Veterinary Medicines Directorate

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

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Protect Flea and Worm Treatment Tablets for Very Small Dogs
Protect Flea and Worm Treatment Tablets for Small Dogs
Protect Flea and Worm Treatment Tablets for Medium Dogs
Protect Flea and Worm Treatment Tablets for Large Dogs

Date Created: 9th September 2014

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Protect Flea and Worm Treatment Tablets for Very Small Dogs Protect Flea and Worm Treatment Tablets for Small Dogs Protect Flea and Worm Treatment Tablets for Medium Dogs Protect Flea and Worm Treatment Tablets for Large Dogs
Applicant	Novartis Animal Health UK Ltd Frimley Business Park Frimley Camberley Surrey GU16 7SR
Active substance(s)	Milbemycin oxime Lufenuron
ATC Vetcode	QP54AB51
Target species	Dogs
Indication for use	Protect Flea and Worm Treatment is used for the prevention of fleas (*Ct. felis, Ct. canis*, preadult stages), and for the concurrent prevention of heartworm (elimination of L3/L4 larval stages of *Dirofilaria immitis)* and/or treatment of adult stages of gastrointestinal nematodes such as hookworms (*Ancylostoma caninum)*, roundworms (*Toxocara canis)* and whipworms (*Trichuris vulpis*).

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 these products are identical to Program Plus Film-Coated Tablets. The initial application for Program Plus was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

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 of the product(s) 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.

(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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