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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

Presentation

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

Uses

Cabergoline is an ergoline derivative with a potent, selective and long-lasting inhibitory effect on prolactin secretion. Prolactin is the key hormone for lactogenesis and for the initiation and maintenance of lactation after parturition.

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 Galastop® results in a rapid cessation of lactation and a reduction in the size of the mammary glands.

Dosage and 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 body weight 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.

Contra-indications, warnings, etc

Do not use in pregnant animals since Galastop may cause abortion. Do not use in lactating bitches unless suppression of lactation is required.

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 in animals

Cabergoline has the capacity to cause abortion in bitches in the later stages of pregnancy. Under no circumstances should Galastop be used in pregnant bitches.

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 medicinal product to animals

Wash hands 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.

For animal treatment only. Keep out of reach and sight of children.

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.

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.

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 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.

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.

Interactions

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.

Pharmaceutical precautions

Store below 25°C. Protect from light. Do not refrigerate. After opening, use the product within 28 days. Store in tightly closed original container.

Any unused product or waste materials should be disposed of in accordance with local requirements.

Legal category

Legal category: POM-V

Packaging quantities

Amber type III glass bottle with screw cap, containing 7 ml or 15 ml 0.005% cabergoline oily solution; supplied with a clear type I glass pipette (graduated dropper) with protective cover

Further information

Nil.

Marketing Authorisation Number

Vm 28350/4001

Significant changes

GTIN

GTIN description:	Galastop 7 ml:
GTIN:	03411110039717
GTIN description:	Galastop 15 ml:
GTIN:	03411110100288