SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

KELACTIN 50 microgram/ml oral solution for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of the veterinary medicinal product contains:

Active substance:
cabergoline 50 micrograms

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.
Pale yellow, viscous oily solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dog and cat.

4.2 Indications for use, specifying the target species

The veterinary medicinal product is indicated for the following uses:
- Treatment of false pregnancy in bitches
- Suppression of lactation in bitches and queens

4.3 Contra-indications

- Do not use in pregnant animals since the product may cause abortion.
- Do not use with dopamine antagonist.
- Do not use in case 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 concurrently being treated with hypotensive drugs. Do not use directly after surgery whilst the animal is still under the influence of the anaesthetic agents.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

i) Special precautions for use in animals

Not applicable.

(ii) 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 product or should wear disposable gloves when administering the product.
People with known hypersensitivity to cabergoline or any of the other ingredients in the product should avoid contact with the veterinary medicinal product.
Do not leave unattended filled syringes in 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.

4.6 Adverse reactions (frequency and seriousness)

Possible adverse effects are:
- sleepiness
- anorexia
- 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 will not reoccur after the following administrations.
In very rare cases allergic reactions may occur, such as oedema, urticaria, dermatitis and pruritus.
In very rare cases a transient hypotension may occur.
In very rare cases neurological symptoms may occur, such as sleepiness, muscle tremor, ataxia, hyperactivity and convulsions.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

- 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.

4.8 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.

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

4.9 Amounts to be administered and administration route

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.

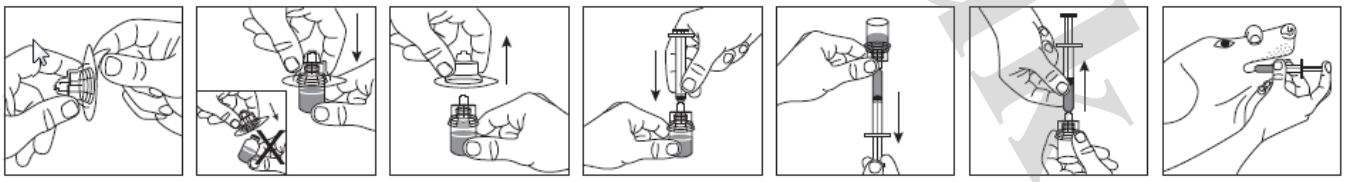
If the signs fail to resolve after a single course of treatment, or if they recur after the end of treatment, then the course of treatment may be repeated.

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

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

a. Remove the cover from the vial adapter package. Do not remove the vial adapter from the blister package.
b. Attach the adapter to the vial; use the blister pack to handle the adapter. Seat the adapter on the vial by pushing down until the spike penetrates the stopper and the adapter snaps in place.
c. Remove and discard the blister package.
d. Attach the syringe to the adapter by firmly pressing the syringe into the vial adapter to avoid leaking of the product when withdrawing the dose from the vial.
e. Withdraw the drug from the vial into the syringe holding the vial upside down.
f. Remove the syringe from the adapter.
g. The drug is now ready for administration.

It is recommended to rinse and dry the syringe following each application.



a. b. c. d. e. f. g.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: prolactin inhibitor belonging to the ergoline derivative group which acts by dopamine agonist activity.
ATCvet Code: QG02CB03.

5.1 Pharmacodynamic properties

The pharmacodynamics of cabergoline have been investigated in various *in-vitro* and *in-vivo* system. The most significant findings can be summarised as follows:
- Cabergoline is a potent inhibitor of prolactin secretion by the pituitary, and as a consequence inhibits prolactin secretion dependent processes such as lactation.
- The mechanism of action of cabergoline is via direct interaction with the D-2 dopaminergic receptor on pituitary lactotroph cells; this interaction is a persistent effect.
- Cabergoline has some affinity for noradrenergic receptors, but does not affect noradrenaline or serotonin metabolism.
- As for other ergoline derivatives, cabergoline has emetic effects (equivalent in potency to those of pergolide and bromocriptine).
- At high doses orally, cabergoline causes a reduction in blood pressure.

5.2 Pharmacokinetic particulars

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 (mean 75 minutes) 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 $_{(0\text{-}24\ h)}$ 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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Triglycerides, medium-chain.
Nitrogen, low-oxygen

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 14 days.

6.4 Special precautions for storage

As packaged for sale: store in a refrigerator (2°C - 8°C).
After first opening: store below 25°C.
Store in upright position.
Keep the vial tightly closed in the outer carton in order to protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

Immediate packaging:
Amber glass type III vials of 15 ml capacity (containing 7 or 15 ml) or type II vials of 30 ml capacity (containing 24 ml) with grey coated bromobutyl rubber closure and aluminium cap, supplied with vial adapter and HDPP dosing syringe (1 ml syringe with 7 ml packaging, and 3 ml syringe with 15 and 24 ml packagings).
Secondary packaging:
Cardboard box containing a single vial of 7 ml, 15 ml or 24 ml.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Veyx-Pharma GmbH
Söhreweg 6
34639 Schwarzenborn
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 27569/4008

9. DATE OF FIRST AUTHORISATION

4 July 2012

10. DATE OF REVISION OF THE TEXT

May 2021

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.

Approved: 19/05/21