We make **happy** happen

The Elanco Animal Health **Vaccine Support Guarantee**

Elanco™

SUPPORT YOU CAN COUNT ON

Our goal is to help you build stronger relationships with your clients; that's why we guarantee the efficacy of our pet vaccine products.

Reimbursement is up to 100% of standard, reasonable diagnostic and treatment costs up to $5,000.

OUR PRODUCT SUPPORT TEAM IS HERE TO HELP YOU FIND SOLUTIONS

Our highly trained and experienced veterinarians, veterinary technicians and regional consulting veterinarians are available 24 hours a day, 7 days a week at 888-545-5973.

EXPANDED SUPPORT FOR PEACE OF MIND*

LONGER COVERAGE

- Four-year coverage on our core antigens**
- Two-year coverage for FeLV
- Fifteen-month coverage for Lyme and Lepto

BROAD COVERAGE

- Up to $5,000 reimbursement for Lyme
  - Coverage includes dogs protected with TruCan™ Lyme or TruCan™ Ultra Lyme
  - Up to $10,000 when patient also uses Credelio® (lotilaner)***
- Up to $5,000 reimbursement for canine parainfluenza

SATISFACTION

- If you experience an issue, our product support team is here to help

FOR MORE INFORMATION ABOUT ELANCO COMPANION ANIMAL VACCINES OR THE ELANCO VACCINE SUPPORT GUARANTEE, PLEASE CALL 1-888-545-5973.

**See reverse for full terms and conditions of vaccine guarantee.*
***Canine core vaccines include canine distemper, adenovirus and parvovirus. Feline core vaccines include feline rhinotracheitis, panleukopenia and calicivirus*
****Credelio is indicated for the treatment and control of tick infestations but has not been approved to reduce the risk of canine Lyme disease.*
Elanco supports patients that follow expert recommendations to use tick preventives as part of a more complete protection plan.

THE ELANCO PORTFOLIO OF VACCINES — FLEXIBLE OPTIONS FOR BROAD PROTECTION

Core Canine Vaccines

	distemper	adenovirus type-2	parvovirus 2b**	parainfluenza	coronavirus	*L. canicola*	*L. grippotyphosa*	*L. icterohaemorrhagiae*	*L. pomona*	*B. burgdorferi*	*B. bronchiseptica*	rabies
TruCan™ Ultra DAP	M	M	M									
TruCan™ Ultra DAP+L4	M	M	M			I	I	I	I			
TruCan™ Ultra DAP+C	M	M	M		I							
TruCan™ Ultra DAP+CL4	M	M	M		I	I	I	I	I			
TruCan™ DAPPi+C	M	M	M	M	I							
TruCan™ DAPPi+L4	M	M	M	M		I	I	I	I			
TruCan™ DAPPi+CL4	M	M	M	M	I	I	I	I	I			
TruCan™ DAPPi	M	M	M	M								
TruCan™ Parvo			M									
TruCan™ PC			M		I							
TruCan™ C					I							
Rabvac® 1												I
Rabvac® 3												I

Lifestyle Canine Vaccines

TruCan™ Lyme										I		
TruCan™ DAPPi+Lyme-CL4	M	M	M	M	I	I	I	I	I	I		
TruCan™ DAPPi+Lyme-L4	M	M	M	M		I	I	I	I	I		
TruCan™ Lyme-L4						I	I	I	I	I		
TruCan™ Ultra Lyme										I		
TruCan™ Ultra L4						I	I	I	I			
TruCan™ B (ORAL)											M	
TruCan™ BAPi (IN)		M		M							M	
TruCan™ L4						I	I	I	I			

**Contains a CPV-2b strain that protects against disease caused by both CPV-2b and CPV-2c. M = modified live I = inactivated/killed

truCan™ ultra

- Highly purified ½ mL vaccines feature PureFil™ Technology
- Designed to reduce discomfort and reactions associated with unwanted protein and debris

truCan™ Lyme

- 92.2% efficacy against natural infection in a highly endemic area and 100% efficacy in a laboratory study[1–2]
- Contains multiple types of outer-surface proteins,[3,4] not just OspA and OspC

Feline Vaccines

	feline herpesvirus (FVR)	calicivirus (novel)	calicivirus (traditional)	panleukopenia	*Chlamydia felis*	feline leukemia virus	rabies
TruFel™ Ultra HC2P hybrid	M	I	I	M			
TruFel™ Ultra HC2P	I	I	I	I			
TruFel™ Ultra FeLV						I	
TruFel™ Ultra HC2P-FeLV	I	I	I	I		I	
TruFel™ Ultra C2		I	I				
TruFel™ HC2P	I	I	I	I			
TruFel™ HC2PCh	I	I	I	I	I		
TruFel™ HC2P-FeLv	I	I	I	I		I	
TruFel™ HC2PCh-FeLV	I	I	I	I	I	I	
TruFel™ FeLV						I	
TruFel™ HCP+FeLV	M		M	M		I	
TruFel™ HCP+Ch-FeLV	M		M	M	I	I	
TruFel™ HCP	M		M	M			
TruFel™ HCP+Ch	M		M	M	I		
TruFel™ HCP (IN)	M		M	M			
TruFel™ HC (IN)	M		M				
Rabvac® 1							I
Rabvac® 3							I

M = modified live I = inactivated/killed

truFel™ ultra HC2P hybrid

- Highly purified ½ mL non-adjuvanted vaccine with exclusive dual-strain calicivirus protection
- Made with PureFil™ Technology, designed to reduce discomfort and reactions associated with unwanted protein and debris

ELANCO VACCINE GUARANTEE GENERAL TERMS AND CONDITIONS

Basic program rules

- Vaccines must have been administered to a healthy pet according to the age and route specified on the label by a licensed veterinarian with a valid client-patient relationship as defined by the AVMA.
- The Elanco vaccine product must have been purchased by a veterinarian and handled and stored in accordance with the label instructions.
- A veterinarian (or appropriate health care team member) must be the primary point of contact for the guarantee to be valid. Elanco will direct all claims from pet owners, breeders and others to the vaccinating veterinarian.
- At the time of a claim, a veterinarian must have the medical records related to the reported case available, including vaccine brand, serial number, location of injection and date of the vaccination.
- At the time of a suspected disease event, a veterinarian must collaborate with Elanco Product Support in designing an appropriate diagnostic and treatment regimen.
- Elanco reserves the right to perform a complete review of information provided, with the ability to accept or deny in full or in part any claim in its sole discretion.
- Reimbursement or refund under this guarantee is the sole and exclusive remedy for any claims or damages in regard to this guarantee. Elanco's liability for reimbursement, refunds or damages under this guarantee, whether in contract or in tort, is limited to $5,000.
- ELANCO DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR PARTICULAR USE.
- Claims involving animal species other than those on the product label are not covered.
- Elanco will not accept any returned product due to package or label changes.
- Elanco reserves the right to end or modify the program, in whole or in part, at any time without notice. Terms and conditions apply to claims submitted after January 1, 2024.

Specifics related to puppies and kittens

- 4-year lack-of-efficacy claims will be considered for pets that have received the required puppy or kitten series followed by a booster vaccination 1 year later.
- The animal must have received the age-appropriate initial vaccination series according to label recommendations, and an Elanco vaccine must be the most recent vaccine used in the series.
- Claims involving puppies and kittens that have not completed age appropriate vaccination, at least 12 weeks of age, or involving onset of disease within 2 weeks of completing the initial immunization series, are not covered.

Specifics related to adult dogs

- One-year coverage for canine *Bordetella bronchiseptica*, parainfluenza, coronavirus and 15-month coverage for *Borrelia burgdorferi*, *Leptospira canicola*, *Leptospira grippotyphosa*, *Leptospira icterohaemorrhagiae* and *Leptospira pomona*.
- For TruCan™ BAPi (IN) and TruCan™ B (ORAL), initial vaccination must be at least 2 weeks prior to introduction into a high-population environment, such as a shelter, kennel, daycare or show circuit.
- For canine patients receiving a TruCan™ Ultra DAP combination or TruCan™ B (ORAL), Elanco will reimburse standard and reasonable charges up to $5,000 associated with the diagnosis and treatment of any patient suffering from respiratory disease due to canine parainfluenza virus infection.
- TruCan™ Ultra DAP combinations and TruCan™ B (ORAL) do not contain canine parainfluenza, and Elanco does not claim that these products will protect against canine parainfluenza.

Specifics related to canine Lyme disease

- In the event that a dog contracts Lyme disease, Elanco will reimburse 100% of standard and reasonable diagnostic and treatment costs up to $5,000 if the dog was properly immunized against Lyme disease (with the most recent vaccine being TruCan™ Ultra Lyme or a TruCan™ Lyme vaccine).
  - Coverage increases up to $10,000 when the patient receives continuous protection (purchase history and proof of prescription is required) with Credelio® (lotilaner) according to the label directions.
- Dogs vaccinated with an Elanco Lyme vaccine within the last 15 months will qualify for the guarantee.

Specifics related to adult cats

- Core vaccines include feline herpesvirus-1, calicivirus and panleukopenia.
- Non-core vaccines include *Chlamydia felis* and feline leukemia virus.
- For feline patients receiving a TruFel™ Ultra HC2P vaccine, Elanco will reimburse standard and reasonable charges up to $5,000 associated with the diagnosis and treatment of any patient suffering from respiratory disease due to feline chlamydiosis.
- TruFel™ Ultra HC2P combinations do not include *Chlamydia felis*, and Elanco does not claim that these products will protect against feline chlamydiosis.
- For an FeLV claim, the medical record must document a negative FeLV test at the time of initial vaccination.
- Cats vaccinated with an Elanco feline leukemia vaccine every 1 to 2 years will qualify for the guarantee.

Specifics related to feline injection site sarcomas

- Use of any brand of feline rhinotracheitis, panleukopenia, calicivirus, *Chlamydia felis*, feline leukemia or rabies vaccine other than an Elanco vaccine within 12 months at the affected site will void this agreement.
- The time frame between vaccination and occurrence of the injection-site sarcoma must not exceed 3 years.
- After diagnosis of the injection-site sarcoma is confirmed by histopathological examination, Elanco will reimburse for standard and reasonable treatment costs shall be up to $3,500.

HAVE QUESTIONS? WE'RE JUST A PHONE CALL AWAY AT 1-888-545-5973.

CREDELIO 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.

Always read, understand and follow the label and use directions.

IMPORTANT SAFETY INFORMATION FOR CREDELIO:

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.

1. Levy SA. Use of a C6 ELISA test to evaluate the efficacy of a whole-cell bacterin for the prevention of naturally transmitted canine Borrelia burgdorferi. Vet Ther. 2002;3(4):420–424.
2. Elanco Animal Health. Data on file.
3. Chu HJ, Chavez LG Jr, Blumer BM, et al. Immunogenicity and efficacy study of a commercial Borrelia burgdorferi bacteria.J Am Vet Med Assoc. 1992;201(3):403–411.
4. Levy SA, Millership J, GlwS, et al. Confirmation of presence of Borrelia burgdorferi outer surface protein C antigen and production of antibodies to Borrelia burgdorferi outer surface protein C in dogs vaccinated with a whole-cell Borrelia burgdorferi bacterin. Intern J Appl Res Vet Med. 2010;8(3):123–128.

Elanco™

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) 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.

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/pyodermatitis 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.

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
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Elanco™