

CREDELIO- lotilaner tablet, chewable
Elanco US Inc.

Credelio™
(lotilaner)

Chewable Tablets

For oral use in dogs

Caution:

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

Description:

CREDELIO (lotilaner) is a beef-flavored, chewable tablet for oral administration to dogs and puppies according to their weight. Each chewable tablet is formulated to provide a minimum lotilaner dosage of 9 mg/lb (20 mg/kg).

Lotilaner has the chemical composition of 5-[(5S)-4,5-dihydro-5-(3,4,5-trichlorophenyl)-5-(trifluoromethyl)-3-isoxazolyl]-3-methyl-N-[2-oxo-2-[(2,2,2-trifluoroethyl)amino]ethyl]-2-thiophenecarboxamide.

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.

Dosage and Administration:

CREDELIO is given orally once a month, 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	

CREDELIO must be administered with food (see **Clinical Pharmacology**).

Treatment with CREDELIO can begin at any time of the year and can continue year-round without interruption.

Contraindications:

There are no known contraindications for the use of CREDELIO.

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.

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.

Adverse Reactions:

In a well-controlled U.S. field study, which included 284 dogs (198 dogs treated with CREDELIO and 86 dogs treated with an oral active control), there were no serious adverse reactions.

Over the 90-day study period, all observations of potential adverse reactions were recorded. Reactions that occurred at an incidence of 1% or greater are presented in the following table.

Dogs with Adverse Reactions in the Field Study

Adverse Reaction (AR)	CREDELIO Group: Number (and Percent) of Dogs with the AR (n=198)	Active Control Group: Number (and Percent) of Dogs with the AR (n=86)
Weight Loss	3 (1.5%)	2 (2.3%)
Elevated Blood Urea Nitrogen (BUN)	2 (1.0%)*	0 (0.0%)
Polyuria	2 (1.0%)*	0 (0.0%)
Diarrhea	2 (1.0%)	2 (2.3%)

*Two geriatric dogs developed mildly elevated BUN (34 to 54 mg/dL; reference range: 6 to 31 mg/dL) during the study. One of these dogs also developed polyuria and a mildly elevated potassium (6.5 mEq/L; reference range: 3.6 to 5.5 mEq/L) and phosphorous (6.4 mg/dL; reference range: 2.5 to 6.0 mg/dL). The other dog also developed a mildly elevated creatinine (1.7 to 2.0 mg/dL; reference range: 0.5 to 1.6 mg/dL) and weight loss.

In addition, one dog experienced intermittent head tremors within 1.5 hours of administration of vaccines, an ear cleaning performed by the owner, and its first dose of CREDELIO. The head tremors resolved within 24 hours without treatment. The owner elected to withdraw the dog from the study.

In an Australian field study, one dog with a history of seizures experienced seizure activity (tremors and glazed eyes) six days after receiving CREDELIO. The dog recovered without treatment and completed the study. In the U.S. field study, two dogs with a history of seizures received CREDELIO and experienced no seizures throughout the study.

In three well-controlled European field studies and one U.S. laboratory study, seven dogs experienced episodes of vomiting and four dogs experienced episodes of diarrhea between 6 hours and 3 days after receiving CREDELIO.

Post-Approval Experience (2023):

The following adverse events are based on post-approval adverse drug experience reporting for CREDELIO. Not all adverse events are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data.

The following adverse events reported in dogs are listed in decreasing order of reporting frequency:

Vomiting, diarrhea (with and without blood), lethargy, anorexia, seizure, pruritus, ataxia, urinary-related signs (polyuria, polydipsia, urinary incontinence, and inappropriate urination), and muscle tremor.

Contact Information:

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Elanco US Inc. at 1-888-545-5973.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

Clinical Pharmacology:

Following oral administration of 43 mg/kg (approximately 1X the maximum labeled dose), peak lotilaner concentrations were achieved between 6 hours and 3 days in dogs 2 months of age and between 1 and 7 days in dogs 10 months of age. Dogs 2 months of age had a shorter elimination half-life (average of 9.6 days) than at 10 months of age (average of 28.4 days). Due to reduced drug bioavailability in the fasted state, CREDELIO

must be administered with a meal or within 30 minutes after feeding.

Mode of Action:

Lotilaner is an ectoparasiticide belonging to the isoxazoline group. Lotilaner inhibits insect and acarine gamma-aminobutyric acid (GABA)-gated chloride channels. This inhibition blocks the transfer of chloride ions across cell membranes, which results in uncontrolled neuromuscular activity leading to death of insects and acarines. The selective toxicity of lotilaner between insects and acarines and mammals may be inferred by the differential sensitivity of the insects and acarines' GABA receptors versus mammalian GABA receptors.

Effectiveness:

In well-controlled European laboratory studies, CREDELIO began to kill fleas four hours after administration or infestation, with greater than 99% of fleas killed within eight hours after administration or infestation for 35 days. In a well-controlled U.S. laboratory study, CREDELIO demonstrated 100% effectiveness against adult fleas 12 hours after administration or infestation for 35 days.

In a 90-day well-controlled U.S. field study conducted in households with existing flea infestations of varying severity, the effectiveness of CREDELIO against fleas on Days 30, 60 and 90 compared to baseline was 99.5%, 100% and 100%, respectively. Dogs with signs of flea allergy dermatitis showed improvement in erythema, papules, scaling, alopecia, dermatitis/pyodermitis and pruritus as a direct result of eliminating fleas.

In a well-controlled laboratory study, CREDELIO killed fleas before they could lay eggs, thus preventing subsequent flea infestations for 30 days after the start of treatment of existing flea infestations.

In well-controlled laboratory studies, CREDELIO demonstrated > 97% effectiveness against *Amblyomma americanum*, *Dermacentor variabilis*, *Ixodes scapularis*, *Rhipicephalus sanguineus*, and *Haemaphysalis longicornis* ticks 48 hours after administration or infestation for 30 days. In a well-controlled European laboratory study, CREDELIO started killing *Ixodes ricinus* ticks within four hours after administration.

In two separate, well-controlled laboratory studies, CREDELIO was effective at preventing *Borrelia burgdorferi* infections after dogs were infested with *Ixodes scapularis* vector ticks.

Palatability: In the U.S. field study, which included 567 doses administered to 198 dogs, 80.4% of dogs voluntarily consumed CREDELIO when offered by hand or in an empty bowl, an additional 13.6% consumed CREDELIO when offered with food, and 6.0% required placement of the chewable tablet in the back of the dog's mouth.

Animal Safety:

In a margin of safety study, CREDELIO was administered orally to 24 (8 dogs/group) 8-week-old Beagle puppies at doses of 43 mg/kg, 129 mg/kg, and 215 mg/kg (approximately 1, 3, and 5X the maximum labeled dose, respectively) every 28 days for eight consecutive doses. The 8 dogs in the control group (0X) were untreated. There were no clinically-relevant, treatment-related effects on clinical observations, physical and neurological examinations, body weights, food consumption, electrocardiograms,

clinical pathology (hematology, clinical chemistries, coagulation profiles and urinalysis), gross pathology, histopathology, or organ weights. Blood concentrations of lotilaner confirmed systemic exposure of all treated dogs, although the exposure was less than dose proportional at 5X.

In a well-controlled field study, CREDELIO was used concurrently with other medications, such as vaccines, anthelmintics, antibiotics, steroids, NSAIDs, anesthetics, and antihistamines. No adverse reactions were observed from the concomitant use of CREDELIO with other medications.

Storage Information:

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

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.

Approved by FDA under NADA # 141-494

Manufactured for:
Elanco US Inc
Greenfield, IN 46140 USA
Credelio.com
Revised August 2025

Credelio, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.
© 2025 Elanco or its affiliates

ElancoTM

PA104381X

Fact Sheet for Veterinarians: Emergency Use Authorization of CredelioTM (lotilaner)

CredelioTM
(lotilaner)

Chewable Tablets
For oral use in dogs

Original EUA Authorized Date: 10/24/2025

Emergency Use Authorization for CREDELIO (lotilaner) for New World Screwworm (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) for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*)

larvae (myiasis) in dogs and puppies. However, CREDELIO is not approved for this use. CREDELIO is approved for other uses¹.

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.

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*)².
- Declared “that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals.”

An EUA is a 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 including, but not limited to, when the Secretary of HHS declares circumstances exist justifying the product’s emergency authorization, based on a determination, including but not limited to a public health emergency or a significant potential for a public health emergency that may affect national security and that involves a biological agent³. Criteria for issuing this EUA include:

- The biological agent can cause a serious or life-threatening disease or condition;
- Based on the available scientific evidence (including data from adequate and well-controlled clinical trials, if available), it is reasonable to believe that:
 - o The product may be effective in diagnosing, treating or preventing the serious or life-threatening disease or condition; and
 - o the known and potential benefits of the product - when used to treat such disease or condition - outweigh the known and potential risks of the product;
- There is no adequate, approved, and available alternative to the product for treating the serious or life-threatening disease or condition⁴.

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

Description:

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

Dosage and Administration:

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.

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 scientific evidence available to FDA, including data from published scientific literature, it is reasonable to believe that CREDELIO may be effective for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies; and the known and potential benefits of CREDELIO, outweigh the known and potential risks.

A study conducted by do Vale et al.⁵ 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.

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 posttreatment 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 eleven 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:

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.

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

Contact Information:

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Elanco US Inc. at 1-888-545-5973.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

Information for Animal Owner:

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

Revised October 2025

- 1 On January 19, 2018, CREDELIO was approved to kill 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) 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 <https://public-inspection.federalregister.gov/2025-15918.pdf>
- 3 Emergency Use Authorization of Medical Products and Related Authorities | FDA (<https://www.fda.gov/regulatoryinformation/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities>)
- 4 <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- 5 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.

Principal Display Panel - 3 Tablets 56.25 mg Box Label

3 Tablets

Dogs &
puppies

4.4-6.0 lbs

Credelio™
(lotilaner)

For the treatment and prevention of flea infestations and for the treatment and control of tick infestations in dogs and puppies 8 weeks of age and older

56.25 mg chewable tablet

Kills fleas

Kills ticks

Monthly dose

Give with food

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Approved by FDA under NADA # 141-494

ElancoTM



Principal Display Panel - 3 Tablets 112.5 mg Box Label

3 Tablets

Dogs & puppies

6.1-12.0 lbs

Credelio™
(lotilaner)

For the treatment and prevention of flea infestations and for the treatment and control of tick infestations in dogs and puppies 8 weeks of age and older

112.5 mg chewable tablet

Kills fleas

Kills ticks

Monthly dose

Give with food

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Approved by FDA under NADA # 141-494

Elanco™



Principal Display Panel - 3 Tablets 225 mg Box Label

3 Tablets

Dogs & puppies

12.1-25.0 lbs

**Credelio™
(lotilaner)**

For the treatment and prevention of flea infestations and for the treatment and control of tick infestations in dogs and puppies 8 weeks of age and older

225 mg chewable tablet

Kills fleas

Kills ticks

Monthly dose

Give with food

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Approved by FDA under NADA # 141-494

Elanco™



For complete product information, refer to the package insert.

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.

Dosage and Administration: CREDELIO chewable tablets are given by mouth once a month at the recommended minimum dosage of 9 mg/lb (20 mg/kg). CREDELIO must be administered with food.

Warnings: Not for human use. Keep this and all medications 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.

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.

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

Questions? Consult your veterinarian, call 1-888-545-5973, or visit Credelio.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at <http://www.fda.gov/reportanimalae>.

Manufactured for Elanco US Inc.
Greenfield, IN 46140

Product of China

SH104377B

Elanco

Credelio
(lotilaner)



3 TABLETS Dogs & puppies | 12.1-25.0 lbs

Credelio™
(lotilaner)

For the treatment and prevention of flea infestations and for the treatment and control of tick infestations in dogs and puppies 8 weeks of age and older

225 mg chewable tablet



Kills fleas



Kills ticks



Monthly dose



Give with food

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Approved by FDA under NADA # 141-494

Elanco

3 TABLETS | 12.1-25.0 lbs

Credelio™ (lotilaner)

LOT:

EXP:

SH104377B



Principal Display Panel - 3 Tablets 450 mg Box Label

3 Tablets

Dogs & puppies

25.1-50.0 lbs

Credelio™

(lotilaner)

For the treatment and prevention of flea infestations and for the treatment and control of tick infestations in dogs and puppies 8 weeks of age and older

450 mg chewable tablet

Kills fleas

Kills ticks

Monthly dose

Give with food

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Approved by FDA under NADA # 141-494

ElancoTM



Principal Display Panel - 3 Tablets 900 mg Box Label

3 Tablets

Dogs &
puppies

50.1-100.0 lbs

**Credelio™
(lotilaner)**

For the treatment and prevention of flea infestations and for the treatment and control of tick infestations in dogs and puppies 8 weeks of age and older

900 mg chewable tablet

Kills fleas

Kills ticks

Monthly dose

Give with food

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Approved by FDA under NADA # 141-494

Elanco™



For complete product information, refer to the package insert.

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.

Dosage and Administration: CREDELIO chewable tablets are given by mouth once a month at the recommended minimum dosage of 9 mg/lb (20 mg/kg). CREDELIO must be administered with food.

Warnings: Not for human use. Keep this and all medications 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.

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.

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

Questions? Consult your veterinarian, call 1-888-545-5973, or visit Credelio.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at <http://www.fda.gov/reportanimalae>.

Manufactured for Elanco US Inc. Greenfield, IN 46140

Product of China

SH104379B

Elanco

Credelio
(lotilaner)



3 TABLETS Dogs & puppies 50.1-100.0 lbs

Credelio™
(lotilaner)

For the treatment and prevention of flea infestations and for the treatment and control of tick infestations in dogs and puppies 8 weeks of age and older

900 mg chewable tablet



Kills fleas



Kills ticks



Monthly dose



Give with food

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Approved by FDA under NADA # 141-494

Elanco

3 TABLETS 50.1-100.0 lbs

Credelio™ (lotilaner)

LOT:
EXP:

SH104379B



Principal Display Panel - Emergency Use Authorization

For New World
screw worm (NWS)
under Emergency
Use Authorization
(EUA)

Fact Sheet

www.credelio-nws.com

EP104447A

For New World
screwworm (NWS)
under Emergency
Use Authorization
(EUA)

Fact Sheet



www.credelio-nws.com

EP104447A

CREDELIO

lotilaner tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58198-5452
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lotilaner (UNII: HEH4938D7K) (Lotilaner - UNII:HEH4938D7K)	Lotilaner	56.25 mg

Product Characteristics

Color	White (beige with brownish spots)	Score	no score
Shape	ROUND (biconvex beveled edges)	Size	7mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-5452-3	16 in 1 BOX		
1	NDC:58198-5452-1	1 in 1 CARTON		
1		1 in 1 BLISTER PACK		
2	NDC:58198-5452-4	10 in 1 BOX		
2	NDC:58198-5452-2	2 in 1 CARTON		
2		3 in 1 BLISTER PACK		

3	NDC:58198-5452-6	16 in 1 BOX		
3	NDC:58198-5452-7	1 in 1 CARTON		
3		3 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141494	01/19/2018	

CREDELIO

lotilaner tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58198-5458
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lotilaner (UNII: HEH4938D7K) (Lotilaner - UNII:HEH4938D7K)	Lotilaner	112.5 mg

Product Characteristics

Color	White (beige with brownish spots)	Score	no score
Shape	ROUND (biconvex beveled edges)	Size	9mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-5458-3	16 in 1 BOX		
1	NDC:58198-5458-1	1 in 1 CARTON		
1		1 in 1 BLISTER PACK		
2	NDC:58198-5458-4	10 in 1 BOX		
2	NDC:58198-5458-2	2 in 1 CARTON		
2		3 in 1 BLISTER PACK		
3	NDC:58198-5458-6	16 in 1 BOX		
3	NDC:58198-5458-7	1 in 1 CARTON		
3		3 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
--------------------	--	----------------------	--------------------

NADA	NADA141494	01/19/2018	
------	------------	------------	--

CREDELIO

lotilaner tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58198-5456
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lotilaner (UNII: HEH4938D7K) (Lotilaner - UNII:HEH4938D7K)	Lotilaner	225 mg

Product Characteristics

Color	White (beige with brownish spots)	Score	no score
Shape	ROUND (biconvex beveled edges)	Size	12mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-5456-3	16 in 1 BOX		
1	NDC:58198-5456-1	1 in 1 CARTON		
1		1 in 1 BLISTER PACK		
2	NDC:58198-5456-4	10 in 1 BOX		
2	NDC:58198-5456-2	2 in 1 CARTON		
2		3 in 1 BLISTER PACK		
3	NDC:58198-5456-6	16 in 1 BOX		
3	NDC:58198-5456-7	1 in 1 CARTON		
3		3 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141494	01/19/2018	

CREDELIO

lotilaner tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58198-5454	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	Lotilaner (UNII: HEH4938D7K) (Lotilaner - UNII:HEH4938D7K)	Lotilaner	450 mg	
Product Characteristics				
Color	White (beige with brownish spots)	Score	no score	
Shape	ROUND (biconvex beveled edges)	Size	15mm	
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-5454-3	16 in 1 BOX		
1	NDC:58198-5454-1	1 in 1 CARTON		
1		1 in 1 BLISTER PACK		
2	NDC:58198-5454-4	10 in 1 BOX		
2	NDC:58198-5454-2	2 in 1 CARTON		
2		3 in 1 BLISTER PACK		
3	NDC:58198-5454-6	16 in 1 BOX		
3	NDC:58198-5454-7	1 in 1 CARTON		
3		3 in 1 BLISTER PACK		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA141494	01/19/2018		

CREDELIO

lotilaner tablet, chewable

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58198-5451
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	Lotilaner (UNII: HEH4938D7K) (Lotilaner - UNII:HEH4938D7K)	Lotilaner	900 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	White (beige with brownish spots)	Score	no score
Shape	ROUND (biconvex beveled edges)	Size	19mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-5451-3	16 in 1 BOX		
1	NDC:58198-5451-1	1 in 1 CARTON		
1		1 in 1 BLISTER PACK		
2	NDC:58198-5451-4	10 in 1 BOX		
2	NDC:58198-5451-2	2 in 1 CARTON		
2		3 in 1 BLISTER PACK		
3	NDC:58198-5451-6	16 in 1 BOX		
3	NDC:58198-5451-7	1 in 1 CARTON		
3		3 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141494	01/19/2018	

Labeler - Elanco US Inc. (966985624)

Revised: 2/2026

Elanco US Inc.