B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

VEYLACTIN (CZ, DE, EL, ES, HU, IT, PL, PT, SK)
VEYLACTIN vet (FI, IS, NO)
KELACTIN (BE, CY, FR, LU, NL, UK)
KELACTIN vet (DK, SE)
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

Veyx-Pharma GmbH
Söhrenweg 6
34639 Schwarzenborn
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VEYLACTIN 50 microgram/ml oral solution for dogs and cats (CZ, DE, EL, ES, HU, IT, PL, PT, SK)
VEYLACTIN vet 50 microgram/ml oral solution for dogs and cats (FI, IS, NO)
KELACTIN 50 microgram/ml oral solution for dogs and cats (BE, CY, FR, LU, NL, UK)
KELACTIN vet 50 microgram/ml oral solution for dogs and cats (DK, SE)

cabergoline

3. STATEMENT OF THE ACTIVE SUBSTANCEAND OTHER INGREDIENTS

Each 1 ml contains:
cabergoline 50 micrograms
oral solution
Pale yellow, viscous oily solution.

4. INDICATIONS

The veterinary medicinal product is indicated for the following uses:
- 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 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.

6. ADVERSE REACTIONS

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).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dog and cat

8. DOSAGE FOR EACH SPECIES, ROUTEAND METHOD OF ADMINISTRATION

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.

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

9. ADVICE ON CORRECT ADMINISTRATION

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

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

<u>Preparing the vial for first use:</u>

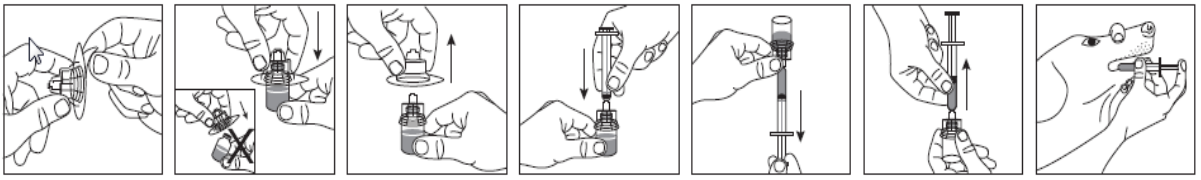
a. Remove the cover from the vial adapter package. Do not remove the blister package from the adapter.

b. Place the vial on a flat surface. Place the adapter, still contained in the blister package, straight from above on the vial, so that the pin of the adapter pierces the stopper in center position. Fix the adapter tightly on the vial by pushing down until it audibly snaps in place.
c. Remove and discard the blister package. The adapter now permanently remains on the vial. It seals the vial tightly and keeps the product ready for use until emptying.

Withdrawal of the required/prescribed amount:

d. Attach the syringe to the adapter by firmly pressing the syringe into the vial adapter, thus 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 in upright position. Leave the adapter on the vial.
g. The drug is now ready for administration.

It is recommended to rinse and dry the syringe following each application. For the next withdrawal, start with step d.



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

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

As packaged for sale: store in a refrigerator (2°C - 8°C).
After first opening: store below 25°C.
Shelf life after first opening the immediate packaging: 14 days.
Store in upright position.
Keep the vial tightly closed in the outer carton in order to protect from light.
Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
Keep out of the sight and reach of children.

12. SPECIAL WARNINGS

Special warnings for each target species:
Additional supportive treatments should involve restriction of water and carbohydrate intake and increase 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 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.

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 (cessation of milk production): 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. Since cabergoline may induce transient hypotension (low blood pressure), the product should not be used in animals concurrently treated with hypotensive drugs.

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 low blood pressure. 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.

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.

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

15. OTHER INFORMATION

Pack sizes: 7 ml, 14 ml and 24 ml.
Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.