

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prevestrus vet 25 mg film-coated tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 tabl: finrozole 25 mg

3. PACKAGE SIZE

7 tablets
14 tablets
28 tablets

4. TARGET SPECIES

Dog (bitch)



5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral administration

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetcare Oy

14. MARKETING AUTHORISATION NUMBER

Vm 42810/5001

15. BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {HDPE BOTTLE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prevestrus vet 25 mg film-coated tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 tabl: finrozole 25 mg

14 tablets

28 tablets

3. TARGET SPECIES

Dog (bitch)



4. ROUTES OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

EXP:

7. SPECIAL STORAGE PRECAUTIONS

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetcare Oy

9. BATCH NUMBER

Lot:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {BLISTER (PVC/PE/PVDC-PAPER/ALU)}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prevestrus vet



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

25 mg

3. BATCH NUMBER

Lot:

4. EXPIRY DATE

EXP:

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prevestrus vet 25 mg film-coated tablets for dogs
Prevestrus vet 50 mg film-coated tablets for dogs
Prevestrus vet 100 mg film-coated tablets for dogs

2. COMPOSITION

Each film-coated tablet contains active substance finrozole: 25 mg, 50 mg or 100 mg.

Prevestrus vet 25 mg: yellow, round, convex film-coated tablet with a diameter of 8 mm.

Prevestrus vet 50 mg: brownish, round, convex film-coated tablet with a diameter of 10 mm.

Prevestrus vet 100 mg: red, round, convex film-coated tablet with a diameter of 12 mm.

3. TARGET SPECIES

Dog (bitch).

4. INDICATIONS FOR USE

To shorten the pro-oestrus and oestrus period, reduce clinical signs of heat, and reduce the risk of pregnancy, during a single oestrus cycle.

5. CONTRAINDICATIONS

Do not use in male dogs and pregnant bitches (see Special warnings).

Do not use in case of hypersensitivity to the active substance or to any of the excipient(s).

6. SPECIAL WARNINGS

Special warnings:

It is important that treatment is started in early pro-oestrus, as soon as signs of pro-oestrus are observed. If treatment is started close to ovulation or once ovulation has occurred, treatment will not be efficacious.

Prior to treatment, pro-oestrus should be confirmed by a veterinary surgeon by vaginoscopy, vaginal cytology or another suitable diagnostic method.

In laboratory and clinical studies used to evaluate the efficacy of the veterinary medicinal product, pro-oestrus was defined as dogs having a turgid/oedematous/plump vulva and sanguineous vulval discharge. On vaginoscopy, the mucosal folds were pink-whitish, greatly enlarged, thickened, rounded, oedematous/plump, and not dry. Vaginal cytology demonstrated predominantly intermediate and superficial cells, alongside erythrocytes.

Bitches should not have contact with entire male dogs during the administration period as data are not available on the effectiveness of the veterinary medicinal product to suppress mating behaviour or reduce the risk of pregnancy before 7 days.

Treatment can result in a temporary increase in progesterone.

The veterinary medicinal product's effects on mating and pregnancy rates following the recommended use have only been evaluated as indirect consequences of its primary effect on reproductive hormone kinetics. No information is available on the direct effect the veterinary medicinal product may exert on oocyte maturation, transport, fertilization and implantation.

Special precautions for safe use in the target species:

The overall systemic exposure, and associated safety margin, of the veterinary medicinal product varies with the prandial status of the bitch. Therefore, the dosage instructions should be closely followed (see Advice on correct administration).

No data are available on the use of the veterinary medicinal product during a bitch's first heat. Therefore, the veterinary medicinal product is only recommended for use in bitches from their second heat onwards.

The safety of the veterinary medicinal product has only been investigated in bitches with normal mammary glands, and normal reproductive organs, confirmed on ultrasound examination, prior to its administration.

The safety of repeated treatments, i.e., in more than one oestrus cycle, has not been investigated.

The safety of the veterinary medicinal product has not been established in bitches less than 10 months of age or weighing less than 2.6 kg.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Finrozole is a selective nonsteroidal aromatase enzyme inhibitor resulting in reduction of oestrogen levels and prevention of follicle maturation. Laboratory studies in rats have shown evidence of foetotoxic and teratogenic effects. Pregnant women and those attempting to conceive should not administer this product. If a broken tablet is rejected by the dog after chewing, it should be disposed of carefully.

Accidental ingestion of this product may be harmful. Avoid ingestion of this product. Any uneaten medicated food should be disposed of immediately and the bowl washed thoroughly. Keep the veterinary medicinal product in the outer packaging. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands thoroughly with soap and water following handling of the product.

Pregnancy and lactation:

The use of the veterinary medicinal product is contraindicated during pregnancy.

The use of the veterinary medicinal product is not recommended during lactation.

Laboratory studies in rats have shown evidence of foetotoxic effects.

Fertility:

In laboratory studies in bitches, the inter-oestrus interval was shortened by approximately one month following 14 consecutive days of treatment with finrozole, but no effect was detected on fertility or pregnancy rate of the subsequent cycle.

Interaction with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy of the veterinary medicinal product when used with any other veterinary medicinal product. Therefore, its concurrent use with products that act on the reproductive hormonal system is not recommended. A decision to use the veterinary medicinal product before or after any other veterinary medicinal product should be made on a case-by-case basis by the responsible veterinary surgeon.

Overdose:

In preliminary clinical field trials, lethargy, anorexia, diarrhoea, and restlessness were occasionally reported following the administration of the veterinary medicinal product at the recommended dose for 14 consecutive days, i.e., twice the recommended duration of treatment.

In a laboratory reproductive safety study, when bitches were exposed to approximately 1.5 times the maximum recommended level of finrozole from the point of ovulation (rather than treatment starting in early pro-oestrus) for 14 days, no reproductive safety concerns were identified.

In a laboratory margin of safety study, following daily exposure to the minimum recommended level of finrozole for 42 days, i.e., six times the recommended duration of treatment, weight loss, increases in serum gamma glutamyl transpeptidase (GGT), hepatomegaly, and decreases in serum cholesterol were observed. However, no pathological changes were detected in liver parenchyma following necropsy.

In the same study, following daily exposure to approximately 2.5 times the maximum recommended level of finrozole for 14 days, no clinically relevant abnormalities were associated with administration of the veterinary medicinal product, other than transiently enlarged ovaries and/or transient ovarian cysts.

7. ADVERSE EVENTS

Dogs:

Common (1 to 10 animals / 100 animals treated):	Ovarian cyst ¹ Mammary hyperplasia (mammary gland enlargement) Emesis (vomiting)
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¹Transiently enlarged ovaries with multicystic appearance on abdominal ultrasound.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder, or the local representative of the marketing authorisation holder, using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral use.

The recommended dose is 5-10 mg/kg bodyweight given once daily for 7 consecutive days.

Treatment must be started in early pro-oestrus (see Special warnings).

To ensure a correct dosage, bodyweight should be determined as accurately as possible.

As the film-coated tablets cannot be split, doses should be administered using the number of tablets shown in the table below:

Bodyweight in kg	Number of tablets to be administered per day		
	25 mg tablet	50 mg tablet	100 mg tablet
2.6 - 5.0	1		
5.1 - 10.0		1	
10.1- 20.0			1
20.1–40.0			2
40.1–60.0			3
60.1–80.0			4

For dogs less than, or equal to, 10.0 kg bodyweight, the 25 mg or 50 mg strengths of the veterinary medicinal product should be used, depending on bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

The veterinary medicinal product should be administered with feed.
Do not crush or break the tablets.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle or blister after EXP. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42810/5001

Blister sheets containing 7 tablets are further packed into a cardboard box of 7 or 14 tablets.

HDPE jars contain 14 or 28 tablets further packed into a cardboard box.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:

Vetcare Oy
P.O. Box 99
24101 Salo
Finland
sadr@vetcare.fi

Manufacturer responsible for batch release:

Eurofins BioPharma Product Testing Finland Oy
Volltikatu 5 and 8
FI-70700 Kuopio
Finland

Lelypharma
Zuiveringweg 42
8243PZ Lelystad
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

Virbac Ltd
Suffolk
IP30 9UP
UK
Tel: +44 (0)1359 243243

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. OTHER INFORMATION

POM-V

Gavin Hall

Approved: 25 February 2026