PARTICULARS TO APPEAR ON THE OUTER BOXES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Galastop 50 µg/ml Oral solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1ml contains: 50 µg cabergoline

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

3 ml, 7 ml and 15 ml

5. INDICATION(S) and METHOD AND ROUTE(S) OF ADMINISTRATION

Dogs. Read the package leaflet before use.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light. Do not refrigerate. Once opened, use the product within 28 days. Store in tightly closed original container.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before disposal.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 28350/4001

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON THE SMALL IMMEDIATE LABELS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Galastop 50 µg/ml Oral solution

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

50 µg cabergoline/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

3, 7 or 15 ml

4. ROUTE(S) OF ADMINISTRATION

Oral

6. BATCH NUMBER

7. EXPIRY DATE

Once opened use by 28 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Keep out of the sight and reach of children.

POM-V
To be supplied only on veterinary prescription.

PACKAGE LEAFLET

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:
Ceva Salute Animale S.p.A,
Via dei Valtorta 48
20127 Milano
Italy

Manufacturer reponsible for batch release:

Vetem S.p.A.,
Lungomore Pirandello 8,
92014 Porto Empedocle (AG),
Italy

Ceva Santé Animale
Z.I. Très le Bois,
22600 Loudéac,
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Galastop 50 µg/ml Oral solution

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

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

4. INDICATION(S)

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. ADVERSE REACTIONS

Use in pregnant animals Experimental data have shown that cabergoline has the capacity to cause abortion in bitches in the later stages of pregnancy: this effect was seen in all bitches tested. Therefore a contra-indication against use of Galastop in pregnancy is essential (Special warnings).

Induction of hypotension Experimental data have shown that cabergoline has a hypotensive effect. This side-effect would not be expected to have adverse effects in clinical use because:

- The degree of this effect is not great and would not be expected to have adverse effects in healthy animals;
- In none of the experiments undertaken with cabergoline for whatever purpose and in whatever species has any evidence been observed of any adverse clinical reactions resulting from this hypotensive effect.

Nevertheless if an animal had low blood pressure for other reasons (e.g. concurrent use of hypotensive drugs, influence of anaesthetic agents), cabergoline might have adverse effects, and a warning to prevent usage of Galastop under such conditions is included (see Special warnings).

Emetic effects The tolerance data show that cabergoline has emetic activity in the dog. This effect appears to be dose related, and is marked at doses of 10 µg/kg and above (the ED50 the dose causing emesis in 50% of treated dogs – being calculated at 19 µg/kg).

In the clinical studies vomiting and anorexia was observed is a proportion of bitches treated as recommended for Galastop: in those studies where frequency was recorded, a total of 361 bitches were treated as recommended; of these 28 bitches (8%) vomited and 58 bitches (16%) showed anorexia.
In most cases these adverse effects were transient and of little significance, occurring after the first one or two treatments only. In only 3 bitches in the clinical trials (less that 1%) was treatment stopped because of vomiting.
In a small proportion of cases (qualitative frequency not available), a degree of drowsiness was observed in the first 2 days of treatment.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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. WITHDRAWAL PERIOD

Not applicable. Galastop is not indicated for use in food producing species.

10. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light. Do not refrigerate. Following withdrawal of the first dose, use the product within 28 days. Store in tightly closed original container.
Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 28 days
Keep out of sight and reach of children.

11. SPECIAL WARNING(S)

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

Special precautions for use in animals
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
Wash hand after use. Avoid contact with skin and eyes wash of any splashes immediately.
Care should be taken to avoid contact between the solution and women of childbearing age.
Women of childbearing age should wear gloves when administering the product.

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
Interactions between cabergoline and other veterinary medicinal products have not been observed. 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.

Incompatibilities
None known.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

13. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2023

14. OTHER INFORMATION

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.

Vm 28350/4001

POM-V
To be supplied only on veterinary prescription.

For animal treatment only.

Approved 13 December 2023