IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

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PRODUCT SUMMARY

EU Procedure number	IE/V/0406/001/DC
Name, strength and pharmaceutical form	Selames 15 mg spot-on solution for cats and dogs ≤ 2.5 kg
Active substance(s)	Selamectin
Applicant	Krka, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto Slovenia
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of procedure	26th September 2018
Target species	Dogs and cats
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. • **Treatment of ear mites** (*Otodectes cynotis*). **Cats:**

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	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*).
ATCvet code	QP54AA05
Concerned Member States	BE, DE, ES, FR, IT, NL, PT, UK

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.
The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

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.

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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 benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

Each pipette contains 15 mg selamectin and the excipients butylhydroxytoluene (E321), isopropyl alcohol and dimethyl sulfoxide.
The product is presented as a translucent polypropylene unit-dose pipette (containing 0.25 ml of solution) with polyethylene or polyoxymethylene or polypropylene closure with spike packaged into a laminated triplex bag composed of polyester, aluminium and polyethylene. Cardboard box containing 1, 3, 6 or 15 pipettes.
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 at 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 substances is selamectin an established active substance. 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 materials. Batch analytical data demonstrating compliance with this specifications have been provided.

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.

D. Control on intermediate products Not applicable.

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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.

F. Stability

Stability data on the active substances have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substances 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.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

The application has been submitted in accordance with paragraph 1 of Article 13 of Directive 2001/82/EC, as amended (a generic veterinary medicinal product). The reference veterinary medicinal products are the centrally authorised product range Stronghold Spot-on for Dogs/Cats – containing selamectin.

III.A Safety Testing

Pharmacological Studies

It was claimed that the candidate product has the same qualitative and quantitative composition in terms of active ingredient as that of the reference product and has similar excipients in the same amounts to that of the reference veterinary medicinal product. The applicant notes that the excipient dimethyl sulfoxide is used in the candidate product, in the same proportion as dipropylene glycol methyl ether within the reference product.
The Applicant conducted two *in vivo* studies for the purposes of demonstrating that the test product (Selamectin) and the reference product (Stronghold) are bioequivalent in both cats and dogs. The bioequivalence studies were conducted using the 60 mg/ml spot on solution in cats and the 120 mg/ml spot-on solution in dogs. A biowaiver was used to support the bioequivalence of the other dosage strengths as per the dose proportionality rule according to the Guideline on the conduct of bioequivalence waivers for veterinary medicinal products (EMA/CVMP/016/00-Rev.2; paragraph 7.2).
Further, as the test product is intended to be administered to the same target species, using the same routes of administration at the same dose rates as already approved

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for the reference product, and bioequivalence has been demonstrated, the omission of the results of safety tests or of pre-clinical and clinical trials can be accepted.

Toxicological studies

This is a generic application according to Article 13(1), and as bioequivalence with a reference product has been demonstrated, the results of toxicological tests are not required.

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

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

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the risk to the user associated with this product is identical to that of the reference product. The proposed user safety statements are broadly in line with those of the reference product and are considered acceptable. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of 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.
- This product is highly flammable; keep away from heat, sparks, open flames or other sources of ignition.
- Do not smoke, eat or drink while handling the product.
- 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 applicators 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.
- Keep out of sight and reach of children.

Environmental Risk Assessment

Phase I

The environmental risk assessment can stop in Phase I, Question No. 3, because the medicine will be used only in non-food animals.

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It is acknowledged that selamectin may be toxic to aquatic organisms and it is accepted that the environmental safety statements agreed for the reference product can be applied to this product.

Conclusion

Based on the data provided, the ERA can stop at Phase I. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

IV. CLINICAL ASSESSMENT See **Part III.A**

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are expected to be equivalent to those of the reference product. In addition, it is considered that the risk to the target species will be similar for both the test and the reference products. The product literature accurately reflects the type and incidence of adverse effects which might be expected.

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 benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

VI. 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 HPRA website.

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.

Changes:

None.

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