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

Lotilaner Elanco 112 mg Chewable Tablets for Dogs (>2.5–5.5 kg)
Lotilaner Elanco 225 mg Chewable Tablets for Dogs (>5.5–11 kg)
Lotilaner Elanco 450 mg Chewable Tablets for Dogs (>11–22 kg)
Lotilaner Elanco 56 mg Chewable Tablets for Dogs (1.3–2.5 kg)
Lotilaner Elanco 900 mg Chewable Tablets for Dogs (>22–45 kg)
Lotilaner Elanco 12 mg Chewable Tablets for Cats (0.5-2.0 kg)
Lotilaner Elanco 48 mg Chewable Tablets for Cats (>2.0-8.0 kg)

Date Created: November 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Lotilaner Elanco 112 mg Chewable Tablets for Dogs (>2.5-5.5 kg) Lotilaner Elanco 225 mg Chewable Tablets for Dogs (>5.5-11 kg) Lotilaner Elanco 450 mg Chewable Tablets for Dogs (>11-22 kg) Lotilaner Elanco 56 mg Chewable Tablets for Dogs (1.3-2.5 kg) Lotilaner Elanco 900 mg Chewable Tablets for Dogs (>22-45 kg) Lotilaner Elanco 12 mg Chewable Tablets for Cats (0.5-2.0 kg) Lotilaner Elanco 48 mg Chewable Tablets for Cats (>2.0-8.0 kg)
Applicant	Elanco GmbH Heinz-Lohmann-Strasse 4 Cuxhaven 27472 Germany
Active substance	Lotilaner
ATC Vetcode	QP53BE04
Target species	Dogs Cats
Indication for use	**Dogs** For the treatment of flea and tick infestations in dogs. For the treatment of demodicosis (caused by *Demodex canis*). **Cats** For the treatment of flea and tick infestations on cats.

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	3/10/2023

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of these products are identical to the parent product (Credelio Chewable Tablets) range. The initial application for Credelio 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 the benefit/risk profile of the products 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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