[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kabergovet 50 microgram/ml oral solution for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Cabergoline 50 µg

Excipient:

Qualitative composition of excipients and other constituents
Triglycerides, medium chain

Pale yellow, viscous oily solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, 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.
Cabergoline may induce transient hypotension in treated animals, do not use in animals concurrently being treated with hypotensive drugs. Do not use directly after surgery, whilst the animal is still under the influence of anaesthetic agents.
Do not use in cases of hypersensitivity to the active substance or to any of the excipient.

3.4 Special warnings

Additional supportive treatments should involve restriction of water and carbohydrate intake and increased exercise.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal product should be administered with caution to animals with impaired liver function.

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

Wash hand after use. Avoid contact with skin and eyes. Wash of any splashes immediately.
Women of childbearing potential and breast-feeding woman 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 should avoid contact with the veterinary medicinal product.
Do not leave unattended filled syringes in the sight and presence of children. In case of accidental ingestion, particularly by a child, seek medical advice 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, cats:

Rare (1 to 10 animals / 10,000 animals treated):	Drowsiness[1], anorexia[1] Vomiting[1,2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypotension[3] Allergic reactions (e.g. oedema, urticaria, pruritus) Allergic dermatitis Neurological symptoms (e.g. sleepiness, muscle tremor, ataxia, convulsion) Hyperactivity

[1] moderate and transient in nature.
[2] 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.
[3] transient.

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:

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 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.
Since cabergoline may induce transient hypotension, the veterinary medicinal product should not be used in animals concurrently treated with hypotensive drugs.

3.9 Administration routes and dosage

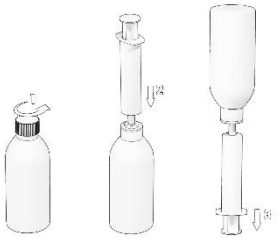
Oral use, either directly into the mouth or by mixing with food.

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 before administration.

How to withdraw the recommended volume from the bottle?



1.Remove the screw cap

2.Connect the supplied syringe to the flask

3.Turn the bottle upside-down to remove the liquid

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 parental 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 D2 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

- T_{max} = 1 hour on day 1 and 0.5-2 hours on day 28;
- C_{max} 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) and on day 28 from 3231 to 19043 pg.h/ml (mean 11137 pg.h/ml).

Elimination

- Terminal plasma half-life in dogs on day 1 ~ 19 hours; 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.

The veterinary medicinal product must not be mixed with other aqueous solutions (e.g. milk).

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months
Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Amber PET bottle of 15 ml capacity (containing 7 or 15 ml) closed by HDPE screw cap with LDPE plug and safety seal supplied with 3 ml PP oral syringe with HDPE plunger.

Package sizes:
Cardboard box with 1 x bottle (7 ml) and 1 oral syringe.
Cardboard box with 1 x bottle (15 ml) and 1 oral syringe.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater <or household waste>.

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

Vet-Agro Multi-Trade Company Sp. z o.o.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kabergovet 50 microgram/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Cabergoline 50 µg

3. PACKAGE SIZE

7 ml
15 ml

4. TARGET SPECIES

Dogs, cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days before…

9. SPECIAL STORAGE PRECAUTIONS

Keep the container 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

{Logo name of the marketing authorisation holder}

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Bottle 7 ml, 15 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kabergovet

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Cabergoline 50 µg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days before…

{Logo name of the marketing authorisation holder}

7 ml
15 ml

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Kabergovet 50 microgram/ml oral solution for dogs and cats

2. Composition

Each ml contains:

Active substance:
Cabergoline 50 µg

Pale yellow, viscous oily solution.

3. Target species

Dogs, 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.
Cabergoline may induce transient hypotension in treated animals, do not use in animals concurrently being treated with hypotensive drugs. Do not use directly after surgery, whilst the animal is still under the influence of anaesthetic agents.
Do not use in cases of hypersensitivity to the active substance or to any of the excipient.

6. Special warnings

Special warnings:

Additional supportive treatments should involve restriction of water and carbohydrate intake and increased exercise

Special precautions for safe use in the target species:

The veterinary medicinal product should be administered with caution to animals with impaired liver function.

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

Wash hand after use. Avoid contact with skin and eyes. Wash of any splashes immediately.

Women of childbearing potential and breast-feeding woman 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 should avoid contact with the veterinary medicinal product.

Do not leave unattended filled syringes in the sight and presence of children. In case of accidental ingestion, particularly by a child, seek medical advice 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 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.
Since cabergoline may induce transient hypotension, the veterinary medicinal product should not be used in animals concurrently treated with hypotensive drugs.

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 parental 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.
The veterinary medicinal product must not be mixed with other aqueous solutions (e.g. milk).

7. Adverse events

Dogs, cats:

Rare (1 to 10 animals / 10,000 animals treated):	Drowsiness[1], anorexia (loss of appetite)[1] Vomiting[1,2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypotension (low blood pressure)[3] Allergic reactions (e.g. oedema (swelling), urticaria (hives), pruritus (itching)) Allergic dermatitis Neurological symptoms (e.g. sleepiness, muscle tremor, ataxia (incoordination), convulsion) Hyperactivity

[1] moderate and transient in nature.
[2] 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.
[3] transient.

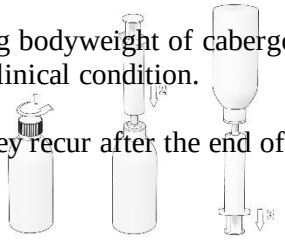
Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report 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: {national system details}

8. Dosage for each species, routes and method of administration

Oral use, 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.



9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible before administration.

<u>How to withdraw the recommended volume from the bottle?</u>

1.Remove the screw cap

2.Connect the supplied syringe to the flask

3.Turn the bottle upside-down to remove the liquid

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the container 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 label 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 or <household waste>.

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

Package sizes:
Cardboard box with 1 x bottle (7 ml) and 1 oral syringe.
Cardboard box with 1 x bottle (15 ml) and 1 oral syringe.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Vet-Agro Multi-Trade Company Sp. z o.o.
Gliniana 32, 20-616 Lublin,
Poland

Contact details to report suspected adverse reactions:

Local representatives <and contact details to report suspected adverse reactions>:

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

17. Other information