Veterinary Medicines Directorate

**United Kingdom**
**Veterinary Medicines Directorate**
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**NATIONAL PROCEDURE**

# PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

**Ridamax 40 mg + 10 mg Spot-on Solution for Small Dogs**
**Ridamax 100 mg + 25 mg Spot-on Solution for Medium Dogs**
**Ridamax 250 mg + 62.5 mg Spot-on Solution for Large Dogs**
**Ridamax 400 mg + 100 mg Spot-on Solution for Extra-large Dogs**

**Date Created: July 2024**

# MODULE 1

## PRODUCT SUMMARY

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| Name, strength and pharmaceutical form | Ridamax 40 mg + 10 mg Spot-on Solution for Small Dogs<br>Ridamax 100 mg + 25 mg Spot-on Solution for Medium Dogs<br>Ridamax 250 mg + 62.5 mg Spot-on Solution for Large Dogs<br>Ridamax 400 mg + 100 mg Spot-on Solution for Extra-large Dogs |
| Applicant | Chanelle Pharmaceuticals Manufacturing Ltd, Loughrea, Co Galway, Loughrea, Ireland |
| Active substance | Imidacloprid<br>Moxidectin |
| ATC Vetcode | QP54AB52 |
| Target species | Dogs |
| Indication for use | For dogs suffering from, or at risk from, mixed parasitic infections:<br>• the treatment and prevention of flea infestation (Ctenocephalides felis)<br>• the treatment of biting lice (Trichodectes canis)<br>• the treatment of ear mite infestation (Otodectes cynotis), sarcoptic mange (caused by Sarcoptes scabiei var. canis), demodicosis (caused by Demodex canis)<br>• the prevention of heartworm disease (L3 and L4 larvae of Dirofilaria immitis)<br>• the treatment of circulating microfilariae (Dirofilaria immitis)<br>• the treatment of cutaneous dirofilariosis (adult stages of Dirofilaria repens)<br>• the prevention of cutaneous dirofilariosis (L3 larvae of Dirofilaria repens)<br>• the reduction of circulating microfilariae (Dirofilaria repens)<br>• the prevention of angiostrongylosis (L4 larvae and immature adults of |

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| | Angiostrongylus vasorum)<br>• the treatment of Angiostrongylus vasorum and Crenosoma vulpis<br>• the prevention of spirocercosis (Spirocerca lupi)<br>• the treatment of Eucoleus (syn. Capillaria) boehmi (adults)<br>• the treatment of the eye worm Thelazia callipaeda (adults)<br>• the treatment of infections with gastrointestinal nematodes (L4 larvae, immature adults and adults of Toxocara canis, Ancylostoma caninum and Uncinaria stenocephala, adults of Toxascaris leonina and Trichuris vulpis).<br>The veterinary medicinal product can be used as part of a treatment strategy for flea allergy dermatitis (FAD). |

# 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

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|---|---|
| Legal basis of original application | Generic application in accordance with Article 8 of VMRs 2013 (Schedule 1, Para 1) as amended. |
| Date of conclusion of the procedure | 23/04/2024 |

## I. SCIENTIFIC OVERVIEW

These applications have been submitted as generic products. The reference products are Advocate Spot-on Solutions at the corresponding strengths. Bioequivalence has been established with regards to the reference products.

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 CONSTITUENTS

### *II.A. Composition*

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

The container/closure system consists of polypropylene pipettes with snap-off caps stored in sachets and then into cartons. 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.

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

## 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.

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

## II.C. Control of Starting Materials

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

The excipients comply with Ph. Eur.

### 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 appropriate for this type of dosage form.

## 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.

#### *Toxicological Studies*

Not required due to the legal basis of the application.

#### *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 a known hypersensitivity to benzyl alcohol, imidacloprid or moxidectin should administer this product with caution. In very rare cases the veterinary medicinal product may cause skin sensitisation or transient skin reactions (for example numbness, irritation, or burning/tingling sensation).
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.
In very rare cases this product may cause respiratory irritation in sensitive individuals.
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 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*

### *Pharmacology*

Not required due to the legal basis of the application.

### *Tolerance in the Target Species*

Tolerance studies were not required because of the legal basis of the application.

### *IV.II. Clinical Documentation*

### *Laboratory Trials*

Not required due to the legal basis of the application.

### *Field Trials*

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.

(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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