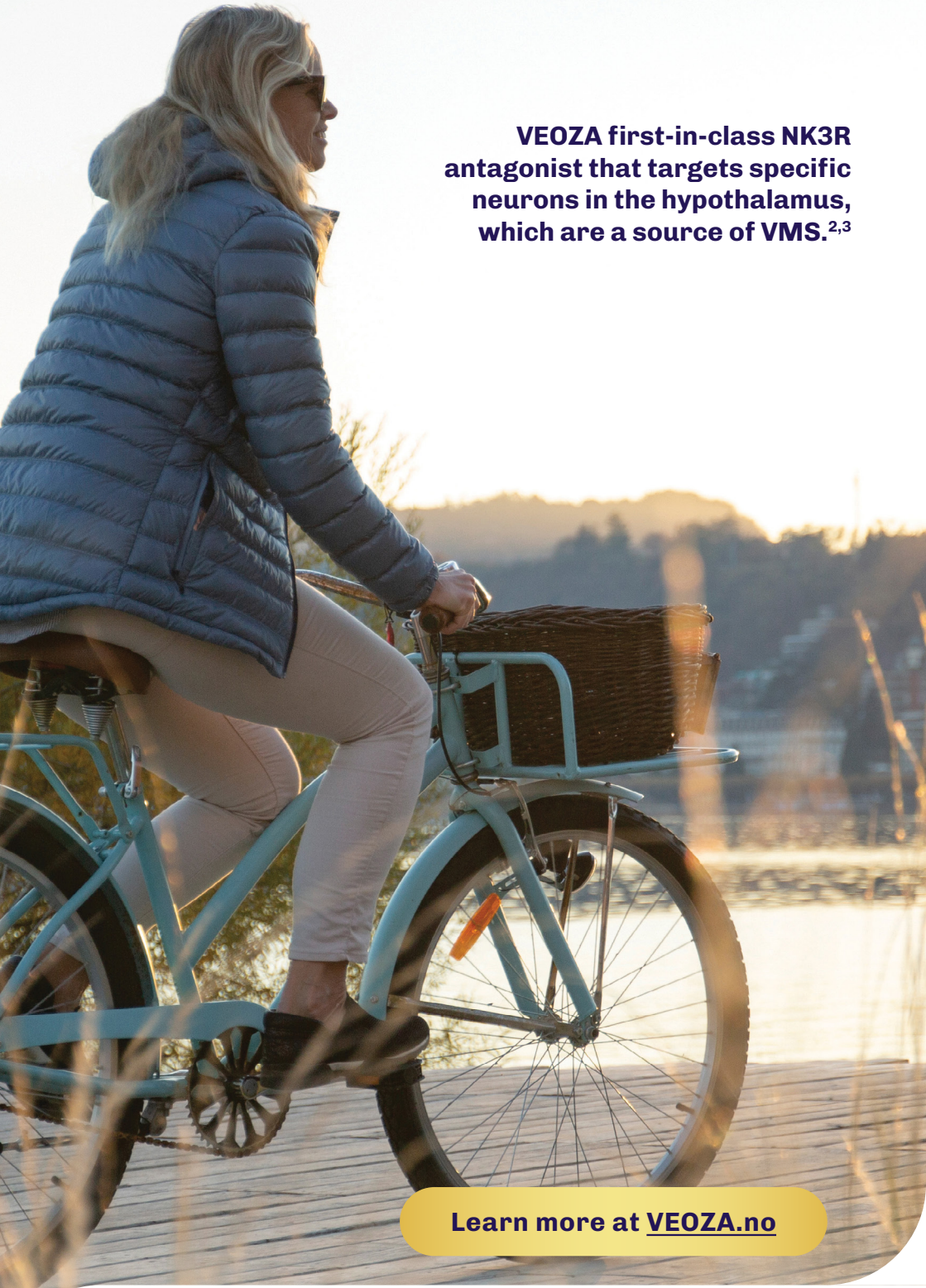
VEOZA™ (fezolinetant) is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause*[1]

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.no

▼ 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

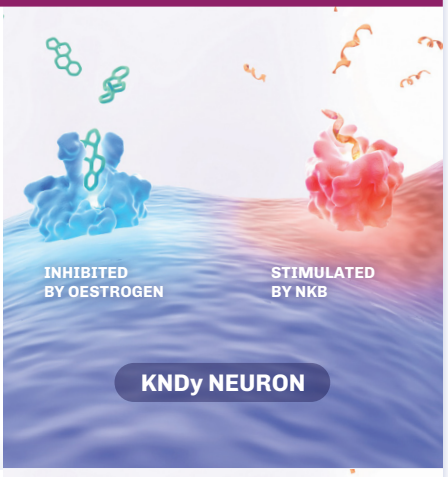
NONHORMONAL

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]

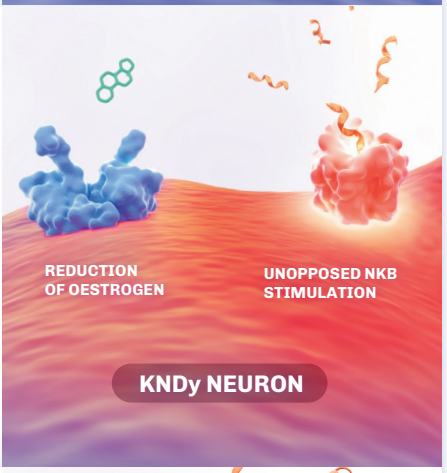
Homeostasis

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]



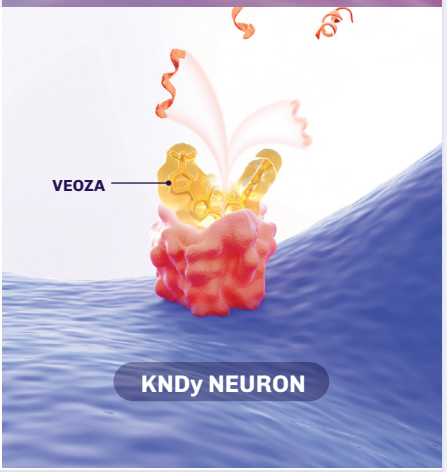
Menopause

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]



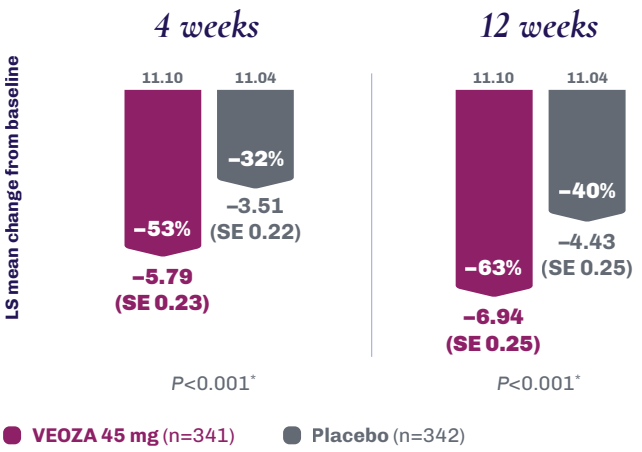
OESTROGEN | OESTROGEN RECEPTOR ALPHA (ERα) | NKB | NK3 RECEPTOR

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

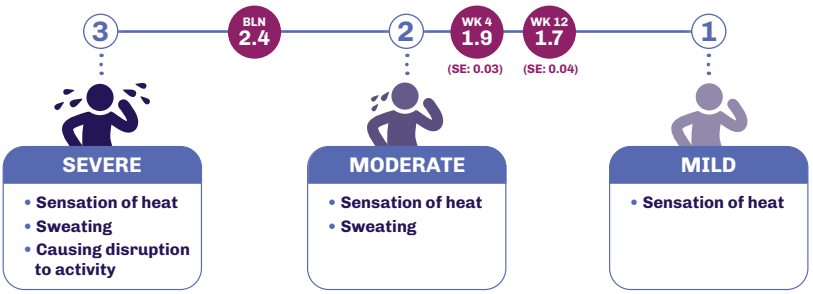
SE=standard error; VMS=vasomotor symptoms

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]

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]

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

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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.

VEOZA™ (fezolinetant) 45 mg filmdrasjerte tabletter

▼**Dette legemiddelet er underlagt særlig overvåking for å oppdage ny sikkerhetsinformasjon så raskt som mulig. Helsepersonell oppfordres til å melde enhver mistenkt bivirkning på elektronisk meldeskjema: www.dmp.no/meldeskjema**

Farmakoterapeutisk gruppe: Middel mot vasomotoriske symptomer ved menopause (G02CX06). **Indikasjoner:** Behandling av moderate til alvorlige vasomotoriske symptomer (VMS) assosiert med menopause (se preparatomtalen (SPC) pkt. 5.1). *__Dosering:__ 45 mg 1 gang daglig. **Kontraindikasjoner:** Overfølsomhet for innholdsstoffene. Samtidig bruk av moderate eller sterke CYP1A2-hemmere. Kjent eller mistenkt graviditet. *__Forsiktighetsregler:__ Diagnosen må inkludere medisinsk (inkl. familie) historie. Under behandlingen skal det utføres periodiske kontroller. Leverfunksjonstester: Skal utføres før behandlingsstart og månedlig i løpet av de tre første månedene med behandling, deretter basert på klinisk vurdering. Behandlingen skal ikke startes eller fortsettes dersom testresultatene oppfyller forhåndsdefinerte kriterier. Pasienten skal informeres om tegn/symptomer på leverskade og rådes til å kontakte lege umiddelbart hvis disse oppstår. Lever-/nyresykdom: Anbefales ikke til personer med Child-Pugh klasse B (moderat) eller C (alvorlig) kronisk leversvikt, eller til personer med alvorlig nedsatt nyrefunksjon. Ikke anbefalt ved onkologisk behandling mot brystkreft eller andre østrogenavhengige maligniteter, eller til kvinner som bruker hormonerstatningsterapi med østrogener (lokale vaginale preparater unntatt). Har ikke blitt studert hos kvinner over 65 år eller hos kvinner med en historie med anfall eller andre krampeforstyrrelser. Dyrestudier har vist reproduksjonstoksisitet. *__Bivirkninger:__ Insomni, diaré, abdominalsmerter, økt ALAT, økt ASAT, alle med frekvens <10%, og legemiddelindusert leverskade (DILI) med ukjent frekvens. **MT-innehaver:** Astellas Pharma Europe B.V., Nederland. **Reseptgruppe:** C **Refusjon:** Nei. **Pakningsstørrelse og pris (pr. 10.02.2025):** *45 mg:* 30 tabletter (blister) 836.90 kr. **Lokal representant:** Astellas Pharma, Tel: +47 66 76 46 00. For mer informasjon se www.felleskatalogen.no

Basert på SPC godkjent: 07.02.2025.

*Avsnittet er omskrevet og/eller forkortet sammenlignet med den godkjente SPC.

Preparatomtalen kan bestilles kostnadsfritt fra den lokale representanten

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