ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE CARTON

Cardboard box containing a single bottle of 3, 10, 15, 25 or 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finilac 50 microgram/ml oral solution for dogs and cats
cabergoline

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Cabergoline 50 microgram

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

3 ml
10 ml
15 ml
25 ml
50 ml

5. TARGET SPECIES

Dog, cat

6. INDICATION(S)

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING, IF NECESSARY

Do not leave unattended filled syringes in presence of children
Read the package leaflet before use

10. EXPIRY DATE

EXP: (month/year)
Once broached use within 28 days

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41821/4018

17. MANUFACTURER'S BATCH NUMBER

Lot. {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 3, 10, 15, 25 or 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finilac 50 microgram/ml oral solution for dogs and cats
cabergoline

2. QUANTITY OF THE ACTIVE SUBSTANCE

Cabergoline 50 microgram/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

3 ml
10 ml
15 ml
25 ml
50 ml

4. ROUTE OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot.

7. EXPIRY DATE

EXP:
Once broached use within 28 days
Once broached use by:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Finilac 50 microgram/ml oral solution for dogs and cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finilac 50 microgram/ml oral solution for dogs and cats
cabergoline

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

1 ml contains:

Active substance:
Cabergoline 50 microgram
A clear, colourless to slightly brownish solution.

4. INDICATIONS

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

5. CONTRAINDICATIONS

Do not use in pregnant animals since the 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. ADVERSE REACTIONS

In very rare cases a transient hypotension may occur. Possible adverse effects are:
- sleepiness
- anorexia (lack or loss of appetite)
- vomiting

These adverse effects are usually of a moderate and transient nature.
Vomiting usually only occurs after the first administration. In this case treatment should not be stopped, since the vomiting is unlikely to reoccur after the following administrations.

In very rare cases allergic reactions may occur, such as oedema (fluid retention), urticaria (hives), dermatitis (inflammation of the skin) and pruritus (itch).
In very rare cases neurological symptoms may occur, such as sleepiness, muscle tremor, ataxia (loss of muscular coordination), hyperactivity and convulsions (seizures).

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.
Alternatively you can report via your national reporting system.

7. TARGET SPECIES

Dogs, cats

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

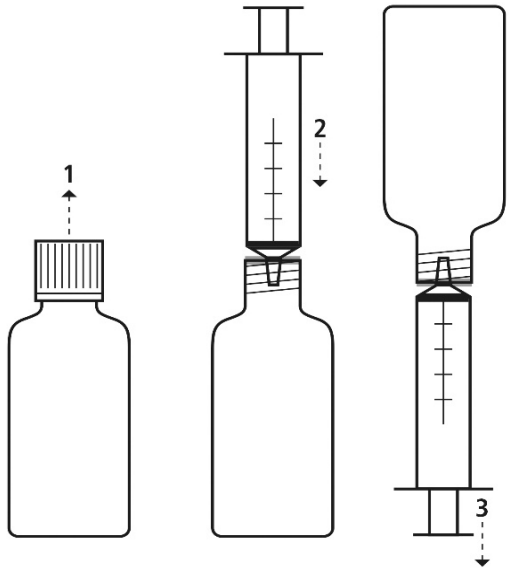
The product should be administered orally either directly into the mouth or by mixing with food.

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.
The weight of treated animal should be accurately determined before administration.

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 PERIOD

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 after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the bottle: 28 days

12. SPECIAL WARNINGS

Special warnings for each target species
Additional supportive treatments should involve restriction of water and carbohydrate intake and increased exercise.
Special precautions for use in animals
Caution is recommended in animals with significantly impaired liver function
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 woman should not handle the product or should wear impervious gloves when administering the product.
If you know you are hypersensitive to cabergoline or any of the other ingredients in the product, you should avoid contact with the product.
Do not leave unattended filled syringes in the presence of children. In the event of accidental ingestion, particularly by a child, seek medical attention immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation

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.

The 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 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 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 on contraindications.

Since cabergoline may induce transient hypotension (low blood pressure), the product should not be used in animals concurrently treated with hypotensive drugs (drugs that lower the blood pressure). See also section contraindications and on adverse reactions.

Overdose (symptoms, emergency procedures, 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.

Incompatibilities

The veterinary medicinal product must not be mixed with other aqueous solutions (e.g. milk). In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2021

15. OTHER INFORMATION

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.

Approved 18 June 2021