

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

Each ml contains:

Active substance:

Cabergoline 50 micrograms

Excipients:

Qualitative composition of excipients and other constituents	
Triglycerides, medium-chain	
Nitrogen, low-oxygen (for purging the vials)	

Pale yellow, viscous oily solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats.

3.2 Indications for use for each 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

3.3 Contraindications

- Do not use in pregnant animals since the veterinary medicinal product may cause abortion.
- Do not use in case of hypersensitivity to the active substance or to any of the excipients.

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:

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.

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 veterinary medicinal product or personal protective equipment consisting of disposable gloves should be worn 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 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.

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):	Vomiting ^{1,2} , anorexia ²
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Allergic reaction; (e.g. oedema, urticaria, dermatitis or pruritus); Hypotension ³ ; Hyperactivity; Neurological symptoms (e.g. sleepiness ² , ataxia, muscle tremor, convulsion)

¹ 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.

² Moderate and transient

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:

- 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.

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.

Do not use with dopamine antagonists.

3.9 Administration routes and dosage

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.

How to withdraw the recommended volume from the vial?

It is recommended to use the vial adapter and syringe included in the packaging to withdraw the veterinary medicinal product from the vial. For that the following steps are necessary:

Preparing the vial for first use:

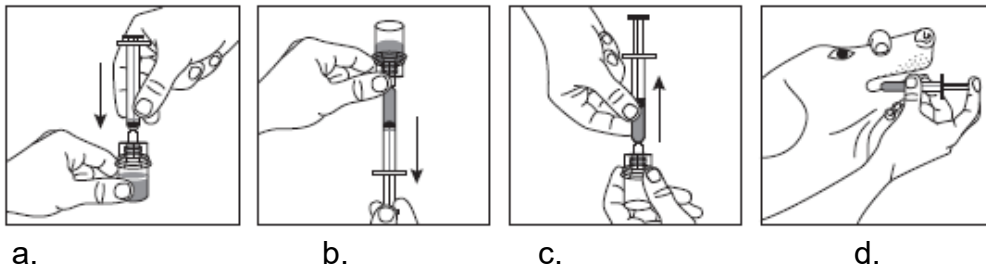
Place the vial on a flat surface. Place the adapter straight from above on the vial, so that the pin of the adapter pierces the stopper in center position. Fix the adapter tightly on the vial by pushing down.

The adapter now permanently remains on the vial. It seals the vial tightly and keeps the veterinary medicinal product ready for use until emptying.

Withdrawal of the required/prescribed amount:

- a. Attach the syringe to the adapter by firmly pressing the syringe into the vial adapter, thus to avoid leaking of the veterinary medicinal product when withdrawing the dose from the vial.
- b. Withdraw the drug from the vial into the syringe holding the vial upside down.
- c. Remove the syringe from the adapter in upright position. Leave the adapter on the vial.
- d. 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 a.



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

The pharmacodynamics of cabergoline have been investigated in various *in-vitro* and *in-vivo* systems. 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.

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 were 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_(0-24 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 $t_{1/2}$ on day 1 ~ 19 hours; $t_{1/2}$ on day 28 ~ 10 hours

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix the veterinary medicinal 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.

5.2 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.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Keep the vial tightly closed in the outer carton in order to protect from light.
Do not freeze.
Do not store above 25 °C after opening.
Store in upright position.

5.4 Nature and composition of immediate packaging

Amber glass type III vials of 15 ml capacity (containing 7 ml or 14 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 14 ml and 24 ml packagings).

Pack sizes:

1 vial (7 ml) with vial adapter and dosing syringe (1 ml) in a cardboard box.
1 vial (14 ml) with vial adapter and dosing syringe (3 ml) in a cardboard box.
1 vial (24 ml) with vial adapter and dosing syringe (3 ml) in a cardboard box.

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.

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

Veyx-Pharma GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 27569/4008

8. DATE OF FIRST AUTHORISATION

04 July 2012

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

July 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Approved 25 August 2026

Gavin Hall