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

Lotimil Plus 112.5 mg/4.22 mg chewable tablets (> 2.8–5.5 kg)
Lotimil Plus 225 mg/8.44 mg Chewable Tablets (> 5.5–11 kg)
Lotimil Plus 450 mg/16.88 mg Chewable Tablets (> 11–22 kg)
Lotimil Plus 56.25 mg/2.11 mg Chewable Tablets (1.4–2.8 kg)
Lotimil Plus 900 mg/33.75 mg Chewable Tablets (> 22–45 kg)

Date Created: December 2024

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Lotimil Plus 112.5 mg/4.22 mg chewable tablets (> 2.8–5.5 kg) Lotimil Plus 225 mg/8.44 mg Chewable Tablets (> 5.5–11 kg) Lotimil Plus 450 mg/16.88 mg Chewable Tablets (> 11–22 kg) Lotimil Plus 56.25 mg/2.11 mg Chewable Tablets (1.4–2.8 kg) Lotimil Plus 900 mg/33.75 mg Chewable Tablets (> 22–45 kg)
Applicant	Elanco Europe Ltd Form 2, Bartley Way Bartley Wood Business Park Hook RG27 9XA United Kingdom
Active substance	Milbemycin oxime Lotilaner
ATC Vetcode	QP54AB51
Target species	Dogs
Indication for use	For use in dogs with, or at risk from, mixed infestations/infections by ticks, fleas, mites, gastrointestinal nematodes, heartworm and/or lungworm. This veterinary medicinal product is only indicated for use when treatment against ticks/fleas/mites and gastrointestinal nematodes or the treatment against ticks/fleas/mites and prevention of heartworm disease/angiostrongylosis is indicated at the same time. Ectoparasites For the treatment of tick (*Dermacentor reticulatus, Ixodes ricinus*, *Rhipicephalus sanguineus* and *I. hexagonus*) and flea (*Ctenocephalides felis* and *C. canis*) infestations in dogs. This veterinary medicinal product provides immediate and persistent killing activity for 1 month for ticks and fleas.

	The veterinary medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD). For the treatment of demodicosis (caused by *Demodex canis*). Gastrointestinal Nematodes Treatment of gastrointestinal nematodes: hookworm (L4, immature adult (L5) and adult *Ancylostoma caninum*), roundworms (L4, immature adult (L5) and adult *Toxocara canis*, and adult *Toxascaris leonina*) and whipworm (adult *Trichuris vulpis*). Heartworm Prevention of heartworm disease (*Dirofilaria immitis*). Lungworm Prevention of angiostrongylosis by reduction of the level of infection with immature adult (L5) and adult stages of *Angiostrongylus vasorum* (lungworm) with monthly administration.

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 8 of VMRs 2013 (Schedule 1, Para 9) as amended.
Date of conclusion of the procedure	18/11/2024

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Credelio Plus 450 mg/16.88 mg Chewable Tablets for Dogs (>11 kg- 22 kg).

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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