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# Veoza (*fezolinetant*)

An overview of Veoza and why it is authorised in the EU

## What is Veoza and what is it used for?

Veoza is a medicine used to treat moderate to severe vasomotor symptoms (also referred to as hot flushes or night sweats) associated with menopause.

Veoza contains the active substance fezolinetant.

## How is Veoza used?

Veoza is available as tablets to be taken by mouth once a day. The medicine can only be obtained with a prescription.

For more information about using Veoza, see the package leaflet or contact your doctor or pharmacist.

## How does Veoza work?

Before menopause, there is a balance between oestrogen hormones and a protein called neurokinin B which 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 vasomotor symptoms.

The active substance in Veoza, fezolinetant, blocks neurokinin B from attaching to its targets in the brain, thereby reducing the number and intensity of hot flushes and night sweats.

## 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.

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## What are the risks associated with Veoza?

For the full list of side effects and restrictions with Veoza, see the package leaflet.

The most common side effects with Veoza (which may affect up to 1 in 10 people) include diarrhoea and difficulty sleeping.

Veoza must not be used together with moderate or strong 'CYP1A2 inhibitor medicines' as these may reduce the breakdown of Veoza in the body and increase the risk of side effects; it must also not be used during pregnancy or if pregnancy is suspected.

## Why is Veoza authorised in the EU?

Veoza was shown to be effective at reducing the frequency and severity of hot flushes associated with menopause; the medicine is well-tolerated with an acceptable safety profile.

The European Medicines Agency therefore decided that Veoza's benefits are greater than its risks and it can be authorised for use in the EU.

## What measures are being taken to ensure the safe and effective use of Veoza?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Veoza have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Veoza are continuously monitored. Suspected side effects reported with Veoza are carefully evaluated and any necessary action taken to protect patients.

## Other information about Veoza

Veoza received a marketing authorisation valid throughout the EU on 7 December 2023.

Further information on Veoza can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/veoza.

This overview was last updated in 12-2023.