

**BRAVECTO- fluralaner solution**  
**Merck Sharp & Dohme Corp.**

-----  
**BRAVECTO®**  
**(fluralaner topical solution) for Dogs**

**Caution**

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

**Description:**

Each tube is formulated to provide a minimum dose of 11.4 mg/lb (25 mg/kg) body weight. Each milliliter contains 280 mg of fluralaner.

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

**Indications:**

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

Bravecto is also indicated for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater.

**Dosage and Administration:**

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

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

**Dosage Schedule**

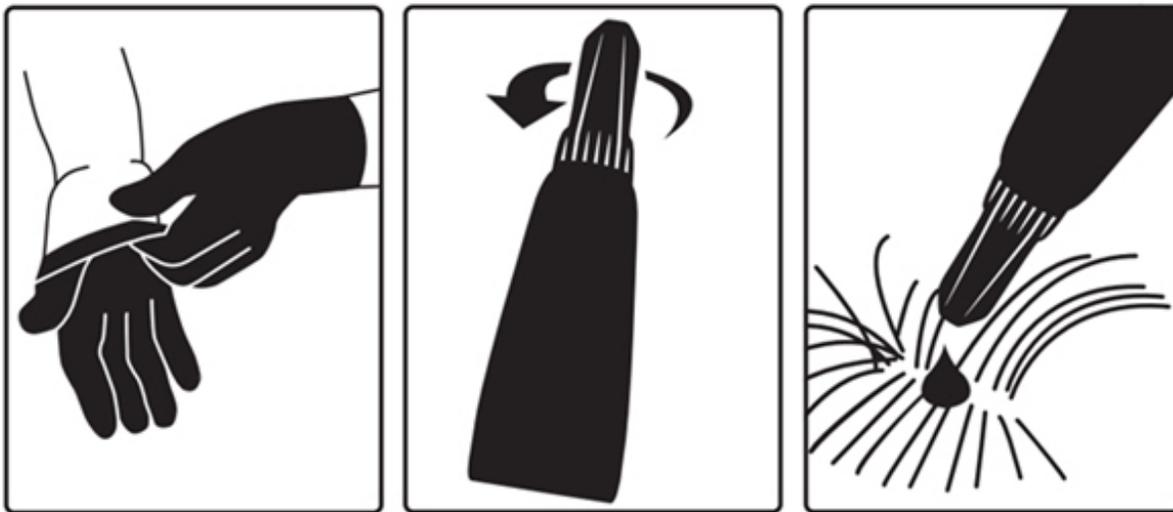
<b>Body Weight Ranges (lb)</b>	<b>Fluralaner content (mg)/tube</b>	<b>Tubes Administered</b>
4.4 - 9.9	112.5	One
>9.9 - 22.0	250	One
>22.0 - 44.0	500	One
>44.0 - 88.0	1000	One

>88.0 - 123.0*	1400	One
----------------	------	-----

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

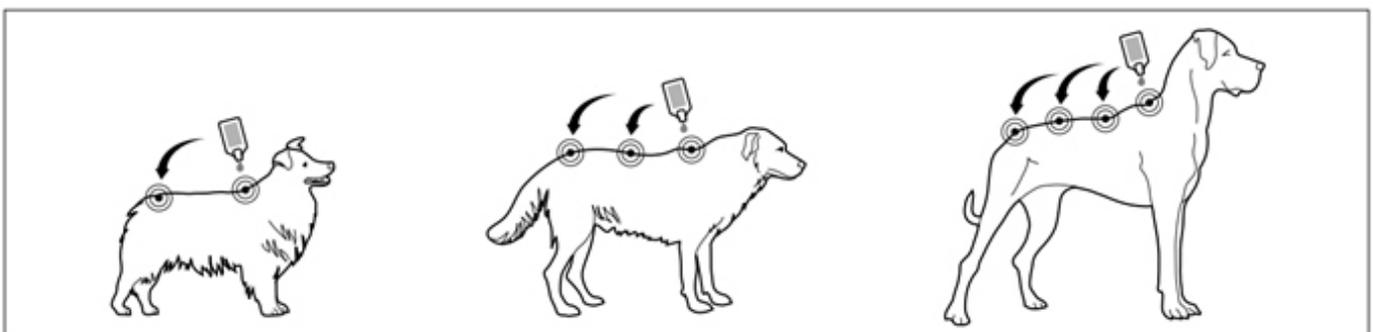
A veterinarian or veterinary technician should demonstrate or instruct the pet owner regarding the appropriate technique for applying Bravecto topically to dogs prior to first use.

**Step 1:** Immediately before use, open the pouch and remove the tube. Put on gloves. Hold the tube at the crimped end with the cap in an upright position (tip up). The cap should be rotated clockwise or counter clockwise one full turn. The cap is designed to stay on the tube for dosing and should not be removed. The tube is open and ready for application when a breaking of the seal is felt.



**Step 2:** The dog should be standing or lying with its back horizontal during application. Part the fur at the administration site. Place the tube tip vertically against the skin between the shoulder blades of the dog.

**Step 3:** Squeeze the tube and gently apply Bravecto in one or more spots starting between the shoulder blades and continuing along the dog's back. Avoid applying an excessive amount of solution in any one spot which may cause some solution to run or drip off of the dog.



Bathing or water immersion 3 days after administration will not reduce the effectiveness of Bravecto against fleas and *Ixodes ricinus* ticks (see **Effectiveness**).

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

### **Contraindications:**

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

## **WARNINGS**

### **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. (see **Animal Safety**).

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 (see **Effectiveness**).

The safety of Bravecto (fluralaner topical solution) in breeding, pregnant, and lactating dogs was evaluated using the oral formulation (see **Animal Safety** and **Clinical Pharmacology** sections). Adverse events have been reported following use of Bravecto (fluralaner) Chews in breeding females.

Before use in breeding female dogs, refer to **Post-Approval Experience** and **Animal Safety** sections.

### **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**

<b>Adverse Reaction (AR)</b>	<b>Bravecto Group: Percent of Dogs with the AR During the 105-Day Study (n= 221 dogs)</b>	<b>Active Control Group: Percent of Dogs with the AR During the 84-Day Study (n= 100 dogs)</b>
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.

### **Post-Approval Experience (2025):**

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

Lethargy, vomiting, application site disorders (including alopecia, pruritus, and erythema), behavioral changes (including hyperactivity and vocalization), anorexia/decreased appetite, seizure, diarrhea, generalized pruritus, tremors, and ataxia.

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.

### **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/reportanimalae>.

### **Clinical Pharmacology:**

Peak fluralaner concentrations are achieved between 7 and 42 days following topical administration and the elimination half-life ranges between 14 and 29 days. The bioavailability of fluralaner following oral and topical administration is approximately 25%.

### **Mode of Action:**

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

### **Effectiveness:**

In well-controlled laboratory studies, Bravecto killed fleas and reduced the numbers of live fleas on dogs by >99% and 100% within 24 and 48 hours, respectively, post-infestation for 12 weeks. In well-controlled laboratory studies, Bravecto demonstrated  $\geq 93.3\%$  effectiveness against *Dermaacentor variabilis*, *Ixodes scapularis* and *Rhipicephalus sanguineus* 48 hours post-infestation for 12 weeks. Bravecto demonstrated  $\geq 90\%$  effectiveness against *Amblyomma americanum* 72 hours post-infestation for 8 weeks, but failed to demonstrate  $\geq 90\%$  effectiveness beyond 8 weeks.

In a well-controlled U.S. field study, a single dose of Bravecto reduced fleas by  $\geq 99.8\%$  for 12 weeks. Dogs with signs of flea allergy dermatitis showed improvement in erythema, alopecia, papules, scales, crusts, and excoriation as a direct result of eliminating flea infestations.

In a European laboratory study, Bravecto demonstrated  $\geq 98.2\%$  effectiveness against fleas and *Ixodes ricinus* ticks after multiple water immersion or shampooing occasions, the first occurring 3 days after application, for 12 weeks.

## **Animal Safety:**

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

There were no clinically-relevant, treatment-related effects on physical examination, body weights, food consumption, clinical pathology (hematology, clinical chemistries, coagulation tests, and urinalysis), gross pathology, histopathology, or organ weights. Cosmetic changes at the application site included matting/clumping/spiking of hair, wetness, or a greasy appearance.

*Oral Safety Study:* In a safety study, one dose of Bravecto topical solution was administered orally to 8- to 10-month-old-puppies at 1× the maximum labeled dose of 56 mg/kg. The dogs in the control group (0×) were administered saline orally.

There were no clinically-relevant, treatment-related effects on physical examination, body weights, food consumption, clinical pathology (hematology, clinical chemistries, coagulation tests, and urinalysis), gross pathology, histopathology, or organ weights. Five of the six treated dogs experienced salivation immediately after administration. One treated animal experienced loose feces with blood three hours after administration. One treated animal experienced vomiting eight hours after administration.

*Reproductive Safety:* Reproductive safety was evaluated for Bravecto Chews, NADA 141-426 (see **Clinical Pharmacology**). Bravecto Chews were administered orally to intact, reproductively- sound male and female Beagles at a dose of up to 168 mg/kg (equivalent to 3× the maximum treatment dose) on three to four occasions at 8-week intervals. The dogs in the control group (0×) were untreated.

There were no clinically-relevant, treatment-related effects on the body weights, food consumption, reproductive performance, semen analysis, litter data, gross necropsy (adult dogs) or histopathology findings (adult dogs and puppies). One adult treated dog suffered a seizure during the course of the study (46 days after the 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 was used concurrently with other medications, such as vaccines, anthelmintics, antibiotics, steroids and sedatives.

## **Storage Information:**

Do not store above 86°F (30°C). Store in the original package in order to protect from moisture. The pouch should only be opened immediately prior to use.

**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.

Approved by FDA under NADA # 141-459

Distributed by:

Intervet, Inc., (d/b/a Merck Animal Health),  
Rahway, NJ 07065

Fluralaner (active ingred.) Made in Japan.

Formulated in France

Copyright © 2025 Intervet Inc, a subsidiary of Merck & Company Inc. All rights reserved.

Rev. 01/2026

243659 R3

**PRINCIPAL DISPLAY PANEL - 112.5 MG Tube Carton**

BRAVECTO®  
(fluralaner)  
Topical Solution

4.4-9.9 lb

1 Tube

Kills fleas and ticks

For dogs and puppies 6 months of age and older

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

CONTENTS: 1 TUBE CONTAINING 112.5 MG  
FLURALANER

Approved by FDA under NADA # 141-459

NON  
COATING  
AREA

**BRAVECTO**<sup>®</sup>  
(fluralaner)  
Topical Solution



**BRAVECTO**<sup>®</sup>  
(fluralaner)  
Topical Solution



4.4-9.9 lb

1 Tube



**BRAVECTO**<sup>®</sup>  
(fluralaner)  
Topical Solution

 4.4-9.9 lb

1 Tube

CONTENTS:  
1 TUBE CONTAINING  
112.5 MG FLURALANER



**Kills fleas and ticks**

For dogs and puppies 6 months of age and older

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

CONTENTS: 1 TUBE CONTAINING 112.5 MG FLURALANER

Approved by FDA under NADA # 141-459

**Application Instructions:**

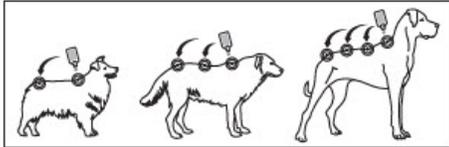
A veterinarian or veterinary technician should demonstrate or instruct the pet owner regarding the appropriate technique for applying Bravecto topically to dogs prior to first use.

**Step 1:** Immediately before use, open the pouch and remove the tube. Put on gloves. Hold the tube at the crimped end with the cap in an upright position (tip up). The cap should be rotated clockwise or counter clockwise one full turn. The cap is designed to stay on the tube for dosing and should not be removed. The tube is open and ready for application when a breaking of the seal is felt.



**Step 2:** The dog should be standing or lying with its back horizontal during application. Part the fur at the administration site. Place the tube tip vertically against the skin between the shoulder blades of the dog.

**Step 3:** Squeeze the tube and gently apply Bravecto in one or more spots starting between the shoulder blades and continuing along the dog's back. Avoid applying an excessive amount of solution in any one spot which may cause solution to run and drip off of the dog.

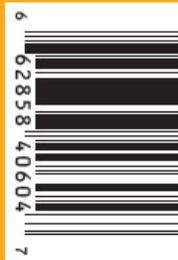


Bathing or water immersion 3 days after administration will not reduce the effectiveness of Bravecto against fleas and *Ixodes ricinus* ticks.

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

**Storage Information:** Do not store above 86°F (30°C). Store in the original package in order to protect from moisture. The pouch should only be opened immediately prior to use.

NON COATING AREA



PSA020F73\_02\_R1  
61x30x152mm  
CM: K+PMS 268  
+PMS 1235

NON COATING AREA



## PRINCIPAL DISPLAY PANEL - 250 MG Tube Carton

BRAVECTO<sup>®</sup>  
(fluralaner)  
Topical Solution

>9.9-22 lb

1 Tube

Kills fleas and ticks

For dogs and puppies 6 months of age and older

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

CONTENTS: 1 TUBE CONTAINING 250 MG  
FLURALANER

Approved by FDA under NADA # 141-459

NON  
COATING  
AREA

**BRAVECTO**<sup>®</sup>  
(fluralaner)  
Topical Solution



**BRAVECTO**<sup>®</sup>  
(fluralaner)  
Topical Solution



>9.9-22 lb

1 Tube



**BRAVECTO**<sup>®</sup>  
(fluralaner)  
Topical Solution

>9.9-22 lb

1 Tube

CONTENTS:  
1 TUBE CONTAINING  
250 MG FLURALANER



**Kills fleas and ticks**

For dogs and puppies 6 months of age and older

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

CONTENTS: 1 TUBE CONTAINING 250 MG FLURALANER

Approved by FDA under NADA # 141-459

**Application Instructions:**

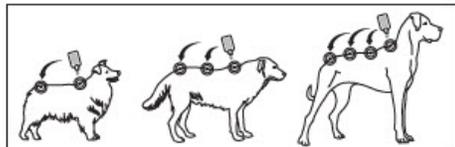
A veterinarian or veterinary technician should demonstrate or instruct the pet owner regarding the appropriate technique for applying Bravecto topically to dogs prior to first use.

**Step 1:** Immediately before use, open the pouch and remove the tube. Put on gloves. Hold the tube at the crimped end with the cap in an upright position (tip up). The cap should be rotated clockwise or counter clockwise one full turn. The cap is designed to stay on the tube for dosing and should not be removed. The tube is open and ready for application when a breaking of the seal is felt.



**Step 2:** The dog should be standing or lying with its back horizontal during application. Part the fur at the administration site. Place the tube tip vertically against the skin between the shoulder blades of the dog.

**Step 3:** Squeeze the tube and gently apply Bravecto in one or more spots starting between the shoulder blades and continuing along the dog's back. Avoid applying an excessive amount of solution in any one spot which may cause solution to run and drip off of the dog.



Bathing or water immersion 3 days after administration will not reduce the effectiveness of Bravecto against fleas and *Ixodes ricinus* ticks.

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

**Storage Information:** Do not store above 86°F (30°C). Store in the original package in order to protect from moisture. The pouch should only be opened immediately prior to use.



PSA020F73 02 R1  
61x29.59x153mm  
CMYK+PMS 268  
+PMS 021C

NON COATING AREA

NON COATING AREA



## PRINCIPAL DISPLAY PANEL - 500 MG Tube Carton

BRAVECTO<sup>®</sup>  
(fluralaner)  
Topical Solution

>22-44 lb

1 Tube

Kills fleas and ticks

For dogs and puppies 6 months of age and older

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

CONTENTS: 1 TUBE CONTAINING 500 MG  
FLURALANER

Approved by FDA under NADA # 141-459

NON  
COATING  
AREA

**BRAVECTO**<sup>®</sup>  
(fluralaner)  
Topical Solution



**BRAVECTO**<sup>®</sup>  
(fluralaner)  
Topical Solution



>22-44 lb

1 Tube



**BRAVECTO**<sup>®</sup>  
(fluralaner)  
Topical Solution



>22-44 lb

1 Tube

CONTENTS:  
1 TUBE CONTAINING  
500 MG FLURALANER



**Kills fleas and ticks**

For dogs and puppies 6 months of age and older

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

CONTENTS: 1 TUBE CONTAINING 500 MG FLURALANER

Approved by FDA under NADA # 141-459

**Application Instructions:**

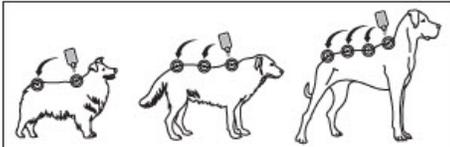
A veterinarian or veterinary technician should demonstrate or instruct the pet owner regarding the appropriate technique for applying Bravecto topically to dogs prior to first use.

**Step 1:** Immediately before use, open the pouch and remove the tube. Put on gloves. Hold the tube at the crimped end with the cap in an upright position (tip up). The cap should be rotated clockwise or counter clockwise one full turn. The cap is designed to stay on the tube for dosing and should not be removed. The tube is open and ready for application when a breaking of the seal is felt.



**Step 2:** The dog should be standing or lying with its back horizontal during application. Part the fur at the administration site. Place the tube tip vertically against the skin between the shoulder blades of the dog.

**Step 3:** Squeeze the tube and gently apply Bravecto in one or more spots starting between the shoulder blades and continuing along the dog's back. Avoid applying an excessive amount of solution in any one spot which may cause solution to run and drip off of the dog.



Bathing or water immersion 3 days after administration will not reduce the effectiveness of Bravecto against fleas and *Ixodes ricinus* ticks.

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

**Storage Information:** Do not store above 86°F (30°C). Store in the original package in order to protect from moisture. The pouch should only be opened immediately prior to use.

NON COATING AREA



PSA020F73 02 R1  
61x29.59x153mm  
CM Y K+PMS 268  
+PMS 368C

NON COATING AREA



## PRINCIPAL DISPLAY PANEL - 1000 MG Tube Carton

BRAVECTO®  
(fluralaner)  
Topical Solution

>44-88 lb

1 Tube

Kills fleas and ticks

For dogs and puppies 6 months of age and older

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

CONTENTS: 1 TUBE CONTAINING 1000 MG  
FLURALANER

Approved by FDA under NADA # 141-459

NON  
COATING  
AREA

**BRAVECTO**<sup>®</sup>  
(fluralaner)  
Topical Solution



**BRAVECTO**<sup>®</sup>  
(fluralaner)  
Topical Solution

 >44-88 lb

1 Tube



**BRAVECTO**<sup>®</sup>  
(fluralaner)  
Topical Solution

 >44-88 lb

1 Tube

CONTENTS:  
1 TUBE CONTAINING  
1000 MG FLURALANER



**Kills fleas and ticks**

For dogs and puppies 6 months of age and older

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

CONTENTS: 1 TUBE CONTAINING 1000 MG FLURALANER

Approved by FDA under NADA # 141-459

**Application Instructions:**

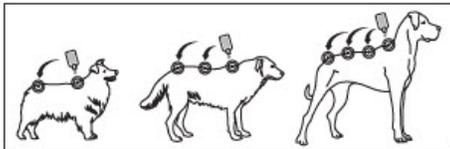
A veterinarian or veterinary technician should demonstrate or instruct the pet owner regarding the appropriate technique for applying Bravecto topically to dogs prior to first use.

**Step 1:** Immediately before use, open the pouch and remove the tube. Put on gloves. Hold the tube at the crimped end with the cap in an upright position (tip up). The cap should be rotated clockwise or counter clockwise one full turn. The cap is designed to stay on the tube for dosing and should not be removed. The tube is open and ready for application when a breaking of the seal is felt.



**Step 2:** The dog should be standing or lying with its back horizontal during application. Part the fur at the administration site. Place the tube tip vertically against the skin between the shoulder blades of the dog.

**Step 3:** Squeeze the tube and gently apply Bravecto in one or more spots starting between the shoulder blades and continuing along the dog's back. Avoid applying an excessive amount of solution in any one spot which may cause solution to run and drip off of the dog.

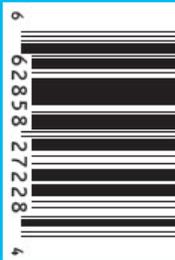


Bathing or water immersion 3 days after administration will not reduce the effectiveness of Bravecto against fleas and *Ixodes ricinus* ticks.

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

**Storage Information:** Do not store above 86°F (30°C). Store in the original package in order to protect from moisture. The pouch should only be opened immediately prior to use.

NON COATING AREA



PSA020F73 01 R2  
61x30x152mm  
CMYK+PMS 268  
+PMS 299C

NON COATING AREA

BRAVECTO<sup>®</sup>

(fluralaner)  
Topical Solution

**>44-88 lb**

**1 Tube**

CONTENTS:  
1 TUBE CONTAINING  
1000 MG FLURALANER

**For complete product information, refer to the package insert.**

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

Bravecto is also indicated for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater.

**Dosage and Administration:**  
Bravecto should be administered topically as a single dose every 12 weeks to provide a minimum dose of 11.4 mg/lb (25 mg/kg) body weight.

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

**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/reportanimalae>.

Fluralaner (active ingred.)  
Made in Japan.  
Formulated in France  
Distributed by Intervet Inc  
(d/b/a Merck Animal Health),  
Rahway, NJ 07065

Copyright © 2025 Intervet Inc,  
a subsidiary of  
Merck & Company Inc.  
All rights reserved. Rev. 01/2026

highly flammable

**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. 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.

The safety of Bravecto (fluralaner topical solution) in breeding, pregnant, and lactating dogs was evaluated using the oral formulation (see **Animal Safety** and **Clinical Pharmacology** sections). Adverse events have been reported following use of Bravecto (fluralaner) Chews in breeding females.

Before use in breeding female dogs, refer to **Post-Approval Experience** and **Animal Safety** sections.

243666 R2  
027967

## PRINCIPAL DISPLAY PANEL - 1400 MG Tube Carton

BRAVECTO<sup>®</sup>  
(fluralaner)  
Topical Solution

>88-123 lb

1 Tube

Kills fleas and ticks

For dogs and puppies 6 months of age and older

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

CONTENTS: 1 TUBE CONTAINING 1400 MG  
FLURALANER

Approved by FDA under NADA # 141-459

NON  
COATING  
AREA

**BRAVECTO**<sup>®</sup>  
(fluralaner)  
Topical Solution

1



**BRAVECTO**<sup>®</sup>  
(fluralaner)  
Topical Solution



>88-123 lb

1 Tube



**BRAVECTO**<sup>®</sup>  
(fluralaner)  
Topical Solution

>88-123 lb

1 Tube

CONTENTS:  
1 TUBE CONTAINING  
1400 MG FLURALANER



**Kills fleas and ticks**

For dogs and puppies 6 months of age and older

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.  
CONTENTS: 1 TUBE CONTAINING 1400 MG FLURALANER

Approved by FDA under NADA # 141-459

**Application Instructions:**

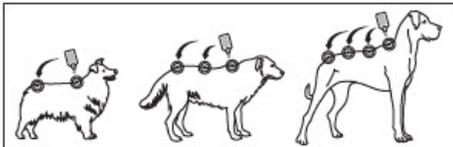
A veterinarian or veterinary technician should demonstrate or instruct the pet owner regarding the appropriate technique for applying Bravecto topically to dogs prior to first use.

**Step 1:** Immediately before use, open the pouch and remove the tube. Put on gloves. Hold the tube at the crimped end with the cap in an upright position (tip up). The cap should be rotated clockwise or counter clockwise one full turn. The cap is designed to stay on the tube for dosing and should not be removed. The tube is open and ready for application when a breaking of the seal is felt.



**Step 2:** The dog should be standing or lying with its back horizontal during application. Part the fur at the administration site. Place the tube tip vertically against the skin between the shoulder blades of the dog.

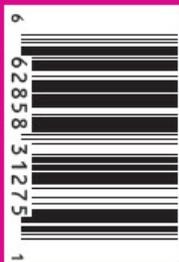
**Step 3:** Squeeze the tube and gently apply Bravecto in one or more spots starting between the shoulder blades and continuing along the dog's back. Avoid applying an excessive amount of solution in any one spot which may cause solution to run and drip off of the dog.



Bathing or water immersion 3 days after administration will not reduce the effectiveness of Bravecto against fleas and *Ixodes ricinus* ticks.

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

**Storage Information:** Do not store above 86°F (30°C). Store in the original package in order to protect from moisture. The pouch should only be opened immediately prior to use.



PSA020F73 02 R1  
61x29.59x153mm  
CMYK+PMS 268  
+Rhodamine red

NON COATING AREA

NON COATING AREA



**BRAVECTO**  
(fluralaner)  
Topical Solution

 >88-123 lb

1 Tube

CONTENTS:  
1 TUBE CONTAINING  
1400 MG FLURALANER

For complete product information, refer to the package insert.

**Indications:**

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

Bravecto is also indicated for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater.

**Dosage and Administration:**

Bravecto should be administered topically as a single dose every 12 weeks to provide a minimum dose of 11.4 mg/lb (25 mg/kg) body weight.

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

**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/reportanimalae>.

Fluralaner (active ingred.)  
Made in Japan.  
Formulated in France  
Distributed by Intervet Inc  
(d/b/a Merck Animal Health),  
Rahway, NJ 07065

Copyright © 2025 Intervet Inc, a  
subsidiary of  
Merck Et Company Inc.  
All rights reserved. Rev. 01/2026



highly flammable



**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. 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.

The safety of Bravecto (fluralaner topical solution) in breeding, pregnant, and lactating dogs was evaluated using the oral formulation (see Animal Safety and Clinical Pharmacology sections). Adverse events have been reported following use of Bravecto (fluralaner) Chews in breeding females.

Before use in breeding female dogs, refer to Post-Approval Experience and Animal Safety sections.

243668 R2

**BRAVECTO**  
fluralaner solution

**Product Information**

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:0061-5500	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
FLURALANER (UNII: WSH8393RM5) (FLURALANER - UNII:WSH8393RM5)		FLURALANER	112.5 mg	
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0061-5500-02	1 in 1 CARTON		
1		1 in 1 POUCH		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
NADA	NADA141459	07/30/2016		

<b>BRAVECTO</b>				
fluralaner solution				
<b>Product Information</b>				
<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:0061-5501	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
FLURALANER (UNII: WSH8393RM5) (FLURALANER - UNII:WSH8393RM5)		FLURALANER	250 mg	
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0061-5501-02	1 in 1 CARTON		
1		1 in 1 POUCH		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
NADA	NADA141459	07/30/2016		

# BRAVECTO

fluralaner solution

## Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:0061-5502
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FLURALANER</b> (UNII: WSH8393RM5) (FLURALANER - UNII:WSH8393RM5)	FLURALANER	500 mg

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0061-5502-02	1 in 1 CARTON		
1		1 in 1 POUCH		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141459	07/30/2016	

# BRAVECTO

fluralaner solution

## Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:0061-5503
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FLURALANER</b> (UNII: WSH8393RM5) (FLURALANER - UNII:WSH8393RM5)	FLURALANER	1000 mg

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0061-5503-02	1 in 1 CARTON		
1		1 in 1 POUCH		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141459	07/30/2016	

## BRAVECTO

fluralaner solution

### Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0061-5504
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FLURALANER (UNII: WSH8393RM5) (FLURALANER - UNII:WSH8393RM5)	FLURALANER	1400 mg

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0061-5504-02	1 in 1 CARTON		
1		1 in 1 POUCH		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141459	07/30/2016	

**Labeler** - Merck Sharp & Dohme Corp. (001317601)

Revised: 2/2026

Merck Sharp & Dohme Corp.