IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Strantel 230/20 mg Flavoured Film-Coated Tablets for Cats

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

PRODUCT SUMMARY

EU Procedure number	IE/V/0332/001/MR
Name, strength and pharmaceutical form	Strantel 230/20 mg Flavoued Film-Coated Tablets for Cats
Active substance(s)	Praziquantel Pyrantel embonate
Applicant	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea, Co. Galway, Ireland
Legal basis of application	Hybrid application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of procedure	23rdDecember 2013
Target species	Cat
Indication for use	For the treatment of mixed infections caused by the following gastrointestinal roundworms and tapeworms: **Roundworms:** *Toxocara cati*, *Toxascaris leonina,* **Tapeworms:** *Dipylidium caninum, Taeniataeniaeformis, Echinococcus multilocularis.*
ATCvet code	QP52AA51
Concerned Member States	BG, CZ, DE, EE, EL, ES, FI, FR, HR, HU, IS, IT, LT, LV, NL, PL, PT, SI, SK, UK

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation

submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

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.

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 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. QUALITY ASPECTS

A.Qualitative and Quantitative Particulars

The product contains 20 mg praziquantel and 230 mg pyrantel embonate as active substances with the excipients maize starch, microcrystalline cellulose, magnesium stearate, crospovidone, colloidal anhydrous silica, grilled meat flavour and opadry II white.
The tablets are to be packaged in blister packs. Two different blister types are used:

1. Blister packs made up of 45 micrometre soft temper aluminium foil and 20 micrometre hard temper aluminium foil.
2. Blister packs made up of PVC/PE/PCTFE white opaque copolymer and 20 micrometre hard temper aluminium foil. 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.
Process validation data on the product have been presented in accordance with the relevant European guidelines.

C.Control of Starting Materials

The active substances 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 specifications are considered adequate to control the quality of the materials. Batch analytical data demonstrating compliance with the specifications have been provided.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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 substances have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substances 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

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Based on the *in vivo*and *in-vitro*bioequivalence data provided (see Part 4), it is accepted that the pharmacological and toxicological profiles of the active substances will be similar for both test and reference product. Therefore, the results of basic pharmacological or toxicological studies are not required.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the product does not present any greater risk to the user relative to that posed by the authorised product, Drontal Cat tablets. The product is presented in blister and foil packaging in order to minimise the risk of exposure to users, including children.

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

Environmental Risk Assessment
The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV. CLINICAL ASSESSMENT

Pharmacology
The legal basis for the application is in accordance with Article 13(3) of Directive 2001/82/EC as amended (hybrid).

The test product (Prazitel Cat tablets) is the same as the reference product Drontal Cat tabletsin terms of qualitative and quantitative composition of the active substances (praziquantel and pyrantel embonate) and has the same pharmaceutical form (tablet).

In support of the present application, the applicant has provided the results of a bioequivalence study conducted in cats comparing the pharmacokinetic profiles of praziquantel, hydroxy-praziquantel and pyrantel embonate following administration of the test product with that following administration of the reference product. Based on the findings of this study, the applicant concluded that the test product (Prazitel Cat tablets)and the reference product, Drontal Cat tablets are bioequivalent for praziquantel. However, bioequivalence could not be concluded with respect to the extent of absorption of pyrantel.

Pyrantel is poorly absorbed following oral administration. In the *in vivo*study bioequivalence was not demonstrated for pyrantel based on AUC_{last}. The 90% confidence intervals for the ratio of the means were 64.9 – 102.5%. If this deviation from the standard acceptance limits of 80 – 125% is considered in the context of the expected bioavailability of pyrantel following oral administration, then is likely to be of only limited clinical significance. With a small proportion of the dose being systemically available, any difference in plasma concentrations will be proportionately greater than any difference in concentrations remaining at the site of action, locally in the GIT. The applicant provided published literature which supports the argument that pyrantel embonate exhibits low solubility, is poorly absorbed from the gastrointestinal tract and that it is largely excreted unchanged in the faeces.

The applicant conducted an *in vitro* dissolution study between the test product and the reference product, Drontal Cat tablets. The dissolution profile for both tablets is comparable in all dissolution media for praziquantel and pyrantel embonate, with greater than 85% dissolution achieved within 15 minutes. Based on *in vitro* dissolution data it is accepted that for both Prazitel Cat tablets and Drontal Cat tabletsthe dissolution profile will be similar.

Based on the totality of data (*in-vivo* and *in-vitro* bioequivalence data and published literature) are considered, it is accepted that the efficacy profile of the test product will be comparable to that of the reference product. The proposed conditions of use of the product (target species, indication and posology) are the same as those authorised for the reference product.

Tolerance in the Target Species of Animals

Given that:

·Strantel Cat tablets have been formulated to have the same composition, in terms of active substances, as the authorised reference product, Drontal Cat tablets,

·that all excipients in the formulation are commonly used in the manufacture of tablets for animal and human use and are generally regarded as safe,

·the proposed conditions of use of Strantel Cat tablets are identical to those of the authorised reference product, *·in vitro* dissolution profiles for both test and reference products are comparable in all dissolution media for all active substances indicating similar rate of release of active substances following ingestion,

it can be assumed that Strantel Coated Tablets for Catsare unlikely to present any greater risk to the target animal relative to that posed by the reference product, Drontal Cat tablets.

Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies

The efficacy claims for this product reflect those authorised for Drontal Cat tablets and can be accepted.

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

VI. 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 HPRA website.

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.

Changes:
None.