SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Galastop 50 µg/ml Oral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of product contains:

Active substance:
Cabergoline .....50 µg

Excipients:

Qualitative composition of excipients and other constituents
Fractionated coconut oil (Miglyol 812).

A pale yellow, viscous solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

Galastop is indicated for the following uses:

• *Treatment of false pregnancy in bitches*: Inhibition of prolactin secretion by cabergoline results in a rapid resolution of the signs of false pregnancy, including lactation and behavioural changes.

• *Suppression of lactation in bitches*: Suppression of lactation in the bitch may be required under certain clinical circumstances (for example following removal of puppies soon after birth, or following early weaning). Inhibition of prolactin secretion by cabergoline results in a rapid cessation of lactation and a reduction in the size of the mammary glands.

3.3 Contraindications

• Do not use in pregnant animals since Galastop may cause abortion.

• Galastop 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.

• Do not use with dopamine antagonist.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:
Cabergoline has the capacity to cause abortion in bitches in the later stages of pregnancy, and under no circumstances should Galastop be used in pregnant bitches (see 4.3 above).
Cabergoline may induce transient hypotension in treated animals and use of Galastop in animals concurrently being treated with hypotensive drugs, or in animals directly after surgery whilst the animal is still under the influence of anaesthetic agents, might result in more significant hypotension and such usage is contra-indicated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid contact with skin and eyes. Wash off any splashes immediately.
Women of childbearing age should take care to avoid contact with the veterinary medicinal product.
Women of childbearing age should wear personal protective equipment consisting of impermeable gloves when handling the veterinary medicinal product.
Wash hand after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Anorexia[1]
Common (1 to 10 animals / 100 animals treated):	Vomiting[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Drowsiness[1], muscle tremor, ataxia, twitching, trembling Hyperactivity, restlessness, aggression, distress, hyperexcitation Hypotension[2] Allergic reaction

[1] Transient, usually only occur at the moment of first one or two administrations.
[2] Transitory. See also section "Special precautions for safe use in target animal species".

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 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 bitches in the later stages of pregnancy and under no circumstances should Galastop be used in pregnant bitches.
Galastop is indicated for the suppression of lactation in bitches: inhibition of prolactin secretion by cabergoline results in a rapid cessation of lactation and a reduction in the size of the mammary glands. Galastop should not be used in lactating bitches 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, Galastop should not be administered concurrently with drugs which have dopamine antagonist activity (such as phenothiazines, butyrophenones), as these might reduce its prolactin inhibiting effects.

3.9 Administration routes and dosage

Galastop 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 µg/kg bodyweight of cabergoline) once daily for 4-6 consecutive days, depending on the severity of the clinical condition.

For dogs less than 5 kg bodyweight it is advisable to measure the dosage in drops, 3 drops being equivalent to 0.1 ml.
The solution can be given either with the dropper or the syringe.
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.

For treatment of false pregnancy clinical studies have demonstrated efficacy between 80-100%.
Behavioural signs are alleviated first, followed by reduction in mammary gland enlargement, then finally suppression of lactation.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The experimental data indicate that a single overdose with Galastop 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. It is unlikely that the administration of dopamine antagonist drugs would be necessary, but this course of action could 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

ATC-vet code : QG02CB03

4.2 Pharmacodynamics

Cabergoline is a prolactin inhibitor belonging to the ergoline derivative group which acts by dopamine agonist activity.

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. Peak prolactin inhibition is reached at 4-8 hours and persists for several days, depending on the dose. The antiprolactin effect of cabergoline is longer lasting than that of metergoline, bromocriptine and pergolide.

• The mechanism of action of cabergoline is via direct interaction with the dopamine receptor on pituitary lactotroph cells; this interaction is a persistent effect.

• Apart from its effect on prolactin dependent processes, cabergoline does not have any other significant endocrine effects.

• In the Central Nervous System, cabergoline has dopamine agonist activity, acting via the D-2 dopaminergic receptors.

• 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).

• Given parenterally, or at high doses orally, cabergoline causes a reduction in blood pressure.

4.3 Pharmacokinetics

Pharmacokinetic studies were performed in both rats and dogs. The studies in rats were undertaken with radiolabeled cabergoline, by oral or intravenous administration, at a dose of 0.5 mg/kg bodyweight. The studies in dogs were performed with a daily dose of 80 µg/kg bodyweight (the dogs were treated for 30 days; pharmacokinetic assessments made on day 1 and 28). The source of the information given below is specified (rat data or dog data).

Absorption:
• Absorption after oral administration is nearly complete (rat data);

• T_{max} = 1 hour on day 1 and 0.5-2 hours (mean 75 minutes) on day 28 (dog data);

• 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 (dog data);

• $AUC_{(0\text{-}24\ h)}$ 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 $pg.h.ml^{-1}$) (dog data).

Distribution:
In terms of tissue to plasma concentration ratio (AUC), the tissue uptake was very high for liver, pituitary, adrenals, spleen, kidneys, lung (260-100), followed by ovaries, uterus, heart (50-30). In the brain the levels were of the same order of magnitude as in plasma (rat data).

Biotransformation:
• Assessment of plasma metabolites consistent amounts on four metabolites (FCE 21589, FCE 21904 and two unknown) were detected in plasma in addition to unchanged cabergoline which accounted for about 26% of plasma radioactivity from 2 to 48 hours after oral administration. Large amounts of metabolites were already present at the first sampling times (0.5 and 1.0 hours) suggesting a rapid biotransformation of cabergoline even of presystemic origin (rat data);

• Assessment of excreted metabolites in the urine excreted up to 24 hours after oral and intravenous dosing, about 25% of the excreted radioactivity was represented by unchanged drug, about 50% by the metabolite 6-ADL (FCE 21589) and the remaining 25% by other currently unknown metabolites (rat data).

Elimination:
• Plasma half life in dogs t½ on day 1 ~ 19 hours; t½ on day 28 ~ 10 hours (dog data);

• Tissue half life in rats The rate of elimination from most tissues (t½ ~ 17 hours)

except for the pituitary where elimination was particularly slow (t½ ~ 60 hours) (rat data).

• Excretion route in rats The main route of excretion was faecal; not more than 10% of the dose was recovered in the urine (rat data).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

Do not store above 25°C.
Protect from light.
Do not refrigerate.
Store in tightly closed original container.

5.4 Nature and composition of immediate packaging

Immediate packaging:
Amber Type III glass bottle with screw cap (3 ml, 7 ml or 15 ml) solution supplied with a clear Type I glass pipette (graduated dropper) with protective cover.

Amber Type III glass vial with polyethylene cap and polyethylene syringe insert (3, 7 or 15 ml).
Polypropylene syringe.

Secondary packaging:
Cardboard box containing a single bottle of 3 ml, 7 ml and 15 ml.
Cardboard box containing a single bottle of 3 ml, 7 ml and 15 ml with a syringe.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Ceva Salute Animale S.p.A

7. MARKETING AUTHORISATION NUMBER

Vm 28350/4001

8. DATE OF FIRST AUTHORISATION

22 April 1996

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

November 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 09 December 2025