

United Kingdom Veterinary Medicines Directorate Woodham Lane New Haw Addlestone Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Johnson's One Dose Easy Wormer 230 mg/20 mg Film-coated Tablets for Cats and Kittens

Date Created: August 2019

Johnson's One Dose Easy Wormer 230 mg/20 mg Film-coated Tablets for Cats and Kittens

Bayer plc

Application for National Procedure Publicly Available Assessment Report

MODULE 1

PROPOSED PRODUCT SUMMARY

Name, strength and pharmaceutical form	Johnson's One Dose Easy Wormer 230 mg 20 mg Film-coated Tablets for Cats and Kittens
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: <i>Toxocara cati, Toxascaris leonina, Dipylidium</i> <i>caninum, Taenia taeniaeformis</i>

Bayer plc

Application for National Procedure Publicly Available Assessment Report

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)

Johnson's One Dose Easy Wormer 230 mg/20 mg Film-coated Tablets for Cats and Kittens

Bayer plc

Application for National Procedure Publicly Available Assessment Report

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	31 st 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.

Johnson's One Dose Easy Wormer 230 mg/20 mg Film-coated Tablets for Cats and Kittens

Bayer plc

Application for National Procedure Publicly Available Assessment Report

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.

(www.gov.uk/check-animal-medicine-licensed)

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.

(www.gov.uk/check-animal-medicine-licensed)