

Date of Approval: December 17, 2025

# FREEDOM OF INFORMATION (FOI) SUMMARY

## APPLICATION FOR CONDITIONAL APPROVAL

Application Number 141-619

Credelio Quattro™-CA1

(lotilaner, moxidectin, praziquantel, and pyrantel chewable tablets)

Dogs

Credelio Quattro™-CA1 is indicated for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies 8 weeks of age and older, and weighing 3.3 pounds or greater.

Sponsored by:

Elanco US Inc.

## Executive Summary

Credelio Quattro™-CA1 (lotilaner, moxidectin, praziquantel, and pyrantel chewable tablets) is conditionally approved for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies 8 weeks of age and older, and weighing 3.3 pounds or greater.

The Food and Drug Administration (FDA) determined that Credelio Quattro™-CA1 is eligible for conditional approval for the labeled use under section 571(a)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) because the drug treats a serious or life-threatening disease in dogs, addresses an unmet animal health need, and demonstrating effectiveness would require complex or particularly difficult studies. An animal drug that meets these criteria is eligible for conditional approval.

A conditionally approved animal drug has been shown to be safe and has a reasonable expectation of effectiveness. During the conditional approval period, the sponsor can legally market the drug for the labeled use while collecting the remaining effectiveness data. The conditional approval is valid for one year. The sponsor can ask FDA to renew the conditional approval annually for up to four more years, for a total of five years of conditional approval. To receive a renewal from FDA, the sponsor must show active progress toward demonstrating substantial evidence of effectiveness for full approval.

Credelio Quattro™ is already fully approved under New Animal Drug Application (NADA) 141-581 for the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of roundworm (immature adult and adult *Toxocara canis* and adult *Toxascaris leonina*), hookworm (fourth stage larvae, immature adult, and adult *Ancylostoma caninum* and adult *Uncinaria stenocephala*), and tapeworm (*Dipylidium caninum*, *Taenia pisiformis*, and *Echinococcus granulosus*) infections. Credelio Quattro™ kills adult fleas and is approved 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 3.3 pounds or greater. Credelio Quattro™ is also approved for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

Credelio Quattro™ and Credelio Quattro™-CA1 contain the same active ingredients (lotilaner, moxidectin, praziquantel, and pyrantel) at the same doses. Credelio Quattro™-CA1 is available in five strengths of flavored chewable tablets formulated according to the weight of the dog.

To support reasonable expectation of effectiveness, the sponsor provided one literature article summarizing a study in dogs naturally infested with *C. hominivorax* that were treated with Credelio™ (lotilaner). Based on the study results, Credelio™ demonstrated larval expulsion rates of 80.5%, 93%, and 93% at 2, 6, and 24 hours post-treatment, respectively, demonstrating overall effectiveness of 100% at 24 hours post-treatment, with all remaining larvae found dead upon mechanical removal. The study showed that the primary mechanism of action against *C. hominivorax* was live larval expulsion rather than direct killing, with a mean larvicidal effectiveness of 41.1% at 24 hours. The extrapolation of the effectiveness of Credelio™ in this article to Credelio Quattro™-CA1 for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies 8 weeks of age and older, and weighing 3.3 pounds or greater is supported by use of the same active ingredient (lotilaner) at the same dose (20 mg/kg) and demonstration that moxidectin, praziquantel, and pyrantel pamoate do not interfere with the effectiveness of lotilaner in the original approval of Credelio Quattro™ (NADA 141-581). FDA concluded the study summary was acceptable to support reasonable expectation of effectiveness for conditional approval.

FDA did not require new safety studies in dogs for this conditional approval. The doses of lotilaner, moxidectin, praziquantel, and pyrantel in Credelio Quattro™-CA1 is identical to the dose in Credelio Quattro™, which is fully approved under NADA 141-581. Therefore, the safety of the drug in dogs is supported by the target animal safety and effectiveness studies conducted for the approval of NADA 141-581.

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**I. GENERAL INFORMATION**

**A. File Number**

Application Number 141-619

**B. Sponsor**

Elanco US Inc.  
450 Elanco Circle  
Indianapolis, IN 46221

Drug Labeler Code: 058198

**C. Proprietary Name**

Credelio Quattro™-CA1

**D. Drug Product Established Name**

lotilaner, moxidectin, praziquantel, and pyrantel chewable tablets

**E. Pharmacological Category**

Antiparasitic

**F. Dosage Form**

Chewable tablet

**G. Amount of Active Ingredient**

Each chewable tablet contains:

56.25 mg lotilaner, 0.056 mg moxidectin, 14.25 mg praziquantel, and 14.25 mg pyrantel\*

112.5 mg lotilaner, 0.113 mg moxidectin, 28.5 mg praziquantel, and 28.5 mg pyrantel\*

225 mg lotilaner, 0.225 mg moxidectin, 57 mg praziquantel, and 57 mg pyrantel\*

450 mg lotilaner, 0.45 mg moxidectin, 114 mg praziquantel, and 114 mg pyrantel\*

900 mg lotilaner, 0.9 mg moxidectin, 228 mg praziquantel, and 228 mg pyrantel\*

\*As pamoate salt

**H. How Supplied**

Credelio Quattro™-CA1 (lotilaner, moxidectin, praziquantel, and pyrantel chewable tablets) is available in five strengths of flavored chewable tablets formulated according to the weight of the dog. Each chewable tablet size is available in packages of 1, 6, or 12 tablets.

**I. Dispensing Status**

Prescription (Rx)

**J. Dosage Regimen**

Credelio Quattro™/Credelio Quattro™-CA1 is given orally at the minimum dosage of 9 mg/lb (20 mg/kg) lotilaner, 0.009 mg/lb (0.02 mg/kg) moxidectin, 2.28 mg/lb (5 mg/kg) praziquantel, and 2.28 mg/lb (5 mg/kg) pyrantel (as pamoate salt). Credelio Quattro™/Credelio Quattro™-CA1 must be administered with food. Care should be taken to ensure that the dog consumes the complete dose and that part of the dose is not lost or refused. If vomiting occurs within an hour after administration, readminister a new dose of Credelio Quattro™/Credelio Quattro™-CA1.

**Credelio Quattro™:**

Credelio Quattro™ is given once a month. If a dose is missed, give Credelio Quattro™ immediately and resume a monthly dosing schedule.

**Dosing Schedule:**

Body Weight (lbs)	Tablets to Administer	Lotilaner per Tablet (mg)	Moxidectin per Tablet (mg)	Praziquantel per Tablet (mg)	Pyrantel* per Tablet (mg)
3.3 - 6	1	56.25	0.056	14.25	14.25
6.1 - 12	1	112.5	0.113	28.5	28.5
12.1 - 25	1	225	0.225	57	57
25.1 - 50	1	450	0.45	114	114
50.1 - 100	1	900	0.9	228	228
>100	Administer the appropriate combination of tablets				

\*As pamoate salt

***Credelio Quattro™-CA1:***

**New World Screwworm (NWS) Myiasis Treatment**

A single dose of Credelio Quattro™-CA1 is reasonably expected to treat *C. hominivorax* present at the time of treatment. Re-infestation with *C. hominivorax* may occur sooner than one month. Treatment should be used in conjunction with the mechanical removal of larvae (live and dead) remaining in the wound after treatment.

**K. Route of Administration**

Oral

**L. Species/Class**

Dogs

## M. Indication

Credelio Quattro™-CA1 is indicated for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies 8 weeks of age and older, and weighing 3.3 pounds or greater.

## II. EFFECTIVENESS

**Conditional Dose:** The conditional dose for the indication “for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies 8 weeks of age and older, and weighing 3.3 pounds or greater” is 9 mg/lb (20 mg/kg) of lotilaner, 0.009 mg/lb (0.02 mg/kg) of moxidectin, 2.28 mg/lb (5 mg/kg) of praziquantel, and 2.28 mg/lb (5 mg/kg) of pyrantel (as pamoate salt), given orally. The safety data and the data to demonstrate reasonable expectation of effectiveness provide support for this conditional dose.

### A. Dosage Characterization

The conditionally approved dose that is effective against *C. hominivorax* is the same as the dosage characterized for the original approval of NADA 141-581. The FOI Summary for the original approval of NADA 141-581 dated October 7, 2024, contains dosage characterization information for dogs.

### B. Reasonable Expectation of Effectiveness

Reasonable expectation of effectiveness for Credelio Quattro™-CA1 (lotilaner, moxidectin, praziquantel, and pyrantel chewable tablets) for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies 8 weeks of age and older, and weighing 3.3 pounds or greater is based on published scientific literature. The evidence supporting effectiveness is based on a published article in dogs with naturally acquired New World screwworm (NWS) myiasis treated with Credelio™ (lotilaner). The extrapolation of effectiveness data from Credelio™ to Credelio Quattro™-CA1 is supported by use of the same approved lotilaner dose (minimum 20 mg/kg) for both products and non-interference data from the original approval of Credelio Quattro™. The published article demonstrates reasonable expectation of effectiveness for Credelio Quattro™-CA1 for the treatment of infestations caused by NWS (*C. hominivorax*) larvae (myiasis) in dogs and puppies 8 weeks of age and older, and weighing 3.3 pounds or greater.

The study is summarized below.

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

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).

**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).

**Table II.2. Overall Effectiveness**

<b>Hours after Treatment</b>	<b>Percent Effectiveness</b>
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 during the study.

There are limitations of the data supporting the benefits of Credelio Quattro™-CA1 for the treatment of infestations caused by NWS larvae. The do Vale et al. study was conducted in a limited population of 11 naturally infested dogs in Brazil, and the inferential value to the United States population is unknown. The primary mechanism of action against *C. hominivorax* appears to be live larval expulsion. Additionally, the use of mechanical removal coupled with the lack of a control group confound the ability to define a pure treatment effect.

The extrapolation of the effectiveness of Credelio™ in this article to Credelio Quattro™-CA1 for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies 8 weeks of age and older, and weighing 3.3 pounds or greater is supported by use of the same active ingredient (lotilaner) at the same dose (20 mg/kg). In addition, data from the original approval of Credelio Quattro™ under NADA 141-581 demonstrated that neither moxidectin nor praziquantel nor pyrantel interfere with the effectiveness of lotilaner.

### **III. TARGET ANIMAL SAFETY**

As the dosage of lotilaner, moxidectin, praziquantel, and pyrantel in Credelio Quattro™-CA1 is identical to that of Credelio Quattro™ for dogs, approved under NADA 141-581, the target animal safety for Credelio Quattro™-CA1 is supported by the target animal safety studies conducted for the approval of Credelio Quattro™. The FOI Summary for the original approval of NADA 141-581 dated October 7, 2024, contains a summary of target animal safety studies for dogs.

### **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 approval of this NADA.

## V. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Credelio Quattro™-CA1:

Not for use in humans. Keep this and all drugs out of reach of children. Wash hands after handling. If accidentally ingested, seek medical attention immediately.

## VI. AGENCY CONCLUSIONS

The data submitted in support of this application satisfy the requirements of section 571(b) of the FD&C Act. The data demonstrate that Credelio Quattro™-CA1, when used according to the label, is safe and has a reasonable expectation of effectiveness for the conditions of use in the General Information Section above.

### A. Conditional Approval Eligibility

In 2018, the legislation reauthorizing FDA's animal drug user fee program (Animal Drug User Fee Program, or ADUFA, IV) expanded the conditional approval pathway to allow certain additional new animal drugs that are not Minor Use/Minor Species (MUMS) drugs to be eligible for conditional approval. As provided in section 571(a)(1)(A)(ii) of the FD&C Act, as amended by ADUFA IV, to qualify for conditional approval, the non-MUMS new animal drug must meet the following two criteria:

1. The new animal drug is intended to treat a serious or life-threatening disease or condition OR addresses an unmet animal or human health need; AND
2. A demonstration of effectiveness would require a complex or particularly difficult study or studies.

Credelio Quattro™-CA1 was determined to be eligible for conditional approval under these provisions because it controls a serious or life-threatening disease or condition, addresses an unmet animal health need, and the demonstration of effectiveness requires a complex or particularly difficult study or studies. The tissue damage caused by *C. hominivorax* in dogs can be serious and is often deadly to the animal. Therefore, the conditionally approved use of Credelio Quattro™-CA1 addresses a serious or life-threatening disease or condition. The treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies 8 weeks of age and older, and weighing 3.3 pounds or greater is also an unmet animal health need because currently there is no approved animal drug in the United States (U.S) for this use in dogs. Finally, demonstrating effectiveness would require a complex or particularly difficult study, or studies, because *C. hominivorax* has been eradicated in the U.S., making it impossible to conduct studies in the U.S. using naturally infested animals to provide substantial evidence of effectiveness. Additionally, there are significant animal welfare concerns when considering whether to conduct studies with this parasite. Therefore, the FDA determined that Credelio Quattro™-CA1 met the eligibility criteria for conditional approval.

**B. Marketing Status**

Credelio Quattro™-CA1 is conditionally approved for one year from the date of approval and is annually renewable for up to four additional one-year terms.

This product may be dispensed only by or on the order of a licensed veterinarian (Rx marketing status). Adequate directions for lay use cannot be written because the product is indicated for the prevention of heartworm infections (*Dirofilaria immitis*) in dogs, which requires veterinary examination and testing to ensure dogs are negative for adult heartworm disease prior to administration of the product to dogs.

**C. Exclusive Marketing Rights**

Credelio Quattro™-CA1, as approved in our approval letter, does not qualify for exclusive marketing rights under section 573(c) of the FD&C Act because it is not a designated new animal drug under section 573(a) of the FD&C Act.

**D. Patent Information**

For current information on patents, see the Green Book Reports in the Animal Drugs @ FDA database.