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)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

DIXIE PERMETHRIN 715 mg Spot-On solution for Dogs
DIXIE PERMETHRIN 1430 mg Spot-On solution for Dogs

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0290/001-002/DC
Name, strength and pharmaceutical form	Dixie Permethrin 715 mg Spot-On solution for Dogs Dixie Permethrin 1430 mg Spot-On solution for Dogs
Applicant	QUIMICA DE MUNGUÍA S.A. Derio Bidea, 51 48100 Munguía- Vizcaya SPAIN
Active substance(s)	Permethrin
ATC Vet code	QP53AC04
Target species	Dogs
Indication for use	Treatment and prevention of external parasites~~-~~ infestations in dogs caused by fleas (*Ctenocephalides canis, Ctenocephalides felis*) and ticks (*Rhipicephalus sanguineus*). The veterinary medicinal product prevents infestations for up to 4 weeks following administration. One treatment provides an insecticidal effect for 3 weeks against mosquitoes (*Aedes aegypti*). One treatment provides a repellent effect for one week against sand flies (*Phlebotomus perniciosus*).

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	Decentralised application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of the original procedure	D210: 19/12/18
Date product first authorised in the Reference Member State (MRP only)	NA
Concerned Member States for original procedure	PL, PT, FR, IT, UK, HR

I. SCIENTIFIC OVERVIEW

***For public assessment reports for the first authorisation in a range**:*

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 715 mg/ml of permethrin and the excipient propylene glycol monomethyl ether

The container/closure system is white opaque plastic spot-on pipettes of COEX- High Density Polyethylene –Extrusion material. Each pipette is protected in a heat-sealed aluminium sachet.

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.

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

C. Control of Starting Materials

The active substance is permethrin. 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.

D. Control on intermediate products

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

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 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.

G. Other Information

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III. SAFETY AND RESIDUES ASSESSMENT

As this is a generic application according to Article 13.3, bibliographic information on the pharmaceutical effects of permethrin has been provided.

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

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users, the environment and the consumers.

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 permethrin has been provided.

Toxicological Studies

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

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. The user warnings proposed are in accordance with those of 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 (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

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