



**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**

Elanco Milbemycin – Praziquantel 12.5 mg/125 mg Tablets for Dogs

Date Created: January 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Elanco Milbemycin – Praziquantel 12.5 mg/125 mg Tablets for Dogs
Applicant	Elanco Europe Ltd Form 2, Bartley Way Bartley Wood Business Park Hook RH27 9XA United Kingdom
Active substance	Milbemycin Oxime and Praziquantel
ATC Vetcode	QP54AB51
Target species	Dogs
Indication for use	<p>In dogs: treatment of mixed infections by adult cestodes and nematodes of the following species susceptible to praziquantel and milbemycin oxime:</p> <ul style="list-style-type: none"> • Cestodes: <ul style="list-style-type: none"> ○ <i>Dipylidium caninum</i> ○ <i>Taenia</i> spp. ○ <i>Echinococcus</i> spp. ○ <i>Mesocestoides</i> spp. • Nematodes: <ul style="list-style-type: none"> ○ <i>Ancylostoma caninum</i> ○ <i>Toxocara canis</i> ○ <i>Toxascaris leonine</i> ○ <i>Trichuris vulpis</i> ○ <i>Crenosoma vulpis</i> (Reduction of the level of infection) ○ <i>Angiostrongylus vasorum</i> (Reduction of the level of infection by immature adult (L5) and adult parasite stages; see specific treatment and prevention disease schedules under section 4.9 “Amounts to be administered and administration route”) ○ <i>Thelazia callipaeda</i> (see specific treatment schedule under section

	<p style="text-align: center;">4.9 “Amounts to be administered and administration route”</p> <p>The product can also be used in the prevention of heartworm disease (<i>Dirofilaria immitis</i>) if concomitant treatment against cestodes is indicated.</p>
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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	29/12/2022

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Milbemax Tablets for Dogs and Milbemax Tablets for Small Dogs and Puppies.

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.

(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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