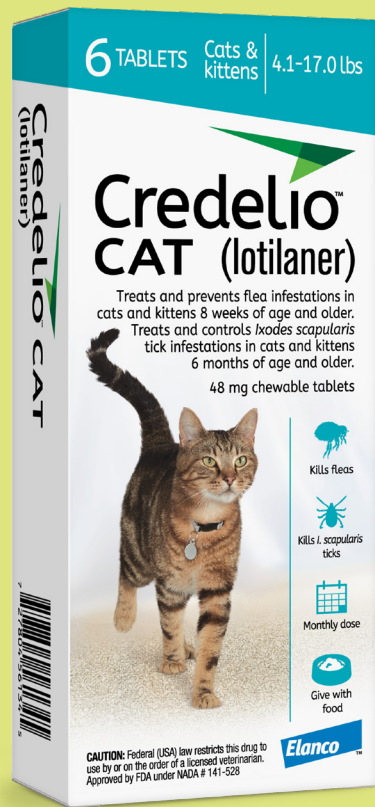


A Well Protected Cat is a Happy Cat.

Credelio® CAT (lotilaner) is the
only oral flea and tick protection
that's made just for cats.



Credelio™
CAT (lotilaner)



Tasty Flea and Tick Protection for Cats

Cats can be picky when it comes to flea and tick treatment. That's why Credelio Cat was specifically designed to meet cats' flea and tick protection needs in a tiny tablet that is easy for pet owners to administer. It is the first and only oral flea and tick product for cats, formulated especially for your feline patients.

DESIGNED ESPECIALLY

FOR CATS

Fleas and Ticks: Cats' hidden enemies

When a cat comes to your clinic with itchy skin, hair loss or small, crusted bumps, fleas are a likely culprit — even if you don't see the fleas. In fact, both fleas and ticks are difficult to detect in cats.

Flea and tick detection challenges in cats:

- Infrequent veterinarian visits and challenges of examining a cat.
- Cats groom off the fleas and ticks they can reach.
- Cats' reactions to fleas and ticks may seem like typical cat behavior (i.e., increased grooming).
- Ticks only spend a few days out of the year on the cat.
- Fleas and immature tick stages are difficult to see.

Credelio Cat development focused on cats' needs for:



Lasting flea and tick control



Appealing smell and flavor



Easy oral administration

Nearly 3 out of every 4 of cat owners agree they would like to try new and improved methods of flea and tick control for their cats.¹



- 6 hours** Starts killing fleas within 6 hours
- 8 hours** Kills 98.8% of fleas by 8 hours and 99.3% by 12 hours²
- 24 hours** Kills 100% of fleas by 24 hours³

Flea efficacy

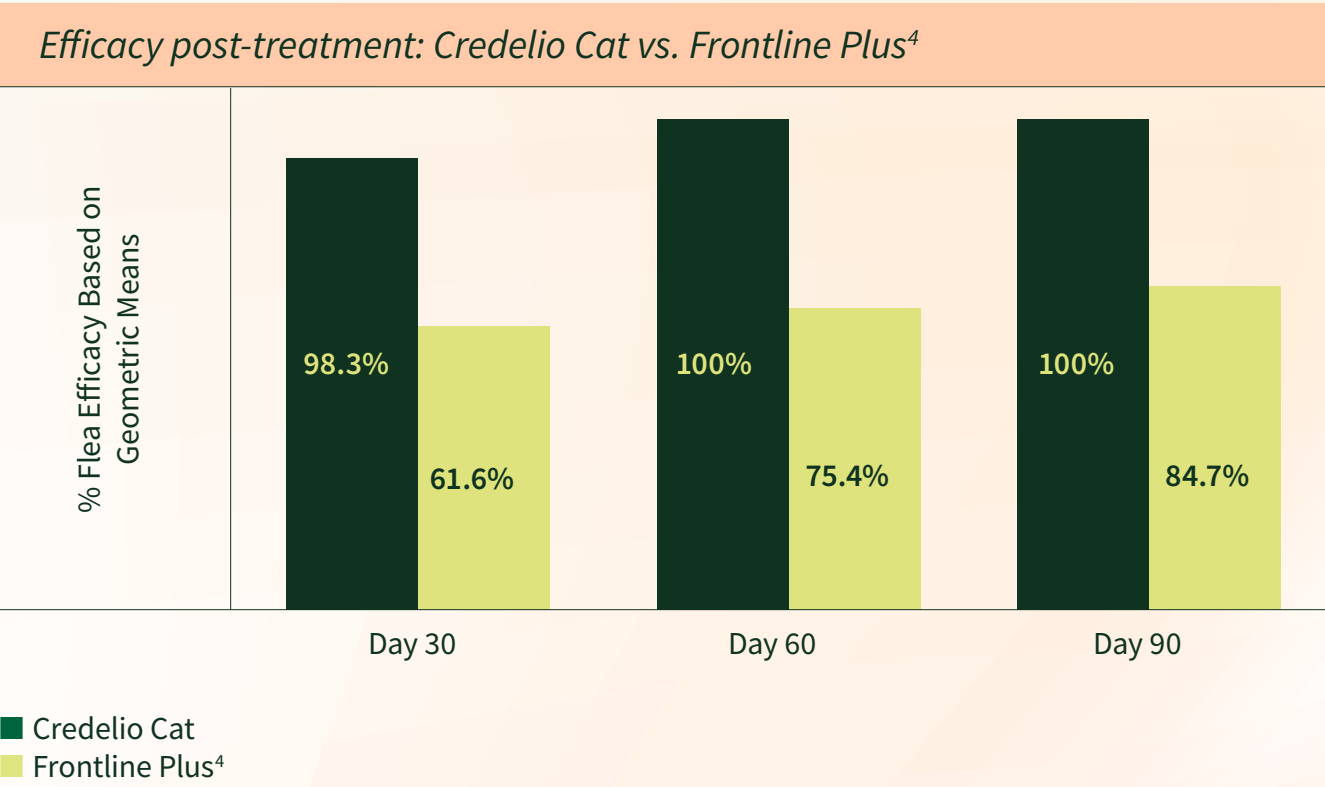
Credelio Cat kills fleas before they can lay eggs. It maintains fast-acting and sustained flea efficacy throughout the entire month — no drop-off. ^{2,3}

Credelio Cat is approved for the treatment and prevention of flea infestations in cats 8 weeks and older weighing 2.0 pounds or more.

Flea control should be one of the first steps for any cat that presents with:

- Hair loss from excessive grooming or rubbing
- Miliary dermatitis
- Eosinophilic granuloma complex
- Itching and rubbing around the head and neck

Credelio Cat’s flea efficacy outperformed Frontline® Plus in a 90-day Study



Improved Flea Allergy Dermatitis (FAD) Signs Due to Quick Flea-Kill

Fad Percent Improvement ⁵					
Clinical Sign	Pruitus	Papules/ Scabs	Redness	Hair loss	Dermatitis/ pyodermatitis
Lotilaner post-treatment	95.9%	100%	100%	100%	100%

Without the use of steroids, 100% of cats showed improvement in FAD signs in a field study.^{4,5}



HAPPY EARS.

HAPPY TAIL. HAPPY CAT.

Tick efficacy

Effective, sustained
Ixodes scapularis tick kill

I. scapularis, also known as the black-legged or deer tick, is the most common tick infesting cats. It is most often found on the head, neck and ears and can be a threat year-round.⁶

Credelio Cat kills 97-100% of *I. scapularis* ticks at 72 hours after administration or infestation throughout the month.⁷

Credelio Cat is approved for the treatment and control of *I. scapularis* in cats 6 months and older weighing 2.0 pounds or more.



Efficacy Against Ticks⁷

Species	Efficacy Measured At:	Measurement Point 1	Measurement Point 2	Measurement Point 3	Measurement Point 4	Measurement Point 5
1 <i>I. scapularis</i>	72 hours	100% Day 3	99.5% Day 10	99.5% Day 17	97.4% Day 24	98.7% Day 31
2 <i>I. scapularis</i>	72 hours	100% Day 3	99.6% Day 3	99.6% Day 17	99.2% Day 24	99.1% Day 31

Indoor cats are at-risk too:

Unattached, crawling ticks can be carried into the home by people or other pets. This is why indoor cats need tick control just like outdoor cats do.

An Extra-Purified Active Ingredient

Credelio Cat chewables are formulated with extra-purified lotilaner.

Lotilaner was hand-picked from over 1,000 isoxazoline compounds during development for its efficacy and safety profile.⁸



Benefits of Extra Purification

The manufacturing process removes the inactive lotilaner enantiomer, with several benefits to your patients:

- Better efficacy with the same dose of drug⁸
- Allows for a potent, small chewable that's easy for cats to take⁸
- Less potential for side effects⁹
- Less strain on the cat's system⁸

FORMULATED JUST FOR CATS

Made Especially for Cats

While palatability is important, cats actually have 70% fewer tastebuds than dogs and rely heavily on their olfactory sense when determining what is desirable to eat.¹⁰

Credelio Cat development:

- Highly emphasized product smell and flavor
- Heavily considered cats' unique eating behaviors and physiology
- Tested multiple flavor/smell attributes

Delicious Vanilla Yeast Flavor



Testing determined that vanilla and yeast were the power combo Credelio Cat needed.



Tiny, Tasty, and Easy to Give

Real-world administration success

In a U.S. field study, 99.5% of cat owners (645/648 doses) successfully administered Credelio Cat to a diverse range of cats.⁴

Palatability Score ⁴	
Tablets accepted voluntarily	46.9%
Tablets accepted placed in mouth	52.6%
Successfully dosed by pet owner	99.5%
Tablets could not be administered by pet owner (Two cats successfully redosed by clinic study staff)	0.5%

In another field study conducted in Europe, 100% of Credelio Cat chewables were successfully dosed by cat owners¹¹

Dosing		
Body weight*	2.0 to 4.0 lbs	4.1 to 17.0 lbs
Lotilaner per chewable tablet (mg)	12	48

*For cats weighing more than 17 lbs, administer the appropriate combination of chewable tablets.



Easy alternative to topicals

Topicals have their place in your clinic’s flea and tick portfolio. Yet some also have shortcomings:

- Messy, greasy application or odor.
- Isolation period from other pets and children.
- Difficulty or concern with applying to damaged or irritated skin from FAD.
- Inconsistent spreading of ingredients over the skin or haircoat.



Talk to your Elanco sales rep about Credelio Cat, the first oral flea and tick product for cats.



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.

Important Safety Information

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 or lactating cats. The effectiveness of Credelio CAT against *Ixodes scapularis* in kittens less than 6 months of age has not been evaluated. The most frequently reported adverse reactions are weight loss, tachypnea and vomiting. For full prescribing information see Credelio CAT package insert.

¹Elanco Animal Health. Data on file. ²Cavalleri D, Murphy M, Seewald W, et al. Laboratory evaluation of the efficacy and speed of kill of lotilaner (Credelio®) against *Ctenocephalides felis* on cats. *Parasite Vector*. 2018;11:408. ³Paarlberg T, Karadzovska D, Helbig R. Efficacy of lotilaner (Credelio™) against experimentally induced infestations of the adult cat flea, *Ctenocephalides felis*, and flea eggs following oral administration to cats. *Parasite Vector*. 2021;14:139. ⁴Chappell K, Paarlberg T, Seewald W, et al. A randomized, controlled field study to assess the efficacy and safety of lotilaner flavored chewable tablets (Credelio® CAT) in eliminating fleas in client-owned cats in the USA. *Parasite Vector*. 2021;14:127. ⁵Credelio Cat. Freedom of Information Summary. NADA 141-528. ⁶Little SE, Barrett AW, Nagamori Y, et al. Ticks from cats in the United States: Patterns of infestation and infection with pathogens. *Vet Parasitol*. 2018;257:15. ⁷Credelio Cat. Freedom of Information Summary Supplement. NADA 141-528. ⁸Toutain C, Seewald W, Jung M. The intravenous and oral pharmacokinetics of lotilaner in dogs. *Parasite Vector*. 2017;10:522. ⁹Food and Drug Administration. Development of new stereoisomeric drugs. Available from: <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/guidances/ucm122883.htm>. Accessed March 19, 2021. ¹⁰Pekel AY, Mülazımoğlu SB, Acar N. Taste preferences and diet palatability in cats. *J Appl Anim Res*. 2020;48(1):281. ¹¹Cavalleri D, Murphy M, Seewald W, et al. A randomized, controlled field study to assess the efficacy and safety of lotilaner (Credelio®) in controlling ticks in client-owned cats in Europe. *Parasite Vector*. 2018;11:411.



CredelioTM 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

Credelio, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates. © 2024 Elanco or its affiliates

Rev. date November 2024

