AGENCE NATIONALE DU
MEDICAMENT VETERINAIRE

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

SELASPOT SPOT-ON SOLUTION

DATE: 13/01/2023

French agency for food, environnemental and occupational health safety– French Agency for Veterinary Medicinal Products
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MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0431/001-008/DC
Name, strength and pharmaceutical form	Selaspot 15 mg spot-on solution for cats and dogs ≤ 2.5 kg Selaspot 30 mg spot-on solution for dogs 2.6–5.0 kg Selaspot 45 mg spot-on solution for cats 2.6–7.5 kg Selaspot 60 mg spot-on solution for cats 7.6–10.0 kg Selaspot 60 mg spot-on solution for dogs 5.1–10.0 kg Selaspot 120 mg spot-on solution for dogs 10.1–20.0 kg Selaspot 240 mg spot-on solution for dogs 20.1–40.0 kg Selaspot 360 mg spot-on solution for dogs 40.1–60.0 kg
Applicant	Bimeda Animal Health Limited Unit 2/3/4 Airton Close, Tallaght, Dublin 24, Ireland
Active substance(s)	Selamectin
ATC Vetcode	QP54AA05
Target species	Cats, dogs
Indication for use	**Treatment and prevention of flea infestations** caused by *Ctenocephalides* spp. for one month following a single administration. This is as a result of the adulticidal, larvicidal and ovicidal properties of the product. The product is ovicidal for 3 weeks after administration. Through a reduction in the flea population, monthly treatment of pregnant and lactating animals will also aid in the prevention of flea infestations in the litter up to seven weeks of age. The product can be used as part of a treatment strategy for flea allergy dermatitis and through its ovicidal and larvicidal action may aid in the control of existing environmental flea infestations in areas to which the animal has access. **Prevention of heartworm disease** caused by *Dirofilaria immitis* with monthly administration. **Treatment of ear mites** (*Otodectes cynotis*). **Cats:** .Treatment of biting lice infestations *(Felicola subrostratus*) .Treatment of adult roundworms (*Toxocara cati*) .Treatment of adult intestinal hookworms (*Ancylostoma tubaeforme*). **Dogs:** .Treatment of biting lice infestations (*Trichodectes canis*) .Treatment of sarcoptic mange (caused by *Sarcoptes scabiei*) .Treatment of adult intestinal roundworms (*Toxocara canis*).

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website https://www.anses.fr/en/thematique/veterinary-medicine-anmv

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	21 December 2022
Concerned Member States for original procedure	DE, ES, IT

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. Composition

The product is presented as a spot-on solution and contains selamectin (15, 30, 45, 60, 60 120, 240 or 360 mg depending on the pipette size) and excipients butylhydroxytoluene, isopropyl alcohol and dipropylene glycol monomethyl ether.
The packaging of the finished product is as described on the SPC. The particulars of the containers and controls performed are provided and conform to the regulation.
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.
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 selamectin, an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.
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.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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

E. Control on intermediate products

Not applicable.

F. 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 site have been provided demonstrating compliance with the specification.

G. Stability

A re-test period for the active substance is set in the certificate of suitability issued by EDQM.

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.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

This application for marketing authorisation is being made according to the provisions of Article 13.1 of Directive 2001/82/EC as amended by Directive 2004/28/EC.

The reference veterinary medicinal product is Stronghold, marketed by ZOETIS, which has been authorized in European Union since 25/11/1999.

The bioequivalence between the candidate and the reference product has been adequately demonstrated.

Toxicological Studies

As this is a generic application according to Article 13.1 (Directive No 2001/82/EC), and bioequivalence with a reference product has been accepted, results of toxicological tests are not required.

The safety aspects of this product are expected to be identical to those of the reference product.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

Phase I:

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 non-food animals. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

III.B Residues documentation

Not applicable.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

The bioequivalence between the candidate and the reference product has been adequately demonstrated.
The pharmacological aspects of this veterinary medicinal product are identical to the reference product.

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13.1 (Directive No 2001/82/EC), and bioequivalence with the reference product has been accepted, results of tolerance tests are not required.

The safety aspects of this product are identical to those of the reference product.

Warnings and precautions as listed on the product literature are in line with those of the reference product.

Resistance

A literature review of current published information concerning resistance to selamectin was provided. This does not permit to highlight changes of the current situation in Europe for dogs and cats, since the approval of the reference product. However specific warnings pertaining to the risk of resistance have been introduced in the SPC.

IV.B Clinical Studies

As this is a generic application in accordance with Article 13.1 (Directive No 2001/82/EC) and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this veterinary medicinal 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.