



(fluralaner) Chews 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 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 this product.

**WARNINGS**

**Human 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 or without blood), anorexia, pruritus, polydipsia, seizure, allergic reactions (including hives, swelling, erythema), dermatitis (including crusts, pustules, rash), tremors and ataxia.

**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](http://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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Rev. 03/20



(fluralaner) flavored chew 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. 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.

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: Percent of Dogs with the AR During the 182-Day Study (n=224 dogs)	Active Control Group: Percent 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 (2019):**

The following adverse events are based on post-approval adverse drug experience reporting. 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 for fluralaner: 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.

**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](http://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/AnimalVeterinary/SafetyHealth>.

**How Supplied:**

Bravecto is available in five strengths for use in dogs (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.

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

Fluralaner (active ingred.) Made in Japan.

Formulated in Austria

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**Parasite protection  
made easy**



# START WITH BRAVECTO.



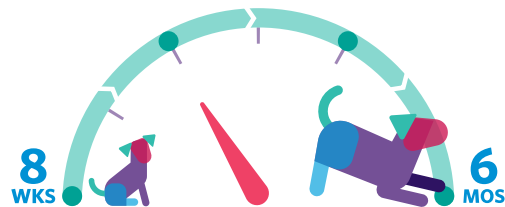
**BRAVECTO**  
**1-MONTH**  
(fluralaner) Chews

.....  
**Designed for puppies**  
8 weeks of age and  
older, and weighing  
4.4 pounds or greater.

## BRAVECTO® 1-MONTH CHEWS

### Essential flea and tick protection for puppies\*

Puppies grow up. Fast! With BRAVECTO 1-MONTH Chews, puppies can get just the right amount of protection they need for their growing bodies.



**BRAVECTO 1-MONTH CHEWS**  
for a rapidly growing puppy

\*BRAVECTO 1-MONTH Chews for Dogs kills adult fleas, prevents flea infestations, and treats and controls ticks (black-legged tick, American dog tick, and brown dog tick) for one month in dogs and puppies 8 weeks of age and older. BRAVECTO 1-MONTH Chews also treats and controls lone star ticks for one month in dogs and puppies 6 months of age and older.



# STAY WITH BRAVECTO.



**BRAVECTO**  
(fluralaner)  
Chews

.....  
**As your pup grows up...**  
Once puppies reach 6 months  
of age, they transition to  
extended-duration BRAVECTO® Chews.

## EXTENDED-DURATION BRAVECTO CHEWS: 12-WEEK† PROTECTION IN ONE TASTY CHEW

### Long-lasting

Only extended-duration BRAVECTO Chews provides up to 12 weeks† of protection from fleas and ticks with just one dose.



### Fast-acting

Extended-duration BRAVECTO Chews starts killing fleas within just 2 hours of dosing and reaches 100% efficacy in 12 hours.†

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



# NEVER FORGET A DOSE!



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Download your very own  
dosing calendar, now, at  
**us.bravecto.com**  
or scan code.

### IMPORTANT SAFETY INFORMATION:

**BRAVECTO 1-MONTH** Chews are for dogs 8 weeks of age and older. Side effects may include itching, diarrhea, vomiting, decreased appetite, elevated ALT, lethargy, and weight loss. 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** Chews are not effective against *A. americanum* in puppies less than 6 months of age. **BRAVECTO Chews for Dogs:** The most commonly reported adverse reactions include vomiting, decreased appetite, diarrhea, lethargy, polydipsia, and flatulence. **BRAVECTO Chews** have not been shown to be effective for 12-weeks' duration in puppies less than 6 months of age. **BRAVECTO Chews** are not effective against lone star ticks beyond 8 weeks of dosing. 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**  
(fluralaner)

Reference: 1. Taenzler J, Wengenmayer C, Williams H, et al. Onset of activity of fluralaner (BRAVECTO™) against *Ctenocephalides felis* on dogs. *Parasit Vectors*. 2014;7:567.

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