MINISTERIO DE SANIDAD
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)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

DIPTRON PLUS 26.8 mg/240 mg spot-on solution for very small dogs
DIPTRON PLUS 67 mg/600 mg spot-on solution for small dogs
DIPTRON PLUS 134 mg/1200 mg spot-on solution for medium dogs
DIPTRON PLUS 268 mg/2400 mg spot-on solution for large dogs

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QUIMICA DE MUNGUIA, S.A	DCP
Publicly available assessment report	

PRODUCT SUMMARY

EU procedure number	ES/V/0447/001/DC ES/V/0447/001/DC ES/V/0447/001/DC ES/V/0447/001/DC
Name, strength and pharmaceutical form	DIPTRON PLUS 26.8 mg/240 mg spot-on solution for very small dogs DIPTRON PLUS 67 mg/600 mg spot-on solution for small dogs DIPTRON PLUS 134 mg/1200 mg spot-on solution for medium dogs DIPTRON PLUS 268 mg/2400 mg spot-on solution for large dogs
Applicant	Quimica De Munguia S.A. Derio Bidea 51, Mungía, 48100 Bizkaia Spain
Active substance(s)	Fipronil and Permethrin
ATC vetcode	QP53AC54
Target species	Dogs
Indication for use	In dogs, to be used against infestations with fleas and/or ticks when repellent (anti-feeding) activity is also necessary against sand-flies and/or mosquitoes. Fleas: Treatment and prevention of infestations by fleas (*Ctenocephalides felis*). Fleas on dogs are killed within 24 hours following treatment. One treatment provides persistent efficacy against new infestations with adult fleas for four weeks. The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this condition has previously been diagnosed by a veterinarian. Ticks: Treatment of infestations with *Ixodes ricinus* ticks. One application provides four weeks persistent acaricidal efficacy against tick infestations (*Ixodes ricinus, Dermacentor reticulatus and Rhipicephalus sanguineus*). If ticks of some species (*Dermacentor reticulatus* or *Rhipicephalus sanguineus*) are present at the time of application, not all ticks may be killed within 48 hours. Sand-flies and mosquitoes: One treatment provides repellent (anti-feeding) activity against sand-flies (*Phlebotomus perniciosus*) and against mosquitoes (*Culex pipiens, Aedes aegypti*) for four weeks.

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PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Hybrid application in accordance with Article 19(1) of Regulation (EU) 2019/6.
Reference product (RP)	EFFITIX 26.8 mg/240 mg spot-on solution for very small dogs EFFITIX 67 mg/600 mg spot-on solution for small dogs EFFITIX 134 mg/1200 mg spot-on solution for medium dogs EFFITIX 268 mg/2400 mg spot-on solution for large dogs
Marketing authorisation holder	Virbac S.A.
MS where the RP is or has been authorised	ES
Marketing authorisation number	3098 ESP 3099 ESP 3100 ESP 3101 ESP
EU procedure number	FR/V/0371/001 FR/V/0371/002 FR/V/0371/003 FR/V/0371/004
Date of authorisation	September 2014
Date of completion of the original decentralised procedure	Day 210: 06/08/2025
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	PT
Withdrawn CMS during original decentralised procedure	-

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP 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 VMP was demonstrated according to the claims made in the SPC.

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

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

2.A. Product description

The VMP contain *fipronil (6.10% w/v) and permethrin (54.50% w/v)* as active substances and the excipients: diethylene glycol monomethyl ether, benzyl alcohol, BHT (E321) and BHA (E320).

The container/closure system is a white opaque plastic spot-on pipette packaged in a heat-sealed aluminium sachet.

The choice of preservatives is justified.

The VMP is an established pharmaceutical form, and its development is adequately described in accordance with the relevant European guidelines.

2.B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

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

2.C. Production and control of starting materials

The active substance, Fipronil, is an established substance described in the European Pharmacopeia/National pharmacopeia. 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, Permethrin 40:60, is an established substance not described in the European Pharmacopeia/National pharmacopeia of a member state/pharmacopeia of a third country. 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.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this VMP.

2.D. Control tests carried out on isolated intermediates during the manufacturing process

NA

2.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 VMP.

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.

2.F. Stability tests

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 VMP throughout its shelf life when stored under the approved conditions.

2.G. Other information

NA

3. SAFETY DOCUMENTATION (safety and residues tests)

3.A. Safety tests

Pharmacological studies

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, results of pharmacological tests are not required.

Toxicological studies

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, results of toxicological tests are not required.

User safety

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, the candidate formulation will not present an unacceptable risk for the user than the reference product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

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

3.B. Residues documentation

Not applicable.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, efficacy studies (preclinic and clinic) are not required.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP 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 VMP for humans and the environment is acceptable.

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POST-AUTHORISATION PROCEDURES

None.