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Galastop® 50 µg/ml Oral solution

Species: Dogs

Therapeutic indication:Pharmaceuticals: Hormones and therapeutically related products: Others

Active ingredient: Cabergoline

Product: Galastop® 50 µg/ml Oral solution

Product index: Galastop

Incorporating:

Qualitative and quantitative composition

1 ml of product contains:

Active substance:

Cabergoline 50 µg

Excipients:

For the full list of excipients, see Pharmaceutical particulars.

Pharmaceutical form

Oral solution. A pale yellow, viscous non aqueous solution for oral administration containing 50 µg/ml cabergoline in a miglyol base.

Clinical particulars

Target species

Dogs.

Indications for use, specifying the 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.

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.

Special warnings for each target species

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

Special precautions for use

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 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

Wash hands after use. Avoid contact with skin and eyes. Wash off 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.

Adverse reactions (frequency and seriousness)

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 (see Use in pregnancy, lactation or lay).

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 Use in pregnancy, lactation or lay).

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 in 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 than 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.

Use during pregnancy, lactation or lay

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.

Amounts to be administered and administration route

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.

Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

Withdrawal period

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

Pharmacological particulars

ATCvet code: QG02CB03

Pharmacodynamic properties

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.

Pharmacokinetic particulars

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).

Tmax = 1 hour on day 1 and 0.5-2 hours (mean 75 minutes) on day 28 (dog data);

Cmax 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 (0-24 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 of 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).

Pharmaceutical particulars

List of excipients

Fractionated coconut oil (Miglyol 812).

Incompatibilities

None known.

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

Special precautions for storage

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.

Nature and composition of immediate packaging

Immediate packaging:

Amber Type III glass bottle with screw cap, containing 3 ml, 7 ml or 15 ml 0.005% cabergoline oily 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.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

Marketing Authorisation Holder (if different from distributor)

Ceva Salute Animale S.p.A., Viale Colleoni 15, 20864 Agrate Brianza (MB), Italy

Marketing Authorisation Number

UK: Vm**:** 28350/4001

Significant changes

Date of the first authorisation or date of renewal

22 April 1996.

Date of revision of the text

January 2014

Any other information

Nil

Legal category

Legal category:POM-V

GTIN

GTIN description: Galastop 7 ml

GTIN:03411110039717

GTIN description: Galastop 15 ml

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GTIN:03411110100288