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.

It's simple. We are so confident in our BRAVECTO products that if your clients are unsatisfied, we'll refund the purchase price and provide additional reimbursements for up to $2500 as outlined in the guide below.

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 distributor who has purchased directly from Merck Animal Health, with their veterinarian's prescription. BRAVECTO products include:

- BRAVECTO® (fluralaner) Chews for Dogs
- BRAVECTO® 1-MONTH (fluralaner) Chews for Dogs and Puppies
- BRAVECTO® (fluralaner topical solution) for Dogs or Cats
- BRAVECTO® PLUS (fluralaner and moxidectin topical solution) for Cats

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 reserves the right to modify this program, in whole or in part, at any time for any reason.

General Requirements

If your client is unsatisfied, they must meet the following guidelines and requirements to qualify for reimbursement:

- All BRAVECTO products must be used according to label directions.
- An itemized receipt for the purchase of the product must be submitted to Merck Animal Health. The receipt must show:
  - The owner's name
  - The dog's or cat's name(s)
  - Place of purchase (which must be within the last 12 months)
  - 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 one 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. Additional diagnostics to confirm disease may be requested. • 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 within 1 month 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 within 1 month or anytime after starting BRAVECTO 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. 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 1-MONTH (fluralaner) Chews: indicated for dogs 8 weeks of age and older. The most commonly reported adverse reactions include itching, diarrhea, vomiting, decreased appetite, elevated ALT, lethargy, and weight loss. **BRAVECTO 1-MONTH** is not effective against *A. americanum* in puppies less than 6 months of age. **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 (fluralaner topical solution) for Dogs:** The most commonly reported adverse reactions include vomiting, hair loss, diarrhea, lethargy, decreased appetite, and moist dermatitis/rash. **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 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.

BRAVECTO Chews and **Topical Solution for Dogs** have not been shown to be effective for 12-weeks' duration in puppies or kittens less than 6 months of age. **BRAVECTO Chews** and **Topical Solution for Dogs** are not effective against the lone star tick beyond 8 weeks of dosing. **BRAVECTO Topical Solution for Dogs and Cats** and **BRAVECTO PLUS for Cats** are for topical use only. Avoid oral ingestion. The safety of **BRAVECTO Topical Solution for Cats** and **BRAVECTO PLUS** have not been established in breeding, pregnant and lactating cats.

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 PAGE.

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®
(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

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.

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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) 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.

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.

The safety of Bravecto 1-Month has not been evaluated in breeding, pregnant and lactating dogs.

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.

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.

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MERCK Animal Health