

BRAVECTO™ SATISFACTION GUARANTEE

12-WEEK FLEA AND TICK PROTECTION^{1*}

1 CHEW

0 WORRIES



If your clients are not achieving the level of flea and tick control that was desired, please call our team of flea and tick control experts to see if they qualify for our BRAVECTO Satisfaction Guarantee. Our team will work with you to ensure that your clients are satisfied. If not, Merck Animal Health will work with the attending veterinarian to ensure the pet owner is refunded for the purchase of BRAVECTO.

Lack of Effectiveness

- Claims for lack of effectiveness cannot be made until 12 weeks following the initial treatment.
- There is a one-time offer for lack of effectiveness claims, and only one offer is granted per pet.
- Households of 6 or more dogs and/or cats are not eligible.
- The satisfaction guarantee does not cover any other costs, including but not limited to those associated with the control of fleas/ticks, the treatment of flea/tick-borne diseases, medical treatments or procedures, including treatment of Flea Allergy Dermatitis.

Palatability/Ingestion

- BRAVECTO is highly palatable.¹ For pets unable to be dosed with BRAVECTO, Merck Animal Health will work with the veterinarian to ensure the pet owner is refunded for the purchase of BRAVECTO.
- For maximum effectiveness, it is recommended to re-dose any pet that vomits within 3 hours of receiving BRAVECTO.[†] Merck Animal Health can send a replacement chew to the veterinarian for re-dosing (limit of 2 replacements per pet).

[†]All treatment recommendations should be at the discretion of the attending veterinarian.

Eligibility Requirements and Specifics of the Program

- An established veterinary-client-patient relationship must exist and the product must have been prescribed by, and purchased through, a licensed veterinarian.
- BRAVECTO must be used according to label directions.
- All pets in the household must be treated with an approved flea/tick product while BRAVECTO is in use. Untreated pets may harbor a flea infestation.
- An itemized receipt for the purchase of BRAVECTO from a veterinarian must be submitted to Merck Animal Health. The receipt must show the owner's name, the pets' name(s), place of purchase, date of purchase (which must be within the last 12 months), quantity purchased, product brand name, and purchase price.
- If multiple doses were purchased for multiple pets, but are only indicated for one pet on the receipt, the hospital staff will be asked to note this on the receipt.
- Merck Animal Health reserves the right to cancel or amend the Satisfaction Guarantee program at any time.

For technical assistance or to report a suspected adverse drug reaction, contact Merck Animal Health at 1-800-224-5318.

*Bravecto kills fleas, prevents flea infestations, and kills ticks (black-legged tick, American dog tick, and brown dog tick) for 12 weeks. Bravecto also kills lone star ticks for 8 weeks.

IMPORTANT SAFETY INFORMATION: The most common adverse reactions recorded in clinical trials were vomiting, decreased appetite, diarrhea, lethargy, polydipsia, and flatulence. Bravecto has not been shown to be effective for 12-weeks' duration in puppies less than 6 months of age. Bravecto is not effective against lone star ticks beyond 8 weeks after dosing.

Reference: 1. Bravecto [prescribing information]. Summit, NJ: Merck Animal Health; 2014.

Please see reverse side for full Prescribing Information.

BRAVECTO™
(FLURALANER)



BRAVECTO™ (FLURALANER)

Flavored chews for dogs.

Caution:

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

Descriptions:

Each chew is formulated to provide a minimum dose of 11.4 mg/lb (25 mg/kg) body weight.

The chemical name of fluralaner is (±)-4-[5-(3,5-dichlorophenyl)-5-(trifluoromethyl)-4,5-dihydroisoxazol-3-yl]-2-methyl-N-(2-oxo-2-(2,2,2-trifluoroethylamino) ethyl)benzamide.

Indications:

Bravecto kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations [*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), and *Rhipicephalus sanguineus* (brown dog tick)] for 12 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater. Bravecto is also indicated for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater.

Dosage and Administration:

Bravecto should be administered orally as a single dose every 12 weeks according to the **Dosage Schedule** below to provide a minimum dose of 11.4 mg/lb (25 mg/kg) body weight.

Bravecto may be administered every 8 weeks in case of potential exposure to *Amblyomma americanum* ticks (See **EFFECTIVENESS**).

Bravecto should be administered with food.

Dosage Schedule

Body Weight Ranges (lb)	Fluralaner Content (mg)	Chews Administered
4.4 – 9.9	112.5	One
>9.9 – 22.0	250	One
>22.0 – 44.0	500	One
>44.0 – 88.0	1000	One
>88.0 – 123.0*	1400	One

*Dogs over 123.0 lb should be administered the appropriate combination of chews.

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

Contraindications:

There are no known contraindications for the use of the product.

Warnings:

Not for human use. Keep this and all drugs out of the reach of children. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product. Wash hands thoroughly with soap and water immediately after use of the product.

Precautions:

Bravecto has not been shown to be effective for 12-weeks duration in puppies less than 6 months of age. Bravecto is not effective against *Amblyomma americanum* ticks beyond 8 weeks after dosing (See **EFFECTIVENESS**).

Adverse Reactions:

In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and 70 dogs were administered an oral active control every 4 weeks and were provided with a tick collar); there were no serious adverse reactions. All potential adverse reactions were recorded in dogs treated with Bravecto over a 182-day period and in dogs treated with the active control over an 84-day period. The most frequently reported adverse reaction in dogs in the Bravecto and active control groups was vomiting.

Percentage of Dogs with Adverse Reactions in the Field Study

Adverse Reaction (AR)	Bravecto Group: Percentage of Dogs with the AR During the 182-Day Study (n=224 dogs)	Active Control Group: Percentage of Dogs with the AR During the 84-Day Study (n=70 dogs)
Vomiting	7.1	14.3
Decreased Appetite	6.7	0.0
Diarrhea	4.9	2.9
Lethargy	5.4	7.1
Polydipsia	1.8	4.3
Flatulence	1.3	0.0

In a well-controlled laboratory dose confirmation study, one dog developed edema and hyperemia of the upper lips within one hour of receiving Bravecto. The edema improved progressively through the day and had resolved without medical intervention by the next morning.

For technical assistance or to report a suspected adverse drug reaction, contact Merck Animal Health at 1-800-224-5318. Additional information can be found at www.bravecto.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VEIS or online at <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

Clinical Pharmacology:

Peak fluralaner concentrations are achieved between 2 hours and 3 days following oral administration, and the elimination half-life ranges between 9.3 to 16.2 days. Quantifiable drug concentrations can be measured (lower than necessary for effectiveness) through 112 days. Due to reduced drug bioavailability in the fasted state, fluralaner should be administered with food.

Mode of Action:

Fluralaner is for systemic use and belongs to the class of isoxazoline-substituted benzamide derivatives. Fluralaner is an inhibitor of the arthropod nervous system. The mode of action of fluralaner is the antagonism of the ligand-gated chloride channels (gamma-aminobutyric acid (GABA)-receptor and glutamate-receptor).

Effectiveness:

Bravecto began to kill fleas within two hours after administration in a well-controlled laboratory study. In a European laboratory study, Bravecto killed fleas and *Ixodes ricinus* ticks and reduced the numbers of live fleas and *Ixodes ricinus* ticks on dogs by > 98% within 12 hours for 12 weeks. In a well-controlled laboratory study, Bravecto demonstrated 100% effectiveness against adult fleas 48 hours post-infestation for 12 weeks. In well-controlled laboratory studies, Bravecto demonstrated ≥ 93% effectiveness against *Dermacentor variabilis*, *Ixodes scapularis* and *Rhipicephalus sanguineus* ticks 48 hours post-infestation for 12 weeks. Bravecto demonstrated ≥ 90% effectiveness against *Amblyomma americanum* 72 hours post-infestation for 8 weeks, but failed to demonstrate ≥ 90% effectiveness beyond 8 weeks.

In a well-controlled U.S. field study, a single dose of Bravecto reduced fleas by ≥ 99.7% for 12 weeks. Dogs with signs of flea allergy dermatitis showed improvement in erythema, alopecia, papules, scales, crusts, and excoriation as a direct result of eliminating flea infestations.

Palatability: In a well-controlled U.S. field study, which included 559 dogs administered to 224 dogs, 80.7% of dogs voluntarily consumed Bravecto within 5 minutes, an additional 12.5% voluntarily consumed Bravecto within 5 minutes when offered with food, and 6.8% refused the dose or required forced administration.

Animal Safety:

Margin of Safety Study: In a margin of safety study, Bravecto was administered orally to 8- to 9-week-old puppies at 1, 3, and 5X the maximum label dose of 56 mg/kg at three, 8-week intervals. The dogs in the control group (0X) were untreated.

There were no clinically-relevant, treatment-related effects on physical examinations, body weights, food consumption, clinical pathology (hematology, clinical chemistries, coagulation tests, and urinalysis), gross pathology, histopathology, or organ weights. Diarrhea, mucoid and bloody feces were the most common observations in this study, occurring at a similar incidence in the treated and control groups. Five of the twelve treated dogs that experienced one or more of these signs did so within 6 hours of the first dosing. One dog in the 3X treatment group was observed to be dull, inappetent, with evidence of bloody diarrhea, vomiting, and weight loss beginning five days after the first treatment. One dog in the 1X treatment group vomited food 4 hours following the first treatment.

Reproductive Safety Study: Bravecto was administered orally to intact, reproductively-sound male and female Beagles at a dose of up to 168 mg/kg (equivalent to 3X the maximum label dose) on three to four occasions at 8-week intervals. The dogs in the control group (0X) were untreated.

There were no clinically-relevant, treatment-related effects on the body weights, food consumption, reproductive performance, semen analysis, litter data, gross necropsy (adult dogs) or histopathology findings (adult dogs and puppies). One adult treated dog suffered a seizure during the course of the study (46 days after the second treatment). Abnormal salivation was observed on 17 occasions: in six treated dogs (11 occasions) after dosing and four control dogs (6 occasions).

The following abnormalities were noted in 7 pups from 2 of the 10 dams in only the treated group during gross necropsy examination: limb deformity (4 pups), enlarged heart (2 pups), enlarged spleen (3 pups), and cleft palate (2 pups). During veterinary examination at Week 7, two pups from the control group had inguinal testicles, and two and four pups from the treated group had inguinal and cryptorchid testicles, respectively. No undescended testicles were observed at the time of necropsy (days 50 to 71).

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

Storage Information:

Do not store above 86°F (30°C).

How Supplied:

Bravecto is available in five strengths (112.5, 250, 500, 1000, and 1400 mg fluralaner per chew). Each chew is packaged individually into aluminum foil blister packs sealed with a peelable paper backed foil lid stock. Product may be packaged in 1, 2, or 4 chews per package.

NADA 141-426, Approved by FDA

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