Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Prazpronto 20mg Spot-on Solution for Cats and Kittens

Date Created: April 2019

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0690/001/MR
Name, strength and pharmaceutical form	Prazpronto 20mg Spot-on Solution for Cats and Kittens, Spot-on solution
Applicant	Chanelle Pharmaceuticals Manufacturing Ltd, Loughrea, Co Galway, Ireland
Active substance(s)	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.
Date of conclusion of the mutual recognition procedure	13th March 2019
Date product first authorised in the Reference Member State (MRP only)	28th April 2015
Concerned Member States for Mutual Recognition procedure	France, Germany, Ireland, Italy, The Netherlands, Spain

I. SCIENTIFIC OVERVIEW

This was a generic application for Prazpronto 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 QUANTITATIVE PARTICULARS OF THE CONSTIUENTS

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. The manufacturing process consists of a simple dissolution of the active substance followed by filtration and filling into pipettes.

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 supplied in accordance with an appropriate Certificate of Suitability. Praziquantel is monographed within European Pharmacopoeia (Ph. Eur), supplemented with a test and limits for residual solvents. 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 excipients are described in the Ph. Eur. The packaging for the product meets the required specifications.

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. The tests are similar to the tests for the finished product.

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. Control tests on the finished product are: 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 24 months at 25^{o}C/60% RH, 12 months at 30^{o}C/ 65% RH and 6 months at 40^{o}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)

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 irritating to the skin and eyes.
- Care should be taken to avoid the contents of the tube coming into contact with the skin, eyes and mouth, including hand-to-mouth and hand-to-eye contact.
- 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 eat, drink or smoke during application.
- In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.
- Laboratory studies with the excipient N-methyl-2-pyrrolidone in rabbits and rats have shown evidence of teratogenic, foetotoxic, maternotoxic and reprotoxic effects. Avoid direct contact with the product and application site.
- Do not stroke or groom animals until the area of application is dry (at least one hour after application).
- Wash hands thoroughly after use.
- Keep product in the outer carton until ready to use.
- Store away from food, drink and animal feeding stuffs.

Environmental Safety

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

Pharmacodynamics

Praziquantel is active against all stages of development of intestinal tapeworms. The substance is very rapidly absorbed and distributed throughout the parasite. Both *in vivo* and *in vitro* studies have shown that praziquantel causes severe

damage to the parasite integument, resulting in contraction, paralysis and death of the parasite

Pharmacokinetics

Praziquantel is quickly absorbed through the skin after dermal application of the recommended dose of 8 mg / kg body weight of cats. Maximum serum concentrations are reached after approx. 3 hours at approx. 0.06 mg / l.

As studies in various animal species show, praziquantel is rapidly metabolized in the liver. The main metabolites of praziquantel are monohydroxyhexyl derivatives. Excretion is predominantly via the kidneys.

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.

Pharmacology

Pharmacodynamics

Praziquantel is active against all stages of development of intestinal tapeworms. The substance is very rapidly absorbed and distributed throughout the parasite. Both *in vivo* and *in vitro* studies have shown that praziquantel causes severe damage to the parasite integument, resulting in contraction, paralysis and death of the parasite.

Pharmacokinetics

Praziquantel is quickly absorbed through the skin after dermal application of the recommended dose of 8 mg / kg body weight of cats. Maximum serum concentrations are reached after approx. 3 hours at approx. 0.06 mg / l.

As studies in various animal species show, praziquantel is rapidly metabolized in the liver. The main metabolites of praziquantel are monohydroxyhexyl derivatives. Excretion is predominantly via the kidneys.

Tolerance in the Target Species

The tolerance profile of the product is essentially similar to that of the reference product. No additional data were required.

Resistance

There was no evidence of resistance in the target parasites in European isolates. No additional data were required.

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 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 Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

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.

(www.gov.uk/check-animal-medicine-licensed)