Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Selaspot 15 mg Spot-on Solution for Cats and Dogs ≤ 2.5 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 30 mg Spot-on Solution for Dogs 2.6 – 5.0 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

Date Created: June 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Selaspot 15 mg Spot-on Solution for Cats and Dogs ≤ 2.5 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 30 mg Spot-on Solution for Dogs 2.6 – 5.0 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	Oy Medfiles Ltd, Volttikatu 5, Kuopio, FI - 70700, Finland
Active substance	Selamectin
ATC Vetcode	QP54AA05
Target species	Cats & Dogs
Indication for use	**Cats and dogs:** • **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. The product may be safely administered to animals infected with adult heartworms, however, it is recommended, in accordance with good veterinary practice, that all animals 6 months of age or more living in countries where a vector exists should be tested for existing adult heartworm infections before beginning medication with the product. It is also recommended that dogs should be tested periodically for adult heartworm infections, as an integral part of a heartworm prevention strategy, even when the product has been administered monthly. This product is not effective against adult *D. immitis.* • **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 Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic applications in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	22/03/2023

I. SCIENTIFIC OVERVIEW

These were generic applications submitted in accordance with Article 13(1) of Directive 2001/82/EC as amended. The reference products are the Stronghold product range; Stronghold 15 – 240 mg Spot-on Solution for Cats and Dogs and Stronghold 360 mg Spot-on Solution for Dogs authorised via the centralised procedure in November 1999 and March 2015 respectively and marketed by Zoetis Belgium.

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, any reactions observed are indicated in the SPC.[1] 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 [2] of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTIUENTS

II.A. Composition

The products are spot-on solutions containing 60 mg or 120 mg of selamectin per ml of solution. The extractable volume of the eight presentations range from 0.25 ml to 3.00 ml resulting in strengths between 15 mg and 360 mg. The solutions also contain butylhydroxytoluene (BHT) as antioxidant and the excipients dipropylene glycol monomethyl ether and isopropyl alcohol.

[1] SPC – Summary of product Characteristics.
[2] Efficacy – The production of a desired or intended result.

The container/closure system consists of a white polypropylene pipette packaged in an aluminium foil-foil blister pack. The particulars of the containers and controls performed are provided and conform to the regulation.

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

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

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of sequential addition and mixing of the excipients and active substance.

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

II.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.

A valid Certificate of Suitability was provided.

The excipients Butylhydroxytoluene and isopropyl alcohol are both supplied to Ph. Eur. grade and are required to comply with the current version of their respective monographs.
The excipient Dipropylene glycol monomethyl ether is not described in a pharmacopoeia, this is used in the reference product and the applicant provided specification details and Certificates of analysis for two batches are provided.

As the finished product specifications include a test for microbial quality and as the formulations themselves are not likely to support microbial growth it is considered acceptable that the specifications for the ingredients do not include tests for microbiological quality.

The active substance, Selamectin for Veterinary Use, is packed in double polyethylene bags in an aluminium foil bag, placed in a fibre drum. The Certificate of Suitability, states that the retest period is 30 months when thus stored.

The finished product primary packaging is a unit-dose clear pipette. The pipettes are moulded from a natural colour polypropylene film and are packaged in an aluminium foil-foil blister pack and placed in paperboard cartons. The pipettes have pre-attached colour-coded, polypropylene caps, which are used to puncture the tube seal immediately prior to application.

II.C.4. Substances of Biological Origin

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

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.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 site have been provided demonstrating compliance with the specification. Control tests on the finished product are those for appearance, identification, uniformity of mass, HPLC assay, water, microbial and yeast counts.

II.F. Stability

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.

G. Other Information

Store in the original blister package in order to protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.
Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

The reference products are Stronghold Spot-on Solution for cats and dogs at the same doses (Zoetis Belgium), which have been authorised throughout the EU since November 1999, via a centralised procedure (360 mg dose via an extension since March 2015). These are generic products which have similar

formulations with identical active substance and excipients to the respective reference products and have the same pharmaceutical form (spot-on solution). The generic products are to be used in the same species, for the same indications, in the same doses and using the same posology as the reference products. Pharmacological and toxicological data have not been submitted, except to support the user risk assessment (URA). A URA and environmental risk assessment (ERA) were submitted and a Safety Expert Report.

III.A Safety Documentation

User Safety

The applicant supplied an abbreviated URA, using the highest strength (360 mg) as a reasonable worst-case scenario, since all of the products are presented in similar child-resistant packaging, the 360 mg represents the greatest application volume and quantity of active substance, and would represent the highest active substance dose to animal surface area ratio if applied to a 40 kg dog. This approach was considered to be acceptable.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore the following applicant's user recommendations are appropriate:,

This product is highly flammable; keep away from heat, sparks, open flames or other sources of ignition.

The product is a skin and eye irritant. Do not smoke, eat or drink while handling the product.
Wash hands after use and wash off any product in contact with the skin immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and seek medical advice immediately and show the package leaflet or the label to the physician.

Avoid direct contact with treated animals until the application site is dry. On the day of treatment, children must not handle treated animals and the animals should not be permitted to sleep with their owners, especially children. Used pipettes should be disposed of immediately and not left within the sight or reach of children.

People with sensitive skin or known allergy to veterinary medicinal products of this type should handle the veterinary medicinal product with caution.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

Phase I:

The applicant has submitted a Phase I ERA which follows the VICH GL6 decision tree and ends at Question 3 based on use in non-food animals only. As selamectin is known to be toxic to the aquatic environment, risk mitigation was included advising that dogs should not be allowed to swim in watercourses. The disposal and risk mitigation advice are appropriate. The product is not expected to pose an unacceptable risk to the environment when used as recommended in the SPC.

The product will only be used in non-food animals and as a result environmental exposure will be low. A Phase II ERA was not required.

IV. CLINICAL DOCUMENTATION

The applicant has stated that as these applications are submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended and as bioequivalence between the test and reference products has been established, no preclinical or clinical data are required. A waiver in accordance with section 7.1.b) of the Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/2000-Rev.3) can be accepted based on the systemic action of selamectin against the indicated endoparasites and blood-sucking ectoparasite species.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the products are used in accordance with the Summary of Product Characteristics the benefit/risk profile of the products is favourable.

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 Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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