

Date of Authorization: November 21, 2025

FREEDOM OF INFORMATION (FOI) SUMMARY

Original Emergency Use Authorization (EUA)

EUA 006664

Credelio™ CAT

(lotilaner)

Chewable Tablet

Cats

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

Sponsored by:

Elanco US Inc.

Table of Contents

I. GENERAL INFORMATION3

II. EFFECTIVENESS.....5

 A. Dosage Characterization5

 B. Evidence Supporting Emergency Use Authorization5

III. TARGET ANIMAL SAFETY7

IV. HUMAN FOOD SAFETY7

V. USER SAFETY7

VI. AGENCY CONCLUSIONS.....8

 A. Duration of Authorization: Revision and Revocation8

 B. Marketing Status8

I. GENERAL INFORMATION

A. File Number

EUA 006664

B. Sponsor

Elanco US Inc.
450 Elanco Circle
Indianapolis, IN 46221

Drug Labeler Code: 058198

C. Proprietary Name

Credelio™ CAT

D. Drug Product Established Name

lotilaner

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Chewable Tablet

G. Amount of Active Ingredient

Each chewable tablet contains 12 mg or 48 mg lotilaner.

H. How Supplied

Credelio™ CAT is available in two chewable tablet sizes for use in cats: 12 and 48 mg lotilaner. Each chewable tablet size is available in color-coded packages containing 1 chewable tablet. The 48 mg chewable tablet size is also available in color-coded packages containing 3 or 6 chewable tablets.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Credelio™ CAT is given orally at the minimum dosage of 2.7 mg/lb (6 mg/kg).

Dosage Schedule:

Body Weight	Lotilaner Per Chewable Tablet (mg)	Chewable Tablets Administered
2.0 to 4.0 lbs	12	One
4.1 to 17.0 lbs	48	One
Over 17.0 lbs	NA	Administer the appropriate combination of chewable tablets

Credelio™ CAT must be administered with food.

K. Route of Administration

Oral

L. Species/Class

Cats

M. Food and Drug Administration (FDA) Approved Indications

Credelio™ CAT kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) for one month in cats and kittens 8 weeks of age and older, and weighing 2.0 pounds or greater.

Credelio™ CAT is also indicated for the treatment and control of *Ixodes scapularis* (black-legged tick) infestations for one month in cats and kittens 6 months of age and older, and weighing 2.0 pounds or greater.

N. Emergency Authorized Use

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

O. Limitations of Authorized Use

Credelio™ CAT (lotilaner) is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Credelio™ CAT (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 2.7 mg/lb (6 mg/kg) dose, given orally. The FOI Summary for the original approval of NADA 141-528, dated December 9, 2019, contains dosage characterization information for cats.

B. Evidence Supporting Emergency Use Authorization

In accordance with Section 564 of the FD&C Act, the sponsor demonstrated that it is reasonable to believe that Credelio™ CAT may be effective for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens based on published scientific literature. The evidence supporting effectiveness is based on a published article in cats with naturally acquired Old World screwworm (OWS) and a published article in dogs with naturally acquired New World screwworm (NWS). Collectively, the data support that it is reasonable to believe that Credelio™ CAT may be effective for the treatment of infestations caused by NWS (*C. hominivorax*) larvae (myiasis) in cats.

1. Published Literature

- a. Han, HS, Yasmin, L (2020). *Chrysomya bezziana* (Diptera: Calliphoridae) infestation in two Malaysian cats treated with oral lotilaner. *Vet Dermatol*, 31:335.

This study evaluated the effectiveness of lotilaner¹ for the treatment of naturally acquired Old World screwworm (OWS) myiasis in two cats in Malaysia. Both cats with active cutaneous myiasis caused by *Chrysomya bezziana* larvae were enrolled based on clinical presentation and larval burden. One cat was a 3-year-old male intact cat with a foul-smelling wound on the left hind paw containing burrowing larvae. The second cat was a 9-year-old male neutered cat with an exudative open wound on the right cervical neck region with burrowing larvae. Both cats received a single oral administration of Credelio™ CAT. One cat received 6 mg/kg, and the other received 26 mg/kg Credelio™ CAT (consistent with the dose band of 6.0 to 26 mg/kg for the approved flea and tick indications). The study did not include a control group.

Results demonstrated 100% larvicidal effectiveness within 24 hours post-treatment in both cases. After treatment, both cats were hospitalized for either 10 or 11 days and wounds were cleaned and flushed until re-epithelization occurred. All collected larvae were confirmed as *C. bezziana*.

¹ Same formulation as Credelio™ CAT.

No adverse events related to Credelio™ CAT treatment were observed throughout the study. Because of the effectiveness demonstrated against OWS myiasis in treated cats, it is reasonable to believe that administration of Credelio™ CAT would result in drug levels that may be effective to treat NWS myiasis.

- b. 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: $[(\text{number of dead larvae expelled} + \text{number of live larvae expelled} + \text{number of dead larvae removed}) / \text{total number of larvae}] \times 100$.

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

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

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.

Because effectiveness was observed against NWS myiasis in dogs treated with lotilaner at the dose approved for the treatment of flea and tick infestations, it is reasonable to believe that administration of Credelio™ CAT at the dose approved to treat flea and tick infestations may be effective to treat NWS myiasis in cats.

III. TARGET ANIMAL SAFETY

Because target animal safety was established with the original approval of NADA 141-528, dated December 9, 2019, FDA did not require target animal safety studies for this authorization. The safety of Credelio™ CAT has not been evaluated in cats less than 8 weeks of age or less than 2.0 lbs. It is reasonable to believe that the known and potential benefits of Credelio™ CAT outweigh the known and potential risks for cats of all ages and weights because NWS is potentially fatal in cats if left untreated, therefore justifying including cats less than 8 weeks of age or less than 2.0 lbs in this authorization.

IV. HUMAN FOOD SAFETY

This drug is intended for use in cats. 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™ CAT:

Not for human use. Keep this and all drugs out of the reach of children. Keep Credelio™ CAT in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

VI. AGENCY CONCLUSIONS

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

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).