

## 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. 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. Monitoring of liver function in women with known or suspected hepatic disorder is advised. 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). 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, and increased alanine aminotransferase (ALT) and aspartate aminotransferase (AST), all with a frequency of less than 10%.

**Marketing authorisation holder:** Astellas Pharma Europe B.V., The Netherlands.

**Norway: Dispensing group:** C. **Reimbursement:** No. **Pack size and price** (pr 16.01.2024): 45 mg: 30 tabl. (blister) 836.90 kr. **Local representative:** Astellas Pharma, Tel: +47 66 76 46 00. For more information see [www.felleskatalogen.no](http://www.felleskatalogen.no).

Based on authorised SmPC dated 16 February 2024.

**\*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.**