Veterinary Medicines Directorate

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Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Ridamax 40 mg + 4 mg Spot-on Solution for Small Cats and Ferrets
Ridamax 80 mg + 8 mg Spot-on Solution for Large Cats

Date Created: April 2024

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Ridamax 40 mg + 4 mg Spot-on Solution for Small Cats and Ferrets Ridamax 80 mg + 8 mg Spot-on Solution for Large Cats
Applicant	Chanelle Pharmaceuticals Manufacturing Ltd, LoughreaCo Galway, Loughrea, Ireland
Active substance	Imidacloprid Moxidectin
ATC Vetcode	QP54AB52
Target species	Cats Ferrets
Indication for use	For cats suffering from, or at risk from, mixed parasitic infections: • the treatment and prevention of flea infestation (*Ctenocephalides felis*) • the treatment of ear mite infestation (*Otodectes cynotis*) • the treatment of notoedric mange (*Notoedres cati*) • the treatment of the lungworm *Eucoleus aerophilus* (syn. *Capillaria aerophila*) (adults) • the prevention of lungworm disease (L3/L4 larvae of *Aelurostrongylus abstrusus*) • the treatment of the lungworm *Aelurostrongylus abstrusus* (adults) • the treatment of the eye worm *Thelazia callipaeda* (adults) • the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immitis*) • the treatment of infections with gastrointestinal nematodes (L4 larvae, immature adults and adults of *Toxocara cati* and *Ancylostoma tubaeforme*). The veterinary medicinal product can be used

	as part of a treatment strategy for flea allergy dermatitis (FAD). For ferrets suffering from, or at risk from, mixed parasitic infections: • the treatment and prevention of flea infestation (*Ctenocephalides felis*) • the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immitis*).

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

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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 conclusion of the procedure	17/01/2024

I. SCIENTIFIC OVERVIEW

These applications have been submitted as generic products in accordance with Article 13(1). The reference products are Advocate Spot-on Solutions for Cats and Ferrets at the corresponding strengths.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains of moxidectin and imidacloprid and the excipients benzyl alcohol, butylhydroxytoluene (E321) and propylene carbonate.

The container/closure system consists of polypropylene pipettes with snap-off caps. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence of preservative 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 dissolution and mixing.

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

II.C. Control of Starting Materials

The active substances are moxidectin and imidacloprid which are established active substances described in the European Pharmacopoeia. The active substances are manufactured in accordance with the principles of good manufacturing practice.

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

The excipients and packaging also comply with the relevant monographs.

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

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

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, solubility, identification, water content, related substances, assay and potency.

II.F. Stability

Stability data on the active substances 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.

G. Other Information

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Store in the original package in order to protect from light and moisture.
Do not store above 25°C.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Not required due to the legal basis of the application. Bioequivalence was established with the reference products.

Toxicological Studies

Not required.

User Safety

A user risk assessment was provided 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. Therefore the following applicant's user recommendations are appropriate:,

- People with known hypersensitivity to benzyl alcohol, imidacloprid or moxidectin should administer this product with caution. In very rare cases this product may cause skin sensitisation or transient skin reactions (for example numbness, irritation or burning/tingling sensation).
- In very rare cases this product may cause respiratory irritation in sensitive individuals.
- In order to prevent children getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.
- Avoid contact with skin, eyes or mouth.
- Do not eat, drink or smoke during application.
- Wash hands thoroughly after use.
- After application do not stroke or groom animals until the application site is dry.
- This may be ensured by treating animals in the evening. Do not allow recently treated animals to sleep with owners, especially children.

- In case of accidental spillage onto skin, wash off immediately with soap and water.
- If the product accidentally gets into eyes, they should be thoroughly flushed with water.
- If skin or eye symptoms persist, or the product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label to the physician.

Environmental Safety

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

Phase I:

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

IV.I. Pre-Clinical Studies

Not required due to the legal basis of the application.

IV.II. Clinical Documentation

Not required due to the legal basis of the application.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that the benefit/risk profile of the products are 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.

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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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