

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lystralin 100 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains

Active substance:

Finrozole: 100 mg.

Excipients:

Qualitative composition of excipients and other constituents
Tablet core:
Cellulose, microcrystalline
Starch, pregelatinised
Calcium hydrogen phosphate dihydrate
Croscarmellose sodium
Magnesium stearate
Silica, colloidal anhydrous
Film coating:
<u>Opadry:</u> Hypromellose Titanium dioxide Iron oxide Triacetin
<u>Surelease:</u> Ethylcellulose Triglycerides, medium chain Oleic acid

Red, round, convex film-coated tablet with a diameter of 12 mm.

3. CLINICAL INFORMATION

3.1 Target species

Dog (bitch).

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in male dogs and pregnant bitches (see section 3.7. Use during pregnancy, lactation or lay).

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

3.4 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.

3.5 Special precautions for use

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 (see Section 4.3 Pharmacokinetics). Therefore, the dosage instructions presented in Section 3.9 should be closely followed.

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.

Special precautions for the protection of the environment:

Not applicable

3.6 Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Ovarian cyst ¹ Mammary hyperplasia Emesis
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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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 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.

3.9 Administration routes and dosage

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 section 3.4 Special warnings).

The veterinary medicinal product should be administered with feed (see section 4.3 Pharmacokinetics).

Do not crush or break the tablets.

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:

	Number of tablets to be administered per day
Body weight in kg	100 mg tablet
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC Vet Code: QG03XX90

4.2 Pharmacodynamics

Finrozole is a selective nonsteroidal aromatase inhibitor, leading to a temporary decrease in oestrogen production and a temporary accumulation or a higher rate of production of androgens. This decrease in oestrogen production leads to a disappearance of clinical signs of pro-oestrus and oestrus (swelling and discharge of the vulva, appearance of vaginal folds, licking of the vulva and mating behaviour). The potential indirect effects of finrozole on conception, nidation, and pregnancy itself, are currently unknown.

4.3 Pharmacokinetics

The bioavailability of finrozole is significantly lower when the veterinary medicinal product is administered to fasted dogs. Exposure to finrozole is increased depending on the amount of food the veterinary medicinal product is administered with. Additionally, exposure to finrozole (C_{max} and AUC) is significantly increased when the veterinary medicinal product is administered crushed, rather than as whole tablets. Therefore, the dosage instructions presented in Section 3.9 should be closely followed.

Finrozole consists of two enantiomers. The main enantiomer, MPV-2213d, has 10 times higher plasma levels than enantiomer MPV-2213a.

Following oral administration of the veterinary medicinal product at a dose of 5 mg/kg with a small amount of feed (approximately 25% of the daily ration), the following pharmacokinetic parameters apply for the main enantiomer MPV-2213d:

$C_{\max} = 517.88 \text{ ng*ml}^{-1}$
 $T_{\max} = 3.5 \text{ hr}$
 $T_{1/2} = 6.11 \text{ hr}$
 $AUC_t = 6980.6 \text{ ng*hr*ml}^{-1}$

The absolute bioavailability of MPV-2213d under these dosing conditions was 38%. However, the coefficient of variation of this parameter was 65%.

Following daily administration of the veterinary medicinal product at 10 mg/kg with a small amount of feed (approximately 25% of the daily ration) for 14 consecutive days, mild accumulation of finrozole was observed.

The precise pharmacokinetics of finrozole following oral administration of the veterinary medicinal product at a dose of 5-10 mg/kg with a full meal for 7 consecutive days are unknown, but are expected to reflect greater exposure than the values presented above.

Based on observations in both rats and humans, finrozole is expected to undergo hepatic metabolism in dogs.

The main route of finrozole elimination is via urine.

The main metabolite in plasma and urine is glucuronide conjugate M1b.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Tablets are packed in PVC/PE/PVDC-aluminium blisters or in HDPE jars.

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

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

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetcare Oy

7. MARKETING AUTHORISATION NUMBER

Vm 42810/5003

8. DATE OF FIRST AUTHORISATION

13 February 2026

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

July 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 08 July 2026