**IPAR**

**Publicly Available Assessment Report for a**
**Veterinary Medicinal Product**

# Exitel 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**

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|---|---|
| EU Procedure number | IE/V/0330/001/MR |
| Name, strength and pharmaceutical form | Exitel 230/20 mg Flavoued Film-Coated Tablets for Cats |
| Active substance(s) | Praziquantel<br><br>Pyrantel embonate |
| Applicant | Chanelle Pharmaceuticals Manufacturing Ltd.<br><br>Loughrea, Co. Galway,<br>Ireland |
| Legal basis of application | Hybrid application in accordance with Article 13(3) of Directive 2001/82/EC as amended. |
| Date of Authorisation | 12thJuly 2013 |
| Target species | Cat |
| Indication for use | For the treatment of mixed infections caused by the following gastrointestinal roundworms and tapeworms:<br><br>**Roundworms:** *Toxocara cati*, *Toxascaris leonina,*<br>**Tapeworms:** *Dipylidium caninum, Taeniataeniaeformis, Echinococcus multilocularis.* |
| ATCvet code | QP52AA51 |
| Concerned Member States | AT, BE, CZ, DE, EL, ES, FI, FR, IT, LU, PT, RO, SE, 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

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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 µm soft temper aluminium foil and 20 µm hard temper aluminium foil.
2.Blister packs made up of PVC/PE/PCTFE white opaque copolymer and 20 µm 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 for the manufacturing process has 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 approvedconditions.
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 ASSESSMENT**

The product has been formulated to have the same qualitative and quantitative composition, in terms of active substances, as the authorised reference product, Drontal Cat tablets.
Given that bioequivalence could not be demonstrated through bioavailability studies, the present application was submitted in accordance with Article 13(3) of the Directive, as amended (so called 'hybrid' application).

***III.A Safety Testing***

***Pharmacological Studies***

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 (Exitel Coated Tablets for Cats)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 and the extent of formation of hydroxy-praziquantel.

The applicant conducted an *in vitro* dissolution study between the test product and the authorised product, Drontal Cat tablets. This study confirmed comparable dissolution for Exitel Coated Tablets for Cats and Drontal Cat tablets in all dissolution media for all active substances. Based on *in vitro* dissolution it is accepted that the safety and efficacy profile for both Exitel Coated Tablets for Cats and Drontal Cat tablets will be similar.

***Toxicological Studies***

Based on *in vitro*dissolution it is accepted that the toxicological profile for both Exitel and reference product will be similar.

***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 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

### *IV.A Pre-Clinical Studies*

***Pharmacology***

The product has been formulated to have the same qualitative and quantitative composition, in terms of active substances, as the authorised reference product, Drontal Cat tablets.
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The applicant conducted an *in vitro* dissolution study between the test product and the authorised product, Drontal Cat tablets. This study confirmed comparable dissolution for Exitel Coated Tablets for Cats and Drontal Cat tablets in all dissolution media for all active substances. Based on *in vitro* dissolution it is accepted that the safety and efficacy profile for both Exitel Coated Tablets for Cats and Drontal Cat tablets will be similar.

***Tolerance in the Target Species of Animals***

Given that:

- Exitel 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 Exitel 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 Exitel 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*

Based on *in vitro* dissolution it is accepted that the efficacy profile for both Exitel Coated Tablets for Cats and Drontal Cat tablets will be similar.
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.