ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Drontal Plus XL Flavour Tablets

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Drontal Plus XL Flavour Tablets
Applicant	Bayer plc
Active substance(s)	Fenbantel Pyrantel embonate Praziquantel
ATC Vetcode	QP52AF30
Target species	Dogs
Indication for use	For the control of the following roundworms and tapeworms in adult dogs: Ascarids: *Toxocara canis, Toxascaris leonina* (adult and late immature forms). Hookworms: *Uncinaria stenocephala, Ancylostoma caninum* (adults) Whipworms: *Trichuris vulpis* (adults) Tapeworms: *Echinococcus* spp. *Taenia* spp. and *Dipylidium caninum* (adult and immature forms).

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Veterinary Medicines Directorate website (www.vmd.defra.gov.uk)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed Consent application in accordance with Article 13c of Directive 2001/82/EC as amended.

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product is/are identical to Bob Martin 3 in 1 Dewormer XL Tablets for Large Dogs. The initial application for Bob Martin 3 in 1 Dewormer XL Tablets for Large Dogs 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 for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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.

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