Fact Sheet for Veterinarians: Emergency Use Authorization of Credelio (lotilaner) Chewable Tablets for New World Screwworm (NWS)

Credelio
(lotilaner)
Chewable Tablets
For oral use in dogs

Original EUA Authorized Date: 10/24/2025

Emergency Use Authorization of Credelio (lotilaner) Chewable Tablets for NWS

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the approved product Credelio (lotilaner) chewable tablets for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies. Credelio is not approved for this use.

Credelio (lotilaner) (NADA 141-494) is approved for other uses in dogs and puppies.[1]

Limitations of Authorized Use

Credelio (lotilaner) chewable tablets is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Credelio (lotilaner) chewable tablets 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 declaration is terminated or the authorization is revoked sooner.

Justification for Emergency Use of Animal Drugs for NWS

The Secretary of the U.S. Department of Health and Human Services (HHS) has:

- determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves NWS (*Cochliomyia hominivorax*); and

- declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals.[2]

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[1] On January 19, 2018, Credelio was approved to kill adult fleas and is indicated for the treatment 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) and *Rhipicephalus sanguineus* (brown dog tick)] for one month in dogs and puppies 8 weeks of age and older, and weighing 4.4 pounds or greater. On September 3, 2019, Credelio received a supplemental approval for the prevention of flea infestations (*Ctenocephalides felis*) for one month in dogs and puppies 8 weeks of age and older, and weighing 4.4 pounds or greater. On October 24, 2025, Credelio received a supplemental approval for the treatment and control of *Haemaphysalis longicornis* (longhorned tick) tick infestations for one month in dogs and puppies 8 weeks of age and older, weighing 4.4 pounds or greater, and for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

[2] See U.S. Department of Health and Human Services, Declaration of Emergency Pursuant to the Federal Food, Drug, and Cosmetic Act for New World Screwworm, August 20, 2025: https://www.federalregister.gov/documents/2025/08/20/2025-15918/declaration-of-emergency-pursuant-to-the-federal-food-drug-and-cosmetic-act-for-new-world-screwworm

An EUA is an FDA authorization for the emergency use of an unapproved product or unapproved use of an approved product (i.e., drug, biological product, or device) in the United States under certain circumstances declared by the Secretary of HHS to justify emergency use authorization, including, among others, a determination that there is a public health emergency or a significant potential for a public health emergency that may affect national security and that involves a biological agent.[3]

Criteria for issuing this EUA include:

- The biological agent(s) can cause a serious or life-threatening disease or condition;
- Based on the totality of available scientific evidence (including data from adequate and well-controlled clinical trials, if available), it is reasonable to believe that:
    - the product may be effective in diagnosing, preventing, or treating the serious or life-threatening disease or condition; and
    - the known and potential benefits of the product - when used to diagnose, prevent, or treat such disease or condition - outweigh the known and potential risks of the product; and
- There is no adequate, approved,[4] and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.[5]

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Product Description

Refer to the Credelio package insert for full **Product Description** information.

Dosage and Administration

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

[3] Emergency Use Authorization of Medical Products and Related Authorities | FDA (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities)
[4] "Approved" products include conditionally approved products for purposes of EUAs issued under section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.
[5] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

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.

Credelio is not available as scored tablets. The effectiveness of the administration of less than full tablets has not been evaluated.

Risk-Benefit Consideration for Dogs on Other Isoxazolines:

If a dog is currently receiving another isoxazoline product for routine ectoparasite control, veterinarians should consider administering Credelio to dogs diagnosed with NWS myiasis based on a risk-benefit assessment and the emergency nature of NWS myiasis treatment.

Information Supporting Emergency Use Authorization

Based on the totality of scientific evidence available to FDA, including data from published scientific literature, it is reasonable to believe that Credelio (lotilaner) chewable tablets may be effective for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies; and when used under the conditions described in the authorization, the known and potential benefits of Credelio (lotilaner) chewable tablets outweigh the known and potential risks.

A study conducted by do Vale et al.[6] evaluated the effectiveness of Credelio for the treatment of naturally acquired 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. The age of the enrolled dogs (5 males, 6 females) ranged from 1.5 to 10.0 years, weighing between 3.3 to 25.0 kg. All dogs 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. The dogs were observed 2- and 6-hours post-treatment, at which times expelled larvae were collected and quantified. At 24 hours post-treatment, the remaining larvae were mechanically removed from the wound and counted.

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

The study demonstrated 100% overall effectiveness (number of expelled live and dead larvae and dead larvae mechanically removed) against *C. hominivorax* larvae at 24 hours post-treatment with expulsion of larvae of 80.5% and 93% at 2 and 6 hours after treatment, respectively. The mean larvicidal effectiveness was 41.1% at 24 hours. There were no adverse reactions during the study.

There are limitations of the data supporting the benefits of Credelio 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 available clinical data supporting the effectiveness of Credelio against *C. hominivorax* larvae, along with the established safety profile, support the potential benefit of Credelio in the authorized patient population for the treatment of infestations caused by NWS larvae.

Contraindications

There are no known contraindications for the use of Credelio.

Warnings

User Safety Warnings

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

To obtain a Safety Data Sheet (SDS), contact Elanco US Inc. at 1-888-545-5973 or https://www.elanco.com/us/elanco-safety-data-sheets.

Precautions

Lotilaner is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. Seizures have been reported in dogs receiving isoxazoline class drugs, even in dogs without a history of seizures. Use with caution in dogs with a history of seizures or neurologic disorders.

The safe use of Credelio in breeding, pregnant, or lactating dogs has not been evaluated.

The safety of Credelio has not been evaluated in dogs less than 8 weeks of age or less than 4.4 lbs.

Adverse Reactions

Refer to the Credelio package insert for full prescribing information, including **Animal Safety**, **Adverse Reactions**, and **Post-Approval Experience**.

As described in the Letter of Authorization, veterinary facilities and veterinarians must report all **SERIOUS ADVERSE EVENTS*** potentially related to Credelio (lotilaner) use under this EUA (1) by contacting Elanco US Inc. at 1-888-545-5973, (2) by downloading and submitting Form FDA 1932a available at https://www.fda.gov/reportanimalae, or (3) contacting FDA at 1-888-FDA-VETS to request this form.

When reporting adverse events on Form FDA 1932a, include the following elements when applicable and/or available:

- Patient demographics (e.g., age, species and breed, sex, weight)
- The statement "Credelio (lotilaner) use for NWS under an EUA" under the **"Adverse Event/Product Problem/Product Use Error"** heading
- Information about the serious adverse event (e.g., signs and symptoms, test/laboratory data, timing of drug administration in relation to the occurrence of the event, duration of the event, treatment required to mitigate the event, evidence of event improvement/disappearance after stopping/reducing the dosage, evidence of reappearance after reintroduction, clinical outcomes)
- Patient's pre-existing medical conditions and use of concomitant products
- Information about the product (e.g., dosage, route of administration, lot number)

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- An event that causes an abortion, stillbirth, or infertility
- A congenital anomaly or birth defect in offspring of treated animals
- A prolonged or permanent disability (e.g., persistent or significant incapacity or disruption of normal life functions)
- An event that requires professional intervention (e.g., important medical events that may require a medical/surgical intervention to prevent a death, life-threatening event, hospitalization, disability)

Reporting of lack of effectiveness, nonserious adverse events, or product quality defects is strongly encouraged via the mechanisms and including the information identified above for **SERIOUS ADVERSE EVENTS**.

Additional Information for Veterinarians

Veterinary facilities and veterinarians will ensure that they are aware of and adhere to the terms of the Letter of Authorization. Fact Sheets will be made available to veterinarians.

Veterinary facilities and veterinarians will ensure that the client is aware that the drug is authorized for emergency use, but not approved, for the treatment of NWS myiasis and advise the client of the risks, benefits, and any alternatives.

Veterinary facilities will maintain health records that include the following information: client name, patient name, patient age, disease manifestation, number of doses prescribed or administered per patient, lot number prescribed or administered, and other drugs co-administered. The records shall be maintained in a manner that allows veterinary facilities to identify in a reasonable time which patients received drugs subject to this EUA.

Veterinary facilities will maintain any health records for the authorized use in the Letter of Authorization for at least two years following the termination of the declaration or the revocation of the authorization, or until notified by HHS, or FDA, whichever is sooner. Such records will be made available to Elanco US Inc., HHS, and FDA for inspection upon request.

Information for Client (e.g., Animal Owner or Caretaker)

The lifecycle for *C. hominivorax* is as short as 21 days and wounds can be rapidly infested. Proper wound care and management practices are essential for preventing NWS myiasis. Dogs may become reinfested following treatment.

Animal owners should be advised that:

- Gloves should be worn if cleaning the wound, or the dog's bedding, or disposing of larvae.
- Dogs should be housed to prevent exposure to NWS flies until wounds have fully healed.
- Live larvae may exit the wound and be deposited on bedding or areas where the dog sits or lies after treatment.
- If expelled larvae are seen, owners should place the larvae in a sealed container with rubbing alcohol.
- If there is worsening of the wound, the owner should contact the veterinarian.

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.

Storage Information

Store at 15-25°C (59-77°F), excursions permitted between 5 to 40°C (41 to 104°F).

Manufactured for:
Elanco US Inc
Greenfield, IN 46140 USA

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