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]

TREAT *the* HEAT

VEOZA A NOVEL NON-HORMONAL APPROACH TO TREATING VMS SYMPTOMS ASSOCIATED WITH MENOPAUSE

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

VEOZA is the first-in-class selective neurokinin 3 (NK3) receptor antagonist to be licensed. It directly blocks neurokinin B (NKB), a known trigger of VMS, from binding on the kisspeptin/neurokinin B/dynorphin (KNDy) neuron.[1,3,4]

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

Contraindications include hypersensitivity to ingredients, concomitant use with moderate/strong CYP1A2 inhibitors, and known or suspected pregnancy. Drug-induced liver injury (DILI) has been reported; perform liver function tests (LFTs) before treatment, monthly for the first 3 months, and as needed. Discontinue if ALT/AST > 5x ULN OR ALT/AST ≥ 3x ULN with: total bilirubin > 2x ULN OR symptoms of liver injury. Common undesirable effects include diarrhea (3.2%) and insomnia (3.0%). Refer to the SmPC for full prescribing details.

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.
See section 4.8 of the SmPC for how to report adverse reactions.

Adverse events should be reported.
For Ireland, Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance, Website: www.hpra.ie or Astellas Pharma Co. Ltd. Tel: +353 1 467 1555, E-mail: irishdrugsafety@astellas.com.

REDEFINE HOW YOU TARGET VMS

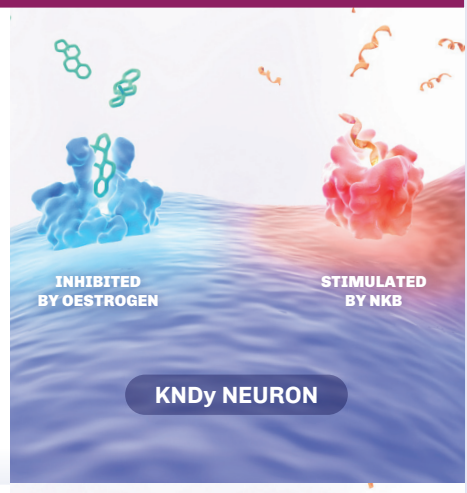
VEOZA IS NOT A HORMONE.[1]

It is the first-in-class selective NK3 receptor antagonist to be licensed. It directly blocks NKB, a known trigger of VMS, from binding on the KNDy neuron.[1,3,4]

Give your eligible patients another way to treat the heat of VMS day and night

Homeostasis

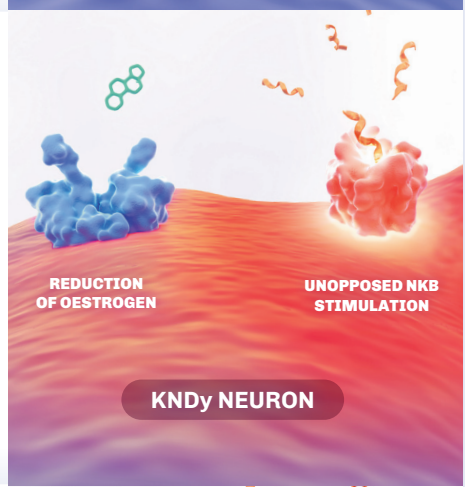
KNDy neurons in the hypothalamus are inhibited by oestrogen and stimulated by the neuropeptide, NKB. This balance contributes to **body temperature regulation**.[3]



Menopause

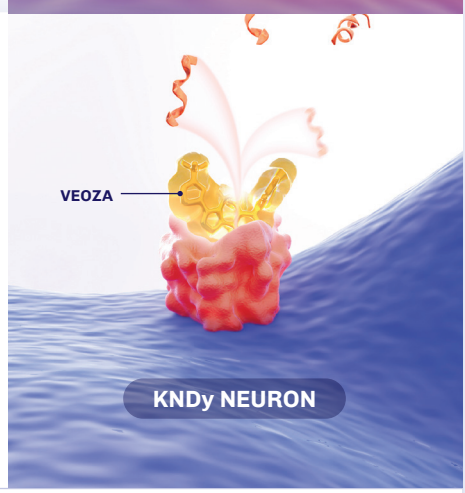
Oestrogen decline during the menopause transition disrupts this balance with NKB. **Unopposed, NKB signalling** causes heightened KNDy neuronal activity.[3]

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, NKB: neurokinin B, NK3: neurokinin 3, ORα: oestrogen receptor alpha, VMS: vasomotor symptoms.

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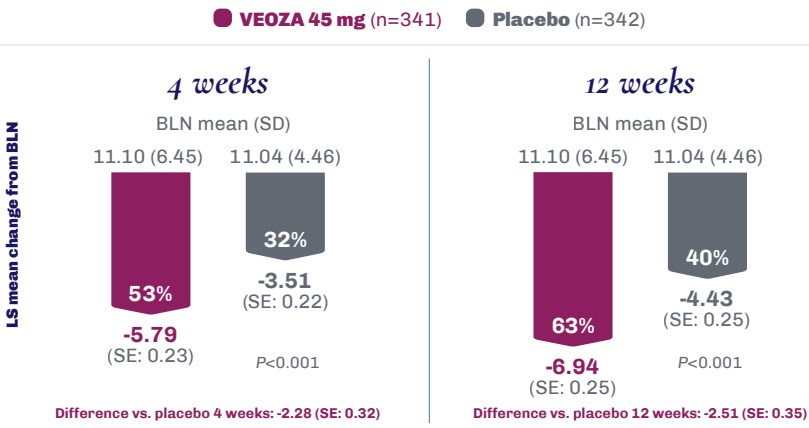
REDUCE FREQUENCY AND SEVERITY OF VMS

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]

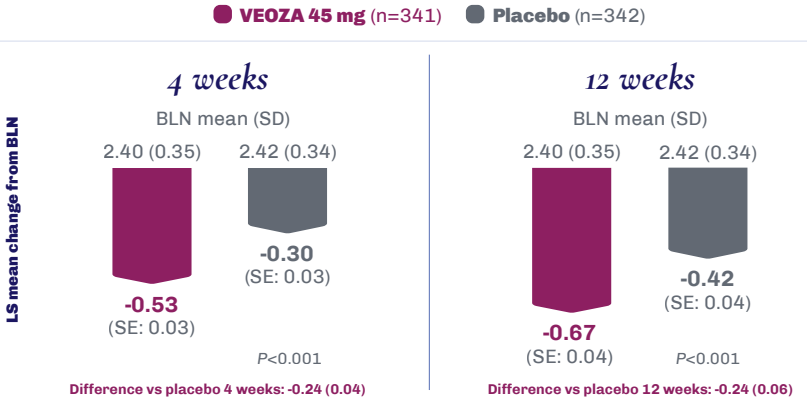
POOLED CO-PRIMARY ENDPOINT DATA FROM THE PHASE 3 STUDIES SKYLIGHT 1 AND SKYLIGHT 2



VEOZA provided a clinically meaningful (≥2 hot flushes per 24 hours) reduction in moderate to severe VMS *over 24 hours vs. placebo at weeks 4 and 12.*[1]

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

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



VEOZA provided a statistically significant reduction in the severity of moderate to severe VMS *over 24 hours vs. placebo at weeks 4 and 12.*[1]

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]

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

Least squares (LS): least squares 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.[1,5,6]

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

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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]

Adverse reaction[1]	Frequency[1]
Diarrhoea	Common*
Abdominal pain	Common*
Insomnia	Common*
Alanine aminotransferase (ALT) increased	Common*
Aspartate aminotransferase (AST) increased	Common*

*Common is a frequency of ≥1/100 to <1/10.

Across the Phase 3 studies, the most common adverse reactions with VEOZA were diarrhoea (3.2%) and insomnia (3.0%).
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. The most serious adverse reaction was an event of endometrial adenocarcinoma (0.1%).[1]

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.

ALT: alanine aminotransferase, AST: aspartate aminotransferase, VMS: vasomotor symptoms.

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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 associated with menopause

VMS: vasomotor symptoms.

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1 TABLET A DAY

DOSING & ADMINISTRATION[1]

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)[1]

45 mg orally once daily[1]

Take with liquids and swallow whole. Do not break, crush, or chew tablets. 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, a double dose should not be taken to make up for a forgotten individual dose.

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[1]

Discontinue VEOZA if[1]:

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

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

Long-term treatment

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.**

Hepatic impairment

VEOZA is not recommended for use in inidividuals with Child-Pugh Class B or C (moderate to severe chronic hepatic impairement). The elderly in special populations.

Elderly

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

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

*eGFR less than 30 ml/min/1.73 m².
**End-stage renal disease is eGFR below 15 ml/min/1.73 m².

eGFR: estimated glomerular filtration rate.

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HELP REDUCE THE IMPACT VMS MAY HAVE ON YOUR ELIGIBLE PATIENTS' DAYS AND NIGHTS[1]

VEOZA IS NOT A HORMONE

It's the first-in-class selective NK3 receptor antagonist to be licensed that directly blocks a source of hot flushes and night sweats.[1,3]

VEOZA MET ALL PRIMARY ENDPOINTS WITHIN THE SKYLIGHT 1 AND SKYLIGHT 2 PHASE 3 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

Reduced VMS frequency and severity in 1 week.[6] Patients taking VEOZA experienced a reduction in the number and severity of VMS.[1]

SAFETY PROFILE 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]

NK3: neurokinin 3, VMS: vasomotor symptoms.

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ABBREVIATED SUMMARY OF PRODUCT CHARACTERISTICS
For full prescribing information refer to the Summary of Product Characteristics (SPC).

▼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. **NAME OF THE MEDICINAL PRODUCT**: Veoza 45 mg film-coated tablets **QUALITATIVE AND QUANTITATIVE COMPOSITION**: Each film-coated tablet contains 45 mg of fezolinetant. For the full list of excipients, see section 6.1 of the SPC. **PHARMACEUTICAL FORM**: Film-coated tablet (tablet). Round, light red tablets (approximately 7 mm diameter × 3 mm thickness), debossed with the company logo and '645' on the same side. **CLINICAL PARTICULARS**: **Therapeutic indications**: Veoza is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause (see section 5.1 of the SPC). **Posology and method of administration**: The recommended dose is 45 mg once daily. Benefit of long-term treatment should be periodically assessed since the duration of VMS can vary by individual. *Missed dose*: If a dose of Veoza is missed or not taken at the usual time, the missed dose should be taken as soon as possible, unless there is less than 12 hours before the next scheduled dose. Individuals should return to the regular schedule the following day. *Elderly*: Fezolinetant has not been studied for safety and efficacy in women initiating Veoza treatment over 65 years of age. No dose recommendation can be made for this population. *Hepatic impairment*: No dose modification is recommended for individuals with Child-Pugh Class A (mild) chronic hepatic impairment (see section 5.2 of the SPC). Veoza is not recommended for use in individuals with Child-Pugh Class B (moderate) or C (severe) chronic hepatic impairment. Fezolinetant has not been studied in individuals with Child-Pugh Class C (severe) chronic hepatic impairment (see section 5.2 of the SPC). *Renal impairment*: No dose modification is recommended for individuals with mild (eGFR 60 to less than 90 ml/min/1.73 m^2) or moderate (eGFR 30 to less than 60 ml/min/1.73 m^2) renal impairment (see section 5.2 of the SPC). Veoza is not recommended for use in individuals with severe (eGFR less than 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 (see section 5.2 of the SPC). *Paediatric population:* There is no relevant use of Veoza in the paediatric population for the indication of moderate to severe VMS associated with menopause. Method of administration: Veoza should be administered orally once daily at about the same time each day with or without food and taken with liquids. Tablets are to be swallowed whole and not broken, crushed, or chewed due to the absence of clinical data under these conditions. **Contraindications**: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the SPC. Concomitant use of moderate or strong CYP1A2 inhibitors (see section 4.5 of the SPC). Known or suspected pregnancy (see section 4.6 of the SPC). **Special warnings and precautions for use**: Medical examination/consultation: 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. Liver disease: Veoza is not recommended for use in individuals with Child-Pugh Class B (moderate) or C (severe) chronic hepatic impairment. Women with active liver disease or Child-Pugh Class B (moderate) or C (severe) chronic hepatic impairment have not been included in the clinical efficacy and safety studies with fezolinetant (see section 4.2 of the SPC) and this information cannot be reliably extrapolated. The pharmacokinetics of fezolinetant has been studied in women with Child-Pugh Class A (mild) and B (moderate) chronic hepatic impairment (see section 5.2 of the SPC). Drug-induced liver injury (DILI): Elevations in serum alanine aminotransferase (ALT) levels and serum aspartate aminotransferase (AST) at least 3 times the upper limit of normal (ULN) were observed in women treated with fezolinetant, including serious cases with increased total bilirubin and symptoms suggesting liver injury. Elevated liver function tests (LFTs) and symptoms suggestive of liver injury were generally reversible on discontinuation of therapy. LFTs must be performed prior to treatment initiation with fezolinetant. Treatment should not be started if ALT or AST is ≥ 2 x ULN or if total bilirubin is elevated (e.g., ≥ 2 x ULN). LFTs must be performed monthly during the first three months of treatment, then based on clinical judgement. LFTs must also be performed when symptoms suggestive of liver injury occur. Treatment should be discontinued in the following situations: - 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. Patients should be informed about the signs and symptoms of liver injury and should be advised to contact their doctor immediately once these occur. Known or previous breast cancer or oestrogen-dependent malignancies: Women undergoing oncologic treatment (e.g., chemotherapy, radiation therapy, anti-hormone therapy) for breast cancer or other oestrogen-dependent malignancies have not been included in the clinical studies. Therefore, Veoza is not recommended for use in this population as the safety and efficacy are unknown. 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 Veoza should be based on a benefit-risk consideration for the individual. Concomitant use of hormone replacement therapy with oestrogens (local vaginal preparations excluded): Concomitant use of fezolinetant and hormone replacement therapy with oestrogens has not been studied, and therefore concomitant use is not recommended. Seizures or other convulsive disorders: Fezolinetant has not been studied in women with a history of seizures or other convulsive disorders. There were no cases of seizures or convulsive disorders during clinical studies. A decision to treat these women with Veoza should be based on a benefit-risk consideration for the individual. **Interactions:** Effect of other medicinal products on fezolinetant: *CYP1A2 inhibitors*: Fezolinetant is primarily metabolised by CYP1A2 and to a lesser extent by CYP2C9 and CYP2C19. Concomitant use of fezolinetant with medicinal products that are moderate or strong inhibitors of CYP1A2 (e.g., ethinyl oestradiol containing contraceptives, mexiletine, enoxacin, fluvoxamine) increase the plasma C_{max} and AUC of fezolinetant. Concomitant use of moderate or strong CYP1A2 inhibitors with Veoza is contraindicated (see section 4.3 of the SPC). Co-administration with fluvoxamine, a strong CYP1A2 inhibitor, resulted in an overall 1.8-fold increase in fezolinetant C_{max} and 9.4-fold increase in AUC; no change in t_{max} was observed. Given the large effect of a strong CYP1A2 inhibitor and supportive modelling, the increase in fezolinetant concentrations is expected to be of clinical concern also following concomitant use with moderate CYP1A2 inhibitors (see section 4.3 of the SPC). The increase in fezolinetant exposure was however not predicted to be clinically relevant following concomitant use with weak CYP1A2 inhibitors. *CYP1A2 inducers: In vivo data:* Smoking (moderate inducer of CYP1A2) decreased fezolinetant C_{max} to a geometric LS mean ratio of 71.74%, while AUC decreased to a geometric LS mean ratio of 48.29%. The efficacy data did not point to relevant differences between smokers and non-smokers. No dose modification is recommended for smokers. *Transporters*: *In vitro data:* Fezolinetant is not a substrate of P-glycoprotein (P-gp). Major metabolite ES259564 is a substrate of P-gp. Effect of fezolinetant on other medicinal products: *Cytochrome P450 (CYP) enzymes*: *In vitro data:* Fezolinetant and ES259564 are not inhibitors of CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, and CYP3A4. Fezolinetant and ES259564 are not inducers of CYP1A2, CYP2B6, and CYP3A4. *Transporters*: *In vitro data:* Fezolinetant and ES259564 are not inhibitors of P-gp, BCRP, OATP1B1, OATP1B3, OCT2, MATE1, and MATE2-K (IC_{50} > 70 µmol/l). Fezolinetant inhibited OAT1 and OAT3 with IC_{50} values of 18.9 µmol/l (30 × $C_{max,u}$) and 27.5 µmol/l (44 × $C_{max,u}$), respectively. ES259564 does not inhibit OAT1 and OAT3 (IC_{50} > 70 µmol/l). **Undesirable effects:** Summary of the safety profile: The most frequent adverse reactions with fezolinetant 45 mg were diarrhoea (3.2%) and insomnia (3.0%). There were no serious adverse reactions reported at an incidence greater than 1% across the total study population. On fezolinetant 45 mg, four serious adverse reactions were reported. The most serious adverse reaction was an event of endometrial adenocarcinoma (0.1%). The most frequent adverse reactions leading to dose discontinuation with fezolinetant 45 mg were alanine aminotransferase (ALT) increased (0.3%) and insomnia (0.2%). Tabulated list of adverse reactions: The safety of fezolinetant has been studied in 2203 women with VMS associated with menopause receiving fezolinetant once daily in phase 3 clinical studies. Adverse reactions observed during clinical studies and from spontaneous reporting are listed below by frequency category in each system organ class. Frequency categories are defined as follows: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1 000 to < 1/100); rare (≥ 1/10 000 to < 1/1 000); very rare (< 1/10 000); and not known (cannot be estimated from the available data). **Table 1. Adverse reactions for fezolinetant 45 mg**

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)*

*see Description of selected adverse reactions Description of selected adverse reactions: *ALT increased/AST increased/DILI*: In clinical trials, elevations in ALT levels > 3 x ULN occurred in 2.1% of women receiving fezolinetant compared to 0.8% of women receiving placebo. Elevations in AST levels > 3 x ULN occurred in 1.0% of women receiving fezolinetant compared to 0.4% of women receiving placebo. 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 (see section 4.4 of the SPC). **Overdose:** Doses of fezolinetant up to 900 mg have been tested in clinical studies in healthy women. At 900 mg, headache, nausea, and paraesthesia were observed. In the case of overdose, the individual should be closely monitored, and supportive treatment should be considered based on signs and symptoms. Reporting of suspected adverse reactions: Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system. **België/Belgique:** Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten / Agence fédérale des médicaments et des produits de santé; www.fagg.be / www.afmps.be; Afdeling Vigilantie / Division Vigilance: Website/Site internet: www.eenbijwerkingmelden.be / www.notifieruneffetindesirable.be; e-mail: adr@fagg-afmps.be **Ireland:** HPRA Pharmacovigilance, Website: www.hpra.ie or Astellas Pharma Co. Ltd. Tel: +353 1 467 1555, E-mail: irishdrugsafety@astellas.com. **Nederland:** Nederlands Bijwerkingen Centrum Lareb; Website: www.lareb.nl **Luxembourg/ Luxemburg** : Centre Régional de Pharmacovigilance de Nancy ou Division de la pharmacie et des médicaments de la Direction de la santé ; Site internet : www.guichet.lu/pharmacovigilance **MARKETING AUTHORISATION HOLDER:** Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, The Netherlands **MARKETING AUTHORISATION NUMBERS:** EU/1/23/1771/001-004 **DATE OF REVISION OF THE TEXT:** February 2025 **Job Bag Number:** MAT-IE-VEO-2025-00015 Detailed information on this medicinal product is available on the website of the European Medicines Agency https://www.ema.europa.eu. **Ireland:** Astellas Pharma Co. Ltd., Tel.: +353 1 467 1555. SPC may be found at www.medicines.ie. Delivery Status: subject to medical prescription. Astellas Pharma B.V., **NL:** Sylviusweg 62, 2333BE Leiden, Netherlands **BE/LU:** Medialaan 50, 1800 Vilvoorde, Belgium **IE: Legal classification:** POM/S1A.

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.