VEOZA™
fezolinetant

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This promotional item has been developed by Astellas and is intended for UK Healthcare Professionals only.

CASE STUDY COMPENDIUM

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These case studies were collated by UK Healthcare Professionals.

The patients in the studies have all given their permission for their anonymised case studies to be collated by Astellas Pharma and used in educational and promotional materials.

The content included in each case study is an accurate summary and provides a fair representation of the patient's experience of the information provided by the treating clinician.

Please be aware that unless otherwise indicated, the case studies included in this compendium were completed before the requirement for liver monitoring upon the initiation of VEOZA.

For complete details on the liver monitoring requirements in the UK, please refer to page 10.

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

For further information on VEOZA (fezolinetant) please scan or click on the QR code to visit our website www.veoza.co.uk

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AGE	ONSET OF VMS	TREATMENT DURATION
57	4 years	12 months

MEDICAL HISTORY AND COMORBIDITIES

- Atrial Fibrillation
- Hypertension
- Chronic Kidney Disease
- Vertigo

ADVERSE EVENTS

None reported

SYMPTOMS AT INITIATION

- Completely unable to sleep due to night sweats
- On a bad day/night hot flushes every 15 minutes
- Severe impact on daily life
- Exhausted due to lack of sleep
- Interfering with daily functioning

BASIS FOR TREATMENT DECISION

- HRT caused bleeding problems
- Did not want Tibolone due to stroke risk
- Did not want side effects associated with Oxybutynin^

VMS AT INITIATION

Severe
40+ hot flushes in 24 hours

VMS AT 3 MONTHS OF VEOZA TREATMENT

Mild/Moderate
0 hot flushes at night
0-10 in the day

RESPONSE TO TREATMENT WITH VEOZA

- Good – 50-60% reduction in hot flushes
- No more night sweats, resulting in dramatically improved sleep
- Some hot flushes in the day but much more manageable

CLINICIAN'S COMMENTS

"I think it's impossible to overestimate the impact that improved sleep quality has on wellbeing. This lady was struggling to function, her life ruled by night sweats and hot flushes occurring day and night. She felt exhausted.

VEOZA reduced the frequency of VMS, but had a particularly beneficial impact on symptoms during the night, allowing her sleep, energy levels and brain function to recover.

She was extremely averse to HRT and so relieved to find an effective treatment she could have.

She still experiences good and not so good days but the improvement in her sleep quality has enabled normal functioning.

My patient is relieved to have found a suitable treatment for her".

VEOZA is not recommended in patients with severe renal impairment or with end-stage renal disease.

^Oxybutynin is not licensed for vasomotor symptoms associated with menopause and therefore this treatment would be off-label.

HRT, hormone replacement therapy.

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AGE	ONSET OF VMS	TREATMENT DURATION
57	3 years	6 months

MEDICAL HISTORY AND COMORBIDITIES

- Factor V Leiden homozygous status

ADVERSE EVENTS

None reported

SYMPTOMS AT INITIATION

- Hot flushes, night sweats, low mood and sleep disturbance
- Experiencing intense heat and redness in face which was having adverse impact on her home and work life

BASIS FOR TREATMENT DECISION

- Patient did not want HRT due to increased risk of blood clot with Factor V Leiden homozygous status
- Did not want SSRI* as not depressed

VMS AT INITIATION

Moderate to Severe
10-12 hot flushes in 24 hours

VMS AT 6 MONTHS OF VEOZA TREATMENT

2-3 hot flushes in 24 hours

RESPONSE TO TREATMENT WITH VEOZA

- Symptoms improved from week 3 with reduced hot flushes, better sleep and improved quality of life
- Patient's day to day functioning improved at home and work

*SSRIs are not licensed for vasomotor symptoms associated with menopause, therefore this treatment would be off-label.

HRT, hormone replacement therapy; SSRI, selective serotonin reuptake inhibitors.

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CLINICIAN'S COMMENTS

Symptoms improved from week 3 of taking VEOZA.
Patient has improved quality of life.

Patient is satisfied with quality of life using VEOZA and vaginal oestrogen*.

"She was otherwise fit and healthy with a BMI of 24 and following a healthy diet and practising weight bearing exercises on a regular basis. She had been to her GP who had prescribed her vaginal oestrogen pessaries for genitourinary symptoms and offered an SSRI** (medication) for vasomotor symptoms and low mood. The GP had referred her to a specialist menopause clinic for advice about transdermal HRT. She started using vaginal oestrogen with good benefit however didn't start the SSRI** as she felt she wasn't depressed.

In the specialist menopause clinic, there was discussion about non-HRT as well as hormonal treatments for hot flushes, night sweats and sleep disturbance. Although evidence about long-term safety of transdermal HRT is minimal related to specific conditions like factor V Leiden, clinical experience suggests that transdermal HRT can be a treatment option for her.

She was not willing to try systemic HRT due to concerns about thrombosis/stroke and decided to opt for an alternative non-hormonal therapy; fezolinetant. She started taking an oral 45mg VEOZA tablet daily and had a follow up after 6 months of treatment with fezolinetant. Her hot flushes, night sweats and sleep improved from the third week of taking fezolinetant and she was satisfied with her current quality of life; combining fezolinetant and vaginal oestrogen*. She had not noticed any side effects.

She was on the waiting list for menopause CBT through her GP however felt that she may not pursue this anymore."

*Concomitant use of fezolinetant and hormone replacement therapy with oestrogens (local vaginal preparations excluded) has not been studied, and therefore concomitant use is not recommended.

**SSRIs are not licensed for vasomotor symptoms associated with menopause, therefore this treatment would be off-label.

SSRIs, selective serotonin reuptake inhibitors; VMS, vasomotor symptoms; HRT, hormone replacement therapy; CBT, cognitive behaviour therapy.

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AGE	ONSET OF VMS	TREATMENT DURATION
55	2 years	6 months

MEDICAL HISTORY AND COMORBIDITIES

- Hypothyroidism
- Cyclical PMS symptoms

ADVERSE EVENTS

None reported

SYMPTOMS AT INITIATION

- Hot flushes – intense sensation of heat around face and neck
- Brain fog
- Night sweats
- Fluctuating mood
- Vaginal dryness

BASIS FOR TREATMENT DECISION

- Breakthrough bleeding on HRT
- Progestrogen sensitivity (low mood and bloating)

VMS AT INITIATION

Moderate to Severe
12-15 hot flushes in 24 hours

VMS AT 6 MONTHS OF VEOZA TREATMENT

3-4 hot flushes in 24 hours

RESPONSE TO TREATMENT WITH VEOZA

- Reduction in hot flushes and night sweats
- Improved quality of life
- Improved sleep

HRT, hormone replacement therapy; VMS, vasomotor symptoms.

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CLINICIAN'S COMMENTS

"A 55-year-old woman was referred to the clinic with persistent breakthrough bleeding on HRT for menopause and progestogen sensitivity symptoms.

She had tried various preparations for HRT including transdermal oestrogen (patches and gel) combined with natural micronised progesterone and medroxyprogesterone acetate (both cyclically and continuous) but had suffered from constant breakthrough bleeding. She did not want to have an intrauterine progestogen coil. She had also experienced side effects from progestogens such as low mood, bloating and fluid retention.

She had multiple pelvic ultrasound scans over two years and two hysteroscopy procedures which did not reveal any pathology.

Her medical history included past history of premenstrual symptoms and hypothyroidism (for which she took levothyroxine 75 mcg daily orally).

She had reached a point in her treatment journey where the side effects of HRT were adversely impacting her life, and she wanted non-hormonal treatments. She discussed fezolinetant and started with 45 mg daily dose. She noticed a rapid improvement in her hot flushes within the first two weeks and continued to have good suppression of hot flushes at the 6-month follow up. She is also using vaginal oestrogen* for genitourinary symptoms alongside fezolinetant.

The reduction in hot flushes and improved sleep has improved her overall functioning and quality of life."

*Concomitant use of fezolinetant and hormone replacement therapy with oestrogens (local vaginal preparations excluded) has not been studied, and therefore concomitant use is not recommended.

HRT, hormone replacement therapy.

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AGE	ONSET OF VMS	TREATMENT DURATION
55	4 months	3 months

MEDICAL HISTORY AND COMORBIDITIES

- Postnatal depression
- Anxiety
- Abdominoplasty
- Hypertension
- Vestibular balance disorder
- Hay fever

ADVERSE EVENTS

None reported

SYMPTOMS AT INITIATION

- Had been taking HRT but experienced unscheduled bleeding
- Stopped HRT and hot flushes and night sweats had returned
- Hot flushes day and night necessitates a fan
- Sleep affected

BASIS FOR TREATMENT DECISION

- Non-hormonal options were discussed e.g. Venlafaxine* and Oxybutynin** but explained that not all are licenced
- Felt that Fezolinetant offered a licensed option with a favourable side effect profile

VMS AT INITIATION

Severe
20 hot flushes in 24 hours

VMS AT 3 MONTHS OF VEOZA TREATMENT

1 hot flush in 24 hours

RESPONSE TO TREATMENT WITH VEOZA

- Severity of VMS changed from severe at baseline to mild at month 3
- Frequency of hot flushes reduced
- Patient's sleep improved
- Improved quality of life

LIVER FUNCTION TESTING

Liver function tests performed and all results normal. Will continue with annual liver function testing***.

Please see page 10 for details of the requirements for liver function testing with VEOZA.

CLINICIAN'S COMMENTS

"Patient is now sleeping well as the VMS have no impact on her life. She notices she gets a small rise in temperature early evening. Has given her quality of life back without the side effect of bleeding."

*Venlafaxine is not licensed for the treatment of vasomotor symptoms associated with menopause, therefore treatment would be off-label.

**Oxybutynin is not licensed for the treatment of vasomotor symptoms associated with menopause, therefore treatment would be off-label.

***LFTs were tested and normal prior to therapy, were then done monthly for the first 3 months and no abnormalities noted, and will then be monitored as per SmPC.

VMS, vasomotor symptoms; HRT, hormone replacement therapy.

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AGE	ONSET OF VMS	TREATMENT DURATION
62	7+ years	5 months

MEDICAL HISTORY AND COMORBIDITIES

- Retinal thrombosis 2017
- Currently prescribed Venlaflaxine (for low mood) and topical vaginal estriol

ADVERSE EVENTS

None reported

SYMPTOMS AT INITIATION

- VMS
- GSM

BASIS FOR TREATMENT DECISION

- Discussed herbal therapy and HRT but patient chose to try fezolinetant

VMS AT INITIATION

Severe
3-4 every night and more in the daytime

VMS AT 5 MONTHS OF VEOZA TREATMENT

0 hot flushes at night
1-2 per day

RESPONSE TO TREATMENT WITH VEOZA

- No night sweats

CLINICIAN'S COMMENTS

"The patient is very happy on her treatment and her symptoms are significantly better.

After one month of treatment with fezolinetant night sweats had stopped completely.

The patient still experiences 1-2 hot flushes during the day but says this is manageable and has reported a massive improvement in her quality of life."

GSM, genitourinary syndrome of menopause; HRT, hormone replacement therapy; VMS, vasomotor symptoms.

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The safety profile of VEOZA was evaluated in 2203 women with VMS associated with menopause during Phase 3 clinical studies[1]

Adverse reactions for fezolinetant 45 mg observed during clinical studies and from spontaneous reporting:

MEDDRA SYSTEM ORGAN CLASS	FREQUENCY	ADVERSE REACTION
Psychiatric disorders	Common (≥1/100 to <1/10)	Insomnia
Gastrointestinal disorders	Common (≥1/100 to <1/10)	Diarrhoea, Abdominal pain
Hepatobiliary disorders	Common (≥1/100 to <1/10)	Alanine aminotransferase (ALT) increased, aspartate aminotransferase (AST) increased
	Not known (frequency cannot be estimated from available data)	Drug-induced liver injury (DILI)

- 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 increased ALT (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]
- VEOZA is not recommended for use in patients with Child-Pugh Class B or C chronic hepatic impairment[1]
- Please refer to the VEOZA Summary of Product Characteristics for further details[1]

Requirements for liver function testing[1]

· Serious liver injury has been observed with fezolinetant
· Liver function tests (LFTs) must be performed prior to initiation of fezolinetant. Treatment with fezolinetant must not be initiated if serum alanine aminotransferase (ALT) or serum aspartate aminotransferase (AST) levels are ≥2x ULN or if total bilirubin levels are ≥2x ULN
· During the first three months of treatment, monthly LFTs must be performed, and thereafter based on clinical judgement. LFTs must also be performed when symptoms suggestive of liver injury occur
· Treatment with fezolinetant must be discontinued if:
  · Transaminase elevations are ≥3x ULN with: total bilirubin >2x ULN OR if patients develop symptoms of liver injury;
  · Transaminase elevations >5x ULN
· LFT monitoring should be maintained until LFTs have normalised
· Patients must be advised to immediately seek medical attention if they experience signs or symptoms that may suggest liver injury such as fatigue, pruritus, jaundice, dark urine, pale faeces, nausea, vomiting, decreased appetite and/or abdominal pain

MedDRA, Medical Dictionary for Regulatory Activities; VMS, vasomotor symptoms; ULN, upper limit of normal.

1. Astellas. VEOZA (fezolinetant): Summary of Product Characteristics.

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Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store. Adverse events should also be reported to Astellas Pharma Ltd. on 0800 783 5018.

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MAT-GB-VEO-2025-00084
Date of preparation: June 2025

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