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

Bob Martin Clear Wormer 20 mg Spot-on Solution for Cats and Kittens

Date Created: June 2015

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Bob Martin Clear Wormer 20 mg Spot-on Solution for Cats and Kittens
Applicant	Bob Martin (UK) Ltd Wemberham Lane Yatton Somerset BS49 4BS
Active substance	Praziquantel
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 an application for a generic product Bob Martin Clear Wormer 20 mg Spot-on Solution for Cats and Kittens, submitted in accordance with Article 13 (1) of Directive 2001 /82/EC as amended. The reference product is Droncit Spot-on 20 mg Solution, authorised in the UK since August 2000. The indication is to treat cats for the infestation of mature and immature forms of *Dipylidium caninum* and *Taenia* species. The product is also effective against *Echinococcus multilocularis.* The amount to be administered at a minimum dose rate is 8 mg/kg bodyweight, which equates to 1 tube per 2.5 kg bodyweight. Animals under 1 kg of weight should not be treated with this product.

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 QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains 20 mg of praziquantel per 0.5 ml pipette and the excipients butylhydroxytoluene (E321) and N-methylpyrrolidone. The container/closure system consists of a blister pack of 2 or 4 unit dose tubes in a carton, composed of a white polypropylene tube with a snap-off tab. 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. The manufacturing procedure is a simple dissolution process, followed by filtration and filling into pipettes.

II.C. Control of Starting Materials

The active substance is praziquantel, an established active substance described in the European 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. Acceptable Certificates of Suitability were provided.

The two excipients, N-methylpyrrolidone and butylhydroxytoluene are monographed in the Ph. Eur. and certificates of analysis were provided.

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 bulk solution used to fill the unit dose pipettes is tested prior to the filling of the pipettes. Assay results are then used to set the fill level for the pipettes.

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 impurities, uniformity of dose, moisture 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. A re-test period of 36 months was established from appropriate Certificates of Suitability. Real time and accelerated tests on the finished product, in line with VICH[3] guidelines were performed. Data provided were based on 6 months at 30°C/65% RH, 6 months at 40°C/75% RH and 9 months at 25°C/60% RH.

G. Other Information

Shelf-life of the product as packaged for sale: 2 years
Store away from food, drink and animal feeding stuffs.
Do not store above 25°C.
Store in a dry place in the original package.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

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, in line with that of the reference product, was provided in compliance with the relevant guideline:

[3] VICH – International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products.

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

- This product can be irritant to the skin and eyes.
- Care should be taken to prevent contact of the solution with the skin or eyes.
- If contact with the skin occurs, wash off any skin contamination with soap and water immediately.
- If accidental contact occurs with the eyes, flush 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.
- The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant.
- Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.
- Do not stroke or groom animals until area of application is dry (typically around 1 hour after application).
- Wash hands thoroughly after use.
- Do not eat, drink or smoke during application.
- Store away from food, drink or animal feedingstuffs.

Environmental Safety

Phase I:

A suitable environmental risk assessment was provided which confirmed that a 0.5 ml unit dose of the product will be provided monthly to cats only. No further assessment was required.

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

Tolerance in the Target Species

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

Resistance

Published data were provided which showed that there was no documented resistance of the target parasites to the active substance. Moreover, no data was

found world-wide for any resistance. Adequate warnings and precautions appear on the product literature.

IV.II. Clinical Documentation

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been established, no further studies were required. The 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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