

BRAVECTO®

(fluralaner topical solution) for Cats

Caution:

Federal (USA) 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 18.2 mg/lb (40 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-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 *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 *Demacenter 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.

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 18.2 mg/lb (40 mg/kg) body weight.

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

Dosage Schedule:

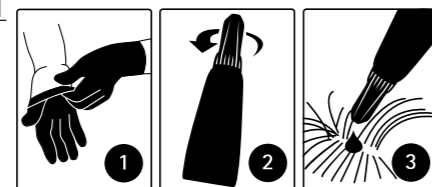
Body Weight Ranges (lb)	Fluralaner content (mg/tube)	Tubes Administered
2.6 – 6.2	112.5	One
>6.2 – 13.8	250	One
>13.8 – 27.5*	500	One

* Cats over 27.5 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 cats prior to first use.

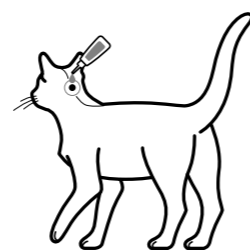
Step 1: Immediately before use, open the pouch and remove the tube. Put on gloves. Hold the tube at the crimped end with the cap in an upright position (tip up). The cap should be rotated clockwise or counter clockwise one full turn. The cap is designed to stay on the tube for dosing and should not be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

The tube is open and ready for application when a breaking of the seal is felt.



Step 2: The cat 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 at the base of the skull of the cat.

Step 3: Squeeze the tube and gently apply the entire contents of Bravecto directly to the skin at the base of the skull of the cat. Avoid applying an excessive amount of solution that could cause some of the solution to run and drip off of the cat. If a second spot is needed to avoid run off, then apply the second spot slightly behind the first spot.



Greasy, oily, or wet appearance may occur at the application site in some cats.

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. 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 *Demacenter variabilis* ticks beyond 8 weeks after dosing (see **Effectiveness**).

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>

Clinical Pharmacology:

Peak fluralaner concentrations are achieved between 7 and 21 days following topical administration and the elimination half-life ranges between 11 and 13 days.

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 a well-controlled European laboratory study, Bravecto killed 100% of fleas 8 hours after treatment and reduced the number of live fleas on cats by > 98% within 12 hours after treatment or post-infestation for 12 weeks. In well-controlled laboratory studies, Bravecto demonstrated > 94% effectiveness against *Ixodes scapularis* and *Haemaphysalis longicornis* 48 hours post-infestation for 12 weeks. Bravecto demonstrated > 98% effectiveness against *Demacenter variabilis* 48 hours post-infestation for 8 weeks, but failed to demonstrate ≥ 90% effectiveness beyond 8 weeks.

In a well-controlled U.S. field study, a single dose of Bravecto reduced fleas by ≥99% for 12 weeks. Cats with signs of flea allergy dermatitis showed improvement in erythema, alopecia, papules, scales, crusts, and excoriation as a direct result of eliminating flea infestations.

Animal Safety:

Margin of Safety Study: In a margin of safety study, Bravecto was administered topically to 11- to 13-week (mean age 12 weeks)-old-kittens at 1, 3, and 5X the maximum labeled dose of 93 mg/kg at three, 8-week intervals (8 cats per group). The cats in the control group (OX) were treated with 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 6- to 7-month-old-kittens at 1X the maximum labeled dose of 93 mg/kg. The kittens in the control group (OX) 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. All treated kittens experienced salivation and four of six experienced coughing immediately after administration. One treated kitten experienced vomiting 2 hours after administration.

In a well-controlled field study Bravecto was used concurrently with other medications, such as vaccines, anthelmintics, antibiotics, steroids and sedatives. No adverse reactions were observed from the concurrent use of Bravecto with other medications.

Storage Conditions:

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 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

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