant

NONHORMONAL

TREAT TARGETED
WITH NONHORMONAL VEOZA



VEOZA first-in-class NK3R antagonist that targets specific neurons in the hypothalamus, which are a source of VMS.[2,3]

Learn more at VEOZA.se

▼ THIS MEDICINAL PRODUCT IS SUBJECT TO ADDITIONAL MONITORING

NK3R=neurokinin 3 receptor; VMS=vasomotor symptoms
*See section 5.1 in SmPC

REDEFINE HOW TO TREAT VMS

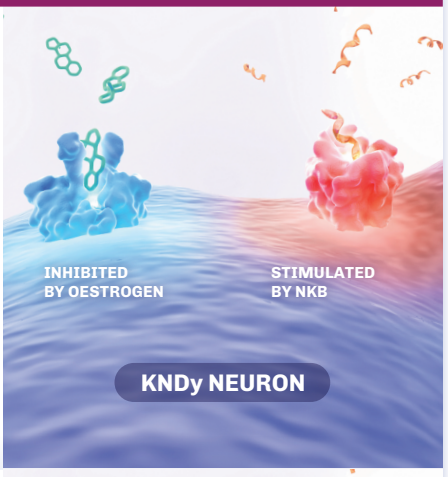
NONHORMONAL

VEOZA IS NOT A HORMONE

It's a first-in-class selective NK3 receptor antagonist that blocks NKB from binding on the KNDy neurons to help reduce heat signals that trigger VMS[2-4]

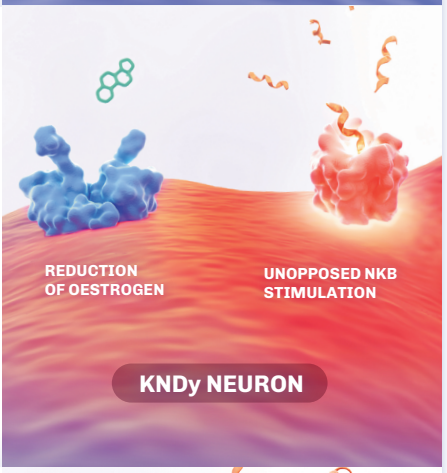
Homeostasis

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



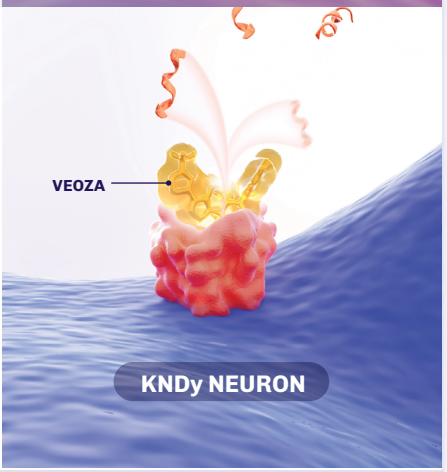
Menopause

Oestrogen decline during the menopausal transition and disrupts the balance between activation by NKB and inhibition by oestrogen. **Unopposed, NKB signalling causes** heightened KNDy neuronal activity. 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** from binding on the KNDy neuron. This action is postulated to restore the balance in KNDy neuronal activity in the thermoregulatory centre of the hypothalamus[2]



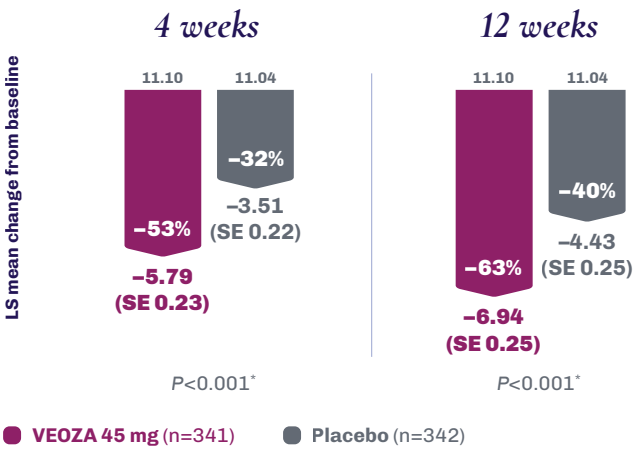
OESTROGEN | OESTROGEN RECEPTOR ALPHA (ERα) | NKB | NK3 RECEPTOR

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

REDUCE AND RELIEVE VMS

VEOZA demonstrated statistically significant reductions in VMS frequency and severity in postmenopausal women at weeks 4 and 12 versus placebo[2]

MEAN CHANGE FROM BASELINE IN MODERATE TO SEVERE VMS FREQUENCY OVER 24 HOURS[2]
COPRIMARY ENDPOINTS (POOLED DATA)



*Improvement compared with placebo, does not indicate statistical significance[2]

LS: least squares mean estimated from a mixed model for repeated measures analysis of covariance[2]

Figure adapted from reference 2

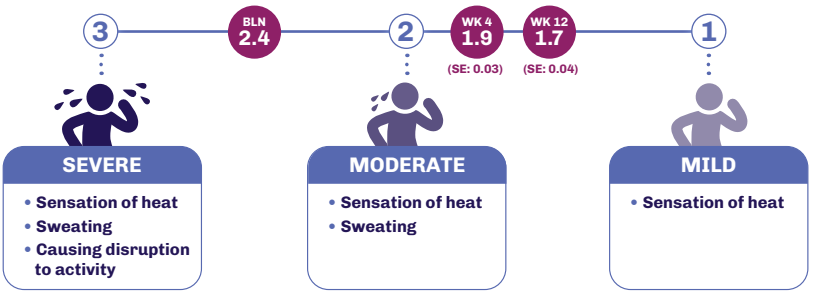
SE=standard error; VMS=vasomotor symptoms

AT WEEK 12,

~2 *out of every* **3**

VMS EPISODES ELIMINATED (63%)

Severity was reduced from moderate/severe → mild/moderate[2,5,6]



vs placebo: 2.1 at week 4 and 2.0 at week 12 (p<0.001*)

*Improvement compared with placebo, does not indicate statistical significance[2]

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

Figure made by Astellas based on the references 2, 5 and 6

BLN=baseline; SE=standard error; VMS=vasomotor symptoms; WK=week

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VEOZA WAS STUDIED FOR SAFETY AND TOLERABILITY

The safety of VEOZA was evaluated in phase 3 clinical studies with 2 203 postmenopausal women receiving VEOZA and from spontaneous reporting in clinical practice[7]

- Across the phase 3 studies, the most common adverse reactions (≥3%) with VEOZA 45 mg were diarrhoea (3.2%) and insomnia (3.0%).[7]

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

Legend: Common (≥ 1/100 to < 1/10); Not known (cannot be estimated from the available data).
*SmPC see section 4.8

- The most frequent adverse reactions leading to dose discontinuation with VEOZA in the Phase 3 trials were an ALT increase (0.3%) and insomnia (0.2%)[7]
- In the clinical trials there were no SAEs at an incidence >1% across the total study population. On VEOZA, 4 SAEs were reported, the most common SAE being endometrial adenocarcinoma (0.1%)[7]

In the long-term safety data (SKYLIGHT 1, 2, and 4), endometrial safety of VEOZA 45 mg was assessed by transvaginal ultrasound and endometrial biopsies (304 postmenopausal women had baseline and post-baseline endometrial biopsies during 52 weeks of treatment)[2]

- 1 case of endometrial adenocarcinoma was observed[7]
- Endometrial biopsy assessments did not identify an increased risk of endometrial hyperplasia or malignancy according to pre-specified criteria for endometrial safety[2]
- Transvaginal ultrasound did not reveal increased endometrial thickness[2]

1 TABLET A DAY

DOSING & ADMINISTRATION[7-10]

Benefit of long-term treatment should be periodically assessed since the duration of VMS can vary by individual[8]

Before starting VEOZA

Perform a baseline liver function test (LFT) prior to initiating treatment with VEOZA
Treatment should not be started if ALT or AST is ≥2x ULN or if total bilirubin is elevated (eg, ≥2x ULN)[7]

Once-daily dosing

One tablet, once a day, no titration necessary
Instruct your patients to take with liquids and swallow whole. Do not break, crush, or chew tablets. Can be taken with or without food[8]
Patients choose when to take VEOZA, and take it about the same time, every day. If a dose is missed or not taken at the usual time, patients should take the missed dose as soon as possible, unless there are fewer than 12 hours before the next scheduled dose. Return to the regular schedule the following day[8]

While using VEOZA

Continue LFTs monthly for the first 3 months of treatment
Additional monitoring may be conducted based on clinical judgement or when symptoms suggestive of liver injury occur[7]

Discontinue VEOZA if[7]:

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

Contraindications

- Hypersensitivity to the active substance or to any of the excipients[9]
- Concomitant use of moderate or strong CYP1A2 inhibitors[9]
- Known or suspected pregnancy. If pregnancy occurs during use of VEOZA, treatment should be withdrawn immediately[9,10]

Special populations

VEOZA is not recommended for use in individuals with severe (eGFR less than 30 ml/min/1.73 m^2) renal impairment or Child-Pugh Class B (moderate) or C (severe) chronic hepatic impairment[8]

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VEOZA is reimbursed with limitations[4,11]

*Subsidized only where menopausal hormone treatment is contraindicated or where menopausal hormone treatment has been discontinued for medical reasons.[11]

REFERENCES: 1. VEOZA SmPC §4.1 02.2025. **2.** VEOZA SmPC §5.1 02.2025. **3.** 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. **4.** Jayasena CN, Comninos AN, Stefanopoulou E, et al. Neurokinin B administration induces hot flushes in women. Sci Rep. 2015;5:8466. **5.** 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. **6.** 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. 2023;108(8):1981-1997. **7.** VEOZA SmPC §4.4 & §4.8 02.2025. **8.** VEOZA SmPC §4.2 02.2025. **9.** VEOZA SmPC §4.3 & §4.5 02.2025. **10.** VEOZA SmPC §4.6 02.2025. **11.** TLV Veoza ingår i högkostnadsskyddet med begränsning (https://www.tlv.se/beslut/beslut-lakemedel/begransad-subvention/arkiv/2024-05-17-veoza-ingar-i-hogkostnadsskyddet-med-begransning.html?query=veoza) accessed 24.01.2025.

VEOZA™ (fezolinetant) 45 mg film-coated tablets

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Pharmacotherapeutic group: Other gynaecologicals, ATC code: G02CX06. **Therapeutic indications**: VEOZA is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause (see Section 5.1 in the Summary of Product Characteristics (SmPC). ***Posology**: Recommended dose is 45 mg once daily. **Contraindications**: Hypersensitivity to the active substance or to any of the excipients; concomitant use of moderate or strong CYP1A2 inhibitors; known or suspected pregnancy. ***Special warnings and precautions for use**: Diagnosis must include medical (including family) history. During treatment, periodic check-ups must be carried out according to standard clinical practice. Liver function tests: Must be performed prior to treatment initiation and monthly during the first three months; thereafter based on clinical judgement. Treatment should not be started or continued if test results meet pre-defined criteria. Patients should be informed about signs and symptoms of liver injury and advised to contact their doctor immediately if these occur. Liver / renal disease: VEOZA is not recommended for use in individuals with Child-Pugh Class B (moderate) or C (severe) chronic hepatic impairment, nor in individuals with severe renal impairment. VEOZA is not recommended in women undergoing oncologic treatment for breast cancer or other oestrogen-dependent malignancies, nor in women using hormone replacement therapy with oestrogens (local vaginal preparations excluded). VEOZA has not been studied in women over 65 years of age, nor in women with a history of seizures or other convulsive disorders. Animal studies have shown reproductive toxicity. ***Undesirable effects**: The listed adverse drug reactions are insomnia, diarrhoea, abdominal pain, increased alanine aminotransferase (ALT) and aspartate aminotransferase (AST), all with a frequency of less than 10%, and drug-induced liver injury with unknown frequency. **Marketing authorisation holder:** Astellas Pharma Europe B.V., The Netherlands.

Sweden: Status of the product: Rx. **Reimbursement:** (F) Subsidized only where menopausal hormone treatment is contraindicated or where menopausal hormone treatment has been discontinued for medical reasons. **Local representative:** Astellas Pharma AB, Tel: +46 (0)40 650 15 00. For more information, pack size and price see www.fass.se.

Based on authorised SmPC dated 07 February 2025.

***The section has been rewritten and/or abbreviated compared to the authorised SmPC. The SmPC can be ordered free of charge from the local representative.**

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