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

Imoxat 40 mg + 4 mg Spot-on Solution for Small Cats and Ferrets
Imoxat 80 mg + 8 mg Spot-on Solution for Large Cats
Imoxat 40 mg + 10 mg Spot-on Solution for Small Dogs
Imoxat 100 mg + 25 mg Spot-on Solution for Medium Dogs
Imoxat 250 mg + 62.5 mg Spot-on Solution for Large Dogs
Imoxat 400 mg + 100 mg Spot-on Solution for Extra Large Dogs

Date Created: January 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Imoxat 40 mg + 4 mg Spot-on Solution for Small Cats and Ferrets Imoxat 80 mg + 8 mg Spot-on Solution for Large Cats Imoxat 40 mg + 10 mg Spot-on Solution for Small Dogs Imoxat 100 mg + 25 mg Spot-on Solution for Medium Dogs Imoxat 250 mg + 62.5 mg Spot-on Solution for Large Dogs Imoxat 400 mg + 100 mg Spot-on Solution for Extra Large Dogs
Applicant	Chanelle Pharmaceuticals Manufacturing Ltd Dublin Road Loughrea Co. Galway Ireland
Active substance	Imidaclopid and moxidectin
ATC Vetcode	QP54AB52
Target species	Dogs, Cats and Ferrets
Indication for use	For dogs suffering from, or at risk from, mixed parasitic infections: • the treatment and prevention of flea infestation (*Ctenocephalides felis*) • the treatment of biting lice (*Trichodectes canis*) • the treatment of ear mite infestation (*Otodectes cynotis*), sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*), demodicosis (caused by *Demodex canis*) • the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immitis*)

	• the treatment of circulating microfilariae (*Dirofilaria immitis*) • the treatment of cutaneous dirofilariosis (adult stages of Dirofilaria repens) • the prevention of cutaneous dirofilariosis (L3 larvae of *Dirofilaria repens*) • the reduction of circulating microfilariae (*Dirofilaria repens*) • the prevention of angiostrongylosis (L4 larvae and immature adults of *Angiostrongylus vasorum*) • the treatment of *Angiostrongylus vasorum* and *Crenosoma vulpis* • the prevention of spirocercosis (*Spirocerca lupi*) • the treatment of *Eucoleus* (syn. *Capillaria*) *boehmi* (adults) • the treatment of the eye worm *Thelazia callipaeda* (adults) • 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*). The veterinary medicinal product can be used as part of a treatment strategy for flea allergy dermatitis (FAD). For cats suffering from, or at risk from, mixed parasitic infections: • 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 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.

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

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	26/02/2023

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product is/are identical to Advocate 40 mg + 4 mg Spot-on Solution for Small Cats and Ferrets, Advocate 80 mg + 8 mg Spot on Solution for Cats, Advocate 40 mg + 10 mg Spot-on Solution for Small Dogs, Advocate 100 mg + 25 mg Spot-on Solution for Medium Dogs, Advocate 250 mg + 62.5 mg Spot-on Solution for Large Dogs and Advocate 400 mg + 100 mg Spot-on Solution for Extra Large Dogs. The initial application for Advocate was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains imidacloprid and moxidectin and the excipients butylhydroxytoluene, propylene carbonate, benzyl alcohol and nitrogen.

The container/closure system consists of single dose pipettes consisting of 4 layers: polypropylene/COC/EVOH/polypropylene that are sealed with a 4-ply foil sachet composed of PET/aluminium foil/nylon/LDPE. 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 mixing and dissolving.

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 moxidectin, 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.

The active substance is imidacloprid, 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.

The excipients are described either in Ph. Eur. or USP NF.

Packaging materials comply.

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, moisture, assays of the active substances, related substances to the active substances, identification of the active substances, identification of butylhydroxytoluene and microbial purity.

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.

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.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Bioequivalence studies were conducted which demonstrated that this product is bioequivalent to the reference product.

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:

- 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.

- In case of accidental spillage onto skin, wash off immediately with soap and water.
- People with known hypersensitivity to benzyl alcohol, imidacloprid or moxidectin should administer the veterinary medicinal 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 very rare cases the veterinary medicinal product may cause respiratory irritation in sensitive individuals.
- If the veterinary medicinal product accidentally gets into eyes, they should be thoroughly flushed with water.
- If skin or eye symptoms persist, or the veterinary medicinal product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label to the physician.

- The solvent in the veterinary medicinal product may stain or damage certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

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 this is a generic 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

***<Delete where appropriate if refused>*.**

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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