BRAVECTO® BRAND PROMISE

We want your clients to feel 100% confident in choosing BRAVECTO® canine and feline products for parasite protection in their beloved dogs and cats. That's why we've created the BRAVECTO® Brand Promise—our way to show that we stand behind each of these innovative products.

We are so confident in our BRAVECTO products, reimbursement up to $2500 may be available if the product does not meet performance expectations. See guidelines below for details.

Just call our support team for details about our **BRAVECTO** Brand Promise, available to any individual who has purchased **BRAVECTO** products from their veterinarian or an authorized retailer with their veterinarian's prescription. Pets are guaranteed protection against fleas and ticks for the following products and durations:

- **BRAVECTO® QUANTUM** (fluralaner for extended-release injectable suspension) - guaranteed for 1 year
- **BRAVECTO®** (fluralaner) Chews for Dogs - guaranteed for 12 weeks
- **BRAVECTO® 1-MONTH** (fluralaner) Chews for Dogs - guaranteed for 1 month
- **BRAVECTO®** (fluralaner topical solution) for Dogs and Cats - guaranteed for 12 weeks
- **BRAVECTO® PLUS** (fluralaner and moxidectin topical solution) for Cats - guaranteed for 2 months

The Companion Animal Parasite Council (CAPC) recommends year-round flea and tick protection. Please contact Merck Animal Health Technical Services at 800-224-5318 with questions or to report an adverse event. Merck Animal Health (MAH) reserves the right to modify this program, in whole or in part, at any time for any reason.

General Requirements

- All **BRAVECTO** products must be used according to label directions.
- **BRAVECTO QUANTUM** must be administered by a veterinary professional.
- An itemized receipt from the veterinary hospital or another MAH authorized retailer for the purchase of the product must be submitted to MAH. The receipt must show:
  - — The owner's name
  - — The dog's or cat's name(s)
  - — Quantity purchased
  - — Product brand name
  - — Purchase price
- If purchased online, proof of veterinarian's prescription is also required.
- If multiple doses were purchased for multiple pets, but are indicated for only 1 pet on the receipt, the hospital staff must note this on the receipt.

BRAVECTO®

BRAVECTO BRAND PROMISE

	Guidelines	Requirements
Ticks	• **BRAVECTO** products for dogs and cats treat and control tick infestations. The **BRAVECTO** Brand Promise does not cover client costs associated with the control of tick infestations in or around living quarters.	• Tick-borne disease claims in dogs and cats will be handled on a case-by-case basis. • Clinical signs or diagnostic results consistent with tick-borne disease. Merck Animal Health Technical Services may request and will support the cost of additional testing. • Proof in the form of an itemized receipt that enough doses of **BRAVECTO** products were purchased for the dog or cat in line with Companion Animal Parasite Council (CAPC) recommendations for year-round flea and tick protection. • For tick-borne disease in dogs: Proof of the dog's negative tick-borne disease test at the time of, or anytime after starting treatment with **BRAVECTO** canine products and a negative yearly test thereafter through the date of the claim. Pet must have been on product for at least 30 days prior to the positive test. Any qualitative antibody test for disease may be used as a screening tool to detect natural exposure to disease. Examples include: IDEXX SNAP® 3Dx®, SNAP® 4Dx® Test, or ANTECH Diagnostics® AccuPlex® 4 Test. Required confirmatory testing will be reimbursed by Merck Animal Health. • For puppies that are started on **BRAVECTO 1-MONTH** Chews prior to 6 months of age, a negative test at the time of, or anytime after starting treatment is recommended, but not required, for the first year of coverage. • To qualify for additional benefits from the Merck Animal Health Immunization Support Guarantee, client must show that: (a) their dog is vaccinated for Lyme disease, as outlined in the Merck Animal Health Companion Animal Biologicals Efficacy Guarantee; (b) the most recent Nobivac® Lyme vaccine was administered in the preceding 12 months; and (c) the most recent Lyme vaccine was a Nobivac® Lyme vaccine. If the dog is diagnosed with Lyme disease, Merck Animal Health will reimburse diagnostic and treatment costs up to $7500 if the patient has received continuous protection with **BRAVECTO** used according to label directions, was vaccinated, AND the last dose was Nobivac® Lyme vaccine.

BRAVECTO® BRAND PROMISE (CONTINUED)

	Guidelines	Requirements
Fleas	• **BRAVECTO** products for dogs and cats kill adult fleas (*Ctenocephalides felis*) and prevent flea infestations. The **BRAVECTO** Brand Promise does not cover client costs associated with the control of flea infestations in or around living quarters.	• The affected dog or cat must be on **BRAVECTO** for a minimum of 12 weeks. • For flea claims, all other pets in the home must also be treated with a flea control product for a minimum of 12 weeks before the report. • Households of 6 or more dogs and/or cats are not eligible.
Heartworms	• **BRAVECTO PLUS** is indicated for the prevention of heartworm disease due to *Dirofilaria immitis* in cats for 2 months.	• Enough doses of **BRAVECTO PLUS** were purchased for the cat in line with Companion Animal Parasite Council (CAPC) recommendations for year-round heartworm protection. Cats treated on a seasonal protocol as per veterinarian's recommendation may be eligible for partial coverage. • Feline heartworm cases will be evaluated on a case-by-case basis.
Ear Mites	• **BRAVECTO** products for dogs and cats are not indicated for the treatment or prevention of ear mites (*Otodectes cynotis*).	• Dogs or cats need to be on a consistent treatment with **BRAVECTO** products. If ear mites are diagnosed by your veterinarian 30+ days after treatment with **BRAVECTO**, we will provide reimbursement for the reasonable and customary cost up to $100 for an approved treatment.
Roundworms and Hookworms	• **BRAVECTO PLUS** treats and controls roundworm (*Toxocara cati*) and hookworm (*Ancylostoma tubaeforme*) infections in cats.	• Cats need to be on a consistent, bimonthly treatment with **BRAVECTO PLUS**. If *T cati* or *A tubaeforme* eggs are diagnosed by your veterinarian, we will provide reimbursement for the reasonable and customary cost up to $100 for an approved treatment.
Tapeworms	• **BRAVECTO** products have not demonstrated efficacy against tapeworms in dogs and cats.	• Dogs and cats need to be on consistent treatment with **BRAVECTO** products for a minimum of 12 weeks. If tapeworms are diagnosed by your veterinarian, we will provide reimbursement for the reasonable and customary cost up to $100 for an approved treatment.

BRAVECTO®

IMPORTANT SAFETY INFORMATION

BRAVECTO (fluralaner) Chews for Dogs: The most commonly reported adverse reactions include vomiting, lethargy, diarrhea, anorexia and pruritus. In some cases, adverse events have been reported following use in breeding females. **BRAVECTO Chews** has not been shown to be effective for 12-weeks' duration in puppies less than 6 months of age. **BRAVECTO Chews** is not effective against lone star ticks beyond 8 weeks of dosing. Indicated for dogs 6 months of age and older. **BRAVECTO 1-MONTH (fluralaner) Chews**: The most commonly reported adverse reactions include itching, diarrhea, vomiting, decreased appetite, elevated ALT, lethargy, and weight loss. Not effective against lone star ticks in puppies less than 6 months of age. Indicated for dogs 8 weeks of age and older. **BRAVECTO (fluralaner topical solution) for Dogs**: The most commonly reported adverse reactions include vomiting, hair loss, diarrhea, lethargy, decreased appetite, and moist dermatitis/rash. **BRAVECTO Topical Solution for dogs** has not been shown to be effective for 12-weeks' duration in puppies less than 6 months of age. **BRAVECTO Topical Solution for Dogs** is not effective against lone star ticks beyond 8 weeks of dosing. For topical use only. Avoid oral ingestion. Indicated for dogs 6 months of age and older. **BRAVECTO QUANTUM** (fluralaner for extended-release injectable suspension) for Dogs: The most commonly reported adverse reactions in a US field study included lethargy, decreased appetite, vomiting, diarrhea, elevated liver enzymes and pruritus. **BRAVECTO QUANTUM** is not effective against lone star ticks beyond 8 months of dosing. Indicated for dogs 6 months of age and older.

BRAVECTO (fluralaner topical solution) for Cats: The most commonly reported adverse reactions include vomiting, itching, diarrhea, hair loss, decreased appetite, lethargy, and scabs/ulcerated lesions. **BRAVECTO Topical Solution for Cats** is not effective against American dog ticks beyond 8 weeks of dosing. **BRAVECTO Topical Solution for Cats** has not been shown to be effective for 12-weeks' duration in kittens less than 6 months of age. The safety of **BRAVECTO Topical Solution for Cats** have not been established in breeding, pregnant and lactating cats. For topical use only. Avoid oral ingestion. Indicated for cats 6 months of age and older. **BRAVECTO PLUS (fluralaner and moxidectin topical solution) for Cats**: The most commonly reported adverse reactions include vomiting, hair loss, itching, diarrhea, lethargy, dry skin, elevated ALT, and hypersalivation. **BRAVECTO PLUS** has not been shown to be effective for 2 months in kittens less than 6 months of age. Use with caution in cats that are heartworm positive. The effectiveness of **BRAVECTO PLUS** to prevent heartworm disease after bathing or water immersion has not been evaluated. The safety of **BRAVECTO PLUS** have not been established in breeding, pregnant and lactating cats. Indicated for cats 6 months of age and older.

All BRAVECTO products contain fluralaner, which 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. 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.

PLEASE SEE BRIEF PRESCRIBING INFORMATION ON FOLLOWING PAGES.

Companion Animal Parasite Council (CAPC) recommends year-round flea and tick protection (www.capcvet.org).
Please contact **Merck Animal Health Technical Services at 800-224-5318** with questions or to report an adverse event.
Merck Animal Health reserves the right to modify this program, in whole or in part, at any time for any reason.

MERCK Animal Health

BRAVECTO® QUANTUM

(fluralaner for extended-release injectable suspension)

150 mg fluralaner per mL when constituted

For subcutaneous use in dogs only

CAUTION:
Federal law restricts this drug to use by or on the order of a licensed veterinarian.

INDICATIONS:
BRAVECTO QUANTUM kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and for 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 months in dogs and puppies 6 months of age and older.

BRAVECTO QUANTUM is also indicated for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for 8 months in dogs and puppies 6 months of age and older.

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

WARNINGS:

User Safety Warnings:
Not for use in humans. Keep this and all drugs out of reach of children.

In case of accidental self-injection:
- Seek medical advice immediately and show the package insert or label to the physician.

In case of accidental skin contact:
- Wash the exposed skin with water for at least 15 minutes.
- If redness and swelling occur, seek medical advice immediately and show the package insert or label to the physician.

In case of accidental eye exposure:
- Wash the eyes with water for at least 15 minutes.
- If wearing contact lenses, rinse the eyes first, then remove contacts and continue to rinse with water.
- If redness and swelling occur, seek medical advice immediately and show the package insert or label to the physician.

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 QUANTUM is not effective against *Amblyomma americanum* ticks beyond 8 months after dosing (see **Effectiveness**).

Prior to administration of BRAVECTO QUANTUM, owners should be informed that this product may take 3-5 days to see a notable reduction in ticks (see **Effectiveness**).

Hypersensitivity reactions, including anaphylaxis, have been reported with the use of this product and should be treated immediately with the same measures used to treat hypersensitivity reactions to vaccines and other injectable products (see **Adverse Reactions**).

The safety and effectiveness of BRAVECTO QUANTUM has not been evaluated in dogs less than 6 months of age.

The safety of BRAVECTO QUANTUM has not been evaluated in breeding, pregnant and lactating dogs. Reproductive adverse events have been reported following use of Bravecto (fluralaner) Chews in breeding females including birth defects (including limb deformities and cleft palate), stillbirth, and abortion.

Before use in breeding female dogs, refer to the **Target Animal Safety** section.

ADVERSE REACTIONS:
In a well-controlled U.S. field study, 225 dogs were administered two doses of BRAVECTO QUANTUM at a 1-year interval and 96 dogs were administered an oral active control every 12 weeks for a total of 6 doses. Over the 455-day study period, all observations of potential adverse reactions were recorded.

Percentage of Dogs with Adverse Reactions in the Field Study

Adverse Reaction (AR)	BRAVECTO QUANTUM (n = 225 dogs)	Active Control (n = 96 dogs)
Lethargy	4.9%	3.1%
Decreased appetite	4.4%	4.2%
Vomiting	4.0%	0%
Diarrhea	2.7%	3.1%
Liver enzymes (serum ALT or ALP) greater than twice the upper reference range[1]	2.7%	2.1%
Pruritus	1.8%	2.1%
Injection site lumps or swelling[2]	1.3%	0%
Seizures[3]	0.9%	0%

[1] Alanine aminotransferase (ALT); Alkaline phosphatase (ALP)
[2] Mild injection site reactions, described as a lump, bump or knot, occurred in three BRAVECTO QUANTUM treated dogs and were all observed within 3 days of the injection. All injection site reactions were self-limiting and resolved following 1, 4, and 27 days after the initial observation.
[3] Two dogs treated with BRAVECTO QUANTUM experienced seizures during the study. One dog with a history of at least one seizure within three months prior to the start of the study, reported 6 seizures in 9 months starting 23 days after the initial dose. Although anticonvulsant medications were not started, no additional seizures were observed during the study following the second dose administered 12 months after the initial dose. A second dog reported 8 seizures starting 57 days after the initial dose. The dog was removed from the study on Day 84 and managed with anticonvulsant medications.

One dog treated in the BRAVECTO QUANTUM group had a hypersensitivity reaction which included hives, facial edema, vomiting, and heavy breathing within the first 12 hours following the initial treatment. The dog was treated with oral antihistamines and recovered within 24 hours of treatment. No additional hypersensitivity reactions were observed in subsequent dosing 12 months later when premedicated with diphenhydramine.

BRIEF SUMMARY:
Please see full prescribing information at us.bravecto.com.

In well-controlled foreign laboratory effectiveness studies, after administration of BRAVECTO QUANTUM, two dogs exhibited slight mucosal hyperemia the day following administration that resolved the following day, one dog exhibited transient erythema 10 minutes post-injection that resolved within 1 hour, and one dog had a nonpainful swollen upper eyelid observed 24 hours post treatment. In a large European field study, pain on injection of BRAVECTO QUANTUM was reported in 5 dogs.

Foreign Market Experience:
The following adverse events were reported voluntarily during post-approval use of BRAVECTO QUANTUM in foreign markets: gastrointestinal reactions (including vomiting, diarrhea, decreased appetite, and acute hemorrhagic diarrhea syndrome), lethargy, injection site reactions (including swelling, lump, pain, bleeding, and abscess), immune-mediated disorders (including hypersensitivity reactions, anaphylaxis, and immune-mediated hemolytic anemia), pruritus, dermatitis, and neurologic reactions (including seizures, ataxia, and tremors).

CONTACT INFORMATION:
For technical information or to report a suspected adverse event, please contact Merck Animal Health at 1-800-224-5318 or https://www.merck-animal-health-usa.com. Safety Data Sheets (SDSs) can be found at https://www.merck.com/products/safety-data-sheets/#. For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or https://www.fda.gov/reportanimalae

EFFECTIVENESS:
Treatment and Prevention of Flea Infestations:
In well-controlled laboratory studies, BRAVECTO QUANTUM was 100% effective against adult fleas by 48 hours after treatment and ≥ 99.7% effective against adult fleas 24 hours post-infestation from one week through 12 months after treatment.

In a well-controlled 455-day U.S. field study conducted in households with existing flea infestations, the effectiveness of BRAVECTO QUANTUM against fleas when administered at 12-month intervals was ≥ 99.2% for 12 months. 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 a well-controlled laboratory study, the onset of effectiveness (≥ 90.0%) against preexisting infestations occurred within 3 days following post-treatment for *Dermacentor variabilis* and *Ixodes scapularis*, and within 4 days post-treatment for *Rhipicephalus sanguineus*. In well-controlled laboratory studies, BRAVECTO QUANTUM demonstrated ≥ 94.0% effectiveness against *Rhipicephalus sanguineus* ticks 48-hours post-infestation starting one week through 12 months after treatment.

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

In a well-controlled laboratory study, the onset of effectiveness (≥ 90.0%) against preexisting *Amblyomma americanum* infestations occurred 5 days post-treatment. In well-controlled laboratory studies, BRAVECTO QUANTUM demonstrated > 93.5% effectiveness against *Amblyomma americanum* at 72-hours post-infestation starting approximately one week through 8 months after treatment but failed to demonstrate effectiveness beyond 8 months.

TARGET ANIMAL SAFETY:
Margin of Safety Study:
In a margin of safety study, 32 healthy intact Beagle dogs (4 dogs/sex/group) aged 6 months were administered BRAVECTO QUANTUM by subcutaneous injection at doses of 0 (0X), 15 (1X), 45 (3X), or 75 (5X) mg/kg every 4 months for a total of 6 doses (Days 1, 120, 239, 358, 477 and 596). Dogs in the control group (0X) were injected with sterile saline. Two dogs died during the study. One male in the 3X group was euthanized due to a prolapsed rectum and replaced on Day 15. One male in the 3X group was euthanized on Day 475 due to seizures. Necropsy determined this dog died of polyarteritis. The administration of BRAVECTO QUANTUM resulted in dose-volume dependent injection site swellings that resolved over time. Injection site swellings in the 1X group lasted up to 32 days after the first injection, up to 62 days after the second injection, and persisted in some dogs throughout the dosing interval after the third through sixth injections. Injection site swellings in the 3X and 5X groups occurred after each injection and persisted in some dogs throughout the dosing interval. No pain was observed during any injection site assessment. Occasional erythema occurred in all treatment groups, including dogs in the control group. Abnormal macroscopic changes at the injection sites included accumulation of tan material only in the dogs administered BRAVECTO QUANTUM. On histopathology, abnormal microscopic observation of the injection sites in dogs administered BRAVECTO QUANTUM included fibrosis (minimal to moderate), granulomatous inflammation (minimal to moderate), and/or histiocytic infiltration (minimal).

Reproductive Safety Study:
Reproductive safety was evaluated for Bravecto Chews, NADA 141-426. Bravecto Chews contains fluralaner, the same active ingredient as in BRAVECTO QUANTUM. Bravecto Chews was administered orally to intact, reproductively-sound male and female Beagle dogs 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 QUANTUM 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 QUANTUM with other medications.

HOW SUPPLIED:
BRAVECTO QUANTUM (fluralaner for extended-release injectable suspension) 20 mL vial product is available in a 1-pack presentation that includes one vial containing 2.51 grams of sterile fluralaner and one vial containing the required 15 mL of sterile vehicle for constitution.

Approved by FDA under NADA # 141-599

Formulated in Germany.
Distributed by Intervet Inc. (d/b/a Merck Animal Health), Rahway, NJ 07065.

Rev. 01/2025

168621 R10

MERCK Animal Health

BRAVECTO®
(fluralaner) Chews

Flavored chews for dogs.

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

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), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (Asian longhorned 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.

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 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.

Adverse events have been reported following use in breeding females. Before use in breeding female dogs, refer to Post-Approval Experience and Animal Safety sections.

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.

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.

Post-Approval Experience (2022):
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, pruritis, polydipsia, seizure, allergic reactions (including hives, swelling, erythema), dermatitis (including crusts, pustules, rash), tremors and ataxia. In some cases, birth defects (including limb deformities and cleft palate), stillbirth, and abortion have been reported after treatment of breeding females.

Contact Information:
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.

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.

Approved by FDA under NADA # 141-426

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

Fluralaner (active ingred.) Made in Japan.
Formulated in Austria

Rev. 10/2022
375232 R4

Approved by FDA under NADA # 141-459

BRAVECTO®
(fluralaner topical solution) for Dogs

BRIEF SUMMARY (For full Prescribing Information, see package insert)

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

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.

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

WARNINGS
Human Warnings:
Not for human use. Keep this and all drugs out of the reach of children. **Do not contact or allow children to contact the application site until dry.** 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. Avoid contact with skin and eyes. If contact with eyes occurs, then flush eyes slowly and gently with water. **Wash hands and contacted skin thoroughly with soap and water immediately after use of the product.**

The product is highly flammable. Keep away from heat, sparks, open flame or other sources of ignition.

Precautions:
For topical use only. Avoid oral ingestion. 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 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.

Adverse Reactions:
In a well-controlled U.S. field study, which included a total of 165 households and 321 treated dogs (221 with fluralaner and 100 with a topical active control), there were no serious adverse reactions.

Percentage of Dogs with Adverse Reactions in the Field Study

Adverse Reaction (AR)	Bravecto Group: Percent of Dogs with the AR During the 105-Day Study (n=221 dogs)	Control Group: Percent of Dogs with the AR During the 84-Day Study (n=100 dogs)
Vomiting	6.3%	6.0%
Alopecia	4.1%	2.0%
Diarrhea	2.7%	11.0%
Lethargy	2.7%	2.0%
Decreased Appetite	1.4%	0.0%
Moist Dermatitis/Rash	0.9%	0.0%

In the field study, two dogs treated with Bravecto with no prior history of seizures each experienced a seizure. One dog had two seizures a day apart about 18 days after its first dose. The dog was started on antiepileptic medication and had no additional seizures during the study. A second dog had a seizure 76 days after its first dose and 3 days after starting fluoxetine for separation anxiety. The fluoxetine was discontinued and the dog experienced no additional seizures during the study. One dog treated with Bravecto was observed by the owner to be off balance for about 30 minutes five days after its first dose and had no similar observations after the second dose. One dog with a history of seizures had a seizure the day after the second dose of the active control.

In two well-controlled laboratory dose confirmation studies, one dog developed mild to moderate redness, flaking, crusts/scabs and alopecia at the treatment site from Day 1 through 14 after application of Bravecto on Day 0, and one dog developed self-limiting generalized erythema (possible allergic reaction) one day after treatment with Bravecto.

In a European field study in cats, there were three reports of facial dermatitis in humans after close contact with the application site which occurred within 4 days of application.

Contact Information:
For a copy of the Safety Data Sheet (SDS) or to report suspected adverse drug events, 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 http://www.fda.gov/reportanimalae.

How Supplied:
Bravecto is available in five strengths for use in dogs (112.5, 250, 500, 1000, and 1400 mg fluralaner per tube). Each tube is packaged individually in a pouch. Product may be supplied in 1 or 2 tubes per carton.

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

Fluralaner (active ingred.) Made in Japan.
Formulated in USA

Rev. 04/19
188575 R3

BRAVECTO®
(fluralaner topical solution) for Cats

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

Indications:
Bravecto kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of *Ixodes scapularis* (black-legged tick) and *Haemaphysalis longicornis* (Asian longhorned tick) infestations for 12 weeks in cats and kittens 6 months of age and older, and weighing 2.6 pounds or greater.

Bravecto is also indicated for the treatment and control of *Dermacentor variabilis* (American dog tick) infestations for 8 weeks in cats and kittens 6 months of age and older, and weighing 2.6 pounds or greater.

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

WARNINGS
Human Warnings:
Not for human use. Keep this and all drugs out of the reach of children.

Do not contact or allow children to contact the application site until 2 hours post application. 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. Avoid contact with skin and eyes. If contact with eyes occurs, then flush eyes slowly and gently with water.

If wearing contact lenses, eyes should be rinsed first, then remove contact lenses and continue rinsing, then seek medical advice immediately. Wash hands and contacted skin thoroughly with soap and water immediately after use of the product. If the product accidentally contacts skin and a sticky residue persists after washing, rubbing alcohol (70% isopropyl alcohol) can be applied to the area to remove the residue.

The product is highly flammable. Keep away from heat, sparks, open flame or other sources of ignition.

Precautions:
For topical use only. Avoid oral ingestion.

Fluralaner 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.

Bravecto has not been shown to be effective for 12-weeks duration in kittens less than 6 months of age. Bravecto is not effective against *Dermacentor variabilis* ticks beyond 8 weeks after dosing.

The safety of Bravecto has not been established in breeding, pregnant and lactating cats.

The effectiveness of Bravecto after bathing or water immersion has not been evaluated.

Adverse Reactions:
In a well-controlled U.S. field study, which included a total of 161 households and 311 treated cats (224 with fluralaner and 87 with a topical active control), there were no serious adverse reactions.

Percentage of Cats with Adverse Reactions (AR) in the Field Study

Adverse Reaction (AR)	Bravecto Group: Percent of Cats with the AR During the 105-Day Study (n=224 cats)	Active Control Group: Percent of Cats with the AR During the 84-Day Study (n=87 cats)
Vomiting	7.6%	6.9%
Pruritus	5.4%	11.5%
Diarrhea	4.9%	1.1%
Alopecia	4.9%	4.6%
Decreased Appetite	3.6%	0.0%
Lethargy	3.1%	2.3%
Scabs/Ulcerated Lesions	2.2%	3.4%

In the field study, two cats treated with fluralaner topical solution experienced ataxia. One cat became ataxic with a right head tilt 34 days after the first dose. The cat improved within one week of starting antibiotics. The ataxia and right head tilt, along with lateral recumbency, reoccurred 82 days after administration of the first dose. The cat recovered with antibiotics and was redosed with fluralaner topical solution 92 days after administration of the first dose, with no further abnormalities during the study. A second cat became ataxic 15 days after receiving its first dose and recovered the next day. The cat was redosed with fluralaner topical solution 82 days after administration of the first dose, with no further abnormalities during the study.

In a European field study, two cats from the same household experienced tremors, lethargy, and anorexia within one day of administration. The signs resolved in both cats within 48-72 hours.

In a European field study, there were three reports of facial dermatitis in humans after close contact with the application site which occurred within 4 days of application.

Post Approval Experience (2020):
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 in cats are listed in decreasing order of reporting frequency:

Application site alopecia, lethargy, hypersalivation, anorexia, vomiting, behavioral disorders (including hyperactivity, hiding, and vocalization), generalized pruritus, application site disorders (including lesion, pruritus, and erythema), ataxia, alopecia, diarrhea, 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 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 http://www.fda.gov/reportanimalae

How Supplied:
Bravecto is available in three strengths for use in cats (112.5, 250, and 500 mg fluralaner per tube). Each tube is packaged individually in a pouch. Product may be supplied in 1 or 2 tubes per carton.

Approved by FDA under NADA # 141-459

Distributed by:
Intervet Inc (d/b/a Merck Animal Health), Madison, NJ 07940
Fluralaner (active ingred.) Made in Japan.
Formulated in USA

 Rev. 05/2022
380283 R5

MERCK Animal Health

Abbreviated for consumer use, not a full PI.

BRAVECTO® 1-MONTH

(fluralaner) Chews for Dogs

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

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), *Rhipicephalus sanguineus* (brown dog tick) and *Haemaphysalis longicornis* (Asian longhorned 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.

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.

The safety of Bravecto 1-Month has not been evaluated in breeding, pregnant and lactating dogs. Adverse events have been reported following use of Bravecto (fluralaner) Chews in breeding females.

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 (2024):
The following adverse events are based on post-approval adverse drug experience reporting for Bravecto 1-Month. 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, anorexia, tremors, ataxia, seizure, pruritus, and allergic reactions (including hives, swelling, and erythema).

The following reproductive adverse events have been reported following use of Bravecto (fluralaner) Chews: birth defects (including limb deformities and cleft palate), stillbirth, and abortion.

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.

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

Distributed by:
Intervet Inc (d/b/a Merck Animal Health), Rahway, NJ 07065
Formulated in Austria

Rev: 05/2024

399706 R3

MERCK Animal Health

BRAVECTO® PLUS

(fluralaner and moxidectin topical solution) for Cats

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

Indications:
Bravecto Plus is indicated for the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment of infections with intestinal roundworm (*Toxocara cati*; 4th stage larvae, immature adults and adults) and hookworm (*Ancylostoma tubaeforme*; 4th stage larvae, immature adults and adults). Bravecto Plus 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 *Haemaphysalis longicornis* (Asian longhorned tick)] for 2 months in cats and kittens 6 months of age and older and weighing 2.6 lb or greater.

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

WARNINGS:

Human Warnings:
Not for human use. Keep this and all drugs out of the reach of children.

Do not contact or allow children to contact the application site until 2 hours post application.

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. Avoid contact with skin and eyes. If contact with eyes occurs, then flush eyes slowly and gently with water. **If wearing contact lenses, eyes should be rinsed first, then remove contact lenses and continue rinsing, then seek medical advice immediately. Wash hands and contacted skin thoroughly with soap and water immediately after use of the product. If the product accidentally contacts skin and a sticky residue persists after washing, rubbing alcohol (70% isopropyl alcohol) can be applied to the area to remove the residue.**

The product is highly flammable. Keep away from heat, sparks, open flame or other sources of ignition.

Precautions:
For topical use only. Avoid oral ingestion.

Fluralaner, one of the ingredients in Bravecto Plus, 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.

Use with caution in cats that are heartworm positive.

Bravecto Plus has not been shown to be effective in kittens less than 6 months of age.

The safety of Bravecto Plus has not been established in breeding, pregnant, and lactating cats.

The effectiveness of Bravecto Plus to prevent heartworm disease after bathing or water immersion has not been evaluated.

Adverse Reactions:
In a well-controlled U.S. field study, which included a total of 176 treated cats (135 with Bravecto Plus and 41 with a monthly topical active control), there were no serious adverse reactions.

Percentage of Cats with Adverse Reactions (AR) in the Field Study

Adverse Reaction	Bravecto Plus Group: Percent of Cats with the AR During the 120-Day Study (n=135 cats)	Active Control Group: Percent of Cats with the AR During the 120-Day Study (n=41 cats)
Vomiting	5.9%	12.2%
Alopecia (not at application site)	5.2%	2.4%
Pruritus	4.4%	12.2%
Application site pruritus	4.4%	4.9%
Diarrhea	3.7%	7.3%
Lethargy	3.7%	9.8%
Dry Skin	3.0%	0.0%
Elevated alanine aminotransferase (ALT)*	3.0%	0.0%
Hypersalivation	1.5%	1.5%
Application site alopecia	0.7%	0.0%

*ALT was greater than twice the upper reference range of 100 IU/L. These cats also had mild elevations of aspartate aminotransferase (AST) (less than twice the upper reference range of 100 IU/L). No clinical signs associated with liver disease were noted in these cats.

In well-controlled laboratory effectiveness studies, the following adverse reactions were seen after application of Bravecto Plus: pyrexia, tachypnea, mydriasis, pruritus, scabbing, and bloody stool.

Foreign Market Experience: The following adverse events were reported voluntarily during post-approval use of the product in cats in foreign markets: polydipsia, swelling of chin and lips, periorbital swelling, blepharospasm, pruritus, erythema, aggression, agitation, pyrexia, mydriasis, hypersalivation, hyperactivity, alopecia, and excessive grooming. These adverse events occurred within 48 hours of administration.

In a European field study for fluralaner topical solution for cats, there were three reports of facial dermatitis in humans after close contact with the application site which occurred within 4 days of application. In foreign market experience reports for Bravecto Plus, one veterinarian experienced tingling and numbness of the fingers, hand, and arm, and swelling of the hand and arm after getting Bravecto Plus on her fingers. Additional signs, including blurred vision and disorientation, occurred after taking an antihistamine.

Post-Approval Experience (2022):
The following adverse events are based on post-approval adverse drug experience reporting for Bravecto Plus. 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:
Application site alopecia, lethargy, hypersalivation, vomiting, anorexia, application site disorders (including pruritus, erythema, and lesions), behavioral disorders (including hiding and hyperactivity), ataxia, generalized pruritus, muscle tremor, alopecia, weight loss, and diarrhea.

Contact Information:
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

How Supplied:
Bravecto Plus is available in three tube sizes to treat cats ranging in weight from 2.6 lb – 27.5 lb (1.2 kg to 12.5 kg). Each tube is packaged individually in a pouch. Product may be supplied in 1 or 2 tubes per carton.

Approved by FDA under NADA # 141-518

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MERCK Animal Health