MINISTERIO
DE SANIDAD, CONSUMO
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agencia española de
medicamentos y
productos sanitarios

DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

MUTUAL RECOGNITION PROCEDURE

FINAL PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

DIXIE fipronil 100 mg/ml spot-on solution for small dogs
DIXIE fipronil 100 mg/ml spot-on solution for medium dogs
DIXIE fipronil 100 mg/ml spot-on solution for large dogs
DIXIE fipronil 100 mg/ml spot-on solution for very large dogs

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0308/001/MR ES/V/0308/002/MR ES/V/0308/003/MR ES/V/0308/004/MR
Name, strength and pharmaceutical form	DIXIE fipronil 100 mg/ml spot-on solution for small dogs DIXIE fipronil 100 mg/ml spot-on solution for medium dogs DIXIE fipronil 100 mg/ml spot-on solution for large dogs DIXIE fipronil 100 mg/ml spot-on solution for very large dogs
Applicant	QUIMICA DE MUNGUÍA S.A. Derio Bidea, 51 48100 Munguía- Vizcaya SPAIN
Active substance(s)	Fipronil
ATC Vet code	QP53AX15
Target species	Dogs
Indication for use	Treatment of flea (*Ctenocephalides felis*) infestations and prevention of re-infestation with fleas through insecticidal effect for up to 5 weeks. One application provides immediate and persistent insecticidal efficacy and prevents new infestations by fleas up to a maximum of 5 weeks. The product prevents new infestations of *Rhipicephalus sanguineus* ticks from day 9 to day 23 after product application. The product has not demonstrated an immediate acaricidal effect, if ticks of these species are present when the product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week. The product can be used as part of the strategy in the treatment of flea allergy dermatitis (FAD), where this has been previously diagnosed by a veterinarian.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Mutual Recognition application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition procedure	D90: 27/09/2018
Date product first authorised in the Reference Member State (MRP only)	23/02/2016
Concerned Member States for original procedure	EL, FR, IT, PL, PT, RO and UK

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

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains fipronil (100 mg/ml) and excipients Butylhydroxytouene, Butylhydroxyanisole, Povidone, Polysorbate 80, Ethanol 96% and Diethylene glycol monoethyl eter.

The container/closure system is a w*hite opaque plastic spot-on pipettes of high density Polyethylene -extrusion material (COEX). Each pipette is packaged in blisters composed by plastic supports (PVC-PE) to hold them and covered by a polyester / polyethylene complex.*

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 from a licensed manufacturing site.
The product is manufactured using conventional manufacturing techniques. Process validation for full-scale batches will be performed post-authorisation.

C. Control of Starting Materials

The active substance is manufactured in accordance with the principles of good manufacturing practices.

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.

D. Control on intermediate products

Not applicable

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 sites have been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substance 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.

III. SAFETY AND RESIDUES ASSESSMENT

III.A Safety Testing

Pharmacological Studies

In accordance with the requirements for this type of application (article 13.3), bibliographic information on the pharmacological effects of fipronil has been provided.

Toxicological Studies

In accordance with the requirements for this type of application (article 13.3), the applicant has provided bibliographical data on the toxicological properties of fipronil.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. The user warnings proposed are the same as those for the reference product.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be used in non-food animals.

Given that this veterinary medicinal product is an ectoparasiticide applied topically to dogs, a recommendation for dogs not entering watercourses for two days after application has been included.

III.B Residues documentation

Not applicable

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

The applicant performed one tolerance study. This study was adequately designed and conducted according to the European Guidelines. No adverse reactions related to the use of the product were observed along the study period. Good tolerance and safety was demonstrated.

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

Laboratory Trials

The applicant conducted one controlled dose confirmation study (under GCP) for each parasite species proposed, on the target animal.

The product literature accurately reflects the conclusions of this study.

Field Trials

On the other hand, two field trials were also conducted: one with ticks and other with fleas.

The product literature accurately reflects the conclusions of these studies.

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

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 veterinary Heads of Agencies website (www.hma.eu).

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.

None