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. Liver function tests: Must be performed prior to treatment initiation and monthly during the first three months; thereafter based on clinical judgement. Treatment should not be started or continued if test results meet pre-defined criteria. Patients should be informed about signs and symptoms of liver injury and advised to contact their doctor immediately if these occur. Liver / renal disease: VEOZA 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.
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). VEOZA 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, increased alanine aminotransferase (ALT) and aspartate aminotransferase (AST), all with a frequency of less than 10%, and drug-induced liver injury with unknown frequency.
Marketing authorisation holder: Astellas Pharma Europe B.V., The Netherlands.
Dispensing group: B. **Reimbursement:** No. **Pack size:** 30 tabl. (blister). See current price on www.medicinpriser.dk. **Local representative:** Astellas Pharma a/s, Arne Jacobsens Allé 15, 2300 Copenhagen. For more information see www.ema.europa.eu.

Based on authorised SmPC dated 21 March 2025.

***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.