14 March 2025
EMA/CVMP/67541/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Prevestrus vet

International non-proprietary name (INN): finrozole

On 13 March 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Prevestrus vet, film-coated tablets intended for use in dogs (bitches). The applicant for this veterinary medicinal product is Vetcare Oy.

Prevestrus vet is a veterinary medicinal product containing finrozole (ATCvet code QG03XX90) as active substance, which is a selective nonsteroidal aromatase inhibitor. When administered at a dose of 5-10 mg per kg body weight during pro-oestrus once daily for 7 consecutive days, finrozole leads to a temporary decrease in oestrogen production which, in turn, leads to a shortening of the follicular phase, reduction of clinical signs of oestrus and decrease of risk of pregnancy in bitches.

The benefit of Prevestrus vet is its efficacy to shorten the pro-oestrus and oestrus period, reduce clinical signs of heat and reduce the risk of pregnancy in bitches.

The most common side effects are ovarian cysts, mammary hyperplasia and emesis.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC) which will be published in the Union Product Database (UPD) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Prevestrus vet and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt 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