Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Elanco Milbemycin – Praziquantel 16 mg/40 mg Film-Coated Tablets for Cats
Elanco Milbemycin – Praziquantel 4 mg/10 mg Film-Coated Tablets for Small Cats and Kittens

Date Created: January 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Elanco Milbemycin – Praziquantel 16 mg/40 mg Film-Coated Tablets for Cats Elanco Milbemycin – Praziquantel 4 mg/10 mg Film-Coated Tablets for Small Cats and Kittens
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	Cats

Indication for use	In cats: treatment of mixed infections by immature and adult cestodes and nematodes of the following species:
	• Cestodes:
	  ○ *Dipylidium caninum*
	  ○ *Taenia* spp.
	  ○ *Echinococcus multilocularis*
	• Nematodes:
	  ○ *Ancylostoma tubaeforme*
	  ○ *Toxocara cati*
	
	Prevention of heartworm disease (*Dirofilaria immitis*) if concomitant treatment against cestodes is indicated.

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 Film-Coated Tablets for Cats and Milbemax Film-Coated Tablets for Small Cats and Kittens.

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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