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BRAVECTO® 1-MONTH

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Intervet/Merck Animal Health

(fluralaner) Chews for Dogs

Caution:

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

Description:

Bravecto 1-Month (fluralaner) is a flavored chew formulated to provide a minimum dose of 4.5 mg/lb (10 mg/kg) body weight of fluralaner.

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 1-Month 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 one month in dogs and puppies 8 weeks of age and older, and weighing 4.4 pounds or greater.

Bravecto 1-Month is also indicated for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for one month in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater.

Dosage and Administration:

Bravecto 1-Month should be administered orally as a single dose monthly according to the **Dosage Schedule** below to provide a minimum dose of 4.5 mg/lb (10 mg/kg) fluralaner.

Bravecto 1-Month should be administered with food.

Dosage Schedule

Body Weight Ranges (lb)	Fluralaner content (mg)	Chews Administered
4.4 - 9.9	45	One
>9.9 - 22.0	100	One
>22.0 - 44.0	200	One
>44.0 - 88.0	400	One
>88.0 - 123.0*	560	One

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

Treatment with Bravecto 1-Month 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.

Keep Bravecto 1-Month in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

Precautions:

Fluralaner 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.

Bravecto 1-Month is not effective against *A. americanum* in puppies less than 6 months of age (see **Effectiveness**).

The safety of Bravecto 1-Month has not been evaluated in breeding, pregnant and lactating dogs (see **Animal Safety**).

Adverse Reactions:

In a well-controlled U.S. field study, which included 271 dogs (201 dogs were administered Bravecto 1-Month every 30 days and 70 dogs were administered an oral active control [an isoxazoline] every 30 days), there were no serious adverse reactions associated with treatment. Over the 90-day study period, all observations of potential adverse reactions were recorded.

Dogs with Adverse Reactions in the Field Study

Adverse Reaction (AR)	Fluralaner Group: Percentage of Dogs with the AR during the 90-Day Study (n= 201 dogs)	Active Control Group: Percentage of Dogs with the AR during the 90-Day Study (n= 70 dogs)
Pruritus	7.0%	10.0%
Diarrhea	3.0%	4.3%
Vomiting	3.0%	4.3%
Decreased Appetite	3.0%	0.0%
Liver enzymes (serum ALT or ALP) greater than twice the upper reference range*	1.0%	1.4%
Lethargy	1.0%	1.4%

Weight loss (>15%)	0.5%	0.0%

*Alanine aminotransferase (ALT); alkaline phosphatase (ALP)

One dog in the Bravecto 1-Month group with a history of seizures managed with anticonvulsant medication had seizure activity 28 days after its first dose; the dog received its second dose later the same day. No additional seizures occurred during the study. One dog in the control group with no history of seizures had seizure activity 12 days after its second dose. The dog was started on anticonvulsant medication and no additional seizures occurred during the study.

During the palatability assessment, four dogs coughed within 1 hour of dosing with Bravecto 1-Month. Palatability was not assessed in the control group.

In well-controlled laboratory effectiveness studies, one dog and three puppies administered Bravecto 1-Month had diarrhea (with or without blood).

Post Approval Experience (2019):

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

Vomiting, lethargy, diarrhea (with and without blood), anorexia, pruritus, polydipsia, seizure, allergic reactions (including hives, swelling, erythema), dermatitis (including crusts, pustules, rash), tremors and ataxia.

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), 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-VETS or online at http://www.FDA.gov/reportanimalae.

Clinical Pharmacology:

Peak fluralaner concentrations are achieved between 1 and 3 days following single or multiple oral administrations of Bravecto 1-Month to young puppies and adult dogs. The elimination half-life ranges from 5.0 to 8.5 days for puppies and 12.6 to 15.7 days for adult dogs. Due to reduced drug bioavailability in the fasted state, Bravecto 1-Month 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:

Treatment and Prevention of Flea Infestations:

In well-controlled laboratory studies in dogs 6 months of age and older, Bravecto 1-Month started killing fleas within 4 hours after treatment and was > 99% effective by 12 hours after treatment or post-infestation for 35 days.

In a well-controlled laboratory study in dogs 8 weeks of age and older, Bravecto 1-Month demonstrated 100% effectiveness against fleas for 30 days.

In a well-controlled 90-day U.S. field study conducted in households with existing flea infestations, the effectiveness of Bravecto 1-Month against fleas on Day 30, 60, and 90 visits compared with baseline was 99.6%, 99.9%, and 99.9%, respectively. 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.

Treatment and Control of Tick Infestations:

In well-controlled laboratory studies in dogs 8 weeks of age and older, Bravecto 1-Month demonstrated ≥97.7% effectiveness against *Rhipicephalus sanguineus* ticks at 48 hours after treatment or infestation for 30 days.

In well-controlled laboratory studies, fluralaner, the active ingredient in Bravecto 1-Month, demonstrated effectiveness against *Ixodes scapularis* and *Dermacentor variabilis*.

In well-controlled laboratory studies in dogs 6 months of age and older, Bravecto 1-Month demonstrated >96% effectiveness against *Amblyomma americanum* at 48- and 72-hours after treatment or infestation for 31 days.

Bravecto 1-Month failed to demonstrate >90% effectiveness against *Amblyomma americanum* in 8-week-old puppies.

Palatability:

In a well-controlled U.S. field study, which included 579 doses administered to 201 dogs, 81.5% of dogs voluntarily consumed Bravecto 1-Month within 5 minutes, an additional 9.0% voluntarily consumed Bravecto 1-Month within 5 minutes when offered with food, and 9.5% required forced administration.

Animal Safety:

Margin of Safety Study:

In a margin of safety study, Bravecto 1-Month was administered orally to 8-week old puppies at 1, 3, and 5X the maximum labeled dose of 22.5 mg/kg with 8 dogs per group at three, 30-day intervals (Days 1, 31 and 61). The dogs in the control group were untreated.

There were no clinically-relevant, treatment-related effects on body weights, food consumption, organ weights, hematology, C-reactive protein, coagulation profile, urinalysis, gross pathology and histopathology. Diarrhea and mucoid or discolored feces were the most common observations, occurring at a similar incidence in the treated and control groups. Vomiting was noted in one dog in the 5X group and one dog in the control group on Day 2. Splayed hind limbs were noted in one dog in the 1X treatment group post-dose on Day 61. Tremors were noted in one dog in each of the 3 fluralaner dose groups on Day 1 at 4 hours post-dose. Trembling was noted in one dog in the 1X group on Day 2. Blood urea nitrogen (BUN) was elevated in one dog in the 3X group on Day 8. BUN and serum creatinine were elevated in one dog in the 5X group on Day 85.

Reproductive Safety Study:

Reproductive safety was evaluated for fluralaner, the active ingredient in BRAVECTO 1-Month (fluralaner). Fluralaner was administered orally to intact, reproductively-sound male and female Beagles at a dose of up to 168 mg/kg on three to four occasions at 8-week intervals. The dogs in the control group 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 dog in the treated group suffered a seizure during the course of the study (46 days after the third 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 1-Month was used concurrently with other medications, such as vaccines, anthelmintics, antibiotics (including topicals), steroids, analgesics, and anesthetics. No adverse reactions were observed from the concurrent use of Bravecto 1-Month with other medications.

Storage Conditions:

Do not store above 86°F (30°C).

How Supplied:

Bravecto 1-Month is available in five strengths (45, 100, 200, 400, and 560 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, 3, or 4 chews per package.

Approved by FDA under NADA # 141-532

Fluralaner (active ingredient) Made in Japan.

Formulated in Austria

Distributed by Intervet Inc (d/b/a Merck Animal Health), Madison, NJ 07940

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	Contents:
>4.4-9.9 lb	1 chew containing 45 mg fluralaner
>9.9-22 lb	1 chew containing 100 mg fluralaner
>22-44 lb	1 chew containing 200 mg fluralaner
>44-88 lb	1 chew containing 400 mg fluralaner
>88-123 lb	1 chew containing 560 mg fluralaner

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