

CREDELIO- lotilaner tablet, chewable
Elanco US Inc.

Credelio™
CAT (lotilaner)

Chewable Tablets

For oral use in cats

Caution:

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

Description:

CREDELIO CAT (lotilaner) is a chewable tablet for oral administration to cats and kittens according to their weight. Each chewable tablet is formulated to provide a minimum lotilaner dosage of 2.7 mg/lb (6 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 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.

Dosage and Administration:

CREDELIO CAT is given orally once a month, 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

NA = not applicable.

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

Treatment with CREDELIO CAT 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 CAT.

Warnings:

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.

Precautions:

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

The safety of CREDELIO CAT has not been established in breeding, pregnant and lactating cats (see **Foreign Market Experience**).

The effectiveness of CREDELIO CAT against *Ixodes scapularis* in kittens less than 6 months of age has not been evaluated.

Adverse Reactions:

In a well-controlled U.S. field study, which included 341 cats (228 cats treated with CREDELIO CAT and 113 cats treated with a topical active control), there were no serious adverse reactions.

Cats with Adverse Reactions in the Field Study

Adverse Reaction (AR)	CREDELIO CAT Group: Number (and Percent) of Cats with the AR (n=228)	Active Control Group: Number (and Percent) of Cats with the AR (n=113)
Weight Loss	5 (2.2%)	2 (1.8%)
Tachypnea	3 (1.3%)	0 (0.0%)
Vomiting	3 (1.3%)	1 (0.9%)
Diarrhea	2 (0.9%)	0 (0.0%)
Anorexia	2 (0.9%)	0 (0.0%)
Elevated blood urea nitrogen (BUN)*	2 (0.9%)	0 (0.0%)

*Two geriatric cats developed mildly elevated blood urea nitrogen (BUN) (42 to 58 mg/dL; reference range: 14 to 36 mg/dL) during the study. One of these cats, which had suspected pre-existing kidney disease, also developed a mildly elevated serum creatinine (2.5 mg/dL; reference range: 0.6 to 2.4 mg/dL) during the study.

Foreign Market Experience: The following adverse events were reported voluntarily during post-approval use of the product in cats in foreign markets: hyperactivity, pruritus, tachypnea, dyspnea, lethargy, vomiting, anorexia, hyperthermia, hypersalivation, tachycardia, mydriasis, tremors, ataxia, seizures, hepatopathy, anaphylactic reactions resulting in death, pancreatitis, immune mediated hemolytic anemia, and glomerulopathy.

Five 3- to 4-week-old nursing kittens (one litter of 2 kittens and one litter of 3) died within three days of the queens receiving CREDELIO CAT. Two pregnant cats spontaneously aborted or had fetal and perinatal deaths within a few days of receiving CREDELIO CAT.

Post-Approval Experience (2024)

The following adverse events are based on post-approval adverse drug experience reporting for CREDELIO CAT. 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 cats are listed in decreasing order of reporting frequency:

Pruritus, vomiting, lethargy, behavioral changes (including hyperactivity, vocalization, and hiding), tachypnea, anorexia, muscle tremor, dyspnea, hyperthermia, and ataxia.

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 26 mg/kg (the maximum labeled dose), peak lotilaner concentrations were achieved in most cats at the 24-hour sampling point. Cats 3 months of age had a shorter elimination half-life (average of 7.5 days) than at 7 months of age (average of 32 days).

Due to reduced drug bioavailability in the fasted state, CREDELIO CAT 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 a well-controlled laboratory study, CREDELIO CAT began to kill fleas six hours after administration, with greater than 98% of fleas killed within 12 hours after administration. In another well-controlled laboratory study, CREDELIO CAT demonstrated 100% effectiveness against adult fleas 24 hours after administration or infestation for 35 days.

In a 90-day well-controlled U.S. field study conducted in cats with existing flea infestations of varying severity, the effectiveness of CREDELIO CAT against fleas on Days 30, 60 and 90 compared to baseline was 98.5%, 100% and 100%, respectively. Cats 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 CAT killed fleas before they could lay eggs, thus preventing subsequent flea infestations after the start of treatment of existing flea infestations for 30 days.

In well-controlled laboratory studies, CREDELIO CAT demonstrated >97% effectiveness against *Ixodes scapularis* ticks 72 hours after administration or infestation for 31 days.

Palatability: In the U.S. field study, which included 648 doses administered to 225 cats, 21.1% of the doses were voluntarily consumed when CREDELIO CAT was offered by hand, on the floor, or in an empty bowl, an additional 25.8% of doses were voluntarily consumed when CREDELIO CAT was offered with food, and 52.6% of doses required placement of the chewable tablet in the back of the cat's mouth.

Owners were unable to administer CREDELIO CAT for 0.5% of doses.

Animal Safety:

In a margin of safety study, CREDELIO CAT was administered orally to 24 (8 cats/group) 8-week-old cats at 1, 3 and 5X the maximum labeled dose of 26 mg/kg every 28 days for eight consecutive doses. The 8 cats in the control group (0X) were untreated.

There were no clinically-relevant, treatment-related effects on physical and neurologic examinations or gross pathology. Dry food consumption was reduced in male cats in all treated groups compared to control cats. Body weights of male cats in the 3X group were less than the control male cats. Vomiting occurred post-dosing in cats in all groups, including the control group, but was increased in the 5X group. At multiple time points, neutrophil counts were decreased (750-2710/ μ L; low end of normal: approximately 2800/ μ L) in cats in all treated groups compared to control cats, including in a cat in the 3X group that died during anesthesia to obtain the electrocardiogram (ECG). From Days 28 to 92, two and three female cats in the 3X and 5X group, respectively, had elevations in blood urea nitrogen (BUN) at least at one time point (37-43 mg/dL; high end of normal: 36 mg/dL). Three cats each in the control, 1X and 5X

groups and six cats in the 3X group had minimal, usually unilateral, tubular regeneration of the kidneys. One cat each in the control, 1X and 5X groups and four cats in the 3X group had minimal generalized lymphoid depletion of the thymus. Four of the five cats in the two high-dose groups (3X and 5X) with the thymus changes also had neutropenia at 25% or more of the time points.

Blood concentrations of lotilaner confirmed systemic exposure in all cats administered lotilaner, although the exposure was less than dose proportional.

Storage Information:

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

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.

Approved by FDA under NADA # 141-528

Manufactured for:
Elanco US Inc
Greenfield, IN 46140 USA

CredelioCAT.com

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Rev. date November 2024

PA104223X

ElancoTM

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

CredelioTM CAT (lotilaner)

Chewable Tablets
For oral use in cats

Original EUA Authorized Date: 11/21/2025

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

larvae (myiasis) in cats and kittens. CREDELIO CAT is not approved for this use.

CREDELIO CAT is approved for other uses¹.

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.

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 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 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:
 - The product may be effective in diagnosing, treating, or preventing the serious or life-threatening disease or condition; and
 - 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 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.

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

Risk-Benefit Consideration for Cats on Other Isoxazolines:

If a cat is currently receiving another isoxazoline product for routine ectoparasite control, veterinarians should consider administering CREDELIO CAT to cats 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 CAT may be effective for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens, and the known and potential benefits of CREDELIO CAT outweigh the known and potential risks.

A study conducted by Han and Yasmin⁵ evaluated the effectiveness of lotilaner⁶ for the treatment of naturally acquired Old World screwworm (OWS, *Chrysomya bezziana*) myiasis in cats in Malaysia. Two client-owned cats with active myiasis caused by *Chrysomya bezziana* larvae were enrolled. The cats included a 3-year-old male intact cat with a wound on the left hind paw and a 9-year-old male neutered cat with a wound on the right cervical neck region. Both cats received a single oral administration of lotilaner at doses of either 6 or 26 mg/kg body weight, following the dose bands for the approved flea and tick indications. The study was a case report and did not include a control group.

After treatment, both cats were hospitalized for 10 and 11 days and wounds were cleansed and flushed with saline solution until re-epithelization occurred. The study demonstrated 100% larvicidal effectiveness against OWS (*Chrysomya bezziana*) at 24 hours post-treatment in both cats. There were no adverse reactions during the study.

A study conducted by do Vale et al.⁷ evaluated the effectiveness of CREDELIO (lotilaner) for the treatment of naturally acquired NWS myiasis in dogs in Brazil. Eleven client-owned dogs with active myiasis caused by *Cochliomyia hominivorax* larvae were enrolled based on lesion severity and larval burden. All dogs received a single oral administration of CREDELIO using 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 *Cochliomyia 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 several limitations of the data supporting the benefits of CREDELIO CAT for the treatment of NWS infestations, as the available study in cats was conducted against a different parasite species (OWS). The Han and Yasmin study was conducted in a limited population of two cats naturally infested with Old World screwworm (*Chrysomya bezziana*) in Malaysia, and the inferential value to the United States population and NWS species is unknown. Additionally, the case report design, lack of a control group, and demonstrated effectiveness in a different parasite species (*Chrysomya bezziana* vs. *Cochliomyia hominivorax*) limits the ability to define a pure treatment effect. The do Vale et al. study was conducted in a limited population of eleven naturally infested dogs in Brazil, and the inferential value to cats is unknown; however, the study used the approved lotilaner dose for the flea and tick indications. In that study, the primary mechanism of action against *Cochliomyia 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 CAT against OWS (*Chrysomya bezziana*) larvae, and the effectiveness data for lotilaner in dogs against NWS, along with the established safety profile, support the potential benefit of CREDELIO CAT 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 CAT.

Warnings:

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.

Precautions:

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

The safe use of CREDELIO CAT in breeding, pregnant, or lactating cats has not been evaluated (see **Foreign Market Experience** on package insert).

The safety of CREDELIO CAT has not been evaluated in cats less than 8 weeks of age or less than 2.0 lbs.

Adverse Reactions:

Refer to the 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 CAT 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 CAT use for NWS under an EUA” under the “**Describe Adverse Event/Product Problem/Event 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, NDC#)

*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 this Letter of Authorization for at least two years following the termination or revocation of the EUA, 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.

Additional Information for Client (e.g., 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. Cats may become reinfested following treatment.

Clients should be advised that:

- Gloves should be worn if cleaning the wound or the cat's bedding or disposing of larvae.
- Cats 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 cat sits or lies after treatment.
- If expelled larvae are seen, clients should place the larvae in a sealed container with rubbing alcohol.
- If there is worsening of the wound, the client should contact the veterinarian.

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 of 1 chewable tablet. The 48 mg chewable tablet size is also available in color-coded packages containing 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

CredelioCAT.com

November 2025

ElancoTM

PA104468X

W1a

1 On December 9, 2019, CREDELIO CAT was approved to kill 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. On April 12, 2021, CREDELIO CAT received a supplemental approval for the treatment and control of tick infestations [*Ixodes scapularis* (black-legged tick)] for one month in cats and kittens 6 months of age and older, and weighing 2.0 pounds or greater.

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>

- 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 FDA's "New World Screwworm: Information for Veterinarians": <https://www.fda.gov/animal-veterinary/safety-health/new-world-screwworm-information-veterinarians>
- 5 Han, HS, Yasmin, L (2020). *Chrysomya bezziana* (Diptera: Calliphoridae) infestation in two Malaysian cats treated with oral lotilaner. *Vet Dermatol*, 31:335-e87.
- 6 Same formulation as CREDELIO CAT.
- 7 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 - 12 mg Box Label

1 TABLET

Cats &
Kittens

2.0-4.0 lbs

Credelio™ **CAT (lotilaner)**

Treats and prevents flea infestations in cats and kittens 8 weeks of age and older.

Treats and controls *Ixodes scapularis* tick infestations in cats and kittens 6 months of age and older.

12 mg chewable tablet

Kills fleas

Kills *I. scapularis* ticks

Monthly dose

Give with food

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

Approved by FDA under NADA # 141-528

Elanco



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Credelio CAT (lotilaner)

For complete product information, refer to the package insert.

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.

Dosage and Administration: CREDELIO CAT chewable tablets are given by mouth once a month at the recommended minimum dosage of 2.7 mg/lb (6 mg/kg). CREDELIO CAT must be administered with food.

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

Precautions: CREDELIO CAT is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. Neurologic adverse reactions have been reported in cats receiving isoxazoline class drugs, even in cats without a history of neurologic disorders. Use with caution in cats with a history of neurologic disorders.

The safe use of CREDELIO CAT in breeding, pregnant or lactating cats has not been established.

The effectiveness of CREDELIO CAT against *Ixodes scapularis* infestations in cats and kittens less than 6 months of age 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 CredelioCAT.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

SH104223A

Elanco

1 TABLET

Cats & kittens

2.0-4.0 lbs

Credelio CAT (lotilaner)

Credelio[™] CAT (lotilaner)

Treats and prevents flea infestations in cats and kittens 8 weeks of age and older. Treats and controls *Ixodes scapularis* tick infestations in cats and kittens 6 months of age and older.

12 mg chewable tablet



Kills fleas



Kills *I. scapularis* ticks



Monthly dose



Give with food

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Approved by FDA under NADA # 141-528

Elanco

1 TABLET 2.0-4.0 lbs

Credelio CAT (lotilaner)



LOT:

EXP:

SH104223A



1 TABLET

KITTEN
KIT

2.0 -
4.0 lbs.

Credelio[™]
CAT (lotilaner)

Treats and prevents flea infestations in cats and kittens 8 weeks of age and older.
Treats and controls *Ixodes scapularis* tick infestations in cats and kittens 6 months of age and older.

12 mg chewable tablet

Kills fleas

Kills *I. scapularis* ticks

Monthly dose

Give with food

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

Approved by FDA under NADA # 141-528

Elanco™

NOT FOR RESALE



Principal Display Panel - 48 mg Box Label

1 TABLET

Cats &
Kittens

4.1-17.0 lbs

**Credelio™
CAT (lotilaner)**

Treats and prevents flea infestations in cats and kittens 8 weeks of age and older.
Treats and controls *Ixodes scapularis* tick infestations in cats and kittens 6 months of age and older.

48 mg chewable tablet

Kills fleas

Kills *I. scapularis*
ticks

Monthly dose

Give with
food

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

Approved by FDA under NADA # 141-528

Elanco



Credelio CAT (lotilaner)

For complete product information, refer to the package insert.

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.

Dosage and Administration: CREDELIO CAT chewable tablets are given by mouth once a month at the recommended minimum dosage of 2.7 mg/lb (6 mg/kg). CREDELIO CAT must be administered with food.

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

Precautions: CREDELIO CAT is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. Neurologic adverse reactions have been reported in cats receiving isoxazoline class drugs, even in cats without a history of neurologic disorders. Use with caution in cats with a history of neurologic disorders.

The safe use of CREDELIO CAT in breeding, pregnant or lactating cats has not been established.

The effectiveness of CREDELIO CAT against *Ixodes scapularis* infestations in cats and kittens less than 6 months of age 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 CredelioCAT.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

SH104223C

Elanco

1 TABLET

Cats & kittens

4.1-17.0 lbs

Credelio CAT (lotilaner)



Credelio™ CAT (lotilaner)

Treats and prevents flea infestations in cats and kittens 8 weeks of age and older.

Treats and controls *Ixodes scapularis* tick infestations in cats and kittens 6 months of age and older.

48 mg chewable tablet



Kills fleas



Kills *I. scapularis* ticks



Monthly dose



Give with food

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Approved by FDA under NADA # 141-528

Elanco

1 TABLET 4.1-17.0 lbs

Credelio CAT (lotilaner)

LOT:

EXP:

SH104223C



3 TABLETS

Cats & Kittens

4.1-17.0 lbs

**Credelio™
CAT (lotilaner)**

Treats and prevents flea infestations in cats and kittens 8 weeks of age and older.

Treats and controls *Ixodes scapularis* tick infestations in cats and kittens 6 months of age and older.

48 mg chewable tablet

Kills fleas

Kills *I. scapularis* ticks

Monthly dose

Give with food

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

Approved by FDA under NADA # 141-528

Elanco



SH104223E

Credelio CAT (lotilaner)

For complete product information, refer to the package insert.

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.

Dosage and Administration: CREDELIO CAT chewable tablets are given by mouth once a month at the recommended minimum dosage of 2.7 mg/lb (6 mg/kg). CREDELIO CAT must be administered with food.

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

Precautions: CREDELIO CAT is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. Neurologic adverse reactions have been reported in cats receiving isoxazoline class drugs, even in cats without a history of neurologic disorders. Use with caution in cats with a history of neurologic disorders.

The safe use of CREDELIO CAT in breeding, pregnant or lactating cats has not been established.

The effectiveness of CREDELIO CAT against *Ixodes scapularis* infestations in cats and kittens less than 6 months of age 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 CredelioCAT.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>.

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Product of China

SH104223E

Elanco

3 TABLETS Cats & kittens 4.1-17.0 lbs

Credelio CAT (lotilaner)

Credelio[™] CAT (lotilaner)

Treats and prevents flea infestations in cats and kittens 8 weeks of age and older.

Treats and controls *Ixodes scapularis* tick infestations in cats and kittens 6 months of age and older.

48 mg chewable tablets



Kills fleas



Kills *I. scapularis* ticks



Monthly dose



Give with food

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Approved by FDA under NADA # 141-528

Elanco

3 TABLETS 4.1-17.0 lbs

Credelio CAT (lotilaner)



7 27804 56290 8

LOT:

EXP:

SH104223E



6 TABLETS

Cats & Kittens

4.1-17.0 lbs

Credelio[™] CAT (lotilaner)

Treats and prevents flea infestations in cats and kittens 8 weeks of age and older.
Treats and controls *Ixodes scapularis* tick infestations in cats and kittens 6 months of age and older.

48 mg chewable tablet

Kills fleas

Kills *I. scapularis* ticks

Monthly dose

Give with food

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

Approved by FDA under NADA # 141-528

Elanco



SH104223G

Credelio CAT
(lotilaner)

For complete product information, refer to the package insert.

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.

Dosage and Administration: CREDELIO CAT chewable tablets are given by mouth once a month at the recommended minimum dosage of 2.7 mg/lb (6 mg/kg). CREDELIO CAT must be administered with food.

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

Precautions: CREDELIO CAT is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. Neurologic adverse reactions have been reported in cats receiving isoxazoline class drugs, even in cats without a history of neurologic disorders. Use with caution in cats with a history of neurologic disorders.

The safe use of CREDELIO CAT in breeding, pregnant or lactating cats has not been established.

The effectiveness of CREDELIO CAT against *Ixodes scapularis* infestations in cats and kittens less than 6 months of age 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 CredelioCAT.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>.

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Product of China

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SH104223G

6 TABLETS Cats & kittens 4.1-17.0 lbs

Credelio CAT
(lotilaner)

Credelio CAT (lotilaner)

Treats and prevents flea infestations in cats and kittens 8 weeks of age and older.
Treats and controls *Ixodes scapularis* tick infestations in cats and kittens 6 months of age and older.

48 mg chewable tablets



Kills fleas



Kills *I. scapularis* ticks



Monthly dose



Give with food

Elanco



6 TABLETS 4.1-17.0 lbs

Credelio CAT
(lotilaner)

LOT:

EXP:

SH104223G



1 TABLET

KITTEN
KIT

4.1 -
17.0 lbs.

Credelio™

CAT (lotilaner)

Treats and prevents flea infestations in cats and kittens 8 weeks of age and older.
Treats and controls *Ixodes scapularis* tick infestations in cats and kittens 6 months of age and older.

48 mg chewable tablet

Kills fleas

Kills *I. scapularis* ticks

Monthly dose

Give with food

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

Approved by FDA under NADA # 141-528

Elanco™

NOT FOR RESALE

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



www.credeliocat-nws.com

EP104468B

CREDELIO

lotilaner tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58198-5487
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lotilaner (UNII: HEH4938D7K) (Lotilaner - UNII:HEH4938D7K)	Lotilaner	12 mg

Product Characteristics

Color	White (white to brownish with brownish spots)	Score	no score
Shape	ROUND (biconvex beveled edges)	Size	5mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-5487-2	16 in 1 BOX		
1	NDC:58198-5487-1	1 in 1 CARTON		
1		1 in 1 BLISTER PACK		
2	NDC:58198-5487-3	7 in 1 BOX		
2		1 in 1 CARTON		
2		1 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141528	04/12/2021	

CREDELIO

lotilaner tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58198-5488
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lotilaner (UNII: HEH4938D7K) (Lotilaner - UNII:HEH4938D7K)	Lotilaner	48 mg

Product Characteristics

Color	White (white to brownish with brownish spots)	Score	no score
Shape	ROUND (biconvex beveled edges)	Size	8mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-5488-4	16 in 1 BOX		
1	NDC:58198-5488-1	1 in 1 CARTON		
1		1 in 1 BLISTER PACK		
2	NDC:58198-5488-5	16 in 1 BOX		
2	NDC:58198-5488-2	1 in 1 CARTON		
2		3 in 1 BLISTER PACK		
3	NDC:58198-5488-6	10 in 1 BOX		
3	NDC:58198-5488-3	1 in 1 CARTON		
3		6 in 1 BLISTER PACK		
4	NDC:58198-5488-7	7 in 1 BOX		
4		1 in 1 CARTON		
4		1 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141528	04/12/2021	

Labeler - Elanco US Inc. (966985624)