Veterinary Medicines Directorate

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Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

RidaWorm 20 mg Spot-on Solution for Cats and Kittens

Date Created: June 2015

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	RidaWorm 20 mg Spot-on Solution for Cats and Kittens
Applicant	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland
Active substance	Praziquantel 20 mg
ATC Vetcode	QP52AA01
Target species	Cats
Indication for use	For the treatment of tapeworms of cats. The product is effective against mature and immature forms of *Dipylidium caninum* and *Taenia* species. The product is also effective against *Echinococcus multilocularis*.

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.

I. SCIENTIFIC OVERVIEW

This was a generic application for RidaWorm 20mg Spot-on Solution for Cats and Kittens. The reference product is Droncit Spot-on 20 mg Solution, authorised in the UK since August 2000.

The product is indicated for the treatment of tapeworms of cats, and is effective against mature and immature forms of *Dipylidium caninum* and *Taenia* species. The product is also effective against *Echinococcus multilocularis*. The product should be administered at a minimum dose rate of 8 mg/kg bodyweight, which equates to 1 tube per 2.5 kg bodyweight. It is not be used in cats weighing less than 1 kg bodyweight.

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, 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.

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

II. QUALITATIVE AND QUANTITIATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains 20 mg of praziquantel and the excipients Butylhydroxytoluene E321 and N-methylpyrrolidone.

The container/closure system consists of blisters of 1, 2, 3, 4 or 6 pipettes in a carton. The product is contained in a white polypropylene tube with a snap-off tab closure. 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.

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 praziquantel, an established active substance described in the European Pharmacopoeia/British Veterinary Pharmacopoeia (Ph. Eur). 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. Both excipients are monographed in the Ph. Eur.

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

The tests performed during production are described, these conform to the specifications provided. These tests are similar to the tests for the finished product. (See below).

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. Tests include those for appearance, identification of active substance and butylhydroxytoluene, container condition check, uniformity of dose, impurities and microbial purity.

II.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. Certificates of Suitability were provided by the manufacturers for the active substance, specifying a re-test period of 36 months. Two batches of the finished product were tested under approved test conditions, for 9 months at 25°C/60% RH, 6 months at 30°C/ 65% RH, (also checked after 12 months storage), and 6 months at 40°C/75% RH. The product was also checked for photostability and freeze-thaw viability. No adverse reactions were noted in the product specificity.

G. Other Information

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

Do not store above 25°C.

Store in a dry place in the original package.

Store away from food, drink and animal feeding stuffs.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

For generics, insert in the relevant sections as appropriate:

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been established, results of pharmacological and toxicological tests are not required.

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 and the environment.

III.A Safety Documentation

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:

- The product can be irritant to the skin and eyes.
- Care should be taken to avoid the contents of the tube coming into contact with the skin or eyes.
- If accidental contact with the skin or eyes occurs, wash off any skin contamination with soap and water immediately. Rinse the affected eyes thoroughly with clean, fresh water.
- In the event of skin or eye contact, seek medical advice if irritation persists and show the Doctor this package.
- Do not stroke or groom animals until the area of application is dry (typically around 1 hour after application).
- Wash hands thoroughly after use.
- Do not eat, drink or smoke during application.
- Keep product in the outer carton.
- Store away from food, drink and animal feedingstuffs.

Environmental Safety

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. The product is not expected to cause issues for the environment when used as recommended.

IV CLINICAL DOCUMENTATION

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been established, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.I. Pre-Clinical Studies

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been established, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.II. Clinical Documentation

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been established, 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 benefit/risk profile of the product(s) is favourable.

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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 Product Information Database of the Veterinary Medicines Directorate website.

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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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