PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finilac 50 microgram/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Cabergoline 50 microgram

3. PACKAGE SIZE

3 ml
10 ml
15 ml
25 ml
50 ml

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral solution

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.: (mm/yyyy)
Once opened use within 28 days.
Once opened use by:

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C.

Keep the bottle in the outer carton in order to protect from light.

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 OF THE MARKETING AUTHORISATION HOLDER

Le Vet. Beheer B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 41821/5023

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Glass bottle }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finilac

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Cabergoline 50 microgram/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days.
Once opened use by:

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Finilac 50 microgram/ml oral solution for dogs and cats

2. Composition

Each ml contains:

Active substance:
Cabergoline 50 microgram

A clear, colourless to slightly brownish solution.

3. Target species

Dogs and cats.

4. Indications for use

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

5. 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.

6. Special warnings

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.

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.

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 Contraindications.
Since cabergoline may induce transient hypotension (low blood pressure), the veterinary medicinal product should not be used in animals concurrently treated with hypotensive drugs (drugs that lower the blood pressure). See also sections Contraindications and Adverse events.

Overdose:
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.

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).

7. 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. 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, routes and method of administration

Oral use.

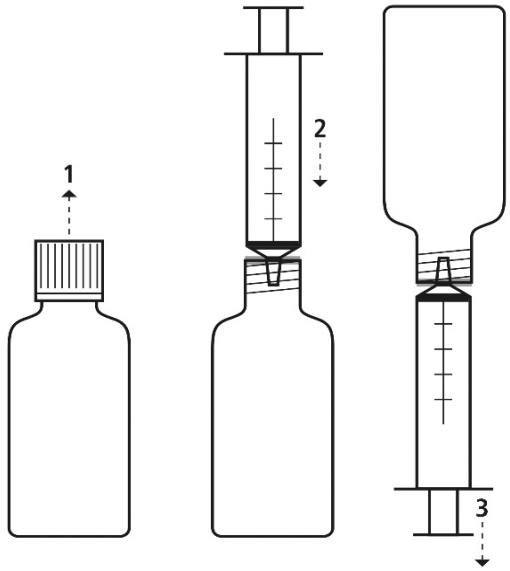
The veterinary medicinal product should be administered orally either directly into the mouth or by mixing with food.

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.

9. Advice on correct administration

1. Remove the screw cap
2. Connect the supplied syringe to the flask
3. Turn the bottle upside-down to suck out the liquid



10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 30°C.
Keep the bottle in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.

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 41821/5023

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.

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:
Le Vet. Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer responsible for batch release:
Dreluso Pharmazeutika Dr. Elten & Sohn GmbH
Südstr. 10 u. 15
31840 Hessisch Oldendorf
Germany

Local representatives and contact details to report suspected adverse reactions:

Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel.: +44 (0)1939 211200

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: 15 January 2025