swissmedic

Summary report on authorisation dated 10 September 2025

Veoza® (active substance: fezolinetant)

Authorisation in Switzerland: 4 December 2023

Film-coated tablets for the treatment of moderate to severe hot flushes (vasomotor symptoms) in postmenopausal women

About the medicinal product

Veoza contains the active substance fezolinetant and is a non-hormonal medicinal product. It is used to treat moderate to severe hot flushes, otherwise known as vasomotor symptoms (VMS), in women after the menopause. The symptoms occur because oestrogen levels decline after the menopause. This can disrupt the body's temperature control, causing hot flushes.

Veoza was authorised as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA), and Swissmedic and the pharmaceutical industry. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least two of the five countries.
The authorisation application for Veoza was submitted to the drug regulatory authorities in Australia and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the application independently.

Further details of the Access joint initiative are published on the Swissmedic website: Access Consortium (swissmedic.ch).

Mode of action

The active substance fezolinetant blocks the messenger substance neurokinin B, which plays a role in body temperature regulation, in the brain. By blocking neurokinin B, Veoza helps reduce the number and intensity of hot flushes and night sweats.

Administration

Veoza is available on prescription only.

Veoza is available as film-coated tablets, each of which contains 45 mg of the active substance fezolinetant.

It is recommended that Veoza be taken once daily, at the same time and with some liquid. It should be swallowed whole, unchewed and unbroken. It does not have to be taken with a meal.

Efficacy

The efficacy of fezolinetant was investigated in two studies involving 1,022 postmenopausal women experiencing moderate to severe hot flushes.

Participants were treated for 12 weeks with either fezolinetant or placebo (a dummy drug).

In the studies that were conducted, fezolinetant reduced the number of hot flushes significantly, averaging a reduction of six to seven hot flushes a day, versus only around four in the placebo group. Fezolinetant also reduced the severity of the symptoms. The effect of the medicine persisted through the entire 52 weeks of treatment.

Precautions, undesirable effects, & risks

Veoza must not be used in those who are hypersensitive to the active substance or any of the excipients.

Since Veoza can cause liver injuries, liver function should be checked regularly.

The most common undesirable effects (affecting fewer than one in ten users) are diarrhoea, insomnia, and stomach pain.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Menopausal hot flushes are a common phenomenon and affect many women in the menopause. Until now, the main treatment option has been hormone therapy. However, this carries risks, such as an increased likelihood of developing breast cancer.

Veoza provides an alternative for women who want to treat their symptoms without hormones and therefore fills an unmet treatment need. Clinical studies have shown that fezolinetant significantly reduces the frequency and severity of the symptoms. The side effects that occur, including liver disorders, can be controlled with supervision and rarely occur in any serious form.

Taking all the risks and precautions into account, and based on the available data, the benefits of Veoza outweigh the risks. Swissmedic has therefore authorised the medicinal product Veoza containing the active substance fezolinetant in Switzerland for the treatment of moderate to severe hot flushes in postmenopausal women

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Veoza®

Information for patients (package leaflet): Information for patients Veoza®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.