



MINISTERIO
DE SANIDAD, CONSUMO
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agencia española de
medicamentos y
productos sanitarios

DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

FINAL PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

**AFILARIA SR 3.4 mg/ml powder and solvent for suspension
for injection for dogs (EL, FR, PT, SI).**

**AFILARIA liberación prolongada 3.4 mg/ml powder and
solvent for suspension for injection for dogs (ES).**

**PREVENGO SR 3.4 mg/ml powder and solvent for suspension
for injection for dogs (IT).**

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0315/001/DC
Name, strength and pharmaceutical form	AFILARIA SR 3.4 mg/ml powder and solvent for suspension for injection for dogs (EL, FR, PT, SI). AFILARIA liberación prolongada 3.4 mg/ml powder and solvent for suspension for injection for dogs (ES). PREVENGO SR 3.4 mg/ml powder and solvent for suspension for injection for dogs (IT).
Applicant	SUPPORT PHARMA, S.L. General Alvarez de Castro, 39 28010 Madrid, Spain
Active substance(s)	Moxidectin
ATC Vet code	QP54AB02
Target species	Dogs
Indication for use	For the prevention of heartworm disease (L3 and L4 larvae of <i>Dirofilaria immitis</i>). For the prevention of cutaneous lesions and of dermatitis caused by <i>Dirofilaria repens</i> (L3 larvae). For the treatment of larval and adult infections of <i>Ancylostomum caninum</i> and <i>Uncinaria stenocephala</i> present at the time of treatment. When administered within 1 month from the beginning of the activity of intermediate host (mosquitos), the product has demonstrated persistent efficacy for the whole duration of the risk of infection season for the heartworm disease caused by <i>D. immitis</i> and for cutaneous lesions caused by <i>D. repens</i> in Europe. A persistent activity was not determined against <i>Ancylostomum caninum</i> and <i>Uncinaria stenocephala</i> .



MODULE 2

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

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Art/icle 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition procedure	Day 210: 05/06/2019
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	EL, FR, IT, PT and SI

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.

II. QUALITY ASPECTS

A. *Qualitative and quantitative particulars*

The medicinal product is a powder and solvent for suspension for injection. The powder (microspheres) contains 10% w/w of Moxidectin as active substance and Cholesterol, Carnauba wax, Hydrogenated palm oil and Glyceryl tristearate as other ingredients. The solvent contains Methyl parahydroxybenzoate and Propyl parahydroxybenzoate as preservatives, and Sodium chloride, Hypromellose, Hydrochloric acid, dilute (for pH adjustment) and Water for injections as other ingredients.

The container/closure systems of the powder (microspheres) and the solvent are 20 ml Type II colourless glass vials, closed with a Type I chlorobutyl rubber stopper and a flip-off aluminium collar. One adapter for the reconstitution and withdrawal of the suspension is provided in addition to the two vials.

The choice of the formulation and the presence of preservatives are justified.

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 licensed manufacturing sites.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. *Control of Starting Materials*

The active substance is Moxidectin, an established substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The information on the active substance is provided by presenting a copy of the current Certificate of Suitability of the Ph. Eur. procedure (CEP) for that substance, granted by EDQM to the manufacturer.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

Scientific data have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

D. Control on intermediate products

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

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

F. Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

The claim of a 3 months stability after reconstitution is based on the demonstration of stability for two batches reconstituted and stored for 3 months at 2°C - 8°C.

G. Other Information

Not applicable

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of safety tests are not required.

III.A Safety Testing

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the user warnings proposed address the identified risks of the product and have been updated in order to reflect the conclusions of the URA.

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. Since the veterinary medicinal product is going to be used only in non-food animals, the ERA concludes at question 3 of phase I. The assessment concluded that the product has an acceptable risk for the environment.

III.B Residues documentation

Not applicable, as the veterinary medicinal product is intended for non-food producing species.



IV. CLINICAL ASSESSMENT (EFFICACY)

This is a generic application according to Article 13(1) of Directive 2001/82/EC, amended by Directive 2004/28/EC. As 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.

IV.A Pre-Clinical Studies

As this was a generic application according to Article 13(1) of Directive 2001/82/EC, amended by Directive 2004/28/EC, and Bioequivalence with a reference product was demonstrated, pre-clinical studies are not required.

IV.B Clinical Studies

As this was a generic application according to Article 13(1) of Directive 2001/82/EC, amended by Directive 2004/28/EC, and Bioequivalence with a reference product was demonstrated, clinical studies are not required.



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 veterinary Heads of 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.

None