Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Wormclear 230 mg/20 mg Ellipsoid Film-coated Tablets for Cats

Date Created: August 2019

MODULE 1

PROPOSED PRODUCT SUMMARY

Name, strength and pharmaceutical form	Wormclear 230 mg 20 mg Ellipsoid Film-coated Tablets for Cats
Applicant	Bayer plc 400 South Oak Way Green Park Reading Berkshire RG2 6AD
Active substance	Pyrantel Embonate 230 mg per tablet Praziquantel 20 mg per tablet
ATC Vetcode	QP52 AA51
Target species	Cats
Indication for use	For the treatment of gastrointestinal roundworms and tapeworms: *Toxocara cati, Toxascaris leonina, Dipylidium caninum*, *Taenia taeniaeformis*

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	Informed Consent application in accordance with Article 13 (c) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	31st July 2019

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Drontal Cat Film-coated Tablets. The initial application for Drontal Cat Film-Coated Tablets was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

II. 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.

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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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