SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finilac 50 microgram/ml oral solution for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Cabergoline 50 microgram

Excipient:

Qualitative composition of excipients and other constituents
Triglycerides, Medium chain

A clear, colourless to slightly brownish solution

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

Treatment of false pregnancy in bitches.
Suppression of lactation in bitches and queens.

3.3 Contraindications

Do not use in pregnant animals since the veterinary medicinal product may cause abortion.
Do not use with dopamine antagonists.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Cabergoline may induce transient hypotension in treated animals. Do not use in animals currently being treated with hypotensive drugs. Do not use directly after surgery whilst the animal is still under the influence of anaesthetic agents.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Caution is recommended in animals with significantly impaired liver function. Additional supportive treatments should involve restriction of water and carbohydrate intake and increased exercise.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.
Avoid contact with skin and eyes. Wash off any splashes immediately.
Women of childbearing potential and breast-feeding women should not handle the veterinary medicinal product or should wear impervious gloves when administering the veterinary medicinal product.
People with known hypersensitivity to cabergoline or any of the other ingredients in the veterinary medicinal product should avoid contact with the veterinary medicinal product.
Do not leave unattended filled syringes in the presence of children. In case of accidental ingestion, particularly by a child, seek medical attention immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Drowsiness[a], Anorexia[a] Vomiting[a,b] Neurological symptom (e.g. somnolence, muscle tremor, ataxia, hyperactivity, convulsion)
Very Rare (<1 animal / 10,000 treated, including isolated reports):	Hypotension[c] Allergic reaction (e.g. allergic oedema, urticaria, allergic dermatitis, pruritus)

[a] usually moderate and transient
[b] usually only occurs after the first administration. In this case treatment should not be discontinued, since the vomiting is unlikely to reoccur after the next administration.
[c] transient

Cats:

Very Rare (<1 animal / 10,000 treated, including isolated reports):	Drowsiness[a] Allergic reaction (e.g. allergic oedema, urticaria, allergic dermatitis, pruritus) Neurological symptom (e.g. somnolence, muscle tremor, ataxia, hyperactivity, convulsion) Hypotension[b]
Undetermined frequency (cannot be estimated from the available data)	Anorexia[a] Vomiting[a,c]

[a] usually moderate and transient

[b] transient
[c] usually only occurs after the first administration. In this case treatment should not be discontinued, since the vomiting is unlikely to reoccur after the next administration.

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:
Cabergoline has the capacity to cause abortion in the later stages of pregnancy and should not be used in pregnant animals. Differential diagnosis between pregnancy and false pregnancy should be made correctly.

Lactation:
The veterinary medicinal product is indicated for the suppression of lactation: inhibition of prolactin secretion by cabergoline results in a rapid cessation of lactation and a reduction in the size of the mammary glands. The veterinary medicinal product should not be used in lactating animals unless suppression of lactation is required.

3.8 Interaction with other medicinal products and other forms of interaction

Since cabergoline exerts its therapeutic effect by direct stimulation of dopamine receptors, the veterinary medicinal product should not be administered concurrently with drugs which have dopamine antagonist activity (such as phenothiazines, butyrophenones, metoclopramide), as these might reduce its prolactin inhibiting effects. See also section 3.3.
Since cabergoline may induce transient hypotension, the veterinary medicinal product should not be used in animals concurrently treated with hypotensive drugs. See also section 3.3 and 3.6.

3.9 Administration routes and dosage

Oral use.

The veterinary medicinal product should be administered orally either directly into the mouth or by mixing with food.

The dosage is 0.1 ml/kg bodyweight (equivalent to 5 microgram/kg bodyweight of cabergoline) once daily for 4-6 consecutive days, depending on the severity of the clinical condition.
If the signs fail to resolve after a single course of treatment, or if they recur after the end of treatment, then the course of treatment may be repeated.
To ensure a correct dosage, body weight should be determined as accurately as possible.

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

The experimental data indicate that a single overdose with cabergoline might result in an increased likelihood of post-treatment vomiting, and possibly an increase in post-treatment hypotension.
General supportive measures should be undertaken to remove any unabsorbed drug and maintain blood pressure, if necessary. As an antidote, the parenteral administration of dopamine antagonist drugs such as metoclopramide might be considered.

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 ATCvet code: QG02CB03

4.2 Pharmacodynamics

Cabergoline is an ergoline derivative. It has dopaminergic activity which leads to inhibition of prolactin secretion by the anterior pituitary. The mechanism of action of cabergoline was studied in *in vitro* and *in vivo* models. The most important details are outlined below:

- Cabergoline inhibits prolactin secretion by the pituitary gland and inhibits all prolactin dependent processes, such as lactation. Maximum inhibition is achieved after 4 to 8 hours and lasts several days depending on the administered dose.
- Cabergoline has no other effects on the endocrine system besides the inhibition of prolactin secretion.
- Cabergoline is a dopamine agonist in the central nervous system by selective interaction with the dopaminergic D_2 receptors.
- Cabergoline has affinity for the noradrenergic receptors, however, this does not cause interference with the noradrenalin and serotonin metabolism.
- Cabergoline is an emetic, like the other ergoline derivatives (in potency comparable to bromocriptine and pergolide).

4.3 Pharmacokinetics

No pharmacokinetic data are available for the recommended dosing regimen in dogs and cats.

Pharmacokinetic studies in dogs were performed with a daily dose of 80 µg/kg bodyweight (16 times the recommended dose). Dogs were treated for 30 days; pharmacokinetic assessments made on day 1 and 28.

Absorption:

- Tmax = 1 hour on day 1 and 0.5-2 hours (mean 75 minutes) on day 28;
- Cmax ranged from 1140 to 3155 pg/ml (mean 2147 pg/ml) on day 1 and from 455 to 4217 pg/ml (mean 2336 pg/ml) on day 28;
- AUC (0-24 h) on day 1 ranged from 3896 to 10216 pg.h.ml-1 (mean 7056 pg.h.ml-1) and on day 28 from 3231 to 19043 pg.h.ml-1 (mean 11137 pg.h.ml-1) .

Elimination:

Plasma half life in dogs t½ on day 1 ~ 19 hours; t½ on day 28 ~ 10 hours

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products nor with other aqueous solutions (e.g. milk).

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 30 °C.
Keep the bottle in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

3 ml (in a bottle of 5 ml capacity), 10 ml, 15 ml, 25 ml and 50 ml brown Type III glass bottle closed by a conical ‘Luer slip’ syringe adapter (low density polyethylene) and a screw cap (high density polyethylene). The bottles are packed in a cardboard box. The 1 ml and 3 ml plastic oral syringes will be enclosed in all package sizes.

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

Le Vet. Beheer B.V.

7. MARKETING AUTHORISATION NUMBERS

Vm 41821/5023
Vm 41821/3017

8. DATE OF FIRST AUTHORISATION

19 February 2015

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

August 2024

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: 12 June 2025