PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Carton)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Galastop 50 µg/ml Oral solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains 50 µg cabergoline.

3. PACKAGE SIZE

3 ml
7 ml
15 ml

4. TARGET SPECIES

Dogs

5. INDICATION(S)

Read the package leaflet before use.

6. ROUTES OF ADMINISTRATION

Oral

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP: {mm/yyyy}
Once broached use within 28 days

9. SPECIAL STORAGE PRECAUTIONS

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

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

Ceva Salute Animale S.p.A

14. MARKETING AUTHORISATION NUMBERS

Vm 28350/4001

15. BATCH NUMBER

Lot

POM-V

To be supplied only on veterinary prescription

PARTICULARS TO APPEAR ON THE SMALL IMMEDIATE PACKAGE (Label 3ml, 7 ml and 15 ml bottle)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Galastop 50 µg/ml Oral solution

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

50 µg cabergoline/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Galastop 50 µg/ml Oral solution

2. Composition

Each ml contains 50 µg cabergoline.
Pale yellow, viscous solution.

3. Target species

Dogs

4. Indications for use

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.

5. 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.

6. Special warnings

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

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 Contraindications).

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 administering the veterinary medicinal product.
Wash hand after use.

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.

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.

Overdose:
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.

Major incompatibilities:
None known.

7. 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 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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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

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.

9. Advice on correct administration

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of sight and reach of children.
Do not store above 25°C.
Protect from light.
Do not refrigerate.
Store in tightly closed original container.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton 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.

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

Vm 28350/4001

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing Authorisation Holder and contact details to report suspected adverse reactions:

Ceva Salute Animale S.p.A
Via dei Valtorta 48
20127 Milano
Italy

Email for the reporting of adverse events: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:

Vetem SpA
Lungomore Pirandello 8
92014 Porto Empedocle
Italy

Ceva Sante Animale
Zone Industrielle Tres le Bois
22600 Loudeac
France

17. Other information

POM-V

To be supplied only on veterinary prescription.

Gavin Hall
Approved: 09 December 2025