Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Veoza 45 mg film-coated tablets

fezolinetant

PLGB 00166/0437

Astellas Pharma Ltd

LAY SUMMARY

Veoza 45 mg film-coated tablets
fezolinetant

This is a summary of the Public Assessment Report (PAR) for Veoza 45 mg film-coated tablets. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product will be referred to as Veoza in this lay summary for ease of reading.

This product has been authorised by MHRA for Great Britain (consisting of England, Scotland and Wales). In coming to its decision, MHRA has relied on a European Commission (EC) decision on 7 December 2023 (EMEA/H/C/005851), in accordance with the advice from the Committee for Medicinal Products for Human Use (CHMP). This is known as the EC Decision Reliance Procedure.

This application was approved under Regulation 50 of the Human Medicines Regulation 2012, as amended (previously Article 8.3 of Directive 2001/83/EC, as amended).

For practical information about using Veoza, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Veoza and what is it used for?
Veoza is a non-hormonal medicine used in menopausal women to reduce moderate-to-severe vasomotor symptoms (VMS) associated with menopause. VMS are also known as hot flashes or night sweats.

How does Veoza work?
Veoza contains the active substance fezolinetant. Before menopause, there is a balance between oestrogens, a female sex hormone, and a protein made by the brain known as neurokinin B (NKB) that regulates the brain's temperature control centre. As the body goes through menopause, oestrogen levels decline and this balance is disrupted, which can lead to VMS. By blocking NKB binding in the temperature control centre, Veoza reduces the number and intensity of hot flashes and night sweats.

How is Veoza used?
The pharmaceutical form of this medicine is a film-coated tablet and the route of administration is oral (by mouth).

The recommended dose is one 45 mg tablet taken by mouth once daily.

Patients should take this medicine at about the same time each day.
The tablet should be swallowed whole with liquids and can be taken with or without food. Patients should not break, crush, or chew the tablet.

For further information on how Veoza is used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with a prescription.

The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

What benefits of Veoza have been shown in studies?
Two main studies involving over 1,000 women showed that Veoza is effective at reducing the number and severity of hot flushes associated with menopause. After 4 weeks of treatment, the number of moderate to severe daily hot flushes was reduced on average by 53% in women taking Veoza 45 mg, compared with a reduction of 32% in women given placebo (a dummy treatment). After 12 weeks of treatment, the average reduction was 63% for women taking Veoza 45 mg, and 40% for women on placebo. The severity of hot flushes was also reduced in women taking Veoza, compared with women on placebo.

What are the possible side effects of Veoza?
For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

The common side effects with Veoza (which may affect up to 1 in 10 people) are:
- diarrhoea
- difficulty sleeping (insomnia)
- increase in levels of certain liver enzymes (ALT or AST), as shown in blood tests
- stomach (abdominal) pain

Why was Veoza approved?
MHRA decided that the benefits are greater than the risks and recommended that this medicine can be approved for use.

What measures are being taken to ensure the safe and effective use of Veoza?
As for all newly-authorised medicines, an Risk Management Plan (RMP) has been developed for Veoza. The RMP details the important risks of Veoza, how these risks can be minimised, any uncertainties about Veoza (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Veoza:

Summary of safety concerns	
Important identified risks	• None
Important potential risks	• None
Missing information	• Use in individuals with Child-Pugh Class B or C (moderate or severe) chronic hepatic impairment.

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Veoza are continuously monitored and

reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

Other information about Veoza
A marketing authorisation was granted in Great Britain on 14 December 2023.

The full PAR for Veoza follows this summary.

This summary was last updated in January 2024.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Veoza 45 mg film-coated tablets (PLGB 00166/0437) could be approved.

The product is approved for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.

The active substance, fezolinetant, is a non-hormonal selective neurokinin 3 (NK3) receptor antagonist. 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.

This product has been authorised by MHRA for Great Britain (consisting of England, Scotland and Wales). In coming to its decision, MHRA has relied on a European Commission (EC) decision on 7 December 2023 (EMEA/H/C/005851), in accordance with the advice from the Committee for Medicinal Products for Human Use (CHMP).
For the scientific discussion of the quality, non-clinical and clinical assessment conducted by the European Medicines Agency (EMA), please refer to the European Public Assessment Report, available on the EMA website.

This application was approved under Regulation 50 of the Human Medicines Regulation 2012, as amended (previously Article 8.3 of Directive 2001/83/EC, as amended).

In line with the legal requirements for children's medicines, the application included an EMA decision on the granting of a class waiver (CW/1/2015).

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A marketing authorisation was granted on 14 December 2023.

II. PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with current guidelines and was satisfactory.

PATIENT INFORMATION LEAFLET

The PIL is in line with current guidelines and is satisfactory.

LABEL

The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS

MHRA considered that the quality data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

IV. NON-CLINICAL ASPECTS

MHRA considered that the non-clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

V. CLINICAL ASPECTS

MHRA considered that the clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

VI. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) has been provided with the application, in accordance with legal requirements.

The PIL has been evaluated via a user consultation with target patient groups, in accordance with legal requirements, on the basis of a bridging report making reference to Veoza 45 mg film-coated tablets (Astellas Pharma Europe B.V). The bridging report submitted by the MAH is acceptable.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the product is acceptable. The non-clinical and clinical data submitted have shown the positive benefit/risk of this product in the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.

The Summaries of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

IX. TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations, where significant changes are made, are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPCs and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**