



Credelio® (lotilaner) Kills Ticks* Faster than NexGard® (afoxolaner) and Simparica Trio® (sarolaner, moxidectin, pyrantel)¹

Head-to-head study finds Credelio® has the fastest initial speed of tick kill and continues to grow that advantage throughout the dosing interval¹



SPEED OF KILL MATTERS

Ticks transmit pathogens to their hosts during the feeding process, with longer feeding periods allowing more pathogens to be passed.^{1,2}

Faster kill means:

- Less risk of pathogen transmission
- Greater pet owner satisfaction



LONE STAR TICK IS NO MATCH FOR CREDELIO

Credelio is more effective than Simparica Trio and NexGard in quickly killing *A. americanum* to control an existing infestation, and maintains that advantage throughout the dosing interval.¹



STUDY DESIGN

- Approximately fifty *A. americanum* ticks were applied to the dogs two days prior to treatment and allowed to attach and feed. Reinfestations occurred on days 21 and 28
- Four groups of eight dogs each were treated according to the label with an isoxazoline-containing product (Credelio, Simparica Trio, or NexGard) or received no treatment at all (control group)
- Periodic tick counts were conducted at different time intervals on days 0 (treatment day), 21 and 28 to determine isoxazoline efficacy throughout treatment period

REFERENCES

¹Elanco Animal Health. Data on file.

²Shaw S, Day M, Birtles R, et al. Tick-borne infectious diseases of dogs. TRENDS in Parasitology. 2001;17.

**Amblyomma americanum* (lone star tick)

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) 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.

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. Seizures have been reported in dogs receiving this class of 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 most frequently reported adverse reactions are weight loss, elevated blood urea nitrogen, polyuria, and diarrhea. For full prescribing information see Credelio package insert.

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STUDY RESULTS¹

Speed of Kill Against *A. americanum* (lone star tick)

DAY OF STUDY	TIME POINT AT WHICH PRODUCT ACHIEVED CONTINUOUS SUPERIOR EFFICACY VERSUS UNTREATED CONTROL GROUP (P < 0.05)		
	Credelio® (lotilaner)	SIMPARICA TRIO® (sarolaner, moxidectin, pyrantel)	NEXGARD® (afoxolaner)
0	12 HRS	24 HRS	24 HRS
21	12 HRS	48 HRS	48 HRS
28	8 HRS	48 HRS	72 HRS



Credelio kills ticks faster¹ than Simparica Trio and NexGard



Only Credelio significantly reduced ticks at all 12- and 24-hour evaluation time points



Only Credelio provides a rapid speed of kill throughout the entire month-long treatment period



Credelio's rapid and consistent speed of tick kill can reduce the risk of tick-borne pathogen transmission and increase pet owner product satisfaction.



Credelio (lotilaner)

Chewable Tablets
For oral use in dogs

Caution:

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

Before using Credelio, please consult the product insert, a summary of which follows:

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) 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.

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 tablets	

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.

See product insert for complete dosing and administration information.

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.

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>.

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* and *Rhipicephalus sanguineus* 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.

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:

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