



VEOZA™

fezolinetant

Publieksprijs/Prix Public
VEOZA™ Tab. 45mg x 28 € 64,51

VEOZA™▼ is the first in class selective neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe Vasomotor Symptoms (VMS) associated with menopause, also known as hot flashes and night sweats.^{1,2}



FIGHT *the* FIRE WITH NONHORMONAL VEOZA™

VEOZA™ directly targets a source of VMS—specific neurons in the hypothalamus.¹



Astellas Pharma B.V., Medialaan 50, 1800 Vilvoorde

▼ This medicinal product is subject to additional monitoring. VEOZA™ is available by prescription only.

R.E.: V. Vanderroost Pharm. D., Astellas Pharma B.V. Medialaan 50, 1800 Vilvoorde, Belgium



VEOZA™

fezolinetant



HELP REDUCE THE IMPACT VMS MAY HAVE ON YOUR PATIENTS' DAYS AND NIGHTS.¹



VEOZA™ IS NOT A HORMONE

It's a first-in-class selective NK3 receptor antagonist that directly blocks a source of hot flashes and night sweats.^{1,3}



VEOZA™ SUSTAINED EFFICACY OVER 52 WEEKS

Reduction of VMS frequency and severity observed to weeks 4 and weeks 12. Patients experienced these benefits from week 1 that sustained for 52 weeks¹.



SAFETY PROFILE OVER 52 WEEKS

Across the Phase 3 studies, the most common adverse reactions ($\geq 3\%$) with VEOZA™ 45 mg were diarrhoea (3.2%) and insomnia (3.0%).¹ The most frequent adverse reactions leading to dose discontinuation were alanine aminotransferase (ALT) increased (0.3%) and insomnia (0.2%).¹



ONCE-DAILY DOSING

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

NK3=neurokinin 3.

MAT-BE-VEO-2024-00018 MAY 2024

REDEFINE YOUR TARGET VMS

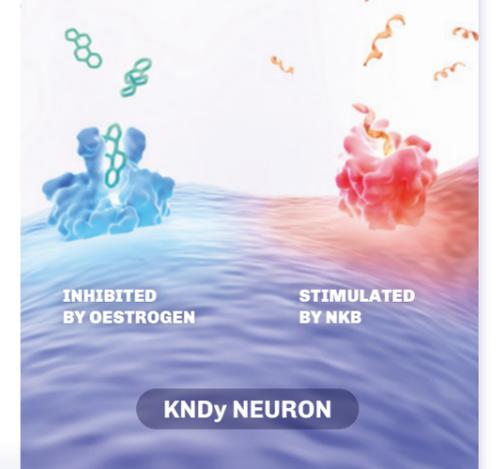


VEOZA™ IS NOT A HORMONE.

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



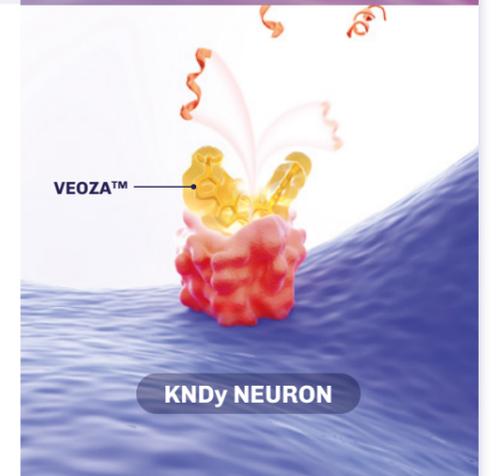
Menopause

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**. This action reduces heat signalling between the temperature control centre to help control hot flashes and night sweats.¹

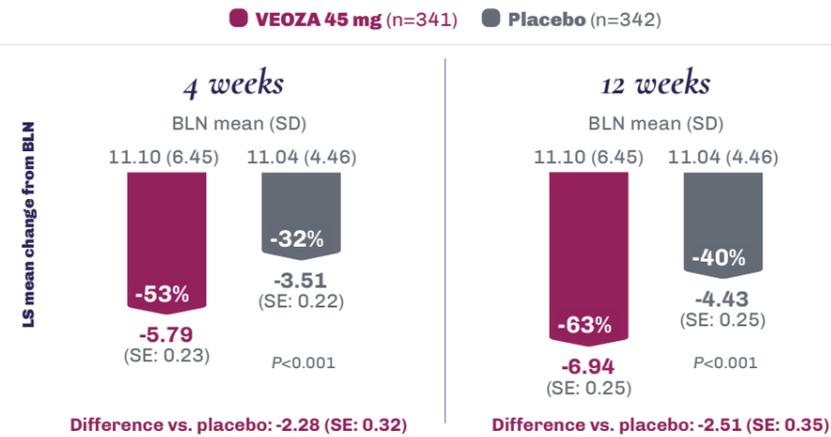


KNDy: kisspeptin/neurokinin B/dynorphin, NKB: neurokinin B. VMS: Vasomotor Symptoms

ACHIEVE FEWER AND LESS SEVERE VMS EPISODES

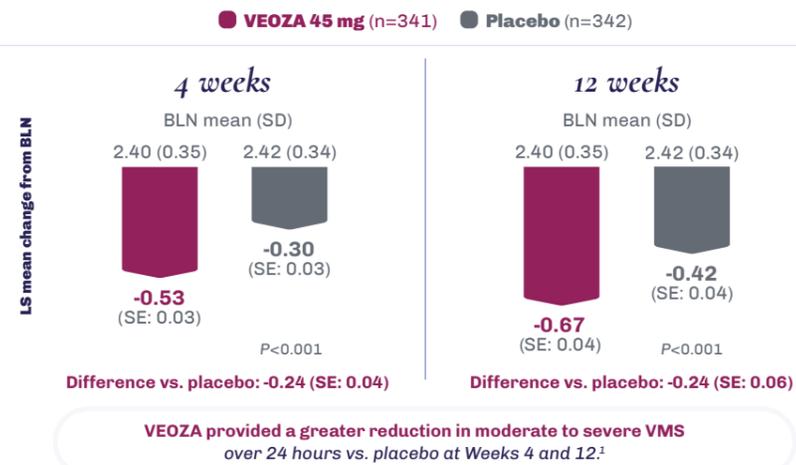
VEOZA™ demonstrates statistically significant reduction in VMS frequency and severity at weeks 4 and 12 vs. placebo.¹

MEAN CHANGE FROM BASELINE IN VMS FREQUENCY¹



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

MEAN CHANGE FROM BASELINE IN VMS SEVERITY¹



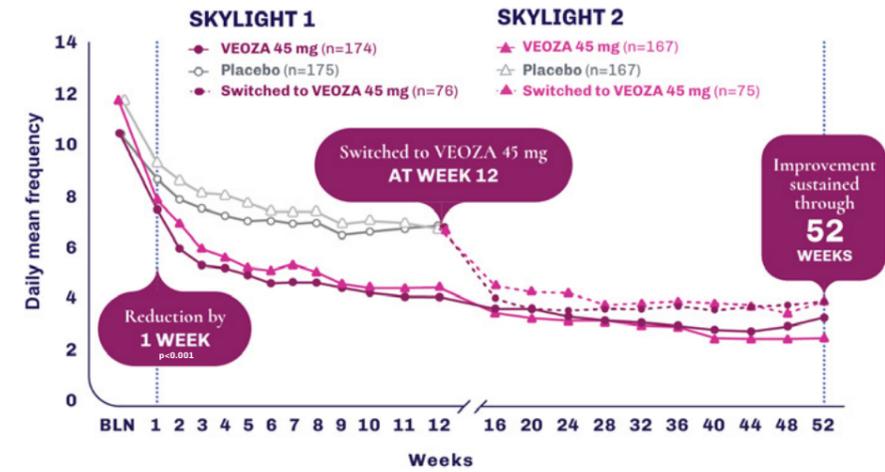
Patients taking VEOZA™ experienced a significant reduction in moderate to severe VMS frequency by Week 4 vs. placebo, which was sustained through 52 weeks.¹

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

RELIEF THAT WORKS FAST AND LASTS¹

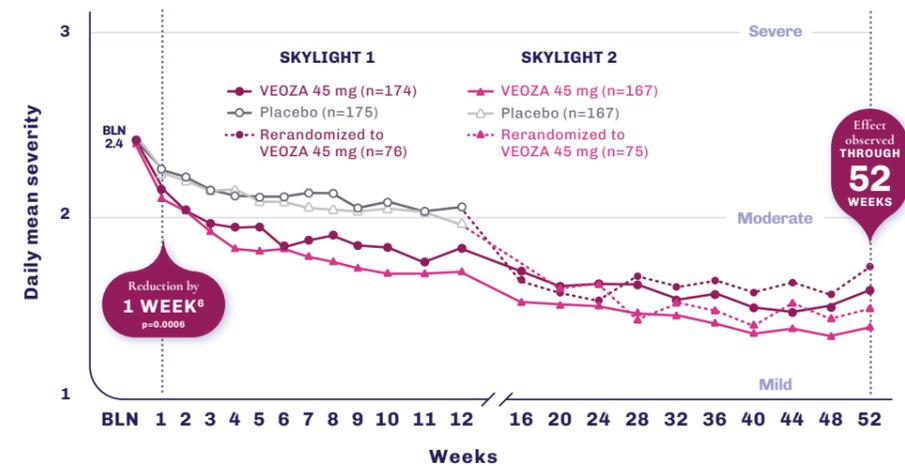
From week 1, patients taking VEOZA™ experienced a reduction in VMS frequency and severity, which was sustained through 52 weeks^{5,6}

MEAN CHANGE FROM BASELINE IN VMS FREQUENCY^{1,5,6}



The effect of VEOZA™ on VMS severity was evident by week 1 and was observed through 52 weeks^{5,6}

MEAN CHANGE FROM BASELINE IN VMS SEVERITY^{1,5,6}



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

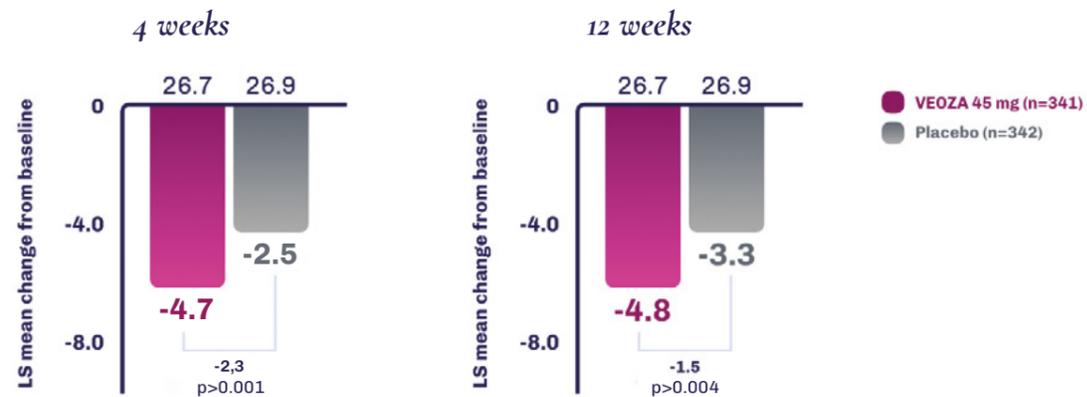
SLEEP

PATIENTS REPORTED SLEEP IMPROVEMENT⁷

- VMS can be associated with sleep disturbance. Hot flush negatively impacts sleep in 82% of women who reported at least moderate VMS.⁷ These sleep problems can lead to substantial impacts on quality-of-life, including affecting work productivity, healthcare utilization, and physical and mental health.⁷
- The effect of VEOZA™ on patient-reported sleep disturbance and impairment in individuals with VMS is analyzed using pooled data from SKYLIGHT 1 and 2 studies.⁷
- Sleep assessment : Patient-Reported Outcomes Measurement Information System Sleep disturbance with PROMIS SD SF 8b.⁷
 - Restless sleep
 - Satisfaction with sleep
 - Refreshing sleep
 - Difficulties sleeping
 - Difficulties getting to sleep
 - Difficulties staying asleep
 - Amount of sleep
 - Sleep quality
- Overall, 1,022 individuals were randomized and took ≥1 dose of study drug.⁷

PROMIS SD SF 8B⁷

MEAN CHANGE FROM BASELINE TO WEEK 12 IN TOTAL SCORE



SUMMARY⁷

- VEOZA™ 45mg had a beneficial effect on sleep disruption.⁷
- Favorable results were obtained by week 4 and maintained through 12 weeks.⁷

EVALUATED FOR SAFETY

SAFETY PROFILE¹

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

- The most frequent adverse reactions with fezolinetant 45 mg were diarrhea (3.2%) and insomnia (3.0%).¹
- There were no serious adverse reactions reported at an incidence greater than 1% across the total study population. The most serious adverse reaction was an event of endometrial adenocarcinoma (0.1%).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%).¹
 - Elevations in alanine-aminotransferase (ALT) level at least 3 times the upper limit of normal (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.
 - Elevated liver function tests (LFTs) and symptoms suggestive of liver injury were generally reversible on discontinuation of therapy.
- In the post-marketing setting drug-induced liver injury (DILI) has been reported: limited number of severe cases with elevations of ALT and/or AST (>10 x ULN) with concurrent elevations in bilirubin and/or alkaline phosphatase (ALP) were reported. In some cases, elevated liver function tests were associated with complaints such as fatigue, pruritus, jaundice, dark urine, pale faeces, nausea, vomiting, decreased appetite, and/or abdominal pain.¹

CONTRAINDICATIONS¹

- Hypersensitivity to the active substance or to any of the excipients.
- Concomitant use of moderate or strong CYP1A2 inhibitors
- Known or suspected pregnancy

HOW TO USE¹



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 $\geq 2x$ ULN or if total bilirubin is elevated (eg, $\geq 2x$ ULN)¹



Once-daily dosing

One pill, one dose, once a day, no titration necessary

Instruct your patients to take with liquids and swallow whole. Do not cut, crush, or chew tablets. Can be taken with or without food¹

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 day¹



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 occur¹

Discontinue VEOZA™ if¹:

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

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

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

Early liver function monitoring may ensure VEOZA™ remains an appropriate treatment choice for your patients. It might also provide a valuable opportunity to check in with patients on their progress with VEOZA

WOMEN ELIGIBLE FOR TREATMENT



Hormone therapy is contraindicated



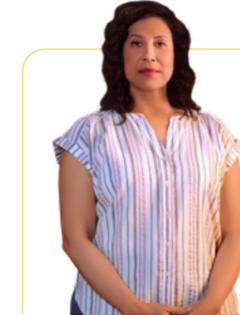
Does not want hormone therapy



Need to stop hormone therapy



Needs to be cautious with HT



Her primary concern is hot flashes and night sweats





Belgium-NL (including price)

Follow link or scan QR code for the VEOZA™ Summary of Product characteristics

www.astellas.com/be/nl/products



Belgium-FR (including price)

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REFERENCES: **1.** VEOZA™ (fezolinetant): Summary of Product Characteristics, Astellas. **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, Fraser GL. Fezolinetant in the treatment of vasomotor symptoms associated with menopause. Expert Opin Investig Drugs 2021; 30(7):681-94. **4.** Jayasena CN, Comminos 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.** Shapiro M, et al. Effect of fezolinetant on sleep disturbance and impairment during treatment of vasomotor symptoms due to menopause. Maturitas 2024;186:107999



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Reduction of VMS frequency and severity observed to weeks 4 and weeks 12. Patients experienced these benefits from week 1 that sustained for 52 weeks¹.



SAFETY PROFILE OVER 52 WEEKS

Across the Phase 3 studies, the most common adverse reactions ($\geq 3\%$) with VEOZA™ 45 mg were diarrhoea (3.2%) and insomnia (3.0%).¹ The most frequent adverse reactions leading to dose discontinuation were alanine aminotransferase (ALT) increased (0.3%) and insomnia (0.2%).¹



ONCE-DAILY DOSING

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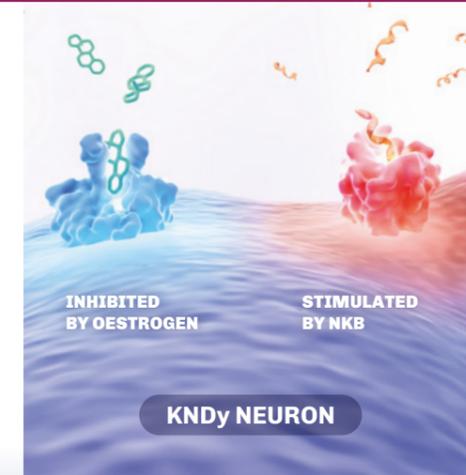


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Homeostasis

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



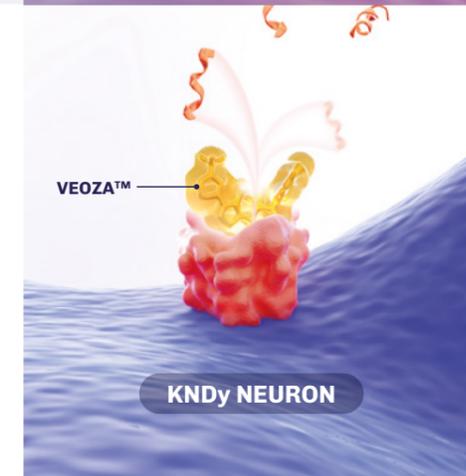
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Oestrogen decline during the menopause transition disrupts this balance with NKB. **Unopposed, NKB signalling** causes heightened KNDy neuronal activity.³ This **triggers heat dissipation** mechanisms, including vasodilation and sweating—VMS.³



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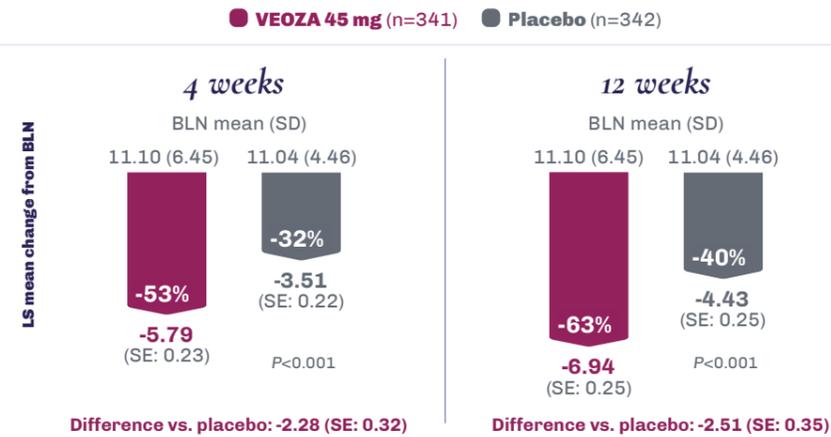


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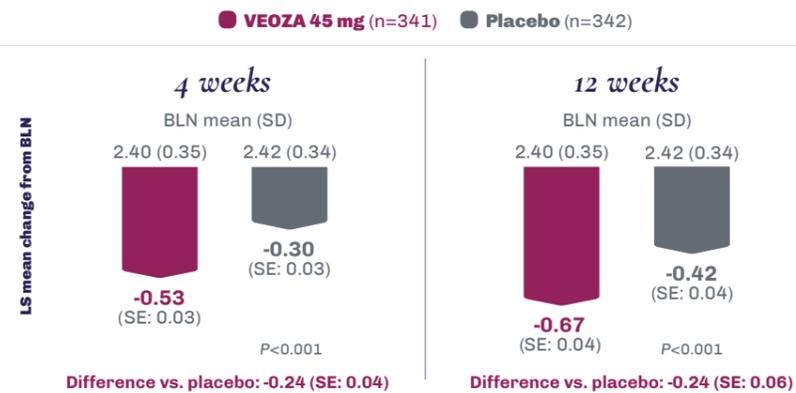
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Frequency and severity data contain a pooled analysis of SKYLIGHT 1 and SKYLIGHT 2. Least squares (LS) mean estimated from a mixed model for repeated measures analysis of covariance.¹

MEAN CHANGE FROM BASELINE IN VMS SEVERITY¹



VEOZA provided a greater reduction in moderate to severe VMS over 24 hours vs. placebo at Weeks 4 and 12.¹



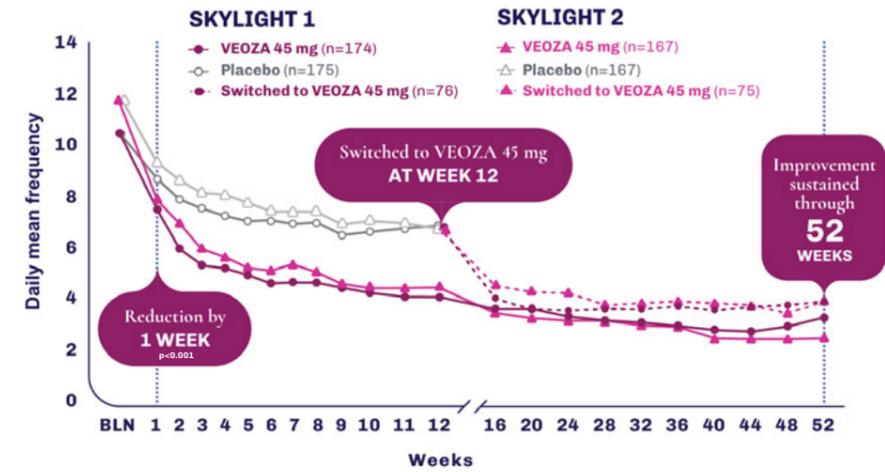
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BLN: baseline, LS: least squares, SD: standard deviation, SE: standard error, VMS: vasomotor symptoms.

RELIEF THAT WORKS FAST AND LASTS¹

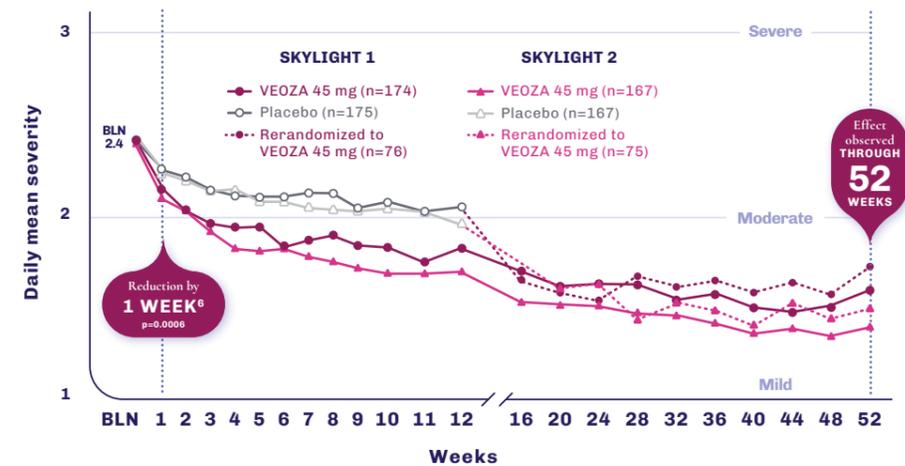
From week 1, patients taking VEOZA™ experienced a reduction in VMS frequency and severity, which was sustained through 52 weeks^{5,6}

MEAN CHANGE FROM BASELINE IN VMS FREQUENCY^{1,5,6}



The effect of VEOZA™ on VMS severity was evident by week 1 and was observed through 52 weeks^{5,6}

MEAN CHANGE FROM BASELINE IN VMS SEVERITY^{1,5,6}



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

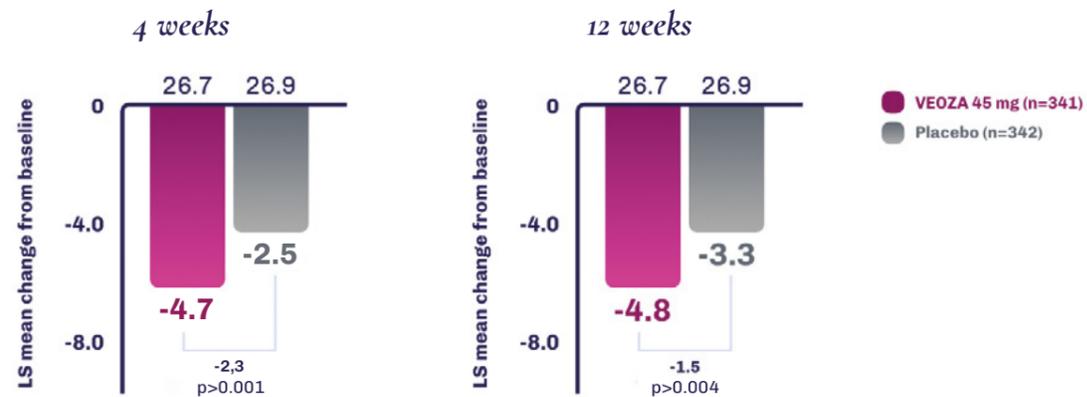
SLEEP

PATIENTS REPORTED SLEEP IMPROVEMENT⁷

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 - Sleep quality
- Overall, 1,022 individuals were randomized and took ≥1 dose of study drug.⁷

PROMIS SD SF 8B⁷

MEAN CHANGE FROM BASELINE TO WEEK 12 IN TOTAL SCORE



SUMMARY⁷

- VEOZA™ 45mg had a beneficial effect on sleep disruption.⁷
- Favorable results were obtained by week 4 and maintained through 12 weeks.⁷

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SAFETY PROFILE¹

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

- The most frequent adverse reactions with fezolinetant 45 mg were diarrhea (3.2%) and insomnia (3.0%).¹
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CONTRAINDICATIONS¹

- Hypersensitivity to the active substance or to any of the excipients.
- Concomitant use of moderate or strong CYP1A2 inhibitors
- Known or suspected pregnancy

HOW TO USE¹



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 $\geq 2x$ ULN or if total bilirubin is elevated (eg, $\geq 2x$ ULN)¹



Once-daily dosing

One pill, one dose, once a day, no titration necessary

Instruct your patients to take with liquids and swallow whole. Do not cut, crush, or chew tablets. Can be taken with or without food¹

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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 occur¹

Discontinue VEOZA™ if¹:

- Transaminase elevations are $\geq 3x$ ULN with: total bilirubin $> 2x$ ULN OR symptoms of liver injury
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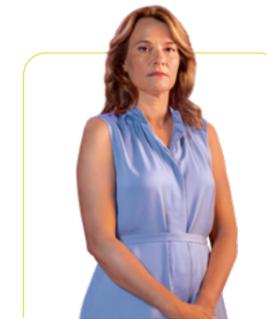
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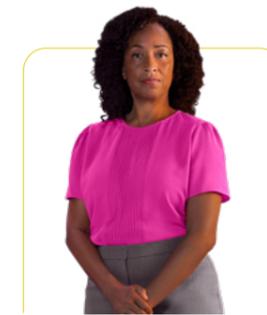
Hormone therapy is contraindicated



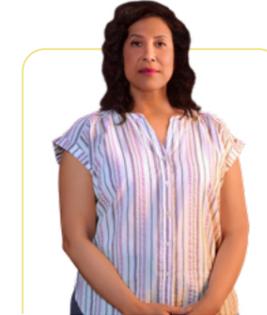
Does not want hormone therapy



Need to stop hormone therapy



Needs to be cautious with HT



Her primary concern is hot flashes and night sweats





Belgium-FR (including price)

Follow link or scan QR code for
the VEOZA™ Summary of Product
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www.astellas.com/be/fr/products

REFERENCES: **1.** VEOZA™ (fezolinetant): Summary of Product Characteristics, Astellas. **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, Fraser GL. Fezolinetant in the treatment of vasomotor symptoms associated with menopause. Expert Opin Investig Drugs 2021; 30(7):681-94. **4.** Jayasena CN, Comminos 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.** Shapiro M, et al. Effect of fezolinetant on sleep disturbance and impairment during treatment of vasomotor symptoms due to menopause. Maturitas 2024;186:107999



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astellas

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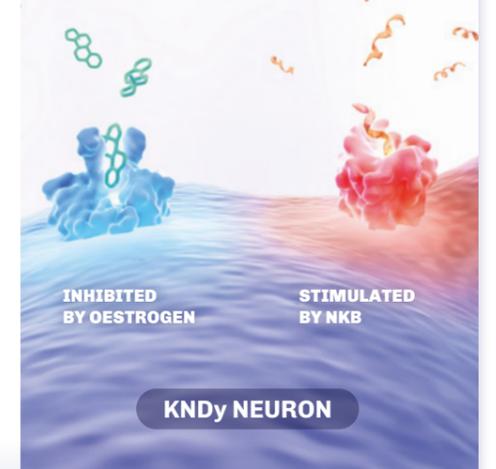


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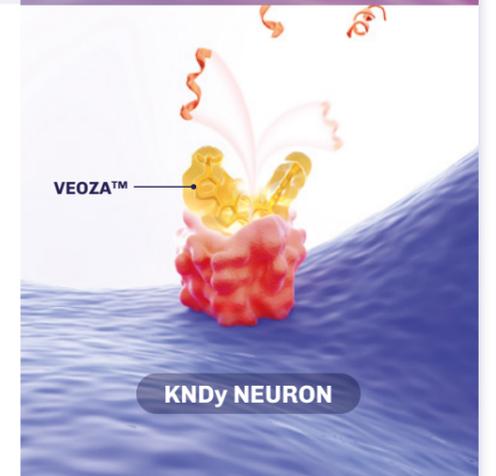
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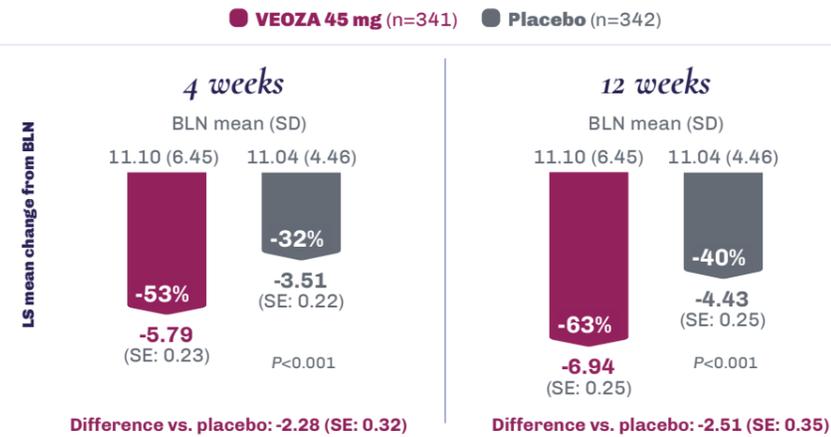


KNDy: kisspeptin/neurokinin B/dynorphin, NKB: neurokinin B. VMS: Vasomotor Symptoms

ACHIEVE FEWER AND LESS SEVERE VMS EPISODES

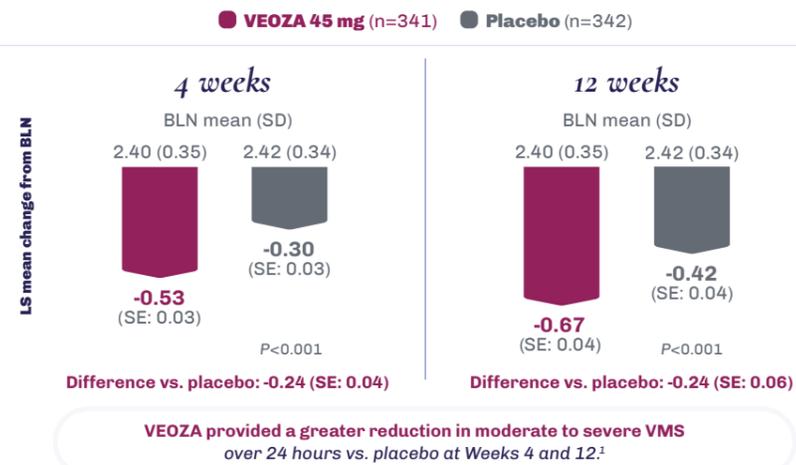
VEOZA™ demonstrates statistically significant reduction in VMS frequency and severity at weeks 4 and 12 vs. placebo.¹

MEAN CHANGE FROM BASELINE IN VMS FREQUENCY¹



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

MEAN CHANGE FROM BASELINE IN VMS SEVERITY¹



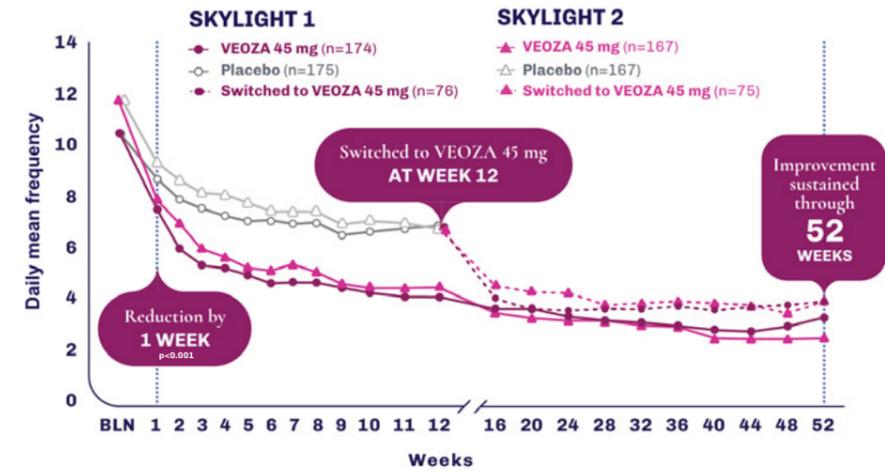
Patients taking VEOZA™ experienced a significant reduction in moderate to severe VMS frequency by Week 4 vs. placebo, which was sustained through 52 weeks.¹

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

RELIEF THAT WORKS FAST AND LASTS¹

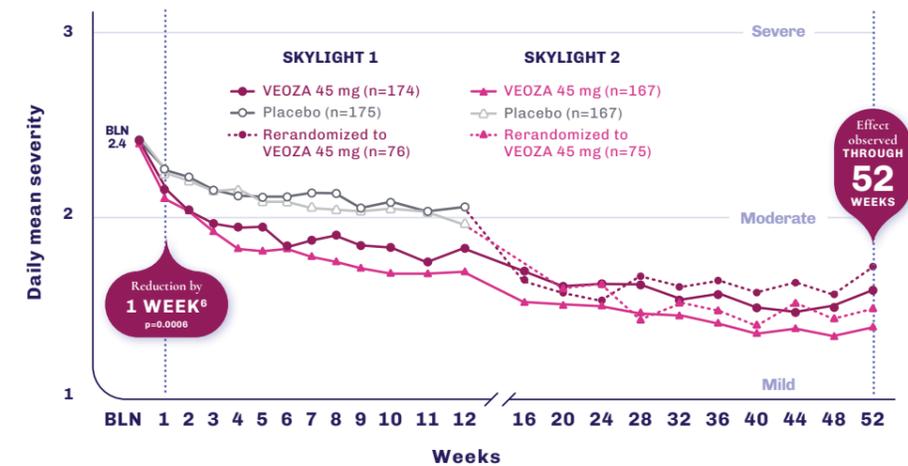
From week 1, patients taking VEOZA™ experienced a reduction in VMS frequency and severity, which was sustained through 52 weeks^{5,6}

MEAN CHANGE FROM BASELINE IN VMS FREQUENCY^{1,5,6}



The effect of VEOZA™ on VMS severity was evident by week 1 and was observed through 52 weeks^{5,6}

MEAN CHANGE FROM BASELINE IN VMS SEVERITY^{1,5,6}



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

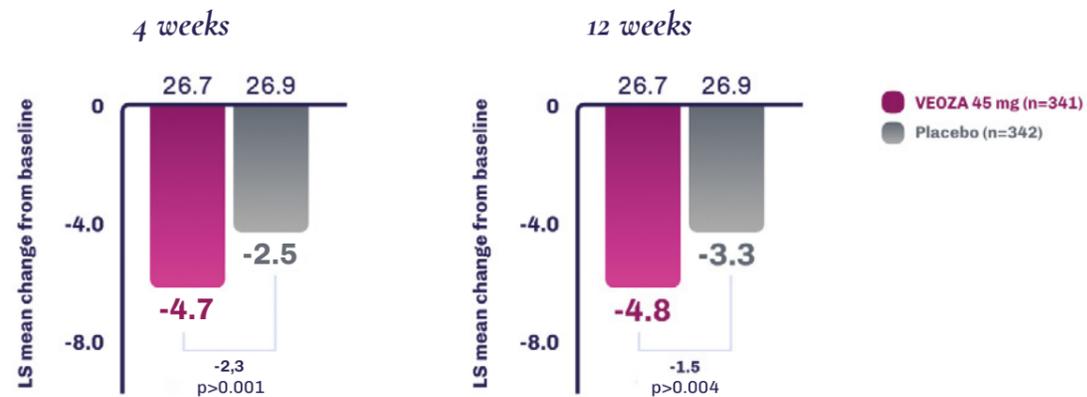
SLEEP

PATIENTS REPORTED SLEEP IMPROVEMENT⁷

- VMS can be associated with sleep disturbance. Hot flush negatively impacts sleep in 82% of women who reported at least moderate VMS.⁷ These sleep problems can lead to substantial impacts on quality-of-life, including affecting work productivity, healthcare utilization, and physical and mental health.⁷
- The effect of VEOZA™ on patient-reported sleep disturbance and impairment in individuals with VMS is analyzed using pooled data from SKYLIGHT 1 and 2 studies.⁷
- Sleep assessment : Patient-Reported Outcomes Measurement Information System Sleep disturbance with PROMIS SD SF 8b.⁷
 - Restless sleep
 - Satisfaction with sleep
 - Refreshing sleep
 - Difficulties sleeping
 - Difficulties getting to sleep
 - Difficulties staying asleep
 - Amount of sleep
 - Sleep quality
- Overall, 1,022 individuals were randomized and took ≥1 dose of study drug.⁷

PROMIS SD SF 8B⁷

MEAN CHANGE FROM BASELINE TO WEEK 12 IN TOTAL SCORE



SUMMARY⁷

- VEOZA™ 45mg had a beneficial effect on sleep disruption.⁷
- Favorable results were obtained by week 4 and maintained through 12 weeks.⁷

EVALUATED FOR SAFETY

SAFETY PROFILE¹

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

- The most frequent adverse reactions with fezolinetant 45 mg were diarrhea (3.2%) and insomnia (3.0%).¹
- There were no serious adverse reactions reported at an incidence greater than 1% across the total study population. The most serious adverse reaction was an event of endometrial adenocarcinoma (0.1%).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%).¹
 - Elevations in alanine-aminotransferase (ALT) level at least 3 times the upper limit of normal (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.
 - Elevated liver function tests (LFTs) and symptoms suggestive of liver injury were generally reversible on discontinuation of therapy.
- In the post-marketing setting drug-induced liver injury (DILI) has been reported: limited number of severe cases with elevations of ALT and/or AST (>10 x ULN) with concurrent elevations in bilirubin and/or alkaline phosphatase (ALP) were reported. In some cases, elevated liver function tests were associated with complaints such as fatigue, pruritus, jaundice, dark urine, pale faeces, nausea, vomiting, decreased appetite, and/or abdominal pain.¹

CONTRAINDICATIONS¹

- Hypersensitivity to the active substance or to any of the excipients.
- Concomitant use of moderate or strong CYP1A2 inhibitors
- Known or suspected pregnancy

HOW TO USE¹



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 $\geq 2x$ ULN or if total bilirubin is elevated (eg, $\geq 2x$ ULN)¹



Once-daily dosing

One pill, one dose, once a day, no titration necessary

Instruct your patients to take with liquids and swallow whole. Do not cut, crush, or chew tablets. Can be taken with or without food¹

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 day¹



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 occur¹

Discontinue VEOZA™ if¹:

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

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

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

Early liver function monitoring may ensure VEOZA™ remains an appropriate treatment choice for your patients. It might also provide a valuable opportunity to check in with patients on their progress with VEOZA

WOMEN ELIGIBLE FOR TREATMENT



Hormone therapy is contraindicated



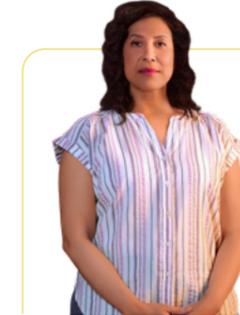
Does not want hormone therapy



Need to stop hormone therapy



Needs to be cautious with HT



Her primary concern is hot flashes and night sweats





Netherlands

Follow link or scan QR code for the VEOZA™ Summary of Product characteristics

www.astellas.com/nl/products

REFERENCES: **1.** VEOZA™ (fezolinetant): Summary of Product Characteristics, Astellas. **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, Fraser GL. Fezolinetant in the treatment of vasomotor symptoms associated with menopause. *Expert Opin Investig Drugs* 2021; 30(7):681-94. **4.** Jayasena CN, Comminos 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.** Shapiro M, et al. Effect of fezolinetant on sleep disturbance and impairment during treatment of vasomotor symptoms due to menopause. *Maturitas* 2024;186:107999