Date of Authorization: October 24, 2025

FREEDOM OF INFORMATION (FOI) SUMMARY

Original Emergency Use Authorization (EUA)

EUA 006662

Credelio™

(lotilaner)

Chewable Tablet

Dogs

Scope of Authorization: For the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies.

Sponsored by:

Elanco US Inc.

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I. GENERAL INFORMATION

A. File Number

EUA 006662

B. Sponsor

Elanco US Inc.
450 Elanco Circle
Indianapolis, IN 46221

Drug Labeler Code: 058198

C. Proprietary Name

Credelio™

D. Drug Product Established Name

lotilaner

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Chewable Tablet

G. Amount of Active Ingredient

Each chewable tablet contains 56.25 mg, 112.5 mg, 225 mg, 450 mg, or 900 mg lotilaner.

H. How Supplied

Credelio™ is available in five chewable tablet sizes for use in dogs: 56.25, 112.5, 225, 450, and 900 mg lotilaner. Each chewable tablet size is available in color-coded packages of 1, 3 or 6 chewable tablets.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Credelio™ is given orally at the minimum dosage of 9 mg/lb (20 mg/kg).

Dosage Schedule:

Body Weight	Lotilaner Per Chewable Tablet (mg)	Chewable Tablets Administered
4.4 to 6.0 lbs	56.25	One
6.1 to 12.0 lbs	112.5	One
12.1 to 25.0 lbs	225	One
25.1 to 50.0 lbs	450	One
50.1 to 100.0 lbs	900	One
Over 100.0 lbs	Administer the appropriate combination of chewable tablets	

Credelio™ must be administered with food.

K. Route of Administration

Oral

L. Species/Class

Dogs

M. U.S. Food and Drug Administration (FDA) Approved Indications

Credelio™ kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations [*Amblyomma americanum* (lone star tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (longhorned tick)] for one month in dogs and puppies 8 weeks of age and older, and weighing 4.4 pounds or greater. Credelio™ is indicated for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

N. Emergency Authorized Use

For the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies.

O. Limitations of Authorized Use

Credelio™ (lotilaner) is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Credelio™ (lotilaner) under section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

II. EFFECTIVENESS

A. Dosage Characterization

This Emergency Use Authorization does not change the previously approved 9 mg/lb (20 mg/kg) dose, given orally. The FOI Summary for the original approval of NADA 141-494, dated January 19, 2018, contains dosage characterization information for dogs.

B. Evidence Supporting Emergency Use Authorization

In accordance with Section 564 of the FD&C Act, the sponsor demonstrated that Credelio™ may be effective for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies based on published scientific literature.

1. Published Literature

   a. do Vale TL, Costa AR, Miranda LM, Silva GF, Silva NCS, Lima TB, Chaves DP, Sager H, Lasmar PVF, Costa-Junior LM (2023). Efficacy of lotilaner against myiasis caused by *Cochliomyia hominivorax* (Diptera: Calliphoridae) in naturally infested dogs. *Parasit Vectors*, 16(1):86.

      This study evaluated the effectiveness of Credelio™ for the treatment of naturally acquired New World screwworm (NWS) myiasis in dogs in Brazil. Eleven client-owned dogs with active myiasis caused by *C. hominivorax* larvae were enrolled based on lesion severity and larval burden. All animals received a single oral administration of Credelio™ at doses ranging from 23.9 to 40.9 mg/kg body weight, following the dose bands for the approved flea and tick indications. The study did not include a control group.

      After treatment, the dogs were kept in individual kennels with a removable tray. Larval expulsion rates, larvicidal effects, and overall effectiveness were assessed at 2, 6, and 24 hours post-treatment, with remaining larvae mechanically removed and identified at 24 hours. The following formulas were used to evaluate effectiveness:

      The **overall effectiveness** was calculated as follows: [(number of dead larvae expelled + number of live larvae expelled + number of dead larvae removed) / total number of larvae] × 100.

      The **larval expulsion rate** was calculated for each time point and for each dog using the formula [(number of dead larvae expelled + number of live larvae expelled) / total number of larvae] × 100.

      The **larvicidal effect** was calculated for each time point and for each dog by the formula [(number of dead larvae expelled + number of dead larvae removed) / total number of larvae] × 100.

All collected larvae were confirmed as *C. hominivorax*. Credelio™ demonstrated larval expulsion rates of 80.5%, 93%, and 93% at 2, 6, and 24 hours post-treatment, respectively.

Table II.1. Larval Expulsion Rate

Hours after Treatment	Percent Effectiveness
2	80.5%
6	93%
24	93%

The overall effectiveness reached 100% at 24 hours post-treatment, with all remaining larvae found dead upon mechanical removal.

Table II.2. Overall Effectiveness

Hours after Treatment	Percent Effectiveness
2	80.5%
6	93%
24	100%

The mean larvicidal effectiveness was 41.1% at 24 hours, suggesting that the overall effectiveness at 24 hours was primarily driven by larval expulsion rather than direct killing.

No adverse effects related to Credelio™ treatment were observed throughout the study. This study demonstrated that Credelio™ may be effective for the treatment of infestations caused by NWS (*C. hominivorax*) larvae (myiasis) in dogs.

III. TARGET ANIMAL SAFETY

Because target animal safety was established with the original approval of NADA 141-494, dated January 19, 2018, the FDA did not require target animal safety studies for this authorization. The safety of Credelio™ has not been evaluated in dogs less than 8 weeks of age or less than 4.4 lbs. It is reasonable to believe that the known and potential benefits of Credelio™ outweigh the known and potential risks for dogs of all ages and weights because NWS is potentially fatal in dogs if left untreated, therefore justifying including dogs less than 8 weeks of age or less than 4.4 lbs in this authorization.

IV. HUMAN FOOD SAFETY

This drug is intended for use in dogs. Because this new animal drug is not intended for use in food-producing animals, FDA did not require data pertaining to drug residues in food (i.e., human food safety) for this authorization.

V. USER SAFETY

The product Fact Sheet contains the following information regarding safety to humans handling, administering, or exposed to Credelio™:

Not for human use. Keep this and all drugs out of the reach of children.

VI. AGENCY CONCLUSIONS

Based on the scientific evidence available to FDA, including data from published scientific literature, it is reasonable to believe that Credelio™, when used as authorized, may be effective for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies; the known and potential benefits of Credelio™ outweigh the known and potential risks; and there is no adequate, approved, and available alternative to Credelio™ for treating NWS myiasis.

A. Duration of Authorization: Revision and Revocation

This EUA will be effective until revoked under section 564(g) of the FD&C Act or until the Secretary's declaration of emergency or threat justifying emergency authorized use is terminated (Section 564(f)(1), with exception for continued use permissible under Section 564(f)(2)). FDA may revoke or revise this authorization if emergency use of this animal drug for NWS myiasis is no longer justified, if the product no longer meets the criteria for issuance of an EUA under section 564(c) of the FD&C Act, or other circumstances make such revision or revocation of the authorization appropriate to protect the public health or safety (section 564(g)(2) of the FD&C Act).

B. Marketing Status

This product is authorized to be dispensed only by or on the order of a licensed veterinarian (Rx marketing status).