Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Krka Wormer 50/144/150 mg Tablets for Dogs
RSPCA WORMaway 50/144/150 mg Tablets for Dogs
Krka Roundworm and Tapeworm Wormer 50/144/150 mg Tablets for Dogs

Date Created: October 2022

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Krka Roundworm and Tapeworm Wormer 50/144/150 mg Tablets for Dogs Krka Wormer 50/144/150 mg Tablets for Dogs RSPCA WORMaway 50/144/150 mg Tablets for Dogs
Applicant	KRKA, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto Slovenia
Active substance	Pyrantel embonate Praziquantel Febantel
ATC Vetcode	QP52AC55
Target species	Dogs
Indication for use	For the treatment of mixed infestations with the following roundworms and tapeworms in adult dogs and puppies: • Nematodes • Ascarids: *Toxocara canis, Toxascaris leonina* (late immature forms and mature forms) • Hookworms: *Uncinaria stenocephala, Ancylostoma caninum* (adults) • Cestodes • Tapeworms: *Taenia* spp.*, Dipylidium caninum*

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

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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 procedure	27/7/2022

I. SCIENTIFIC OVERVIEW

These applications were submitted in accordance with Article 13(1) of Directive 2001/82/EC as amended. The reference product was Drontal Plus Flavour Tablets for Dogs, first authorised in Germany in 1993. The products are indicated for use in dogs, for the treatment of mixed infestations with the following roundworms and tapeworms in adult dogs and puppies: nematodes: ascarids: *Toxocara canis*, *Toxascaris leonina* (late immature forms and mature forms), hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults), and cestodes: tapeworms: *Taenia* spp, *Diplydium caninum*. The dose rate is 15 mg/kg body weight febantel, 14.4 mg/kg pyrantel and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 10 kg body weight. Tablets may be halved/quartered to allow accuracy of dosing.

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.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains praziquantel, pyrantel embonate and febantel and the excipients: lactose monohydrate, maize starch, povidone K30, microcrystalline cellulose, sodium lauryl sulfate, colloidal anhydrous silica, magnesium stearate and meat flavour.

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

The container/closure system consists of an OPA/Al/PVC blister in a cardboard box. 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 wet granulation of the ingredients.

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 pyrantel embonate, praziquantel and febantel which are established active substances described in the European Pharmacopoeia. 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. Acceptable certificates of suitability were provided. Excipients and packaging are suitably controlled with regard to quality.

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

Not applicable.

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 those for: appearance, uniformity of dosage units, uniformity

of mass, identification of praziquantel, identification of pyrantel embonate, identification of febantel, water, hardness, related substances of the active substances, content of the active substances, dissolution of the active substances and microbiological quality.

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 medicinal product as packaged for sale: 3 years
Any part used tablets should be discarded. This medicinal product does not require any special storage conditions.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Due to the legal basis of the application, no pharmacological studies have been submitted.

Toxicological Studies

Due to the legal basis of the application, no toxicological studies have been submitted.

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. Therefore the following user recommendations are appropriate:

- In case of accidental ingestion, seek medical advice and show the package leaflet to the physician.
- In the interest of good hygiene, persons administering the tablets directly to the dog or by adding them to the dog's food, should wash their hands afterwards.

Environmental Safety

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

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.

IV. CLINICAL DOCUMENTATION

IV.I. Pre-Clinical Studies

Pharmacology

Studies were not required due to the legal basis of the application.

Tolerance in the Target Species

Tolerance studies were not required due to the legal basis of the application.

IV.II. Clinical Documentation

Laboratory Trials

The applicant has conducted dose determination and confirmation studies and provided bibliographical data.

Dose confirmation studies:

The applicant has conducted four GCP dose confirmation studies. The studies were generally conducted well, and in accordance with current guidance. Results indicate sufficient efficacy against the target parasites.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that 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 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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