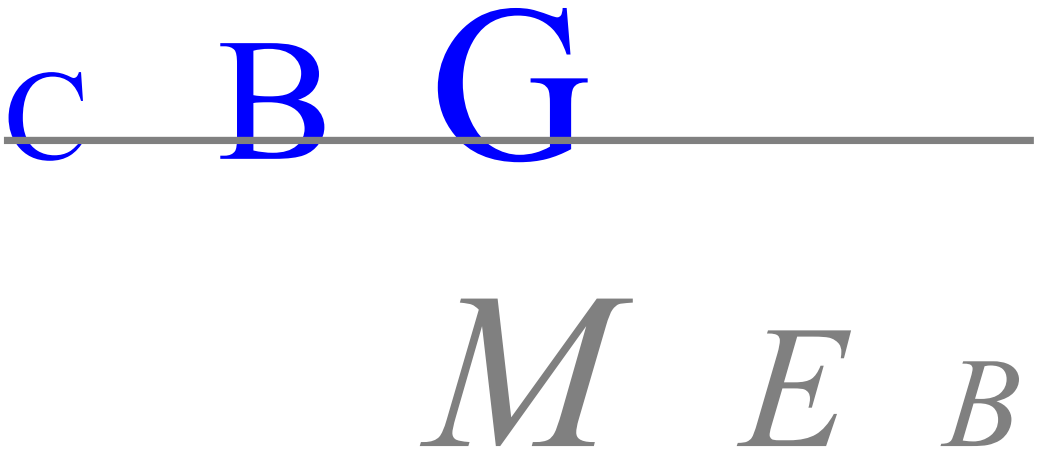

College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Finilac 50 microgram/ml oral solution for dogs and cats

Created: December 2019

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0188/001/DC
Name, strength and pharmaceutical form	Finilac 50 µg/ml oral solution
Applicant	Le Vet. Beheer B.V. Wilgenweg 7 3421 TV Oudewater Nederland
Active substance(s)	Cabergoline
ATC Vetcode	QG02CB03
Target species	Dogs and cats
Indication for use	Treatment of false pregnancy in bitches. Suppression of lactation in bitches and queens.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	16 December 2014
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	AT, BE, CY, CZ, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LU, LV, NO, PL, PT, RO, SE, SI, SK, UK

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species; the slight reactions observed are indicated in the SPC.
The product is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The efficacy of the product was demonstrated according to the claims made in the SPC. The overall risk/benefit analysis is in favour of granting a marketing authorisation.

Finilac is a generic application according to Article 13(1). The reference product is Galastop Sol. Ad us. Vet., registered on 11 July 1989 in the Netherlands under REG NL 6839, of the company CEVA Sante Animale B.V. (the Netherlands).The initial application for Galastop Sol. Ad us. Vet. was assessed before there was a requirement to have a public assessment report; therefore no details in this section are available.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product is an oral solution containing 0.050 mg/ml Carbegoline as the active substance and Triglycerides, medium chain as solvent.

The product is packed in amber Type III glass bottles with nominal volume of 3, 10, 15, 25 or 50 ml, by an inner liner with conical adapter and a cap closure system.

Sterile syringes of 1 ml or 2.5 ml size are packed together with the glass bottles as dosing device.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

The product is manufactured using conventional manufacturing techniques. The process has been validated on three full scale batches.

C. Control of Starting Materials

The active substance is Cabergoline, an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice. Use is made of the CEP procedure.

The applicant has adopted the specifications of the Ph Eur and CEP.

Batch analytical data demonstrating compliance with the CEP have been provided.

The excipient and the packaging materials are is in conformity with the Ph.Eur. requirements

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on intermediate products

Not applicable.

E. Control Tests on the Finished Product

The finished products specification controls the relevant parameters for the pharmaceutical form.

The tests in the specification are considered appropriate to adequately control the quality of the product. The limits for impurities are acceptable in view of the observed increase of degradation products during storage.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

F. Stability

A retest period of 60 months (stored at 2ºC to 8ºC in the original packaging material) could be established of the active substance from the CEP. 6 months accelerated study at 25ºC/60% RH demonstrated no impact on the quality of the active substance.

Stability data on the finished product and in-use stability have been provided in accordance with applicable European guidelines.

The claimed shelf live of 36 months for all presentations, when stored below 30°C is acceptable in view of the provided stability data. The claimed in-use shelf of 28 days can be granted.

Shelf-life of

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

G. Other Information

None.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmaco-toxicological tests are not required. The pharmaco-toxicological aspects of this product are identical to the reference product.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. The following warning sentences are included in the SPC:
"Wash hands after use.
Avoid contact with skin and eyes. Wash off any splashes immediately.
Women of childbearing potential and breast-feeding woman should not handle the product or should wear impervious gloves when administering the product.
If you know you are hypersensitive to cabergoline or any of the other ingredients in the product, you should avoid contact with the product.
Do not leave unattended filled syringes in the presence of children. In the event of accidental ingestion, particularly by a child, seek medical attention immediately and show the package leaflet or the label to the physician."

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines. The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be used in nonfood animals.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Heads of Veterinary Medicines Agencies website (www.HMA.eu).

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

Summary of change	**Section updated**	**Approval date**
Introduction of a new Pharmacovigilance system (Dechra Pharmacueticals PLC DDPS) which has been assessed by the relevant national competent authority/EMA for another product of the same MAH (NL/V/xxxx/WS/021).	N/A	4 July 2019
Renewal (NL/V/0188/001/R/001)	N/A	Pending