12 October 2023
EMA/CHMP/440243/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Veoza

fezolinetant

On 12 October 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Veoza, intended for the treatment of hot flushes (vasomotor symptoms) associated with menopause. The applicant for this medicinal product is Astellas Pharma Europe B.V.

Veoza is a gynaecological product (ATC code: G02CX06) and will be available as a 45 mg film-coated tablet. The active substance is fezolinetant, which is a non-hormonal substance that passes through the blood brain barrier and acts at the level of the thermoregulatory centre of the hypothalamus.

The main benefit of Veoza is a reduction in the frequency and severity of moderate to severe vasomotor symptoms (hot flashes), as demonstrated in two 12-week, randomised, placebo-controlled, double-blind phase 3 studies of identical design in postmenopausal women. The most common side effects are diarrhoea and insomnia. Use during pregnancy is contra-indicated.

The full indication is:

> *Veoza is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause (see section 5.1).*

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union