College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Dronspot 30 mg/7.5 mg Spot-on Solution for Small Cats
Dronspot 60 mg/15 mg Spot-on Solution for Medium Cats
Dronspot 96 mg/24 mg Spot-on Solution for Large Cats

Date Created: September 2017 (by former RMS: UK)
Date amended: October 2019 (by current RMS: NL)

MODULE 1

PRODUCT SUMMARY

EU procedure number	NL/V/0310/001-003 (former number: UK/V/0685/001-003)
Name, strength and pharmaceutical form	Dronspot 30 mg/7.5 mg Spot-on Solution for Small Cats Dronspot 60 mg/15 mg Spot-on Solution for Medium Cats Dronspot 96 mg/24 mg Spot-on Solution for Large Cats
Applicant	Bayer B.V. Animal Health Division Energieweg 1 NL 3641RT Mijdrecht
Active substance	Emodepside Praziquantel
ATC Vetcode	QP52AA51
Target species	Cats
Indication for use	For the treatment of mixed parasitic infections in cats caused by roundworms and tapeworms of the following species: <u>Roundworms (Nematodes)</u> *Toxocara cati* (mature adult, immature adult, L4 and L3) *Toxocara cati* (L3 larvae) – treatment of queens during late pregnancy to prevent lactogenic transmission to the offspring *Toxascaris leonina* (mature adult, immature adult and L4) *Ancylostoma tubaeforme* (mature adult, immature adult and L4) <u>Tapeworms (Cestodes)</u> *Dipylidium caninum* (mature adult and immature adult) *Taenia taeniaeformis* (adult) *Echinococcus multilocularis* (adult)

MODULE 2

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

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 completion of the original mutual recognition procedure	13 March 2019
Date product first authorised in the Reference Member State (MRP only)	27 July 2005
Concerned Member States for original procedure	Belgium, Czech Republic, Finland, Hungary, Italy, Luxenbourg, Poland, Sweden, Slovakia, United Kingdom

I. SCIENTIFIC OVERVIEW

These were generic applications submitted under Article 13 (1) of Directive 2001/82/EC, as amended.

The products are indicated for the treatment of cats of different sizes, suffering from mixed parasitic infections caused by roundworms and tapeworms. The products contain 21.43 mg/ml emodepside and 85.75 mg/ml praziqantel in pipettes containing different dose volumes for topical administration to cats of different sizes.

The recommended minimum doses are 3 mg emodepside/ kg body weight and 12 mg praziquantel/ kg body weight, equivalent to 0.14 ml Dronspot/ kg body weight.

Dronspot 30 mg/7.5 mg spot on solution for small cats contains 0.35 ml of product, equating to 7.5 mg emodepside and 30 mg praziquantel. Dronspot 60 mg/ 15 mg spot-on solution for medium cats contains 0.7 ml of product equating to 15 mg emodepside and 60 mg praziquantel. Dronspot 96 mg/24 mg solution for large cats contains 1.12 ml of product equating to 24 mg emodepside and 96 mg praziquantel.

The reference products are Profender Spot-on Solution for Small Cats, Profender Spot-on Solution for Medium cats and Profender Spot-on Solution for Large Cats, authorised in the UK since July 2005, and produced by the same Marketing Authorisation Holder as that of the proposed products.

The products are 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 CONSTIUENTS

II.A. Composition

The products contain emodepside and praziquantel in varying quantities, to be used in different sizes of cat as defined in the SPC. The excipients are butylhydrozyanisole (E320; as antioxidant), isopropylidene glycerol and lactic acid.

The container/closure system consists of blister packs of 1, 2 or 20 pipettes. 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 a simple mixing, dissolution and filtration process, followed by the filling of the product into vials. Process validation data on the product have been presented in accordance with the relevant European guidelines.

II.C. Control of Starting Materials

The active substances are emodepside and praziquantel. Praziquantel is described in the European Pharmacopoeia (Ph. Eur). Emodepside conforms to agreed specifications. 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 lactic acid and butylated hydroxyanisole are monographed in the Ph. Eur. The packaging materials are in line with European guidelines.

II.C.4. Substances of Biological Origin

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

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

The tests performed on bulk solution retained for six months were satisfactory and conformed to the specifications provided.

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 sites have been provided demonstrating compliance with the specification. Control tests on the finished product include those for: appearance, identity of active substances and associated impurities, uniformity of dosage units, and water component.

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 medical product as packaged for sale: 3 years.

Store in the original package in order to protect from moisture.

Store below 25°C.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

The proposed products were identified as being identical to the reference products in every respect. Therefore, bioequivalence of the proposed products to the reference products was accepted and no pharmacological or toxicological data were required.

User Safety

A user risk assessment was not provided or required for this authorisation, as the proposed products are identical in every respect to the reference products.

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

- Read the package leaflet before use.
- Do not smoke, eat or drink during application.
- Avoid direct contact with application area while it is wet. Keep children away from treated animals during that time.
- Wash hands after use.
- 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 plenty of water.
- If skin or eye symptoms persist, or in case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
- Care should be taken not to allow children to have prolonged intensive contact (for example, by sleeping) with treated cats during the first 24 hours after application of the product.

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

- Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the OIE, specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

Phase I:

A Phase I environmental risk assessment was carried out. 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 and Tolerance in the Target Species

The proposed products are accepted as being bioequivalent to the reference products on the basis of essential similarity. No further data were required for these sections.

Resistance

A literature review conducted confirmed that there were no reports of resistance to the active substances.

IV.II. Clinical Documentation

The proposed products are accepted as being bioequivalent to the reference products on the basis of essential similarity. No further data were required for this section.

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 benefit/risk profile of the products is 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 Heads of Vetrinary Medicines 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.

15 May 2019	Transfer of RMS from UK to NL, EU procedure numbers changed from UK/V/0685/001-003 to NL/V/0310/001-003
17 June 2019	DDPS update
23 August 2019	Tightening of specification limits for Nickel in the finished product