

Veozza (fezolinetant) for hot flushes in menopause - think twice!

Mercedes Pérez-Fernández, Specialist in Internal Medicine and retired rural physician, CESCO Team, Spain
mpf1945@gmail.com

Juan Gérvas, MD, former professor of public health, retired rural general practitioner, CESCO Team, Madrid, Spain.
jgervas@gmail.com [@JuanGrvas](https://t.me/gervassalud)

Vasomotor symptoms in menopause

Hot flushes are waves of heat sometimes accompanied by palpitations that occur in many women before, during and/or after the withdrawal of menstruation.

Hot flushes are vasomotor symptoms (VMS) which are sometimes very uncomfortable and can be relieved by medication, such as oestrogen from "hormone therapy" (associated with an increase in cancers, heart attacks and other problems) and progesterone, as well as "natural" methods from sage to fanning. Hot flushes are generally uncomfortable but bearable, and usually subside spontaneously after months (sometimes years).

Veozza (fezolinetant) efficacy

Veozza is a medicine used to treat moderate to severe vasomotor symptoms (also referred to as hot flushes or night sweats) associated with menopause. Its active ingredient, fezolinetant, at a dose of 45 mg, acts in the brain on a receptor on neurons (in fact these neurokinin 3 receptor antagonists, NK3, have been studied unsuccessfully for serious psychiatric illnesses such as schizophrenia).

Two doses, 30 and 45 mg, were studied in clinical trials, with similar efficacy but greater adverse effects with the higher dose (e.g. six cancers in five women in the 30 mg group and ten cancers in nine women in the 45 mg group).

The clinical effect is modest, reducing three hot flushes per day (from 11 to 8).

Its long-term effectiveness is unknown.

Treatment costs about 500 euros per month.

Veozza (fezolinetant) safety

Side effects included liver and kidney failure. Its use is associated with increased liver enzymes and blood glucose, as well as diarrhoea and insomnia.

A similar drug, pavinetant, was discarded due to severe liver damage.

As noted above, its use was associated with an increase in cancer. This is to be expected since, by modifying the neural and hormonal system that controls temperature, it affects the immune system. There are many agents that induce neoplasms, including SGLT-2 inhibitors, GLP-1 receptor agonists, benzodiazepines, orexin antagonists, etc.

Veozza may interact with CYP1A2 inhibitor drugs (e.g. fluvoxamine, ciprofloxacin, oral contraceptives, acyclovir, allopurinol, cimetidine and others).

Astellas

The Japanese laboratory that produces it, Astellas, is world famous because it is the only one to have been suspended for malpractice twice in the UK (by the pharmaceutical self-regulatory body, the Association of the British Pharmaceutical Industry, ABPI). The ABPI suspended Astellas for inviting more than 100 clinicians to a sham "educational event" meeting in Milan.

In the US in 2014, Astellas paid \$7.3m [£5.6m; €6.6m] to resolve False Claims Act allegations relating to the marketing of Mycamine to children, followed by \$67m relating to Tarceva in 2016.

In 2023, in the US it has developed an entire media campaign of disease awareness to turn hot flushes into a disease and to "teach" women and doctors the best way to "diagnose" and treat them (with VEOZA, no doubt).

Astellas lost a lawsuit in 2011 against the French magazine Prescrire (the best pharmacotherapeutic newsletter in the world) for the magazine's recommendation not to use its drug Protopic, tacrolimus, in atopic dermatitis, because it is associated with skin cancer and lymphomas.

References:

VEOZA (fezolinetant)

<https://www.ema.europa.eu/en/medicines/human/EPAR/veoza>

Heating up the hot flash market with unnecessary, and potentially harmful, drugs
<https://www.baltimoresun.com/2023/05/17/heating-up-the-hot-flash-market-with-unnecessary-and-potentially-harmful-drugs-guest-commentary/>

Risk of neoplasm with the neurokinin 3 receptor antagonist fezolinetant
[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(23\)01634-3/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)01634-3/fulltext)

The European Commission (EC) on December 7 approved VEOZA™ (fezolinetant) 45 mg once daily for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.

<https://ec.europa.eu/health/documents/community-register/html/h1771.htm>

<https://www.prnewswire.com/news-releases/astellas-veoza-fezolinetant-approved-by-european-commission-for-treatment-of-vasomotor-symptoms-associated-with-menopause-302010530.html>

Neurokinin Receptor Antagonist, Fezolinetant, for Treatment of Menopausal Vasomotor Symptoms

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10583986/>

Fezolinetant for treatment of moderate-to-severe vasomotor symptoms associated with menopause (SKYLIGHT 1): a phase 3 randomised controlled study

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(23\)00085-5/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)00085-5/fulltext)

Safety of Fezolinetant for Vasomotor Symptoms Associated With Menopause

https://journals.lww.com/greenjournal/fulltext/2023/04000/safety_of_fezolinetant_for_vasomotor_symptoms.13.aspx

Efficacy and Safety of Fezolinetant in Moderate to Severe Vasomotor Symptoms Associated With Menopause: A Phase 3 RCT

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10348473/>

New menopause drug to treat hot flushes given green light in UK

<https://www.independent.co.uk/news/health/menopause-hot-flushes-drug-treatment-uk-b2465793.html>

FDA. CENTER FOR DRUG EVALUATION AND RESEARCH APPLICATION NUMBER: 216578Orig1s000 CLINICAL REVIEW(S)

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216578Orig1s000MedR.pdf

Repurposing a failed class of schizophrenia drugs to treat menopausal symptoms
<https://rationalpsychiatry.substack.com/p/repurposing-a-failed-class-of-schizophrenia>

Astellas

<https://pharmaphorum.com/news/astellas-suspended-uk-pharma-body-year>

UK response to serial drug company misdemeanour—no action, no shame. Astellas.

<https://www.bmj.com/content/354/bmj.i4022>

Astellas versus Prescrire (Spanish)

<https://elrincondesisifo.org/2011/03/03/el-caso-astellas-versus-prescrire-gana-la-libertad-de-critica-cientifica/>

Astellas' lawsuit against Prescrire: French court rules that Prescrire did not "denigrate" Protopic® (tacrolimus) (English)

<https://english.prescrire.org/en/81/168/46799/0/NewsDetails.aspx>