Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
10117 Berlin
(Germany)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Ridaworm 20mg Spot-on Solution for small cats
Ridaworm 40mg Spot-on Solution for medium cats
Ridaworm 60mg Spot-on Solution for large cats

Date: 25 October 2019

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0316/001-003/DC
Name, strength and pharmaceutical form	Ridaworm 20mg Spot-on Solution for small cats Ridaworm 40mg Spot-on Solution for medium cats Ridaworm 60mg Spot-on Solution for large cats
Applicant	Chanelle Pharmaceuticals Manufacturing Ltd. IDA Industrial Estate IRL- LOUGHREA, GALWAY
Active substance(s)	Praziquantel
ATC Vetcode	QP52AA01
Target species	Cats
Indication for use	For the treatment of infections by tapeworms of cats: The product is effective against mature and immature stages of *Dipylidium caninum* and *Taenia* (*Hydatigera*) *taeniaeformis.*

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicinal Agencies website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13 (3) of Directive 2001/82/EC as amended.
Date of completion of the original Decentralised procedure	25 October 2019
Date product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	ES, FR, IE, IT, NL

I. SCIENTIFIC OVERVIEW

This was a generic application for Ridaworm Spot-on Solution for cats. The reference product is Droncit Spot-on 40 mg/ml, Lösung zum Auftropfen auf die Haut für Katzen, which has been initially authorised in Germany in 1999.

The product is indicated for the treatment of tapeworms of cats, and is effective against mature and immature forms of *Dipylidium caninum* and *Taenia (hydatigera) taeniaeformis*. The veterinary medicinal product (VMD) should be administered at a minimum dose rate of 8 mg/kg bodyweight. It should not be used in cats weighing less than 1 kg bodyweight.

It has been shown that the product can be safely used in the target species, any adverse reactions are indicated in the SPC. The product is safe for the user, and for the environment, when used as recommended.

Suitable warnings and precautions are adequately indicated in the SPC.

The efficacy of the VMD was demonstrated according to the claims made in the SPC.

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

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains 20 mg (Ridaworm 20 mg spot on solution for small cats), 40 mg (Ridaworm 40 mg spot on solution for medium cats) or 60 mg (Ridaworm 60 mg spot on solution for large cats) praziquantel and the excipients butylhydroxytoluene and N-methylpyrrolidone.

The container/closure system comprises white pipettes composed of a heat-formed shell composed of polypropylene/cyclic olefin copolymer/ethylene vinyl alcohol/polypropylene layer. The pipettes are sealed within a 4-ply foil sachet composed of PET/aluminium foil/nylon/LDPE and presented in an outer box.

The choice of the presence of the preservative is justified.

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

B. Method of Preparation of the Product

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

The product is manufactured in accordance with the European Pharmacopoeia and relevant European guidelines.

C. Control of Starting Materials

The active substance is praziquantel, an established active substance described in the European Pharmacopoeia. 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 product.

D. Control on intermediate products

Not applicable.

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.

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.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

None.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13 (3) of Directive 2001/82/EC as amended, and bioequivalence with a reference product has been demonstrated, results of pharmacological and toxicological tests are not required.

Warnings and precautions as listed on the product literature are very similar to those of the reference product and are adequate to ensure safety of the product to users and the environment.

III.A Safety Testing

User Safety

The applicant has provided a user safety assessment 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 pipette coming into contact with the skin, eyes or 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.
- 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. Pregnant women, women intending to conceive and breastfeeding women should not administer the product.
- Do not stroke or groom animals until area of application is dry (at least one hour after application).
- Wash hands thoroughly after use.
- Do not eat, drink or smoke during application.
- Keep the product in the outer carton until ready to use.
- Store away from food, drink and animal feeding stuffs.

Other precautions

- The solvent in the veterinary medicinal product may damage various materials such as plastics, leather or fabrics. Avoid contact of the product or the wet application area (s) with such materials.

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 veterinary medicinal product will only be used in non-food animals.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13 (3) of Directive 2001/82/EC, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this veterinary medicinal product (VMD) are equivalent to those of the reference VMD.

IV.A Pre-Clinical Studies

As this is a generic application according to Article 13 (3) of Directive 2001/82/EC, and bioequivalence with a reference VMD has been demonstrated, pre-clinical efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference VMD.

Pharmacology

Pharmacodynamics

Praziquantel is active against all stages of intestinal tapeworms. The substance is very rapidly absorbed over the parasites surface 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. The basis for the rapid onset of action is in particular the praziquantel-

induced change in the permeability of the parasite membranes for Ca^{++}, leading to dysregulation of the parasite's metabolism and finally to its death.

Pharmacokinetics
Praziquantel is quickly absorbed through the skin after dermal application of the recommended dose of 8 mg/kg body weight to cats. Maximum serum concentrations of approx. 0.06 mg/l are reached approx. 3 hours post application.
As studies in various animal species show, praziquantel is rapidly metabolised in the liver. The main metabolites of praziquantel are monohydroxyhexyl derivatives. Excretion is predominantly *via* the kidneys.

Tolerance in the Target Species of Animals

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

Resistance

Given the legal basis of this application and the fact that the VMD is intended to be administered to the same target species using the same posology, no difference in terms of potential for resistance development is expected between candidate and reference formulation. There is currently no evidence of resistance in the target parasites in European isolates.
Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies

Laboratory Trials & Field Trials

As this is a generic application according to Article 13(3) of Directive 2001/82/EC and bioequivalence with a reference product has been demonstrated, results of clinical studies were not required.

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 risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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 Veterinary Medicinal 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.

<None>